

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

IMPERATIVE CARE, INC.,
Petitioner,

v.

INARI MEDICAL, INC.,
Patent Owner.

Case IPR2026-00169
Patent No. 12,156,669

**DECLARATION OF TROY L. THORNTON
IN SUPPORT OF PETITION FOR *INTER PARTES* REVIEW OF
U.S. PATENT NO. 12,156,669**

<p><i>Imperative Care v. Inari Medical</i> IPR2026-00169 Imperative Care Ex. 1003</p>
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Exhibit No.	Description
1001	U.S. Patent No. 12,156,669 (“the ’669 patent”)
1002	’669 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	Certified File History of U.S. Patent Application 10/371,190 (Schaffer File History)
1010	WIPO Publication No. WO 2018/019829 A1 to Brady et al. (“Brady”)
1011	U.S. Patent No. 11,432,835 B2 to Pons et al. (“Pons”)
1012	U.S. Patent No. 6,776,770 B2 to Treretola
1013	Inari’s Supplemental Infringement Contentions (without claim charts) from <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , No. 24-cv-3117 (N.D. Cal.) (served February 7, 2025)
1014	Merriam-Webster’s Collegiate Dictionary (11th ed. 2014), definition of “port” and “tighten”

Exhibit No.	Description
1015	Merriam-Webster’s Collegiate Dictionary (11th ed. 2014), submitted by Patent Owner as Exhibit 2009 in IPR2024-00157
1016	Deposition Transcript of PO’s Expert Paul Zalesky, Ph.D. dated June 23, 2025
1017	Deposition Transcript of PO’s Expert Paul Zalesky, Ph.D. dated August 27, 2025
1018	Deposition Transcript of PO’s Expert Paul Zalesky, Ph.D. dated November 7, 2025
1019	U.S. Provisional Patent Application No. 62/554,931
1020	Order Regarding Case Schedule and Motion to Stay in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 5:24-cv-03117-EKL (N.D. Cal.)
1021	U.S. Patent No. 11,697,011 (“the ’011 patent”)
1022	U.S. Provisional Application No. 62/474,383
1023	U.S. Provisional Application No. 62/516,582
1024	Decision Granting Institution of <i>Inter Partes</i> Review for U.S. Patent No. 11,697,011 (Paper 7) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2024-01157 (P.T.A.B. Jan. 23, 2025)
1025	Decision Granting Institution of <i>Inter Partes</i> Review for U.S. Patent No. 11,697,012 (Paper 6) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-00156 (P.T.A.B. Apr. 22, 2025)
1026	Decision Granting Institution of <i>Inter Partes</i> Review for U.S. Patent No. 11,554,005 (Paper 10) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-00289 (P.T.A.B. June 18, 2025)

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Exhibit No.	Description
1027	Decision Granting Institution of <i>Inter Partes</i> Review for U.S. Patent No. 11,844,921 (Paper 13) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-00728 (P.T.A.B. Oct. 10, 2025)
1028	Decision Granting Institution of <i>Inter Partes</i> Review for U.S. Patent No. 11,865,291 (Paper 10) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-00989 (P.T.A.B. Oct. 23, 2025)
1029	U.S. Patent Publication No. 2015/0352325 to Quick (“Quick”)
1030	Patent Owner’s Response for U.S. Patent No. 11,697,011 (Paper 13) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2024-01157 (Apr. 18, 2025)
1031	U.S. Patent Publication No. 2010/0042118 A1 to Garrison et al.
1032	U.S. Patent No. 5,938,645 to Gordon (“Gordon”)
1033	U.S. Patent Publication No. 2014/0296868 A1 to Garrison et al.
1034	U.S. Patent Publication No. 2017/0043066 A1 to Laub (“Laub”)
1035	U.S. Patent No. 8,734,374 B2 to Aklog et al. (“Aklog”)
1036	Penumbra, Optimizing Direct Aspiration (May 2013)
1037	AXS Universal Aspiration Set Brochure (2017)
1038	U.S. Patent No. 12,109,384
1039	Supplemental Declaration of Paul Zalesky Ph.D. submitted by Patent Owner as Exhibit 2008 in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2024-01157, U.S. Patent No. 11,697,011
1040	International Standards Organization, Small-bore Connectors for Liquids and Gasses in Healthcare Applications Part 7: Connectors for Intravascular or Hypodermic Applications, 80369-7 (Edition 1, 2016) (“ISO 80369-7”)

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Exhibit No.	Description
1041	O. Nikoubashman et al., Under Pressure: Comparison of Aspiration Techniques for Endovascular Mechanical Thrombectomy, Am J. Neuroradiol. (May 2018) (“Nikoubashman”)
1042	Record of Oral Hearing held on October 29, 2025 in <i>Inter Partes</i> Review for U.S. Patent No. 11,697,011 (Paper 34) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2024-01157 (P.T.A.B. Nov. 17, 2025)
1043	Dorland’s Illustrated Medical Dictionary, 32nd ed. (2012) - Definition of “Port”
1044	U.S. Patent No. 9,526,864 B2 to Quick
1045	Decision Granting Institution of <i>Inter Partes</i> Review for U.S. Patent No. 11,969,333 (Paper 15) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-01021 (P.T.A.B. Dec. 11, 2025)
1046	Decision Granting Institution of <i>Inter Partes</i> Review for U.S. Patent No. 11,974,910 (Paper 15) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-01025 (P.T.A.B. Dec. 11, 2025)

I, Troy L. Thornton, do hereby declare:

I. INTRODUCTION

A. Engagement

1. I have been retained on behalf of Imperative Care, Inc. (“Imperative Care”) to provide my opinion regarding the patentability of Claims 1-5, 8, 10-12 14-19, 22, 24-28, and 30 of U.S. Patent No. 12,156,669 (“the ’669 patent”). For the reasons discussed herein, I have concluded that Claims 1-5, 8, 10-12 14-19, 22, 24-28, and 30 of the ’669 patent are unpatentable because the prior art references anticipate those claims 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 ’669 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 ’669 patent, Inari Medical, Inc. (“Inari” or “Patent Owner”).

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

B. Experience and Qualifications

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

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

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

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

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

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

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

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

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

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

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

14. In summary, I have more than 35 years of experience in the cardiovascular medical device field, including significant experience designing, developing, testing, and manufacturing catheters and catheter systems for minimally invasive cardiovascular procedures. I am therefore very familiar with the concepts of catheters, catheter systems, and hemostasis valves, and I believe I am well placed to comment on the understanding of a person of ordinary skill in the art in the context of the '669 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 '669 patent;
- The level of ordinary skill in the art pertaining to the '669 patent;
- The teachings of the prior art; and
- Whether Claims 1-5, 8, 10-12 14-19, 22, 24-28, and 30 of the '669 patent are anticipated or 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. I have also offered opinions in several other IPRs involving patents owned by Inari and I have considered the filings in those IPRs in forming my opinions, including the institution decisions.

17. I have also relied on my education, training, and experience, and my knowledge of pertinent literature in the field of the '669 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 '669 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. 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.

27. 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.

28. 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.

29. 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.

30. 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, 8, 10-12 14-19, 22, 24-28, and 30 of the '669 patent would have been non-obvious, as further explained in Section § X (Heading: "Secondary Considerations") below.

D. Person of Ordinary Skill in the Art

31. It is my understanding that when interpreting the claims of the '669 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 '669 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.

32. 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.

33. 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.

34. Based on my review of the specification and claims of the '669 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.

35. 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.

36. I am aware that in related IPRs, the Board preliminarily determined that a person of ordinary skill in the art for patents related to the '669 patent would have had an undergraduate degree in mechanical engineering or a related engineering discipline and "2-4 years of design or engineering experience related to products in the field of the invention, which involves endovascular devices and the surgical procedures that use such devices." Ex. 1027 ('921 IPR Institution Decision) at 11-12; *see also* Ex. 1028 ('291 Institution Decision) at 12-13. The Board further clarified that "[s]uch devices include, but are not necessarily limited to, hemostasis valves and catheters for minimally-invasive vascular surgeries" and that a person of ordinary skill in the art "need not have had first-hand experience *designing* hemostasis valves." Ex. 1027 ('921 IPR Institution Decision) at 12 (emphasis in original). The Board further stated that a person of ordinary skill in the art's "experience related to developing such devices 'could be as simple as

bench testing and looking at clinical data” and that a person of ordinary skill in the art “would have had an understanding of such devices’ design requirements as determined by the needs of the physician, patient, and procedure, which understanding may be informed by work experience and/or study.” *Id.*

37. The Board’s preliminary decision in the related IPRs aligns with my opinion regarding the qualifications of a person of ordinary skill in the art for the ’669 patent, which includes an undergraduate degree in mechanical engineering or a related engineering discipline and 2-4 years of catheter design experience. Accordingly, my opinions regarding the unpatentability of the challenged claims of the ’669 patent would not change if the Board’s preliminary definition of a person of ordinary skill in the art from the related IPRs were applied here. Additionally, my opinions would not change if the definition of a person of ordinary skill in the art deviated slightly from the definition I have articulated herein by, for example, requiring slightly more experience, or some experience with specific types of catheter technology.

E. The Prior Art Is from the Same Field as the ’669 Patent

38. 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 ’669 patent, e.g., devices for aspirating unwanted material from a patient and hemostasis valves used during intravascular procedures. The references are

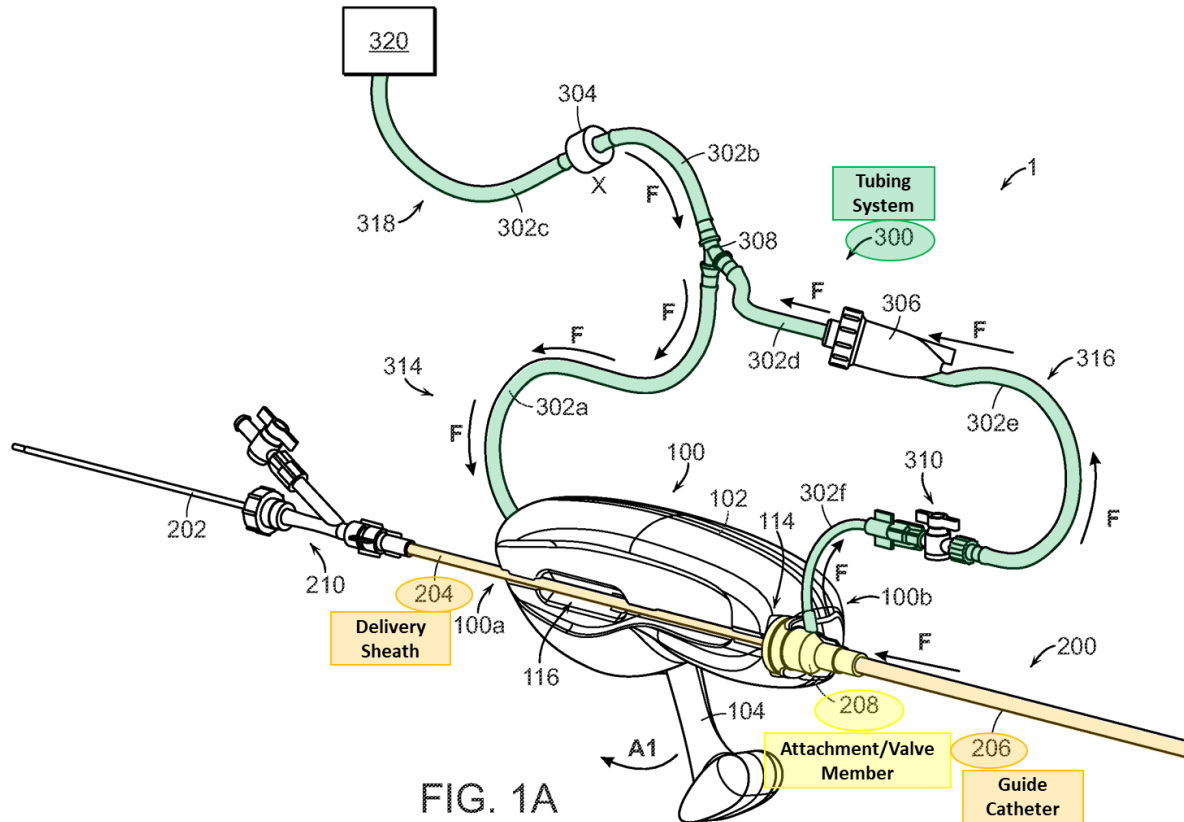
also pertinent to the problem the inventor was focused on, e.g., removing clots, emboli, and thrombi from a patient's blood vessel and sealing a catheter during intravascular procedures to prevent excessive blood loss.

III. THE '669 PATENT

A. Summary of the '669 Patent

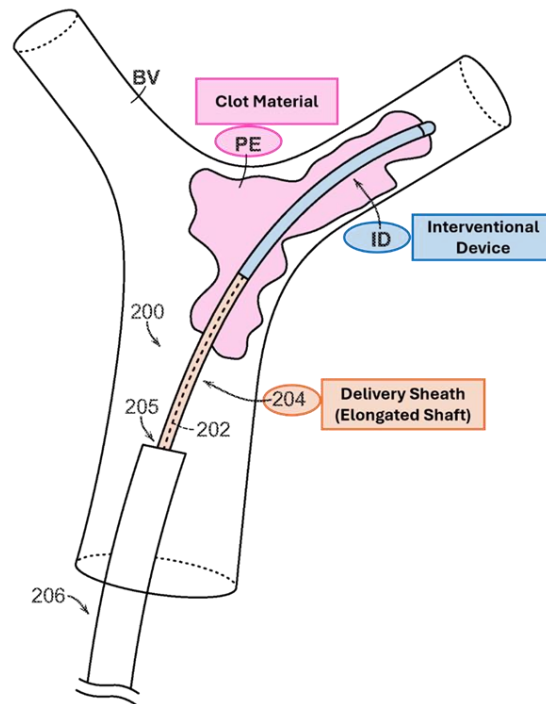
39. The '669 patent is titled "Single Insertion Delivery System for Treating Embolism and Associated Systems and Methods" and describes a retrieval system for intravascular removal of clot material. Ex. 1001 ('669 patent) at 3:53-4:3. The '669 patent explains that the system can treat various clots including pulmonary embolisms ("PE") and cerebral embolisms. *Id.* at 4:4-10. The retrieval system has a "clot retrieval system 1," which includes "retraction and aspiration device 100 (RA device 100)," "catheter system 200," and "tubing system 300." *Id.* at 4:45-48.

40. The catheter system 200 has a guide catheter 206 [pink below] and a delivery sheath 204 which may "individually comprise an elongated shaft" [orange below]. *Id.* at 5:7-20. 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" [green below].



Id. at 6:13-22, Fig. 1A.

41. The '669 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]:



Id. at 5:22-31; Fig. 2A

42. The '669 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 6:50-55. The tubing system 300 has a “first portion 314” coupled to a pressure source and a “second portion 316.” *Id.* at 6:60-63. 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”:

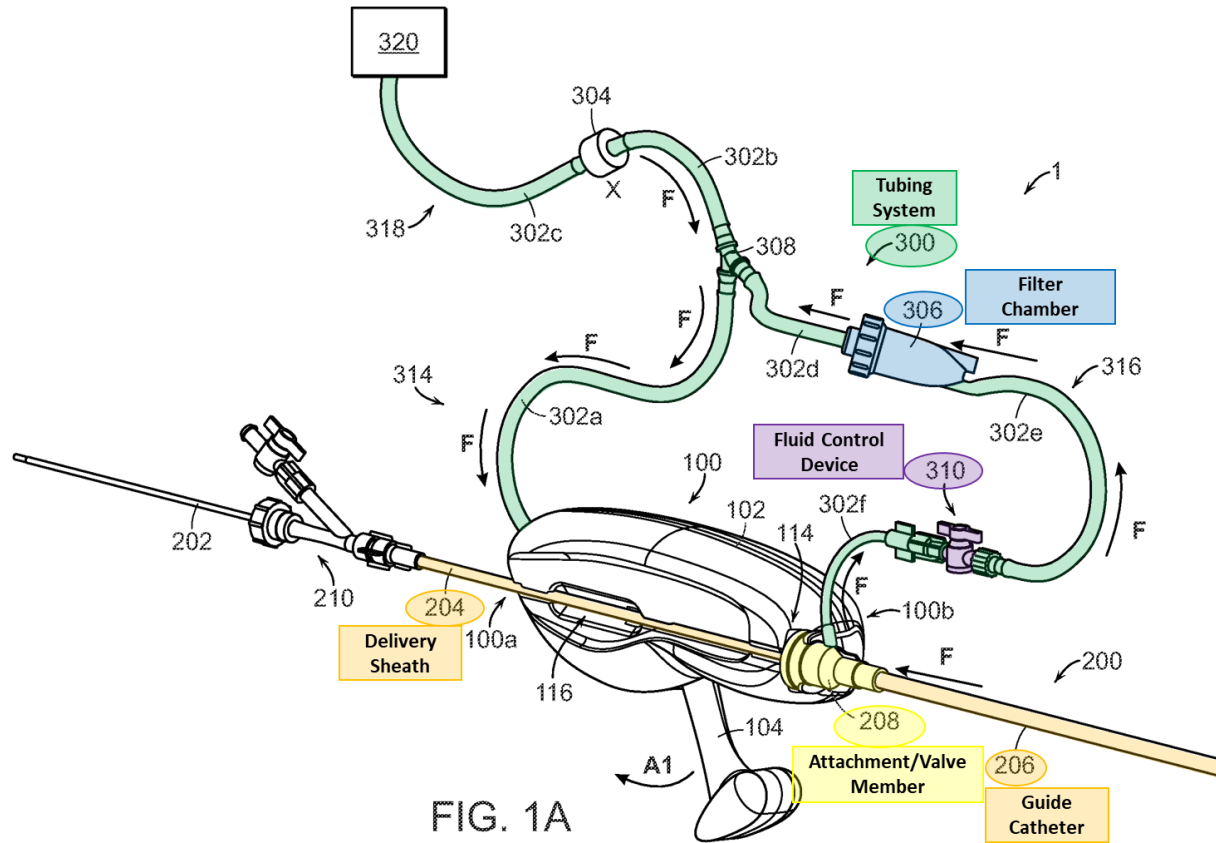


FIG. 1A

Id., 7:8-23, Fig. 1A.

43. The '669 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”:

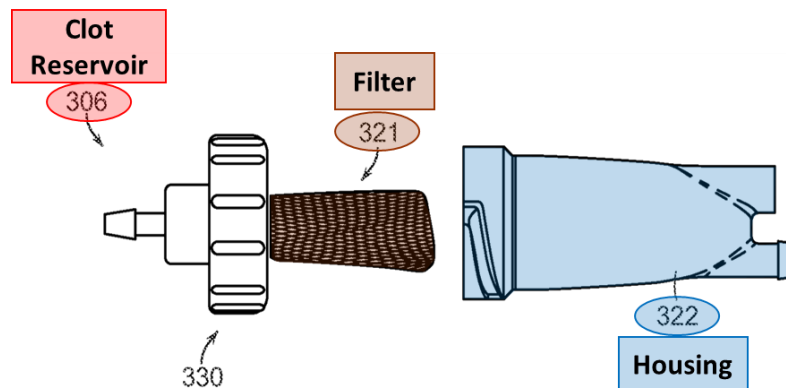


FIG. 3C

Id. at 8:64-9:1; Fig. 3C. The housing can further include “a port 324 [orange] configured to be removably, fluidly coupled to the catheter system 200” and a “fluid connector (e.g., a barbed outlet) 332 [green] for connecting to the tubing system 300”:

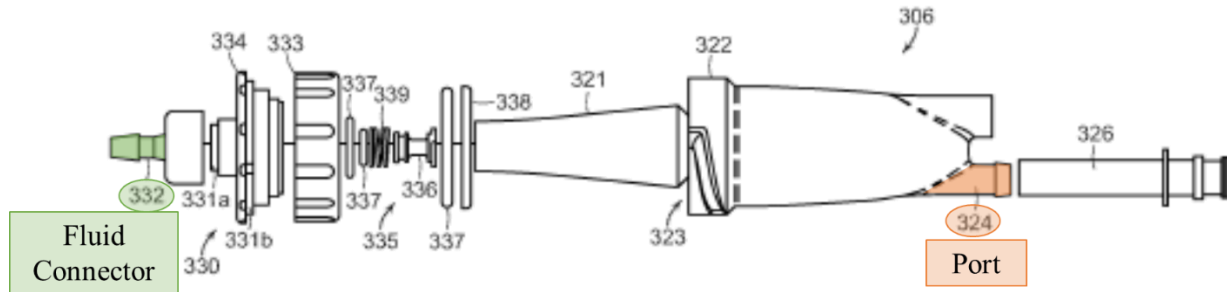


FIG. 3A

Id. at 9:1-17, Fig. 3A

44. The '669 patent discloses that the attachment member 208 “can be, for example, a hemostasis valve configured to maintain hemostasis [...] as the delivery sheath 204, the pull member 202, the guidewire, the interventional device ID, and/or other components of the catheter system 200 are inserted through the valve 445.”

Id. at 10:61-11:2; Fig. 7A, 7B. The '669 patent describes a valve having a “tubular member (e.g., an elongate member) 1372” that extends through the valve. *Id.* at 17:64-67. 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”:



45. The valve disclosed in the '669 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 18:6-11. The actuation mechanism “can be a manual actuator such as one or more buttons 1378.” *Id.* at 18:12-14. 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 18:27-30. The valve also includes a bias feature, such as a spring, that biases the actuator toward the open or closed configuration. *Id.* at 18:24-27.

46. The '669 patent also allegedly incorporates by reference U.S. Patent Application No. 62/554,931 titled "Hemostasis Valves and Methods of Use." *Id.* at 17:41-47. The '931 application is Exhibit 1019 and includes additional descriptions of the hemostasis valve, which I discuss in the claim construction section below.

B. The Challenged Claims

47. The challenged claims include Claims 1-5, 8, 10-12 14-19, 22, 24-28, and 30 of the '669 patent. Claims 1 and 15 are the only independent claims.

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

1. An aspiration system, comprising:
 - a vacuum source;
 - connection tubing fluidically coupled to the vacuum source;
 - a catheter fluidically coupled to the vacuum source;
 - a filter chamber fluidically coupled to the connection tubing at a location apart from the vacuum source, wherein the filter chamber comprises a housing and a filter within the housing, and wherein the housing includes—
 - a port configured to be fluidically coupled to the catheter;
 - and
 - a fluid connector configured to be fluidically coupled to the connection tubing; and
 - wherein the filter is in the housing along a first fluid path, wherein the first fluid path fluidically couples the port and the fluid connector, and wherein the catheter is fluidically coupled to the vacuum source via the filter chamber along the first fluid path;
 - a flow controller fluidically coupling the filter chamber to the catheter, wherein the flow controller is along the first fluid path between the filter chamber and the catheter; and
 - a hemostasis valve fluidically coupled to the catheter along a second fluid path at least partially different than the first fluid path,

wherein the hemostasis valve is configured to maintain hemostasis by inhibiting proximal fluid flow along the second fluid path when an interventional device is inserted through the hemostasis valve and the catheter.

Ex. 1001 ('669 patent) at Claim 1.

C. Prosecution History

49. I have reviewed the '669 patent's prosecution history. I see that the Patent Examiner issued a single non-final office action rejecting original claim 10 as indefinite and stating that original claims 1-9 and 11-22 were allowable. Ex. 1002 ('669 Prosecution History) at 316-321. The Examiner stated that Quick (US 20150352325, Ex. 1029) was the best prior art reference, but it did not disclose the following limitations:

a filter chamber coupled to the connection tubing at a location apart from the vacuum source, wherein the filter chamber comprises a housing and a filter within the housing, and wherein the housing includes a port configured to be fluidically coupled to the catheter; and a fluid connector configured to be coupled to the connection tubing; and wherein the filter is in the housing along a first flow path, wherein the filter fluidically couples the port and the fluid connector, and wherein the catheter is fluidically coupled to the vacuum source via the filter chamber along the first flow path; and a hemostasis valve fluidically coupled to the catheter along a second flow path at least partially different than the first flow path, wherein the hemostasis valve is configured to maintain hemostasis by preventing proximal fluid flow along the second flow path when an interventional device is inserted through the hemostasis valve and the catheter.

Id. at 319-320. I understand that Garrison, Goff, Brady, Schaffer, and Hartley were cited to the Examiner on Information Disclosure Statements during prosecution, but

that Pons was not cited to the Examiner. Neither the Examiner nor PO discussed any of the prior art references that form the basis of Grounds 1-11 below (Garrison, Goff, Brady, Pons, Schaffer, Hartley) during prosecution of the '669 Patent.

IV. CLAIM CONSTRUCTION

50. Claims 12 and 26-28 of the '669 patent require a hemostasis valve having “a *filament* coupled to the button and the tubular member.” Ex. 1001, Claims 12, 26-28 (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, 11,554,005, 11,969,333, 11,844,921, 11,865,291, and 12,016,580. I understand that the '011, '012, '921, and '291 patents depend from the '931 application that is allegedly incorporated by reference into the '669 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 '669 patent) would have understood the term “filament” in the claims of the '669 patent to mean at least: “one or more threads, lines, cords, ropes, ribbons, flat wires, sheets, or tapes.”

51. 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, ’005, ’921, and ’291 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. 1026 (’012 Institution Decision) at 21, n.12. 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 Other IPRs

52. I have reviewed the Board’s Institution Decisions from the ’011 patent, ’012 patent, ’005 patent, ’921 patent, and ’291 patent IPRs. Below is a summary of the relevant portions relating to “filament.”

1. The ’011 Patent IPR

53. 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. 1024 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).

54. 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.*

55. 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 were substantially rigid.” *Id.* at 18.

2. The ’012 Patent IPR

56. 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. 1025 (’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.*

57. 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.

58. 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 form[s] into a loop’ where the ‘diameter of the loop’ reduces when the end portion(s) 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.*

3. The ’005 Patent IPR

59. I see that in the ’005 Patent IPR, the Board adopted its analyses from both the ’011 and ’012 Patent IPRs. Ex. 1026 (’005 Patent Institution Decision) at 14-18. For claim 1 of the ’005 patent, the Board adopted its preliminary construction from the ’011 Patent IPR and determined that the “filament” recited in claim 1 did not require flexibility. *Id.* at 16. However, for claim 10 of the ’005 patent, the Board adopted its preliminary construction from the ’012 Patent IPR

because claim 10 recites that the filament forms a “loop” like the claims of the ’012 patent. *Id.* at 16-18.

4. The ’921 and ’291 Patent IPRs

60. In the ’921 and ’291 Patent IPRs, the Board adopted its preliminary construction from the ’012 Patent IPR and determined that the claimed “filament” is limited to “flexible” filaments. Ex. 1027 (’921 Patent Institution Decision) at 14-18; Ex. 1028 (’291 Patent Institution Decision) at 16-21. In the ’921 Patent IPR, the Board focused on the patent’s description that the filament can be “loosened” and “tightened” and determined that “[t]hese descriptions from the patent appear at this stage more consistent with the view that the filament is characteristically flexible, not rigid.” Ex. 1027 (’921 Patent Institution Decision) at 15. In the ’291 Patent IPR, the Board focused on the claim language requiring that the filament is “formed in a loop around the tubular sidewall.” Ex. 1028 (’291 Patent Institution Decision) at 17.

B. Construction of “Filament”

61. As explained above, I have previously construed “filament” in IPRs involving Patent Owner and Petitioner. Below, I substantially repeat the analysis I previously provided.

62. I understand from counsel that the claim construction analysis should begin with the language of the claims. Here, the claims do not provide much

information about the meaning of “filament.” Claims 12 and 26-28 of the ’669 patent require the filament seal and unseal a hemostasis valve by moving the button to a first position to “tighten the filament to allow the tubular member to collapse” and actuating the button “from a first position to a second position to loosen the filament.” Ex. 1001 (’669 patent) at Claims 12, 26-28. 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.”

63. The specification of the ’669 patent does not provide any further guidance on the structures or materials that form a “filament.” The ’669 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 (’669 patent) at 18:6-11. Like claims 12 and 26-28, 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 1374 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 18:28-40. 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.”

64. However, the ’931 Application, which the ’669 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. 1019 (’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.

65. 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):

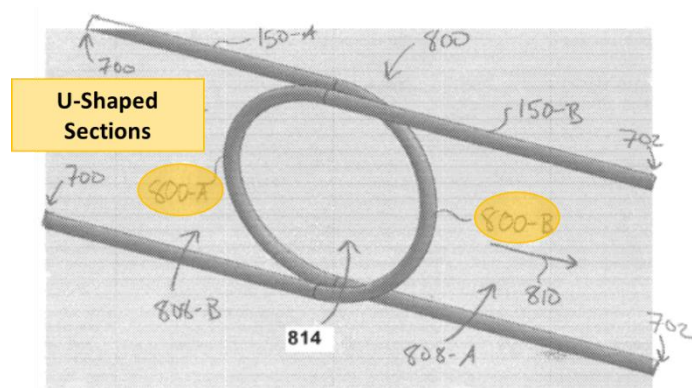


Figure 8

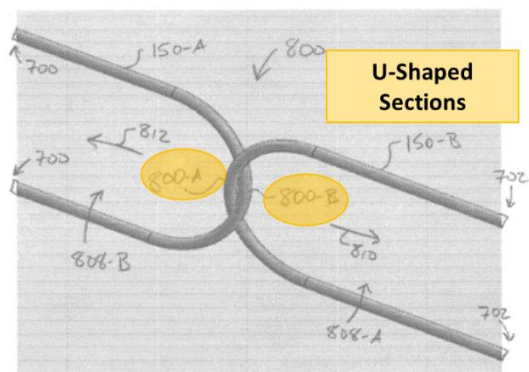


Figure 9

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).

66. 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 ’669 patent.

67. 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 ’669 patent to mean at least: “one or more threads, lines, cords, ropes, ribbons, flat wires, sheets, or tapes.”

C. The Claims of the ’669 Patent Are Not Limited to “Flexible” Filaments

68. I do not believe the claims of the ’669 patent should be limited to only “flexible” filaments. For clarity, I agree that the term “filament” in the ’669 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 ’669 patent nor the ’931 application allegedly incorporated by reference into the ’669 patent use the word “flexible” to describe the filament. And neither the ’669 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 exists along a spectrum, I would not be able to tell whether a material was “flexible” enough to qualify as a filament based on the information in the ’669 patent or the ’931 application.

69. As summarized above, I am aware that the Board preliminarily construed “filament” in the claims of the ’012 and ’291 patents and claim 10 of the ’005 to require *only* “flexible” filaments. However, I see some differences in the claims that I think impact the Board’s analysis. The claims of the ’012 and ’291 patents and claim 10 of the ’005 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 ’669 patent do not include this limitation and do not require that the filament form a “loop” or “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 ’669 patent merely require depressing and releasing a button to loosen or tighten the filament which allows unsealing or sealing of the tubular member of the valve.

70. Looking at the ’931 application, I believe that the filaments in Figures 8 and 9 meet the claim limitations of the ’669 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. 1019 (’931 application) at [00068]. Specifically, the ’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.*

71. 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. 1025 ('012 Patent Institution Decision) at 19-20. However, the '669 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 '669 patent prosecution history does not support a construction of “filament” that is limited only “flexible” filaments.

72. 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. 1038 at claim 1 (emphasis added). The claim further recites that the actuator can apply tension to the filament to “decreas[e] 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.

73. As summarized above, I am aware that the Board preliminarily construed “filament” in the claims of the '921 patent to require *only* “flexible” filaments based on the description in the specification that the filament can be

“loosened” and “tightened.” Ex. 1027 (’921 Patent Institution Decision) at 15. But, the word “loosened” is not synonymous with “flexible.” For example, the term “loosen” in the dictionary submitted by Patent Owner in the ’011 Patent IPR means “to release from restraint.” Ex. 1015. The term “loosen” does not have any relationship to flexibility because many relatively inflexible items can be loosened, such as screws and u-bolts. Movement of the filaments in the embodiments in Figures 8 and 9 of the ’931 application would release the restraint around the elongate member and increase the size of the encircled area, even if those filaments are determined by the Board to be relatively inflexible. Similarly, releasing the actuator buttons would move the filaments in the embodiments in Figures 8 and 9 of the ’931 application in opposite directions, causing the filaments to “tighten” around the tubular member, even if those filaments are relatively inflexible. Therefore, I don’t see the use of “loosened” or “tightened” in the ’669 patent or the ’931 application to require only “flexible” filaments.

74. In the ’011 Patent IPR, Patent Owner also relied on the bight embodiments depicted in Figures 8 and 9 of the ’011 patent and suggested that the filament must be flexible enough to “slacken when formed in a bight,” but this also fails to resolve the uncertainty created by its proposed construction. *See* Ex. 1030 (’011 Patent IPR, Patent Owner Response) at 34. The ’931 application does not state that the bights “slacken” when the actuator buttons are depressed, and Figures

V. SUMMARY OF IPR GROUNDS

75. I have identified the following grounds of unpatentability in this

Declaration:

Ground	Reference(s)	35 U.S.C. Section	Challenged Claims
1	Garrison	§102	1-5, 10-11, 14-19, 24-25, 30
2	Garrison	§103	1-5, 8, 10-11, 14-19, 22, 24-25, 30
3	Garrison + Goff	§103	1-5, 8, 10-11, 14-19, 22, 24-25, 30
4	Garrison + Brady	§103	14, 30
5	Garrison + Goff + Brady	§103	14, 30
6	Garrison + Pons	§103	14, 30
7	Garrison + Goff + Pons	§103	14, 30
8	Garrison + Schaffer	§103	12, 26-28
9	Garrison + Goff + Schaffer	§103	12, 26-28
10	Garrison + Schaffer + Hartley	§103	12, 26-28
11	Garrison + Goff + Schaffer + Hartley	§103	12, 26-28

VI. GROUNDS 1-2: CLAIMS 1-5, 8, 10-11, 14-19, 22, 24-25, 30
ANTICIPATED OR OBVIOUS IN VIEW OF GARRISON

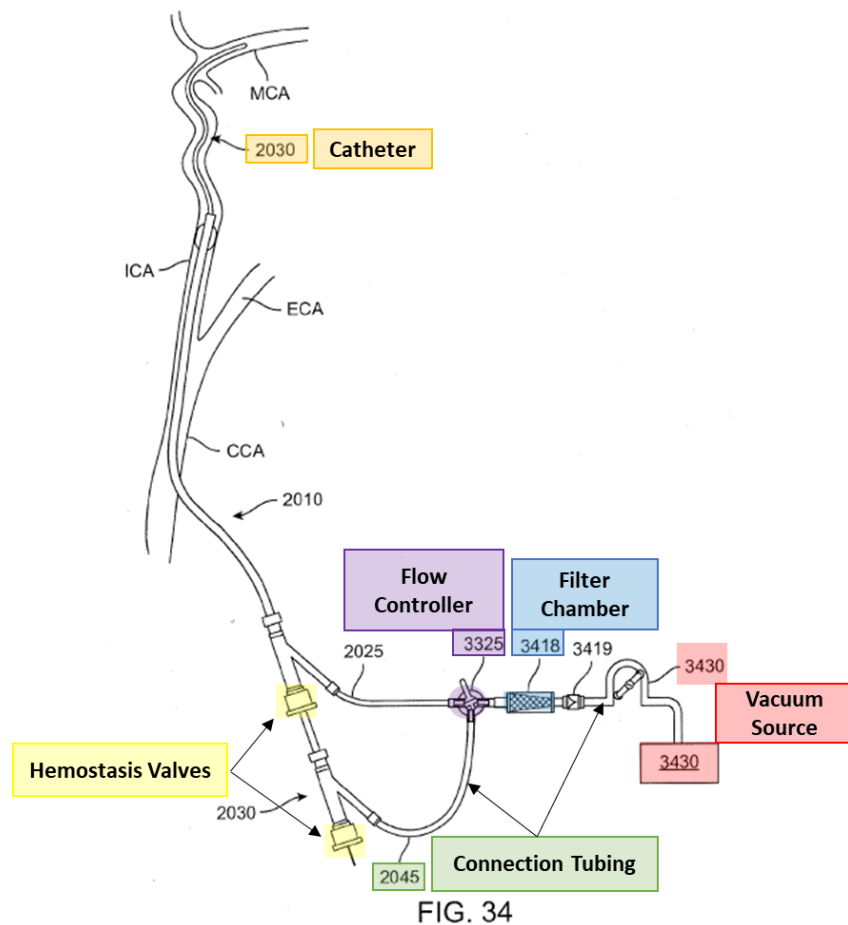
A. Claim 1

76. As I explain in detail below, Garrison discloses each of the limitations recited in Claim 1 of the '669 patent and therefore anticipates Claim 1. As I also explain below, even if the Board concludes that Garrison does not anticipate Claim 1, Claim 1 would have been obvious to a person of ordinary skill in the art in view of Garrison.

1. Preamble – “An aspiration system”

77. The preamble of Claim 1 recites: “An aspiration system.” If the Board finds that the preamble of Claim 1 is limiting, Garrison discloses an aspiration system.

78. Garrison discloses a system “to provide aspiration and passive flow reversal for the purpose of facilitating removal of the occlusion as well as minimizing distal emboli.” Ex. 1006 (Garrison) at [0007]. Garrison discloses an embodiment, depicted in Figure 34, that includes an aspiration catheter 2030 [orange] coupled to a vacuum source [red] via connection tubing [green] (i.e., flow line 2045):



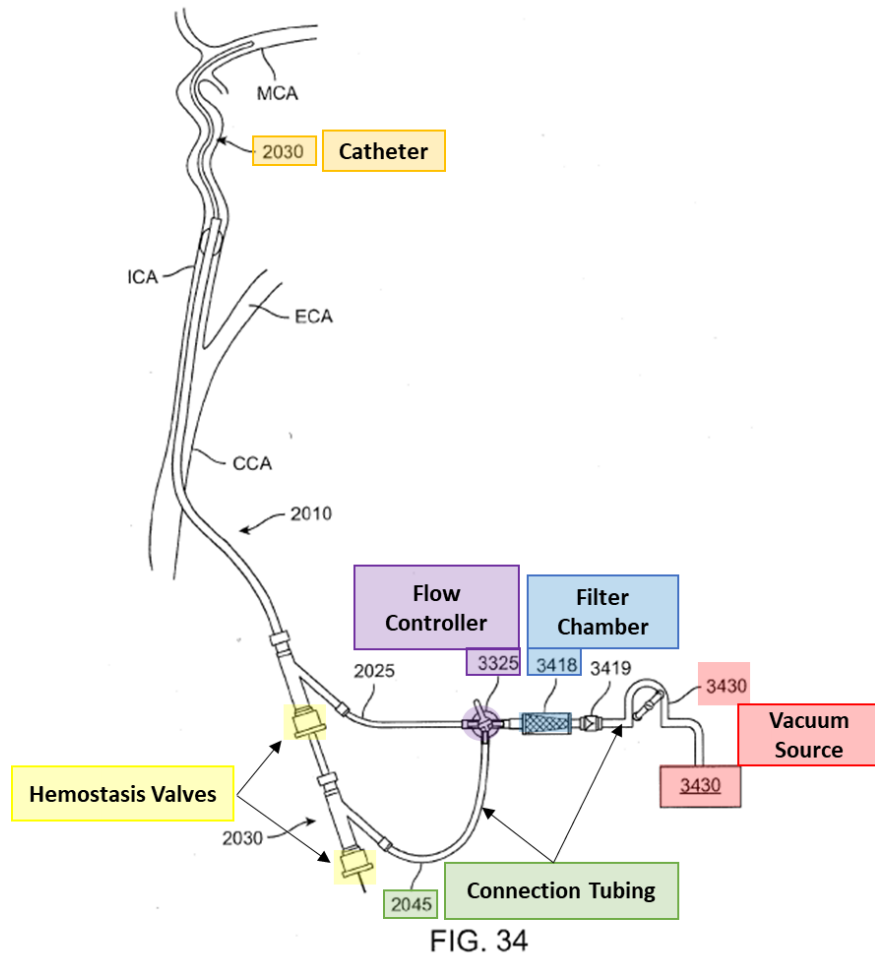
Id. at Fig. 34; *see also id.* at [0131]-[0134] (describing embodiment in Figure 34).

The embodiment in Figure 34 also includes a flow controller [purple] and filter chamber [blue] that is fluidly connected to the system along the flow path between the aspiration catheter and vacuum source. *Id.*

2. “vacuum source”

79. Claim 1 next recites a “vacuum source.” Garrison discloses this limitation.

80. Garrison's aspiration system includes an aspiration source 3430 [red] that is coupled to the aspiration catheter via flow line 2045:

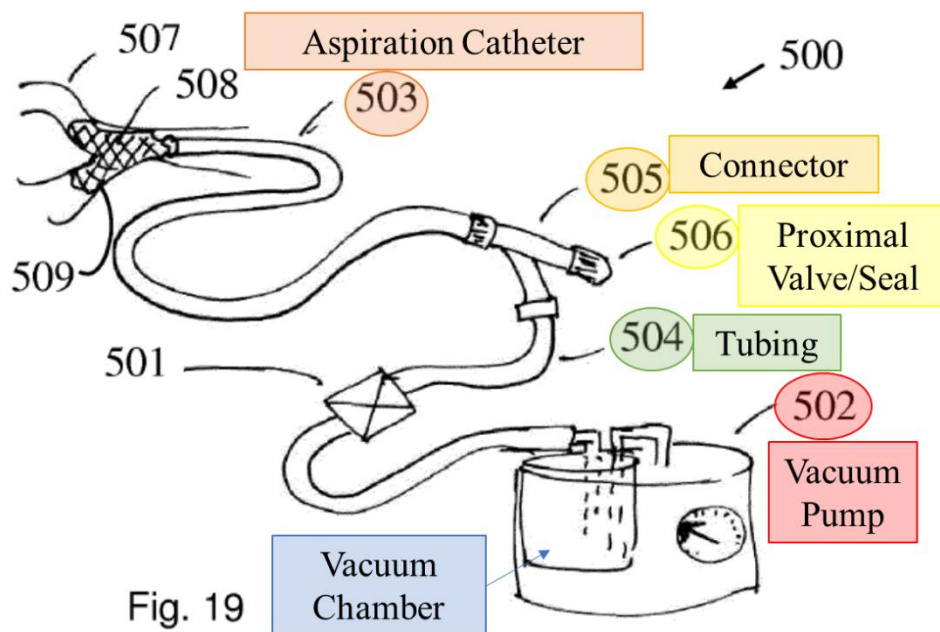
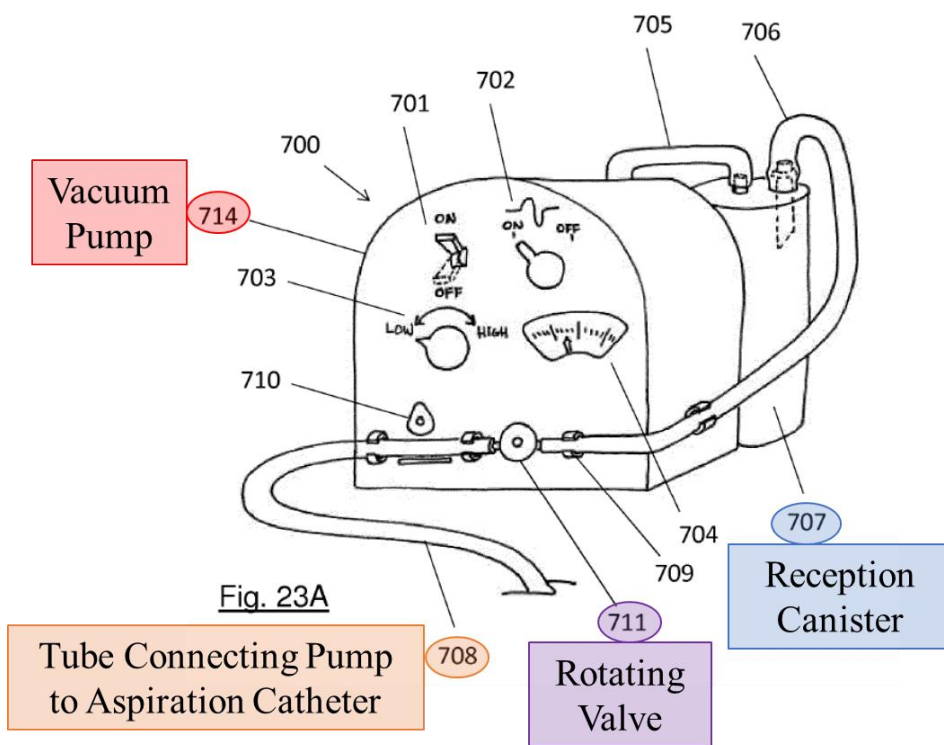


Ex. 1006 (Garrison) [0131], Fig. 34.) Garrison discloses that its aspiration source may be a “an aspiration pump, a regular or locking syringe, a hand-held aspirator, hospital suction, or the like.” *Id.* at [0134]. Each of those options is a “vacuum source” because it provides aspiration (i.e., suction) by creating a vacuum.

81. I am aware that in related IPRs, Patent Owner has argued that the aspiration source in Figure 34 of Garrison can only be a peristaltic pump due to the

illustration in Figure 34. I disagree with Patent Owner's argument, which is inconsistent with Garrison. As noted in the preceding paragraph, Garrison expressly states that its aspiration source may be "an aspiration pump, a regular or locking syringe, a hand-held aspirator, hospital suction, or the like." *Id.* at [0134]. It would therefore be contrary to Garrison's express disclosure to interpret Figure 34 as requiring a peristaltic pump. In fact, Garrison only mentions a peristaltic pump once, in paragraph 135, where it states that "peristaltic pumps are known to cause damage to blood cells." Ex. 1006 (Garrison) at [0135]. Given these descriptions in Garrison, a person of ordinary skill in the art would not have understood that the aspiration source 3430 in Figure 34 must be a peristaltic pump.

82. A person of ordinary skill in the art in January 2018 would have been familiar with many types of aspiration pumps that would be suitable for use as the aspiration source in Garrison's aspiration system. For example, Brady discloses an aspiration pump that is "particularly suited to removing clot from cerebral arteries in patients suffering acute ischemic stroke (AIS), from coronary native or graft vessels in patients suffering from myocardial infarction (MI), and from pulmonary arteries in patients suffering from pulmonary embolism (PE) and from other peripheral arterial and venous vessels in which clot is causing an occlusion":



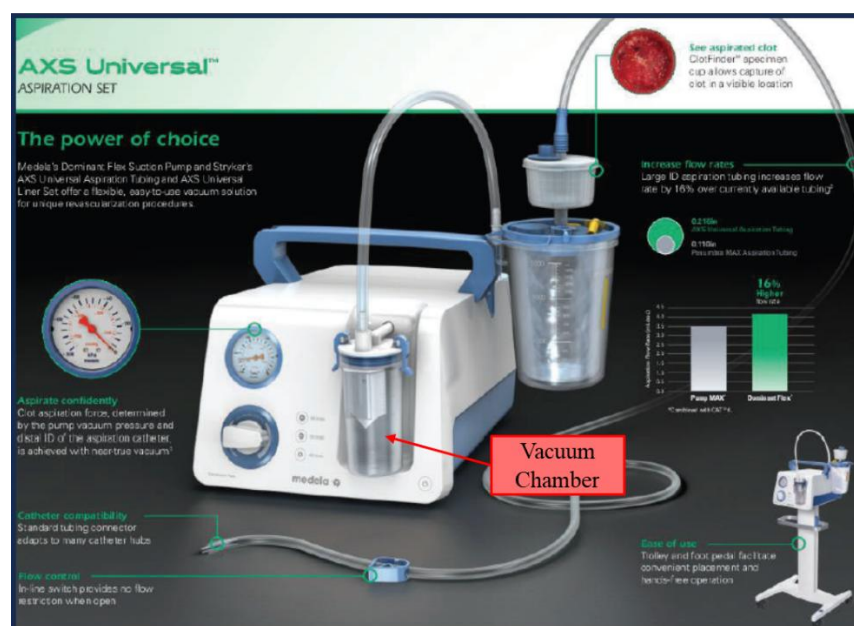
Ex. 1010 (Brady) at 1:13-17, 20:19-29, 21:16-32, Figs. 19, 23A. Brady's pump generates vacuum in a reception canister, which is then applied to an aspiration

catheter (not shown) via tubing. *Id.* 21:16-32. This design is similar to several commercial aspiration pumps, such as the Penumbra Max and Medela Dominant Flex, that were available prior to 2018 and used to aspirate clot material:

Penumbra Pump



Medela Pump



Ex. 1036 (Penumbra Max Pump); Ex. 1037 (AXS Brochure). A person of ordinary skill in the art would have understood that Garrison's broad disclosure of an "aspiration pump" would encompass these types of prior art aspiration pumps.

3. "catheter fluidically coupled to the vacuum source"

83. Claim 1 next recites a "catheter fluidically coupled to the vacuum source." Garrison discloses this limitation.

84. Garrison's aspiration system includes an aspiration catheter 2030 that is fluidically coupled to the vacuum source 3430 via the flow line 2045 (i.e., connection tubing):

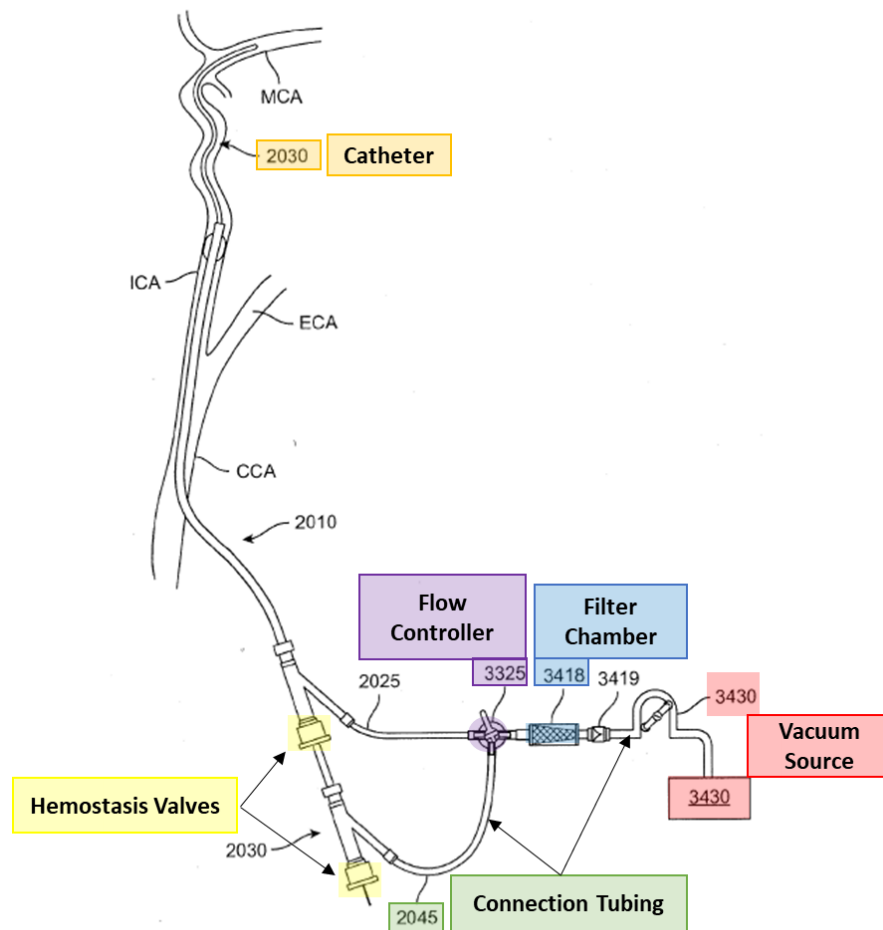


FIG. 34

Ex. 1006 (Garrison) at [0130]-[0134], Fig. 34. Garrison explains that the aspiration catheter 2030 is “connected to sources of passive or active aspiration via flow lines 2025 or 2045 (FIG. 1) on the devices.” *Id.* at [0130]. A person of ordinary skill in the art would have therefore understood that the flow lines would enable aspirated fluid and clot material from the aspiration catheter to the vacuum source, and thus the aspiration catheter is “fluidically coupled” to the vacuum source.

4. **“a filter chamber fluidically coupled to the connection tubing at a location apart from the vacuum source”**

85. Claim 1 next recites “a filter chamber fluidically coupled to the connection tubing at a location apart from the vacuum source, wherein the filter chamber comprises a housing and a filter within the housing.” Claim 1 then recites additional limitations for the filter housing, requiring that the housing includes: (1) “a port configured to be fluidically coupled to the catheter,” (2) “a fluid connector configured to be fluidically coupled to the connection tubing,” and (3) “wherein the filter is in the housing along a first fluid path, wherein the first fluid path fluidically couples the port and the fluid connector, and wherein the catheter is fluidically coupled to the vacuum source via the filter chamber along the first fluid path.” Garrison discloses each of these limitations for the “filter chamber” or renders them obvious.

86. Garrison's aspiration system includes a filter 3418 [blue] that is fluidly coupled to the flow line 2045 (i.e., connection tubing) [green] between the proximal end of the aspiration catheter 2030 [orange] and the vacuum source 3430 [red]:

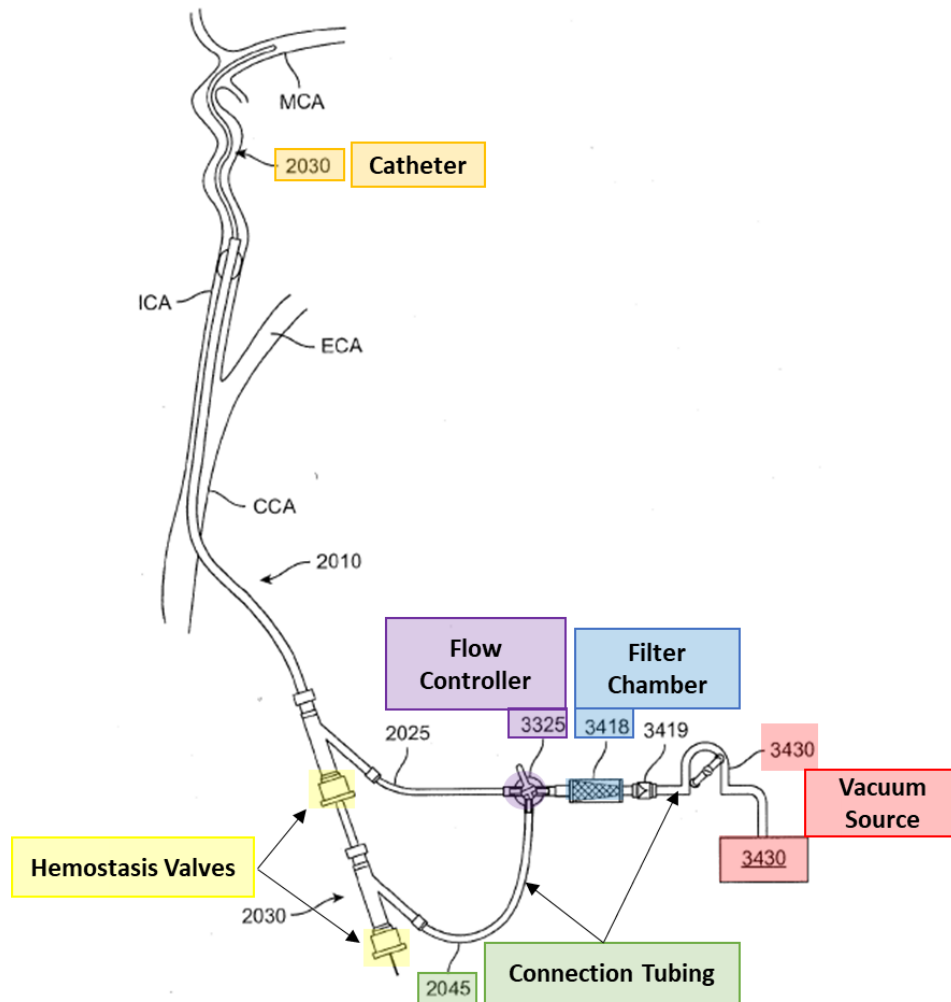


FIG. 34

Ex. 1006 (Garrison) at [0130]-[0134], Fig. 34. As illustrated in Figure 34, Garrison's filter 3418 includes a housing or "chamber" and a filter placed within the housing. The filter 3418 is therefore a "filter chamber." *Id.* Figure 34 also shows that the filter 3418 is fluidically coupled to the flow line 2045 (i.e., connection tubing) at a location that is apart from the vacuum source. *Id.*

a. **“a housing and a filter within the housing”**

87. As I explained in the preceding paragraph, Garrison’s Figure 34 shows that the filter 3418 includes a housing [red] and a filter [purple] located within the housing [red]:

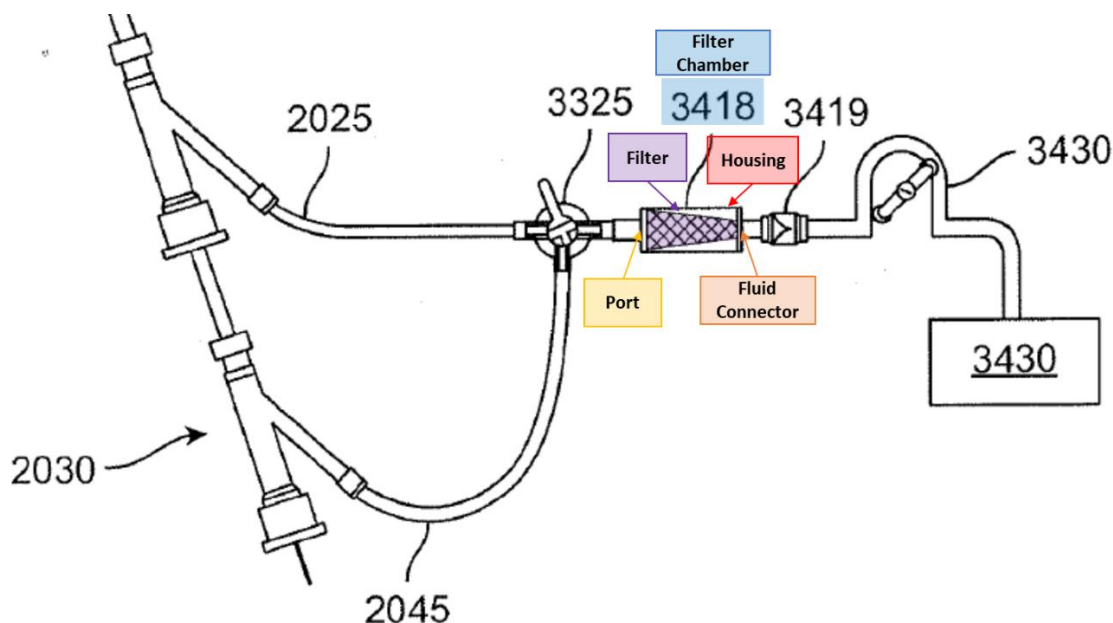


FIG. 34

Id. While Garrison does not specifically describe a “housing” in the text, Figure 34 illustrates the housing, and a person of ordinary skill in the art would have understood that the filter must have a housing around it otherwise blood would pour out of the device.

b. **“a port configured to be fluidically coupled to the catheter”**

88. A person of ordinary skill in the art would have understood that Garrison’s filter 3418 necessarily includes “a port configured to be fluidically coupled to the catheter.”

89. A person of ordinary skill in the art would have understood that the plain and ordinary meaning of “port” is simply an opening for intake or exhaust of a fluid. *See, e.g.*, Ex. 1014 (Merriam Webster); Ex. 1043 (Dorland’s). “Port” was a commonly used term in the medical device field to refer to an opening that allowed for fluid flow. For example, I worked with many catheters that included a balloon “port” that allowed fluid to pass into the catheter for inflating a balloon or an infusion “port” that allowed infusion fluid to pass into the catheter so that it could be delivered to the treatment site. Claim 1 does not specify any features or structure for the “port” aside from requiring that it is “configured to be fluidically coupled to the catheter.” The specification of the ’669 patent similarly lacks any description of specific features or structures for the “port 324” aside from stating that it is “configured to be removably, fluidly coupled to the catheter system 200”:

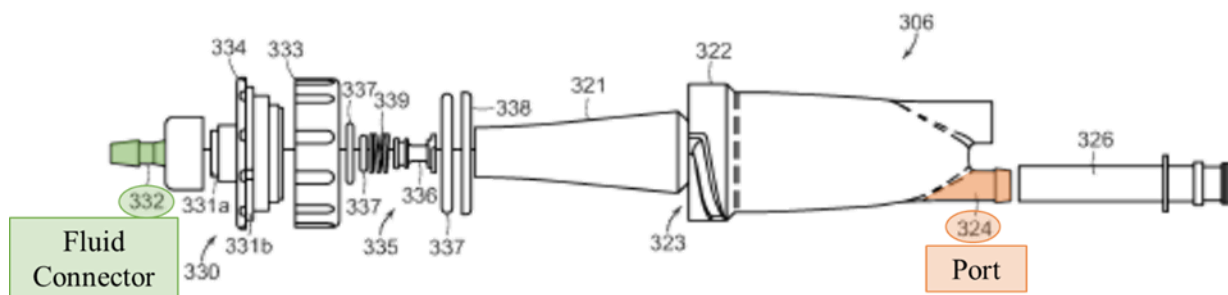


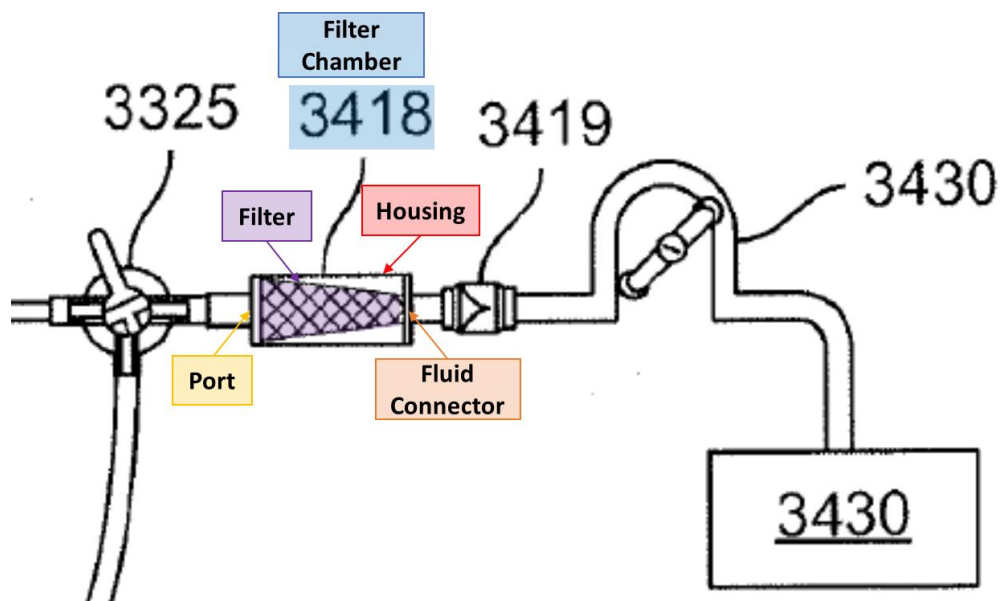
FIG. 3A

Ex. 1001 (’669 patent) at 9:1-3, Fig. 3A.

90. Garrison states that the filter 3418 is “coupled with the flow line 2045.” Ex. 1006 (Garrison) at [0131]. A person of ordinary skill in the art would have

recognized that the housing of the filter 3418 would necessarily include a port (i.e., opening) at its distal end that is “coupled with the flow line 2045.” *Id.* If the housing did not include such a port, aspirated blood and clot material would not be able to flow from the flow line 2045 into and through filter, rendering the filter inoperable. In addition, if the filter did not include openings on each end that were configured to fluidly couple the filter housing to the tubing, then the vacuum pressure generated by the vacuum source would be unable to reach the aspiration catheter, rendering the entire aspiration system inoperable. Therefore, a person of ordinary skill in the art would have understood that Garrison’s filter housing necessarily includes a “port.”

91. The person of ordinary skill’s understanding of Garrison’s filter is further confirmed by Figure 34, which illustrates that a port (i.e., opening) fluidly connects the filter to the aspiration catheter 2030 via the flow line 2045:



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

92. Even if the Board concludes that Garrison's filter housing does not necessarily include a "port," it is my opinion that a person of ordinary skill in the art in January 2018 would have found it obvious to couple Garrison's filter 3418 to the flow line 2045 using conventional connectors, such as Luer-type (e.g., Luer slip and Luer lock) and barb connectors, all of which were conventional and well-known in the art at that time. As I explained above, a person of ordinary skill would have understood that Garrison's filter housing must have at least two openings for the filter to be fluidly coupled to the aspiration system. Although Garrison does not expressly describe how its filter is coupled to the tubing, Garrison incorporates by reference several patents and publications that describe attaching catheter components using "a conventional luer fitting" or improvements to such fittings. *Id.* at [0064], [0130], [0144]; Ex. 1031 (Garrison '118) at [0130]; *see also* Ex. 1032 (Gordon) at 8:45, 8:63 (describing an "auxiliary Luer port"); Ex. 1033 (Garrison '868) at [0056]-[0059] (describing improvements to the "standardized ... locking Luer taper design"). Luer connectors use tapered male and female fittings to create leak-free connections between components in intravascular or hypodermic medical devices, such as tubing and catheters. *See, e.g.,* Ex. 1040 (ISO 80369-7) at 3.1. All the conventional connectors like Luer connectors and barbed connectors included openings extending through the connector to allow the passage of fluid. A person

of ordinary skill in the art would have therefore understood that these conventional Luer-type connections would encompass a “port” when used with the housing of Garrison’s filter 3418.

93. 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.

94. 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.

95. 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.

96. 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.

c. **“a fluid connector configured to be fluidically coupled to the connection tubing”**

97. A person of ordinary skill in the art would have understood that Garrison's filter 3418 necessarily includes “fluid connector” (a connector that allows the passage of fluid) at its proximal end that is configured to be fluidly coupled to the flow line 2045 (i.e., connection tubing).

98. A person of ordinary skill in the art would have understood that the plain and ordinary meaning of the “fluid connector” recited in Claim 1 is simply an opening that allows passage of fluid between the filter housing and the connection

tubing. Claim 1 does not specify any features or structure for the “fluid connector” aside from requiring that it is “configured to be fluidically coupled to the connection tubing.” The specification of the ’669 patent describes a “fluid connector (e.g., a barbed outlet) 332 for connecting to the tubing system 300” but does not otherwise describe the structure or features of the “fluid connector.” Ex. 1001 (’669 patent) at 9:11-13.

99. Garrison states that the filter 3418 is “coupled with the flow line 2045.” Ex. 1006 (Garrison) at [0131]. A person of ordinary skill in the art would have recognized that the housing of the filter 3418 would necessarily include a fluid connector (i.e., outlet opening) at its proximal end that is “coupled with the flow line 2045.” *Id.* If the housing did not include such a fluid connector, aspirated blood would not be able to flow through the filter and out of the filter housing into the flow line, rendering the filter inoperable. In addition, if the filter did not include openings on each end that were configured to fluidly couple the filter housing to the tubing, then the vacuum pressure generated by the vacuum source would be unable to reach the aspiration catheter, rendering the entire aspiration system inoperable. Therefore, a person of ordinary skill in the art would understand that Garrison’s filter housing necessarily includes a “fluid connector.”

100. The person of ordinary skill's understanding of Garrison's filter is further confirmed by Figure 34, which illustrates that a fluid connector fluidly connects the filter to the flow line tubing:

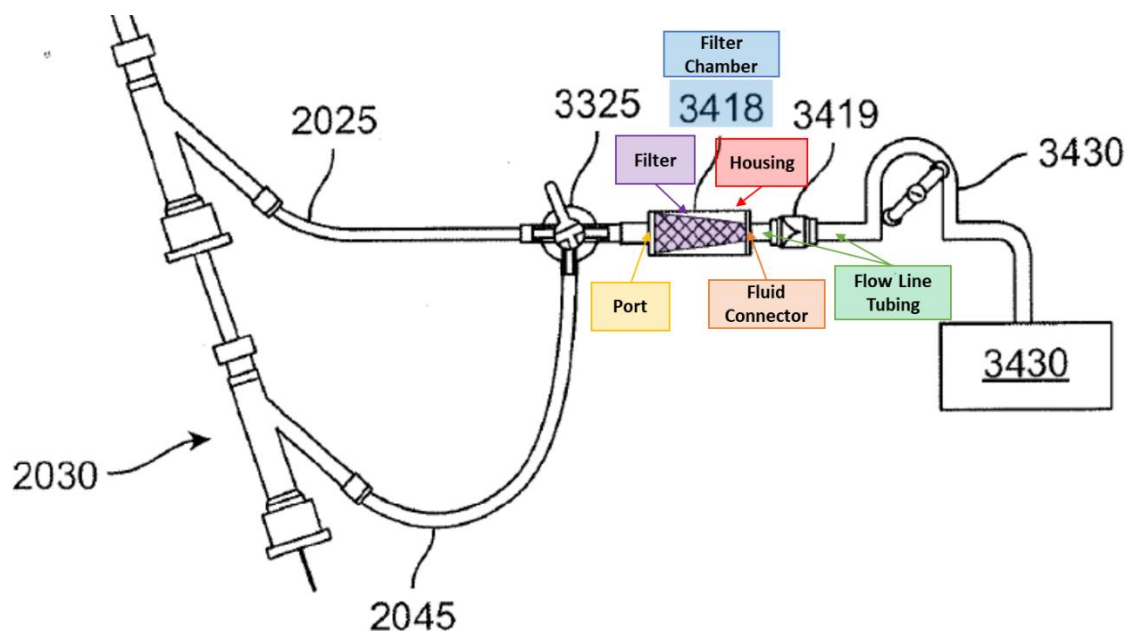


FIG. 34

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

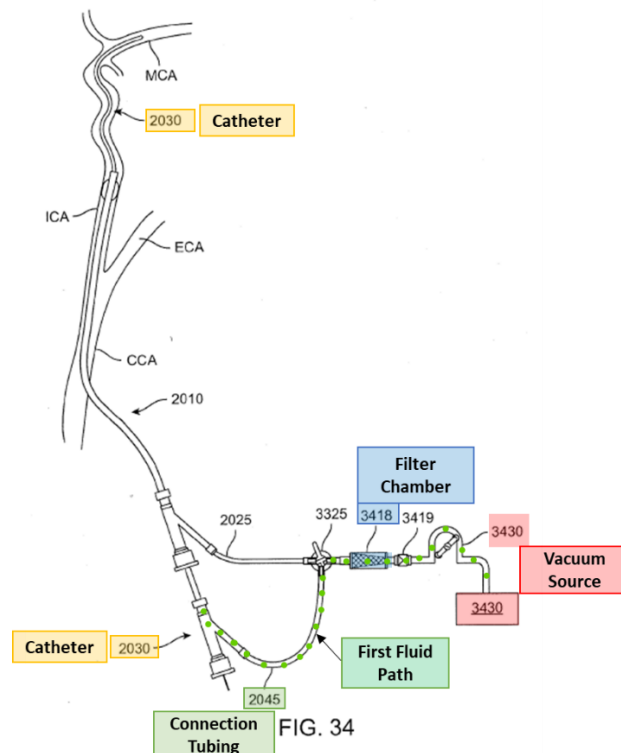
101. Even if the Board concludes that Garrison's filter housing does not necessarily include a "fluid connector," it is my opinion that a person of ordinary skill in the art in January 2018 would have found it obvious to couple Garrison's filter 3418 to the flow line 2045 using conventional connectors, such as a Luer-type (e.g., Luer slip and Luer lock) and barb connectors for the same reasons I explained in the preceding section. *Supra* §VI.A.4.b. A person of ordinary skill in the art would have understood that those conventional Luer-type connections would

constitute a “fluid connector” when used with the housing of Garrison’s filter 3418 because they connect the filter housing to the flow line and permit the passage of fluid, and for the additional reasons I explained above with respect to the “port.”

Id.

- d. **“the filter is in the housing along a first fluid path, wherein the first fluid path fluidically couples the port and the fluid connector, and wherein the catheter is fluidically coupled to the vacuum source via the filter chamber along the first fluid path”**

102. Garrison’s filter 3418 is “coupled with the flow line 2045.” Ex. 1006 (Garrison) at [0131]. Figure 34 shows that the filter is coupled with the flow line along a first fluid path that extends from the vacuum source to the distal tip of the aspiration catheter, which is illustrated with green dots in the figure below:



Id. at [0130]-[0134], Fig. 34. Thus, Garrison's aspiration catheter 2030 is coupled to the vacuum source 3430 via the filter 3418 (i.e., filter chamber) along a first fluid path as recited in Claim 1.

103. The first fluid path in Garrison's system extends through the filter 3418 as shown in Figure 34 below:

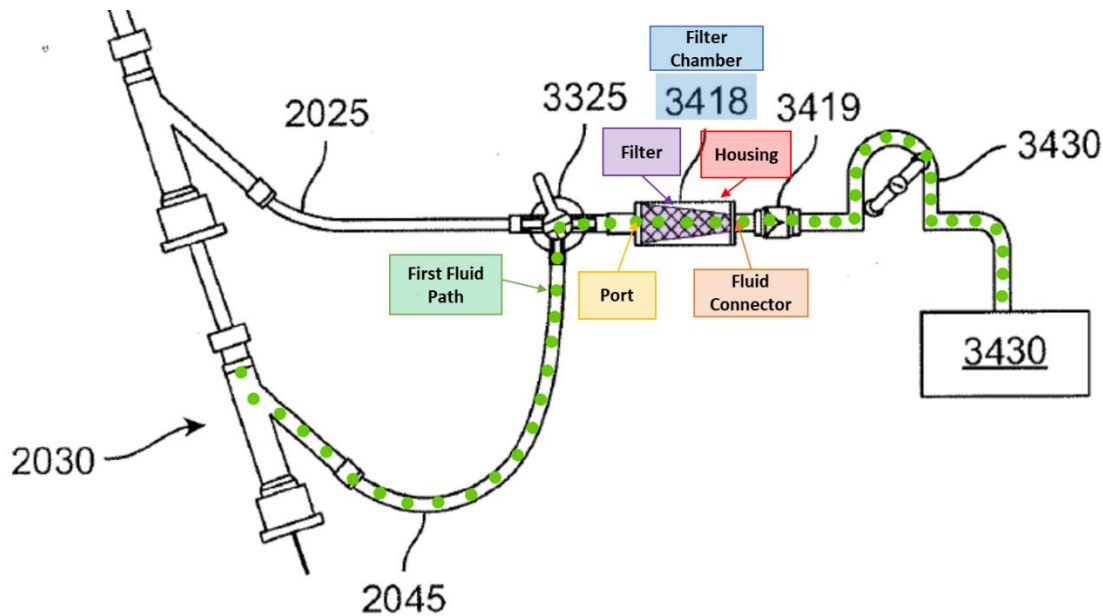


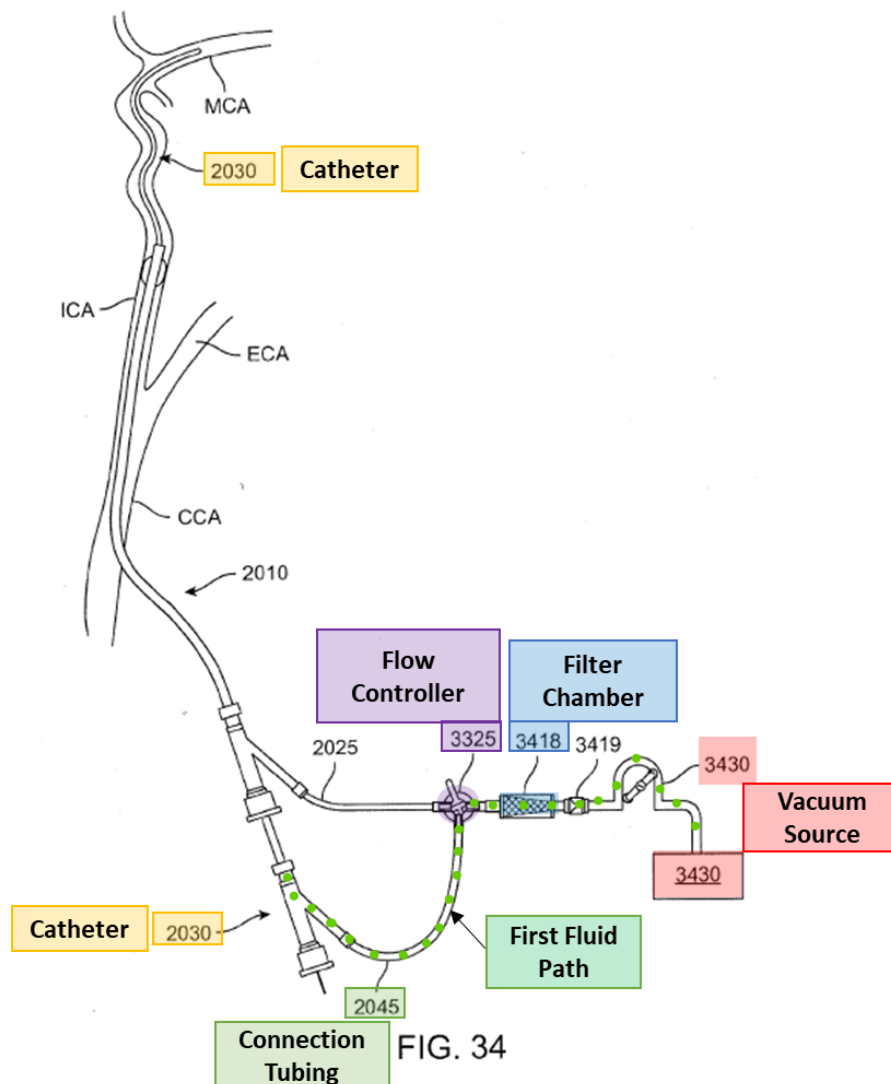
FIG. 34

Id. at Fig. 34 (excerpt). The first fluid path therefore fluidically couples the port on the distal end of the filter with the fluid connector on the proximal end of the filter, allowing aspirated blood to flow from the port through the fluid connector.

5. **“a flow controller fluidically coupling the filter chamber to the catheter, wherein the flow controller is along the first fluid path between the filter chamber and the catheter”**

104. Claim 1 next recites a “flow controller fluidically coupling the filter chamber to the catheter, wherein the flow controller is along the first fluid path between the filter chamber and the catheter.” Garrison discloses this limitation.

105. Garrison’s aspiration system includes a valve 3325 [purple] placed along the fluid path between the filter [blue] and the aspiration catheter [orange]:

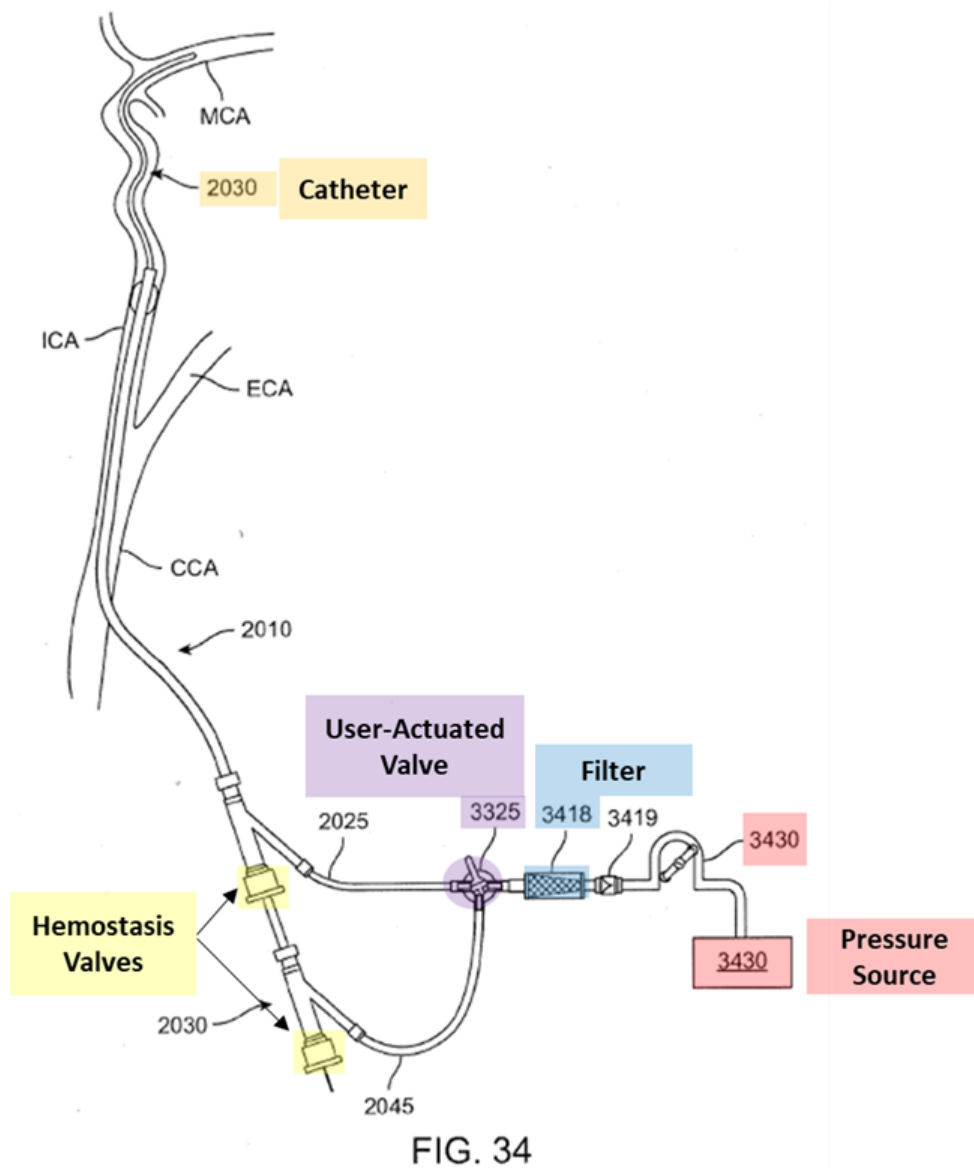


Ex. 1006 (Garrison) at Fig. 34, [0131]-[0134]. Garrison explains that the “valve 3325 controls which device is connected to the aspiration source 3430.” *Id.* at [0132]. Garrison further explains that “[t]he valve may be a 3-way or 4-way stopcock” and that it “enable[s] one device, the other device, both devices, or neither device to be connected to the aspiration source at any given time.” *Id.* Garrison also states that the valve can “be a flow controller with a simple actuation which selects the configuration as described above.” *Id.* Given these disclosures, a person of ordinary skill in the art would have understood that Garrison’s valve 3325 is a “flow controller” that fluidically couples the aspiration catheter 2030 to the filter 3418 along the first fluid path.

6. **“a hemostasis valve fluidically coupled to the catheter along a second fluid path at least partially different than the first fluid path, wherein the hemostasis valve is configured to maintain hemostasis by inhibiting proximal fluid flow along the second fluid path when an interventional device is inserted through the hemostasis valve and the catheter”**

106. Claim 1 next recites a “hemostasis valve fluidically coupled to the catheter along a second fluid path at least partially different than the first fluid path, wherein the hemostasis valve is configured to maintain hemostasis by inhibiting proximal fluid flow along the second fluid path when an interventional device is inserted through the hemostasis valve and the catheter.” Garrison discloses this limitation.

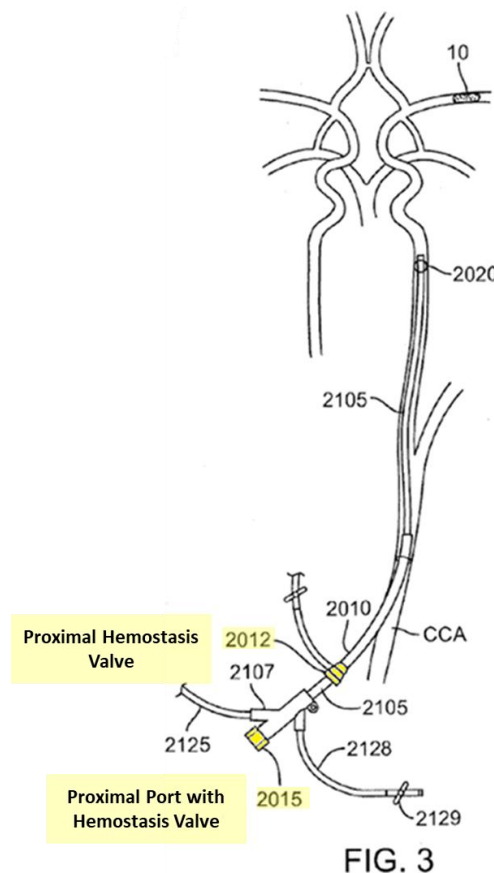
107. Garrison discloses a catheter 2030 [orange] having a hemostasis valve [yellow] in its proximal hub 2065 (item 2065 not labeled in Figure 34):



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

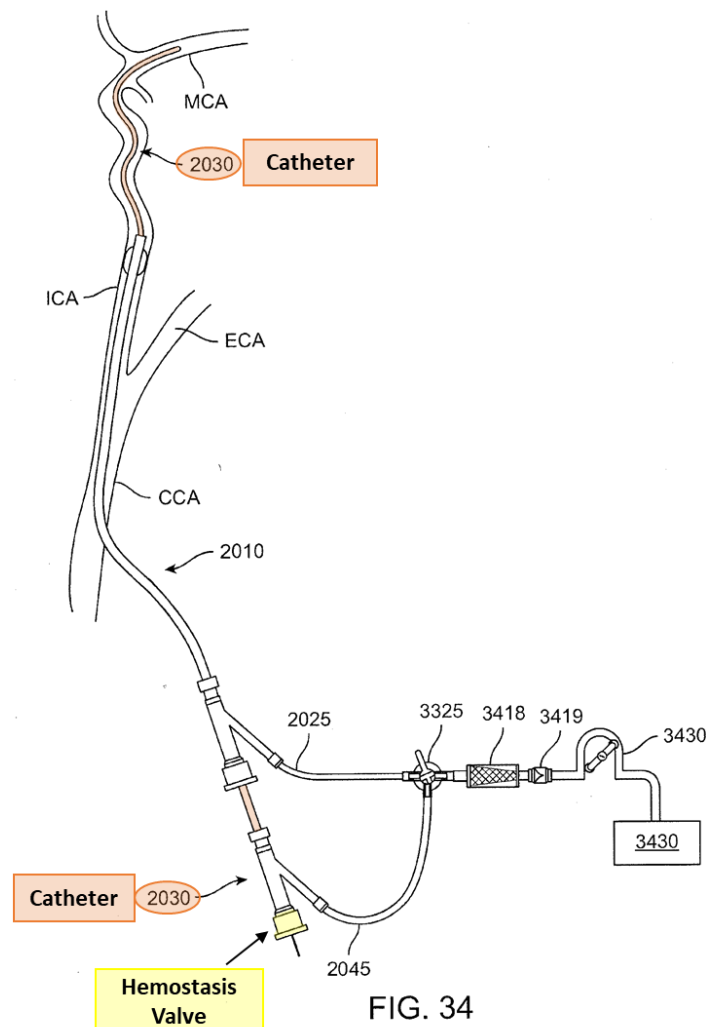
discloses that “the hemostasis valve may be integral to the catheter proximal adaptor.” *Id.* Garrison further discloses that the hemostasis valve can take many configurations, including “an adjustable-opening valve such as a Tuohy-Borst or rotating hemostasis valve (RHV)” or “a passive seal hemostasis valve.” *Id.* at [0098].

108. Figure 34 (above) does not expressly label the proximal adaptor and hemostasis valve, but other, related figures do. For example, Figure 3 identifies a “proximal adaptor having a proximal port 2015 *with a hemostasis valve* to allow introduction of devices while preventing or minimizing blood loss during the procedure”:



Id. at [0053] (emphasis added), Fig. 3; *see also id.* at [0050]-[0053], [0059], [0062], Figs. 1-3, 6 (Garrison also explains that the arterial access device also has a hemostasis valve 2012). The location of the hemostasis valves shown in Figure 3 is the customary location for a hemostasis valve on a catheter.

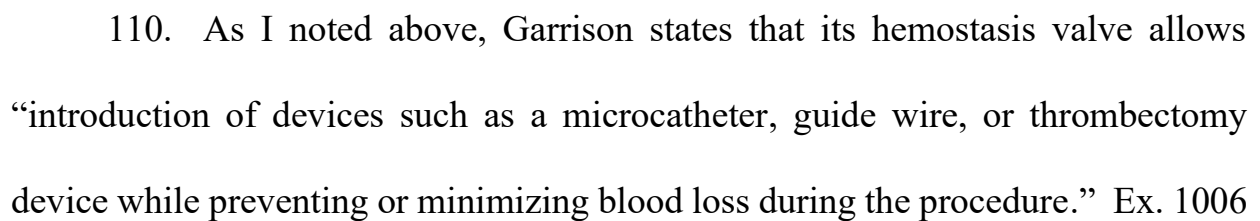
109. A person of ordinary skill in the art would have understood that catheter 2030's hemostasis valve is located at the end of the proximal hub/adaptor as in Figure 3 at least because that is the location where a user would insert other devices through the hub and where sealing would be necessary:



Id. As shown above, the second fluid path is “at least partially different than the first fluid path” at least because the second fluid path extends through the proximal



Ex. 1001 ('669 Patent) at Fig. 1A.

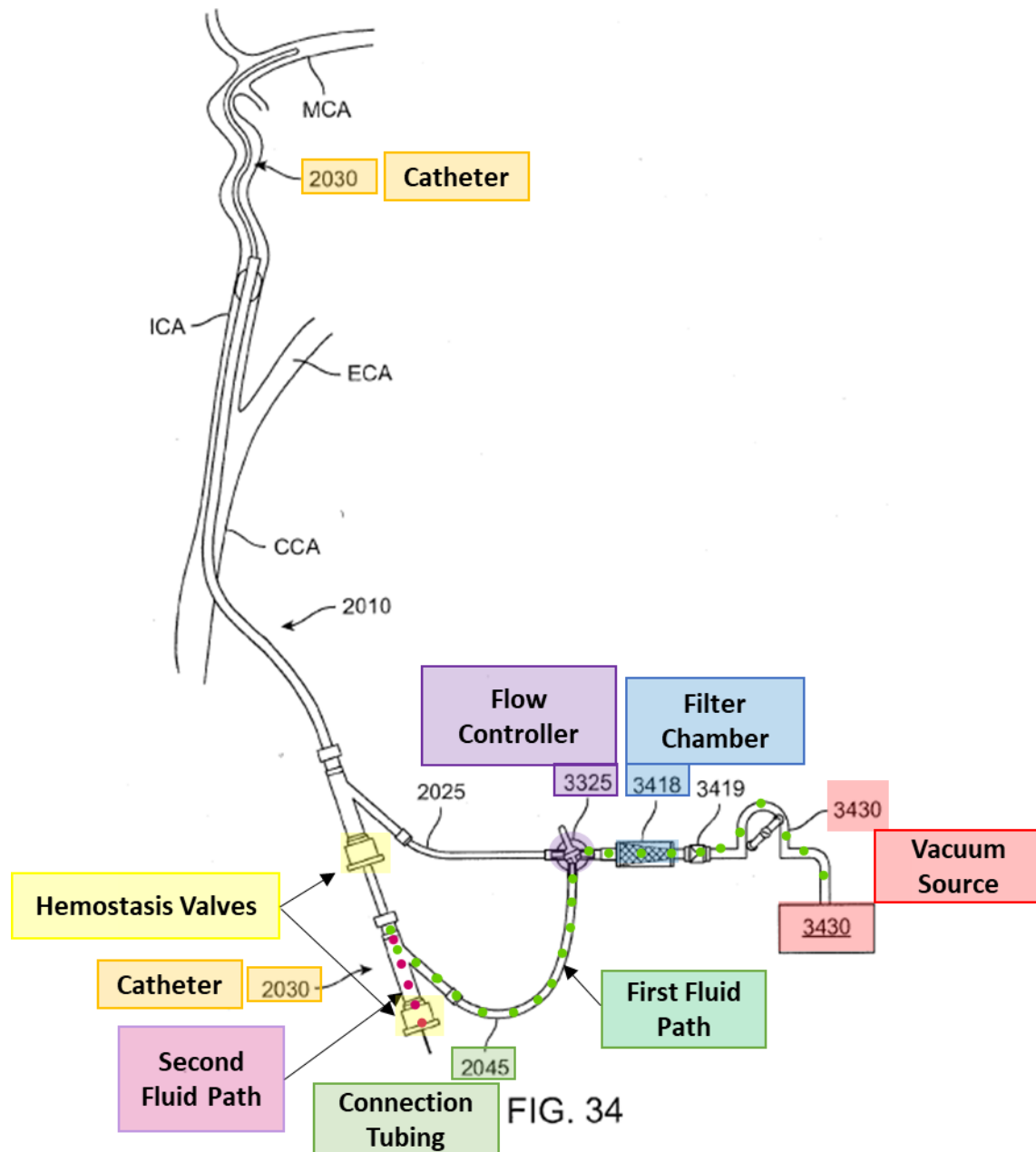


(Garrison) at [0098]. Given this disclosure, a person of ordinary skill in the art would have understood that Garrison’s hemostasis valve is “configured to maintain hemostasis by inhibiting proximal fluid flow along the second fluid path when an interventional device [e.g., microcatheter, guide wire, or thrombectomy device] is inserted through the hemostasis valve and the catheter” as recited in Claim 1.

B. Claim 2 – “the flow controller comprises a flow control unit between the filter chamber and the catheter”

111. Claim 2 recites: “The aspiration system of claim 1 wherein the flow controller comprises a flow control unit between the filter chamber and the catheter.” Garrison anticipates or renders Claim 2 obvious.

112. As I explained previously for Claim 1, Garrison’s aspiration system includes a valve 3325 (i.e., a flow controller) [purple] that is placed along the first fluid path between the filter 3418 (blue) and the aspiration catheter 2030 [orange]:



Ex. 1006 (Garrison) at Fig. 34, [0131]-[0134]. Garrison discloses that valve 3325 could be a stopcock or “flow controller with a simple actuation.” *Id.* at [0132]-[0133], Fig. 35. Garrison explains that the stopcock/flow controller “controls which device is connected to the aspiration source 3430.” *Id.* at [0132]. The stopcock and

flow controller are therefore “flow control units” because they control which, if any, of the catheters are fluidly connected to the aspiration source.

C. Claim 3 – “the flow control unit comprises a user-actuable valve”

113. Claim 3 recites: “The aspiration system of claim 2 wherein the flow control unit comprises a user-actuable valve.” Garrison anticipates or renders Claim 3 obvious.

114. Garrison states that the valve 3325 (i.e., the flow controller) “may be a 3-way or 4-way stopcock.” Ex. 1006 (Garrison) at [0132]. Garrison’s stopcock valve includes a lever that is rotated by the user to change the orientation of the valve and couple or decouple the pressure source from the catheters:

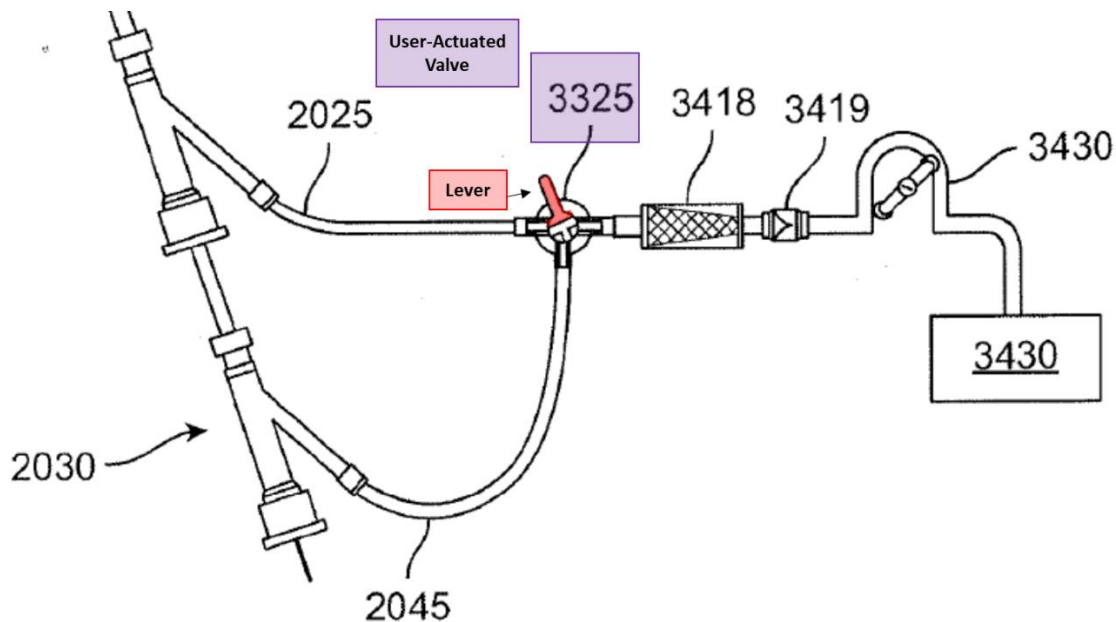


FIG. 34

Id. at Fig. 34. Garrison's stopcock valve is therefore a "user-actuable valve" as recited in Claim 3.

115. Garrison discloses that its flow controller, identified by reference number 3400, "may include one or more control interfaces that a user may actuate to regulate which device is being aspirated," which is illustrated in Figure 35:

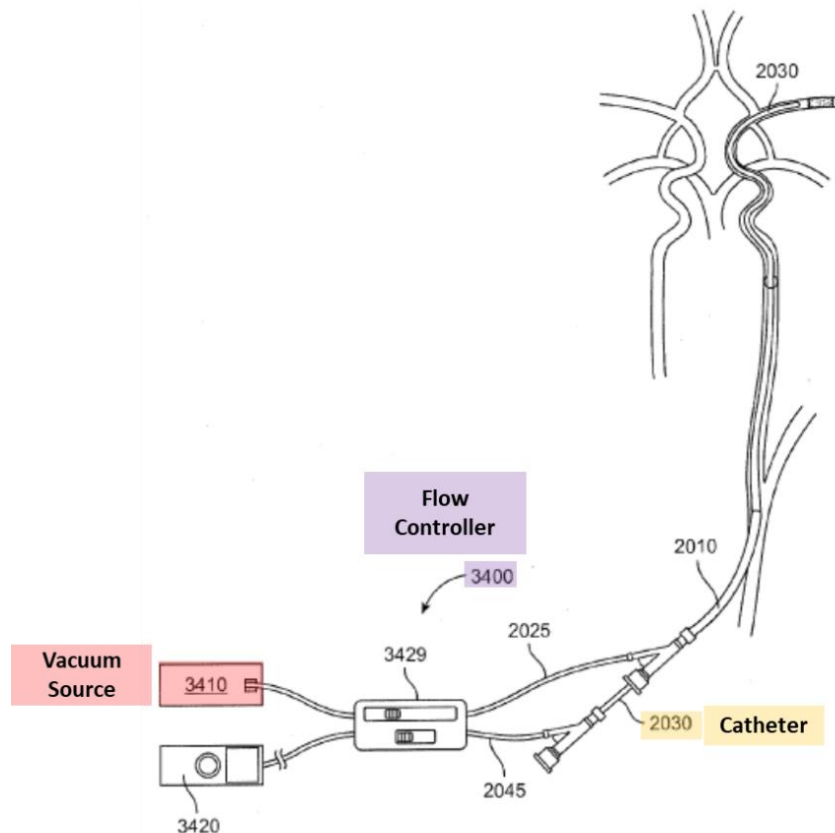


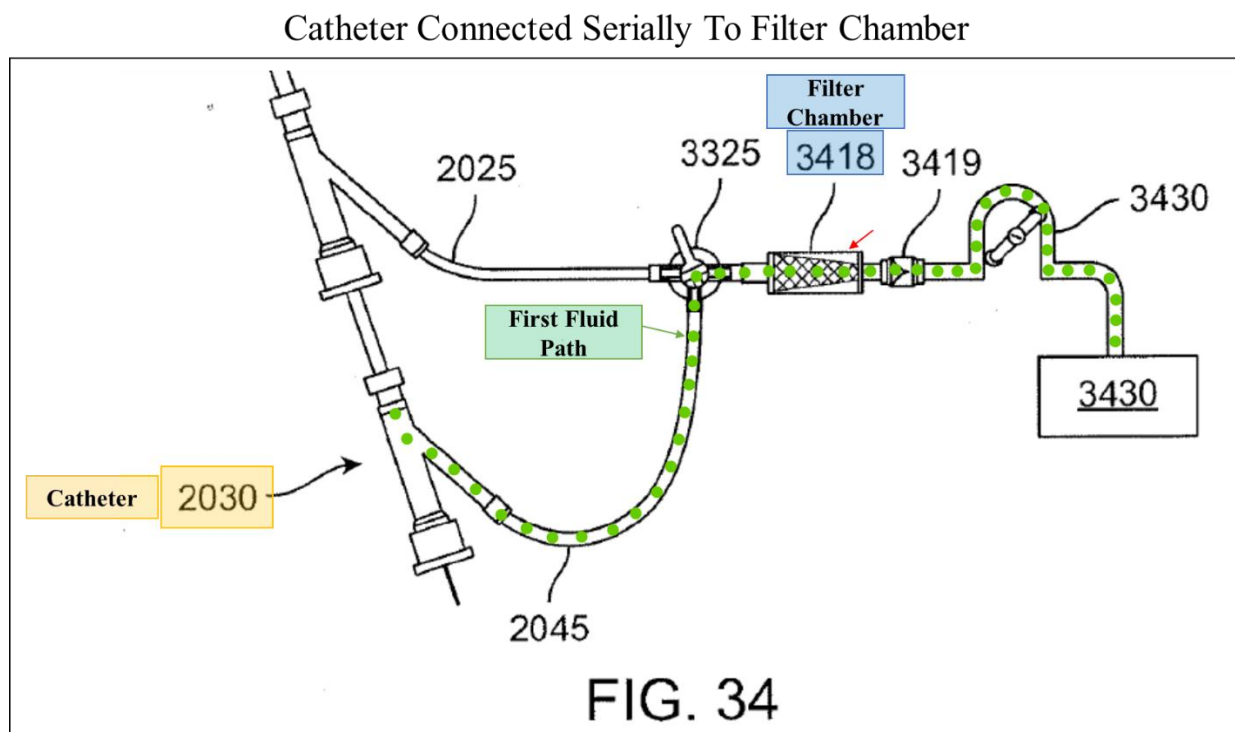
FIG. 35

Id. at [0133], Fig. 35. Accordingly, the flow controller is also a "user-actuable valve" as recited in claim 3.

D. Claim 4 – “the catheter is fluidically connected in serial to the filter chamber along the first fluid path”

116. Claim 4 recites: “The aspiration system of claim 1 wherein the catheter is fluidically connected in serial to the filter chamber along the first fluid path.” Garrison anticipates or renders Claim 4 obvious.

117. As shown in Figure 34, Garrison’s aspiration catheter 2030 is fluidly connected in serial to the filter 3418 (i.e., the filter chamber) along the first fluid path:



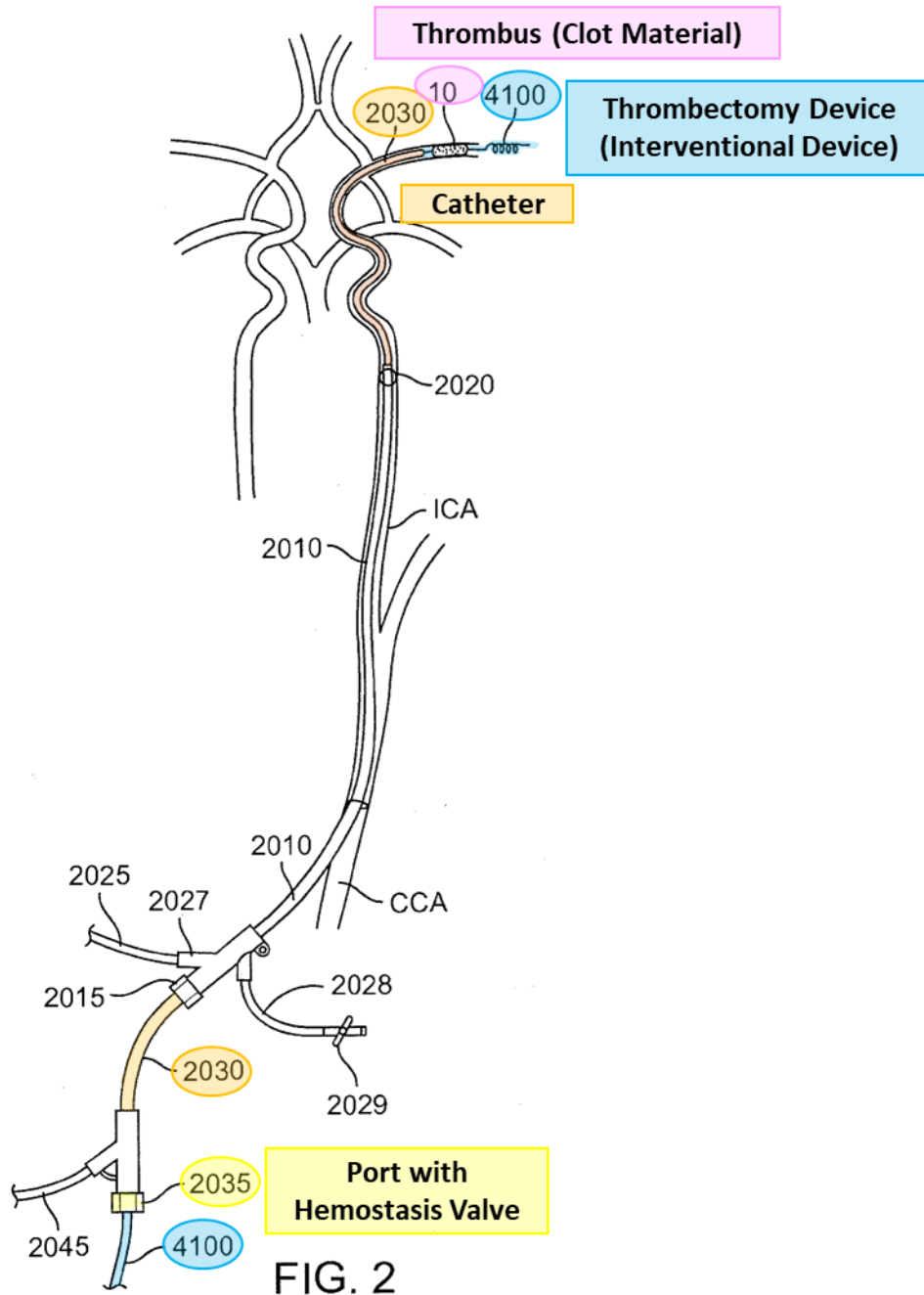
Ex. 1006 (Garrison) at [0130]-[0134], Fig. 34 (excerpt).

E. Claim 5 – “further comprising the interventional device”

118. Claim 5 recites: “The aspiration system of claim 1, further comprising the interventional device.” Garrison anticipates or renders Claim 5 obvious.

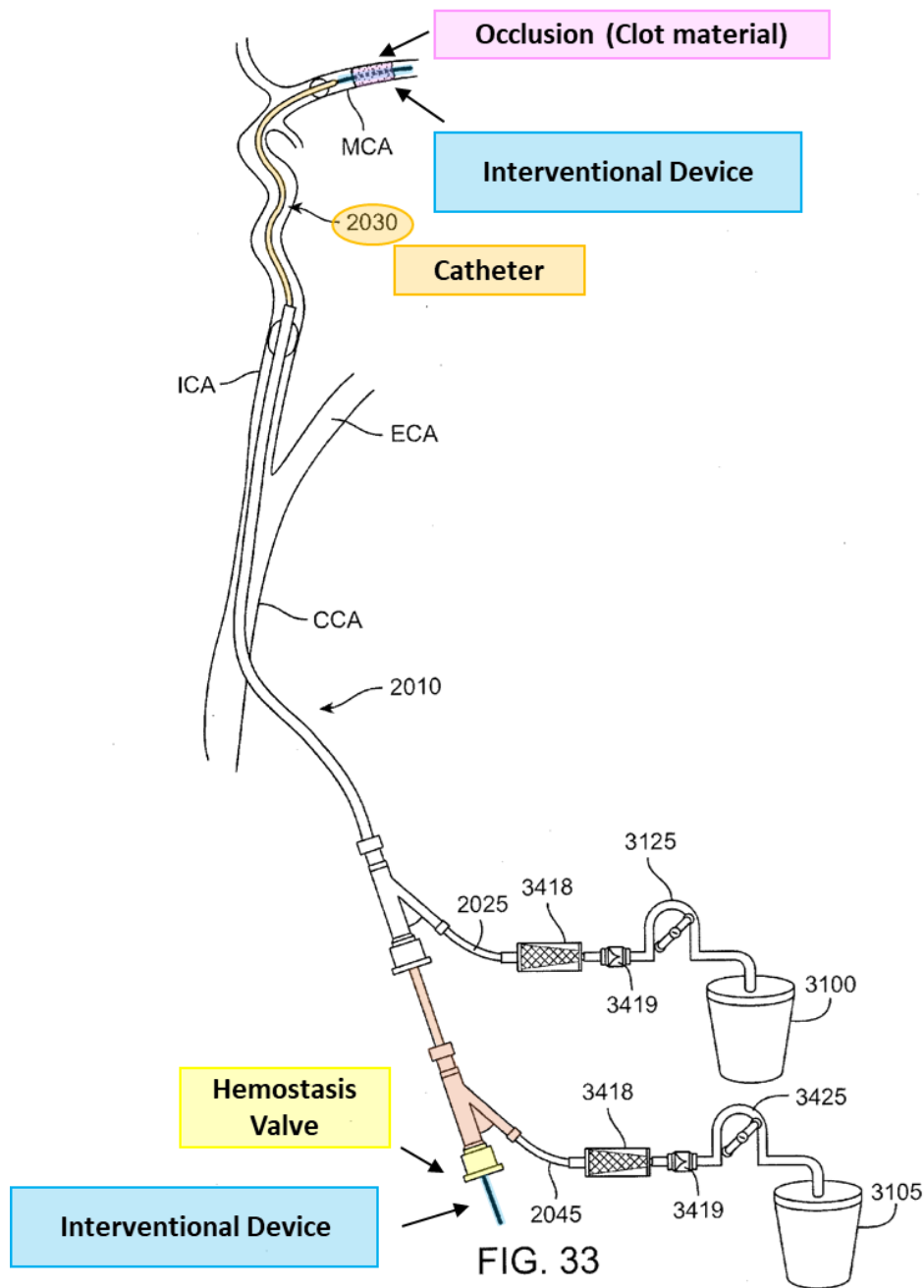
119. Garrison discloses that its catheter 2030 may “provide distal access for additional devices ... at a location distal of the distal-most end of the arterial access device 2010.” Ex. 1006 (Garrison) at [0054]. Garrison also discloses that catheter 2030’s proximal hub 2065 may “allow introduction of 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].

120. As shown in Fig. 2, Garrison illustrates a thrombectomy device 4100 (interventional device) [blue] advanced distally through the hemostasis valve [yellow] of catheter 2030 [orange] to engage the thrombus 10 (clot material) [pink] in a blood vessel:



Id. at [0056], Fig. 2.

121. Garrison's Figure 33 also illustrates an interventional device [blue] advanced distally through the hemostasis valve [yellow] of the catheter 2030 [orange] so the distal end is near the clot material [pink]:



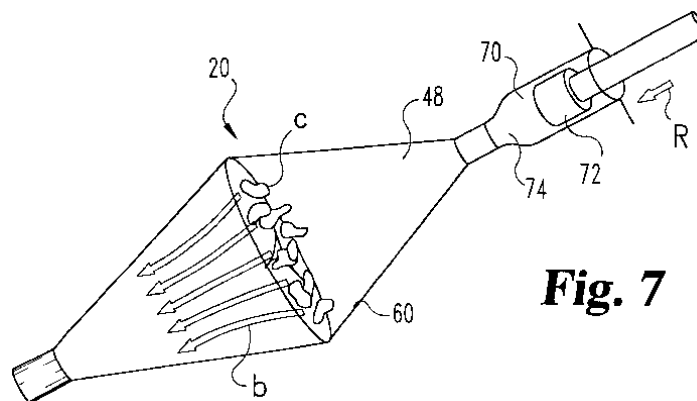
Ex. 1006 (Garrison) at Fig. 33; [0131], [0050]-[0051]; *see also e.g., id.* at Fig. 2.

F. Claim 8 – “the filter is removable from within the housing”

122. Claim 8 recites: “The aspiration system of claim 1 wherein the filter is removable from within the housing.” Garrison renders Claim 8 obvious.

123. As I explained for Claim 1 previously, Garrison discloses a filter 3418 that includes a housing and a filter within the housing for removing unwanted material from the blood. Ex. 1006 (Garrison) at [0131], Fig. 34. Garrison does not expressly state that its filter is **removable** from its filter housing/canister. However, in my opinion, a person of ordinary skill in the art in January 2018 would have found it obvious to include a removable filter in Garrison's system. A person of ordinary skill in the art would have been motivated to include a removable filter in Garrison's system so that the physician could retrieve samples, empty the housing, and clean or replace the filter.

124. Even if Garrison's filter housing was not already openable, filter housings/canisters that could be unscrewed (Figure 8) or unclamped (Figure 9) were well known, as illustrated in Figures 7-9 of the Tretola reference below:



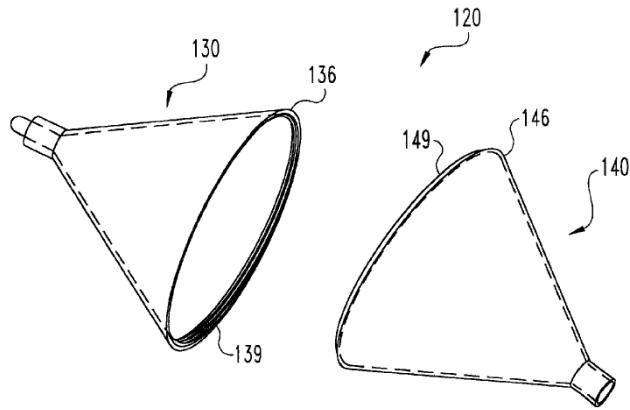


Fig. 8

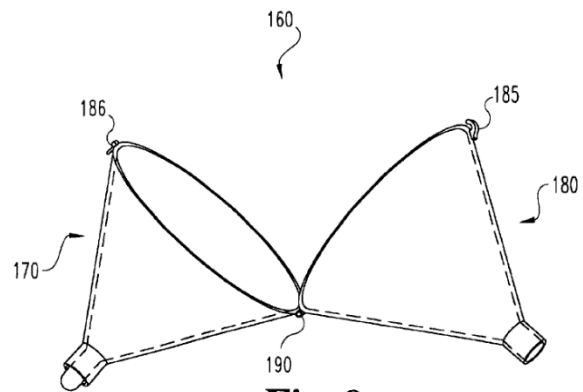


Fig. 9

Ex. 1012 (Tretola) at 5:65-6:28, Figs. 7-9. A person of ordinary skill in the art would have recognized that the parts needed to create a removable filter that could be used in Garrison would have been simple and predictable mechanical parts such as hinges, clips, interlocking tabs, or screw threads. These types of simple and predictable parts would have been well understood by a person of ordinary skill in the art in January 2018. Thus, a person of ordinary skill in the art would have reasonably expected success in designing Garrison to have a removable filter. Further, a person of ordinary skill in the art had only two options for the filter in an aspiration system – a removable filter or a fixed filter. A person of ordinary skill in the art would have found it obvious to use either finite, predictable option with a reasonable expectation of success.

G. **Claim 10 – “the filter encloses a region within the housing, wherein the fluid connector is proximal to the enclosed region along the first fluid path, and wherein the filter includes a plurality of pores sized to inhibit clot material from flowing therethrough and to permit blood to flow therethrough”**

125. Claim 10 recites: “The aspiration system of claim 1 wherein the filter encloses a region within the housing, wherein the fluid connector is proximal to the enclosed region along the first fluid path, and wherein the filter includes a plurality of pores sized to inhibit clot material from flowing therethrough and to permit blood to flow therethrough.” Garrison anticipates or renders Claim 10 obvious.

126. As illustrated in Figure 34 below, the filter in Garrison’s filter 3418 encloses a region within the filter housing and includes a plurality of pores:

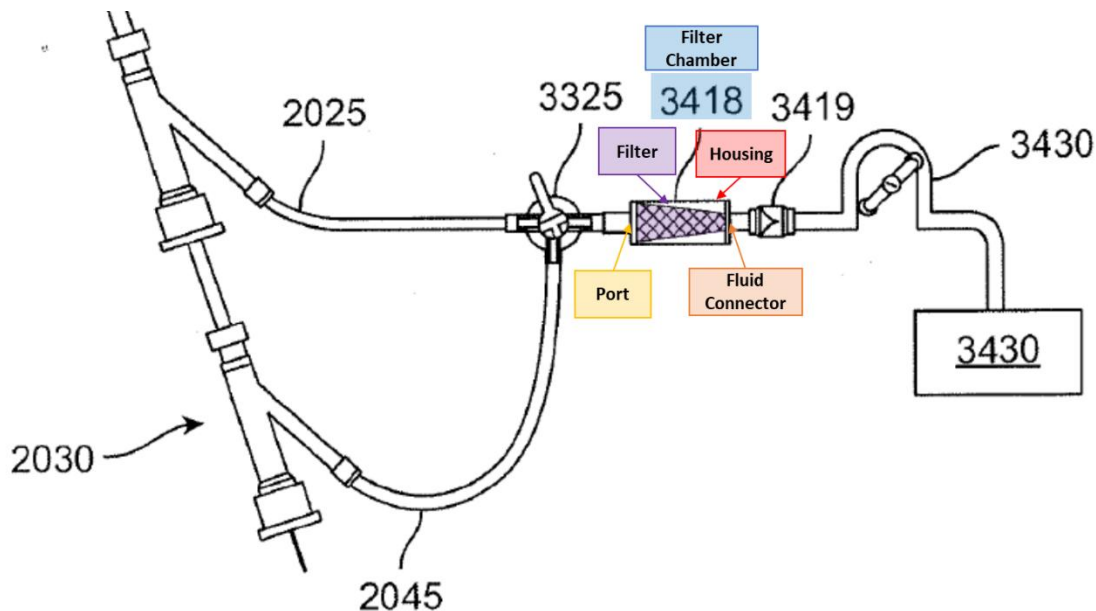


FIG. 34

Ex. 1006 (Garrison) at Fig. 34. As shown in Figure 34 above, Garrison’s filter 3418 also includes a fluid connector that is located proximal to the enclosed region

formed by the filter. *Id.* As I explained for Claim 1, the fluid connector fluidly couples the filter 3418 to the vacuum source 3430. *Supra* §VI.A.4.c.

127. A person of ordinary skill in the art would have understood that the purpose of the pores illustrated in Garrison’s filter is to “inhibit clot material from flowing therethrough and to permit blood to flow therethrough.” The filter must do so to filter the clot material from the aspirated blood, which is the entire purpose of the filter. If the pores did not inhibit clot material from passing through, then the filter would be inoperable for its intended purpose. Similarly, if the pores did not allow aspirated blood to pass through, then the filter would quickly clog and prevent the suction force generated by the vacuum source to be applied to the aspiration catheter, rendering the entire system inoperable.

128. Even if the Board concludes that Garrison does not disclose a filter with a “plurality of pores sized to inhibit clot material from flowing therethrough and to permit blood to flow therethrough,” it is my opinion that a person of ordinary skill in the art in January 2018 would have found it obvious to use a filter with such pores in Garrison’s system. Aspiration filters with these types of pores were well-known in prior art prior to 2018 for use with blood clot aspiration systems. *See, e.g.,* Ex. 1012 (Treretola) at 5:10-24 (disclosing clot filter with semipermeable membrane that may be “a medical grade mesh material with a pore size between about 0.01 mm and about 1.0 mm”); Ex. 1034 (Laub) at [0024], [0039]-[0040]

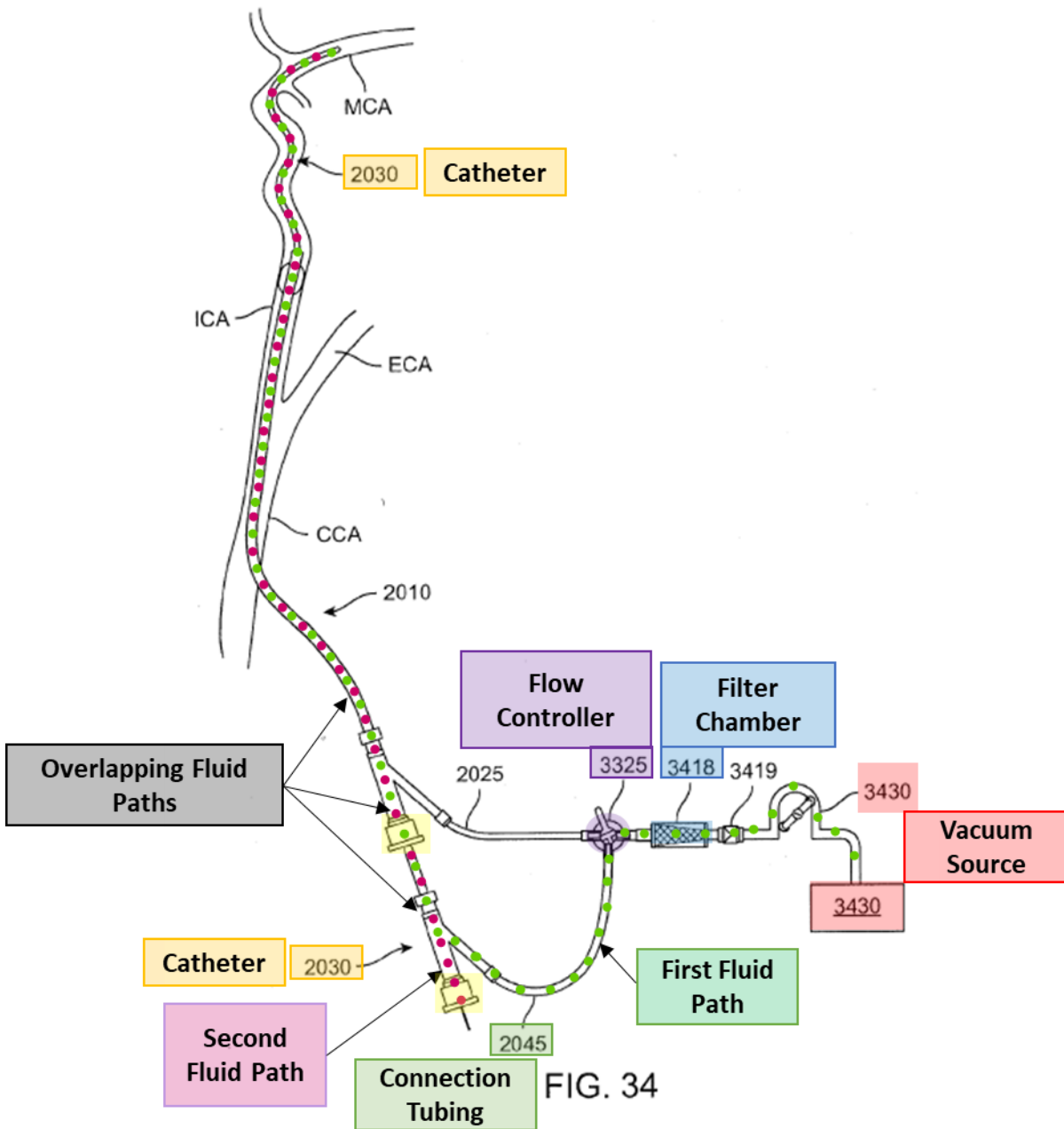
(disclosing an aspiration system with a filter having a “screen, mesh, membrane, etc., that is configured to allow blood or other fluid to flow through while preventing passage of the solid materials”); Ex. 1035 (Aklog) 11:24-53 (disclosing an aspiration system with a filter having a permeable sheet that “may include a plurality of pores sufficiently sized, so as to permit fluid from the site of interest to flow therethrough, while preventing any undesirable material captured from the site of interest from moving downstream”). The parts needed to create such a filter (e.g., a screen, mesh, membrane, or permeable sheet) were simple and predictable and would have been well understood and readily available to a person of ordinary skill in the art at the time. Thus, a person of ordinary skill in the art would have reasonably expected success in designing Garrison’s filter to have pores “sized to inhibit clot material from flowing therethrough and to permit blood to flow therethrough.”

H. Claim 11 – “a distal portion of the first fluid path and a distal portion of the second fluid path overlap”

129. Claim 11 recites: “The aspiration system of claim 1 wherein a distal portion of the first fluid path and a distal portion of the second fluid path overlap.” Garrison anticipates or renders Claim 11 obvious.

130. In Figure 34 of Garrison, a distal portion of the first fluid path [green dots] overlaps with a distal portion of the second fluid path [magenta dots],

beginning at the y-connector of the catheter hub and extending to the distal tip of the aspiration catheter:



Ex. 1001 ('669 Patent) at Fig. 1A.

131. Claim 14 recites: “The aspiration system of claim 1 wherein the vacuum source comprises a vacuum chamber, wherein the connection tubing is fluidically coupled to the vacuum chamber, and wherein the catheter is fluidically



coupled to the vacuum chamber via the filter chamber along the first fluid path.”

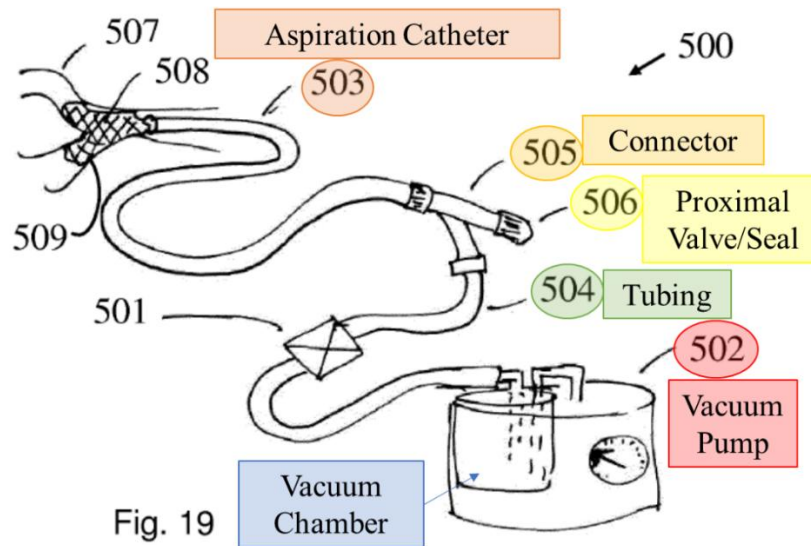
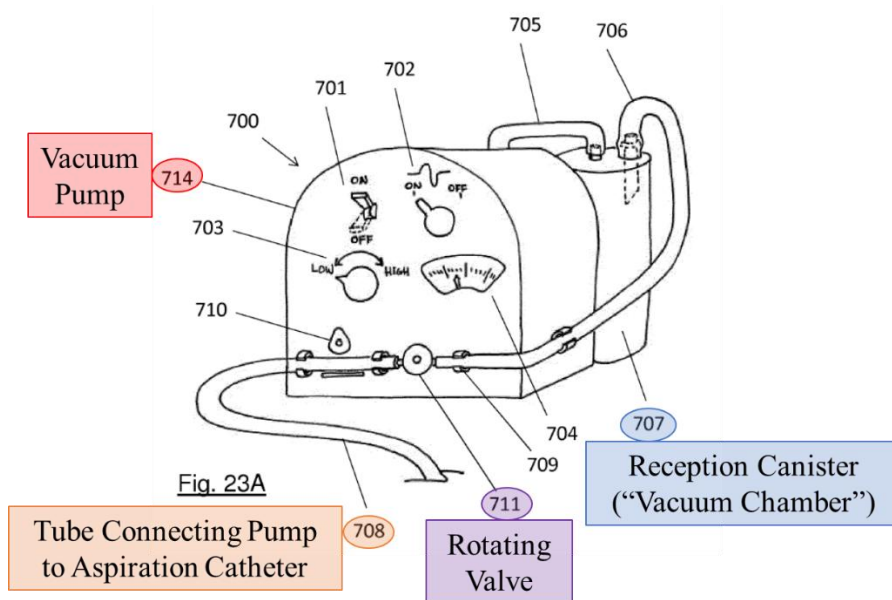
Garrison anticipates or renders Claim 14 obvious.

132. Garrison states that the aspiration source used with its system “may be an aspiration pump, a regular or locking syringe, a hand-held aspirator, hospital suction, or the like.” Ex. 1006 (Garrison) at [0134]; *see also id.*, [0071]-[0072], [0131]. In Garrison’s embodiments that use a syringe as the aspiration source, the chamber of the syringe is a “vacuum chamber” at least because vacuum pressure is generated in the syringe chamber as the plunger is withdrawn. In fact, the only example of a “pressure source”¹ that is disclosed in the ’669 patent is a syringe. Ex. 1001 (’669 patent) at 6:1-7, 15:33-36, 15:40-42, 20:50-53, 20:57-60, 21:28-33. A person of ordinary skill in the art would therefore conclude that a “vacuum chamber” must at least encompass the chamber of a syringe. If it did not, Claim 14 would not cover any of the embodiments or examples disclosed in the ’669 patent.

133. In Garrison’s embodiments where the aspiration source is an aspiration pump, a person of ordinary skill in the art would have understood that the aspiration

¹ Although the claims of the ’669 patent recite that the system includes a “vacuum source,” the specification does not use the term “vacuum source” to describe any of the components. Instead, the specification refers to a “pressure source.” Ex. 1001 (’669 patent) at 6:1-7.

pump would include a chamber in which vacuum pressure is generated for being applied to the aspiration catheter, as was well known in the prior art in 2018. For example, as I discussed previously for claim 1, Brady discloses an aspiration pump for use in thrombectomy procedures that generates vacuum in a reception canister, which is then applied to an aspiration catheter via tubing:

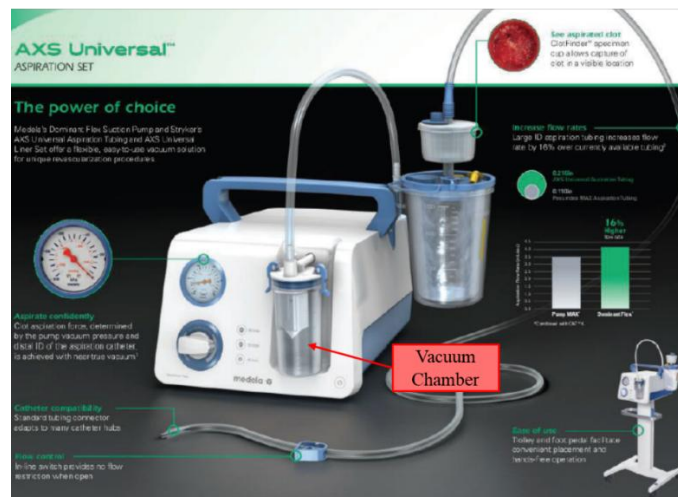


Ex. 1010 (Brady) at 1:13-17, 20:19-29, 21:16-32, Figs. 19, 23A. As I also explained for claim 1, several prior art commercial aspiration pumps used in thrombectomy procedures used a similar configuration with a vacuum chamber, including the Penumbra Max pump and the Medela Dominant Flex pump:

Penumbra Pump



Medela Pump



134. As illustrated in Figure 34 below, Garrison's vacuum source (e.g., syringe) [red] is fluidically coupled to the aspiration catheter 2030 [orange] via the filter 3418 (i.e., filter chamber) [blue] along the first fluid path [green]:



- 81 -

lines 2025 or 2045.” *Id.* at [0130]; *see also id.* at [0132] (“FIG. 34 shows a system whereby both the arterial access device 2010 and catheter 2030 are connected to the same aspiration source 3430 via flow lines 2025 and 2045, respectively.”). A person of ordinary skill in the art would have therefore recognized that Garrison’s vacuum source is fluidically coupled to the first fluid path via the connection tubing that makes up the flow line 2045. *Id.* Accordingly, Garrison’s vacuum chamber (i.e., the chamber on the syringe or aspiration pump) would be fluidically coupled to the connection tubing making up flow line 2045 and the aspiration catheter 2030 via the filter chamber.

J. Claim 15

135. Claim 15 is an independent claim that recites many of the same limitations as independent Claim 1, which I addressed above. The primary difference between Claim 1 and Claim 15 is that Claim 15 recites a “second port” in the filter housing instead of a “fluid connector.” In my opinion, Claim 15 is anticipated or obvious in view of Garrison.

1. Preamble – “An aspiration system”

136. The preamble of Claim 15 recites: “An aspiration system.” If the Board concludes that this preamble is limiting, Garrison discloses an “aspiration system” for the reasons I explained previously for Claim 1. *Supra* §VI.A.1.

2. **“vacuum source”**

137. Claim 15 next recites “a vacuum source.” Garrison discloses this limitation for the reasons I explained previously for Claim 1. *Supra* §VI.A.2.

3. **“a catheter fluidically coupled to the vacuum source via a first fluid path”**

138. Claim 15 next recites “a catheter fluidically coupled to the vacuum source via a first fluid path.” Garrison discloses this limitation for the reasons I explained previously for Claim 1. *Supra* §VI.A.3.

4. **“a filter chamber along the first fluid path and spaced apart from the vacuum source, wherein the filter chamber comprises a housing and a filter within the housing”**

139. Claim 15 next recites “a filter chamber along the first fluid path and spaced apart from the vacuum source, wherein the filter chamber comprises a housing and a filter within the housing.” Garrison discloses this limitation for the reasons I explained previously for Claim 1. *Supra* §VI.A.4.a.

140. Like Claim 1, Claim 15 recites several additional limitations for the “housing” of the filter chamber. As I explain below, Garrison discloses or renders each of these additional limitations obvious.

a. **“a first port configured to be fluidically coupled to the catheter”**

141. Claim 15 recites that the housing includes “a first port configured to be fluidically coupled to the catheter.” Garrison discloses this limitation or renders it obvious for the reasons I explained previously for Claim 1. *Supra* § VI.A.b.

b. “a second port configured to be fluidically coupled to the vacuum source”

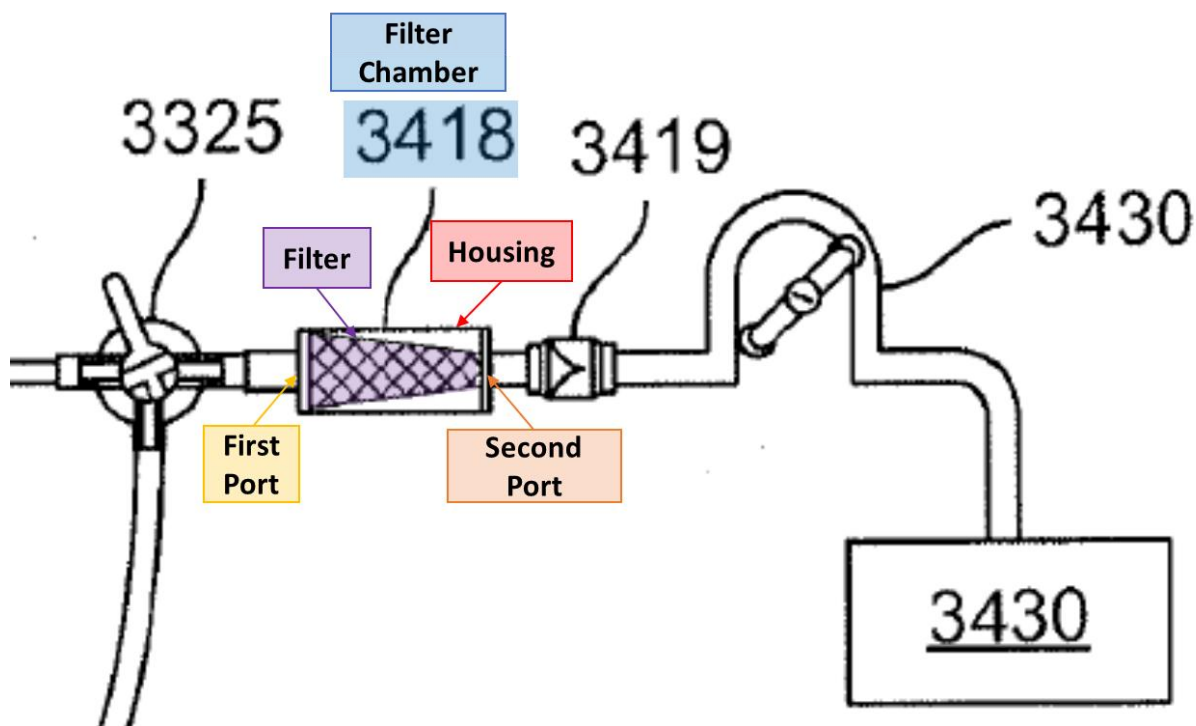
142. Claim 15 recites that the housing includes “a second port configured to be fluidically coupled to the vacuum source.” Garrison discloses this limitation or renders it obvious.

143. As I explained previously for Claim 1, a person of ordinary skill in the art would have understood that the plain and ordinary meaning of “port” in Claim 15 is simply an opening for intake or exhaust of a fluid. *See, e.g.*, Ex. 1014 (Merriam Webster) at 3; Ex. 1043 (Dorland’s). Claim 15 does not specify any features or structure for the “second port” aside from requiring that it is “configured to be fluidically coupled to the vacuum source.” The specification of the ’669 patent similarly lacks any description of specific features or structures for the “port 324” aside from stating that it is “configured to be removably, fluidly coupled to the catheter system 200.” Ex. 1001 (’669 patent) at 9:1-3.

144. As I explained previously for Claim 1, a person of ordinary skill in the art would have recognized that the housing of the filter 3418 would necessarily include a second port (i.e., outlet opening) at its proximal end that is “coupled with the flow line 2045.” Ex. 1006 (Garrison) at [0131]. If the housing did not include such a port, aspirated blood would not be able to flow through filter and out of the filter housing into the flow line, rendering the filter inoperable. In addition, if the filter did not include openings on each end that were configured to fluidly couple

the filter housing to the tubing and vacuum source, then the vacuum pressure generated by the vacuum source would be unable to reach the aspiration catheter, rendering the entire aspiration system inoperable. Therefore, a person of ordinary skill in the art would understand that Garrison necessarily discloses a “second port” in its filter housing.

145. The person of ordinary skill’s understanding of Garrison’s filter is further confirmed by Figure 34, which illustrates that a second port (i.e., outlet opening) fluidly connects the filter to the flow line tubing and vacuum source:



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

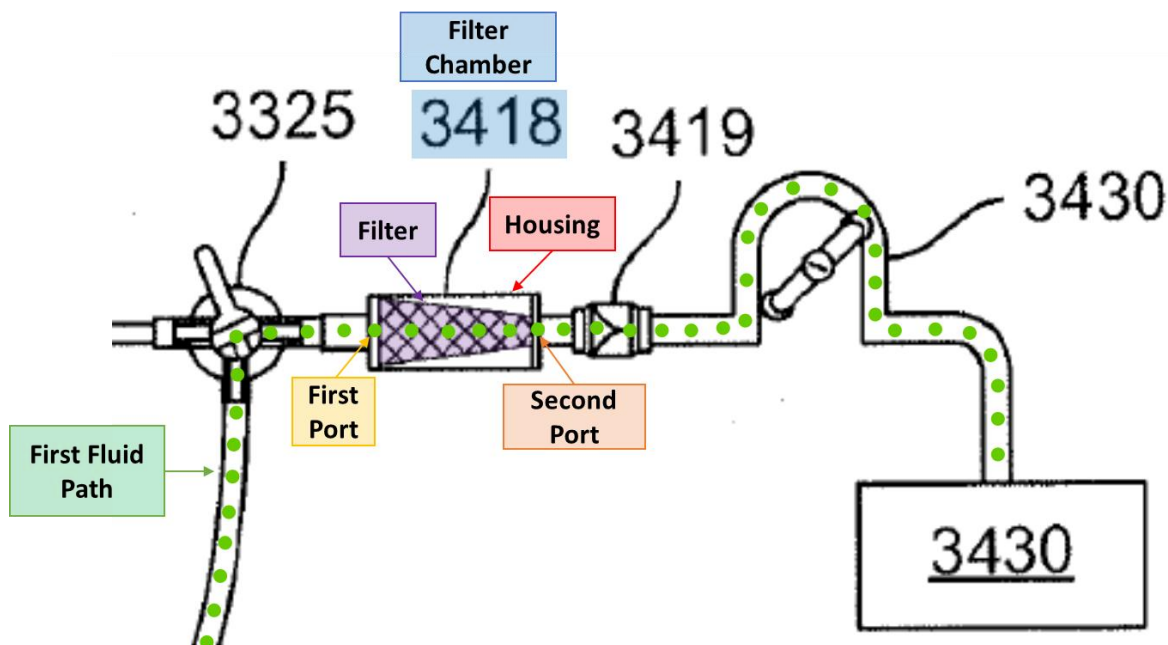
146. Even if the Board concludes that Garrison does not disclose a “second port” in its filter housing, it is my opinion that a person of ordinary skill in the art

in January 2018 would have found it obvious to couple Garrison's filter 3418 to the flow line 2045 using conventional connectors, such a Luer-type (e.g., Luer slip and Luer lock) and barb connectors for the same reasons I explained previously for Claim 1. *Supra* §VI.A.b. A person of ordinary skill in the art would have understood that those conventional connections would include a "second port" when used with the housing of Garrison's filter 3418 for the same reasons I explained above for Claim 1. *Id.*

c. **"the filter is in the housing along the first fluid path between the first port and the second port"**

147. Claim 15 recites that "the filter is in the housing along the first fluid path between the first port and the second port." Garrison discloses this limitation.

148. As shown in Figure 34 below, the filter in Garrison's filter 3418 is "along the first fluid path between the first port and the second port":



Ex. 1006 (Garrison) at [0130]-[0134], Fig. 34.

5. **“a flow controller fluidically coupling the filter chamber to the catheter, wherein the flow controller is along the first fluid path between the filter chamber and the catheter”**

149. Claim 15 next recites “a flow controller fluidically coupling the filter chamber to the catheter, wherein the flow controller is along the first fluid path between the filter chamber and the catheter.” Garrison discloses this limitation for the reasons I explained previously for Claim 1. *Supra* §VI.A.5.

6. **“a hemostasis valve fluidically coupled to the catheter along a second fluid path at least partially different than the first fluid path, wherein the hemostasis valve is configured to maintain hemostasis by inhibiting proximal fluid flow along the second fluid path when an interventional device is inserted through the hemostasis valve and the catheter”**

150. Claim 15 concludes by reciting “a hemostasis valve fluidically coupled to the catheter along a second fluid path at least partially different than the first fluid path, wherein the hemostasis valve is configured to maintain hemostasis by inhibiting proximal fluid flow along the second fluid path when an interventional device is inserted through the hemostasis valve and the catheter.” Garrison discloses this limitation for the reasons I explained previously for Claim 1. *Supra* §VI.A.6.

K. Claim 16 – “the flow controller comprises a flow control unit between the filter chamber and the catheter”

151. Claim 16 recites: “The aspiration system of claim 15 wherein the flow controller comprises a flow control unit between the filter chamber and the catheter.” Garrison anticipates or renders Claim 16 obvious for the same reasons I explained for Claims 2 and 15. *Supra* §§VI.B, VI.J.

L. Claim 17 – “the flow control unit comprises a user-actuable valve”

152. Claim 17 recites: “The aspiration system of claim 16 wherein the flow control unit comprises a user-actuable valve.” Garrison anticipates or renders Claim 17 obvious for the same reasons I explained for Claims 3, 15, and 16. *Supra* §§VI.C, VI.J, VI.K.

M. Claim 18 – “the catheter is fluidically connected in serial to the filter chamber along the first fluid path”

153. Claim 18 recites: “The aspiration system of claim 15 wherein the catheter is fluidically connected in serial to the filter chamber along the first fluid path.” Garrison anticipates or renders Claim 18 obvious for the same reasons I explained for Claims 4 and 15. *Supra* §§VI.D, VI.J.

N. Claim 19 – “further comprising the interventional device”

154. Claim 19 recites: “The aspiration system of claim 15, further comprising the interventional device.” Garrison anticipates or renders Claim 19 obvious for the same reasons I explained for Claims 5 and 15. *Supra* §§VI.E, VI.N.

O. Claim 22 – “the filter is removable from within the housing”

155. Claim 22 recites: “The aspiration system of claim 15 wherein the filter is removable from within the housing.” Garrison renders Claim 22 obvious for the same reasons I explained for Claims 8 and 15. *Supra* §§VI.F, VI.J.

P. Claim 24 – “the filter encloses a region within the housing, wherein the second port is proximal to the enclosed region along the first fluid path, and wherein the filter includes a plurality of pores sized to inhibit clot material from flowing therethrough and to permit blood to flow therethrough”

156. Claim 24 recites: “The aspiration system of claim 15 wherein the filter encloses a region within the housing, wherein the second port is proximal to the enclosed region along the first fluid path, and wherein the filter includes a plurality of pores sized to inhibit clot material from flowing therethrough and to permit blood to flow therethrough.” Garrison anticipates or renders Claim 24 obvious for the same reasons I explained for Claims 10 and 15. *Supra* §§VI.G, VI.J.

Q. Claim 25 – “a distal portion of the first fluid path and a distal portion of the second fluid path overlap”

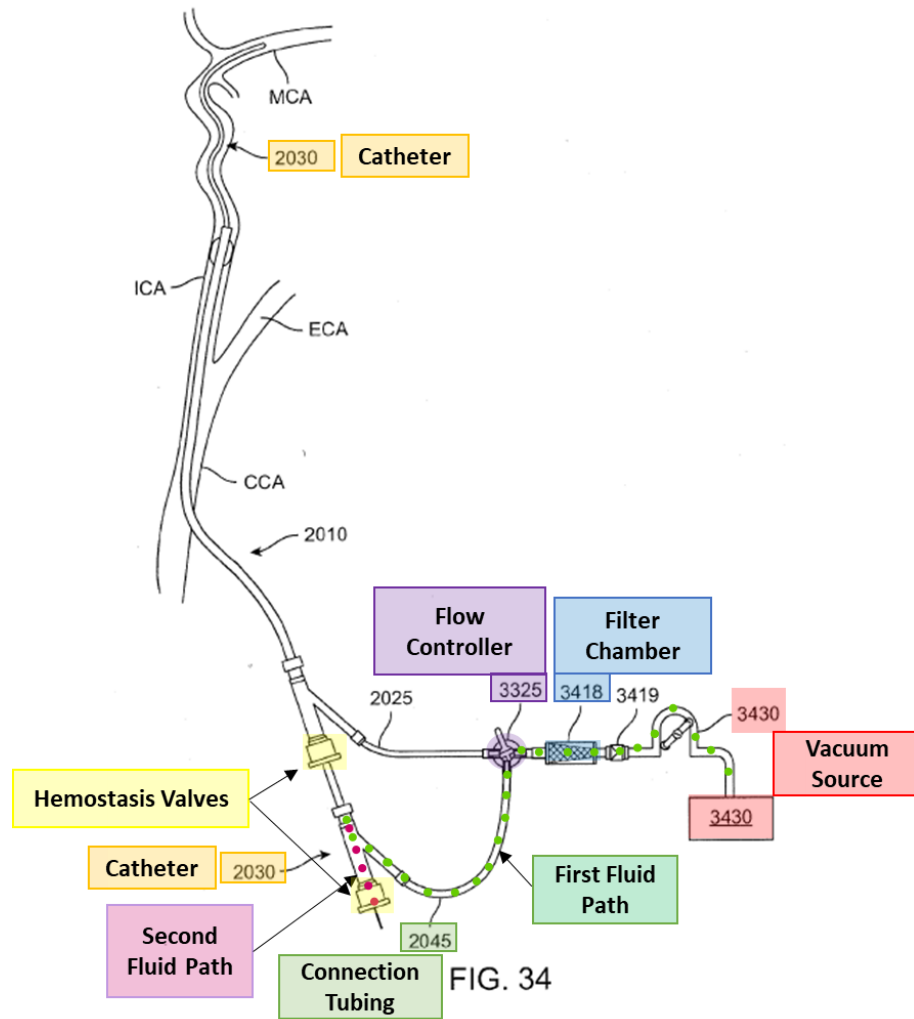
157. Claim 25 recites: “The aspiration system of claim 15 wherein a distal portion of the first fluid path and a distal portion of the second fluid path overlap.” Garrison anticipates or renders Claim 25 obvious for the same reasons I explained for Claims 11 and 15. *Supra* §§VI.H, VI.J.

R. Claim 30 – “the vacuum source comprises a vacuum chamber, and wherein the catheter is fluidically coupled to vacuum chamber via the first fluid path”

158. Claim 30 recites: “The aspiration system of claim 15 wherein the vacuum source comprises a vacuum chamber, and wherein the catheter is fluidically coupled to vacuum chamber via the first fluid path.” Garrison anticipates or renders Claim 25 obvious for the same reasons I explained for Claims 14 and 15. *Supra* §§VI.I, VI.J.

VII. GROUND 3: CLAIMS 1-5, 8, 10-11, 14-19, 22, 24-25, 30 OBVIOUS IN VIEW OF GARRISON AND GOFF

159. As I explained above for Grounds 1-2, Garrison discloses a filter 3418 [blue] that is located along a first fluid path [green dots] between the proximal end of its aspiration catheter 2030 [orange] and the vacuum source [red]:



Ex. 1006 (Garrison) at Fig. 34. Although Garrison illustrates many features of the filter in Figure 34, Garrison does not describe the details of its filter in text, but as I explained above for Grounds 1-2, it is my opinion that a person of ordinary skill in the art would have recognized that Garrison's filter 3418 would necessarily include the generic components recited in the claims of the '669 patent, including the "housing," "port," and "fluid connector." However, even if the Board concludes that Garrison does not disclose or render the claimed filter obvious, Goff discloses

a prior art thrombectomy filter having each of the recited limitations for the “filter chamber” recited in the challenged claims of the ’669 patent.

160. As I explain further below, it is my opinion that a person of ordinary skill in the art in January 2018 would have been motivated to use Goff’s thrombectomy filter in Garrison’s aspiration system and would have reasonably expected success in doing so. It is therefore my opinion that Claims 1-5, 8, 10-11, 14-19, 22, 24-25, and 30 of the ’669 patent would have been obvious in view of Garrison combined with Goff.

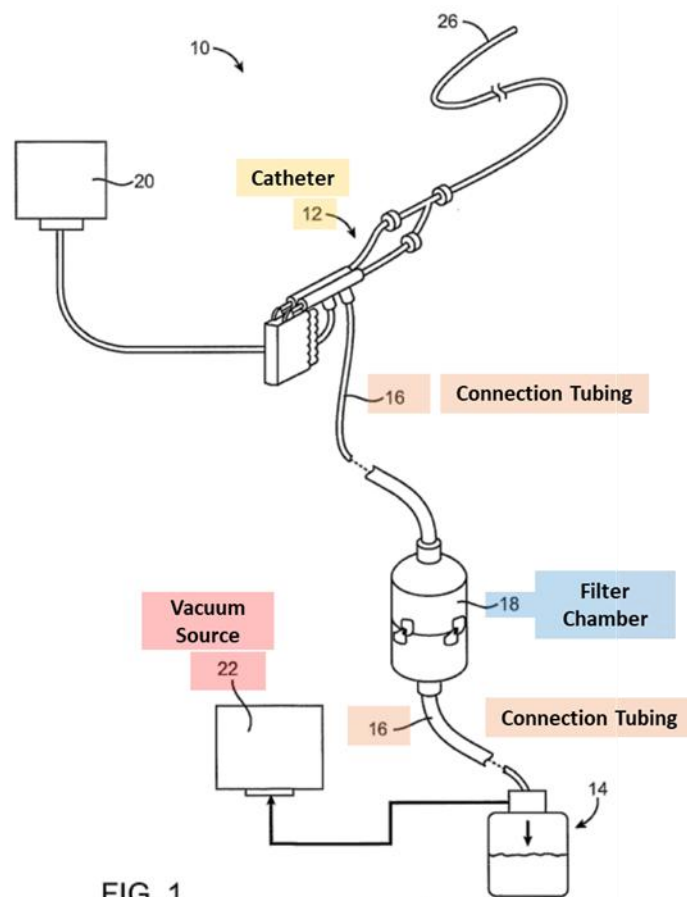
A. Claims 1-5, 11, 14

1. **“a filter chamber fluidically coupled to the connection tubing at a location apart from the vacuum source, wherein the filter chamber comprises a housing and a filter within the housing, and wherein the housing includes—a includes a port configured to be fluidically coupled to the catheter; and a fluid connector configured to be fluidically coupled to the connection tubing; and wherein the filter is in the housing along a first fluid path, wherein the first fluid path fluidically couples the port and the fluid connector, and wherein the catheter is fluidically coupled to the vacuum source via the filter chamber along the first fluid path”**

161. Claim 1 recites “a filter chamber fluidically coupled to the connection tubing at a location apart from the vacuum source, wherein the filter chamber comprises a housing and a filter within the housing, and wherein the housing includes—a includes a port configured to be fluidically coupled to the catheter; and a fluid connector configured to be fluidically coupled to the connection tubing; and wherein the filter is in the housing along a first fluid path, wherein the first fluid

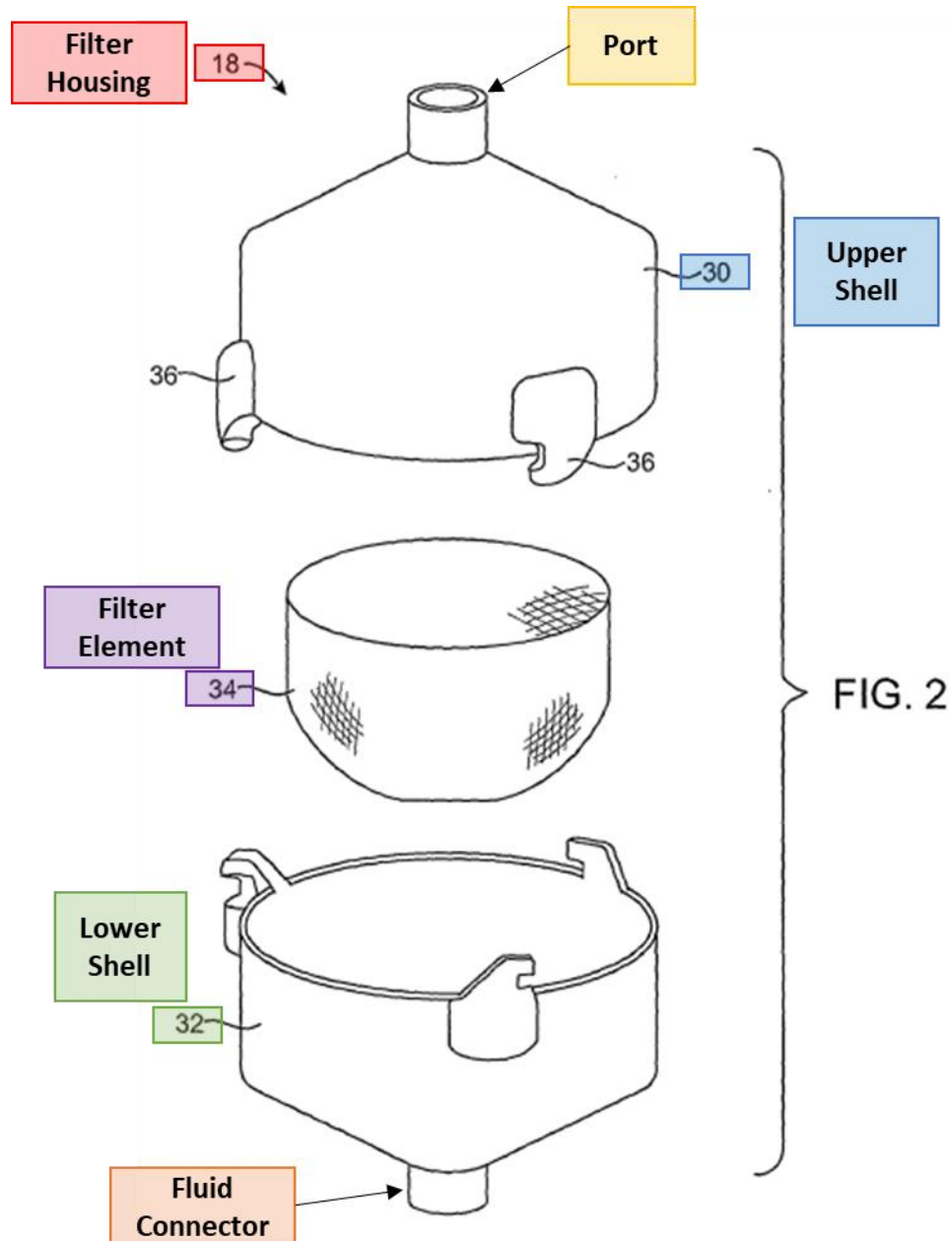
path fluidically couples the port and the fluid connector, and wherein the catheter is fluidically coupled to the vacuum source via the filter chamber along the first fluid path.” Goff discloses the “filter chamber” limitations recited in Claim 1 of the ’669 patent.

162. Goff is titled “methods and systems for filtering aspirated materials.” Ex. 1005 (Goff) at Title. Goff discloses that its aspiration system includes a “filter housing 18” that is coupled between an aspiration catheter 12 and a vacuum source 22 along a fluid path using connection tubing 16:



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

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



Id. at [0025], Fig. 2. Goff also explains that “the filter housing has an upper shell and a lower shell which may be taken apart to permit introduction, removal, and

replacement of the filter element in the interior of the housing.” *Id.* at [0015]. Goff discloses that its filter forms a structure allowing “the separated solid materials [to] be in a convenient structure or assembly to permit easy removal and observation.” *Id.* at [0005].

164. Goff explains that its filter “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]. A person of ordinary skill in the art would have understood that the connector at the upper end of Goff’s filter housing is a “port” (i.e., opening) as recited in Claim 1, and that the connector at the lower end of Goff’s filter housing is a “fluid connector” (i.e., outlet opening) as recited in Claim 1. These connectors are also illustrated in Figure 2 of Goff above. *Id.* at Fig. 2.

165. It is my opinion that a person of ordinary skill in the art would have been motivated to substitute Goff’s filter assembly for the filter 3418 in Garrison. Goff’s filter is used for the same purpose as the filter in Garrison – filtering clots from aspirated blood. *Id.* at [0001]. Goff’s filter is also positioned between the aspiration catheter and the vacuum source with standard medical tubing, like the filter Garrison. *Id.* at [0025]. Thus, substituting Goff’s filter for Garrison’s filter would have merely entailed the substitution of one known element (Goff’s filter) for another (Garrison’s filter) to yield the predictable result of filtering aspirated

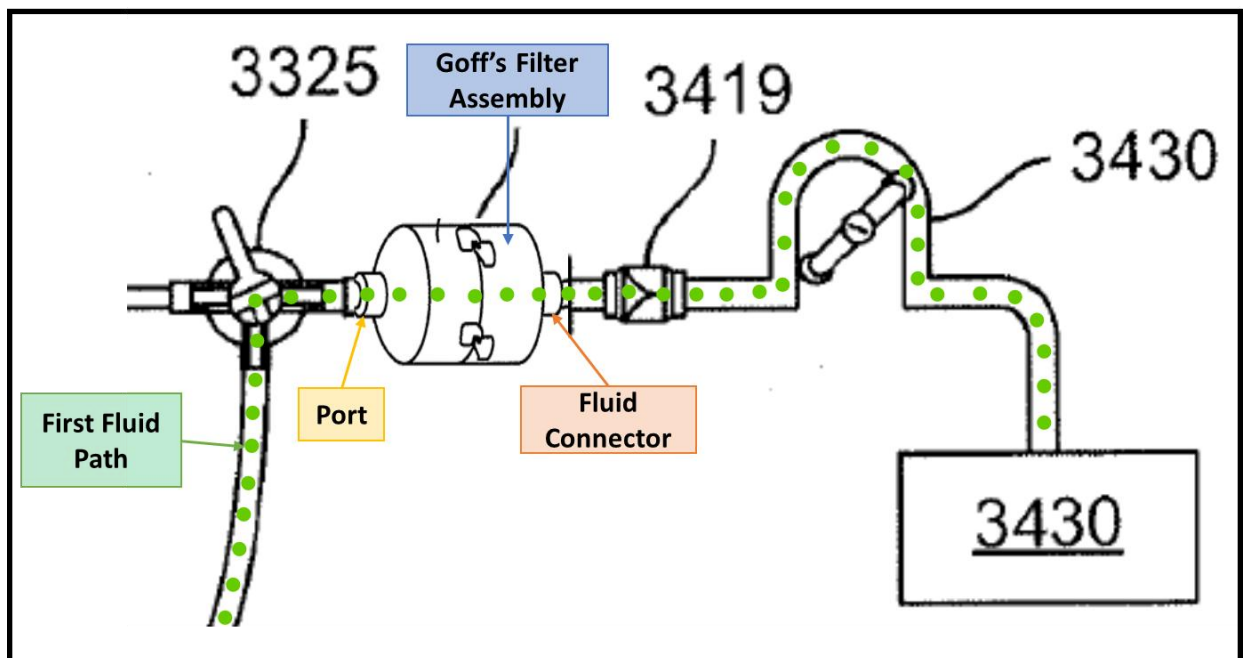
blood. In addition, Goff's disclosure that its filter assembly "permit[s] introduction, removal, and replacement of the filter element in the interior of the housing" and provides "a convenient structure or assembly to permit easy removal and observation" of aspirated clot material would have further motivated a person of ordinary skill in the art to use Goff's filter in Garrison's aspiration system. *Id.* at [0005], [0015].

166. The similarities between the filters in Goff and Garrison would have given a person of ordinary skill in the art a reasonable expectation of success that Goff's filter could be incorporated into Garrison's aspiration system. For example, Goff discloses that its "filter element will have a pore size or screen size selected to separate solid particles at a desired particle size cutoff," the same requirement for Garrison's filter (or any aspiration filter). *Id.* at [0011]. In addition, Goff's filter is fluidly coupled between an aspiration catheter and a vacuum source using conventional connectors and medical tubing, just like the arrangement for Garrison's filter. *Id.* at [0015], [0023]-[0025], Fig. 1; Ex. 1006 (Garrison) at Fig. 34. A person of ordinary skill in the art in January 2018 would have been familiar with these conventional, predictable components and would have reasonably expected success in using them to couple Goff's filter to Garrison's flow line 2045.

167. As I've illustrated in the demonstrative below, which provides and exemplary diagram for incorporating Goff's filter into Garrison's system, a person

of ordinary skill in the art would have understood that when Garrison's filter is substituted for Goff's filter assembly, Garrison's vacuum source would be fluidly coupled to the aspiration catheter along the first fluid path via Goff's filter assembly:

Garrison + Goff



As illustrated above, Goff's filter element would also be within the housing along the first fluid path of Garrison's aspiration system. The first fluid path would also run through and fluidly connect the port and fluid connector that are on opposing ends of the Goff's filter.

2. Remaining Limitations

168. Garrison discloses the remaining limitations recited in Claims 1-5, 11, and 14 of the '669 patent for the reasons I explained previously for Grounds 1-2.

Supra §§VI.A-E, VI.H-I. Therefore, it is my opinion that Garrison in combination with Goff renders Claims 1-5, 11, and 14 obvious.

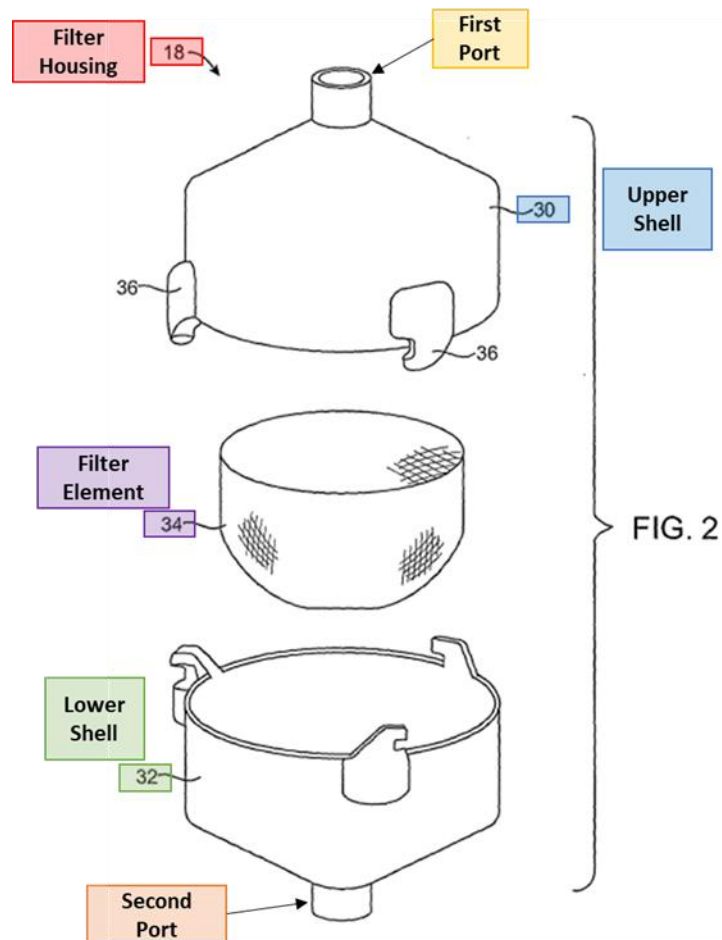
B. Claims 15-19, 25, 30

1. **“a filter chamber along the first fluid path and spaced apart from the vacuum source, wherein the filter chamber comprises a housing and a filter within the housing, and wherein the housing includes— a first port configured to be fluidically coupled to the catheter; and a second port configured to be fluidically coupled to the vacuum source; and wherein the filter is in the housing along the first fluid path between the first port and the second port”**

169. Claim 15 recites: “a filter chamber along the first fluid path and spaced apart from the vacuum source, wherein the filter chamber comprises a housing and a filter within the housing, and wherein the housing includes— a first port configured to be fluidically coupled to the catheter; and a second port configured to be fluidically coupled to the vacuum source; and wherein the filter is in the housing along the first fluid path between the first port and the second port.” Goff discloses the “filter chamber” limitations recited in Claim 15.

170. As I explained previously, Goff discloses that its filter “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.” Ex. 1005 (Goff) at [0015]. A person of ordinary skill in the art would have understood that the connector at the upper end of Goff’s filter housing is a “first port” (i.e., inlet opening) as recited in Claim 15, and that the connector at the lower end of Goff’s

filter housing is a “second port” (i.e., outlet opening) as recited in Claim 15. These connectors (i.e., ports) are also illustrated in Figure 2 of Goff below:



Id. at Fig. 2.

171. Goff discloses all of the remaining limitations for the “filter chamber” (a housing, a filter within the housing along the first fluid path) for the same reasons I explained previously for Claim 1. *Supra* §VII.A.1. A person of ordinary skill in the art would have been motivated to substitute Garrison’s filter for Goff’s filter assembly and would have reasonably expected success in doing so for the same reasons I explained previously for Claim 1. *Supra* §VII.A.1.

2. Remaining Limitations

172. Garrison discloses the remaining limitations recited in Claims 15-19, 25, and 30 of the '669 patent for the reasons I explained previously for Grounds 1-2. *Supra* §§VI.J-N, VI.Q-R. Therefore, it is my opinion that Garrison in combination with Goff renders Claims 15-19, 25, and 30 obvious.

C. Claims 8 and 22 – “the filter is removable from within the housing”

173. Claims 8 and 22 recite that “the filter is removable from within the housing.” Goff discloses this limitation.

174. Goff states that the upper shell and lower shell of its filter housing “may be taken apart to permit introduction, removal, and replacement of the filter element in the interior of the housing.” Ex. 1005 (Goff) at [0015]. A person of ordinary skill in the art would have been motivated to include a removable filter like Goff’s in Garrison’s system so that the physician could retrieve samples, empty the housing, and clean or replace the filter. Accordingly, it is my opinion that Garrison in combination with Goff renders Claims 8 and 22 obvious.

D. Claims 10 and 24 – “the filter encloses a region within the housing, wherein the fluid connector is proximal to the enclosed region along the first fluid path, and wherein the filter includes a plurality of pores sized to inhibit clot material from flowing therethrough and to permit blood to flow therethrough”

175. Claims 10 and 24 recite that “the filter encloses a region within the housing, wherein the fluid connector is proximal to the enclosed region along the

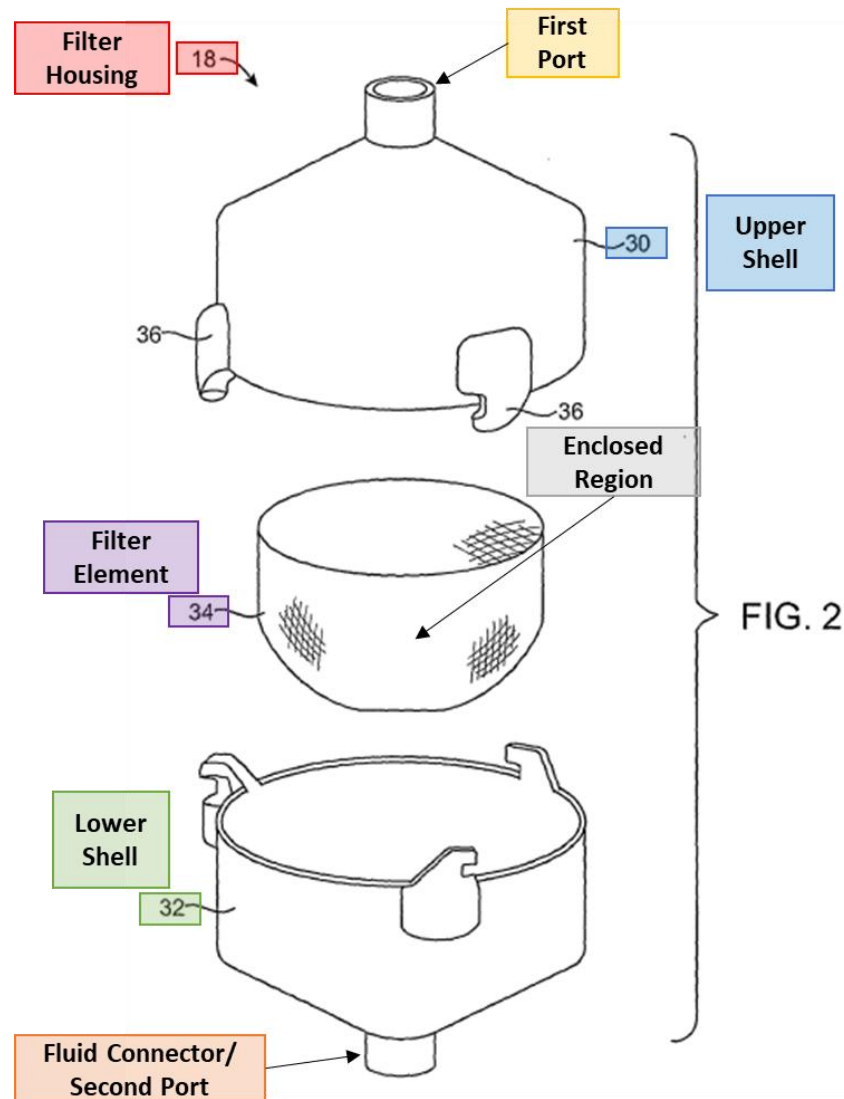
first fluid path, and wherein the filter includes a plurality of pores sized to inhibit clot material from flowing therethrough and to permit blood to flow therethrough.”² Goff discloses these limitations.

176. Goff states that its filter element “may comprise a filter membrane, a mesh, link, or the like, having a pore or mesh size selected to collect and separate solids having a target threshold size or sizes.” Ex. 1005 (Goff) at [0015]. Goff also explains that the “filter element is placed between the aspiration catheter and the aspirate receptacle in order to remove solid materials from the aspirate before the remaining liquid phase of the aspirate flows to the aspirate receptacle.” *Id.* at [0011]. Thus, a person of ordinary skill in the art would have understood that Goff’s filter element includes “a plurality of pores sized to inhibit clot material from flowing therethrough and to permit blood to flow therethrough” as recited in Claims 10 and 24 of the ’669 patent.

177. Goff states that the “geometries in which the filter elements 34 are arranged will depend in large part on the construction of the remainder of the filter assembly” but explains that in the embodiment depicted in Figure 2, “the filter

² Claim 24 depends from Claim 15 and recites a “second port” rather than a “fluid connector” but is otherwise identical to Claim 10.

element 34 is constructed so that it nests within the lower shell 32 of the filter assembly”:



Ex. 1005 (Goff) at [0026], Fig. 2; *see also id.* at [0011]. In this arrangement depicted in Figure 2, Goff’s cylindrical filter element 34 encloses a region within the filter housing 18, specifically the region that is enclosed by the filter. *Id.* As shown in Figure 2 above, Goff’s fluid connector/second port is proximal to the enclosed region formed by the filter element 34. *Id.* As I explained previously for

Claim 1, Goff's filter element would be within the housing along the first fluid path of Garrison's aspiration system, and the first fluid path would also run through the fluid connector/second port at the proximal end of Goff's housing. *Supra* §VII.A.1. Thus, Goff's fluid connector/second port is proximal to the enclosed region along the first fluid path as recited in Claims 10 and 24.

178. Accordingly, it is my opinion that Garrison in combination with Goff renders Claims 10 and 24 obvious.

VIII. GROUNDS 4-7: CLAIMS 14, 30 OBVIOUS OVER GARRISON AND OPTIONALLY GOFF WITH BRADY OR PONS

179. Claims 14 and 30 of the '669 patent recite that "the vacuum source comprises a vacuum chamber" and that the "catheter is fluidically coupled to the vacuum chamber via [the filter chamber along] the first fluid path." Garrison discloses that its aspiration source "may be an aspiration pump, a regular or locking syringe, a hand-held aspirator, hospital suction, or the like." Ex. 1006 (Garrison) at [0134]; *see also id.* at [0071]-[0072], [0131]. As I explained in Grounds 1-2, where Garrison's aspiration source is a syringe, the syringe's chamber would be a "vacuum chamber" as recited in claims 14 and 30. As I also explained in Grounds 1-2, a person of ordinary skill would have understood that where Garrison's aspiration source is an aspiration pump, the aspiration pump would include a canister (i.e., chamber) for building up the vacuum pressure applied to the aspiration

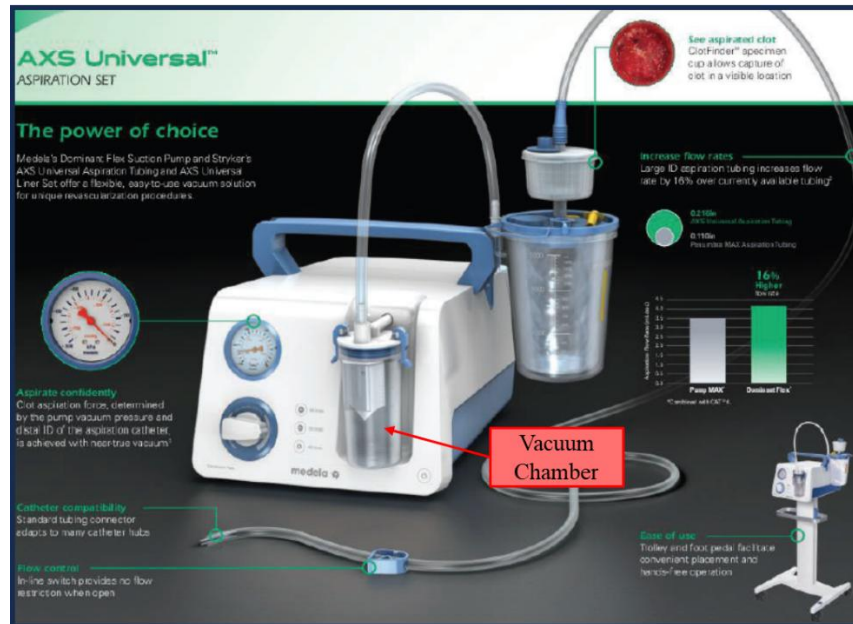
catheter, as was commonly done in the available prior art pumps. However, Garrison does not describe the details of its aspiration pumps in its text and instead presumes that a person of ordinary skill in the art would have been familiar with the available aspiration pumps, such as those I discussed in Grounds 1-2.

180. As I explained in Grounds 1-2, prior art aspiration pumps commonly used vacuum chambers to build up the vacuum pressure that was then applied to an aspiration catheter during thrombectomy procedures. For example, the Penumbra Max and Medela Dominant Flex aspiration pumps incorporated a canister in which vacuum pressure was generated before being applied to an aspiration catheter:

Penumbra Pump



Medela Pump



Ex. 1037 (Penumbra Max Pump); Ex. 1038 (AXS Brochure). Both the Penumbra and Medela aspiration pumps were commercially available prior to January 2018 and had been used clinically to provide aspiration during thrombectomy procedures. Ex. 1041 (Nikoubashman) at 905-906. Similar designs were also disclosed in the Brady and Pons patents, which I discuss in detail below, each of which disclosed electric aspiration pumps designed for thrombectomy procedures that generated vacuum in a canister (i.e., a vacuum chamber) connected to an aspiration catheter via tubing. As I explain below, a person of ordinary skill in the art would have been motivated to use the aspiration pumps disclosed in Brady and Pons as the aspiration source in Garrison's system, and they would have reasonably expected success in doing so. Accordingly, it is my opinion that claims 14 and 30 would have been

obvious to a person of ordinary skill in the art in view of Garrison and optionally Goff in combination with Brady or Pons.

A. “the vacuum source comprises a vacuum chamber”

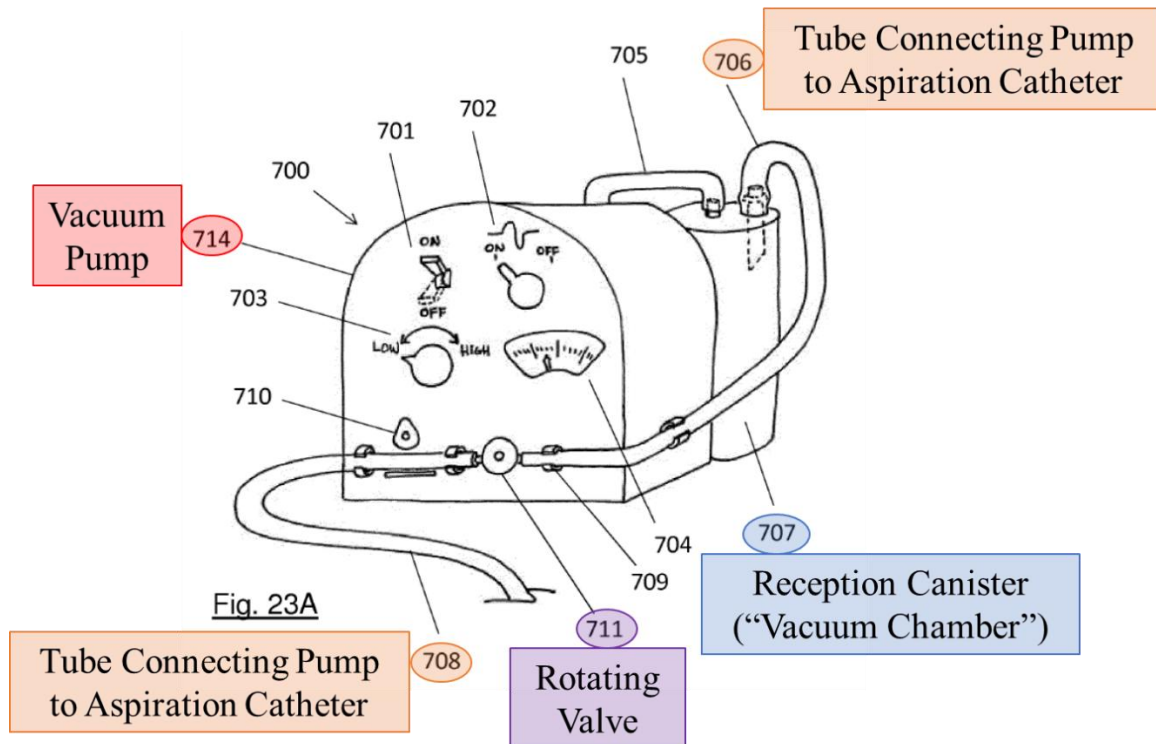
181. Claims 14 and 30 depend from independent claims 1 and 15 respectively, and each recites “wherein the vacuum source comprises a vacuum chamber.” Brady and Pons disclose a vacuum source that comprises a “vacuum chamber” as recited in claims 14 and 30.

1. Brady

182. Brady is an international patent publication entitled “A Clot Retrieval System For Removing Occlusive Clot From A Blood Vessel.” Ex. 1010 (Brady). Brady discloses embodiments of blood clot aspiration systems that generate pulsatile vacuum force to dislodge and aspirate stubborn clot material. *Id.* at Abstract, 1:5-17. Brady discloses that its systems are “particularly suited to removing clot from cerebral arteries in patients suffering acute ischemic stroke (AIS), from coronary native or graft vessels in patients suffering from myocardial infarction (MI), and from pulmonary arteries in patients suffering from pulmonary embolism (PE) and from other peripheral arterial and venous vessels in which clot is causing an occlusion.” *Id.* at 1:15-17.

183. Figure 23A of Brady discloses an embodiment having a vacuum pump 714 that “may comprise a diaphragm or vane or piston pump, or a peristaltic pump,

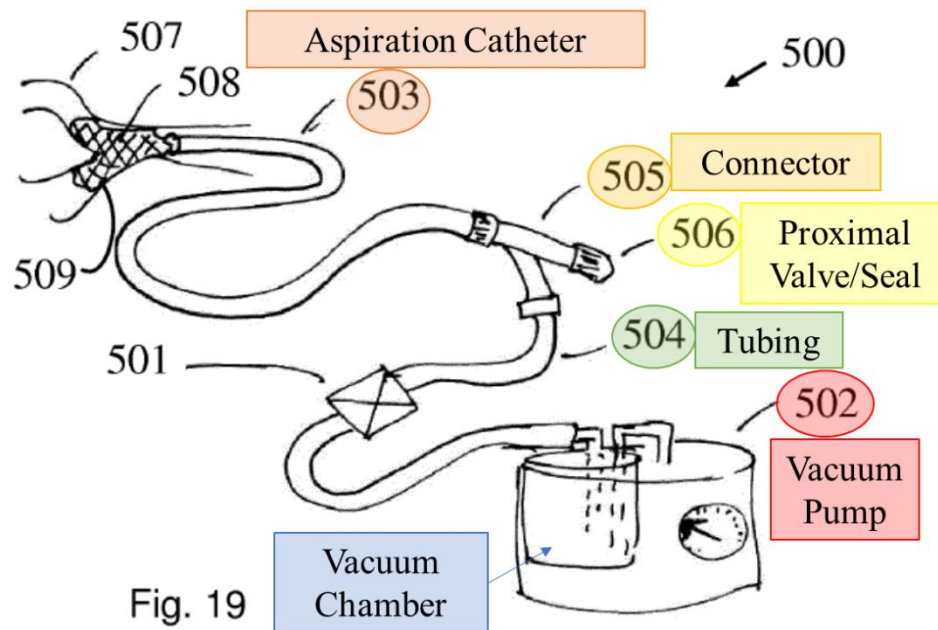
or other means of generating a negative pressure differential.” *Id.* at 21:16-19. In this embodiment, the vacuum pump is connected to reception canister 707 via tubing 705:



Id. at 21:16-32, Fig. 23A. As shown in Figure 23A above, the reception canister is fluidly connected to an aspiration catheter via tubing 706 and 708. *Id.* Brady explains that when the vacuum pump is turned on, the pump “evacuates the canister 707 via tube 705, and thus a suction or aspiration force is transmitted through tubes 706 and 708.” *Id.* at 21:29-32. By “evacu[at]ing the canister 707,” Brady’s pump is creating vacuum pressure within the canister, which is what causes the “suction or aspiration force [to be] transmitted through tubes 706 and 708.” *Id.* Indeed, Brady expressly states that there is “vacuum within the canister 707” when the

pump is turned on. *Id.* at 22:3-4. Brady's reception canister 707 is therefore a "vacuum chamber."

184. Figure 19 of Brady also discloses an aspiration system having a vacuum pump 502 with a vacuum chamber. *Id.* at 20:19-29, Fig. 19. As shown in Figure 19 below, the vacuum chamber is connected to the proximal end of an aspiration catheter 503 via tubing 504:

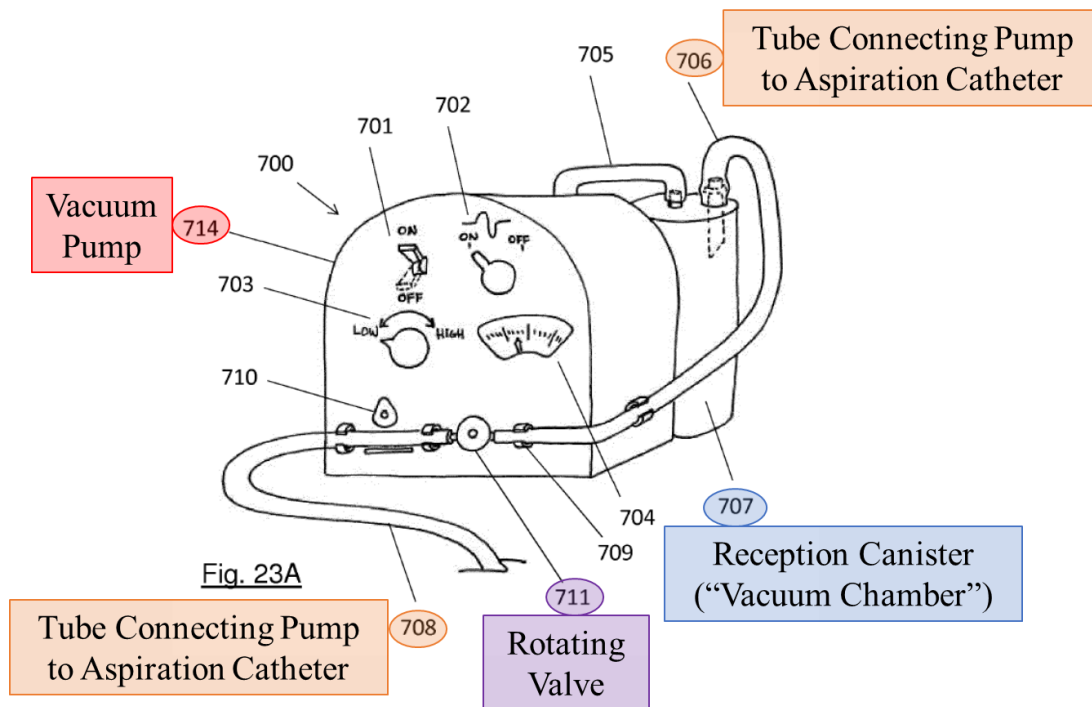


Id. The system in Figure 19 also includes a connector 505 with a y-arm secured to the tubing 504 and a hemostasis valve 506 on the proximal end of the connector. *Id.*

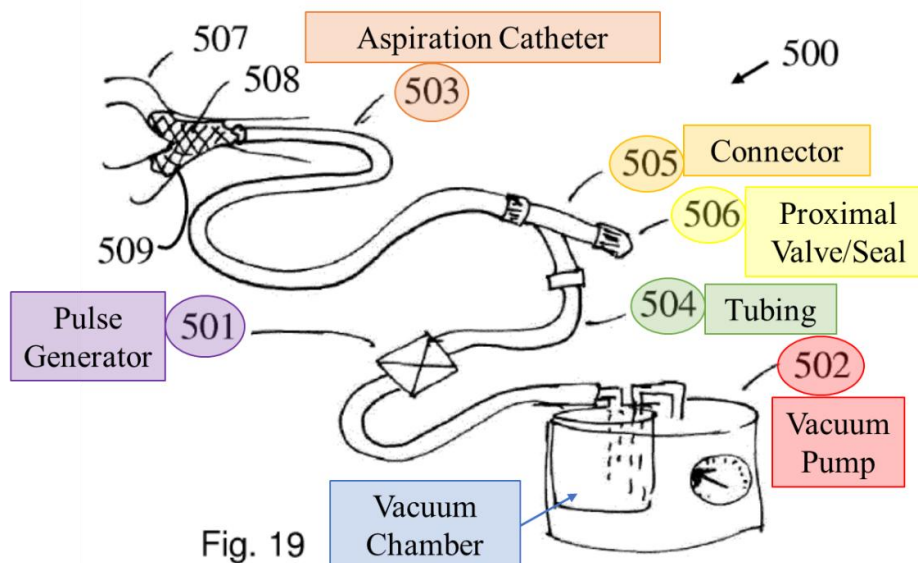
185. A person of ordinary skill in the art would have been motivated to use Brady's vacuum pump, as disclosed in Figures 19 and 23A, as the aspiration source in Garrison's aspiration system for several reasons.

186. First, Brady discloses that its vacuum pump is “particularly suited to removing clot from cerebral arteries in patients suffering acute ischemic stroke (AIS), from coronary native or graft vessels in patients suffering from myocardial infarction (MI), and from pulmonary arteries in patients suffering from pulmonary embolism (PE) and from other peripheral arterial and venous vessels in which clot is causing an occlusion.” *Id.* at 1:13-17. Garrison describes using its aspiration system to treat cerebral blood clots in patients suffering from AIS. Ex. 1006 (Garrison) at [0002]. Thus, a person of ordinary skill in the art would have understood from Brady’s disclosure that Brady’s pump is “particularly suited” for use in the same clinical applications that are disclosed for Garrison’s aspiration system. This would have motivated a person of ordinary skill in the art to use Brady’s pump with Garrison’s system.

187. Second, Brady discloses that its vacuum pumps can be used with an on-off control valve placed along the fluid path to create a rapid pulse of aspiration pressure that “may be beneficial for the retrieval of stubborn clot material.” Ex. 1010 (Brady) at 22:5-6. The embodiment in Brady’s Figure 23A includes a rotating valve 711 that may be closed after the vacuum pump is turned on such that “tube 708 is no longer exposed to the vacuum within canister 707”:



Id. at 22:1-24. Brady then explains that the valve may be opened so that “a vacuum pulse may be delivered through tube 708” to aspirate the clot material. *Id.*, 22:1-24, Fig. 24a-b. The embodiment in Figure 19 uses a similar method that employs a pulse generator 501, which selectively compresses the tubing to create pulsing aspiration:



Id. at 20:19-29, Fig. 19.

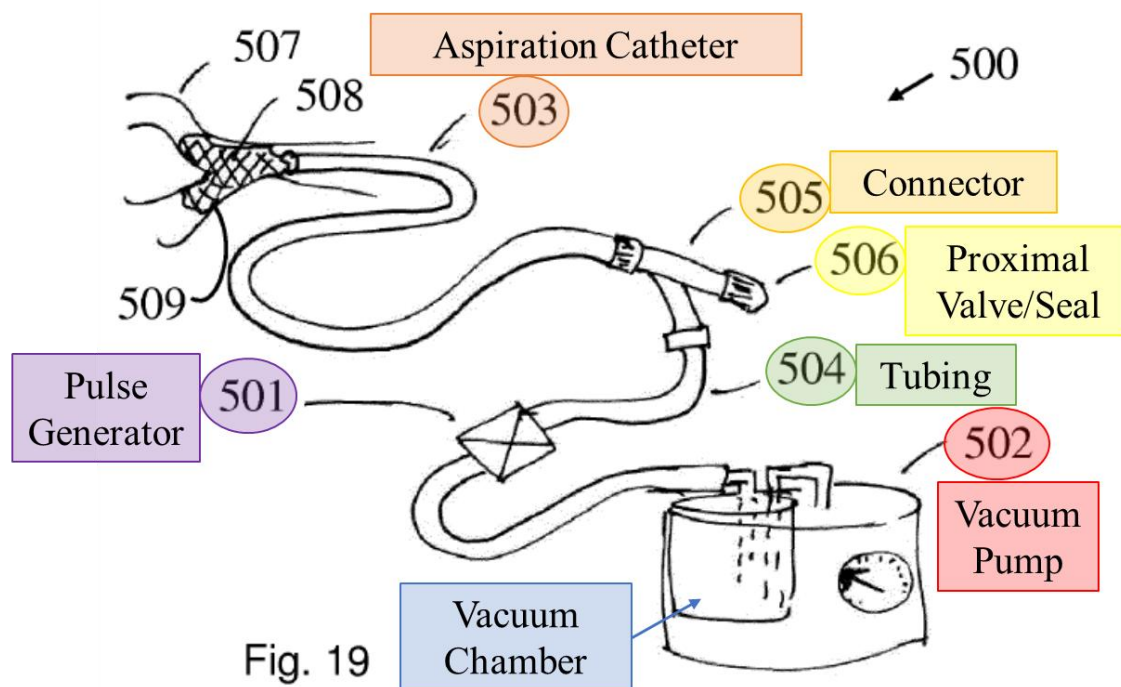
188. Like Brady, Garrison discloses a method of providing a rapid pulse of aspiration force to clot material. Garrison discloses an exemplary method where “a locking syringe (for example a VacLok syringe) is attached to the flow controller and the plunger is pulled back into a locked position by the user while the connection to the flow line is closed prior to the thrombectomy step” and then “when the tip of the aspiration device ... is near or at the face of the occlusion, the user may open the connection to the aspiration syringe.” Ex. 1006 (Garrison) [0134]. Garrison states that this rapid-aspiration method “enable[s] the maximum level of aspiration in a rapid fashion with one user.” *Id.* Given the similarities between the rapid aspiration methods in Brady and Garrison, Brady’s disclosure of generating rapid pulses of aspiration with its vacuum pumps would have motivated a person of ordinary skill in the art to use Brady’s pumps with Garrison’s system to build up vacuum pressure while Garrison’s valve is closed to “enable the maximum level of aspiration in a rapid fashion with one user” when the valve is subsequently opened.

189. Third, combining Brady’s vacuum pumps with Garrison’s aspiration system would have merely entailed a simple substitution of one known component (Brady’s vacuum pump) for another (Garrison’s aspiration source 3430) to yield the predictable result of providing aspiration pressure to Garrison’s catheter.

190. A person of ordinary skill in the art would have reasonably expected success in using Brady's vacuum pumps as the aspiration source in Garrison's Figure 34 because Garrison expressly states that its aspiration source "may be an aspiration pump," and Brady's vacuum pump is an "aspiration pump." Ex. 1006 (Garrison) at [0134]; *see also id.* at [071]-[071], [0131]. Thus, Brady's vacuum pumps are one of the types of aspiration sources that Garrison describes as being suitable for its system.

191. In addition, in both Figure 19 and Figure 23A, Brady's vacuum pumps are connected to an aspiration catheter via medical tubing, and in both figures, the pumps apply vacuum pressure to the catheter through an intermediary on-off control valve or pulse generator. Ex. 1010 (Brady) at 21:16-22:24, Figs. 19, 23A. Garrison's aspiration system uses a similar configuration—the aspiration source 3430 is connected to the proximal end of the aspiration catheter via medical tubing, and the aspiration source 3430 provides the vacuum pressure via the intermediary control valve 3325. Ex. 1006 (Garrison) at [0132], Fig. 34. The similarity in the configurations disclosed in Brady and Garrison would have reinforced the person of ordinary skill in the art's reasonable expectation that Brady's vacuum pumps could be used with Garrison's system. For example, a person of ordinary skill in the art would have recognized that the canister on Brady's vacuum pump could simply be connected to Garrison's check valve 3419 with standard medical tubing,

such as the tubing 706/504 disclosed in Brady. Brady's Figure 19 illustrates this type of configuration in which the vacuum chamber is connected to the y-arm of a connector on the proximal end of an aspiration catheter via tubing:



Ex. 1010 (Brady) at Fig. 19. The configuration in Brady's Figure 19 is very similar to the arrangement in Garrison's Figure 34, and this similarity would have further reinforced a person of ordinary skill in the art's reasonable expectation that Brady's pump could be used as the aspiration source in Garrison's system.

2. Pons

192. Pons, U.S. Patent No. 11,432,835, is entitled Apparatus and Methods for Clot Aspiration and is assigned to Penumbra, Inc. Ex. 1011 (Pons). As Pons explains, Penumbra has manufactured and sold thrombectomy systems and

components since well before January 2018. *See id.* at 2:49-52. For example, Pons describes the prior art Penumbra System mechanical thrombectomy system, which “is a fully-integrated system designed specifically for mechanical thrombectomy by aspiration.” *Id.* at 1:53-56. Pons explains that the Penumbra System used an electric aspiration pump known as the Pump MAX aspiration pump, which included a base unit 12 enclosing a vacuum pump, a collection canister 20 connected to the vacuum pump by vacuum connector 28, and an aspiration tube 22 secured to the collection canister:

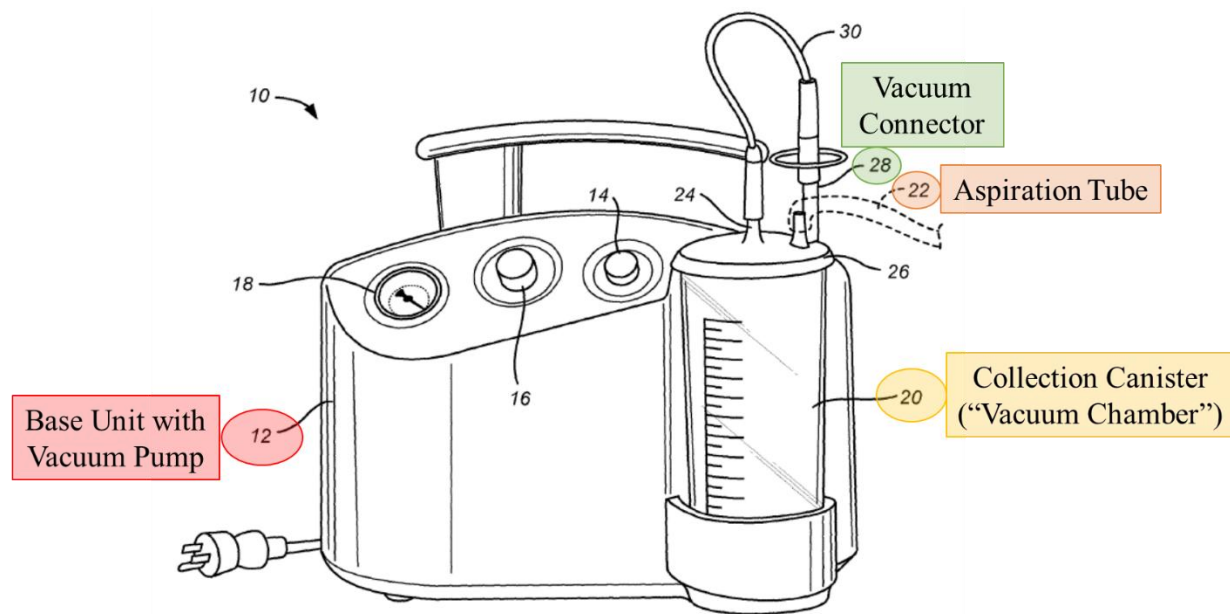
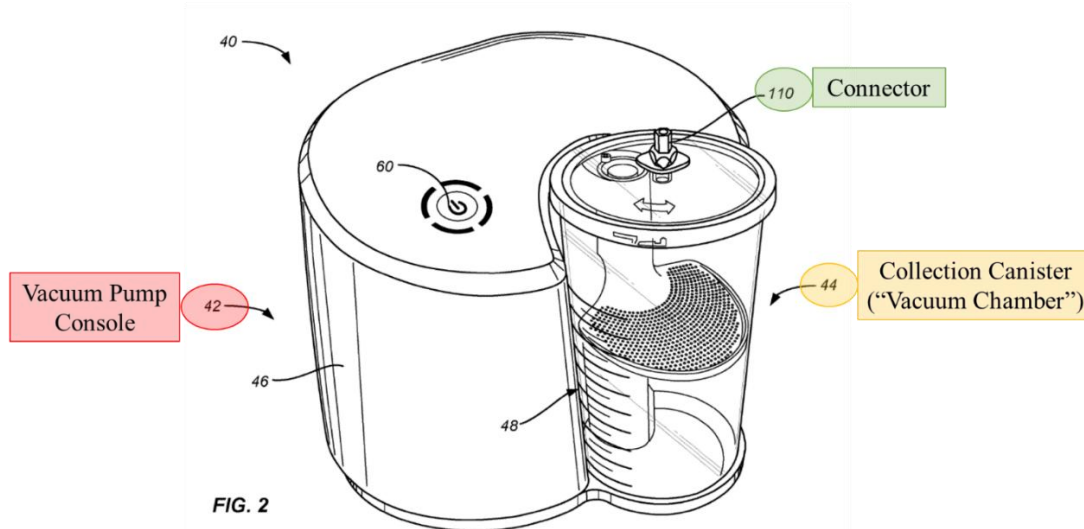


FIG. 1
(PRIOR ART)

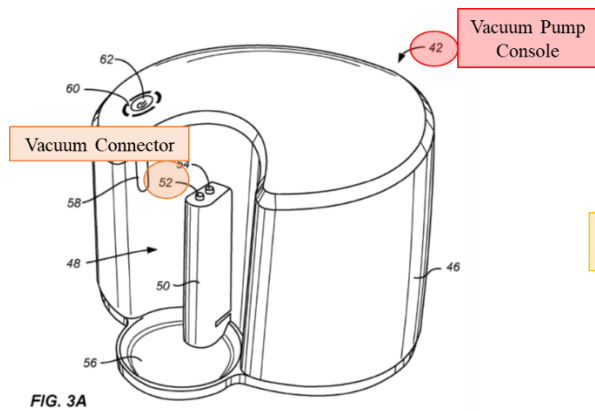
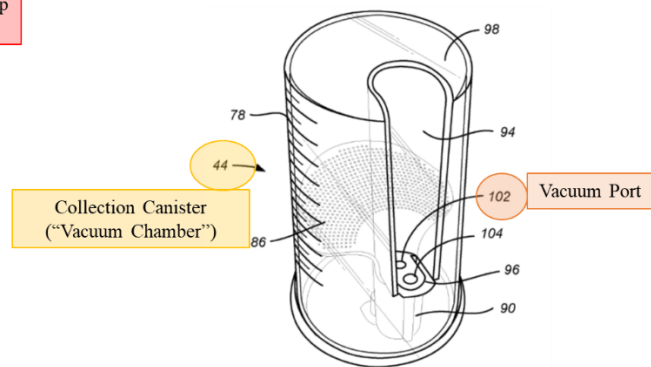
Id. at 1:64-2:13, Fig. 1. Pons explains that “blood and clot are drawn into the collection canister by a partial vacuum which is provided by [the] vacuum connector 28 on the base unit 12 which is connected to the vacuum pump.” *Id.* at

2:7-10. Thus, the collection canister on the Pump MAX aspiration pump was a “vacuum chamber.”

193. Pons discloses “improved vacuum systems including a vacuum console and a collection canister for use with mechanical thrombectomy systems” that are described as improving upon the design of the prior Pump MAX aspiration pump. *Id.* at 2:56-58. Pons’ system includes a vacuum console 42 that houses a vacuum pump and a collection canister 44 secured to the console:



Id. at 6:27-33, Fig. 2. Pons’ collection canister includes a connector 110 at the top “which is attached to a proximal end of a catheter or other tubing” for aspirating blood and thrombus from the patient. *Id.* at 7:63-65. The collection canister also includes a vacuum port 102 which connects to a vacuum connector 52 on the console:



Id. at 7:1-3, 7:65-8:1, Figs. 3A, 5. Pons explains that when the pump is turned on, the pump “will draw vacuum through the connector 52” that is secured to the collection canister, which generates vacuum pressure in the canister to aspirate blood and clot from the patient. *Id.* at 7:1-4. Pons’s console also includes a pressure sensor that “measures vacuum pressure in the canister” generated by the pump. *Id.* at 6:34-58, 7:20-21. Thus, Pons’ collection canister is a “vacuum chamber” at least because it stores vacuum pressure that is applied to an aspiration catheter.

194. A person of ordinary skill in the art would have been motivated to use Pons’ vacuum pump as the aspiration source in Garrison’s system for several reasons.

195. First, Pons discloses that its “vacuum systems can find use with any thrombectomy, embolectomy, atherectomy, or other catheter or probe system where blood and clot are withdrawn wholly or partially by application of a vacuum to the proximal end of any reperfusion catheter, aspiration catheter or probe for the

purpose of clot extraction.” *Id.* at 2:65-3:4. Garrison discloses this type of thrombectomy that is described in Pons. In Garrison’s system, “blood and clot [is] withdrawn ... by application of a vacuum to the proximal end of ... [an] aspiration catheter. *Id.*; Ex. 1006 (Garrison) at e.g., [0164]-[0165] (“A 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. . . . Aspiration is then initiated through the catheter.”); *see also id.* at [0048]-[0049], [0130]-[0134], Fig. 34. Pons’ disclosure that its vacuum system is useful for the same types of thrombectomy systems disclosed in Garrison would have motivated a person of ordinary skill in the art to use Pons’ vacuum pump in Garrison’s system.

196. Second, Pons explains that its system “provides a direct connection between a vacuum pump within the console and an interior of a removable canister ... [which] simplifies connection and routing of the catheter to the vacuum console” and prevents “entanglement of the aspiration tube with external vacuum tubes on the vacuum console.” Ex. 1011 (Pons) at 3:7-15, 3:46-50. A person of ordinary skill in the art would have recognized that these advantages would benefit Garrison’s aspiration system. For example, Pons’ vacuum system would prevent possible entanglement between Garrison’s aspiration tubing and external tubing connecting the canister to the pump. A person of ordinary skill in the art would have been motivated to use Pons’ vacuum pump to achieve those benefits.

197. Third, Pons discloses that its system “provide[s] for improved pressure sensing within the interior of the canister [b]y providing a pressure sensor which measures vacuum pressure directly in the collection canister, [reducing] the risk of clogging of the pressure pathway.” Ex. 1011 (Pons) at 3:15-21, 4:46-50. Again, a person of ordinary skill in the art would have recognized that Pons’ improved pressure sensing would provide a benefit to Garrison’s aspiration system, allowing the user to more accurately and reliably measure the level of vacuum force being generated by the pump. A person of ordinary skill in the art would have therefore been motivated to use Pons’ vacuum pump in Garrison’s system to achieve this benefit.

198. Fourth, combining Pons’ vacuum pump with Garrison’s aspiration system would have merely entailed a simple substitution of one known component (Pons’ vacuum pump) for another (Garrison’s aspiration source 3430) to yield the predictable result of providing aspiration pressure to Garrison’s catheter.

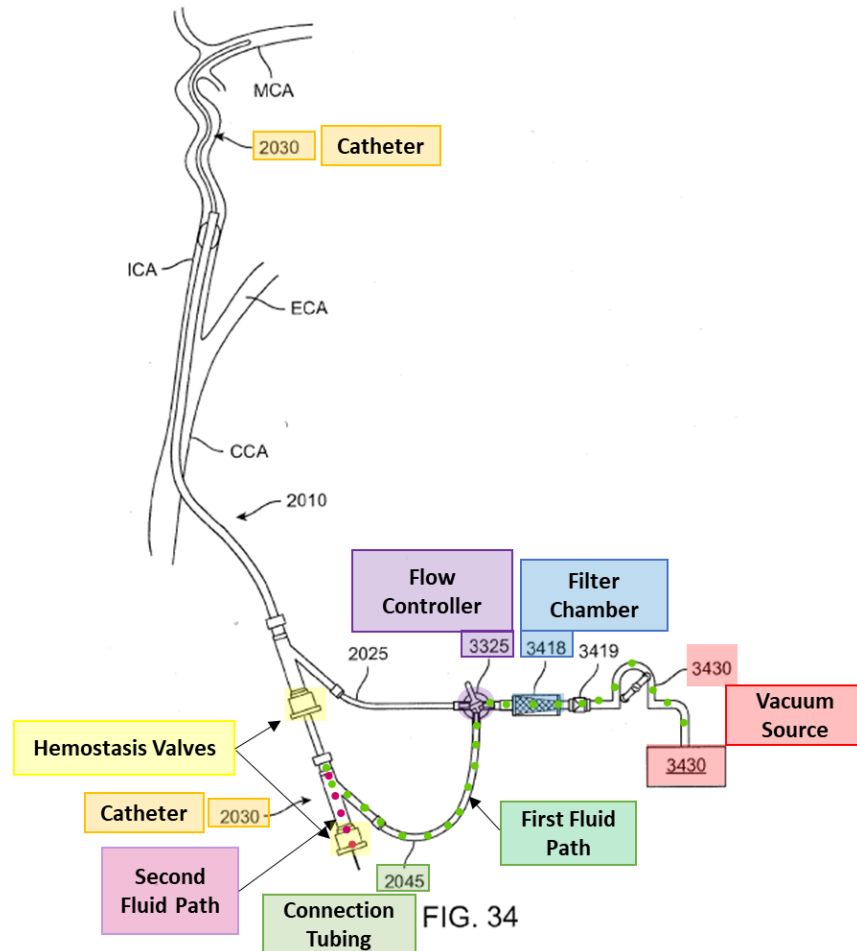
199. A person of ordinary skill in the art would have reasonably expected success in using Pons’ vacuum pump as the aspiration source in Garrison’s Figure 34 because Garrison expressly states that its aspiration source “may be an aspiration pump,” and Pons’ vacuum pump is an “aspiration pump.” Ex. 1006 (Garrison) at [0134]; *see also id.* at [071]-[072], [0131]. Thus, Pons’ vacuum pump is one of the types of aspiration sources that Garrison describes as being suitable for its system.

200. In addition, Pons discloses that its “vacuum systems can find use with any thrombectomy, embolectomy, atherectomy, or other catheter or probe system where blood and clot are withdrawn wholly or partially by application of a vacuum to the proximal end of any reperfusion catheter, aspiration catheter or probe for the purpose of clot extraction.” Ex. 1011 (Pons) at 2:65-3:4. As I explained above, Garrison’s aspiration system is a thrombectomy system in which “blood and clot [is] withdrawn ... by application of a vacuum to the proximal end of ... [an] aspiration catheter” as described in Pons. *Id.*; Ex. 1006 (Garrison) at e.g., [0164]-[0165] (“A 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. . . . Aspiration is then initiated through the catheter.”); *see also id.* at [0048]-[0049], [0130]-[0134], Fig. 34. Accordingly, the Pons’ disclosure of the broad applicability of its aspiration pump, including for the types of thrombectomy systems disclosed in Garrison, would have reinforced the person of ordinary skill in the art’s reasonable expectation that Pons’ vacuum pump could be used with Garrison’s Figure 34.

B. “catheter is fluidically coupled to vacuum chamber via [the filter chamber along] the first fluid path”

201. Claims 14 and 30 also recite that the “catheter is fluidically coupled to vacuum chamber via [the filter chamber along] the first fluid path.” Garrison in combination with Brady or Pons renders this limitation obvious.

202. As shown in Figure 34 below, Garrison's aspiration source 3430 is fluidically coupled to its aspiration catheter 2030 via the filter 3418 (i.e., the filter chamber) that is placed along the first fluid path (green dots):



Ex. 1006 (Garrison) at [0130]-[0134], Fig. 34. As also shown above, Garrison's vacuum source 3430 is fluidically coupled to the first fluid path (green dots) via the connection tubing that makes up the flow line 2045. *Id.* at [0130], [0132], Fig. 34 ("Any or all of the arterial access device 2010 and the catheter 2030 may be connected to sources of passive or active aspiration via flow lines 2025 or 2045

(FIG. 1) on the devices.”). Therefore, a person of ordinary skill in the art would have understood that when Garrison’s aspiration source 3430 is replaced with Brady’s or Pons’ vacuum pump, the vacuum chamber on Brady’s or Pons’ pumps would be fluidically coupled to Garrison’s aspiration catheter 2030 via the first fluid path.

C. Remaining Limitations

203. Garrison and Goff disclose or render obvious the remaining limitations of claims 14 and 30 for the reasons I explained previously for Grounds 1-3. *Supra* §§VII.A-B. Accordingly, it is my opinion that claims 14 and 30 of the ’669 patent would have been obvious to a person of ordinary skill in the art in view of Garrison and optionally Goff in combination with Brady or Pons.

IX. CLAIMS 12, 26-28 OBVIOUS IN VIEW OF GARRISON AND OPTIONALLY GOFF WITH SCHAFFER AND OPTIONALLY HARTLEY

204. The independent claims 1 and 15 of the ’669 patent recite a hemostasis valve that “is configured to maintain hemostasis by inhibiting proximal fluid flow along the second fluid path when an interventional device is inserted through the hemostasis valve and the catheter.” The independent claims do not further specify any structure for the hemostasis valve, but dependent claims 12 and 26-28 recite several additional limitations for the hemostasis valve. As I explained in Grounds 1-2, Garrison discloses that its aspiration system includes a hemostasis valve that allows “introduction of devices such as a microcatheter, guide wire, or

thrombectomy device while preventing or minimizing blood loss during the procedure.” Ex. 1006 (Garrison) at [0098]. However, Garrison does not describe the details of its hemostasis valves and instead presumes that a person of ordinary skill in the art would have been familiar with the available valves.

205. As I describe in detail below, Schaffer, alone and combined with Hartley, discloses hemostasis valves having all of the features recited in Claims 12 and 26-28 of the ’669 patent. In my opinion, a person of ordinary skill in the art in January 2018 would have found it obvious to use the hemostasis valve disclosed by Schaffer, alone or as modified in view of Hartley, in Garrison’s aspiration system. Accordingly, Claims 12 and 26-28 are obvious in view of Garrison and optionally Goff in combination with Schaffer and optionally Hartley.

A. Claim 12

206. Claim 12 recites the “aspiration system of claim 1 wherein - the hemostasis valve comprises a tubular member, a button, a spring coupled to the button, and a filament coupled to the button and the tubular member, the button is configured to be actuated from a first position to a second position to loosen the filament to allow the tubular member to expand to unseal the hemostasis valve to allow the interventional device to be inserted through the hemostasis valve, and the spring is configured to bias the button to the first position.” Schaffer discloses the

hemostasis valve limitations recited in Claim 12 or renders them obvious in view of Hartley.

1. **“the hemostasis valve comprises a tubular member, a button, a spring coupled to the button”**

207. Schaffer discloses a hemostasis valve that “comprises a tubular member, a button, [and] a spring coupled to the button.”

208. Schaffer discloses an adjustable opening “fluid stasis valve” for use with catheters to prevent the flow of blood through the valve. Ex. 1007 (Schaffer) at [0002], [0046], [0055]. Schaffer’s hemostasis valve includes a “seal module 100” that comprises “a flexible, elongate tubular structure 101.” *Id.* at [0049], [0051], [0054], [0075]. The seal module 100 defines a lumen 193:

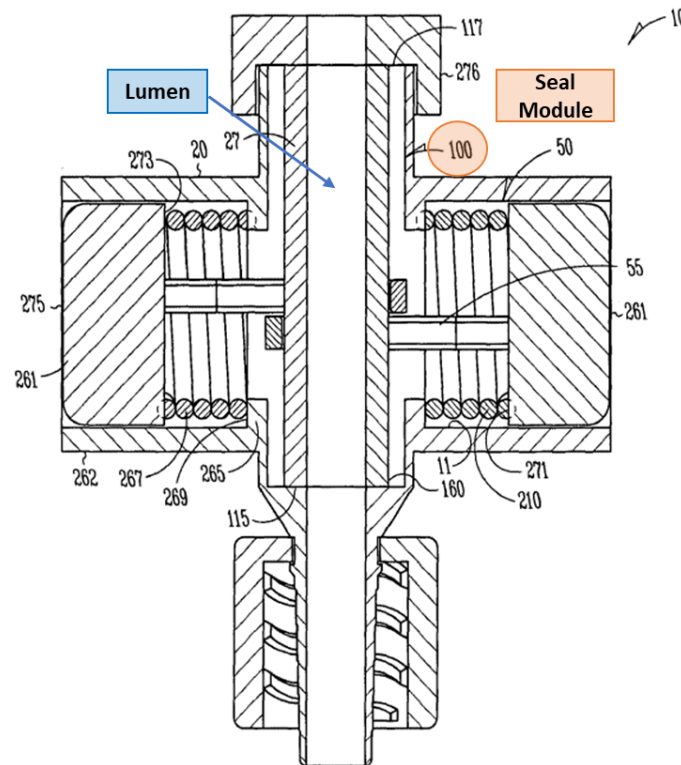
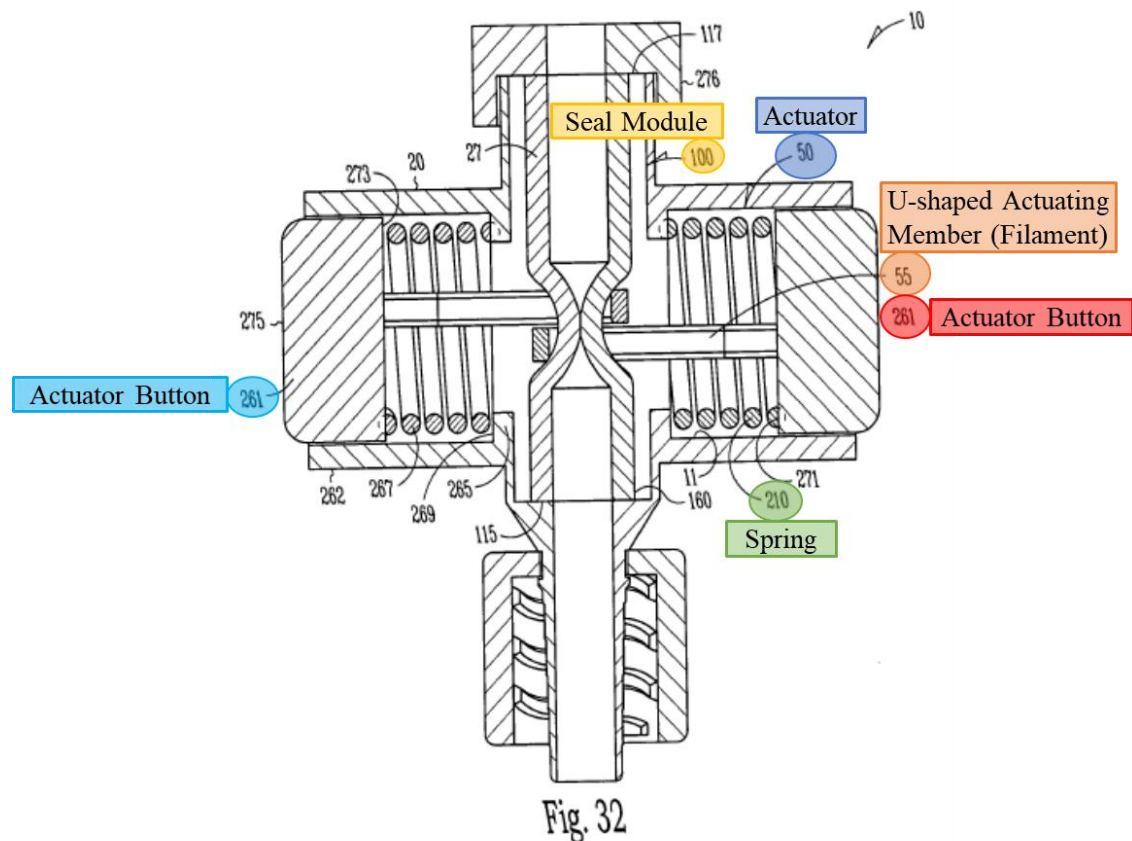


Fig. 34

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.”

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



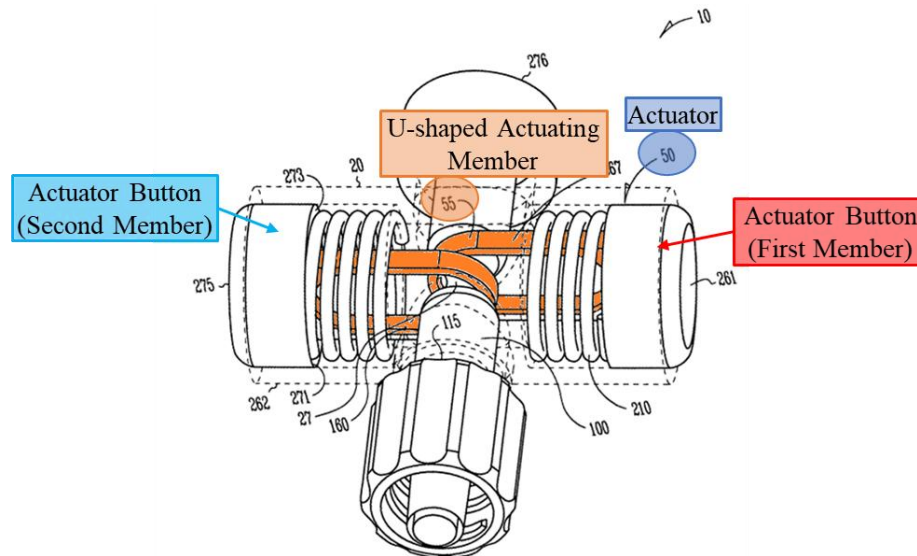
Id. at [0075]-[0076], Figs. 31-32.

2. “a filament coupled to the button and the tubular member”

a. Schaffer

210. Schaffer discloses “a filament coupled to the button and the tubular member.”

211. 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 ’669 patent. *Supra* §IV.

212. 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 ’669 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.*

213. I notice in related IPRs that Patent Owner characterizes Schaffer's actuating members as "rigid." Ex. 1024 ('011 patent Institution Decision) at 38; Ex. 1025 ('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."

214. Notably, Schaffer does expressly describe one of the other components of its hemostasis valve, the support member 168 that surrounds the seal member, as being formed from "biased weaving or tubular braiding of *rigid* material." Ex. 1007 (Schaffer) at [0070] (emphasis added). This conveys to a person of ordinary skill that the inventors of Schaffer knew how to describe a material as "rigid." If the actuating members were actually "rigid," a person of ordinary skill would have expected the inventors to say so, as they did with the support member 168. But they did not, which suggests to a person of skill that the actuating members are not limited to "rigid materials."

215. 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 in order to provide optimal sealing. 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.

216. Figures 31-34 of Schaffer also convey to a person of ordinary skill in the art that the U-shaped actuating members are thin and flexible. Schaffer's figures illustrate the actuating members as plastic or metal pieces with a thickness that is substantially less than their length. *See* Ex. 1007 (Schaffer) at Figs. 31-34. In addition, although Schaffer does not provide precise dimensions for the U-shaped actuating members, a person of ordinary skill in the art would have recognized that they would be thin and flexible based on the depiction of the actuating members in relation to the other components of the hemostasis valve. For example, Schaffer depicts the actuating members having the same thickness as the coils of the compression spring, which must be relatively flexible to function:

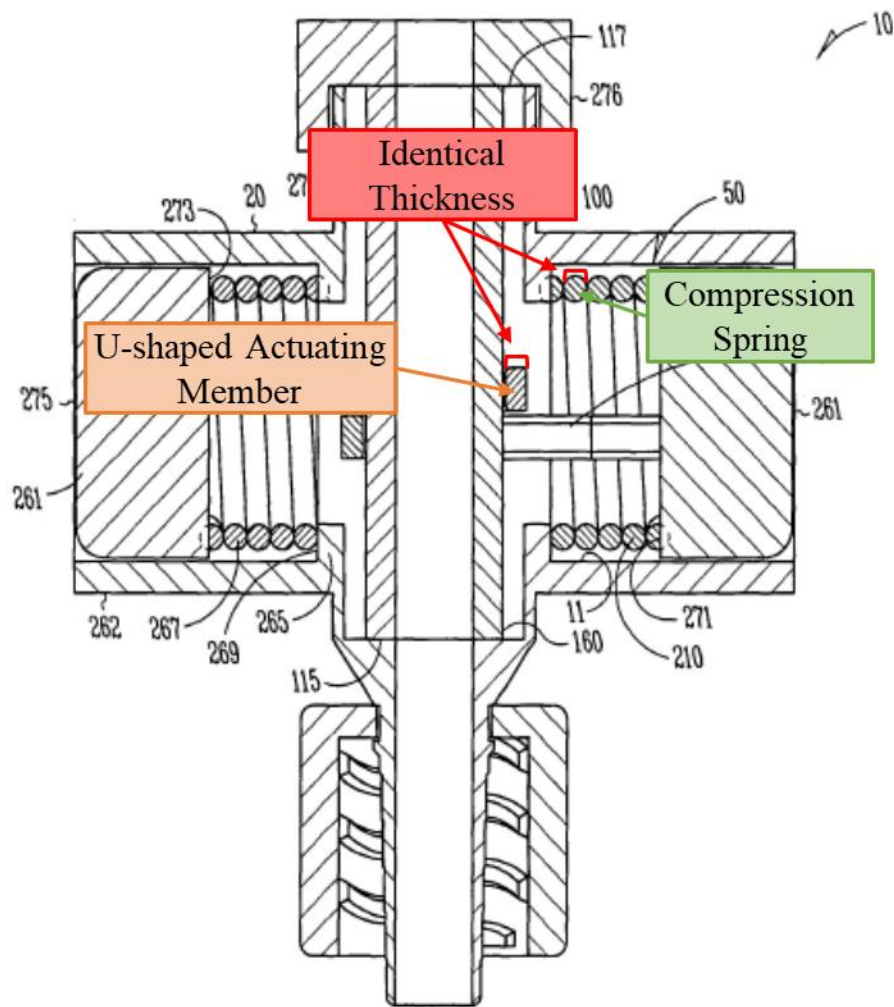


Fig. 34

Id. at Fig. 34. A person of ordinary skill would have understood that a component formed from metal or plastic with such dimensions would have significant flexibility. Notably, the '669 patent illustrates the filament 150 having a thickness that is slightly larger than the coils of its compression springs:

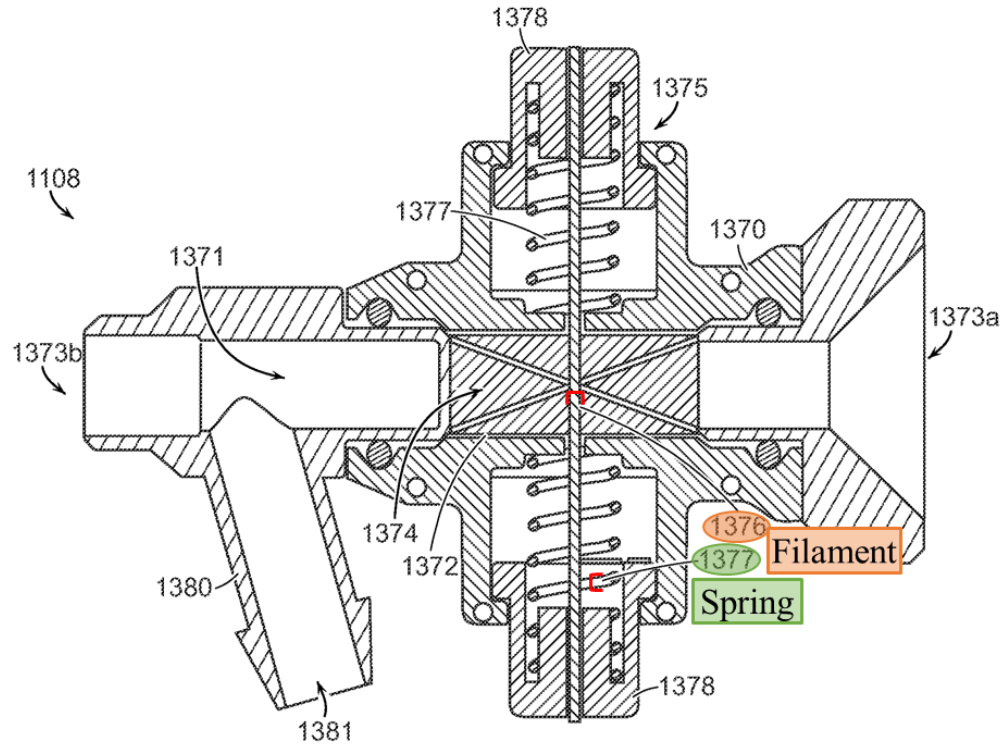


FIG. 13A

Ex. 1001 ('669 patent) at Fig. 13A.

217. I am aware that in related IPR proceedings, PO's expert Dr. Zalesky testified in his deposition that he believes Schaffer's figures illustrate the actuating members as being "certainly thicker than filaments" and roughly 10mm thick. Dr. Zalesky's interpretation of Schaffer's figures is not reasonable. If Schaffer's actuating members were 10mm thick as Dr. Zalesky suggests, the other components of Schaffer's valve would be unreasonably and unworkably large:

Fig. 34

Ex. 1007 (Schaffer) at Fig. 34. For example, as I've illustrated above, the lumen of Schaffer's valve in Dr. Zalesky's interpretation would be 30mm (i.e., 90F), which is far larger than any catheters used for intravascular procedures. In addition, the total width of Schaffer's valve in this scenario would be roughly 300mm (nearly a foot wide), which would be far too large for any operator to reasonably handle. Accordingly, I disagree with Dr. Zalesky's interpretation of Schaffer.

218. 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]. I am also aware that during the oral hearing for the '011 Patent IPR, Judge Majors stated that he believed Schaffer's disclosure that the “actuators [are made] out of machined aluminum or machined plastic, and they're -- want to slide along the exterior of the housing” suggests that the actuating members are rigid. Ex. 1042 ('011 Oral Hearing Tr.) at 27:23-28:9. 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. In his deposition, Dr. Zalesky agreed that metallic or polymeric filaments could be manufactured by machining. Ex. 1016 (Zalesky June 2025 Tr.) at 99:7-17. In addition, Schaffer's description that “the actuators 50 are configured cylindrically to slide along the cylindrical interior wall 11 of the housing,” which is the disclosure that Judge Majors appear to have referenced during the oral hearing, does not mean that the actuating members must be rigid. Schaffer's U-shaped actuating members are secured to the buttons of the actuators 50. Ex. 1007 (Schaffer) at [0075]-[0076]. Thus, while the buttons themselves may require some level of rigidity to slide along the interior of the housing when they are pressed, the actuating members do not need to have similar rigidity. Rather, the actuating members would move within

the housing to constrict and relax around Schaffer's seal member as the buttons are pressed or released regardless of whether the actuating members are rigid or flexible.

219. 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.

220. 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 ’669 patent’s filament does.

221. However, even if the Board finds that Schaffer’s actuating members were relatively rigid, a person of ordinary skill in the art would have found it obvious to use “flexible” materials to form the actuating members. A person of ordinary skill in the art would have been motivated to use a thin, flexible material so that the actuating members could conform as much as possible to the outer surface of the seal module and the tool inserted therethrough. Not all tools have a circular profile so using more flexible actuating members allows the members to more closely conform to the tools.

222. Schaffer’s U-shaped actuating members (i.e., filament) are coupled to the actuator buttons, as shown in Figure 31 below:

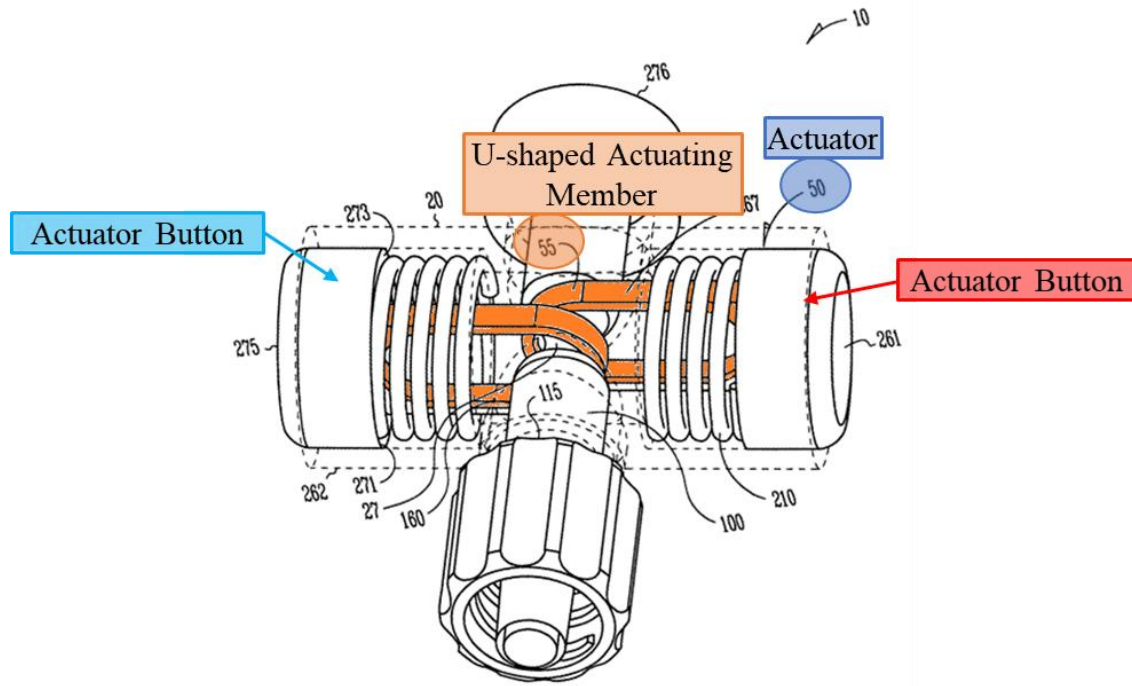
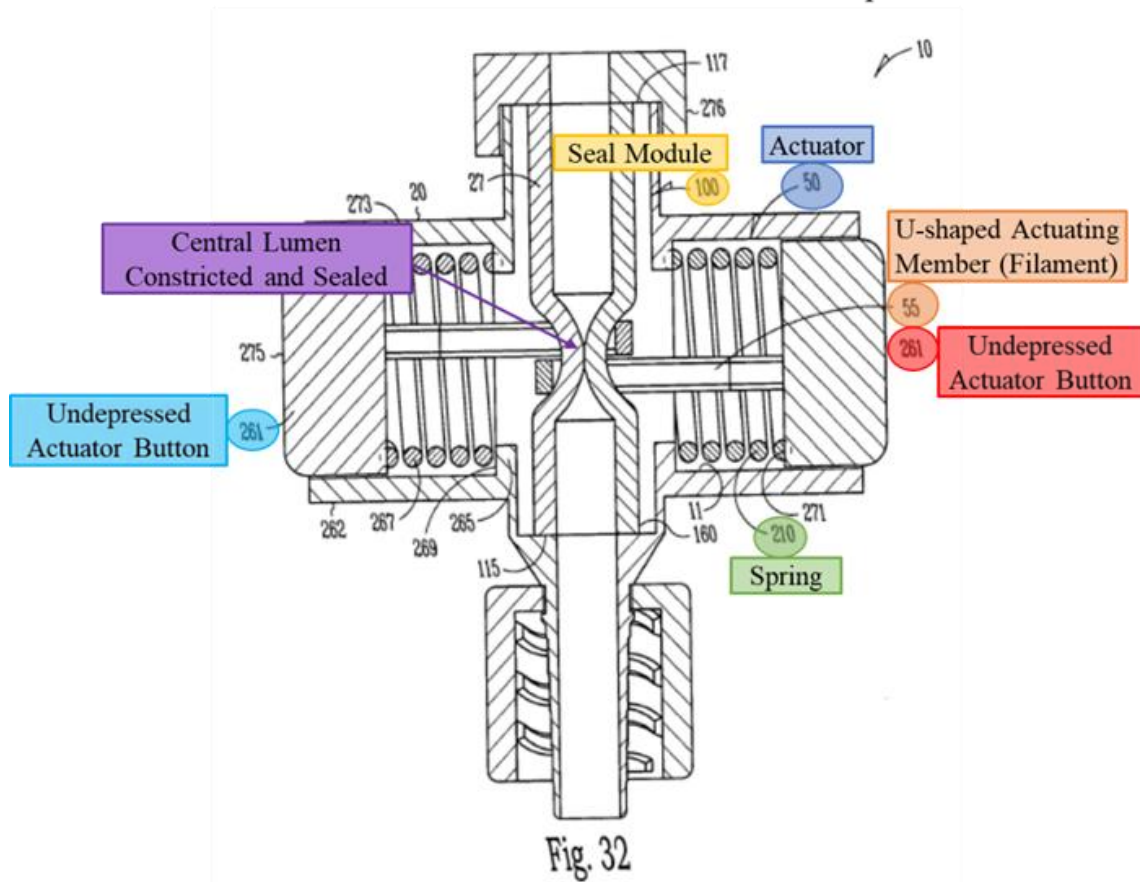


Fig. 31

Id. at [0076], Fig. 31. The actuating members are also coupled to the tubular member. Schaffer discloses that in a first position, shown in Figure 32 below, the U-shaped actuating members are “at least partially circumferentially [sic] disposed about the portion 108 of the seal module 100 depressing and at least partially collapsing a portion 108 of the containment structure 160 by a compressive force 67 (e.g. by a spring 210)”:

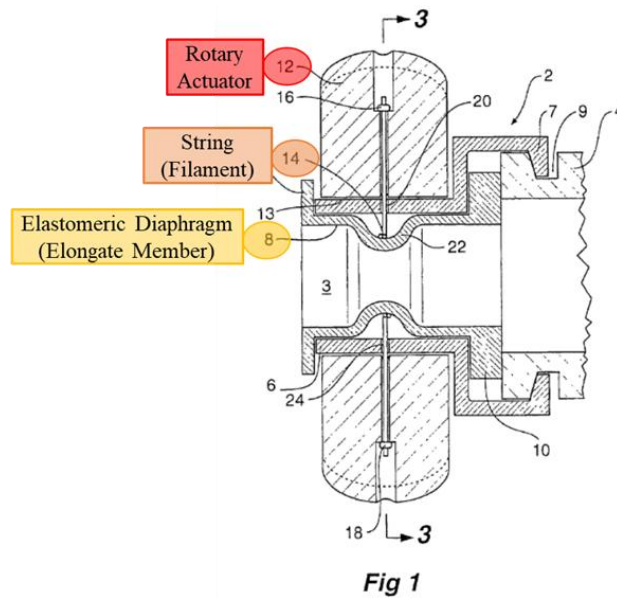
First Position – Actuator Buttons Undepressed



Id., at [0077], Fig. 32.

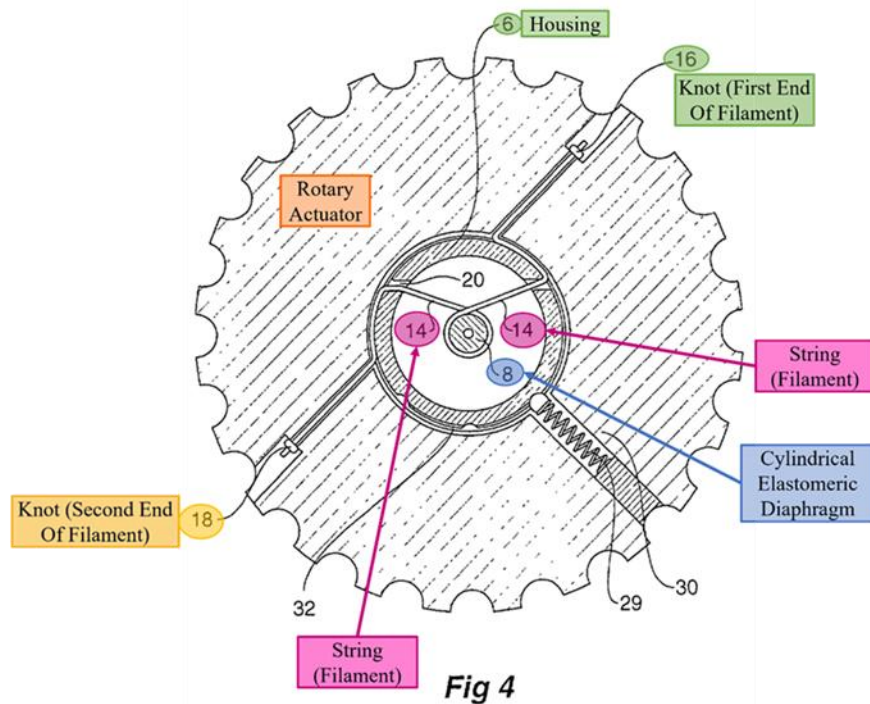
b. Schafter and Hartley

223. If the Board finds that 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:



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.

224. 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”:

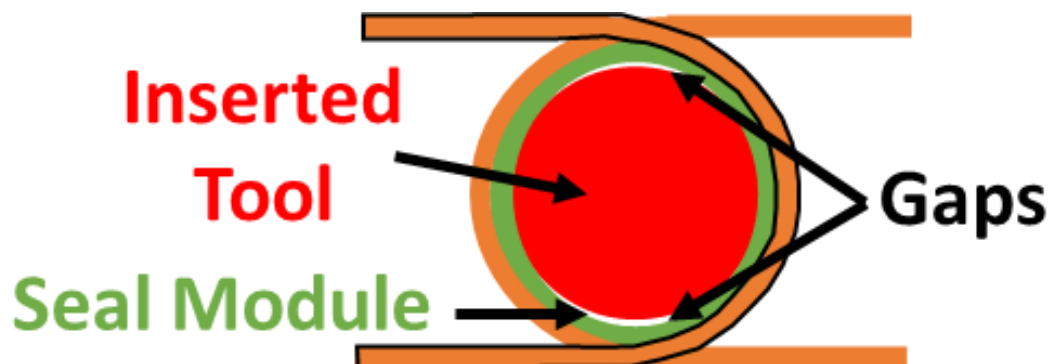


Ex. 1008 (Hartley) at [0031], Fig. 4.

225. 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].

226. 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.

227. 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 selfsealing" would have further motivated a person of ordinary skill in the art to substitute Hartley's string for Schaffer'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.

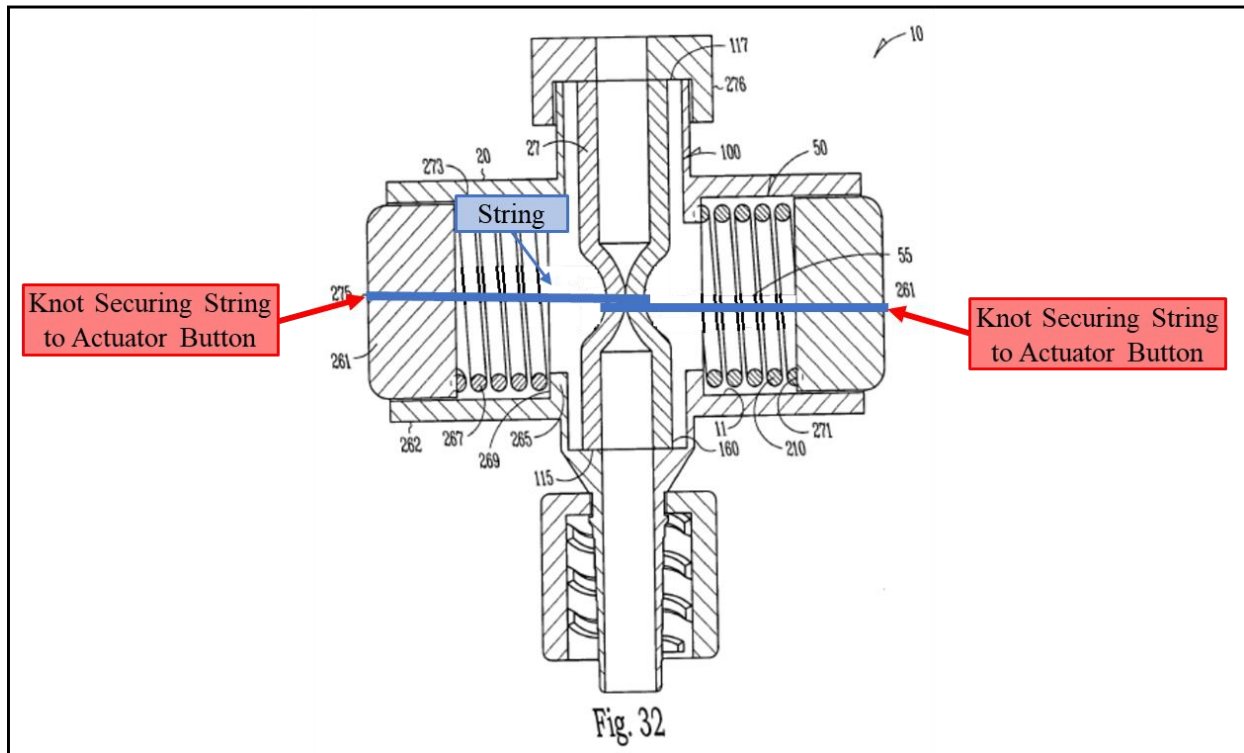
228. A person of ordinary skill in the art had a finite number of materials to select from to constrict a tubular member in a hemostasis valve in January 2018. Hartley and Schaffer disclose two such materials: Hartley's string and Schaffer's actuating members (which can be plastic or metal). A person 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.

229. 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 collectively 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.

230. 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



231. Also, a person of ordinary skill in the art 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.*

232. 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].

233. 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.

i. **Schaffer's Seal Module Would Not Dissuade A Person Of Ordinary Skill From Combining Schaffer With Hartley's String**

234. I am aware that in related proceedings 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 because Schaffer discloses an exemplary embodiment with a "gelatinous" or "sticky" seal module with "selfclosing" properties. Ex. 1030 ('011 IPR, Patent Owner Response) at 46-52. I disagree for several reasons.

235. First, 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] (emphasis added).

236. Second, Schaffer discloses that the “sticky” or “gelatinous” seal module is an optional feature for some embodiments, but it does not state or suggest that it is required for all embodiments, including the embodiment depicted in Figures 31-34. *See id.* at [0059], [0081]. Moreover, 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].

237. Third, 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 very “sticky” or “gelatinous” materials would not have the requisite resilience to return to its uncollapsed configuration.

Thus, even if the seal module had some stickiness, a person of ordinary skill in the art would have understood that the seal module cannot be so sticky as to prevent the seal module from retracting to its unsealed state when the constricting force from the actuating members is removed. *See id.*; *see also id.* at [0054] (“The third central seal member 165 is sized and configured to maintain an open lumen 193 when no compressive force 67 is applied.”).

238. A person of ordinary skill in the art would have understood that small gaps may form with Schaffer’s valve, particularly if the tool inserted through the valve does not match the size or shape of Schaffer’s U-shaped actuating members or if the members do not conform sufficiently to the size or shape of the tool inserted. Each of Schaffer’s U-shaped actuating members is secured to the actuator buttons at two fixed, spaced-apart points:

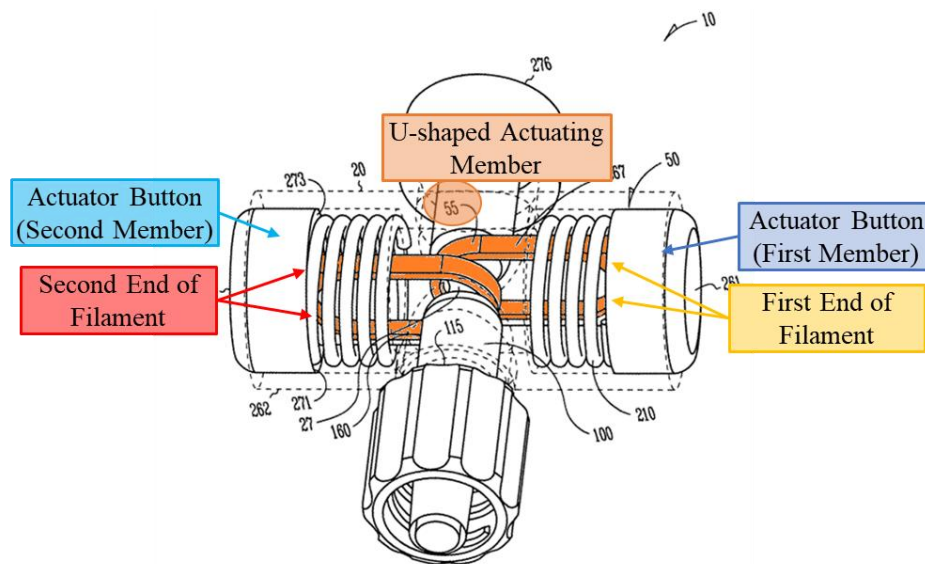
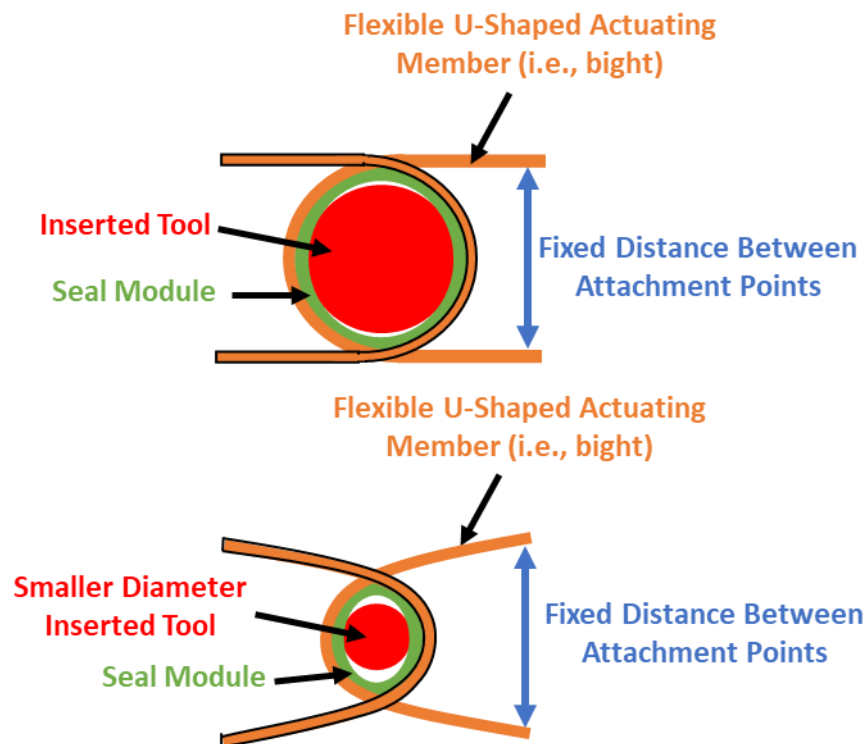
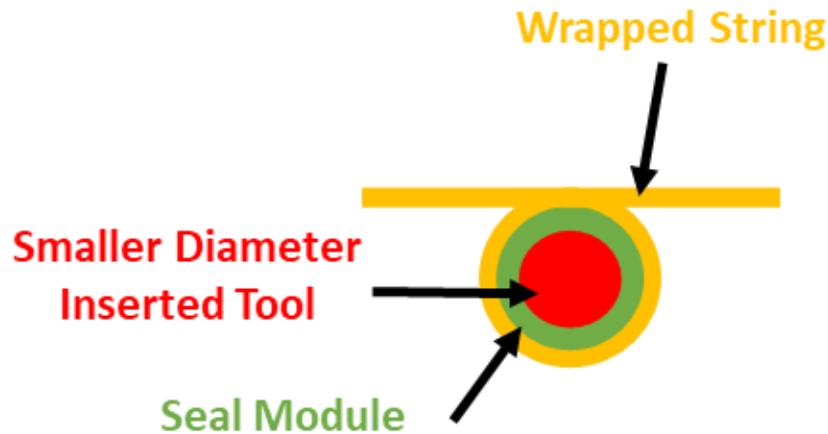


Fig. 31

Id. at Fig. 31. Because of this arrangement, even when the U-shaped actuating members (or bights) are relatively flexible, the fixed attachment points to the actuator buttons may prevent the U-shaped actuating members from completely conforming to the exterior of a tool with a smaller diameter than the distance between the attachment points, as I've illustrated below:

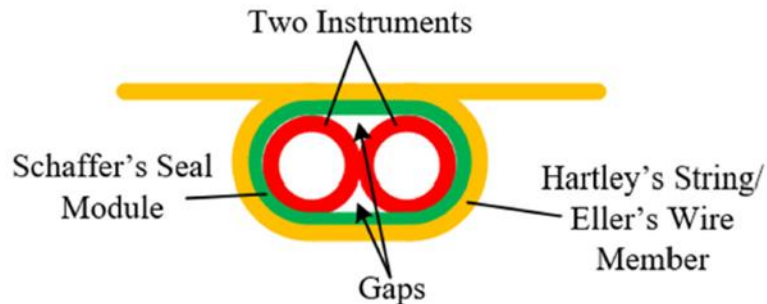


Because Hartley's string member would be wrapped around Schaffer's seal module with each respective end secured to the opposing actuator buttons, the string/wire member would be better able to conform to the varying diameter tools in this situation:



239. I am also aware that in the related IPR proceedings, Patent Owner argues that Schaffer’s valve with Hartley’s string would seal “less effectively” when two instruments are inserted through the valve. Ex. 1030 (’011 IPR, Patent Owner Response) at 51. Patent Owner cites to Schaffer’s disclosure of an embodiment with sealing member that is “so compliant that it forms a seal around the instruments 260 even if the instruments 260 are irregularly shaped.” Ex. 1007 (Schaffer) at [0068]. This particular disclosure appears in the section of Schaffer referring to Figures 12-15 (not Figure 30-34), which describes a three-piece valve that closes as a result of “pressure from the antegrade flow 272,” not an actuator. *Id.* at [0068]-[0069]; *see also id.* at [0063] (referencing Figures 12-15). Clearly, this embodiment operates differently than the embodiment in Figures 30-34. *See id.* at [0069] (“While this arrangement may not be as friction-less as the other embodiments using an actuator 50, it may offer the advantages of ‘hands-free’ operation.”).

Patent Owner also provides the following illustration as alleged support for its argument:



Ex. 1030 ('011 IPR, Patent Owner Response) at 52. Patent Owner's illustration does not depict the compliant sealing member described in Schaffer's Paragraph [0068]. The sealing member depicted in Patent Owner's illustration is not "so compliant that it forms a seal around the instruments 260 even if the instruments 260 are irregularly shaped." In addition, Patent Owner does not explain how the illustration would be any different if the string was replaced with two U-shaped actuating members. Because of the non-compliant seal depicted in the illustration, the same gaps would exist with U-shaped actuating members. Accordingly, Patent Owner's illustration is not representative of Schaffer's valve and does not demonstrate that Schaffer's valve would work less effectively with a string.

ii. **Substituting Schaffer's U-Shaped Actuating Members With Hartley's String Would Not Change Schaffer's Principles Of Operation**

240. I am aware that in the related IPR proceedings, Patent Owner and Dr. Zalesky assert that substituting Schaffer's U-shaped actuating members with

Hartley's string would "change Schaffer's principles of operation." Patent Owner and Dr. Zalesky provide three rationales for why they believe this to be the case: (1) Hartley's string would not "forcibly disengage" from Schaffer's seal module, (2) Hartley's string would prevent "easy assembly" of Schaffer's valve, and (3) Hartley's string would reduce the durability of Schaffer's valve. *See* Ex. 1030 ('011 IPR, Patent Owner Response) at 52-60; Ex. 1039 ('011 Zalesky Supp. Decl.) at §§VIII.E-F. I disagree with each of these assertions for the reasons I explain below.

(a) Hartley's String Would Not Prevent "Forcible Disengagement" From Schaffer's Seal Module

241. I disagree with Patent Owner's contention that depressing Schaffer's actuator buttons would not allow Hartley's string to "forcibly disengage opposing outer walls 27 of the seal module 100 allowing the portion 108 of the containment structure 160 to retract to an uncollapsed configuration." Ex. 1007 (Schaffer) at [0077]. 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.” *Id.* 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 ’669 patent’s filament does.

(b) Hartley’s String Would Not Prevent Assembly Of Schaffer’s Valve

242. Patent Owner and Dr. Zalesky argue that Hartley’s string would “introduce assembly difficulties” to Schaffer’s valve and would prevent assembly of the valve using the exemplary steps provided in paragraph 83 of Schaffer. I disagree.

243. First, I note that Schaffer does not claim to be easy to manufacture or assemble.

244. Second, Schaffer states that the assembly steps in paragraphs 82-83 are “one option” or “an example.” Ex. 1007 (Schaffer) at [0082]-[0083]. Schaffer does not state or suggest that the exemplary processes described in paragraphs 82-83 are the only way to assemble the valve.

245. Third, as I explained during my deposition in the Litigation, Hartley’s string would not have made Schaffer’s valve so much more difficult to manufacture that it would have discouraged a person of ordinary skill in the art from making the

combination. A person of ordinary skill in the art would have known of many ways to assemble the valve with the string or wire member. For example, a tapered fixture could be used to introduce the seal module through the looped string/wire member that is already attached to the buttons. Alternatively, the seal module could be positioned in the valve and the string/wire member could be looped around the module, then the springs and buttons inserted before the string/wire member is attached to the buttons. Schaffer's housing could also be formed from two detachable pieces, which would allow the internal components of the valve to be assembled prior to closing the housing. After the string/wire member and seal module are assembled, the housing could then be secured through well-known means such as adhesives, screws, or clips.

246. Notably, the '669 patent is silent on how its disclosed hemostasis valves can or should be assembled. The '669 patent therefore presumes that it would have been within the capabilities of a person of ordinary skill in the art to determine how to assemble its valves. Thus, the '669 patent is consistent with my opinion that a person of ordinary skill in the art would have known of many ways to assemble a hemostasis valve with a string like the valve that would result from the combination of Schaffer and Hartley.

247. Fundamentally, Schaffer's valve uses simple, predictable components and a person of skill would have had ample training and experience to manufacture the valve using Hartley's string.

(c) **Hartley's String Or Eller's Wire Member
Would Not Weaken The Durability Of
Schaffer's Valve**

248. I disagree with Patent Owner's assertion that substituting Schaffer's U-shaped actuating members with Hartley's string would weaken the durability of Schaffer's valve. Hartley uses the string for the same purpose it would be used in Schaffer's valve and it does not suggest any issues with durability. In addition, a person of ordinary skill in the art in 2018 would have known of many durable materials that could be used to form a string for use in a medical device, such as polypropylene or other suture material. Accordingly, to the extent that a person of ordinary skill in the art was concerned about the durability of the valve, they could have simply used one of the known, durable materials to form the string. Durability concerns would not have dissuaded a person of ordinary skill in the art from substituting Schaffer's U-shaped actuating members with Hartley's string.

249. I also note that the same durability concerns that Patent Owner raises for Hartley's string would apply equally to the filaments disclosed in the '669 patent. Therefore, I do not believe that durability provides any basis to distinguish the '669 patent from the prior art.

3. **“the button is configured to be actuated from a first position to a second position to loosen the filament to allow the tubular member to expand to unseal the hemostasis valve to allow the interventional device to be inserted through the hemostasis valve”**

250. Schaffer, alone and in combination with Hartley’s string, discloses “the button is configured to be actuated from a first position to a second position to loosen the filament to allow the tubular member to expand to unseal the hemostasis valve to allow the interventional device to be inserted through the hemostasis valve.”

251. Schaffer’s hemostasis valve functions by increasing tension on the actuating members (i.e., filament) to close the valve to fluid flow and loosening tension on the actuating members (i.e., filament) to open the valve. Schaffer discloses that in a first position, the U-shaped actuating members are “at least partially circumferentially [sic] disposed about the portion 108 of the seal module 100 depressing and at least partially collapsing a portion 108 of the containment structure 160 by a compressive force 67 (e.g. by a spring 210).” Ex. 1007 (Schaffer) at [0077]. This position is depicted in Figure 32, which shows that the central lumen is constricted and sealed in the first position:

Fig. 32

Id. at [0077], Fig. 34.

252. Thus, moving Schaffer's actuator buttons to the second position loosens the actuating members (i.e., filament) from the tubular member and allows the tubular member to expand to unseal the valve. As I explained previously, a person of ordinary skill in the art would have reasonably expected that this same loosening mechanism would occur if Schaffer's U-shaped actuating members were replaced with Hartley's string. *Supra* ¶¶231-232.

4. "the spring is configured to bias the button to the first position"

253. Schaffer, alone or combined with Hartley's string, discloses that "the spring is configured to bias the button to the first position."

254. Schaffer discloses that in a first position, the U-shaped actuating members are "at least partially circumferentially [sic] disposed about the portion 108 of the seal module 100 depressing and at least partially collapsing a portion 108 of the containment structure 160 ***by a compressive force 67 (e.g. by a spring 210).***" Ex. 1007 (Schaffer) at [0077] (emphasis added). Thus, the compressive force of Schaffer's spring biases the actuator buttons to the first position in which the lumen of Schaffer's valve is sealed.

5. Motivation to Combine

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

256. First, Garrison describes combining "an adjustable-opening valve" 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 would have reasonably expected success in combining, Schaffer's valve with Garrison based on Garrison's express suggestion to do so.

257. Second, Schaffer discloses that its hemostasis valve is intended "for use with catheters" and provides "a durable stasis valve that blocks the flow of gas or fluid completely and immediately with or without an instrument in place within the gas/fluid path." Ex. 1007 (Schaffer) at [0002], [0008]. Schaffer further discloses that a range of instruments can be used within the valve, such as "a catheter, guidewire, needle, or fiber." *Id.* at [0056], [0074]. Thus, Schaffer's valve would allow for tools to be inserted through Garrison's proximal hub/adaptor 2065, as disclosed in Garrison, while preventing blood from leaking through the ports during the procedure.

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

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

260. Fifth, a person of ordinary skill in the art in January 2018 had a finite number of predictable hemostasis valves to choose from, including Schaffer's valve. A person of ordinary skill in the art would have found it obvious to try any of these hemostasis valves in combination with Garrison's system. Moreover, the

known valves, including Schaffer's adjustable-opening hemostasis valve, were simple mechanical structures that operate in a predictable way. I cannot see any technical reason that a person of ordinary skill in the art would not have been able to attach Schaffer's valve to the aspiration catheters in Garrison. For this additional reason, a person of ordinary skill in the art would have reasonably expected success in combining any of the known valves with Garrison.

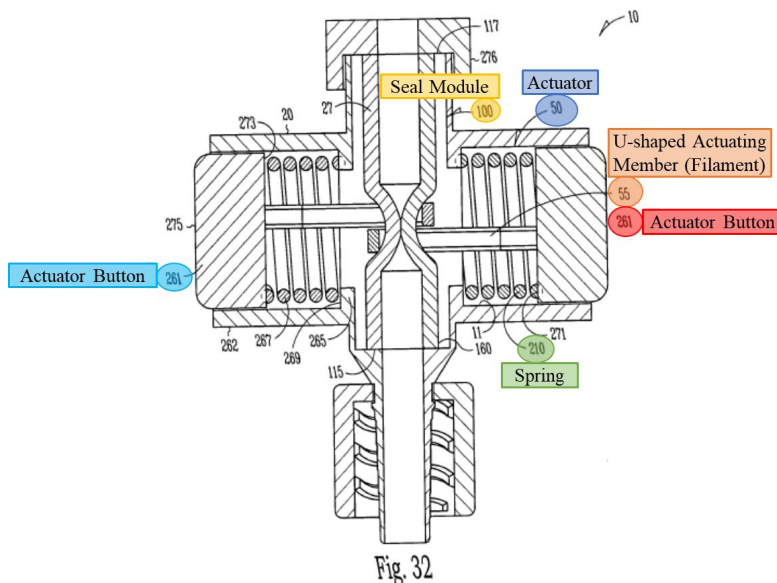
B. Claim 26 – “the hemostasis valve comprises a tubular member, a button, and a filament coupled to the button and the tubular member, and wherein the button is configured to be actuated from a first position to a second position to loosen the filament to allow the tubular member to expand to unseal the hemostasis valve to allow the interventional device to be inserted through the hemostasis valve”

261. Claim 26 recites the “aspiration system of claim 15 wherein the hemostasis valve comprises a tubular member, a button, and a filament coupled to the button and the tubular member, and wherein the button is configured to be actuated from a first position to a second position to loosen the filament to allow the tubular member to expand to unseal the hemostasis valve to allow the interventional device to be inserted through the hemostasis valve.” Garrison and optionally Goff in combination with Schaffer and optionally Hartley renders Claim 26 obvious for the same reasons I explained previously for Claim 12. *Supra* §IX.A.

C. **Claim 27 – “the button is movable from the second position to the first position to tighten the filament to allow the tubular member to collapse and seal about a portion of the interventional device”**

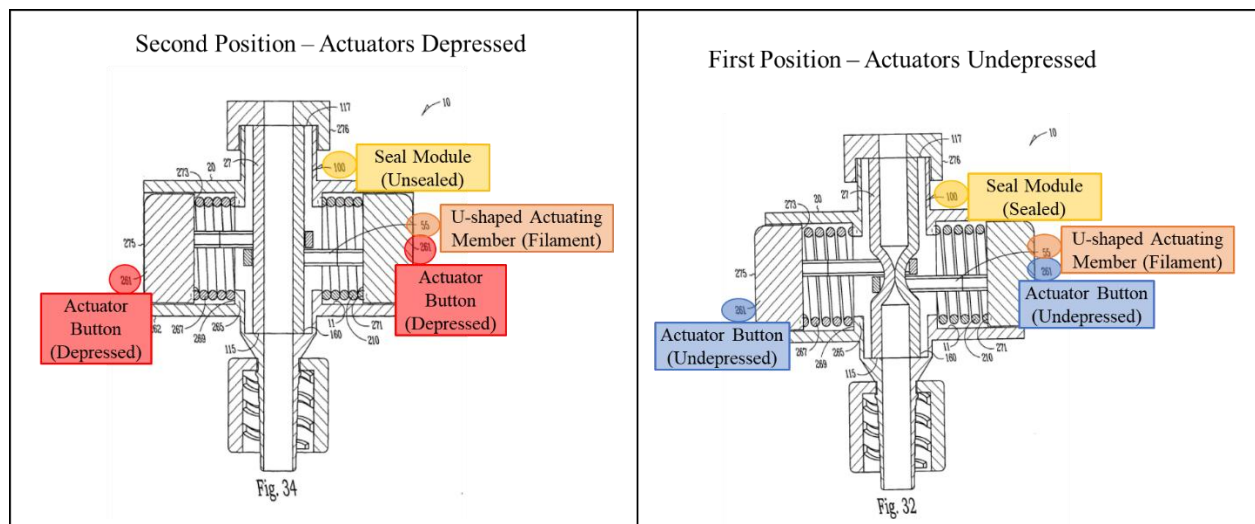
262. Claim 27 recites the “aspiration system of claim 26 wherein the button is movable from the second position to the first position to tighten the filament to allow the tubular member to collapse and seal about a portion of the interventional device.” Garrison and optionally Goff in combination with Schaffer and optionally Hartley renders Claim 27 obvious.

263. As I explained previously for Claim 12, Schaffer’s valve includes two spring-loaded actuator buttons 261 that are “movable from a first position to a second position on opposing sides of the housing”:



Ex. 1007 (Schaffer) at [0075]-[0076], Figs. 31-32. Schaffer discloses that when there is no depressing force on the actuator buttons, the springs cause the actuator buttons to move away from the seal module, tightening the U-shaped actuating

members around the seal module to constrict and seal the valve, which is illustrated in Figures 32 and 34:



Id. at [0077]. As I explained previously for Claim 12, a person of ordinary skill in the art would have reasonably expected that the same tightening would occur when the buttons move from the second to the first position if Schaffer’s U-shaped actuating members were replaced with Hartley’s string. *Supra* §IX.A.3.

D. Claim 28 – “the hemostasis valve further comprises a spring configured to bias the button to the first position”

264. Claim 28 recites the “aspiration system of claim 27 wherein the hemostasis valve further comprises a spring configured to bias the button to the first position.” Garrison and optionally Goff in combination with Schaffer and optionally Hartley renders Claim 28 obvious for the same reasons I explained previously for Claim 12. *Supra* §IX.A.

X. SECONDARY CONSIDERATIONS

265. I am not aware of any secondary considerations of nonobviousness relating to the claims of the '669 patent.

266. The methods and devices claimed in the '669 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 included the conventional components recited in the claims of the '669 patent. *See, e.g., supra* §VI (discussing Garrison).

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

XI. CONCLUSION

268. For the foregoing reasons, it is my opinion that of Claims 1-5, 8, 10-12 14-19, 22, 24-28, and 30 of the '669 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.

269. 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.

270. 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 December 12, 2025 in Kihei, HI.

troy thornton

Troy Thornton