UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

IMPERATIVE CARE, INC.,
Petitioner,

v.

INARI MEDICAL, INC.,
Patent Owner.

Case No. IPR2025-01264
Patent No. 12,016,580

DECLARATION OF TROY L. THORNTON IN SUPPORT OF PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 12,016,580

Imperative Care v. Inari Medical
US Patent 12,016,580
Imperative Care Ex. 1003

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TABLE OF EXHIBITS

Exhibit No.	Description
1001	U.S. Patent No. 12,016,580 (“the ’580 patent”)
1002	’580 Patent Prosecution History
1003	Expert Declaration of Troy Thornton
1004	Resume of Troy Thornton
1005	WIPO Publication No. WO 2006/124307 A2 to Goff et al. (“Goff”)
1006	U.S. Patent Publication No. 2015/0173782 A1 to Garrison et al. (“Garrison”)
1007	U.S. Patent Publication US 2003/0225379 A1 to Schaffer et al. (“Schaffer”)
1008	U.S. Patent Publication No. 2003/0116731 A1 to Hartley (“Hartley”)
1009	U.S. Patent Publication No. 2015/0352325 A1 to Quick (“Quick”)
1010	U.S. Patent Publication No. 2010/0042118 A1 to Garrison et al.
1011	U.S. Patent No. 8,734,374 B2 to Aklog et al. (“Aklog”)
1012	U.S. Patent Publication No. 2017/0043066 A1 to Laub (“Laub”)
1013	U.S. Patent No. 6,776,770 B2 to Trerotola (“Trerotola”)
1014	U.S. Patent No. 5,938,645 to Gordon (“Gordon”)
1015	U.S. Patent Publication No. 2014/0296868 A1 to Garrison et al.
1016	Certified File History of U.S. Patent Application 10/371,190 (Schaffer File History)
1017	U.S. Provisional Patent Application No. 62/554,931 (the “’931 application”)

Exhibit No.	Description
1018	U.S. Patent No. 6,481,439 B1 to Lewis et al.
1019	U.S. Patent No. 5,256,150 to Quiachon et al.
1020	WIPO Publication No. WO 2018/019829 A1 to Brady et al. ("Brady")
1021	U.S. Patent No. 12,109,384 B2 to Merritt et al.
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)

Exhibit No.	Description
1030	Save, Jeffrey L., Time is Brain – Quantified, American Heart Association Journals, available at http://www.stokeaha.org (2005).
1031	Decision Granting Institution of IPR, IPR2024-01157, U.S. Patent No. 11,697,011 B2
1032	Decision Granting Institution of IPR, IPR2025-00156, U.S. Patent No. 11,697,012 B2
1033	Decision Granting Institution of IPR, IPR2025-00289, U.S. Patent No. 11,554,005 B2
1034	Merriam-Webster's Collegiate Dictionary – Previously Submitted by Patent Owner as Ex. 2002 in IPR2024-00289 – Definition of "Loosen"
1035	U.S. Patent No. 7,998,104 B2 to Chang
1036	U.S. Patent No. 8,157,760 B2 to Craido et al.
1037	Plaintiff Inari's Supplemental Preliminary Disclosure of Asserted Claims and Infringement Contentions Pursuant to Patent Local Rules 3-1 and 3-2 in *Inari Medical, Inc. v. Imperative Care, Inc.,* 5:24-cv-03117-EKL (N.D. Cal.)
1038	Case Management and Scheduling Order (Dkt. #54) in *Inari Medical, Inc. v. Imperative Care, Inc.,* 5:24-cv-03117-EKL (N.D. Cal.)
1039	Imperative Care, Inc.'s Notice of Motion and Motion to Stay Pending *Inter Partes* Review in *Inari Medical, Inc. v. Imperative Care, Inc.,* 5:24-cv-03117-EKL (N.D. Cal.)
1040	Order Regarding Case Schedule and Motion to Stay in *Inari Medical, Inc. v. Imperative Care, Inc.,* 5:24-cv-03117-EKL (N.D. Cal.)

I, Troy L. Thornton, do hereby declare:

I. INTRODUCTION

A. Engagement

1. I have been retained on behalf of Imperative Care, Inc. ("Imperative Care") to provide my opinions regarding the patentability of Claims 1, 5-6, 9-30, and 33-34 of U.S. Patent No. 12,016,580 ("the '580 patent"). For the reasons discussed herein, I have concluded that Claims 1, 5-6, 9-30, and 33-34 of the '580 patent are unpatentable because the prior art references anticipate them or render them obvious.

2. I understand that this Declaration supports Imperative Care's Petition for the above-captioned *inter partes* review ("IPR") of the '580 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 '580 patent, Inari Medical, Inc. ("Inari" or "Patent Owner").

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

B. Experience and Qualifications

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

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

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

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

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

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

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

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

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

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

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

14. In summary, I have more than 35 years of experience in the cardiovascular medical device field, including significant experience designing, developing, testing, and manufacturing catheters and catheter systems for minimally invasive cardiovascular procedures. I am therefore very familiar with the concepts of catheters, catheter systems, and hemostasis valves, and I believe I am well placed to comment on the understanding of a person of ordinary skill in the art in the context of the ’333 patent.

C. Topics of Opinions

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

- The subject matter described and claimed in the ’580 patent;
- The level of ordinary skill in the art pertaining to the ’580 patent;
- The teachings of the prior art; and
- Whether Claims 1, 5-6, 9-30, and 33-34 of the ’580 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 ’580 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 ’580 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, January 2018).

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

C. Obviousness

24. I understand that a patent claim may also be unpatentable if it is rendered "obvious" by the prior art. I have been instructed that a claim is "obvious" if the claimed subject matter as a whole would have been obvious to a person of ordinary skill in the art at the time of the alleged invention. I understand that in considering obviousness I must consider the scope and content of the prior art, the differences between the claimed subject matter and the prior art, and the level of ordinary skill in the art at the time of the invention.

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

26. The prior art references applied in this Declaration are analogous art that is usable in an obviousness combination. The references are from the same field as the '580 patent, e.g., devices for aspirating unwanted material from a patient. The references are also pertinent to the problem the inventor was focused on, e.g., removing clots, emboli, and thrombi from a patient's blood vessel.

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

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

- combining prior art elements according to known methods to yield predictable results;
- simple substitution of one known element for another to obtain predictable results;
- a predictable use of prior art elements according to their established functions;
- applying a known technique to a known device (method or product) ready for improvement to yield predictable results;
- choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success; and
- some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.

29. A prior art reference may also suggest a limitation of the claims. In that case, even if the prior art reference does not explicitly or inherently disclose the limitation, the motivation to modify the prior art reference to include the

limitation may exist within the prior art reference itself. Thus, the limitation would have been obvious over that prior art reference alone. This is the case if a person of ordinary skill in the art would have had a simple design choice or a finite number of identified, predictable solutions, for example, and if the modification furthers the goals of the prior art reference.

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

31. An obviousness analysis also must consider whether there are additional factors that would indicate that the invention would not have been obvious. These factors include whether there was: (i) a long-felt need in the industry; (ii) any unexpected results; (iii) skepticism of the invention; (iv) a teaching away from the invention; (v) commercial success; (vi) praise by others for the invention; and (vii) copying by others. I am not aware of any evidence under these factors that would suggest that Claims 1, 5-6, 9-30, and 33-34 of the ’580 patent

would have been non-obvious, as further explained in Section § VIII (Heading: "Secondary Considerations") below.

D. Person of Ordinary Skill in the Art

32. It is my understanding that when interpreting the claims of the '580 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 '580 patent is January 26, 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 ’580 patent, it is my opinion that a person of ordinary skill in the art would have had an undergraduate degree in mechanical engineering or a related engineering discipline and 2-4 years of catheter design experience and, where necessary, would have consulted with a physician regarding the methods of treatment.

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

III. THE ’580 PATENT

A. Summary of the ’580 Patent

37. The ’580 patent is titled “Single Insertion Delivery System for Treating Embolism and Associated Systems and Methods” and describes a retrieval system for intravascular removal of clot material. Ex. 1001 (’580 patent) at 3:46-63. The ’580 patent explains that the system can treat various clots including pulmonary embolisms (“PE”) and cerebral embolisms. *Id.* at 3:64-4:3. The retrieval system has a “clot retrieval system 1,” which includes “retraction aspiration device 100 (RA device 100),” “catheter system 200,” and “tubing system 300.” *Id.* at 4:42-45.

38. The catheter system 200 has a guide catheter 206 and a delivery sheath 204 which may "individually comprise an elongated shaft" [orange below]. *Id.* at 5:4-16. The catheter system 200 also includes an "attachment/valve member 208" [yellow below] which can "secure the catheter 200 to the RA device 100" and "fluidly couple an aspiration lumen of the catheter system 200 […] to the tubing system 300."

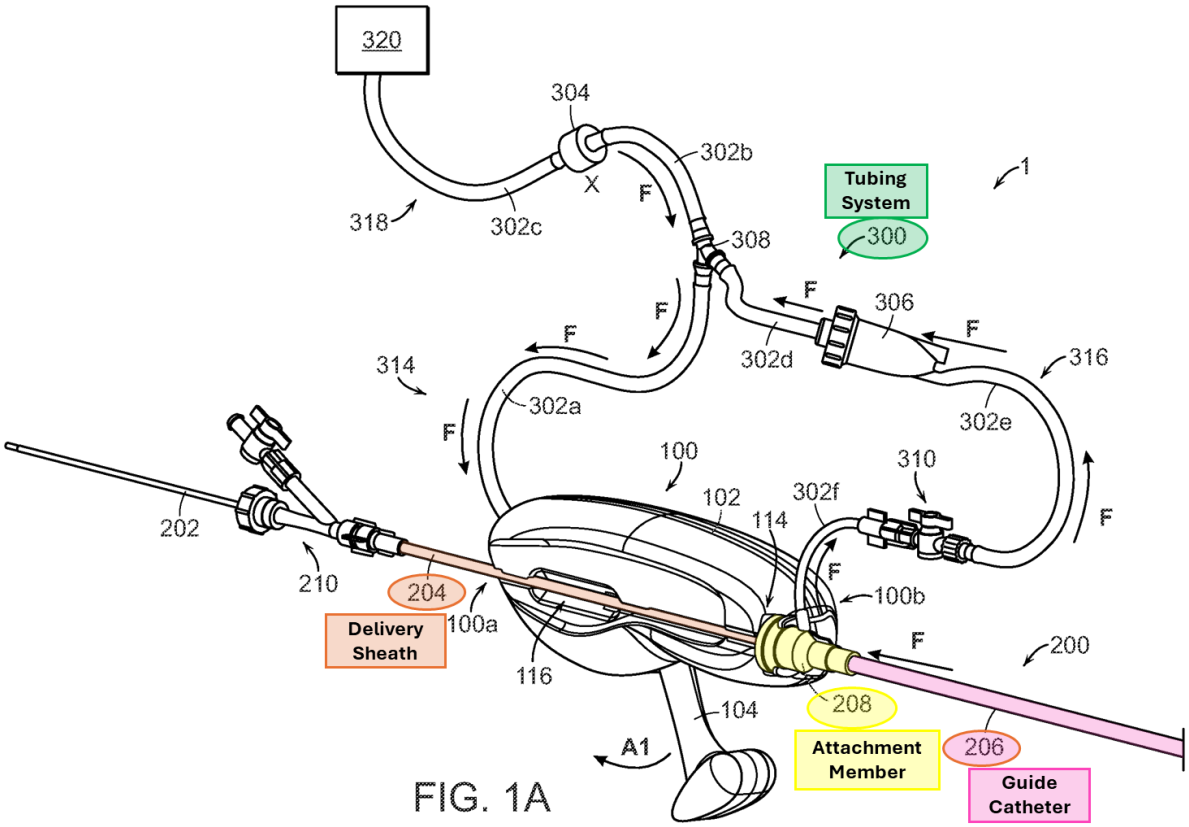


FIG. 1A

Id. at 6:9-18, Fig. 1A.

39. The '580 patent discloses "an interventional device ID, such as a clot removal and/or clot treatment device" [blue], which can be "housed within delivery

sheath 204 [orange]" and "positioned at least partially within the clot material PE" [pink]:

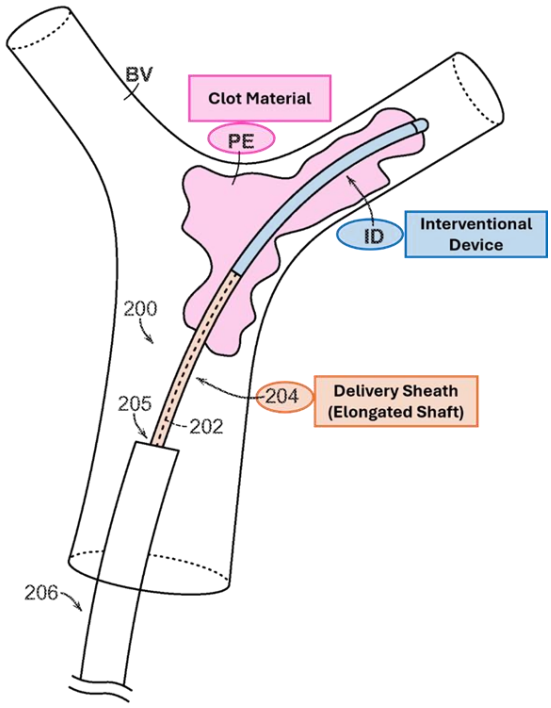


FIG. 2A

Id. at 5:18-27; Fig. 2A

40. The '580 patent discloses the "tubing system 300 of the clot retrieval system 1 fluidly couples the pressure source of the RA device 100 to the aspiration lumen of the catheter system 200." *Id.* at 6:49-51. The tubing system 300 has a "first portion 314" [red] coupled to a pressure source and a "second portion 316 [green]." *Id.* at 6:49-59. The second portion 316 has a "clot reservoir 306" [blue] and "second fluid control unit 310" [purple], which may "be a stopcock or a clamp that is externally operated to regulate the flow of liquid through the second portion 316 of the tubing system 300":

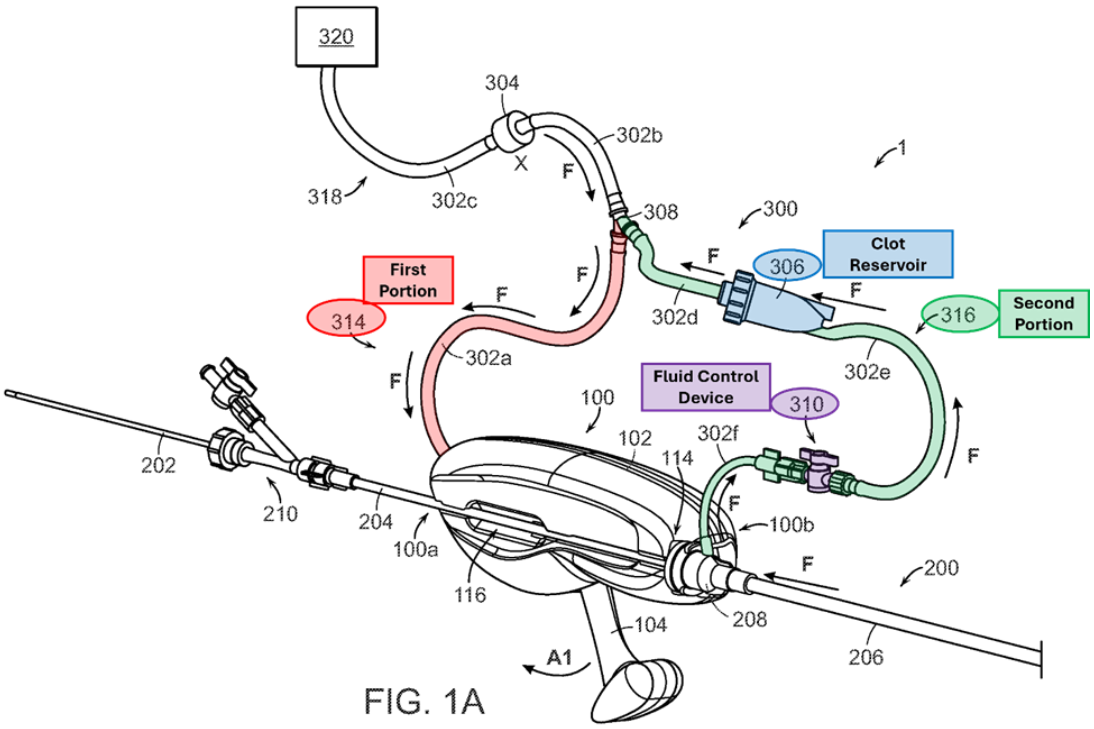


FIG. 1A

Id., 7:15-19, Fig. 1A.

41. The '580 patent further discloses that the "clot reservoir 306 includes a housing 322 [blue]" and "a filter 321 [brown] configured to be positioned within the housing 322":

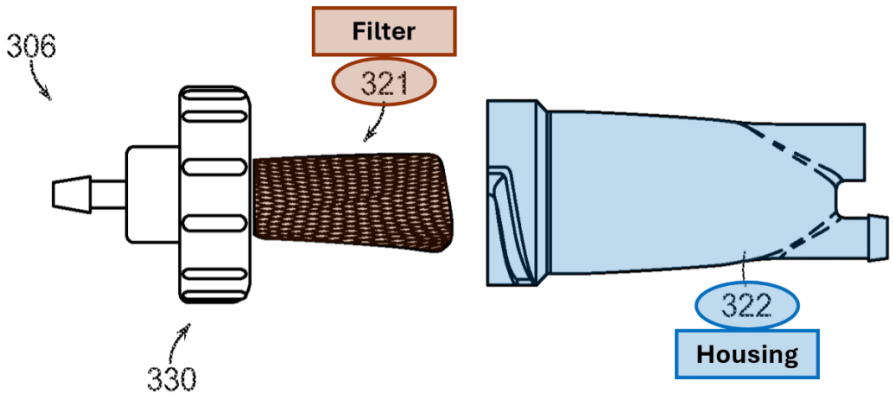


FIG. 3C

Id. at 8:61-67; Fig. 3C.

42. The ’580 patent discloses that the attachment member 208 “can be, for example, a hemostasis valve configured to maintain hemostasis […] as the delivery sheath 204, and/or other components of the catheter system 200 are inserted through the valve 445”. *Id.* at 10:3-11:5; Fig. 7A. The ’580 patent describes a valve having a “tubular member (e.g., an elongate member) 1372” that extends through the valve. *Id*. at 18:5-8. The tubular member has a “thin-walled compliant tubular structure” that facilitates “the uniform collapse of the tubular member 1372 and the sealing of the tubular member 1372”:

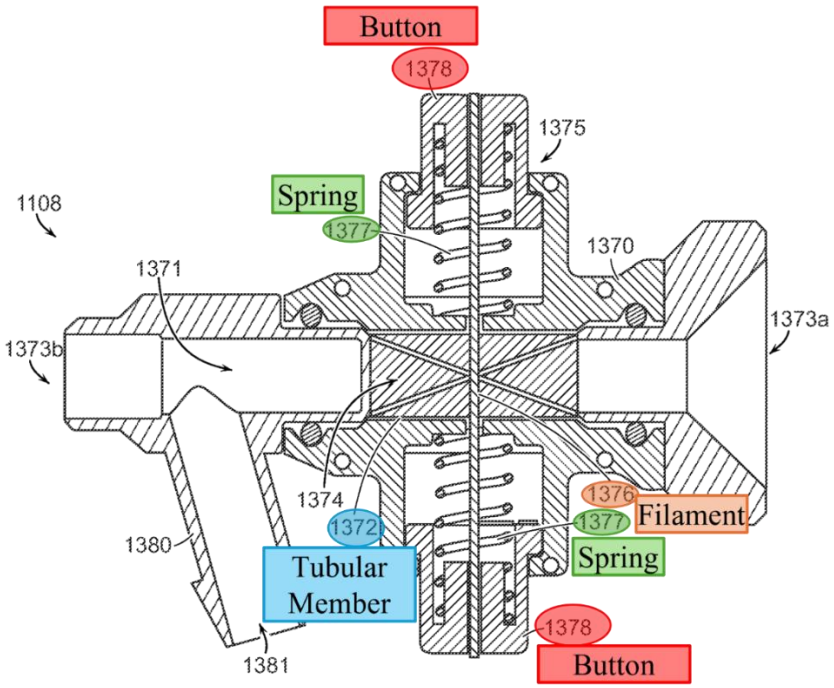


FIG. 13A

Id., 18:8-14, Fig. 19.

43. The valve disclosed in the ’580 patent also includes an “actuation mechanism 1375” that can “collapse and seal the tubular member 1372 via

compression and/or constriction of one or more filaments 1376." *Id.* at 18:15-20. The actuation mechanism "can be a manual actuator such as one or several buttons 1378." *Id.* at 18:21-23. The "actuation mechanism 1375 can tighten the filament 1376 to constrict or compress the tubular member 1372 to seal the central lumen 1374 of the tubular member 1372." *Id.* at 18:35-40. The valve also includes a "bias feature," such as a spring, that biases the actuator toward the open or closed configuration. *Id.* at 18:32-35.

44. The '580 patent also allegedly incorporates by reference U.S. Patent Application No. 62/554,931 titled "Hemostasis Valves and Methods of Use." *Id.* at 17:46-55. The '931 application is Exhibit 1017 and includes additional descriptions of the hemostasis valve, which I discuss in the claim construction section below.

B. The Challenged Claims

45. The challenged claims include Claims 1, 5-6, 9-30, and 33-34 of the '580 patent. Claim 1 is the only independent claim.

46. Claim 1 states:

> 1. A method for the intravascular treatment of clot material within a blood vessel, the method comprising:
>
> positioning a distal portion of an elongated shaft proximate to the clot material within the blood vessel;
>
> pre-charging a vacuum in a pressure source;
>
> fluidly connecting the pressure source to the elongated shaft to apply the pre-charged vacuum to the elongated shaft to aspirate a first portion of the clot material into the elongated shaft;

unsealing an attachment member coupled to a proximal portion of the elongated shaft;

advancing an interventional device distally through the attachment member and the elongated shaft; and

engaging the interventional device with a second portion of the clot material remaining within the blood vessel.

Ex. 1001 ('580 patent) at Claim 1.

C. Prosecution History

47. I have reviewed the '580 patent's prosecution history. From my review of the References, it appears that Garrison, Goff, and Hartley were listed on an IDS submitted to the Examiner. However, I do not see that any of these references were cited or applied by the Examiner. PO does not appear to have identified Schaffer, Laub, or Aklog on an IDS. I see that the Patent Examiner issued a single non-final office allowing claims 21-31 and rejecting claims 32-40 as either anticipated by US No. 2015/0352325 A1 to Quick ("Quick") (Ex. 1009) or rendered obvious by Quick in view of U.S. Patent No. 5,256,150 to Quiachon ("Quiachon") (Ex. 1019). Ex. 1002 ('580 Prosecution History) at 1050.

48. The Examiner rejected claim 32 as anticipated by Quick. Claim 32 was an apparatus claim, recited below:

32. A system for the intravascular treatment of clot material within a blood vessel, comprising:

an elongated shaft having a distal portion and a proximal portion, wherein the distal portion of the elongated shaft is configured to be positioned proximate to the clot material within the blood vessel;

an attachment member coupled to the proximal portion of the elongated shaft;

a pressure source configured to generate a vacuum;

a fluid control device fluidly coupling the pressure source to the elongated shaft, wherein the fluid control device is movable between an open position and a closed position, wherein the fluid control device fluidly connects the pressure source to the elongated shaft in the open position, wherein the fluid control device fluidly disconnects the pressure source from the elongated shaft in the closed position, wherein the pressure source is configured to generate a pre-charged vacuum within the pressure source when the fluid control device is in the closed position, and wherein moving the fluid control device to the open position after generating the pre-charged vacuum is configured to apply the pre-charged vacuum to the elongated shaft to aspirate a first portion of the clot material into the elongated shaft; and

an interventional device configured to be advanced through the attachment member and the elongated shaft to engage a second portion of the clot material remaining in the blood vessel.

Ex. 1002 at 1046-1047. I see that the rejected claim 32 contains all the system components required by allowed claim 1 of the '580 patent.

49. The Examiner found that Quick disclosed every limitation of pending independent claim 21 (issued claim 1) except the step of "pre-charging a vacuum in a pressure source and fluidly connecting the pressure source to the elongated shaft to apply the pre-charged vacuum to the elongated shaft to aspirate a first portion of the clot material into the elongated shaft." Ex. 1002 at 1050-1051. Notably, Garrison discloses this precise method step, which the Examiner appears to have overlooked.

50. After the Examiner issued the non-final office action, Patent Owner filed an amendment cancelling pending claims 32-40 and adding claims 41-63, which depend from claim 21. *Id.* at 700-708. The'580 patent subsequently issued.

IV. CLAIM CONSTRUCTION

51. Claims 15-17 of the '580 patent require a hemostasis valve having "a ***filament*** coupled to the button and the tubular member, and wherein unsealing the hemostasis valve includes pressing the button to loosen the filament" and "releasing the button to tighten the ***filament***", and further "wherein releasing the button to tighten the ***filament*** includes driving the button with the spring to tighten the ***filament***". Ex. 1001, Claims 15-17 (emphasis added). I have offered a construction for "filament" in previous IPRs involving Patent Owner and Petitioner, including IPRs for U.S. Patent Nos. 11,697,011, 11,697,012, and 11,554,005. I understand that the '011 and '012 patents depend from the '931 application that is allegedly incorporated by reference into the '580 patent. Consistent with my previous analysis, it is my opinion that a person of ordinary skill in the art in January 2018 (the earliest priority date of the '580 patent) would have understood the term "filament" in the claims of the '580 patent to mean at least: "one or more threads, lines, cords, ropes, ribbons, flat wires, sheets, or tapes."

52. In the previous IPRs, Patent Owner has argued that my construction of "filament" is incomplete because I did not limit the claims to "flexible" filaments.

However, the debate about whether the term "filament" is limited to "flexible" filaments does not impact my views on unpatentability. If the Board decides that "filament" is limited to "flexible" filaments, that decision is relevant only to Inari's arguments about Schaffer. The meaning of "filament" does not have any impact on my opinions regarding Schaffer in combination with Hartley because Inari has never disputed that Hartley describes "flexible" filaments. As the Board preliminarily found in the Institution Decisions for the '011,'012, and '005 Patents, Hartley includes a "filament," regardless of whether the claims are limited to "flexible" filaments. The Board specifically found that Patent Owner "does not dispute that Hartley … disclose[s] a flexible filament (e.g., flexible string or flexible wire)." Ex. 1032 ('012 Institution Decision) at 21, n.13. The Board also preliminarily found that a person of ordinary skill in the art would have found it obvious to combine Hartley's filament with Schaffer's valve. Therefore, Schaffer in combination with Hartley renders the claimed "filament" obvious regardless of the construction of "filament."

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

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

1. The ’011 Patent IPR

54. In the ’011 patent IPR, I understand that the Institution Decision was Paper 7. In the Institution Decision, the Board found that it did not need to “expressly construe the term ‘filament’ in the manner urged by Petitioner.” Ex. 1031 at 13 (Imperative Care was the Petitioner). However, the Board agreed with “Petitioner that a filament as claimed *encompasses* one or more threads, lines, cords, ropes, ribbons, flat wires, sheets, or tapes.” *Id.* (emphasis in original). The Board observed that the ’011 patent “lists those structures explicitly, but suggests that those are only examples and, thus, the term ‘filament’ may be broader than those structures.” *Id.* I agree with the Board that ’011 patent identifies those structures as examples of “filament” and that additional structures could fall within the meaning of a filament. However, I understand that the Board needs to construe the terms only to the extent necessary to resolve the issues presented in the IPR. In this IPR, I believe my construction of “filament” resolves the issues presented because the structures identified in the construction (e.g., threads, lines, cords, ropes, ribbons, flat wires, sheets, or tapes) are found in the prior art (as I explain below).

55. I see that the Board also addressed Patent Owner’s argument that “filament” should mean “a thin, flexible length of material formed by one or more strands of material.” The Board did not adopt Patent Owner’s construction. *Id.* at 15 (Inari was the Patent Owner). The Board observed that “the ’011 patent never

uses the words 'thin' or 'flexible' to describe the 'filament.'" *Id.* The Board also observed that "the words 'thin' and 'flexible' inject potential ambiguities as a relative term" because "flexibility and rigidity exist along a spectrum …." *Id.*

56. I see the Board also addressed Patent Owner's argument that the filament must be flexible to "circumferentially constrict" the lumen to create a seal. The Board stated, "Wanting for further explanation, however, is why two bights like shown in Figures 8-9 that cooperatively receive an elongate member in 'encircled area 816' cannot 'circumferentially constrict' the elongate member and lumen when pulled in opposite directions (810-812) even if those bights are substantially rigid." Ex. 1031 at 18.

2. <u>The '012 Patent IPR</u>

57. I see that the Board adopted a different preliminary construction of the term "filament" in the '012 patent IPR. There, the Board found that the "claims, as understood by the POSA, suggest that the filament must be flexible." Ex. 1032 ('012 Patent Institution Decision) at 15. The Board focused on the specific language in the claims of the '012 patent to reach this conclusion. The Board specifically focused on the limitations, "a first filament formed into a loop around the collapsible tubular sidewall" and that the "diameter of the valve lumen decreases in response to reducing a diameter of the loop." *Id.* Additionally, the Board

credited Patent Owner's expert testimony that the loop must be flexible to have its diameter reduced. *Id.*

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

59. The Board also addressed the interplay between the '011 and '012 patents. The Board said, "[t]here is no irreconcilable inconsistency" between its preliminary constructions in the '011 and '012 patent IPRs. *Id.* at 18. The Board explained that claim 1 of the '011 patent "does not require that the 'filament forms into a loop' where the 'diameter of the loop' reduces when the end portions of the filament are pulled," unlike the challenged claims in the '012 patent. *Id.* Thus, the Board found that "Claim 1 in the ['011 patent IPR] is arguably broader concerning the 'filament' and would purport to encompass, for example, both loop and bight embodiments." *Id.*

B. <u>Construction of "Filament"</u>

60. As explained above, I have previously construed "filament" in IPRs involving Patent Owner and Petitioner. Below, I substantially repeat the analysis I

previously provided. I understand from counsel that the claim construction analysis should begin with the language of the claims.

61. I understand from counsel that the claim construction analysis should begin with the language of the claims. Here, the claims do not provide much information about the meaning of "filament." Claims 15-17 of the '580 patent require the filament seal and unseal a hemostasis valve by "pressing the button to loosen the filament" and "releasing the button to tighten the filament." Ex. 1001, Claims 15-17. The claims further require the filament is "coupled to the button and the tubular member." *Id.* While this language identifies some functions the filament must perform, the claim language does not identify the structures, material, or material properties that form a "filament."

62. The specification of the '580 patent does not provide any further guidance on the structures or materials that form a "filament." The '580 patent specification describes "attachment member 1108 can further include an actuation mechanism 1375 coupled to the tubular member 1372 and configured to collapse and seal the tubular member 1372 via compression and/or constriction of one or more filaments 1376 coupled to the tubular member 1372." Ex. 1001, 18:14-19. Like claims 15-17, the specification further describes "the actuation mechanism 1375 can tighten the filament 1376 to constrict or compress the tubular member 1372 to seal the central lumen 1372 of the tubular member 1372," and "one or more

of the buttons 1378 may be depressed to, for example, loosen the filament 1376 and allow expansion of the tubular member 1372 to unseal the central lumen 1374 of the tubular member 1372." *Id.* at 18:34-47. Like the claims, this language identifies some functions the filament must perform, but does not identify the structures, material, or material properties that form a "filament."

63. However, the '931 Application, which the '580 patent purports to incorporate by reference, does identify structures and materials that may form a "filament." The '931 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. 1017 ('931 Application) at [0046]. The '931 Application also says that "the filament can comprise a single strand such as, for example, a monofilament, [or] the filament can comprise a plurality of strands that can be, for example, twisted, woven, grouped, and/or fused to form the filament." *Id.* The '931 Application also states that "***the filament 150 can comprise one or several threads, lines, cords, rope, ribbon, flat wire, sheet, or tape***." *Id.* (emphasis added). I have used this specific description of "filament" for my construction.

64. The '931 Application also explains that "the filament 150 can comprise multiple filaments, and specifically, as shown in Figures 7 through 9, the filament 150 can comprise a first filament 150-A and a second filament 150-B." *Id.* at [0064]. Figure 7 illustrates an embodiment where the filament is comprised of

multiple loops, and Figures 8 and 9 below illustrate embodiments where the filament is comprised of a "U-shaped section between the two ends of the filament 150" (i.e., a bight):

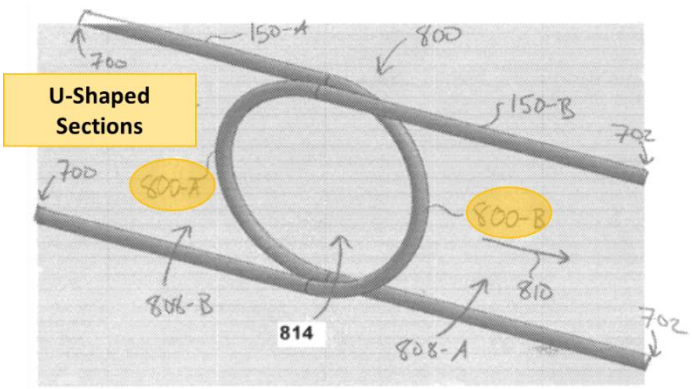


Figure 8

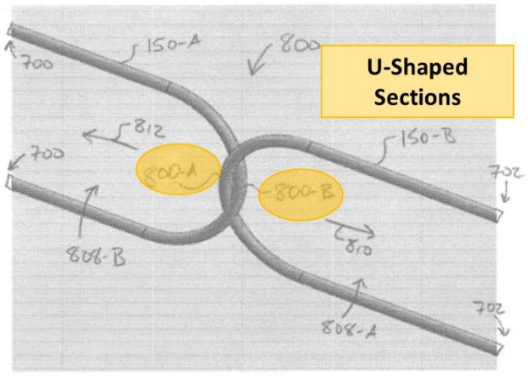


Figure 9

Id. at [0066]-[0068], Figs. 7-9. Focusing specifically on the embodiments having the "U-shaped section," the '931 Application explains that the filaments can have "any desired cross-sectional shape." *Id.* at [0067]-[0070]. The '931 Application also identifies some exemplary dimensions for the filaments but does not specify any mandatory diameter, thickness, or cross-sectional dimensions for the filament. *Id.* at [0070]. The '931 Application also does not require the filament to have a specific amount of flexibility or hardness (or provide any guidance regarding those properties).

65. I understand that the prosecution history can also be relevant in construing patent claims because it can provide insight into how the applicant and the Patent Examiner understood the claims. However, neither the Examiner nor

Patent Owner substantively discussed the "filament" limitation during prosecution of the '580 patent.

66. Thus, in view of the above analysis of the claim language, specification, and prosecution history, I believe that a person of ordinary skill in the art in January 2018 would have understood the term "filament" recited in the claims of the '580 patent to mean at least: "one or more threads, lines, cords, ropes, ribbons, flat wires, sheets, or tapes."

C. The Claims of the '580 Patent Are Not Limited to "Flexible" Filaments

67. I do not believe the claims of the '580 patent should be limited to only "flexible" filaments. For clarity, I agree that the term "filament" in the '580 patent encompasses "flexible" filaments. However, I do not see any language or descriptions in the patent that would limit the claims to only "flexible" filaments. Neither '580 patent nor the '931 application allegedly incorporated by reference into the '580 patent use the word "flexible" to describe the filament. And neither the '580 patent nor the '931 application provides any criteria for flexibility that would help a person of ordinary skill in the art determine whether a specific material was "flexible." While the '931 application identifies some potential dimensions for the "filament(s)," the application states that those dimensions are exemplary, not mandatory. Because flexibility exits along a spectrum, I would not be able to tell

whether a material was "flexible" enough to qualify as a filament based on the information in the '580 patent or the '931 application.

68. As summarized above, I am aware that the Board preliminarily construed "filament" in the claims of the '012 patent to require *only* "flexible" filaments. However, I see some differences in the claims that I think impact the Board's analysis.[1] The claims of the '012 patent require "a filament formed into a loop around the tubular sidewall" and that pulling on the first end of the filament results in "reducing a diameter of the lumen in response to reducing a diameter of the loop." The claims of the '580 patent do not include this limitation and do not require that the filament form a "loop" or that "that pulling on the first end of the filament results in "reducing a diameter of the lumen in response to reducing a diameter of the loop." Rather, the claims of the '580 patent merely require depressing and releasing a button to loosen or tighten the filament and to allow sealing or unsealing of the tubular member of the valve.

69. Looking at the '931 application, I believe that the filaments in Figures 8 and 9 meet the claim limitations of the '580 patent because placing or removing tension on the filaments in Figures 8 and 9 would open and close the lumen of the valve to fluid flow. *See* Ex. 1017 ('931 application) at [00068]. Specifically, the

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

’931 application specification explains movement of the constricting mechanism “decreases the size of the encircled area 814 and constricts, collapses, and/or seals the elongate member 132 extending through the encircled area 814.” *Id.*

70. I also see that the Board preliminarily limited the ’012 patent claims to “flexible” filaments based, in part, on the ’012 patent prosecution history. Ex. 1032 (’012 Patent Institution Decision) at 19-20. However, the ’580 patent prosecution is different and does not include any restriction requirement response like the one provided in the ’012 patent. *See* Ex. 1002 (does not include restriction). Thus, the ’580 patent prosecution history does not support a construction of “filament” that is limited only “flexible” filaments.

71. I also know that Patent Owner has obtained patent claims in related patents that specifically require a “flexible” filament. For example, Patent Owner’s U.S. Patent No. 12,109,384 includes claims reciting, “a first filament extending in a first loop around the tubular member, wherein the first filament ***is flexible***.” Ex. 1021 at claim 1 (emphasis added). The claim further recites that the actuator can apply tension to the filament to “decrease the dimension of the first loop.” *Id.* I have been informed that each term in a claim has meaning. Therefore, the limitation that the filament is “flexible” in the ’384 patent suggests that some filaments in the patent are not “flexible,” otherwise the words “is flexible” in the claims would be superfluous.

72. I also see in the ’005 Patent IPR that Patent Owner has argued that the description of a filament as being “loosened” supports its construction requiring flexibility. I see that Patent Owner tries to equate “loosened” with “flexible.” But, the word “loosened” is not synonymous with “flexible.” The term “loosen” in the dictionary submitted by Patent Owner means “to release from restraint.” Ex. 1034. The term “loosen” does not have any relationship to flexibility because many relatively inflexible items can be loosened, such as screws and u-bolts. The filaments in the embodiments in Figures 8 and 9 of the ’931 application are “loosened” to allow expansion of the elongate member, even if they are determined by the Board to be relatively inflexible. Therefore, I don’t see the use of “loosened” in the ’580 patent or ’931 application to require only “flexible” filaments.

V. SUMMARY OF IPR GROUNDS

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

Ground	Reference(s)	35 U.S.C.	Challenged Claims
1	Garrison	§102	1, 5, 9, 11-14, 18, 21-22, 24-28, 30, 33-34
2	Garrison	§103	1, 5, 9, 11-14, 18, 21-22, 24-28, 30, 33-34
3	Garrison and Schaffer	§103	1, 5-6, 9, 11-18, 21-30, 33-34
4	Garrison and Hartley	§103	1, 5, 9, 11-14, 18, 21-22, 24-28, 30, 33-34
5	Garrison, Schaffer, and Hartley	§103	15-17
6	Garrison and Goff	§103	18-22, 24-28
7	Garrison, Schaffer, and Goff	§103	18-29
8	Garrison, Hartley, and Goff	§103	18-22, 24-28
9	Garrison and Laub	§103	10
10	Garrison and Aklog	§103	10
11	Garrison, Laub, and Schaffer	§103	10
12	Garrison, Laub, and Hartley	§103	10
13	Garrison, Aklog, and Schaffer	§103	10
14	Garrison, Aklog, and Hartley	§103	10

VI. GROUNDS 1–8: – GARRISON ALONE OR COMBINED WITH HARTLEY, SCHAFFER, AND/OR GOFF

A. Claim 1

1. Preamble

74. The preamble of Claim 1 recites: "A method for the intravascular treatment of clot material within a blood vessel." If the Board finds that the preamble of Claim 1 is limiting, Garrison discloses this limitation.

75. Garrison discloses systems and methods to intravascularly treat clot material by aspirating (i.e., suctioning) clot material from a patient's blood vessels. Ex. 1006 (Garrison) at abstract, [0007]. Garrison illustrates a clot treatment system having at least two intravascular aspiration catheters (2010 [pink] and 2030 [orange]) coupled to an aspiration or pressure source [red]:

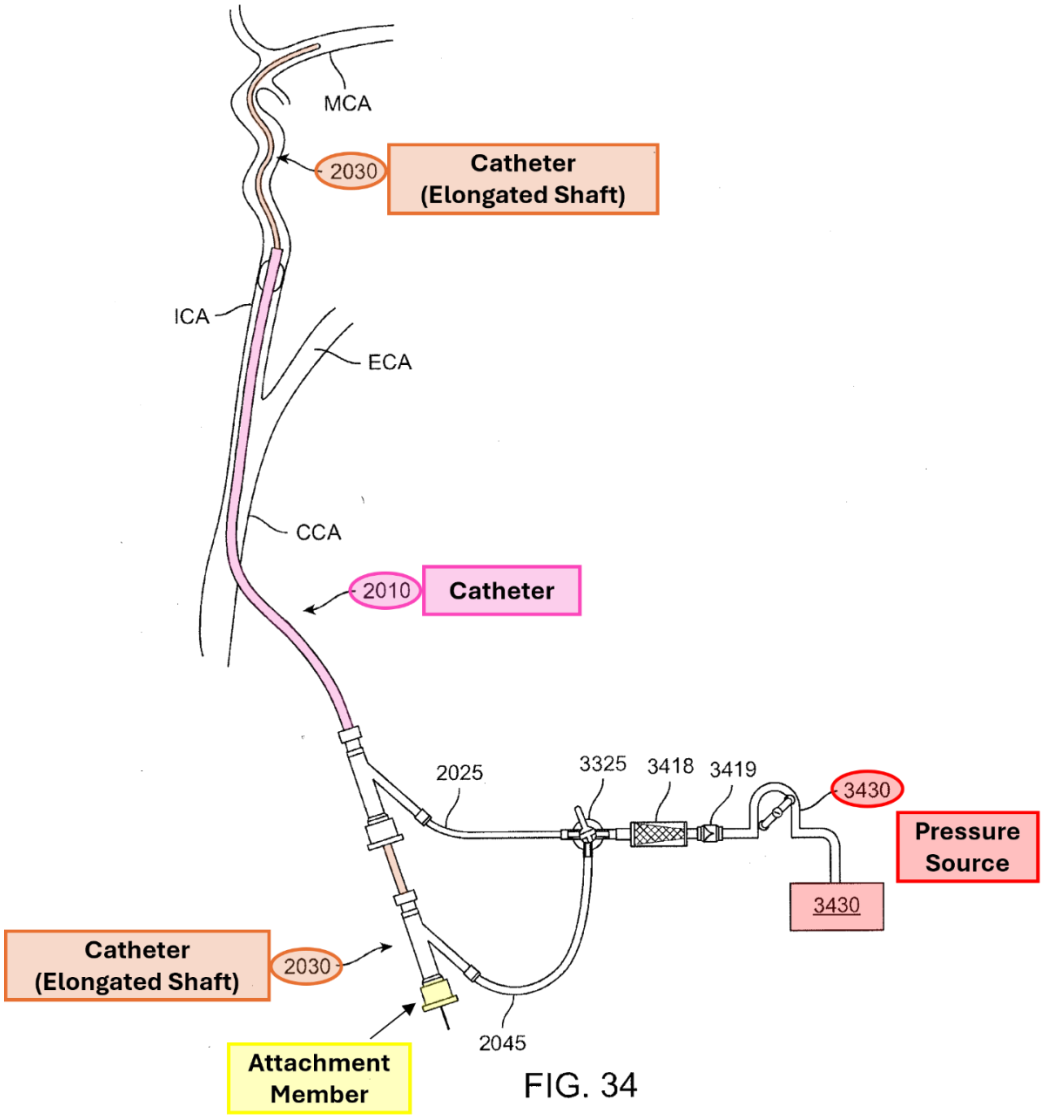


FIG. 34

Id. at Fig. 34, [0131]-[0134].

76. The catheter disclosed in Garrison "has an external dimension that is sized and shaped for insertion into a blood vessel." *Id.* at [0098], Fig. 34. Garrison explicitly discloses that "the catheter may be used to aspirate an occlusion in the blood vessel," and Garrison discloses methods of doing so. *Id.* at [0109], [0162]-[0166]. Further, Figures 2 and 33-34 illustrate catheters 2010 and 2030 positioned within a patient's blood vessels to remove clot material. *Id.*; *see also id.* at [0162]-

[0167]. Thus, Garrison discloses methods for the intravascular treatment of clot material within a blood vessel.

2. <u>"Positioning a distal portion of an elongated shaft proximate to the clot material within the blood vessel"</u>

77. Claim 1 next recites the method step of: "positioning a distal portion of an elongated shaft proximate to the clot material within the blood vessel." Garrison discloses this limitation.

78. Garrison discloses a catheter having a lumen that is "formed of an elongated catheter body." *Id.* at abstract, [0008], [0098], [0109]. Thus, Garrison describes an "elongated shaft".

79. Garrison further discloses that catheter 2030 is "placed through the arterial access device 2010 or the guide catheter 2105 and positioned such that the distal tip reaches the treatment site" within a blood vessel. *Id.* at [0164], *see also id.* at [0098], [0111]-[0113], Figs. 2, 24A-25B, 26-28, 33, 35. Garrison further discloses positioning the tip of the aspiration catheter "near or at the face of the occlusion":

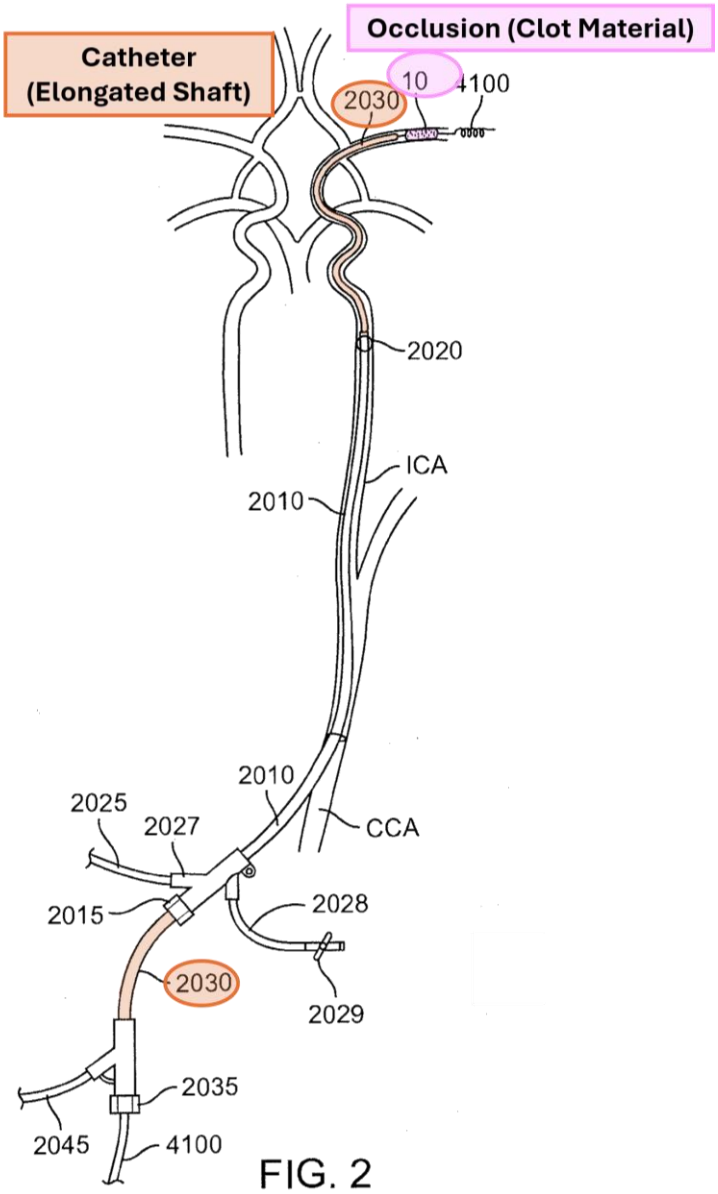


FIG. 2

Id. at Fig. 2, [0050]-[0055]. Thus, Garrison discloses "positioning a distal portion of an elongated shaft proximate to the clot material within the blood vessel."

3. <u>"Pre-charging a vacuum in a pressure source"</u>

80. Claim 1 next recites the method step of: "pre-charging a vacuum in a pressure source." Garrison discloses this limitation.

81. Garrison discloses a system including a valve 3325 [purple] along the fluid path [green] between the aspiration source (e.g., pressure source) [red] and the aspiration catheter 2030 (e.g., elongated shaft) [orange]:

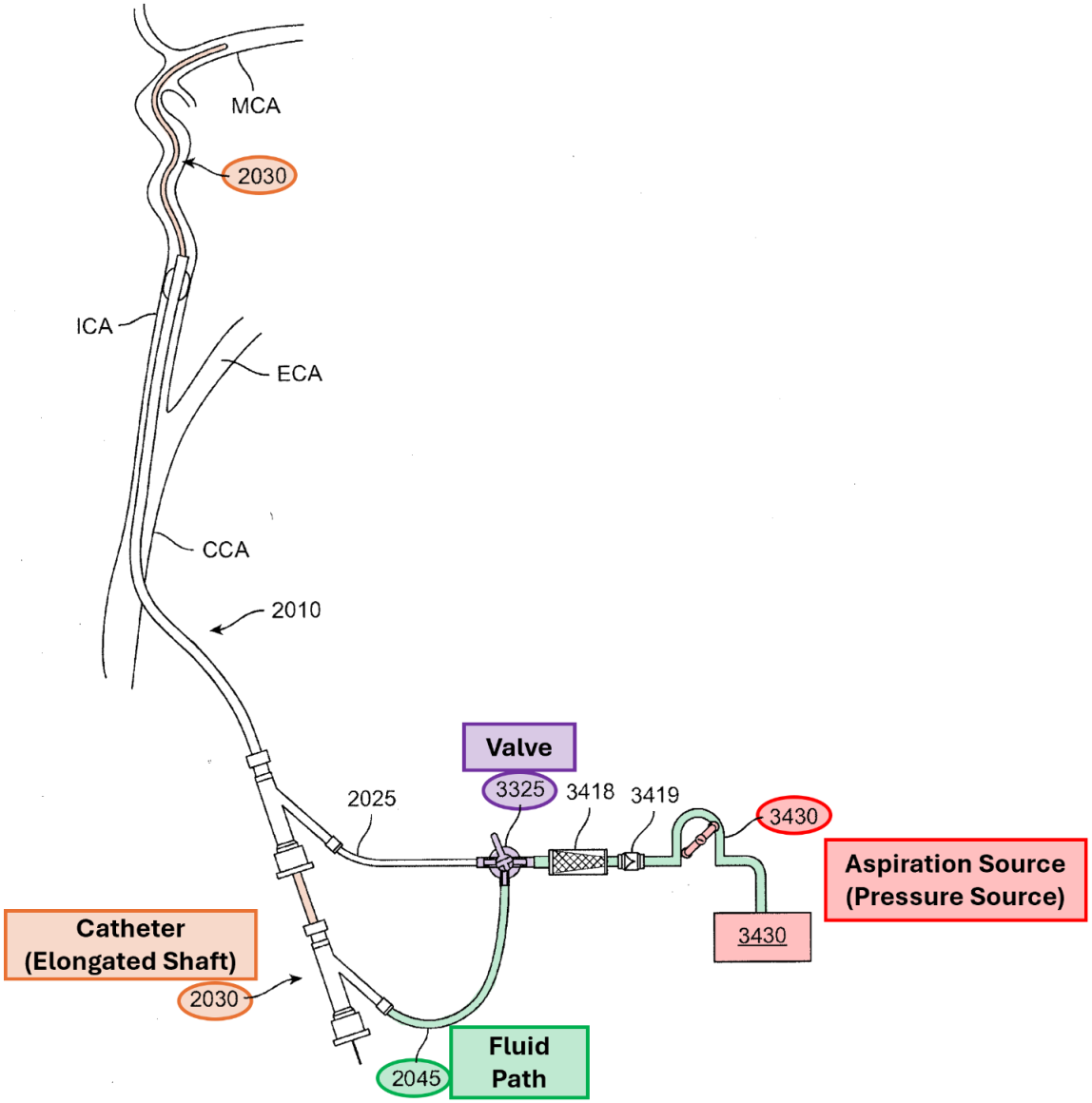


FIG. 34

Id. at Fig. 34, [0131]-[0134]. Garrison further discloses that the aspiration source can be a syringe, in addition to other types of aspiration sources such as pumps. *Id.* at [0131]; *see also* [0071], [0129], [0134].

82. The valve 3325 disclosed in Garrison "controls which device [i.e., catheter 2010 or 2030] is connected to the aspiration source 3430." *Id*. Garrison describes that the valve can be "a 3-way or 4-way stopcock" or a "flow controller" and "enable[s] one device, the other device, both devices, or neither device to be connected to the aspiration source at any given time." *Id.*; *see also id.* at [0049].

83. Garrison further discloses pre-charging a vacuum in the pressure source as shown in Figure 34. Garrison describes that "a locking syringe (for example a VacLok Syringe) is attached to the flow controller and the plunger is pulled back into a locked position by the user ***while the connection to the flow line is closed*** prior to the thrombectomy step of the procedure." Ex. 1006 (Garrison) at [0134] (emphasis added). Pulling back the syringe plunger while the connection (i.e., flow controller) is closed creates a vacuum and pre-charges the chamber of the syringe (i.e., pressure source). *Id.* at [0134], Fig. 34.

84. Garrison also discloses pre-charging a syringe with a stopcock in its discussion of testing flow rates through different catheters. In this testing, "each catheter was connected to a stopcock and thence to a 30 cc locking syringe." *Id.* at [0129]. The catheter tip was placed in a fluid, then the "catheter and syringe were purged of air, the syringe was emptied, and the stopcock was closed." *Id.* After this preparation, the syringe was "pulled back the full 30 cc volume and locked in place." *Id.* At this point, a vacuum would be pre-charged within the syringe.

Garrison discloses opening the stopcock, which releases the vacuum to create suction through the catheter, and recording the time it took for different amounts of fluid to enter the syringe. *Id.* In both of these examples, Garrison discloses "pre-charging a vacuum in a pressure source."

4. Fluidly connecting the pressure source to the elongated shaft to apply the pre-charged vacuum to the elongated shaft to aspirate a first portion of the clot material into the elongated shaft"

85. Claim 1 next recites the method step of: "fluidly connecting the pressure source to the elongated shaft to apply the pre-charged vacuum to the elongated shaft to aspirate a first portion of the clot material into the elongated shaft." Garrison discloses this limitation.

86. As I explained above, Garrison discloses pre-charging a vacuum within a syringe "while the connection to the flow line is closed prior to the thrombectomy step of the procedure." *Id.* at [0134]. Garrison further discloses that "[d]uring the procedure when the tip of the aspiration device (either the arterial access device or the catheter) is near or at the face of the occlusion, the user may open the connection to the aspiration syringe." *Id.* Garrison discloses that opening the valve after creating the pre-charged vacuum "would enable the maximum level of aspiration in a rapid fashion with one user …." *Id.* This means that opening the valve applies the pre-charged vacuum to the catheter to aspirate a first portion of

clot material into the catheter (elongated shaft). Ex. 1006 (Garrison) at [0165]-[0166].

87. Garrison also discloses this limitation in its testing of flow rates through different catheter sizes. As discussed above, Garrison discloses closing a stopcock and pre-charging a vacuum in a syringe by pulling back the plunger. *Supra* § VI.A.3. Garrison then discloses opening the stopcock to release the pre-charged vacuum and provide suction through the catheter. *Id.* Thus, Garrison discloses at least two examples of "fluidly connecting the pressure source to the elongated shaft to apply the pre-charged vacuum to the elongated shaft to aspirate a first portion of the clot material into the elongated shaft."

5. "Unsealing an attachment member coupled to a proximal portion of the elongated shaft"

88. Claim 1 next recites the method step of: "unsealing an attachment member coupled to a proximal portion of the elongated shaft." Garrison discloses this limitation or renders it obvious. Garrison also renders this limitation obvious in combination with Schaffer or Hartley.

a. Garrison

89. Garrison discloses this limitation or renders it obvious. Garrison's disclosed catheter 2030 includes "a proximal hub 2065" that "has a female Luer configuration for attachment of a syringe during prep and attachment of other components." Ex. 1006 (Garrison) at [0097]. The "proximal hub 2065" is an

"attachment member" at least because it permits the attachment of other devices to the catheter and, as I discuss below, can optionally include a hemostasis valve.

90. Garrison discloses that "a separate hemostasis valve may be attached to a proximal hub 2065, to allow introduction of devices such as a microcatheter, guide wire, or thrombectomy device while preventing or minimizing blood loss during the procedure." Ex. 1006 (Garrison) at [0098]. Garrison also discloses that "the hemostasis valve may be integral to the catheter proximal adaptor." *Id.* Garrison discloses using different types of hemostasis valves with catheter 2030, including "an adjustable-opening valve such as a Tuohy-Borst or rotating hemostasis valve (RHV)." *Id.*

91. Garrison does not label hub/adaptor 2065 in the figures. However, similar hubs/adaptors (2012 and 2015) are labeled for the arterial access sheath 2010 and guide catheter 2105. *Id.* at [0053], [0074]. For example, Garrison's Figure 3 illustrates guide catheter 2105, which has 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":

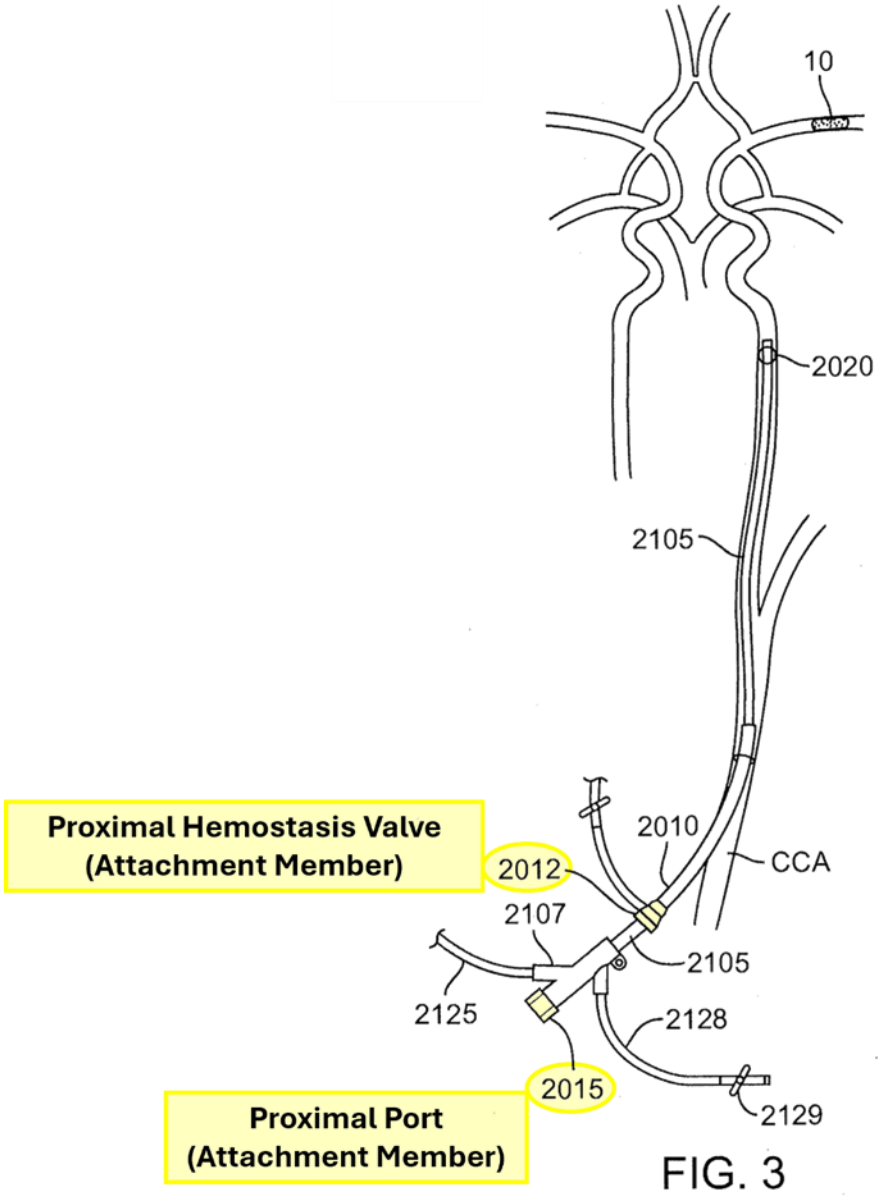


FIG. 3

Id. at [0053], Fig. 3; *see also id.* at [0050]-[0053], [0059], [0062], Figs. 1-3, 6. The figure also identifies the arterial access device having "proximal hemostasis valve 2012." *Id.* at [0053].

92. Catheter 2030's hemostasis valve would be located at the end of the proximal hub/adaptor, as is shown with hemostasis valves 2012 and 2015 in Figure

3, because that is the location where a user would insert other devices through the hub and where sealing would be necessary.

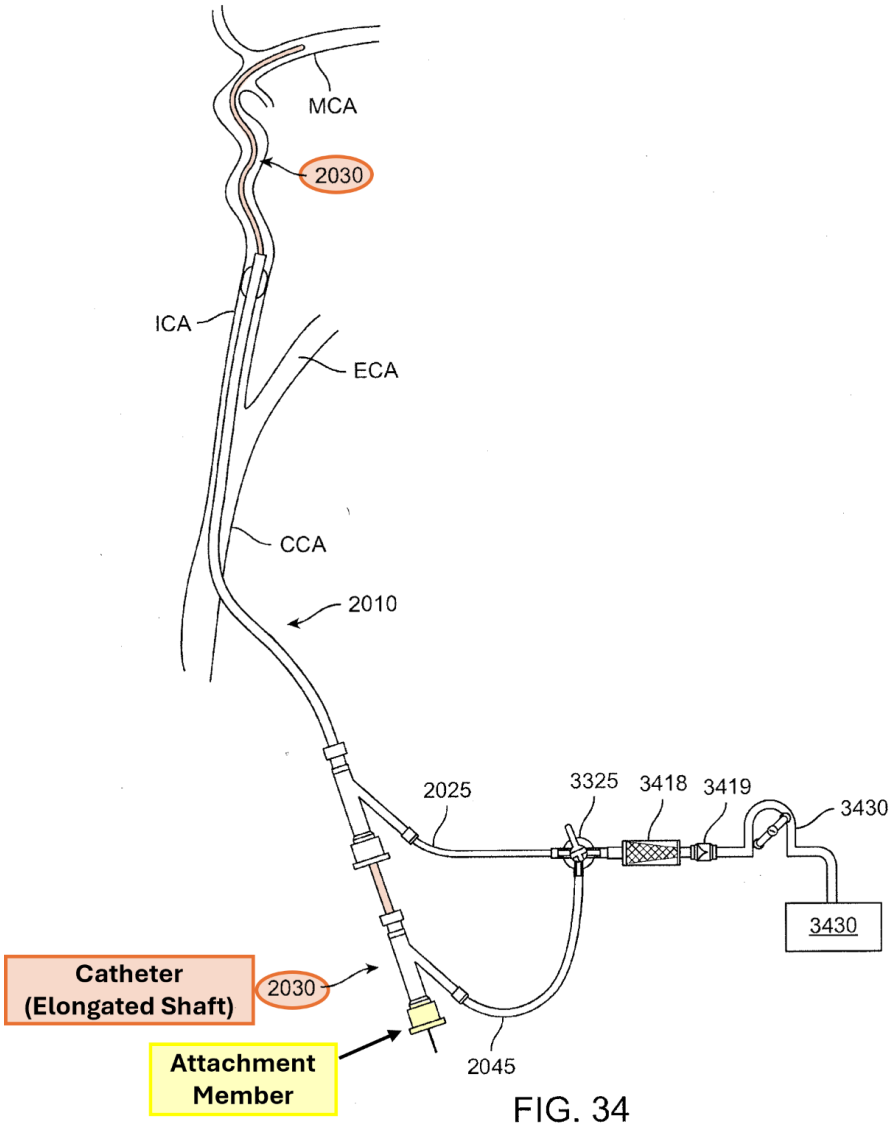


FIG. 34

Ex. 1006 (Garrison) at [0098], Fig. 34. I have identified the location of the attachment member/hemostasis valve in Figure 34 above.

93. As discussed above, the hemostasis valve in Garrison's hub/adaptor permits the "introduction of devices such as a microcatheter, guide wire, or thrombectomy device." *Id.* at [0097]. Garrison also discloses the valve may be "an

adjustable-opening valve such as a Tuohy-Borst or rotating hemostasis valve (RHV)." *Id.* To introduce a device through an RHV as described by Garrison, a user would be required to first unseal the valve. The general operation of an RHV can be seen in, for example, Hartley, which discloses a rotating hemostasis valve that the user rotates to open the valve before inserting devices. Ex. 1008 (Hartley) at [0034]-[0035], Figs. 1-4. Hartley's operation is consistent with my own use of rotating hemostasis valves, for example Tuohy-Borst valves, which the user would turn to open the valve before inserting a device. I personally used rotating hemostasis valves before January 2018.

94. Garrison also discloses a method of removing a first clot from a patient and, "if a secondary more distal treatment site needs to be reached after removal of a first occlusion, a second, smaller diameter catheter may be inserted though the first catheter, and positioned at the distal treatment site." Ex. 1006 (Garrison) at [0165]-[0166]. Again, in this example, the user would have to unseal the RHV to insert the second catheter. If the user did not unseal the valve, the user would not be able to insert a second catheter through the closed RHV.

95. Moreover, to the extent Garrison does not inherently describe unsealing the valve, a person of ordinary skill in the art would have found it obvious to do so. An interventional device cannot be inserted through a closed valve. Attempting to push the device through the closed valve would damage the device

and/or the valve. Thus, a person of ordinary skill in the art would have found it obvious to first unseal/open the valve before inserting the device. Thus, Garrison discloses this limitation or renders it obvious. *Id.*

b. Garrison and Schaffer

96. Garrison combined with Schaffer also renders this limitation obvious. Schaffer discloses an adjustable-opening "fluid stasis valve" for use with catheters to prevent the flow of blood through the valve during medical procedures:

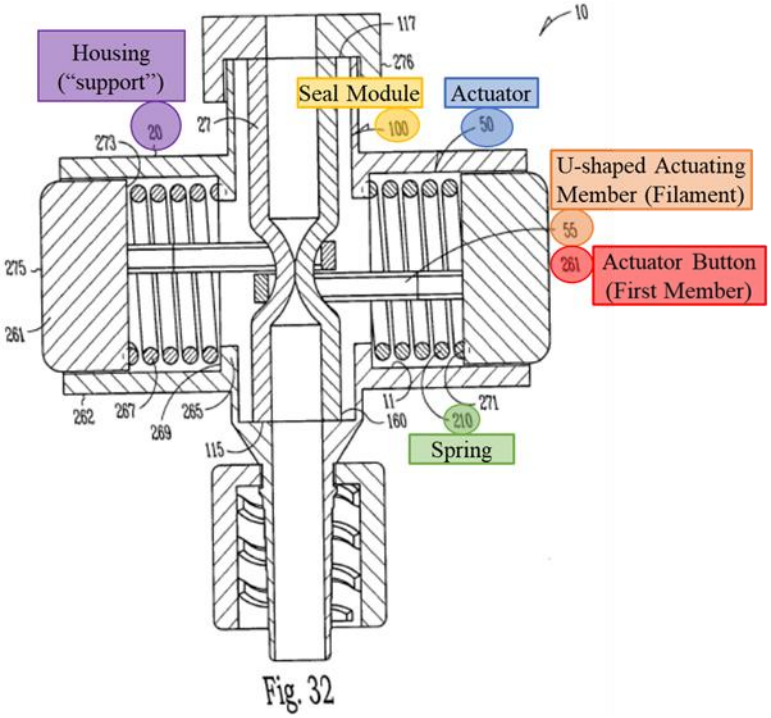


Fig. 32

Ex. 1007 (Schaffer) at [0002], [0046], [0055], Figs. 30-34. Schaffer describes unsealing the valve to permit insertion of another device by pressing one or more of the valve's buttons. *Id.* at [0077]. A person of ordinary skill in the art would have been motivated, and found it obvious, to use Schaffer's valve as the hemostasis

valve on Garrison's catheters (e.g., 2010 and 2030) for several reasons.

97. First, Garrison identifies "an adjustable-opening valve" as an exemplary hemostasis valve that can be combined with its catheters. Ex. 1006 (Garrison) at [0062], [0065], [0098]. Schaffer discloses an adjustable-opening valve and, therefore, a person of ordinary skill in the art would have been motivated to combine, and reasonably expected success in combining, Schaffer's valve with Garrison based on Garrison's express suggestion to do so.

98. Second, Schaffer discloses that its hemostasis valve is "for use with catheters" and "blocks the flow of gas or fluid completely and immediately with or without an instrument in place within the gas/fluid path." Ex. 1007 (Schaffer) at [0002], [0008], [0047], [0049]. Schaffer further discloses that various instruments can be inserted through the valve, such as "a catheter, guidewire, needle, or fiber." *Id.* at [0056], [0074]. Thus, Schaffer's valve performs the function of Garrison's "hemostasis valve" which is to "allow introduction of devices … while preventing or minimizing blood loss during the procedure." Ex. 1006 (Garrison) at [0098]. For this additional reason, a person of ordinary skill in the art would have been motivated to combine, and reasonably expected success in combining, Schaffer's valve with Garrison.

99. Third, a person of ordinary skill in the art would have recognized that Schaffer's hemostasis valve could simplify the operation of Garrison's clot

treatment system. For example, Schaffer's springs bias the valve toward the closed position, eliminating the need to manually seal the valve during procedures as in some prior-art valves. *Id.*

100. Fourth, the combination of Schaffer's valve with Garrison's aspiration catheters would have merely entailed the combination of the known elements of Schaffer's valve and catheter 2030 according to the known method of attaching the valve to a catheter's proximal hub or forming it integrally with the hub to yield the predictable result of minimizing blood loss through the catheter.

101. Fifth, a person of ordinary skill in the art in January 2018 had a finite number of predictable hemostasis valves to choose, including an "adjustable-opening valve" and an RHV. While other hemostasis valves also existed, all of the valves worked in a similar manner. Each of the available valves operated by compressing or moving a flexible member to create a seal around a catheter or other interventional tool. It would have been obvious for a person of ordinary skill in the art to try any of these well-known hemostasis valves with Garrison's catheter 2030. The known valves, like Schaffer's adjustable-opening hemostasis valve, are simple mechanical structures that operate in a predictable way. For this additional reason, a person of ordinary skill in the art would have reasonably expected success in combining Schaffer's valve with Garrison's catheters. *Id.* Thus, Garrison combined with Schaffer renders this limitation obvious.

c. Garrison and Hartley

102. Garrison combined with Hartley also renders this limitation obvious. Hartley discloses a type of RHV that "can be controlled to vary the size of the aperture through the valve and be flexible so that a seal may be formed against an instrument or other object inserted through the access valve." Ex. 1008 (Hartley) at [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":

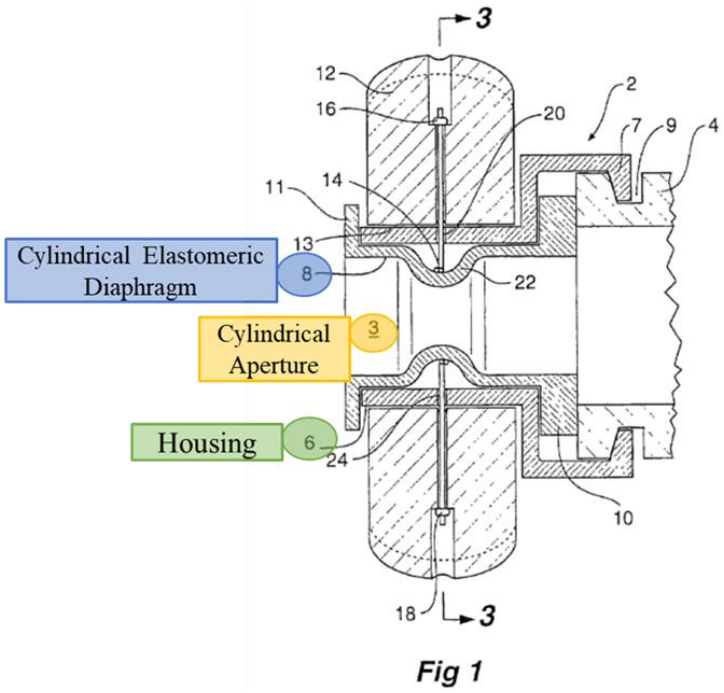


Fig 1

Id. at [0031], Fig. 1. Hartley further 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]. Hartley explains that the valve can be

unsealed to insert an instrument by rotating the valve. (*Id.*, [0034]-[0035].)

103. A person of ordinary skill in the art would have been motivated to combine Hartley's hemostasis valve with Garrison's catheters (e.g., 2010 and 2030), and reasonably expected success in doing so.

104. First, Garrison expressly discloses that catheters 2010 and 2030 can be combined with a "rotating hemostasis valve." Ex. 1006 (Garrison) at [0062], [0098]. Hartley discloses a type of RHV and, therefore, a person of ordinary skill in the art would have been motivated to combine, and reasonably expected success in combining, Hartley's RHV with Garrison based on this explicit suggestion.

105. Second, combining Hartley's valve with Garrison's catheters would have merely entailed the combination of known elements of Hartley's hemostasis valve and Garrison's catheters according to the known method of 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. Catheters having hemostasis valves were well-known in the art before January 2018, as were the procedures to combine a hemostasis valve with a catheter. A person of ordinary skill in the art would have encountered various types of hemostasis valves during their education and career and would have been familiar with how the valves operate. *Id.* The prior-art valves, like Hartley's valve, are simple mechanical

structures that operate in a predictable manner and would have been obvious to combine with Garrison's catheters. *Id.*

106. Third, a person of ordinary skill in the art in January 2018 had a finite number of predictable hemostasis valves to select when trying to seal a catheter. Garrison and Hartley reference some of the known hemostasis valves, including an "adjustable-opening valve such as a Tuohy-Borst or rotating hemostasis valve (RHV)," Hartley's rotating valve, or "a passive seal hemostasis valve." Ex. 1006 (Garrison) at [0098]. A person of ordinary skill in the art would have found it obvious to try any of these hemostasis valves in combination with Garrison's catheters (e.g., 2010 and 2030). The known hemostasis valves, including Hartley's RHV, are simple mechanical structures that operate in a predictable way. Thus, person of ordinary skill in the art would have reasonably expected success in combining any of the well-known valves with Garrison's catheters. Thus, Garrison combined with Hartley renders this limitation obvious.

6. "Advancing an interventional device distally through the attachment member and the elongated shaft"

107. Claim 1 next recites the method step of: "advancing an interventional device distally through the attachment member and the elongated shaft." Garrison discloses this limitation.

108. Garrison discloses that its catheter 2030 may "provide distal access for additional devices … at a location distal of the distal-most end of the arterial access

device 2010." Ex. 1006 (Garrison) at [0054]. Garrison further discloses that "[if] the catheter is unable to reach the treatment site, or if a secondary more distal treatment site needs to be reached after removal of a first occlusion, a second, smaller diameter catheter may be inserted through the first catheter, and positioned at the distal treatment site." *Id.* at [0166].

109. Garrison also discloses that catheter 2030's proximal hub 2065 may "allow introduction of devices such a microcatheter, guide wire, or thrombectomy device". *Id.* at [0098]. The microcatheter, guide wire, or thrombectomy device disclosed by Garrison are "interventional devices" at least because each device is inserted through the patient's vasculature to aid in treating the patient. For example, the thrombectomy devices may include "coil-tipped retrievers, stent retrievers, expandable cages, wire or filament loops, graspers, brushes, or the like." *Id.* at [0144]-[0145].

110. As shown in Fig. 2, Garrison illustrates a thrombectomy device 4100 (interventional device) [blue] advanced distally through the proximal hub (attachment member) [yellow] of catheter 2030 (elongated shaft) [orange] to engage the thrombus 10 (clot material) [pink] in a blood vessel:

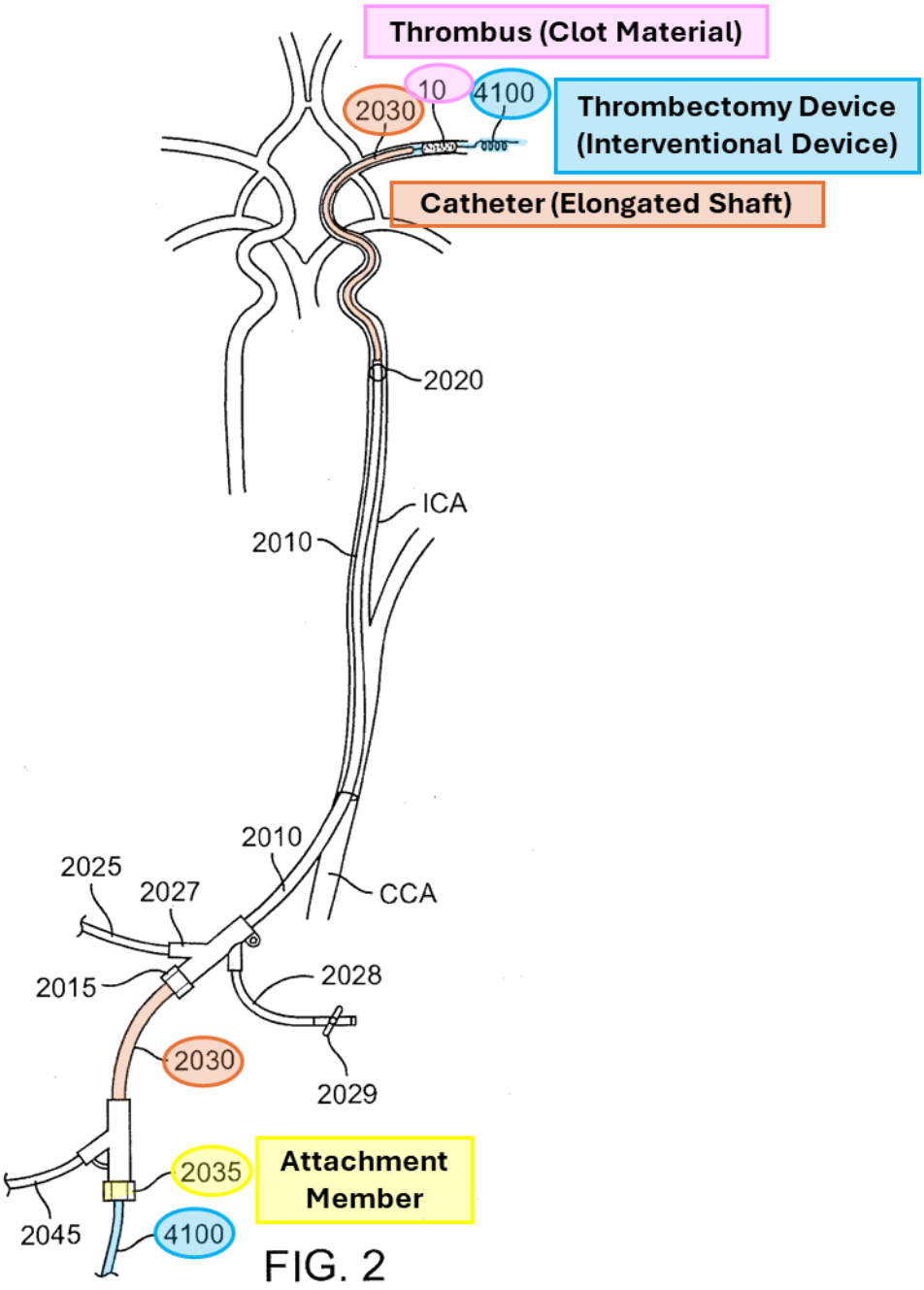


FIG. 2

Id. at [0056]; Fig. 2.

111. Garrison's Figure 33 also illustrates an interventional device [blue] advanced distally through the proximal hub (attachment member) [yellow] of the

catheter 2030 (elongated shaft) [orange] so the distal end is near the clot material [pink]:

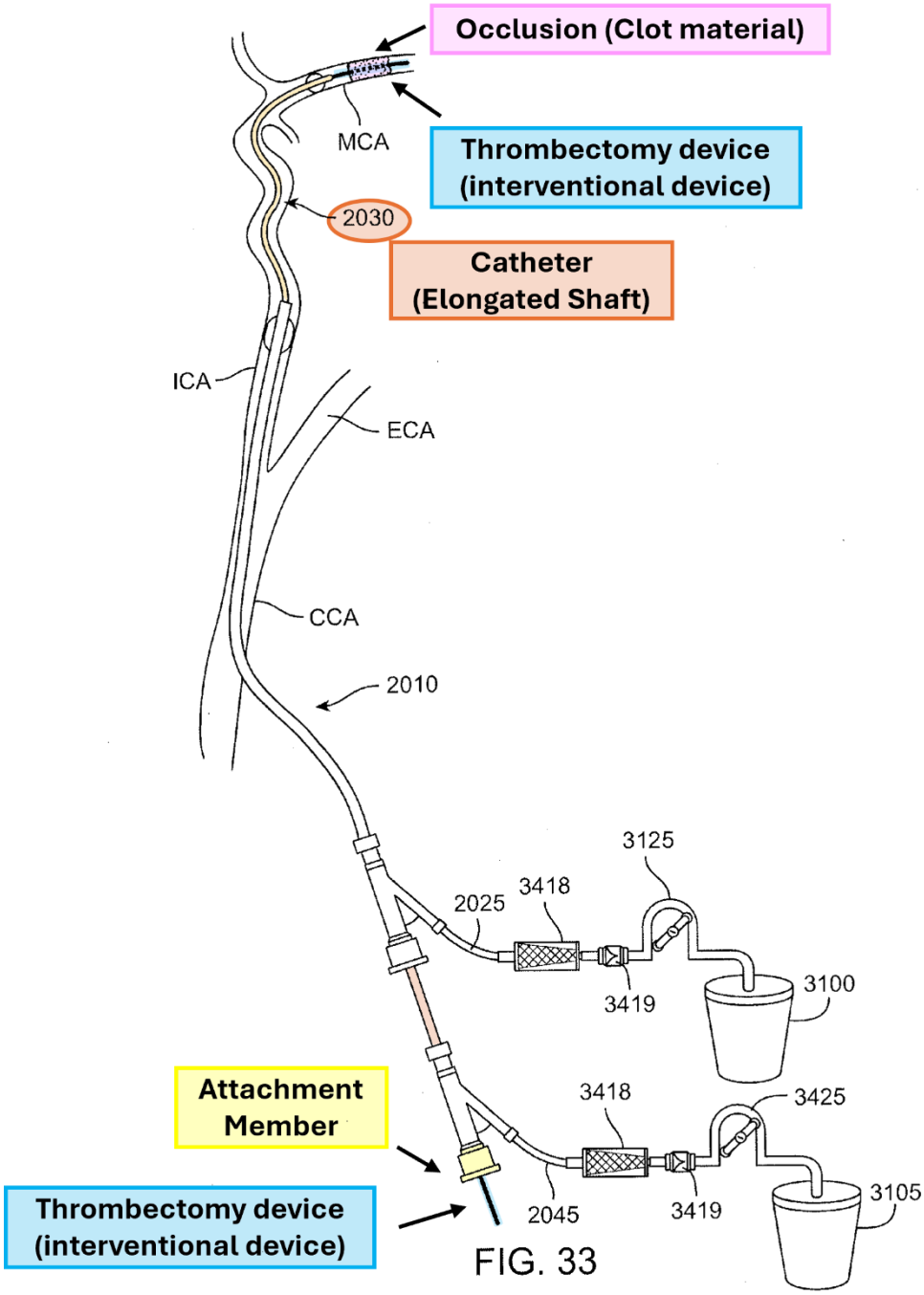


FIG. 33

Ex. 1006 (Garrison) at Fig. 33; [0131], [0050]-[0051]; *see also e.g., id.* at Fig. 2. Thus, Garrison discloses the step of advancing an interventional device distally through the attachment member and the elongated shaft.

7. <u>"Engaging the interventional device with a second portion of the clot material remaining in the blood vessel"</u>

112. Claim 1 next recites the method step of: "engaging the interventional device with a second portion of the clot material remaining in the blood vessel." Garrison discloses this limitation or renders the limitation obvious.

113. Garrison discloses aspirating a first clot through catheter 2030 and then using catheter 2030 "to deliver additional catheters and/or interventional devices to the site of the occlusion." Ex. 1006 (Garrison) at [0055]. *supra* §VI.A.6. Garrison additionally discloses that "if a secondary more distal treatment site needs to be reached after removal of a first occlusion, a second, smaller diameter catheter may be inserted through the first catheter, and positioned at the distal treatment site." *Id.* at [0166]. As I explained above, Garrison discloses many types of interventional devices including an expandable member deliverable through a microcatheter that can remove an occlusion as a single piece or remove portions of an occlusion. *Id.* at [00143].

114. Moreover, Garrison solves the very problem the '580 patent purports to address: the need to deploy separate devices to remove a clot. For example, Garrison recognizes that "aspiration with current catheter designs is limited and

often requires multiple attempts and/or adjunct mechanical thrombectomy devices, thus diminishing the time and reduced distal emboli benefits." Ex. 1006 (Garrison) at [0046]. To solve this problem, Garrison discloses incorporating accessory devices into the system such as thrombectomy device 4100, or other treatment devices such as stent retrievers and snares. *Id.* at [0056]. Garrison explains that the user can deploy these devices after aspirating a first clot portion. *Id.* at [0166]. Garrison also incorporates disruption devices that can break up the clot during aspiration. *Id.* at [0125]-[0126]. Garrison teaches steps to use the device including initiating aspiration and, "if and when a clot becomes stuck in the lumen of the catheter," engaging the disruption device with the clot to aspirate additional portions of the clot. *Id.* Thus, Garrison describes and solves the very problem the '580 patent purports to address and discloses engaging an interventional device with a second portion of clot material.

115. If Garrison does not disclose this limitation, Garrison renders the limitation obvious. As discussed above, Garrison describes aspirating a first clot portion using catheter 2030 before inserting a smaller catheter to remove a second clot portion. Ex. 1006 (Garrison) at [0166]. Garrison also describes inserting various interventional devices through small catheters to capture or break up clots. *See e.g., id.* at [0143]-[0144], [0125]-[0126].

116. A person of ordinary skill in the art would have been motivated to engage an interventional device with the second clot portion based on Garrison. Garrison teaches that the clot may be "too large or too strongly embedded into the vasculature such that it is not possible to remove the occlusion via aspiration alone, [such that] further steps are taken to remove the occlusion." Ex. 1006 (Garrison) at [0165]. Garrison expressly discloses deploying a thrombectomy device to remove such clots. *Id.* Based on this disclosure, a person of ordinary skill in the art would have been motivated to engage the interventional device inserted through catheter 2030 with the second clot portion.

117. Further, a person of ordinary skill in the art would have expected success in inserting an interventional device through catheter 2030 to engage a second clot portion. Garrison discloses that catheter 2030 may be used "to deliver additional catheters and/or interventional devices to the site of the occlusion." Ex. 1006 (Garrison) at [0055]. Similarly, Garrison discloses that the proximal hub 2065 on catheter 2030 can "allow introduction of devices such a microcatheter, guide wire, or thrombectomy device". *Id.* at [0098]. Garrison expressly discloses interventional devices delivered through a microcatheter. *Id.* at [0143], Fig. 39. Thus, a person of ordinary skill in the art would have reasonably expected success in delivering such a device through catheter 2030. For at least these reasons,

Garrison anticipates or renders obvious engaging the interventional device with a second portion of the clot material remaining in the blood vessel.

B. Claim 5 - Attachment member has a diameter that is about equal to an inner diameter of the elongated shaft

a. Garrison

118. Claim 5 depends from Claim 1 and recites: "wherein unsealing the attachment member includes exercising a valve of the attachment member such that a lumen of the attachment member has a diameter that is about equal to an inner diameter of the elongated shaft." I note that the '580 patent appears to equate exercising a valve with opening a valve. Ex. 1001 ('580 patent) at 11:41-47, 12:47-53. Garrison anticipates this claim or renders it obvious alone or in combination with Schaffer or Hartley.

119. Garrison discloses that the diameters of the inner catheters/interventional devices closely match the inner diameters of the outer catheters. In Figure 34, for example, the outer diameter of catheter 2030 approximates the inner diameter of catheter 2010:

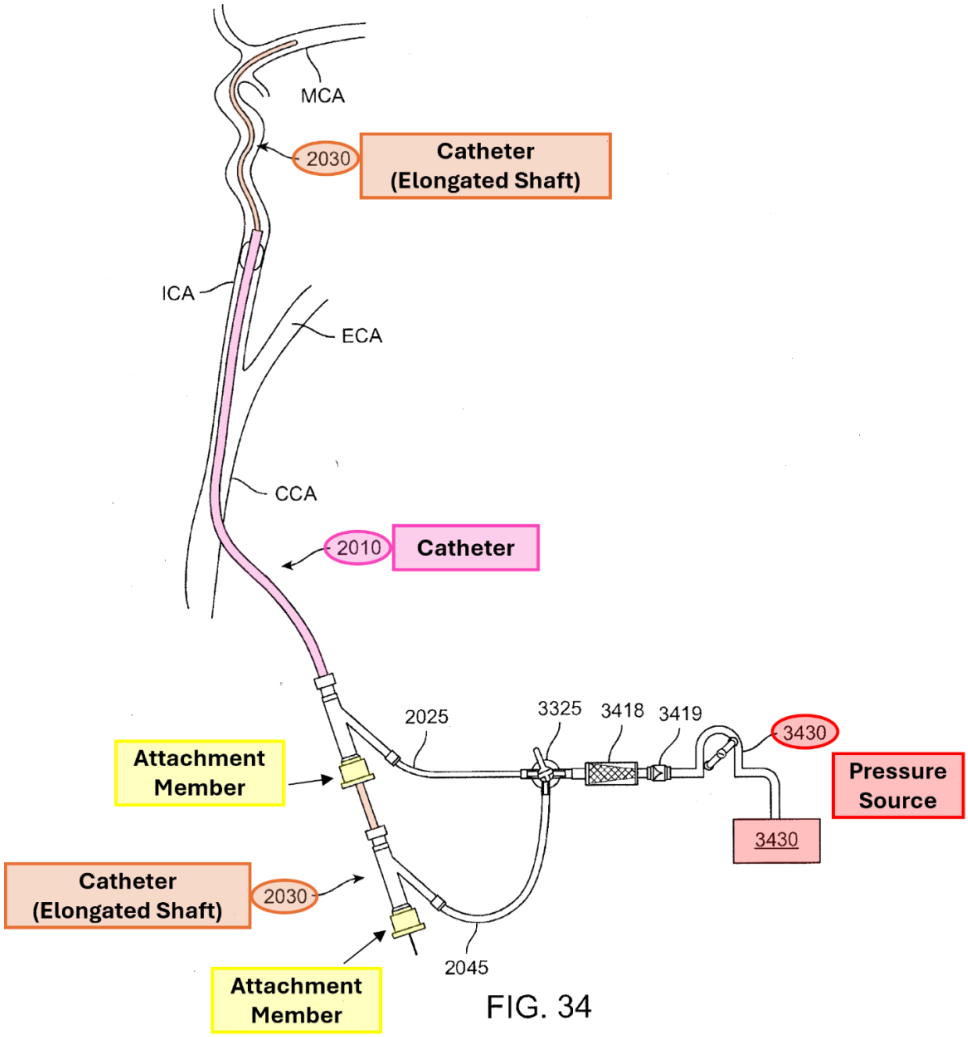


FIG. 34

Ex. 1006 (Garrison) at Fig. 34. Consistent with the illustration, Garrison provides exemplary catheter sizes for different embodiments where the inner diameter of the outer catheter closely approximates the outer diameter of the inner catheter. For example, Garrison discloses an outer catheter with a diameter of 0.086" to 0.088" and an inner catheter with a diameter of 0.083" to 0.085". *Id.* at [0124]. Garrison also explains that a mismatch in size between the telescoping catheters can cause "difficulty in advancing catheters through severe bends and across side branches." *Id.* at [0112].

120. The hemostasis valve in the attachment member must open to a diameter at least as large as the catheter/device going through it. If the hemostasis valve did not open in such a way, the catheter/device would not fit through the valve and/or the friction forces to advance the catheter/device would be unreasonably high. Thus, Garrison inherently discloses opening the valve so that a lumen of the attachment member has a diameter that is about equal to an inner diameter of the elongated shaft (e.g., catheter 2030) because the catheter/device going through Garrison's valves approximate the inner diameter of the elongated shaft.

121. Garrison also renders this limitation obvious. Because the diameter of the inner catheters/devices disclosed in Garrison approximate the diameters of the outer catheters, a person of ordinary skill in the art would have found it obvious to open the valve so that a lumen of the attachment member has a diameter that is about equal to an inner diameter of the elongated shaft. As explained above, if the valve were not opened to a diameter at least as large as the diameter of the catheter/device going through it, the catheter/device would not fit or would create unnecessarily high friction forces. Those friction forces would prevent the catheter/device from easily sliding through the valve. Thus, a person of ordinary skill in the art would have been motivated to, and reasonably expected success in, opening the valve so that a lumen of the attachment member has a diameter that is

about equal to an inner diameter of the elongated shaft to ease insertion of similarly sized devices through the valve.

b. Garrison and Schaffer or Hartley

122. Additionally, Garrison combined with Schaffer or Hartley renders this claim obvious. Schaffer, for example, illustrates a hemostasis valve in which the unsealed valve lumen has a diameter that is equal to the diameter of the connector. The inner diameter of the connector is about the diameter of the catheter (elongated shaft) attached to the connector. Thus, the unsealed valve lumen has a diameter is about equal to the inner diameter of the elongated shaft:

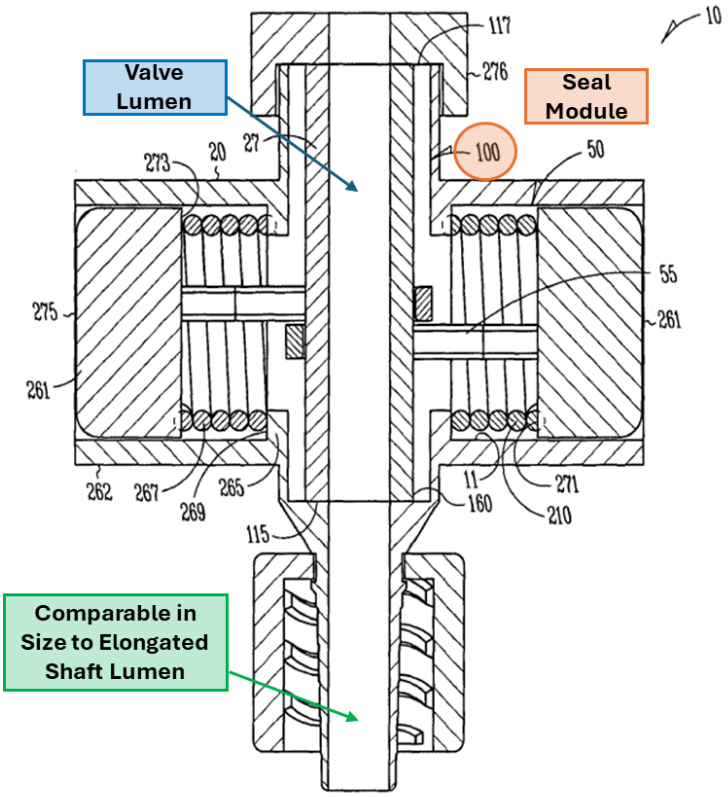


Fig. 34

Ex. 1007 (Schaffer) at Fig. 34. Based on the disclosure of these illustrations and

the knowledge of person of ordinary skill in the art described above, a person of ordinary skill in the art would have been motivated to adopt a similar configuration when combining Schaffer with Garrison to ease insertion of devices through Schaffer's valve.

123. Similarly, Hartley illustrates a hemostasis valve in which the unsealed cylindrical aperture (lumen) of the valve has a diameter that is about equal to an inner diameter of the elongated shaft:

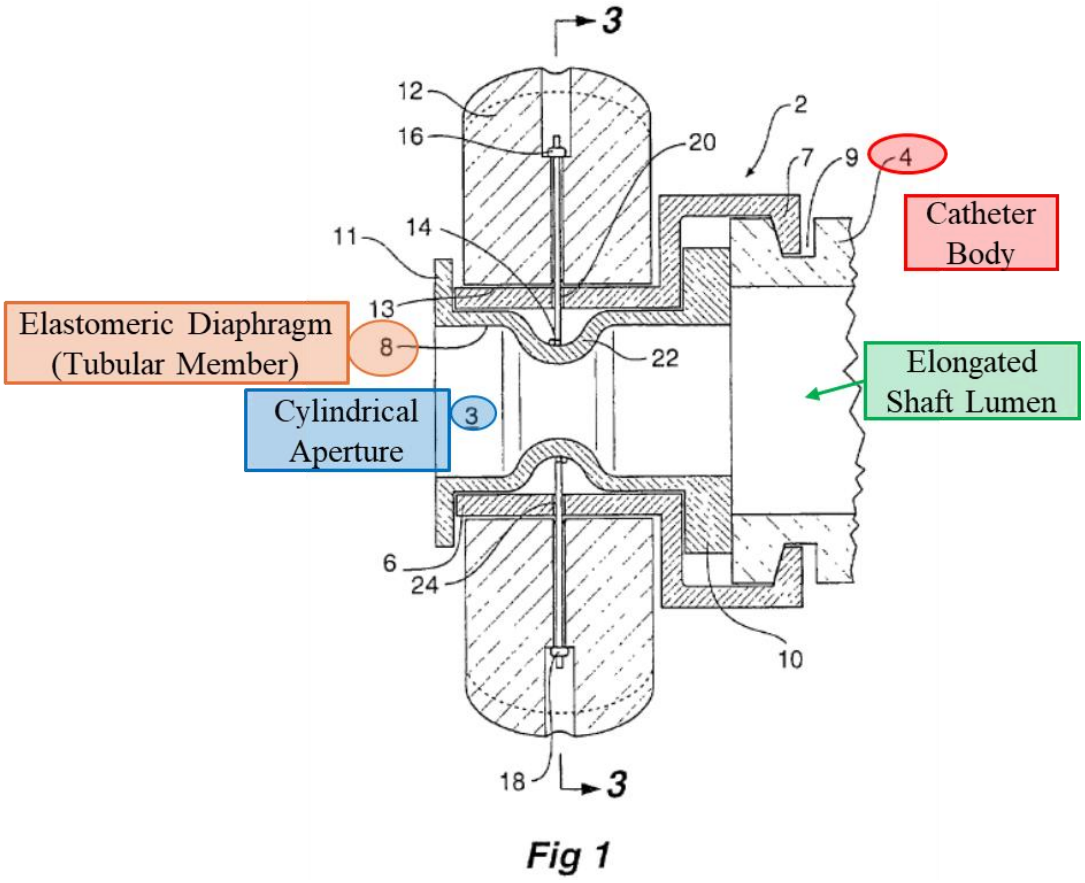


Fig 1

Ex. 1008 (Hartley) at Fig. 1. Based on these illustrations, and the knowledge of person of ordinary skill in the art described above, a person of ordinary skill in the

art would have been motivated to adopt a similar configuration when combining Hartley with Garrison to ease insertion of devices through Hartley's valve.

C. Claim 6 - Unsealing the attachment member includes pressing one or more buttons

124. Claim 6 depends from Claim 1 and recites: "wherein unsealing the attachment member includes pressing one or more buttons on the attachment member." Garrison combined with Schaffer renders this claim obvious.

125. Schaffer's valve includes two spring-loaded actuator buttons 261 "movable from a first position to a second position on opposing sides of the housing":

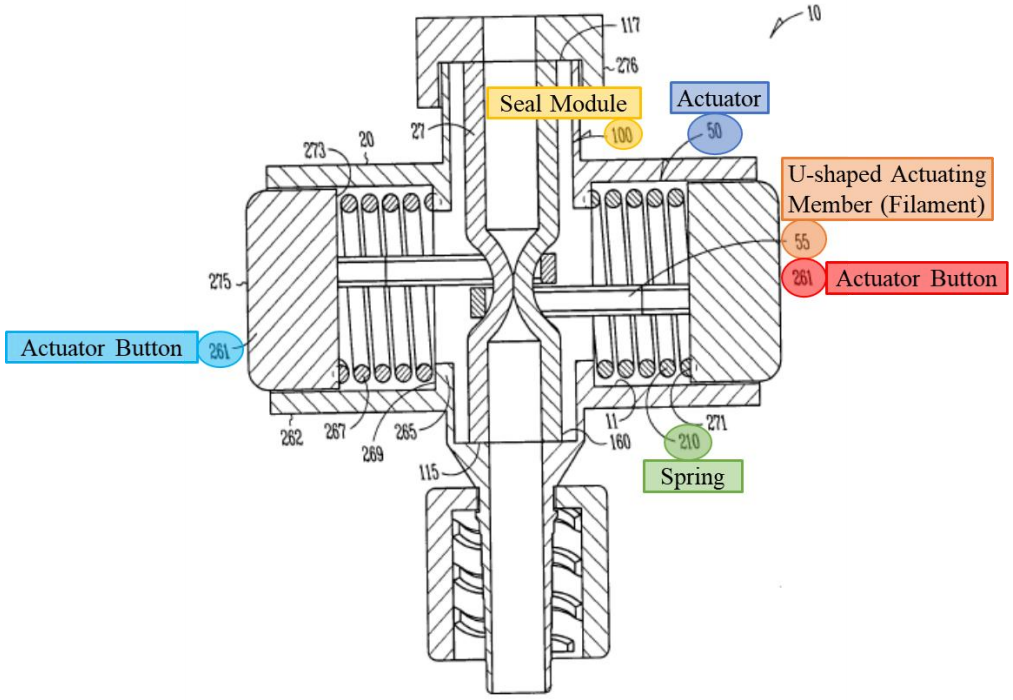
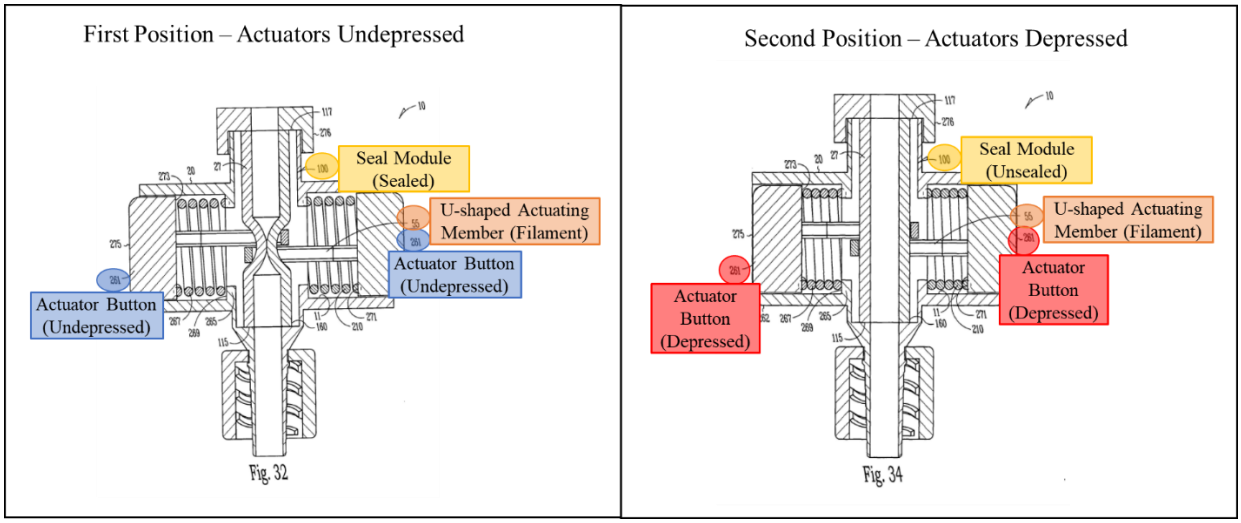


Fig. 32

Ex. 1007 (Schaffer) at [0075]-[0076], Figs. 31-32. When a user presses one or more

of the buttons, Schaffer's valve moves from a first, sealed position to a second, unsealed position as shown:



Id. at [0077], Figs. 32, 34. Thus, Garrison combined with Schaffer's valve renders this claim obvious. A person of ordinary skill in the art would have been motivated to, and reasonably expected success in, combining Schaffer's valve with Garrison's system for the reasons I provided in Claim 1. *Supra* § VI.5.b.

D. <u>Claim 9 - Fluidly connecting the pressure source to the elongated shaft</u>

126. Claim 9 depends from Claim 1 and recites: "wherein fluidly connecting the pressure source to the elongated shaft to apply the pre-charged vacuum generates suction at the distal portion of the elongated shaft." Garrison discloses this claim.

127. As discussed above, Garrison describes an embodiment in which "a locking syringe (for example a VacLok Syringe) is attached to the flow controller and the plunger is pulled back into a locked position by the user while the

connection to the flow line is closed prior to the thrombectomy step of the procedure." Ex. 1006 (Garrison) at [0134]. Once the catheter is positioned near the thrombus, "the user may open the connection to the aspiration syringe" to "enable the maximum level of aspiration in a rapid fashion." *Id.* Because the clot is located at the distal end of the catheter, *see e.g., id.* at Figs. 2, 33, the pre-charged vacuum must generate suction at the distal portion of the elongate shaft, otherwise the system could not rapidly aspirate the clot. Further, Garrison describes a closed system between the pressure source and the distal tip of the catheter. Thus, any pressure generated in the pressure source can only be transmitted to the distal end of the catheter. Thus, Garrison discloses this claim.

E. Claim 11 - The pressure source is fluidly coupled to the elongated shaft via a fluid control device

128. Claim 11 depends from Claim 1 and recites: "wherein the pressure source is fluidly coupled to the elongated shaft via a fluid control device, and wherein (a) opening of the fluid control device fluidly connects the pressure source to the elongated shaft and (b) closing of the fluid control device fluidly disconnects the pressure source from the elongated shaft." Garrison discloses these limitations.

129. The stopcock illustrated in Garrison's Figure 34 and the flow controller discussed in connection with that same figure are fluid control devices at least because they "control which device is connected to the pressure source." Ex. 1006 (Garrison) at [0132]. Garrison explains that closing the stopcock or flow

controller "may enable one device, the other device, both devices, or neither [catheter] to be connected to the aspiration source at any given time." *Id*.

130. As illustrated in Figure 34, the pressure sources is fluidly coupled to the elongated shaft (catheter 2030) via the valve 3325 (fluid control device):

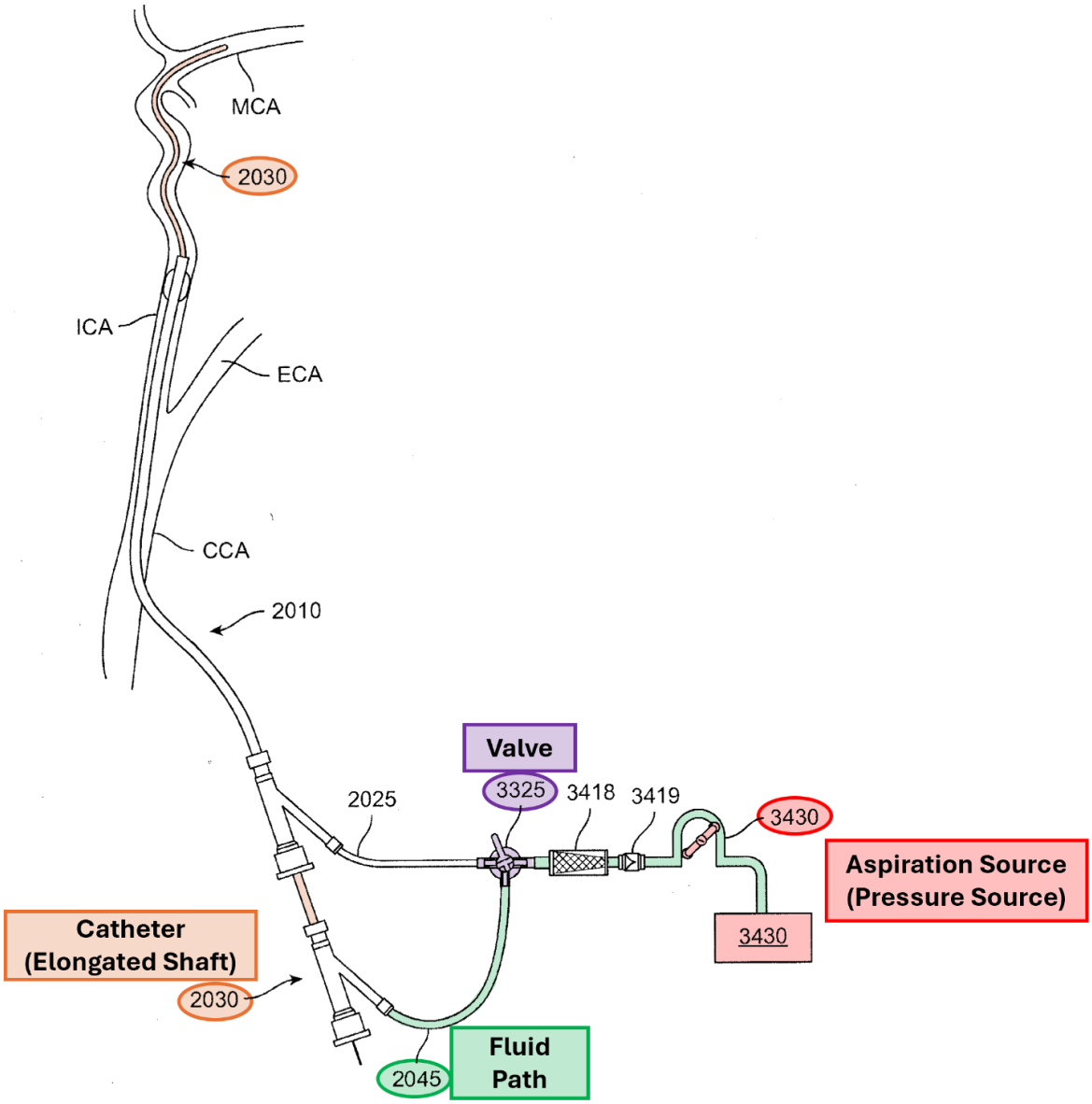


FIG. 34

Id., Fig. 34, [0131]-[0132]. As explained in Claim 9, opening the valve fluidly connects the pressure source to the catheter 2030 (elongated shaft) and applies the pressure to the distal tip of the catheter. *Supra* § VI.D. Thus, Garrison discloses this limitation.

F. Claim 12 - Pre-charging the vacuum in the pressure source

131. Claim 12 depends from Claim 11 and recites: "wherein pre-charging the vacuum in the pressure source includes activating the pressure source while the fluid control device is closed, and wherein fluidly connecting the pressure source to the elongated shaft includes opening the fluid control device." As discussed in claims 1, 9, and 11 above, Garrison discloses this claim. *Supra* §§ VI.A.3-5; § VI.D-E.

G. Claim 13 - The fluid control device comprises a user-actuatable valve

132. Claim 13 depends from Claim 11 and recites: "wherein the fluid control device comprises a user-actuatable valve." The stopcock and flow controller disclosed in Garrison are user-actuatable valves at least because the user must manipulate the valve (e.g., twist the lever of the stopcock 3325 or move the slide of the flow controller 3400) to open or close (actuate) the valve. Ex. 1006 (Garrison) at [0131]-[0134], Figs. 34-35. Thus, Garrison discloses this limitation.

H. Claim 14 - The attachment member comprises a hemostasis valve

133. Claim 14 depends from Claim 1 and recites: "wherein the attachment member comprises a hemostasis valve." As I explained above with respect to claim 1, Garrison discloses this limitation or renders it obvious alone or in combination with Schaffer or Hartley. *Supra* § VI.A.5.

I. Claim 15 - The hemostasis valve includes a tubular member, a button, and a filament

134. Claim 15 depends from Claim 14 and recites: "wherein the hemostasis valve includes a tubular member, a button, and a filament coupled to the button and the tubular member, and wherein unsealing the hemostasis valve includes pressing the button to loosen the filament to allow the tubular member to expand." Garrison combined with Schaffer and optionally Hartley renders this claim obvious.

1. Tubular Member

135. Schaffer's hemostasis valve includes a "seal module 100" that comprises "a flexible, elongate tubular structure 101." Ex. 1007 (Schaffer) at [0049], [0051], [0054], [0075]. The seal module 100 defines a lumen 193:

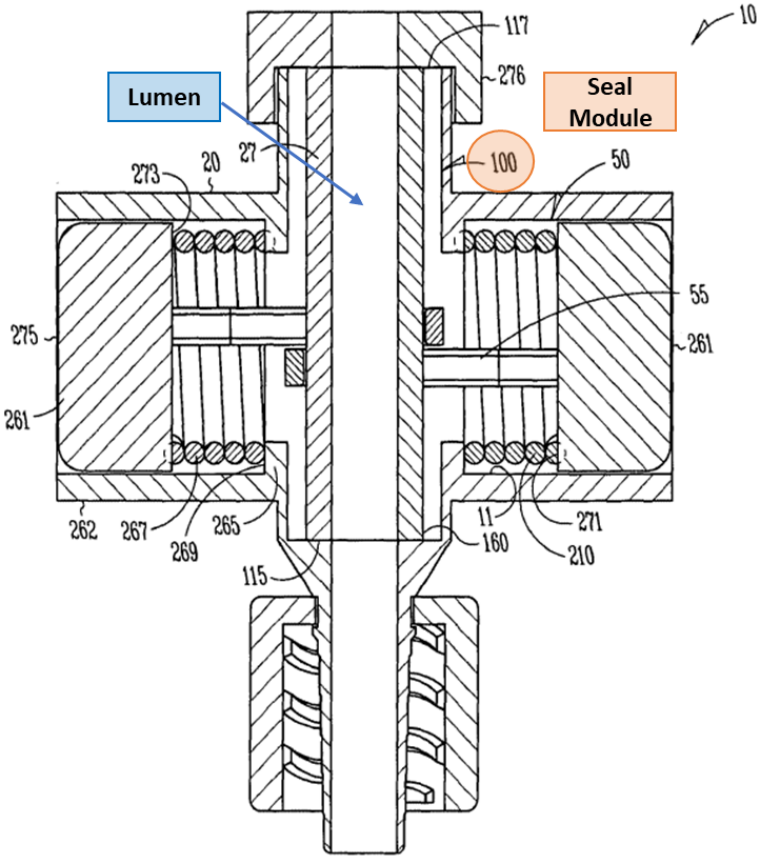


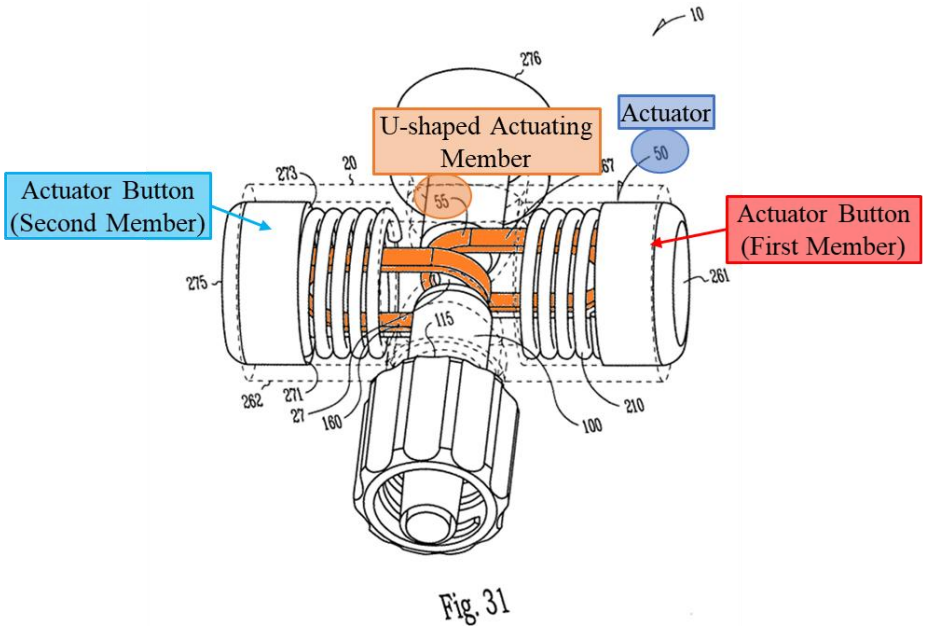
Fig. 34

Id. at [0058], Figs. 12, 34. Schaffer discloses that "a range of instruments [can be] used within the seal module," such as "a catheter, guidewire, needle, or fiber." *Id.* at [0056]. Thus, Schaffer's seal module 100 is "a tubular member."

2. <u>Filament</u>

a. <u>Schaffer</u>

136. Schaffer's valve includes two actuating members, which may be U-shaped, coupled to the actuator buttons:



Ex. 1007 (Schaffer) at [0076], Fig. 31. Schaffer's actuating members are a "filament" as claimed in the '580 patent. *Supra* § IV.

137. Schaffer's actuating members are formed from aluminum or plastic, and resemble a ribbon, flat wire, sheet, or tape. Ex. 1007 (Schaffer) at [0081], Figs. 31-34. The '931 application (allegedly incorporated into the '580 patent) states that the filament can be made from a polymer, which includes Schaffer's plastic, or a metal, which includes Schaffer's aluminum. *Supra* § IV. Likewise, the '931 application states that a filament may be a ribbon, flat wire, sheet, or tape, which includes Schaffer's U-shaped actuating members. *Id*.

138. I notice in related IPRs that Patent Owner characterizes Schaffer's actuating members as "rigid." Ex. 1031 ('011 patent Institution Decision) at 38; Ex. 1032 ('012 patent Institution Decision) at 32. However, Schaffer does not

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

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

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

Id. at [0082]. However, the description that a device is "made from machining" is not dispositive of whether the finished product is rigid or flexible. In the case of

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

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

on the seal module, which in turn allows the seal module "to retract to an uncollapsed configuration where gases and fluids can pass therethrough." Ex. 1007 (Schaffer) at [0077], Fig. 34. Schaffer's buttons move inwardly when force is applied, releasing tension on the actuating members (filaments) and allowing the seal module/tubular member to retract to an uncollapsed configuration, the exact same way that the '580 patent's filament does.

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

142. Schaffer discloses that in a first position (below), the actuating members are "at least partially circumferentially disposed about the portion 108 of the seal module 100 depressing and at least partially collapsing a portion 108 of the containment structure 160 by a compressive force 67 (e.g. by a spring 210)":

First Position – Actuator Buttons Undepressed

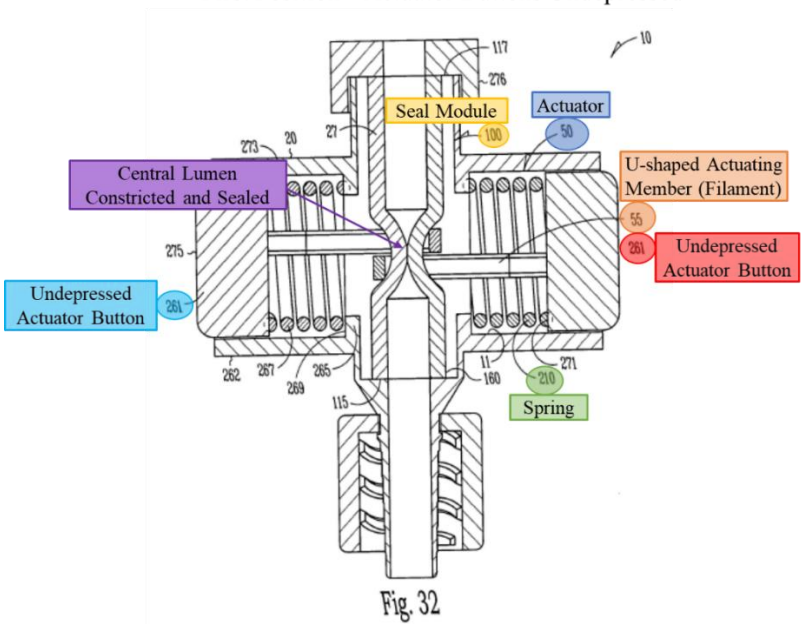


Fig. 32

Ex. 1007 (Schaffer) at [0077], Fig. 32. In a second position (below), the actuator buttons are pressed inwardly, compressing the springs to loosen the actuating members, allowing the seal module 100 to return to its uncollapsed/unsealed configuration so fluid can pass:

Second Position – Actuator Buttons Depressed

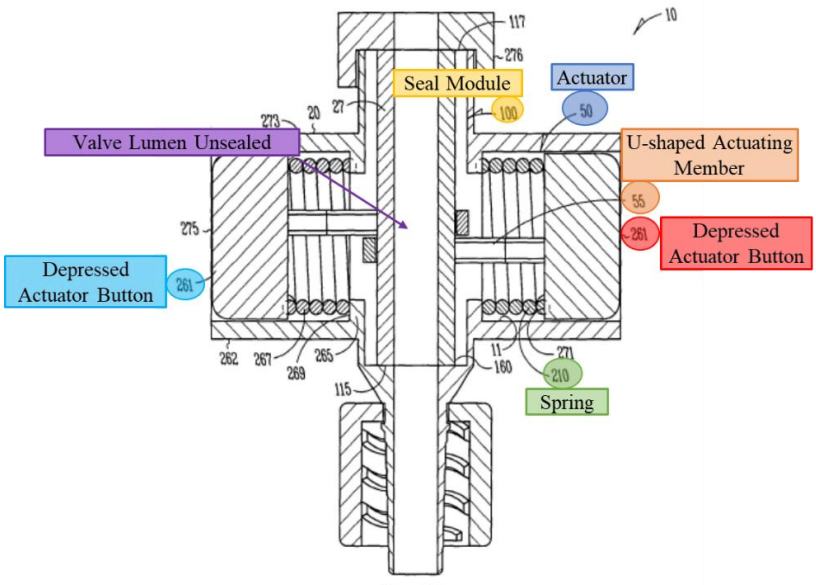


Fig. 34

Id., [0077], Fig. 34. Thus, Garrison combined with Schaffer renders this limitation obvious.

b. Schaffer and Hartley

143. If Schaffer does not disclose a "filament," Hartley does. Hartley describes a hemostasis valve having a cylindrical housing that holds a "cylindrical elastomeric diaphragm," and a rotary actuator mounted to the housing:

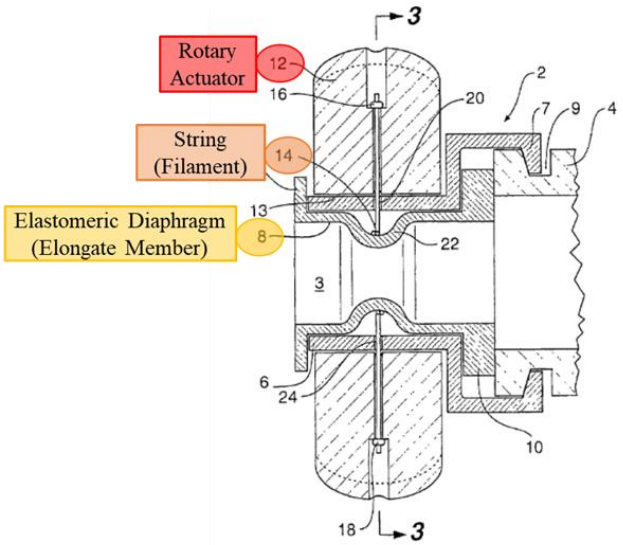
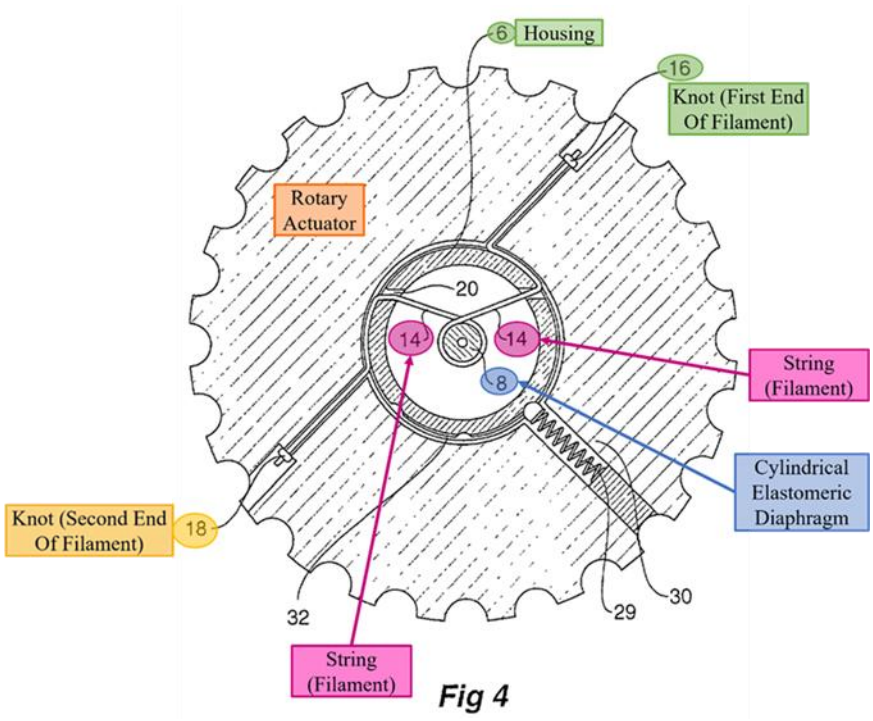


Fig 1

Ex. 1008 (Hartley) at [0031], Fig. 1. Hartley's valve includes a "string 14 … mounted into the rotary actuator." *Id.* Hartley's string 14 is a "filament" because the string is made of at least one or more threads, lines, or cords.

144. Hartley's string is secured to the rotary actuator via knots 16 at the ends of the filament and "is wound preferably twice around the cylindrical diaphragm 8":

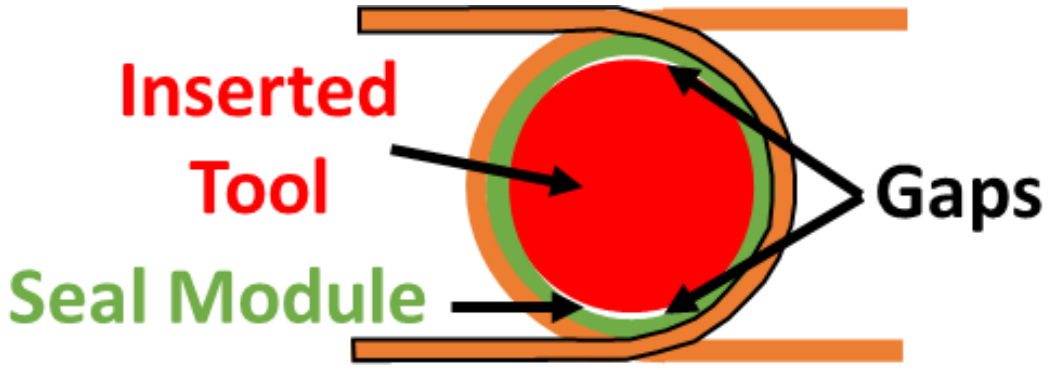


Ex. 1008 (Hartley) at [0031], Fig. 4.

145. Hartley discloses that "[r]otation of the rotary actuator 12 with respect to the cylindrical housing 6 will cause the string 14 to be pulled in both directions at once and hence the cylindrical diaphragm 8 to be constricted." Ex. 1008 (Hartley) at [0031], [0034], Fig. 4. Hartley further discloses the valve "will close over a range of diameters of devices passed through the valve or can close completely down to be self sealing." *Id.* at [0037]. Hartley also discloses that rotation of the valve in the opposite direction "will cause the sutures to loosen again so that the resilient cylindrical diaphragm will retain its original shape." *Id.* at [0034].

146. A person of ordinary skill in the art would have found it obvious to substitute Hartley's string for Schaffer's actuating members in Schaffer's valve. The combination of Hartley's string and Schaffer's valve would have merely entailed substitution of one known element, Hartley's string, for another, Schaffer's actuating members, to yield the predictable result of sealing Schaffer's valve.

147. Hartley's disclosure that its string can "close over a range of diameters of devices passed through the valve or can close completely down to be self-sealing" would have further motivated a person of ordinary skill in the art to substitute Hartley's string for Shaffer's actuating members. Ex. 1008 (Hartley) at [0037]. A person of ordinary skill in the art would have recognized that Hartley's string may seal more effectively across a wider range of tool diameters and shapes than Schaffer's U-shaped actuating members. Depending on the inserted tool, Schaffer's actuating members may form small gaps between the valve's seal module and the tool's outer surface, as I illustrate below:



Hartley's string would not suffer from this potential issue because the string more precisely conforms to the tool diameters.

148. I note in related proceedings that Patent Owner argues a person of ordinary skill in the art would not have been motivated to modify Schaffer's valve with Hartley's string because Schaffer would not result in gaps. Patent Owner Preliminary Response re: '011 patent filed in *Imperative Care, Inc. v. Inari Medical Inc.,* IPR2024-01157, Paper 5 at 28-29 (P.T.A.B. Oct. 29, 2024); Patent Owner Preliminary Response re: '012 patent filed in *Imperative Care, Inc. v. Inari Medical Inc.,* IPR2025-00156, Paper 5 at 43-44 (P.T.A.B. Feb. 25, 2025). However, even Schaffer recognizes it may not form a complete seal with the "gelatinous" and "sticky" valves identified by Patent Owner, stating the valves form a "***nearly*** fluid/gas tight seal." Ex. 1007 (Schaffer) at [0059]. Further, Patent Owner argues that Schaffer's "gelatinous" or "sticky" valve has "selfclosing" properties so it would not form any gaps. Patent Owner Preliminary Response re: '011 patent filed in *Imperative Care, Inc. v. Inari Medical Inc.,* IPR2024-01157, Paper 5 at 29 (P.T.A.B. Oct. 29, 2024). But the portion of Schaffer that refers to a "sticky" or "gelatinous" substance refers to embodiments of the valve having three portions where one of the portions can optionally be made from a "sticky" or "gelatinous" substance having a specific "shore hardness." Ex. 1007 (Schaffer) at [0059]. Schaffer discloses many other materials that would not be "sticky" or "gelatinous"

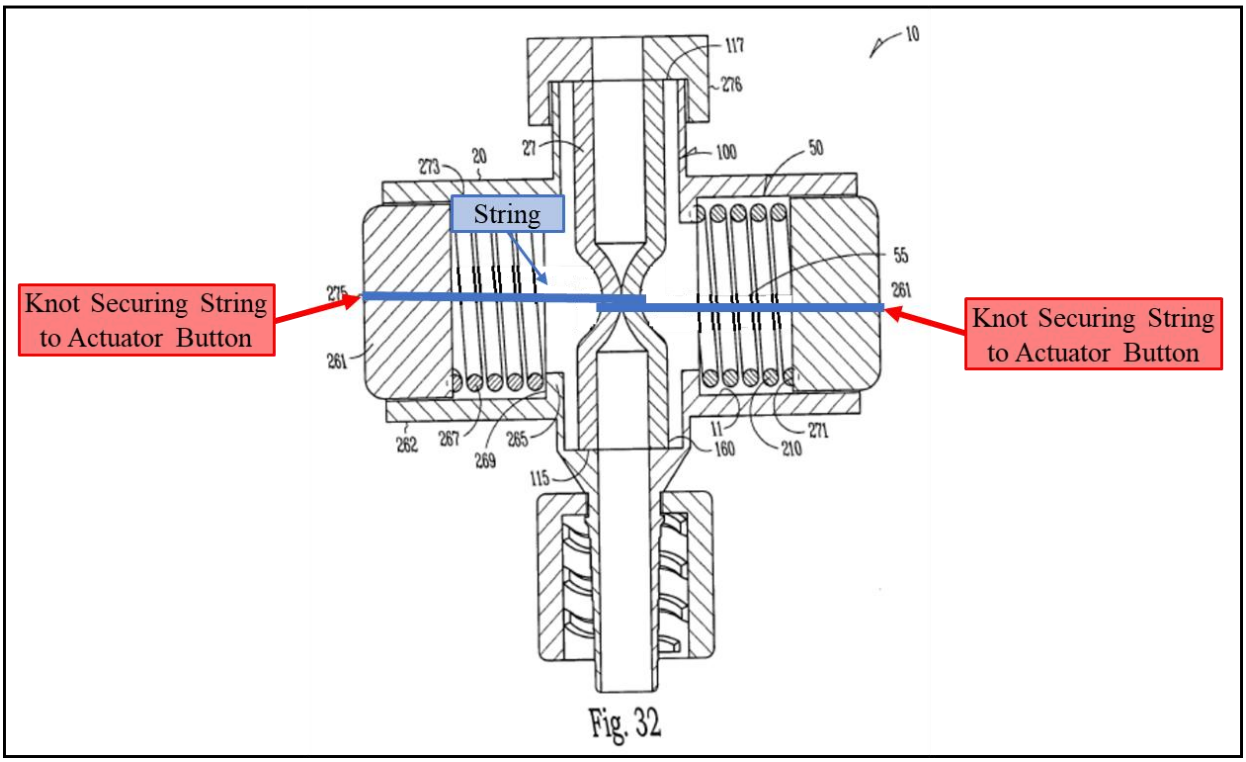
that could make up that same portion of the valve, such as modified vinyl, silicone, or polyurethane. *Id.* Nothing in Schaffer suggests that the third valve portion must be made with a "sticky" or "gelatinous" substance. Additionally, Schaffer makes clear that the valves in Figures 31-34 do not require three portions stating: "The seal module 100 is formed of one or more seal members, as discussed above." *Id.* at [0075]. Further, a person of ordinary skill in the art would have recognized that the "sticky" or "gelatinous" materials would not work well with the seal modules disclosed in Figures 31-34 because those seal modules must "retract to an uncollapsed configuration" when the tension on the module is released by the actuating members. A seal module made of the "sticky" or "gelatinous" materials would not easily return to its uncollapsed configuration because the seal would stick to itself inhibiting the retraction and the seal would not have the requisite resiliency.

149. A person of ordinary skill in the art had a finite number of materials to select from to constrict a tubular member in a hemostasis valve in January 2018. Hartley and Schaffer disclose two such materials: Hartley's string and Schaffer's actuating members (which can be plastic or metal). A person of ordinary skill in the art would have found it obvious to select from these finite, predictable materials for constricting a valve and, as discussed below, would have had a reasonable expectation of success in implementing them.

150. Likewise, a person of ordinary skill in the art would have had a finite number of filament configurations to select from to constrict a tubular member in a hemostasis valve in January 2018. Hartley discloses a string that runs from one side of the valve to the other and wraps around the tubular member, while Schaffer discloses two u-shaped members that collective wrap around the tubular member. A person of ordinary skill in the art would have found it obvious to select either of these finite, predictable configurations for constricting a valve and, as discussed below, would have had a reasonable expectation of success in implementing them.

151. A person of ordinary skill in the art would have had a reasonable expectation of success in substituting Hartley's string for Schaffer's actuating members. Hartley teaches using simple knots to attach the string to the rotary actuator. Ex. 1008 (Hartley) at [0031]. A person of ordinary skill in the art would have reasonably expected that similar knots would secure Hartley's string to Schaffer's actuator buttons. For example, each end of Hartley's string could be threaded through small holes in Schaffer's buttons and knotted on the other side. This simple modification, as can be seen below, would have been well within the skill person of ordinary skill in the art:

Demonstrative Illustration
Schaffer + Hartley's String



152. Also, as can be seen below would have recognized that Hartley's string and Schaffer's actuating members function in similar ways and, therefore, no other modifications to Schaffer's valve would be necessary. Both Hartley and Schaffer collapse a valve lumen by pulling the ends of the actuating members/string in opposite directions. Ex. 1007 (Schaffer) at [0077]; Ex. 1008 (Hartley) at [0031]. Thus, if Hartley's string were incorporated into Schaffer's valve, as can be seen below would have reasonably expected Schaffer's springs to pull the ends of the string in opposite directions to constrict Schaffer's seal module. *Id*.

153. Likewise, a person of ordinary skill in the art would have also reasonably expected that pressing Schaffer's buttons inwardly (i.e., second position) would release the tension on the string, allowing the lumen to open. *See* Ex. 1007 (Schaffer) at [0077]; Ex. 1008 (Hartley) at [0034]. Schaffer's seal module is formed from a "highly deformable, non-compressible material 166 (e.g., plastic)" and is "configured to maintain an open lumen 193 when no compressive force 67 is applied." Ex. 1007 (Schaffer) at [0054]. Thus, Schaffer's seal module has the resilience to open when the tension on the string is released. Moreover, if the resiliency of Schaffer's lumen required adjustment to function with Hartley's string, a person of ordinary skill in the art would have possessed the skills and knowledge to select an appropriate material with the proper resiliency. Schaffer discloses various materials for the seal module, including "modified vinyl, silicone, polyurethane or a combination thereof." *Id.* at [0081].

154. Further, Hartley discloses that winding the string around the central lumen forms an effective seal. Ex. 1008 (Hartley) at [0031], [0037]. Thus, when replacing Schaffer's actuating members with Hartley's string, a person of ordinary skill in the art would have been motivated to similarly wind Hartley's string around Schaffer's seal module. A person of ordinary skill in the art would have reasonably expected success in using this configuration because Hartley teaches the

configuration forms an effective seal. Thus, Schaffer combined with Hartley discloses this limitation.

3. Button

155. Schaffer discloses "pressing the button to loosen the filament to allow the tubular member to expand" as discussed in Claim 6. *Supra* § VI.C. Further, as discussed above, a person of ordinary skill in the art would have reasonably expected that pressing Schaffer's buttons would loosen Hartley's string if it were substituted for Schaffer's actuating members. *Supra* § VI.I.2.b. Thus, Schaffer discloses this limitation, and Garrison combined with Schaffer and optionally Hartley renders Claim 15 obvious.

J. Claim 16 - Releasing the button to tighten the filament

156. Claim 16 depends from Claim 15 and recites: "wherein the method further comprises, after at least partially advancing the interventional device distally through the hemostasis valve, releasing the button to tighten the filament to allow the tubular member to collapse and seal about a portion of the interventional device." Garrison with Schaffer and optionally Hartley renders Claim 16 obvious.

157. Schaffer's valve "blocks the flow of gas or fluid completely and immediately with or without an instrument in place within the gas/fluid path." Ex. 1007 (Schaffer) at [0008]; *see also id.* at [0056]-[0057], [0066]-[0068]. Schaffer discloses that pressing the buttons loosens the actuating members to allow

the seal module to expand and releasing the buttons constricts the seal module. *Id.* at [0075]-[0077]. Thus, Schaffer discloses releasing the buttons to tighten the filament to allow the tubular member to collapse and seal about a portion of the interventional device.

158. If Schaffer does not disclose this limitation, a person of ordinary skill in the art would have found it obvious to release the buttons to tight the filament to allow the tubular member to collapse and seal about a portion of the interventional device. Schaffer's valve is intended to prevent the flow of gas or fluid through the valve. Ex. 1007 (Schaffer) at [0008]. Once an interventional device is positioned through the valve, a person of ordinary skill in the art would have been motivated to release the buttons to close the valve tightly around the device to prevent leaks. Additionally, a person of ordinary skill in the art would have been motivated to release the buttons to free up the user's hands for other parts of the procedure. A person of ordinary skill in the art would have reasonably expected success in releasing the buttons because that is how Schaffer's valve is intended to operate.

159. Hartley's valve is also designed to seal around an instrument inserted through the valve. Ex. 1008 (Hartley) at [0003]. Hartley discloses that the valve "can be opened sufficiently to allow insertion of the device" through the valve and "then the access valve can be constricted around the device to prevent loss of blood or inflation gas from within a body cavity during operation of the device." *Id.* at

[0011]; *see also id.* at [0012]. If Hartley's string were substituted for the actuating members in Schaffer's valve, a person of ordinary skill in the art would have been motivated to release the buttons to close the valve after insertion of an interventional device "to prevent loss of blood" as disclosed in Hartley. Thus, Garrison combined with Schaffer and optionally Hartley renders Claim 16 obvious.

K. <u>Claim 17 - The hemostasis valve further includes a spring,</u>

160. Claim 17 depends from Claim 16 and recites: "wherein the hemostasis valve further includes a spring, and wherein releasing the button to tighten the filament includes driving the button with the spring to tighten the filament." Garrison with Schaffer and optionally Hartley renders Claim 17 obvious.

161. As discussed above and shown below, Schaffer's valve includes two springs that drive the buttons to pull on, or apply tension to, the actuating members to close the valve to fluid flow. Schaffer discloses that in a first position (below), the actuating members are "at least partially circumferentially disposed about the portion 108 of the seal module 100 depressing and at least partially collapsing a portion 108 of the containment structure 160 by a compressive force 67 (e.g. by a spring 210)":

First Position – Actuator Buttons Undepressed

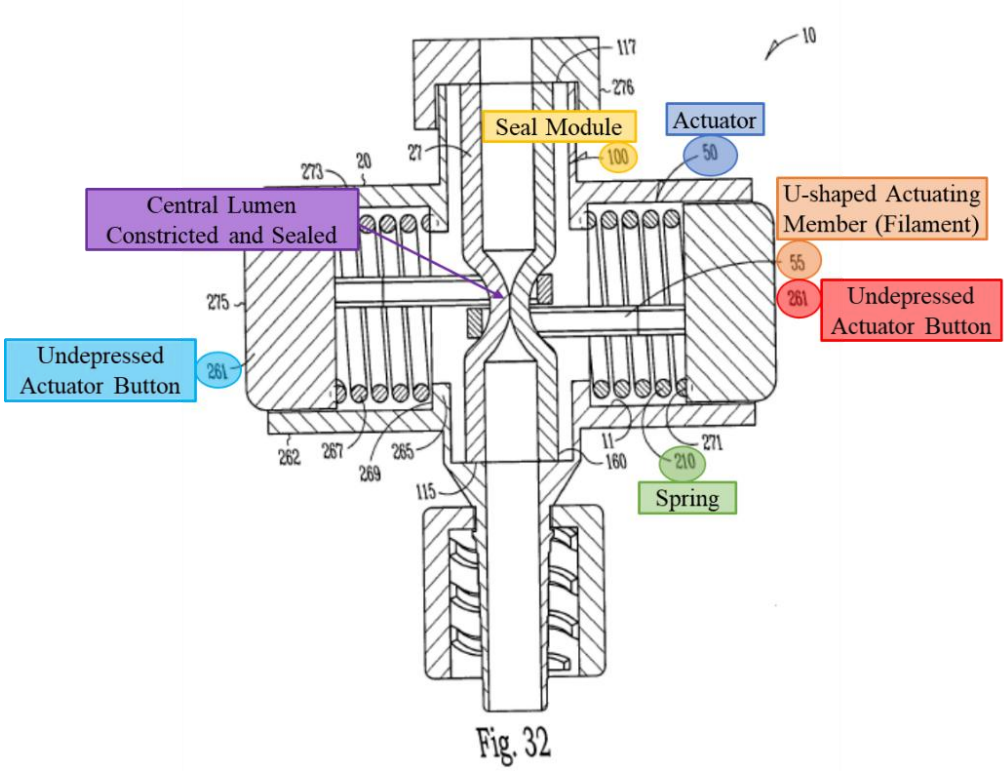


Fig. 32

Ex. 1007 (Schaffer) at [0077], Fig. 32.

162. If Schaffer's actuating members were replaced with Hartley's string, a person of ordinary skill in the art would have reasonably expected the buttons and springs to operate in the same way for the reasons explained in Claim 15. *Supra* § VI.I.2.b. Thus, Garrison with Schaffer and optionally Hartley renders Claim 17 obvious.

L. Claim 18 - Collecting at least some of the first portion of the clot material within a filter chamber

163. Claim 18 depends from Claim 1 and recites: "wherein the method further comprises collecting at least some of the first portion of the clot material within a filter chamber fluidly coupled between the pressure source and the

elongated shaft." Garrison anticipates this claim or renders it obvious alone or in combination with Goff.

a. Garrison

164. The clot treatment system disclosed in Garrison includes a filter 3418 [brown] that is fluidly coupled between the pressure source 3430 [red] and the elongated shaft (catheter 2030) [orange] by flow line 2045 [green]:

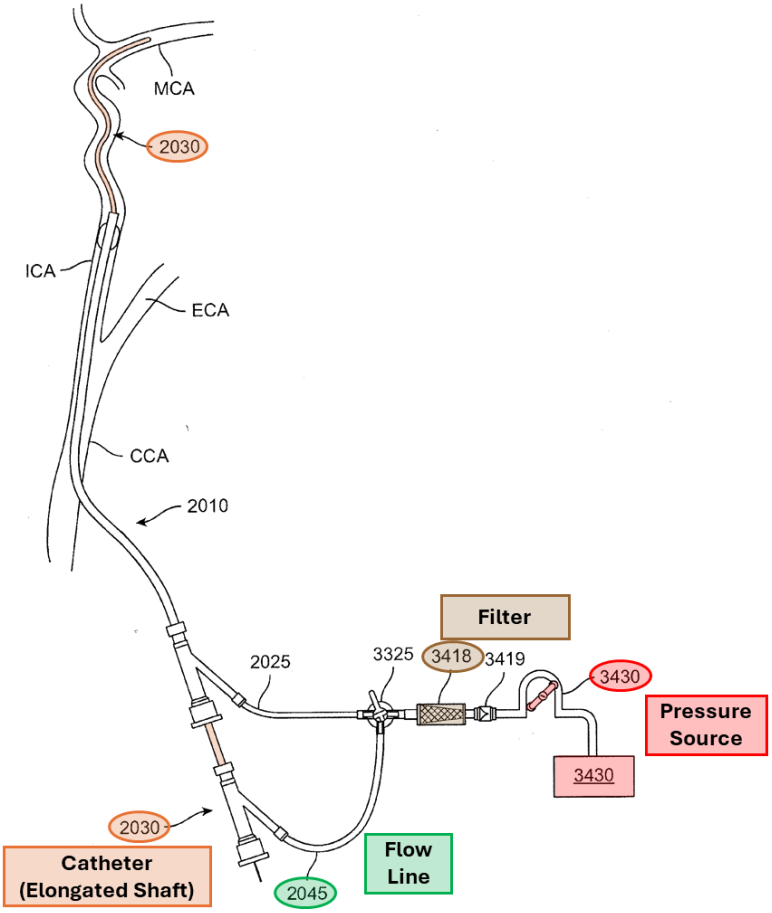
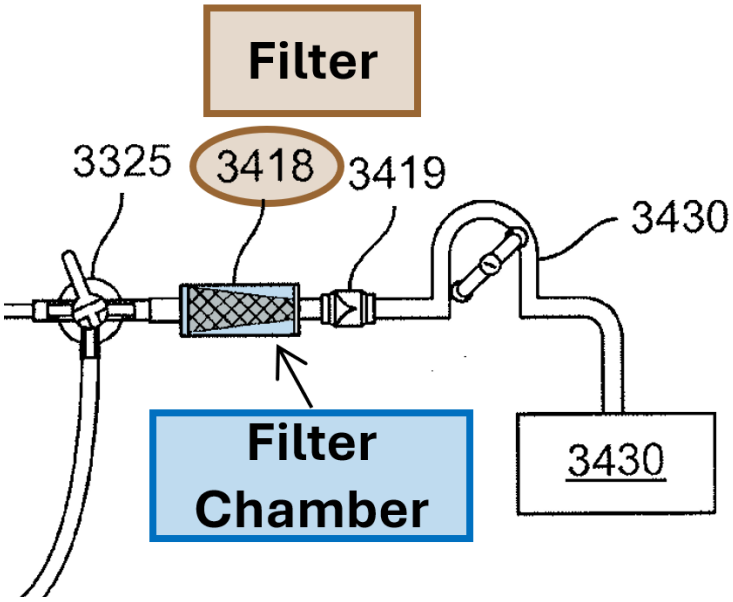


FIG. 34

Ex. 1006 (Garrison) at Fig. 34; *see also id.* at [0131]. As illustrated in the enlarged excerpt of Figure 34 (below), a housing forming a filter chamber [blue] surrounds the filter [brown]:



Id. at Fig. 34. The housing and filter chamber that surrounds the filter is necessary to prevent the blood from leaking out of the system and to maintain pressure across the aspiration system. As shown in Figure 34, the filter chamber is spaced apart from the pressure source and is connected to the pressure source via at least one tube.

165. Garrison's filter chamber captures clot material and separates it from the aspirated blood. *See id.* at [0142]. Similar filters were well-known and commonly used with prior-art aspiration systems to separate clot material from the aspirated blood. *See* Ex. 1005 (Goff) at [0025], Fig. 2. Thus, use of Garrison's system includes collecting at least some of the first portion of the clot material within a filter chamber fluidly coupled between the pressure source and the elongated shaft.

b. Garrison and Goff

166. Garrison combined with Goff also renders this claim obvious. Goff discloses "methods and systems for filtering aspirated material." Ex. 1005 (Goff) at Title. Goff's aspiration system includes a filter housing 18 between the aspiration catheter 12 and the vacuum source (i.e., pressure source):

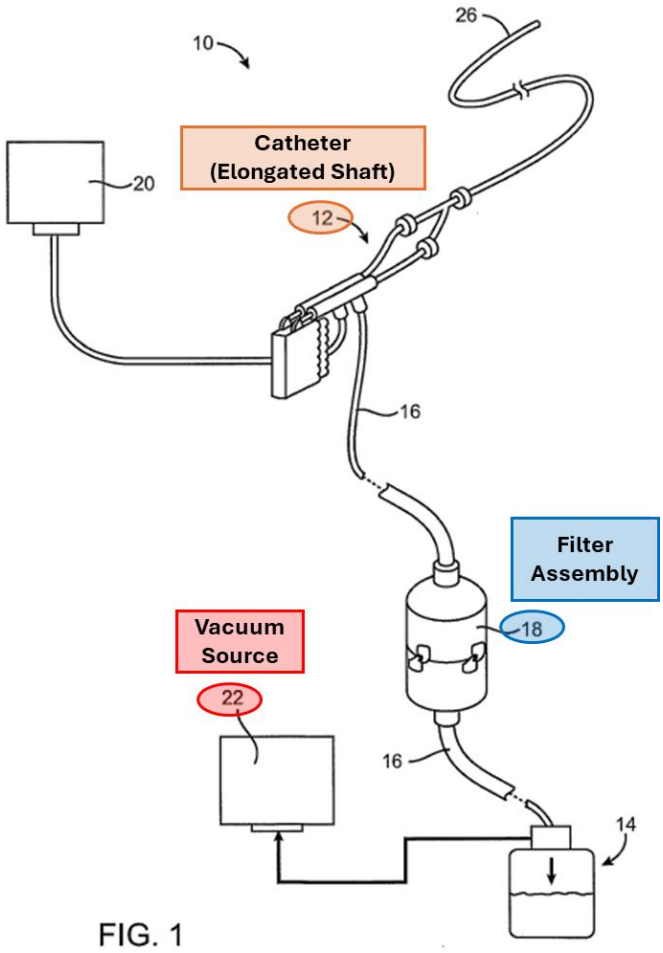
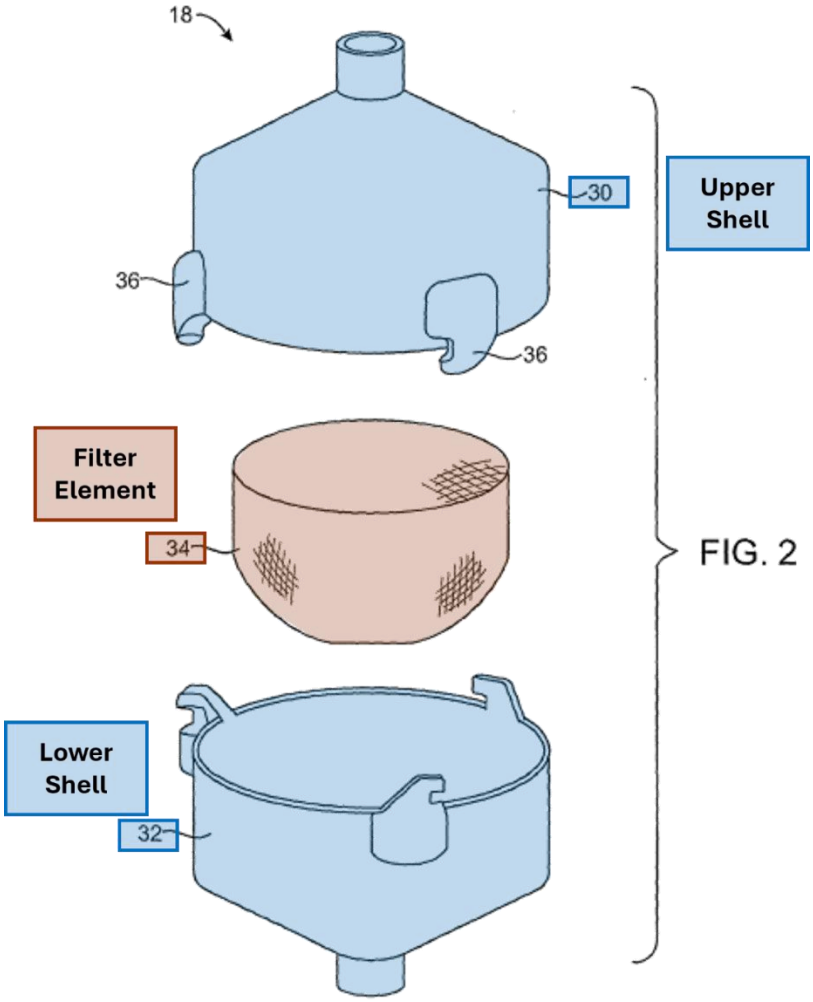


FIG. 1

Id. at [0023]-[0025], Fig. 1.

167. Goff discloses that "filter assembly 18 typically comprises an upper shell 30 [blue], a lower shell 32 [blue], and a filter element 34 [brown] which may be disposed within the interior of the shells":



Id. at [0025], Fig. 2; *see also id.* at [0015].

168. Goff discloses that the filter forms a structure where "the separated solid materials [clot material] be in a convenient structure or assembly to permit easy removal and observation." Ex. 1005 (Goff) at [0005]. Thus, Goff discloses collecting at least some of the first portion of the clot material within a filter chamber.

169. 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 clot material from aspirated blood. Ex. 1005 (Goff) at [0001]. Like Garrison's filter, Goff's filter is also positioned between the aspiration catheter and pressure source. *Id.* at [0025]. Thus, combining Goff's filter with Garrison's system would have merely entailed the combination of the known elements of Goff's filter and Garrison's aspiration system according to the known method of using conventional medical connectors to yield the predictable result of filtering aspirated blood.

170. 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 for incorporating Goff's filter 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," in the same way Garrison's filter functions. Ex. 1005 (Goff) at [0011]. Thus, Garrison combined with Goff renders Claim 18 obvious.

M. Claim 19 - Removing a filter from within the filter chamber

171. Claim 19 depends from Claim 18 and recites: "wherein the method further comprises removing a filter from within the filter chamber to provide access to the at least some of the first portion of the clot material." Garrison combined with Goff renders this claim obvious.

172. Garrison explains that the "filter 3418 and/or check valve 3419 may be coupled with the flow line 2025" implying that the filter can be removed from

the system. Ex. 1006 (Garrison) at [0131]. Garrison also discloses a clear filter housing so the user knows when to empty the container. Further, in January 2018, a person of ordinary skill in the art would have found it obvious to include a removable filter in Garrison's system based on Goff. As discussed above in Claim 18, Goff discloses "methods and systems for filtering aspirated material." Ex. 1005 (Goff) at Title; *supra* § VI.L. Goff discloses that its filter forms a structure where "the separated solid materials be in a convenient structure or assembly to permit easy removal and observation." Ex. 1005 (Goff) at [0005].

173. Goff would have motivated a person of ordinary skill in the art to include a removable filter in Garrison so that the physician could retrieve samples, empty the housing, and clean or replace the filter. If the filter of Garrison were not already openable, Goff would have motivated a person of ordinary skill in the art to configure the filter chamber so that it could be opened to permit this removal or cleaning. Filter chambers that could be unscrewed (Fig. 8, left) or unclasped (Fig. 9, right) were well known:

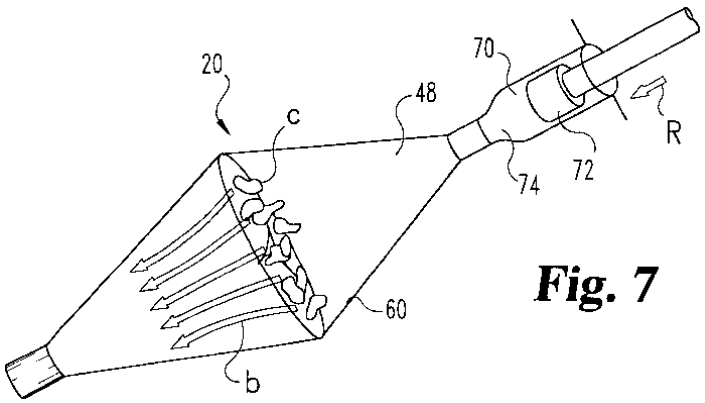


Fig. 7

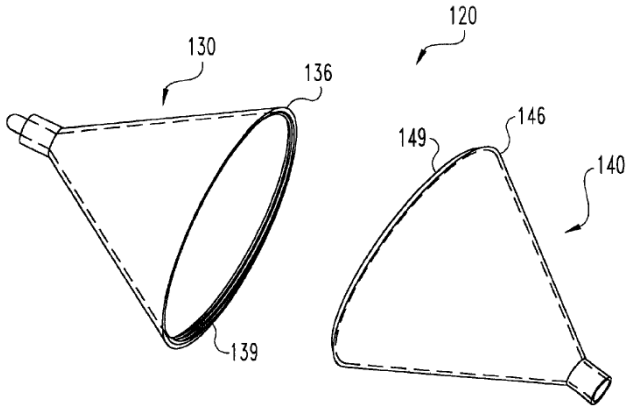


Fig. 8

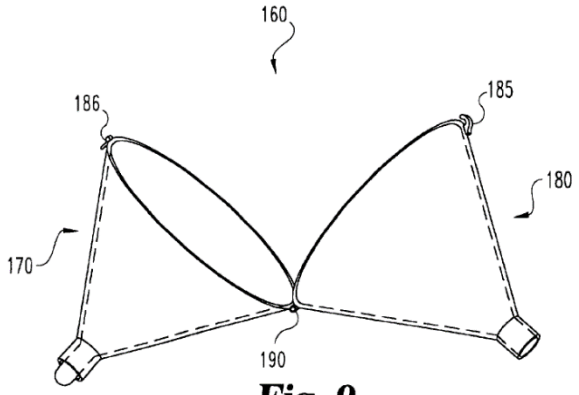


Fig. 9

Ex. 1013 (Trerotola) at 5:65-6:10, Figs. 7-9. A person of ordinary skill in the art would have reasonably expected success in arranging Garrison to have a removable filter because the parts needed to create such a filter (e.g., hinge, clip, interlocking tabs, or screw threads) were simple and predictable and would have been well understood by a person of ordinary skill in the art.

174. Additionally, 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, as discussed in § VI.A.7. *See e.g.*, Ex. 1006 (Garrison) at [0166]. A person of ordinary skill in the art would have recognized that multiple occlusions could clog the filter or fill the chamber, thereby motivating a person of ordinary skill in the art to removably couple the chamber to the system so that the chamber and filter could be cleaned and replaced.

175. Alternatively, a person of ordinary skill in the art would have been motivated to simply substitute Goff's filter assembly for Garrison's filter. As discussed above, Goff's filter has many similarities to Garrison's filter. For example, Goff's filter assembly is used for the same purpose as Garrison's filter – filtering clots from aspirated blood. Ex. 1005 (Goff) at [0001]. Goff's filter assembly is also positioned between the aspiration catheter and aspiration source with standard medical tubing. *Id.* at [0025]. Thus, substituting Goff's filter assembly for Garrison's filter would have merely entailed the substitution of the known element of Goff's filter assembly for another known element of Garrison's filter to yield the predictable result of filtering aspirated blood.

176. Moreover, a person of ordinary skill in the art would have reasonably expected success in making the substitution due to the similarities between the systems. Both systems filter clots from blood aspirated from a patient. Goff specifically 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. Ex. 1005 (Goff) at [0011]. For these reasons, Garrison combined with Goff renders Claim 19 obvious.

N. <u>Claim 20 - The filter includes a plurality of pores</u>

177. Claim 20 depends from Claim 19 and recites: "wherein the filter includes a plurality of pores sized to inhibit the clot material from flowing

therethrough and to permit blood to flow therethrough." Garrison combined with Goff renders this claim obvious.

178. 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. 1005 (Goff) 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.*

179. A person of ordinary skill in the art would have been motivated to use Goff's pore sizes for Garrison's filter, or 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." *Id.* Further, 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.

180. 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 blood and filters are simple, predictable devices that both Goff and Garrison acknowledge were well understood in the art. *Supra* §§ VI.L-M. Thus, Garrison combined with Goff renders Claim 20 obvious.

O. Claim 21 - The filter chamber is fluidly coupled to the elongated shaft via a first fluid path

181. Claim 21 depends from Claim 18 and recites: "wherein the filter chamber is fluidly coupled to the elongated shaft via a first fluid path, wherein the attachment member is fluidly coupled to the elongated shaft along a second fluid path, and wherein the first fluid path branches from the second fluid path." Garrison discloses this limitation.

182. Garrison discloses "first fluid path" fluidly coupling the filter chamber [blue] and an elongated shaft [orange] along flow line 2045, as indicated by the green dashed line:

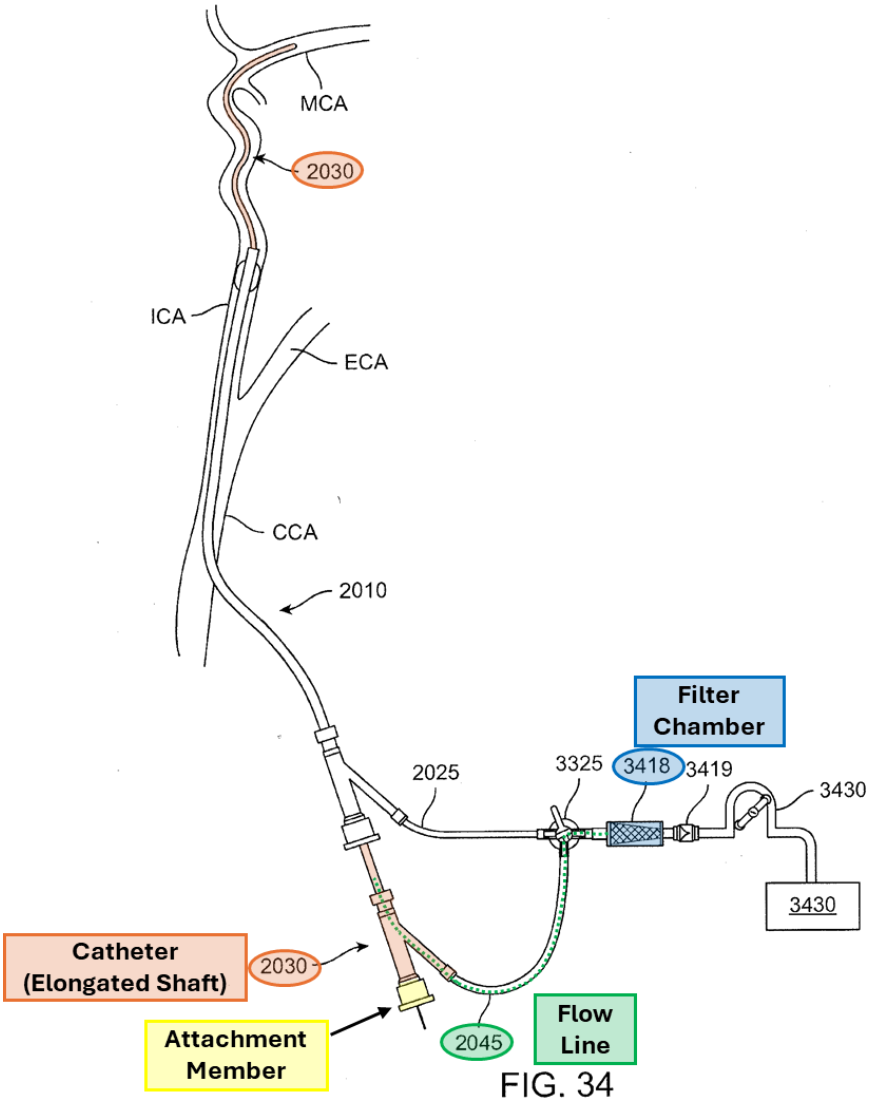


FIG. 34

Ex. 1006 (Garrison) at Fig. 34; *see also id.* at [0131]; *Supra* § VI.A.1.

183. Garrison discloses a "second fluid path" fluidly coupling the attachment member (hemostasis valve) [yellow] to the elongated shaft (catheter) [orange], as illustrated by the dashed red line below:

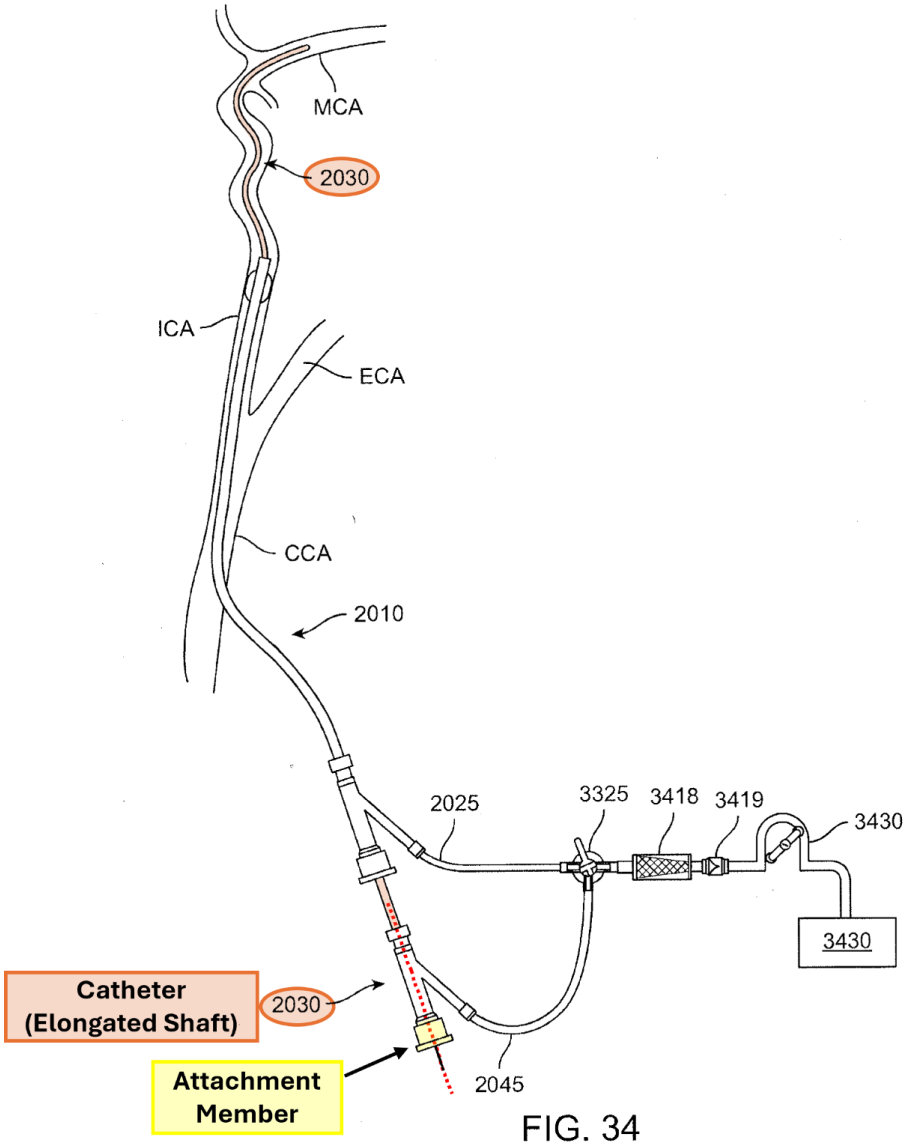


FIG. 34

Ex. 1006 (Garrison) at Fig. 34, [0059], [0131]-[0134]; *Supra* § VI.A.1. Moreover, Garrison's first fluid path [green] branches from the second fluid path [red]:

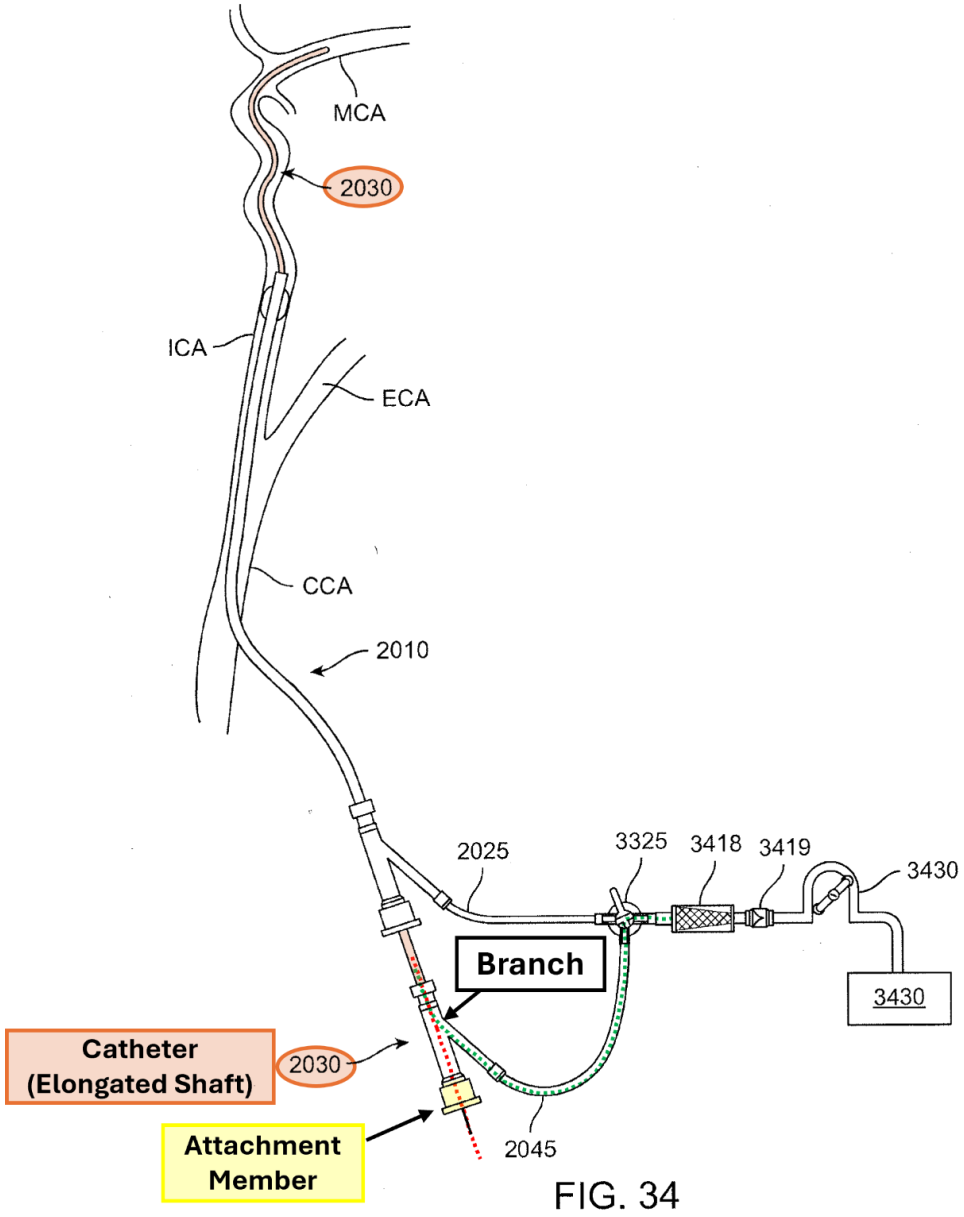


FIG. 34

Ex. 1006 (Garrison) at Fig. 34. The configuration in Garrison is like the configuration described in the '580 patent.

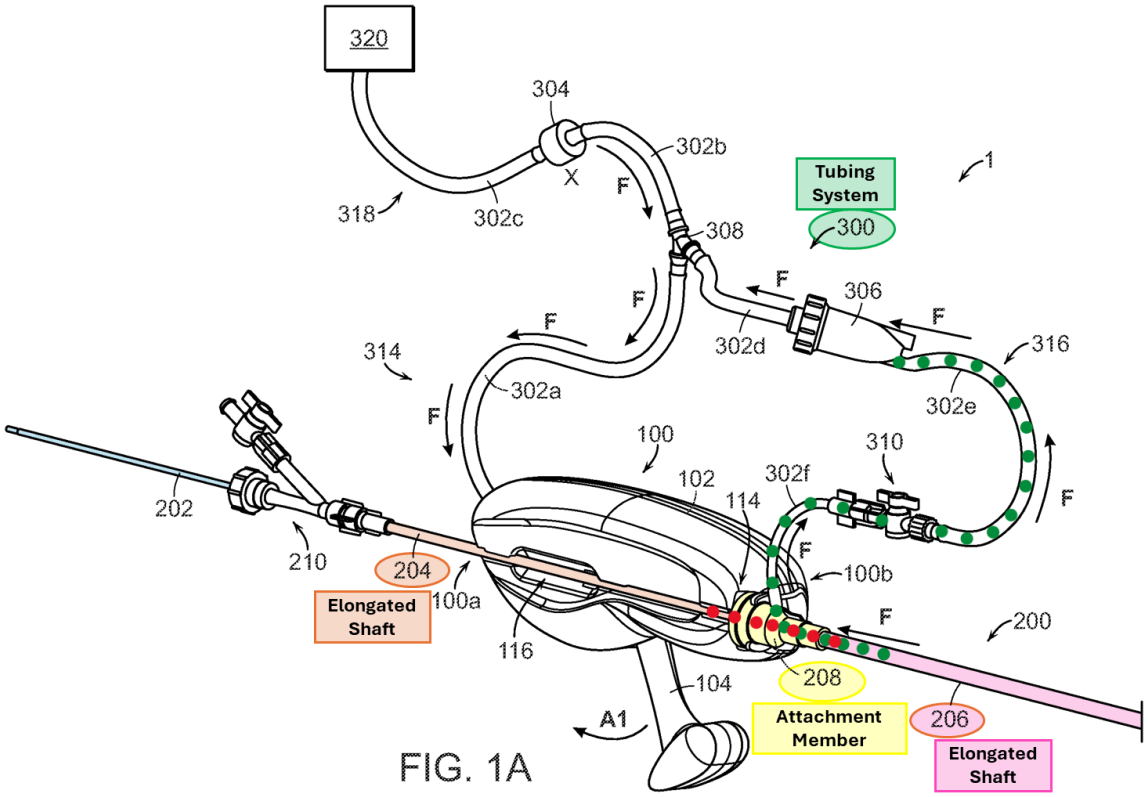


FIG. 1A

Ex. 1001 ('580 patent) at Fig. 1A. Thus, Garrison discloses "the filter chamber is fluidly coupled to the elongated shaft via a first fluid path, wherein the attachment member is fluidly coupled to the elongated shaft along a second fluid path, and wherein the first fluid path branches from the second fluid path."

P. Claim 22 - The attachment member is a hemostasis valve

184. Claim 22 depends from Claim 21 and recites: "wherein the attachment member is a hemostasis valve." Garrison anticipates this claim or renders it obvious alone or combined with Schaffer or Hartley and optionally Goff for the reasons explained in Claims 1, 5-6, and 15. *Supra* §§ VI.A.5, VI.B-C, VI.I.

Q. Claim 23 - Unsealing the hemostasis valve includes actuating at least one button

185. Claim 23 depends from Claim 22 and recites: "wherein unsealing the hemostasis valve includes actuating at least one button of the hemostasis valve." Garrison combined with Schaffer and optionally Goff renders this claim obvious for the reasons provided in Claim 6. *Supra* § VI.C.

R. Claim 24 - The filter chamber is spaced apart from the pressure source

186. Claim 24 depends from Claim 18 and recites: "wherein the filter chamber is spaced apart from the pressure source and connected to the pressure source via at least one tube." Garrison alone or combined with Goff discloses this limitation for the reasons provided in Claim 18. *Supra* § VI.L.

S. Claim 25 - The filter chamber comprises a housing and a filter within the housing

187. Claim 25 depends from Claim 18 and first recites: "wherein the filter chamber comprises a housing and a filter within the housing, and wherein the housing includes – a port configured to be fluidly coupled to the elongated shaft via at least one first tube; and a fluid connector configured to be coupled to the pressure source via at least one second tube." Garrison alone or combined with Goff discloses this limitation.

1. Garrison

188. As shown in Figure 34 below, Garrison's filter is surrounded by a housing that forms a filter chamber. Ex. 1006 (Garrison) at Fig. 34; *supra* § VI.L. Garrison's filter housing is fluidly coupled to the elongated shaft (catheter) by a first tube, and to the pressure source by a second tube:

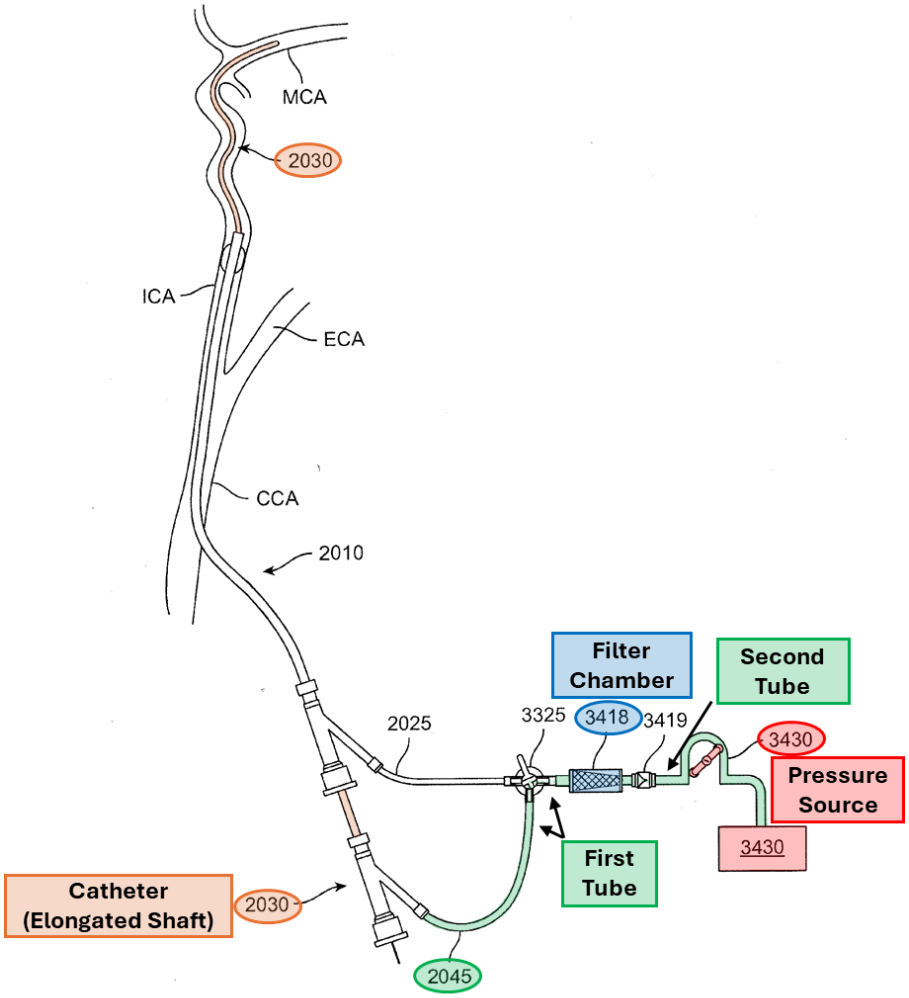


FIG. 34

Ex. 1006 (Garrison) at [0131]-[0134], Fig. 34.

189. Garrison does not expressly describe how its filter is coupled to the tubing. However, in January 2018, a person of ordinary skill in the art would have

found it obvious to couple the filter to the tubing using conventional, removable ports and fluid connectors, such as Luer-type connectors (e.g., Luer slip and Luer lock) and barb connectors. *See* Ex. 1006 (Garrison) at [0062], [0065], Fig. 11; Ex. 1013 (Trerotola) at 4:29-40. In fact, Garrison incorporates by reference patents and publications that describe attaching catheter components using "a conventional luer fitting" or improvements to such fittings. Ex. 1010 (Garrison '118) at [0130]; *see also* Ex. 1014 (Gordon) at 8:45, 8:63 Ex. 1015 (Garrison '868) at [0056]-[0059]. Each standard connector, such as a Luer-type connector is a fluid connector, because it has a lumen to facilitate the passage of fluid, and a port because it includes an opening in the connector to facilitate the passage of fluid.

190. A person of ordinary skill in the art would have been motivated to use conventional connectors, such as Luer type connectors, to connect Garrison's filter to the system for several reasons. First, conventional connectors, such as Luer type connectors, allow physicians to add off-the-shelf tubing and related components simply and quickly. Physicians prefer this flexibility because different procedures and patient conditions may require fewer or additional components, as suggested by the many configurations disclosed in Garrison. Physicians would have been motivated to avoid using unnecessary components due to the additional cost and complexity and would have preferred components that could be easily attached and removed.

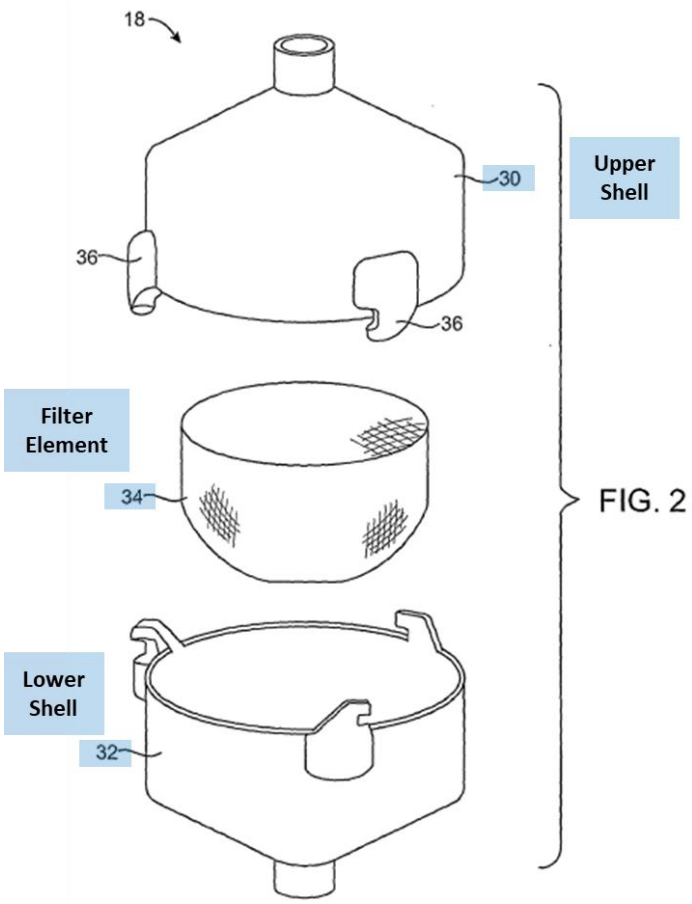
191. Second, the conventional connectors came in standard sizes that made them compatible with other catheter-based medical components, such as tubing and valves. Physicians preferred this compatibility because it increased the options available to the physician during a procedure and, thus, a person of ordinary skill in the art was motivated to include these connectors with medical devices.

192. Third, physicians were familiar with the conventional connectors. 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. The user preference would have motivated a person of ordinary skill in the art to use conventional connectors. Moreover, a person 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 because the connectors were simple, widely used, and predictable.

193. Fourth, combining conventional, removable connectors with Garrison's filter would have merely entailed the combination of the known elements of conventional connectors and filter according to the known method of coupling medical components with conventional connectors to yield the predictable result of connecting medical components.

2. Garrison and Goff

194. Goff would have further motivated a person of ordinary skill in the art to use conventional ports and fluid connectors to join Garrison's filter to the tubing system. 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. 1005 (Goff) at [0025], Fig. 2; *see also id.*, [0015]. As shown in the figure above and below, Goff includes ports and/or fluid connectors at both ends of the filter housing.

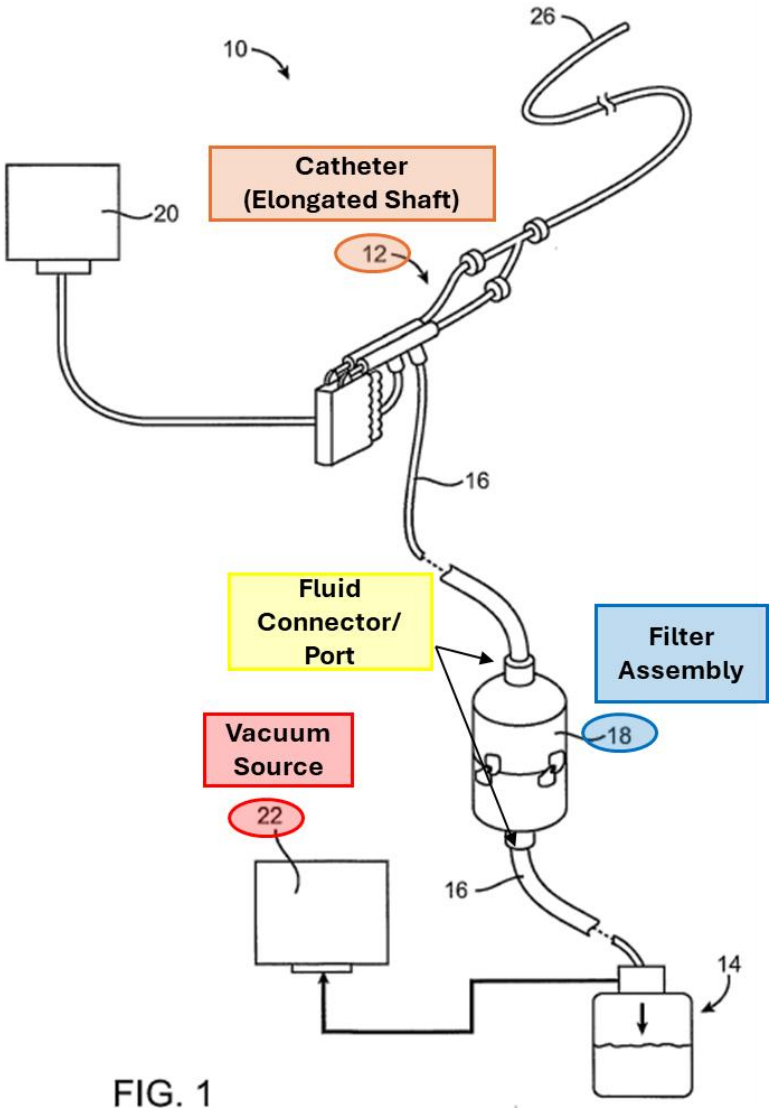


FIG. 1

Id. at Fig. 1.

195. Goff 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.* at [0015]. As discussed above, well-known conventional connectors in January 2018 included, for example, Luer-type connectors and barb connectors that comprised a fluid connector and a port. *Supra* § VI.R. Moreover, Goff discloses that its filter forms a structure where "the

separated solid materials be in a convenient structure or assembly to permit easy ***removal*** and observation." Ex. 1005 (Goff) at [0005]. Thus, Goff would have motivated a person of ordinary skill in the art to couple Garrison's filter to its system with standard ports and fluid connectors so that the filter could be removed, and the clot material removed and/or observed.

196. Alternatively, a person of ordinary skill in the art would have been motivated to use Goff's removable filter in Garrison's aspiration system. As I have repeatedly discussed above, Goff's filter is used for the same purpose as Garrison's filter – filtering clots from aspirated blood. Ex. 1005 (Goff) at [0001]. Likewise, Goff's filter is also positioned between the aspiration catheter and first chamber/pressure source. *Id.* at [0025]. Thus, combining Goff's filter with Garrison's system would have merely entailed the combination of known elements (filter and Garrison's aspiration system) according to known methods (conventional connectors) to yield the predictable result of filtering aspirated blood. 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 for incorporating Goff's filter 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. Ex. 1005 (Goff) at [0011]. Thus, Garrison combined with Goff renders this claim obvious.

T. Claim 26 - The elongated shaft is fluidly coupled to the pressure source via the filter chamber

197. Claim 26 depends from Claim 25 and recites: "wherein the elongated shaft is fluidly coupled to the pressure source via the filter chamber along a first fluid path." Garrison discloses this limitation alone or combined with Goff for the reasons explained for Claim 18 and Claim 21. *Supra* § VI.L, § VI.O.

U. Claim 27 - The attachment member is fluidly coupled to the elongated shaft along a second fluid path

198. Claim 27 depends from Claim 26 and recites: "wherein the attachment member is fluidly coupled to the elongated shaft along a second fluid path at least partially different than the first fluid path." Garrison discloses this limitation alone or combined with Goff for the reasons explained for Claim 18 and Claim 21. *Supra* § VI.L, § VI.O.

V. Claim 28 - The attachment member comprises a hemostasis valve

199. Claim 28 depends from Claim 27 and recites: "wherein the attachment member comprises a hemostasis valve." Garrison anticipates this claim or renders it obvious alone or combined with Schaffer or Hartley and optionally Goff for the reasons explained in Claims 1, 5-6, and 15. *Supra* §§ VI.A.5, VI.B-C, VI.I.

W. Claim 29 - Unsealing the hemostasis valve includes actuating at least one button

200. Claim 29 depends from Claim 28 and recites: "wherein unsealing the hemostasis valve includes actuating at least one button of the hemostasis valve."

Garrison combined with Schaffer and optionally Goff renders this claim obvious for the reasons provided in Claim 6. *Supra* § VI.C.

X. Claim 30 - Translating the interventional device

201. Claim 30 depends from Claim 1 and recites: "wherein engaging the interventional device with the second portion of the clot material remaining within the blood vessel includes translating the interventional device relative to the elongated shaft." Garrison discloses this limitation or renders it obvious.

202. As described in Claim 1, Garrison discloses a variety of interventional devices. *Supra* § VI.A.6-7. For example, Garrison describes an expandable member 3905 that can be delivered to the second clot portion with a microcatheter.

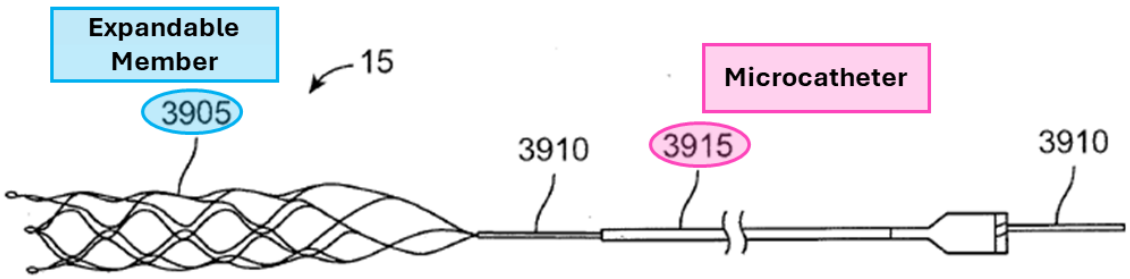


FIG. 39

Ex. 1006 (Garrison) at [0143], Fig. 39. The expandable member 3095 can be expanded at the location of the occlusion and "may capture some or all of the thrombus while being withdrawn into the sheath." *Id.* If the microcatheter were delivered to the clot through catheter 2030, as taught by Garrison, the expandable

member 3095 is translated relative to the elongate shaft at least when it is withdrawn into catheter 2030. *Supra* § VI.A.6-7.

203. Garrison similarly describes an interventional device inserted through a catheter, like catheter 2030, "for morcellating the thrombotic occlusion as it is being aspirated into the catheter." Ex 1006 at [0125]. Once aspiration is started, the interventional device is rotated or "translated back and forth" to break up the clot. *Id.* Thus, Garrison discloses at least two examples of interventional devices that are translated with respect to the elongated shaft. Garrison describes using each of these devices with catheter 2030 and, if it does not, it would have been obvious to use each device with catheter 2030 for the reasons provided in Claim 1. *Supra* § VI.A.6-7.

Y. Claim 33 - Flushing the at least one tube with a fluid

204. Claim 33 depends from Claim 1 and recites: "wherein the pressure source is coupled to the elongated shaft via at least one tube and wherein the method further comprises flushing the at least one tube with a fluid after aspirating the first portion of the clot material into the elongated shaft and/or after engaging the interventional device with the second portion of the clot material." Garrison discloses this limitation.

205. As explained in Claim 21, Garrison's pressure source is coupled to the elongated shaft via at least one tube. *Supra* § VI.O. Garrison further discloses that

the thrombectomy devices, like those discussed in Claim 30 above, may include clot disruption elements such as fluid vortices, ultrasound or laser energy elements, balloons, or the like, ***coupled with flushing*** and aspiration to remove the thrombus." Ex. 1006 (Garrison) at [0144]-[0145] (emphasis added).

206. Garrison also discloses inserting a perfusion catheter through catheter 2030 to treat a clot portion. *Id.* at [0170]. Garrison further discloses that the "perfusion catheter may also be connected to a flush source to perfuse proximal to the occlusion ballon via proximal ports in the perfusion catheter." *Id.; see also id.* at [0146]-[0157]. Garrison also explains that the perfusion may be used "during the procedure," *Id.* at [0165]-[0166]. This means the perfusion may be used during the portion of the procedure to remove the second clot portion. If Garrison does not disclose this limitation, a person of ordinary skill in the art would have found it obvious to use the flushing interventional devices after removal of first clot portion for the reasons provided in Claim 1. *Supra* §§ VI.A.6-7.

Z. Claim 34 - The fluid is saline

207. Claim 34 depends from Claim 33 and recites: "wherein the fluid is saline." Garrison discloses this limitation. Garrison explicitly teaches "flushing of the sheath with saline or contrast solution." Ex. 1006 (Garrison) at [0066]. Moreover, a person of ordinary skill in the art would have understood saline to be

an obvious and conventional fluid for flushing a tube used in an intervascular procedure.

VII. GROUNDS 9-14: GARRISON ALONE OR COMBINED WITH AKLOG AND/OR LAUB RENDERS CLAIM 10 OBVIOUS

A. Claim 10

208. Claim 10 depends from Claim 1 and recites: "wherein the blood vessel is a pulmonary blood vessel." Garrison anticipates this claim or renders the claim obvious in combination with Aklog or Laub.

1. Garrison and Aklog

209. Aklog discloses aspiration systems and methods for aspirating clot material from different parts of a patient's vasculature, including "the pulmonary circulation (e.g., pulmonary arteries), systemic venous circulation (e.g., vena cavae, pelvic veins, leg veins, neck and arm veins) or arterial circulation (e.g., aorta or its large and medium branches)." Ex. 1011 (Aklog) at 7:32-37; *see also id.* at 1:17-24, 5:11-19, 5:28-41, Figs. 1, 6-7. Aklog explains that an obstruction of the pulmonary arteries is "known as pulmonary embolism" and, as indicated by the quote above, Aklog's aspiration system is intended to treat this condition. *Id.* at 2:20-32. Given these disclosures, a person of ordinary skill in the art would have recognized that Aklog describes, or at the very least renders obvious, a "method of treating a pulmonary embolism within a vasculature of a patient."

210. Garrison discloses an aspiration system for the "treatment of cerebral occlusions." Ex. 1006 (Garrison) at [0002]. A person of ordinary skill in the art would have been motivated to use and, to the extent necessary, modify and optimize Garrison's aspiration system to treat pulmonary embolism. Garrison's system is already designed to aspirate clots and Aklog explains that pulmonary embolisms are a harmful type of clot that can block blood flow to the lungs and cause death. *Id.* Thus, a person of ordinary skill in the art would have been motivated to use, and to the extent necessary, modify and optimize the existing and proven technology described in Garrison to treat similar conditions in other parts of the vasculature.

211. 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. 1011 (Aklog) at 5:11-27. Moreover, the aspiration systems described in Garrison and Aklog are similarly configured. As illustrated below, both systems include an aspiration catheter [orange] that is positioned proximate to the clot material prior to aspiration, an aspiration source (e.g., aspiration pump) [red], a filter [blue], and a flow line [green] fluidly coupling the aspiration catheter to the filter and aspiration source:

Garrison

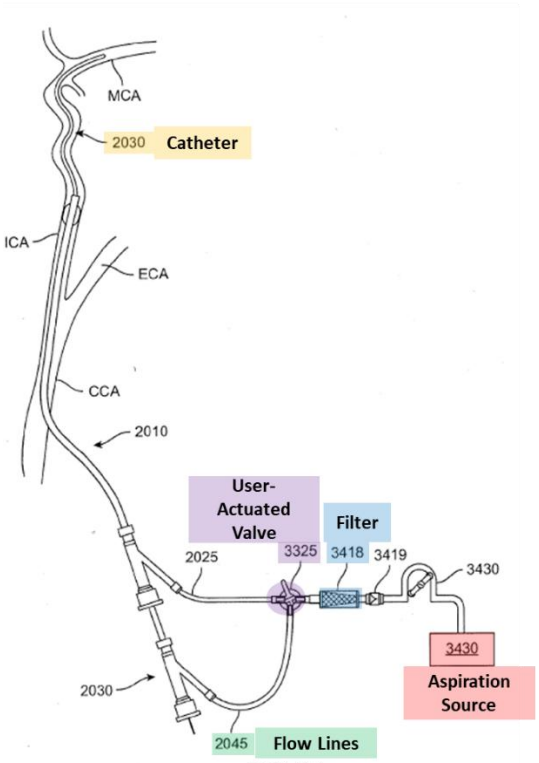


FIG. 34

Aklog

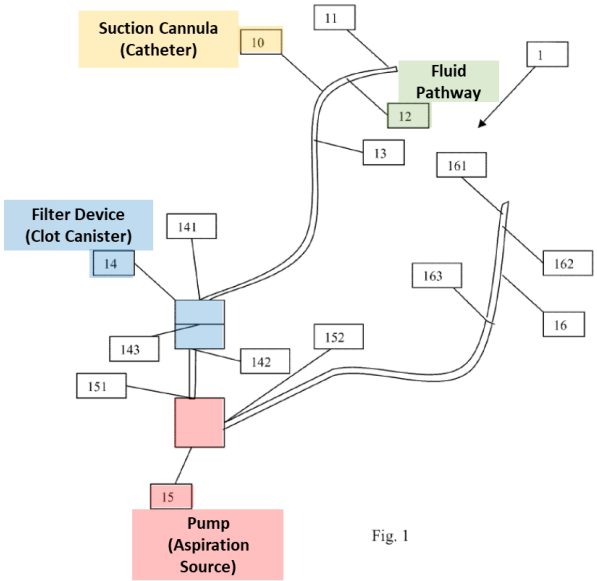


Fig. 1

Ex. 1006 (Garrison) at [0131]-[0134], Fig. 34; Ex. 1011 (Aklog) at 7:47-64, 11:24-35, 11:62-12:14, Fig. 1. Additionally, both systems are inserted into the patient in

the same way (e.g., percutaneously through the femoral artery or vein). Ex. 1011 (Aklog) at 15:30-34 (describing insertion through "femoral vein, femoral artery or jugular vein); Ex. 1006 (Garrison) at [0048] ("Disclosed also are methods and devices that optimize clot aspiration through either transfemoral or transcarotid access approaches."). A person of ordinary skill in the art would have reasonably expected success in adapting Garrison's system to treat the conditions described in Aklog, including PE, based on the similar system configurations, insertion locations, and methods of treatment.

212. A person of ordinary skill in the art would have recognized that Garrison's system would not necessarily have needed any modification to treat pulmonary embolisms. However, some simple modifications could optimize the system to treat pulmonary embolisms, depending on the specific location and size of the clot to be removed, such as increasing the size of the aspiration catheter (and related components), optimizing the flexibility and torque characteristics of the catheter, and potentially adjusting the suction force and adjusting the catheter strength to resist the suction force. Aklog acknowledges that persons of ordinary skill in the art possessed the requisite knowledge to select the appropriate catheter size or adjust suction pressure. For example, while Aklog primarily describes treatments for medium and large vessels, Aklog discloses "that the systems and methods, hereinafter disclosed, can be scaled and adapted for use within smaller

vessels within the body, if desired." Ex. 1011 (Aklog) at 7:43-46. Thus, Aklog presumes that a person of ordinary skill in the art possessed the requisite knowledge to make these simple sizing modifications and I agree with Aklog's presumption. In my own time overseeing engineers developing catheter-based medical devices, the engineers routinely optimized catheter size, flexibility, and torque as a standard part of the design process and would adapt catheters and other components for different sized vasculatures, depending on the location and tortuosity of the target vessel. Even Garrison discloses a range of possible sheath and catheter sizes for its system, further demonstrating that the size of the catheter was not novel or unique. Ex. 1006 (Garrison) at [0063] (describing 6 and 8 French size sheaths); [0070] (describing 10 French size sheaths). Simply put, a person of ordinary skill in the art in January 2018 possessed the necessary knowledge to select an appropriate catheter size for a given application and integrate that catheter into an aspiration system.

213. Aklog also describes one challenge persons of ordinary skill in the art encountered in moving from smaller to larger aspiration catheters – a larger catheter "may aspirate an unacceptable volume of blood, resulting in excessive fluid loss and/or shock in the patient." Ex. 1011 (Aklog) at 7:23-26. Aklog explains that the solution to using larger catheters is to reinfuse the "fluid removed (i.e., suctioned

or aspirated) from the site of interest back into a patient, in order to minimize fluid loss within the patient." *Id.* at 7:47-52.

214. 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.

215. 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 January 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. 1011 (Aklog) at 2:13-19 (emphasis added). Thus, DVT can become a pulmonary embolism or cerebral embolism as it travels through the body. Consequently, a person of ordinary skill in the art developing treatments for clots in one part of the body would naturally consult innovations for treating clots in other parts of the body.

216. Garrison specifically suggests combining components with its aspiration systems that come from aspiration systems for treating other parts of the vasculature. For example, Garrison states that "it may be desirable to incorporate features on the arterial access sheath in order to minimize flow resistance through the insertable portion of the access sheath." Ex. 1006 (Garrison) at [0070]. Garrison incorporates by reference two patents for this purpose: (1) Chang (Ex. 1035), which describes "a method for treating lesions in the ***carotid artery*** of a

mammalian body (*id.*, abstract (emphasis added)), and (2) Craido (Ex. 1036), which describes "[a] system for use in accessing and treating a ***carotid artery***" (*id.*, abstract (emphasis added)).

217. 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 (Lewis) 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 (Gordon) 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.

218. 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 (Brady) 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).

219. Even the challenged '580 Patent acknowledges that persons of ordinary skill in the art would have understood that aspiration systems for one part of the vasculature could be optimized for other portions of the vasculature. For example, the '580 patent states, "Although many of the embodiments are described below with respect to devices, systems, and methods for treating a 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***, etc.)." Ex. 1001 ('580 patent) at 3:64-4:3 (emphasis added). The '580

patent does not identify any special reasons why its aspiration catheters can be used interchangeability across different parts of the vasculature while other aspiration catheters could not. Rather, the '580 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 4:15-20.)

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

2. Garrison and Laub

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

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

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

Garrison

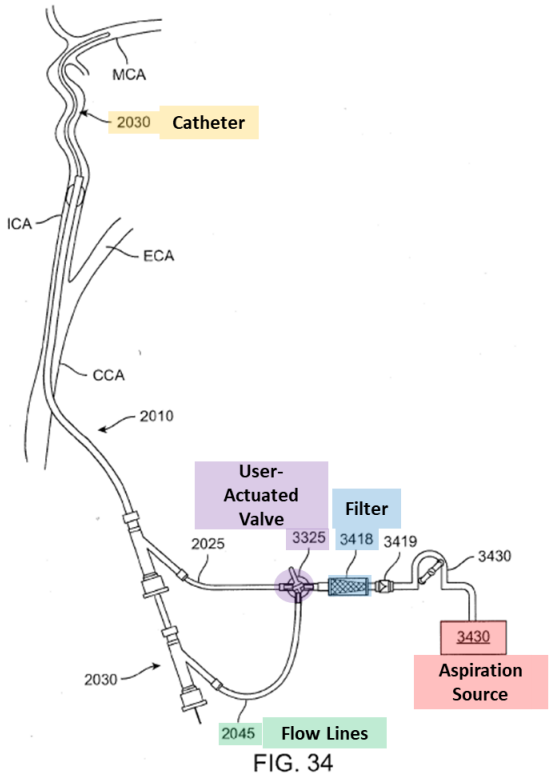


FIG. 34

Laub

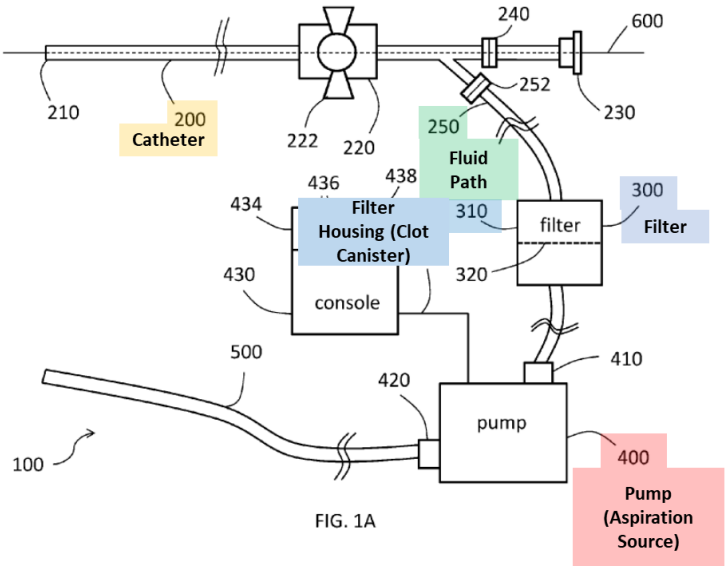


FIG. 1A

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

224. A person of ordinary skill in the art would have recognized that Garrison's system would not necessarily have needed any modification to treat pulmonary embolisms, especially emboli located in the distal end of the pulmonary vasculature. However, some simple modifications could optimize the system to treat pulmonary embolisms, depending on the specific location and size of the clot to be removed, such as increasing the size (i.e., diameter or French size) of the aspiration catheter (and related components), optimizing the flexibility and torque characteristics of the catheter, potentially adjusting the suction force, and adjusting the catheter strength to resist the suction force. Laub reflects that persons of ordinary skill in the art possessed the requisite knowledge to make such adjustments. For example, Laub discloses that its system can use aspiration catheters ranging from 5 to 20 Fr. and in some embodiments has a catheter equal to or greater than 10 Fr. "to allow for aspiration of large thrombi and/or other solid materials from the patient." Ex. 1012 (Laub) at [0028]. Thus, Laub presumes that a person of ordinary skill in the art possessed the requisite knowledge to make these simple modifications and I agree with Laub's presumption for the reasons provided in the Garrison-Aklog ground above.

225. In addition, Laub also discloses systems and methods for reintroducing aspirated blood into the patient to avoid excessive blood loss. Ex. 1012 (Laub) at [0040], [0045]. Garrison also discloses reintroduction systems and procedures to

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

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

for clots in one part of the body would naturally consult innovations for treating clots in other parts of the body.

227. As I also explained in the Garrison-Aklog ground above, Garrison specifically suggests combining components with its aspiration systems that come from aspiration system for treating other parts of the vasculature. *Supra* §VII.A.1. Garrison also incorporates by reference several patents describing thrombectomy devices having aspiration catheters to remove thrombus. *Id.* Likewise, other prior art patents disclose aspiration systems intended for use across all portions of the vasculature, including the '580 Patent. *Id.*

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

modifications, based on Laub and the knowledge of a person of ordinary skill in the art.

VIII. SECONDARY CONSIDERATIONS

229. I am not aware of any secondary considerations of nonobviousness relating to the claims of the ’580 patent.

230. The methods and devices claimed in the ’580 patent are not new and were invented long before January 2018. Therefore, I am not aware of any long-felt need in the industry, unexpected results, skepticism of the invention, or teaching away from the invention. I am also not aware of any praise for the alleged inventions or copying of the alleged inventions by other companies. Many aspiration systems were available on the market by January 2018, and many of those systems were used to perform the conventional method steps with the conventional components recited in the claims of the ’580 patent.

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

IX. CONCLUSION

232. For the foregoing reasons, it is my opinion that Claims 1, 5-6, 9-30, and 33-34 of the ’580 patent are not patentable because they are anticipated by or would have been obvious in view of the prior art discussed above and the

knowledge of one of ordinary skill in the art at the time of the alleged claimed inventions.

233. 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.

234. 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 8, 2025 in Glen Ellen, CA.

troy thornton

Troy Thornton