

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

IMPERATIVE CARE, INC.,
Petitioner,

v.

INARI MEDICAL, INC.,
Patent Owner.

Case No. IPR2025-00289
Patent No. 11,554,005

**DECLARATION OF TROY L. THORNTON
IN SUPPORT OF PETITION FOR *INTER PARTES* REVIEW OF
U.S. PATENT NO. 11,554,005**

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TABLE OF EXHIBITS

Exhibit No.	Description
1001	U.S. Patent No. 11,554,005 (“the ’005 patent”)
1002	Excerpts from the prosecution history of the ’005 patent
1003	Expert Declaration of Troy Thornton
1004	Resume of Troy Thornton
1005	U.S. Patent Publication US 2003/0225379 A1 to Schaffer et al. (“Schaffer”)
1006	U.S. Patent Publication No. 2003/0116731 A1 to Hartley (“Hartley”)
1007	U.S. Patent No. 9,980,813 B1 to Eller (“Eller”)
1008	Drawings Submitted During Prosecution of U.S. Patent Application No. 10/371,190 dated June 18, 2003
1009	U.S. Patent No. 5,429,616 to Schaffer (“Schaffer ’616”)
1010	U.S. Patent Publication US 2011/0144592 A1 to Wong et al. (“Wong”)
1011	U.S. Patent Publication No. 2015/0173782 A1 to Garrison et al. (“Garrison”)
1012	RESERVED
1013	RESERVED
1014	U.S. Patent No. 4,723,550 to Bales et al.
1015	U.S. Patent No. 5,895,376 to Schwartz et al.
1016	U.S. Patent No. 12,109,384 B2 to Merritt et al.
1017	U.S. Patent Application No. 16/117,519 (the “’519 Application”)

Table of Exhibits 1

Exhibit No.	Description
1018	U.S. Patent No. 7,775,501 B2 to Kees (“Kees”)
1019	U.S. Patent Publication No. 2016/022041 A1 to Garrison et al. (“Garrison ’741”)
1020	U.S. Patent No. 6,776,770 B2 to Treretola
1021	U.S. Patent Publication No. 2010/0042118 A1 to Garrison et al.
1022	U.S. Patent No. 5,938,645 to Gordon (“Gordon”)
1023	U.S. Patent Publication No. 2014/0296868 A1 to Garrison et al.
1024	WIPO Publication No. WO 2006/124307 A2 to Goff et al.

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 1-15 of U.S. Patent No. 11,554,005 (“the ’005 patent”). For the reasons discussed herein, I have concluded that Claims 1-15 of the ’005 patent are unpatentable because the prior art references anticipate the 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 ’005 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 ’005 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 '005 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 '005 patent;
- The level of ordinary skill in the art pertaining to the '005 patent;
- The teachings of the prior art; and
- Whether Claims 1-15 of the '005 patent would have been obvious to a person of ordinary skill in the art at the time of the alleged invention, in view of the prior art.

D. Materials Considered

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

17. I have also relied on my education, training, and experience, and my knowledge of pertinent literature in the field of the '005 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 '005 patent.

19. Although I have had some prior exposure to patent matters, I am not an expert in patent law. Therefore, I have been advised of certain principles of patent law applicable in this matter, which I have used in arriving at my

determinations and opinions. The paragraphs below express my understanding of how I must apply these principles in forming my opinions.

A. Claim Construction

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

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

B. Anticipation

22. I understand that a patent claim is unpatentable if it is “anticipated” by a piece of prior art. I have been instructed that a claim is “anticipated” if a prior art reference describes, either expressly or inherently, each limitation of the claim. I understand that this description must be recognizable to a person of ordinary skill in the art at the time of the alleged invention (in this case, August 2018).

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

C. Obviousness

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

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

26. The prior art references applied in this Declaration are analogous art that is usable in an obviousness combination. The references are from the same field as the '005 patent, e.g., devices for aspirating unwanted material from a patient. The references are also pertinent to the problem the inventor was focused on, e.g., removing clots, emboli, and thrombi from a patient's blood vessel and sealing the catheter with a hemostasis valve during such procedures.

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

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

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

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

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

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

31. An obviousness analysis also must consider whether there are additional factors that would indicate that the invention would not have been obvious. These factors include whether there was: (i) a long-felt need in the industry; (ii) any unexpected results; (iii) skepticism of the invention; (iv) a teaching away from the invention; (v) commercial success; (vi) praise by others for the invention; and (vii) copying by others. I am not aware of any evidence under these factors that would suggest that Claims 1-15 of the '005 patent would have been non-

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

D. Person of Ordinary Skill in the Art

32. It is my understanding that when interpreting the claims of the ’005 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 ’005 patent is August 13, 2018. I have been informed that all of the references relied upon in this Declaration qualify as prior art under that priority date.

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

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

35. Based on my review of the specification and claims of the '005 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 product design or engineering experience.

36. I can make this assessment because during my career, I had experience assigning engineers to work on mechanical design projects, including projects to design hemostasis valves or incorporate them into catheter-based projects. For such projects, I would assign an engineer with the experience described above.

III. THE '005 PATENT

A. Summary of the '005 Patent

37. The '005 patent is titled “System for Treating Embolism and Associated Devices and Methods” and describes an aspiration system for intravascular removal of clot material. Ex. 1001 ('005 patent) at 4:10-4:26. The '005 patent explains that the system can treat various clots including pulmonary embolisms (“PE”), cerebral embolism, and deep vein thrombosis (“DVT”). *Id.* at 4:44-4:51. The aspiration system includes an aspiration “assembly 10” having a “catheter subsystem 100,” “pressure source 140,” and “tubing subsystem 120.” *Id.* at 5:18-5:23.

38. The catheter subsystem has a catheter 102 [orange below] “comprising an elongated shaft defining a lumen 104,” and a “valve 106” [yellow below] with a “lumen 109 extending therethrough.” *Id.* at 5:18-5:47. The '005 patent explains

that the valve “is configured to maintain hemostasis during a clot removal procedure by preventing fluid flow in the proximal direction through the valve 106” when other components are inserted, such as “interventional devices” or “other aspiration catheters.” *Id.*

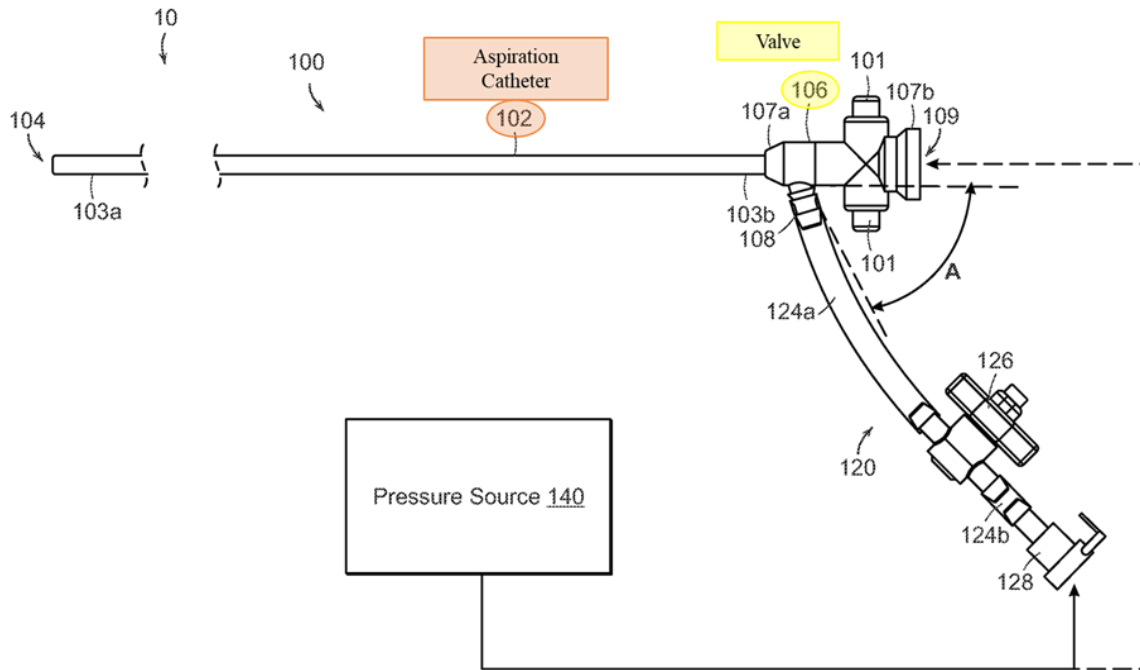


FIG. 1

Id. at Fig. 1.

39. The '005 patent discloses the pressure source [red below] is “configured to generate (e.g., form, create, charge, build-up, etc.) a vacuum (e.g., negative relative pressure) and store the vacuum for subsequent application to the catheter subsystem 100.” *Id.* at 6:50-6:53. “[T]he pressure source can be a pump (e.g., an electric pump coupled to a vacuum chamber) while, in other embodiments, the pressure source can include one or more syringes that can be actuated or

otherwise activated by a user of the assembly 10 to generate and store a vacuum therein.” *Id.* at 7:29-7:34.

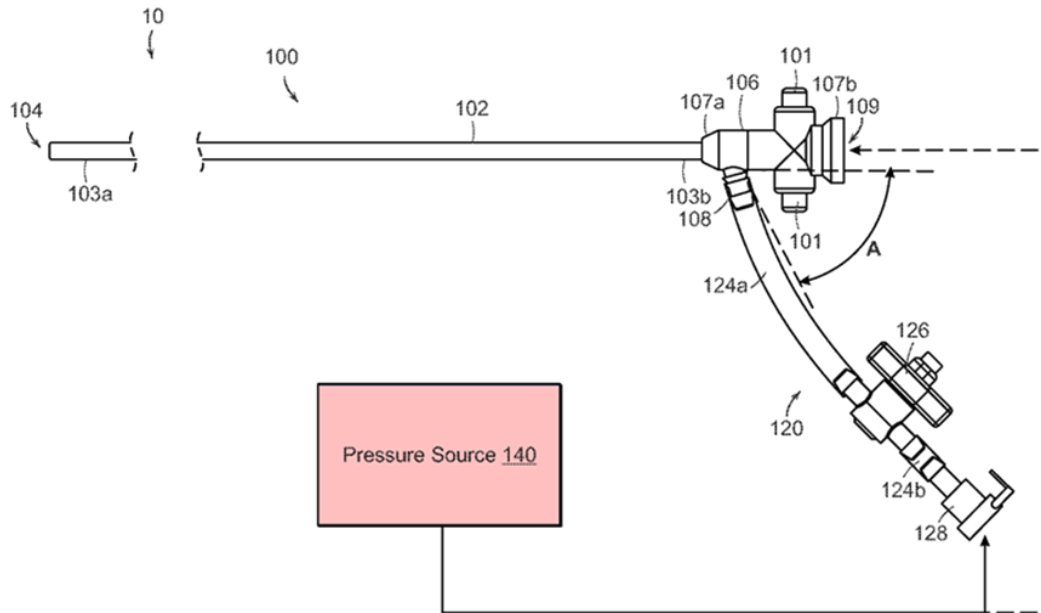


FIG. 1

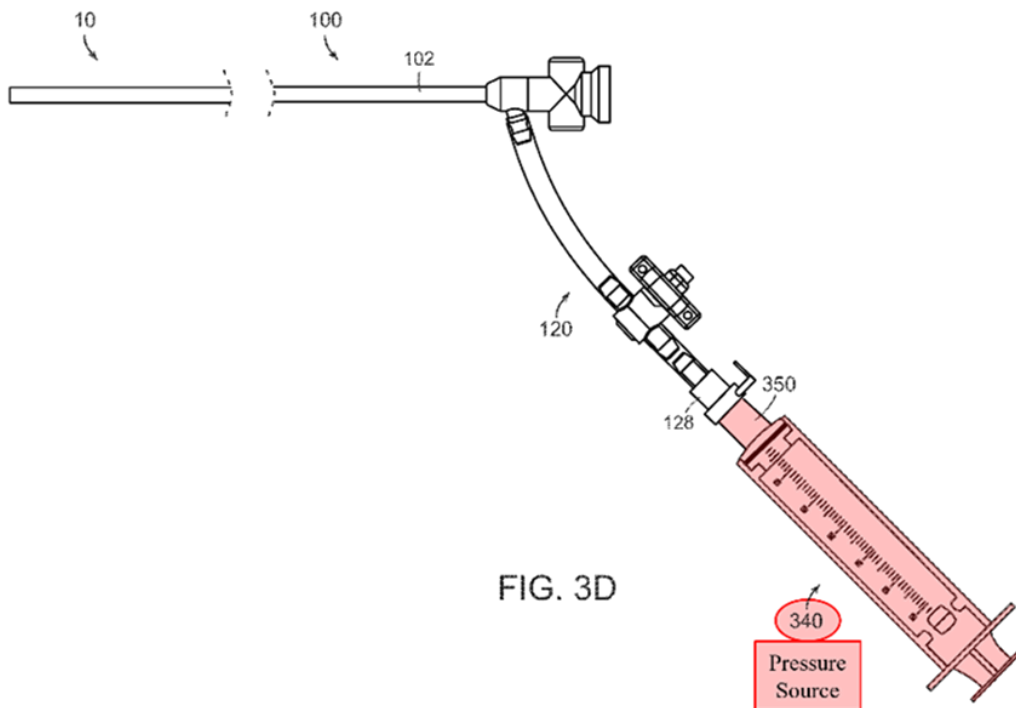


FIG. 3D

Id. at Figs. 1, 3D.

40. The '005 patent explains that the tubing subsystem “fluidly couples the catheter subsystem 100 to the pressure source 140.” *Id.* at 5:66-5:67. The tubing subsystem can include “one or more tubing sections 124,” [green] at least one “fluid control device 126” [purple] such a stopcock, and at least one “connector 128 for fluidly coupling the tubing subsystem 120 to the pressure source 140 and/or other suitable components.” *Id.* at 6:1-6:16.

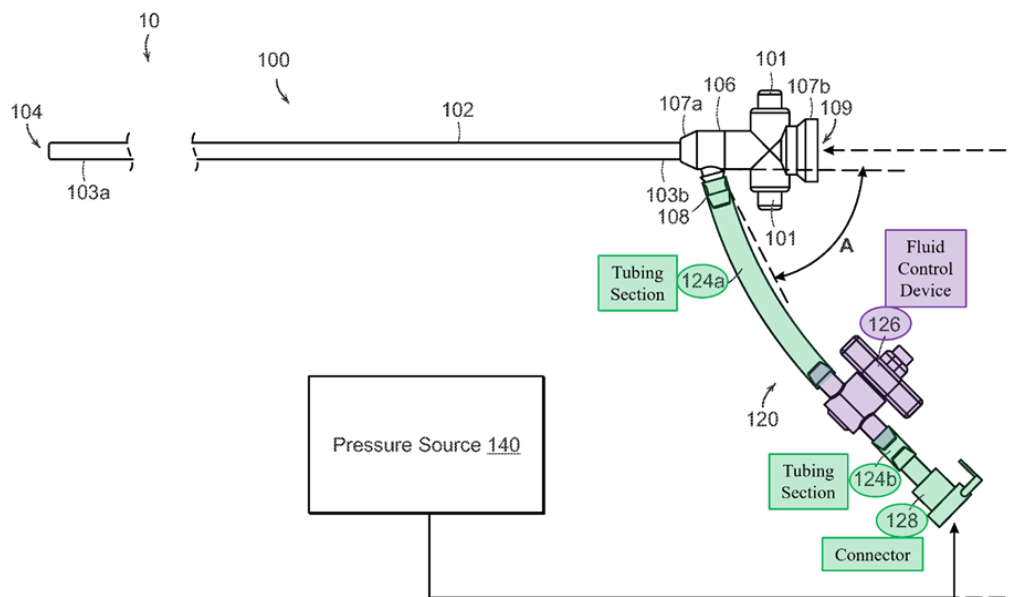
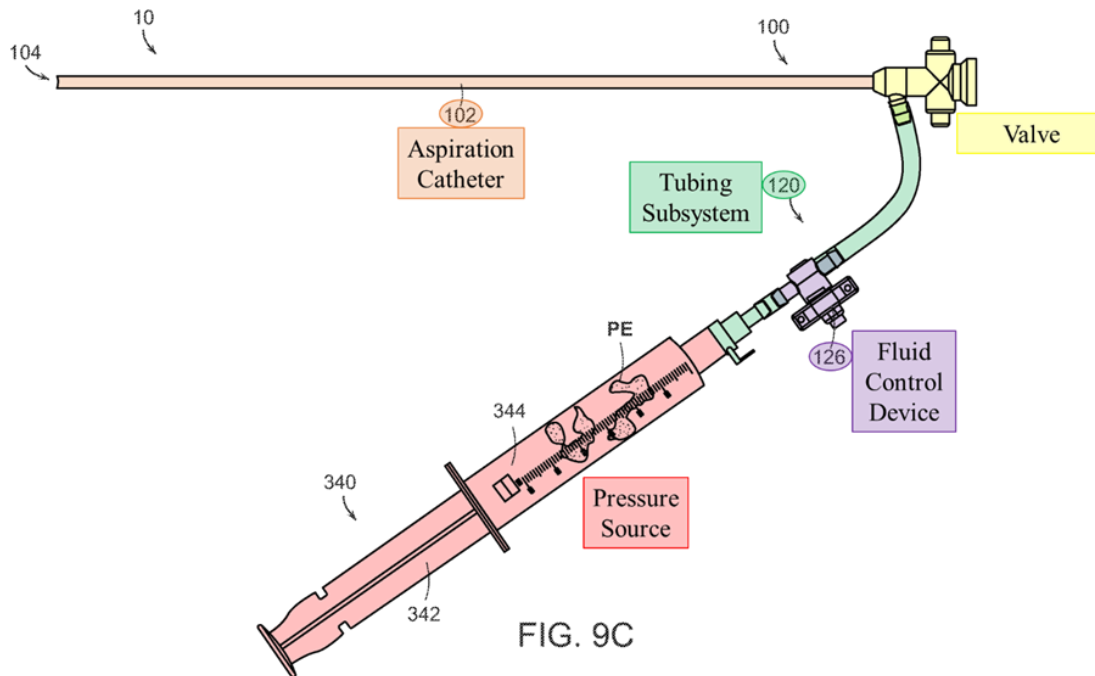


FIG. 1

Id. at Fig. 1.

41. The '005 patent explains that a user “can first close the fluid control device 126 before activating the pressure source 140 to build up vacuum pressure within the pressure source 140 (e.g., a vacuum chamber of the pressure source 140).” *Id.* at 6:56-6:59. After pressure is generated, “the user can actuate (e.g., twist a handle of) the fluid control device 126 to open the fluid control device 126.”

Id. at 18:43-18:47. Opening the fluid control device 126 will “fluidly connect the pressure source 140 to the catheter subsystem 100 and thereby apply or release the vacuum stored in the pressure source 140 to the lumen 104 of the catheter 102.” *Id.* at 6:63-7:5.



Id. at Fig. 9C. The ‘005 patent also explains that “[o]pening of the fluid control device 126 instantaneously or nearly instantaneously applies the stored vacuum pressure to the tubing subsystem 120 and the catheter 102, thereby generating suction throughout the catheter 102.” *Id.* at 7:1-7:5.

42. The ‘005 patent also describes variations of the aspiration system described above. For example, the patent describes variations having a “pressure source 1900” with a “secondary syringe 460” and a “canister 1940.” *Id.* at 31:9-27,

Fig. 19. The “canister 1940 further includes a filter 1942,” which “separates the blood from the clot material within the cannister 1940.” *Id.* at 31:28-36.

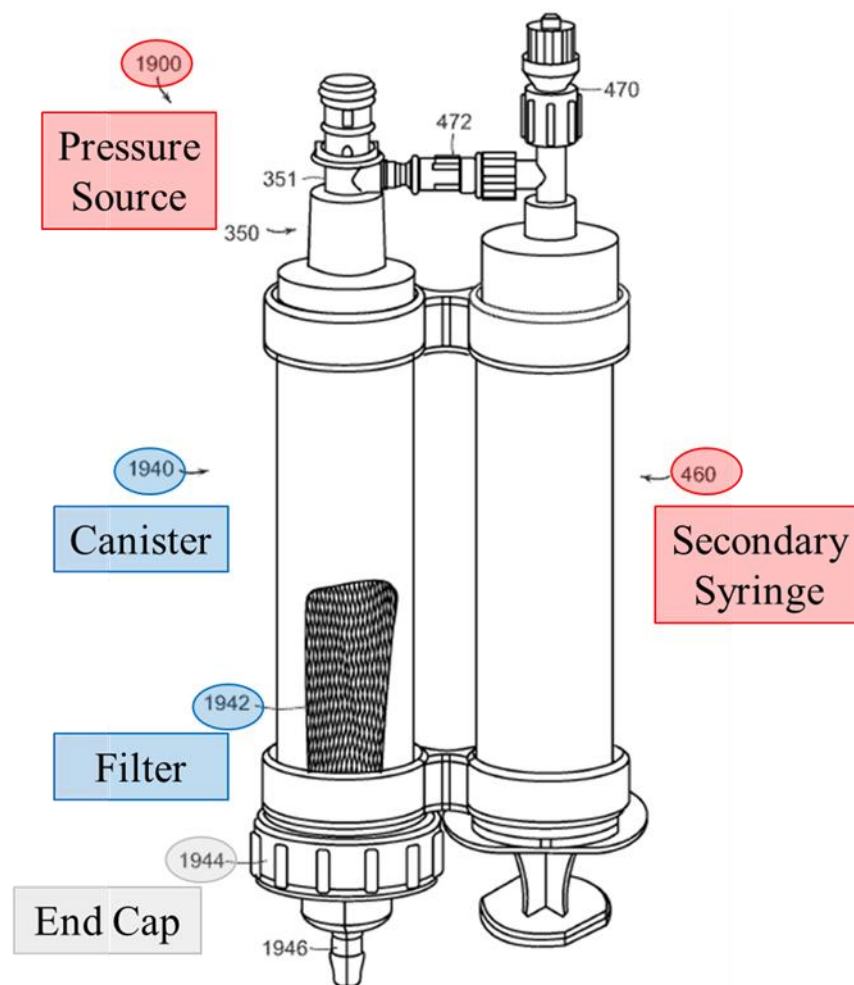


FIG. 19

Id. at Fig. 19.

43. While the claims of the '005 patent recite aspects of a hemostasis valve, the '005 patent does not describe the structure of the hemostasis valve that can be included in valve 106. *See id.* at 5:30-54. But the '005 patent does state that “the valve 106 can be a valve of the type disclosed in U.S. patent application Ser.

No. 16/117,519, filed Aug. 30, 2018, and titled ‘HEMOSTASIS VALVES AND METHODS OF USE,’ which is incorporated herein by reference in its entirety.” *Id.* at 5:50-54. For ease of reference, I refer to U.S. patent application Ser. No. 16/117,519 as the “’519 Application” herein. I do not take any position on whether Patent Owner effectively incorporated the ’519 Application by reference in the ’005 patent, and none of my discussion of the ’519 Application should be construed as an admission or acknowledgement that the ’519 Application was effectively incorporated.

44. The ’519 Application describes a catheter and a hemostasis (or “garrote”) valve for use during minimally invasive intravascular procedures. Ex. 1017 (’519 Application) at [0033]. The hemostasis valve includes an “elongate member 132” extending through the interior of the valve housing 128. *Id.* at [0039]. The ’519 Application explains that the elongate member has a “thin-walled compliant tubular structure” that facilitates “the uniform collapse of the elongate member 132 and the sealing of the elongate member 132”:

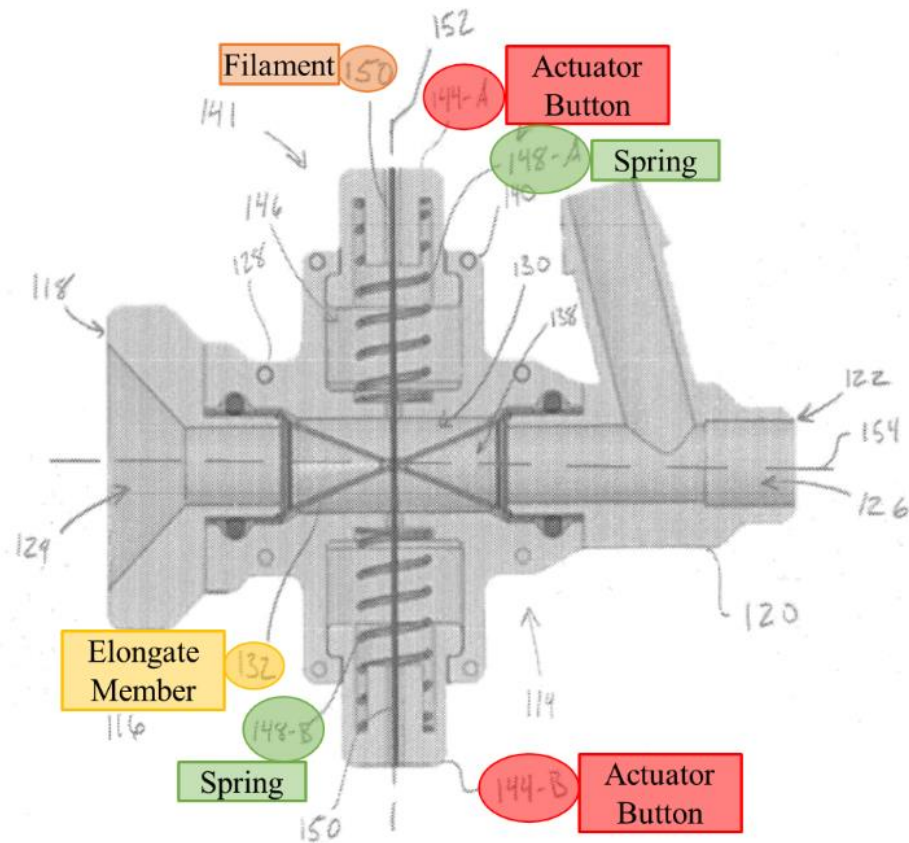


Figure 2

Id. at [0039], Fig. 2.

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

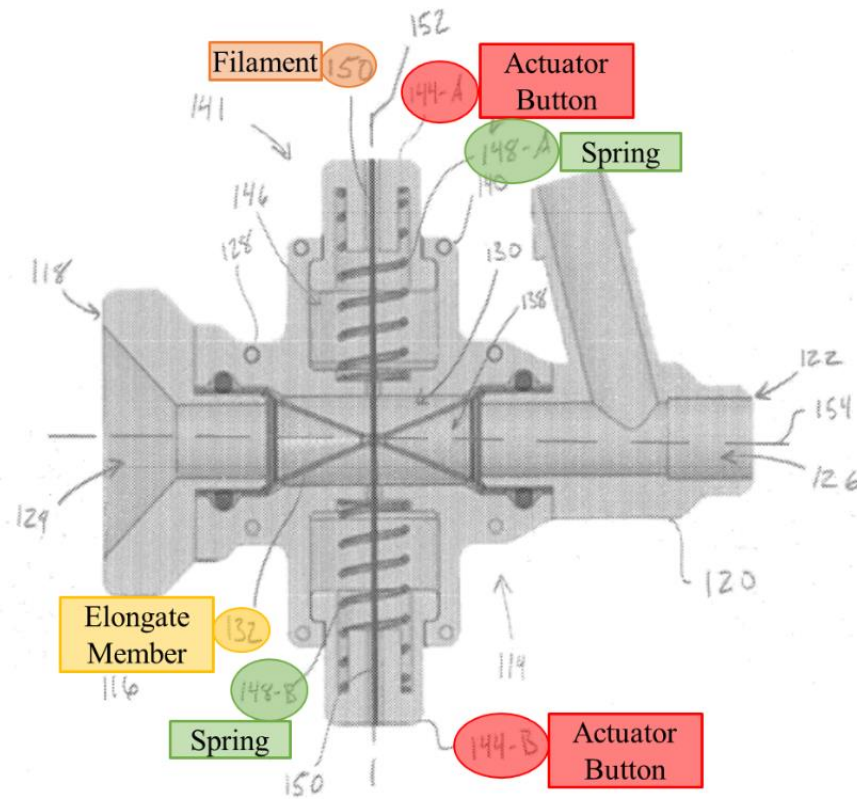


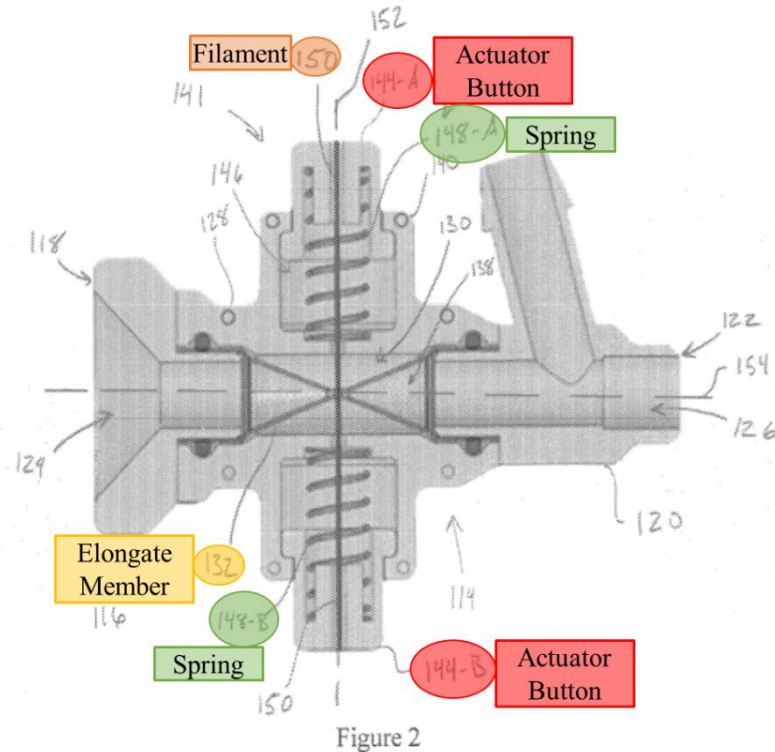
Figure 2

Id., [0042-0043] at Fig. 2. The constricting mechanism includes “an actuator 142 which can be a manual actuator such as one or several buttons 144; and the at least one filament 150 that can extend at least partially around the elongate member 132.”

Id. The “filament 150 can be coupled to the actuator 142 such that the filament 150 selectively constricts, collapses, and/or seals the elongate member 132 ... based on the movement and/or position of the actuator 142.” *Id.* at [0048].

46. The '519 Application also explains that the valve can include a “bias feature,” such as a spring, which biases the valve to either the closed (referred to as first) or open (referred to as second) position when no outside forces are being

applied to the actuator button(s). *Id.* at [0045]. In Figure 2, the springs bias the valve toward the closed configuration:



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

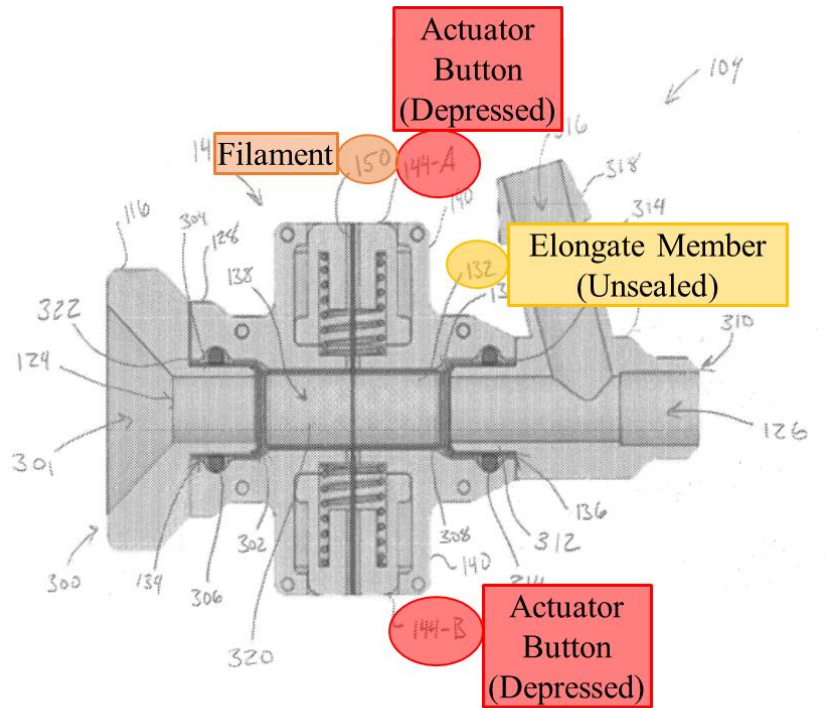


Figure 3

Id.

B. The Challenged Claims

47. The challenged claims include Claims 1-15 of the '005 patent. Claim 1 is the only independent claim.

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

1. A vacuum aspiration system, comprising:
 - a housing;
 - a flow path extending through the housing;
 - an on-off control in the flow path;
 - a first catheter in fluid communication with the flow path and a connector configured to place a source of aspiration in communication with the flow path;
 - a clot cannister fluidly coupled to the flow path; and

a hemostasis valve in the housing configured to receive a second catheter and direct the second catheter through the first catheter, wherein the hemostasis valve comprises:

a tubular member defining a lumen configured to slidably receive the second catheter;

a constricting mechanism including a filament and an actuator coupled to the filament, the filament comprising a first portion extending around at least a portion of the tubular member and a second portion having a first end extending from the first portion in one direction and a second end extending from the first portion in another direction, and the actuator comprises a first member coupled to the first end of the filament and a second member coupled to the second end of the filament, wherein the first member and the second member of the actuator are moveable between (a) a first position wherein the filament circumferentially constricts the lumen to create a seal and (b) a second position wherein the filament is moved to at least partially open the lumen; and

a biasing system configured to bias the first member and the second member to the first position.

Ex. 1001 ('005 patent) at Claim 1.

C. Prosecution History

49. I have reviewed the '005 patent's prosecution history. I see that the Patent Examiner issued a single non-final office action rejecting original claim 1 as being anticipated by U.S. Patent Pub. No. 2016/0220741 ("Garrison '741," Ex. 1019). Ex. 1002 ('005 patent prosecution history excerpt) at 209-217. I notice that the examiner did not have Schaffer during prosecution, and therefore did not consider the unpatentability arguments presented in this Declaration. I also do not see that the examiner ever mentioned Eller during prosecution.

50. In the non-final rejection, the examiner found that Garrison '741 disclosed a vacuum aspiration system (100) having a hemostasis valve (234) in a housing (220), a connector (226) for connecting to a source of aspiration, and first (320) and second (400) catheters, as I've annotated below:

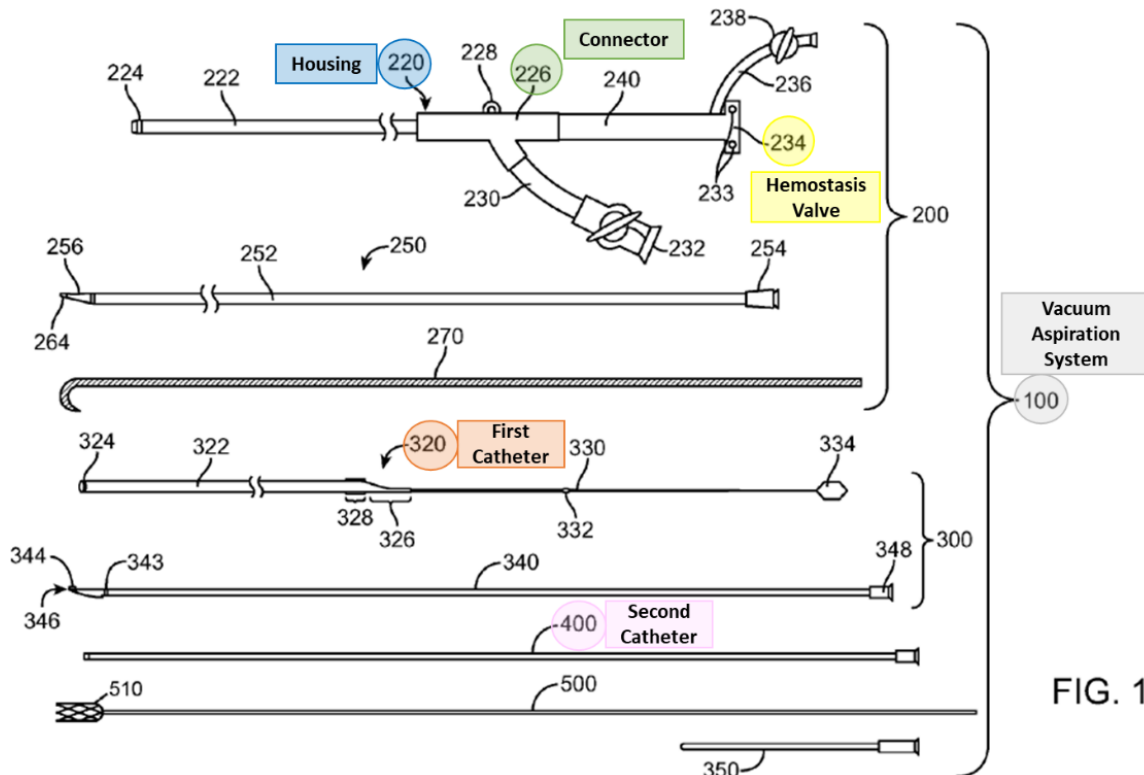


FIG. 1

Id. at 211-212; Ex. 1019 (Garrison '741) at Fig. 1. The examiner also concluded that Garrison '741 disclosed an on-off control (242) and clot cannister (see Fig. 11), as annotated below:

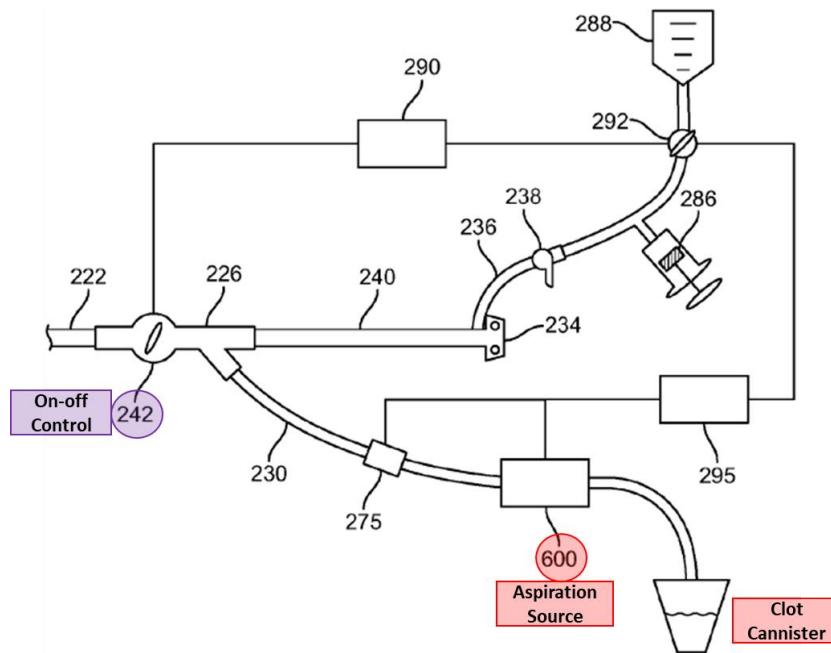


FIG. 11

Ex. 1002 ('005 patent prosecution history excerpt) at 211-212; Ex. 1019 (Garrison '741) at Fig. 11.

51. Although the examiner found that original claim 1 was anticipated by Garrison '741, the examiner found original claims 2 and 11 allowable because they included additional limitations relating to the hemostasis valve (e.g., a “constricting mechanism”). Ex. 1002 ('005 patent prosecution history excerpt) at 212-215. Those limitations are identical to the limitations found in claims 1 and 10 of the '005 patent.

52. The examiner determined that the closest prior art of record to the pending claims was Wong (Ex. 1010), Kees (Ex. 1018), and Hartley (Ex. 1006). *Id.* at 213. The examiner found that Hartley disclosed every limitation of the hemostasis valve recited in original claims 2 and 11 except for an “actuator having

a first member movable coupled to the support and the first spring configured to move the first member.” *Id.* at 214-215. The examiner concluded that neither Wong nor Kees disclosed a “filament” as claimed and further concluded that while “Hartley discloses a filament, a person skilled in the art would recognize that it would [sic] improper to add the filament of Hartley to either device of Wong or Kees for this would conflict with the operation of the devices.” *Id.* at 213-215. The examiner did not provide further information regarding this conclusion.

53. Following the non-final rejection, Patent Owner cancelled pending claim 1 and rewrote pending claim 2 (which issued as claim 1 of the ’005 patent) in independent form to include the limitations relating to the hemostasis valve. *Id.* at 191-199.

IV. CLAIM CONSTRUCTION

54. Independent claims 1 and 10 require a “filament.” I have reviewed the claims, specification, and prosecution history of the ’005 patent and the ’519 Application that is allegedly incorporated by reference into the ’005 patent and in my opinion, a person of ordinary skill in the art in August 2018 would have understood the term “filament” in the claims of the ’005 patent to mean at least: “one or more threads, lines, cords, ropes, ribbons, flat wires, sheets, or tapes.”

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

information about the meaning of “filament.” Claim 1 of the ’005 patent says that the “filament” includes “a first portion extending around at least a portion of the tubular member” and ends that extend in different directions, wherein the filament is moveable between (a) “a first position wherein the filament circumferentially constricts a lumen to create a seal” and (b) “a second position wherein the filament is moved to at least partially open the lumen.” Claim 10 includes similar language for the “filament.” While this language identifies some features that the filament must have (e.g., a first portion, ends that extend in different directions), the claim language does not identify the structures, material, or material properties that form a “filament.”

56. The specification of the ’005 patent does not provide any further guidance on the structures or materials that form a “filament.” The ’005 patent specification does not describe a hemostasis valve having a filament, and it does not use the word “filament” at all. However, the ’519 Application, which the ’005 patent states is incorporated by reference, does identify structures and materials that may form a “filament.” The ’519 Application discloses that the filament can be formed from a range of materials “including, for example, a polymer, a synthetic, and/or a metal.” Ex. 1017 (’519 Application) at [0047]. The ’519 Application also says that “the filament can comprise a single strand such as, for example, a monofilament, [or] the filament can comprise a plurality of strands that can be, for

example, twisted, woven, grouped, and/or fused to form the filament.” *Id.* The ’519 Application also states that “**the filament 150 can comprise one or several threads, lines, cords, rope, ribbon, flat wire, sheet, or tape.**” *Id.* (emphasis added). I have used this specific description of “filament” for my construction.

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

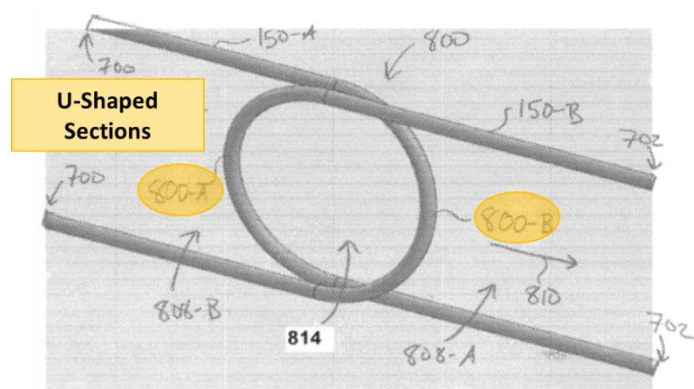


Figure 8

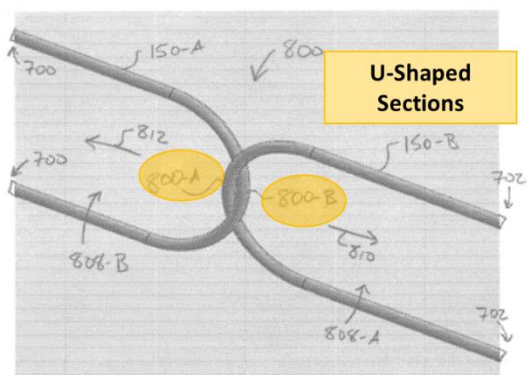


Figure 9

Id. at [0065]-[0067], Figs. 7-9. Focusing specifically on the embodiments having the “U-shaped section,” the ’519 Application explains that the filaments can have “any desired cross-sectional shape.” *Id.* at [0067]-[0070]. The ’519 Application also identifies some exemplary dimensions for the filaments but does not specify

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

58. I understand that the prosecution history can also be relevant in construing patent claims because it can provide insight into how the applicant and the Patent Examiner understood the claims. During prosecution of the '005 patent, the Examiner concluded that the prior art reference Wong, U.S. Patent Publication No. 2011/0144592 (Ex. 1010), failed to disclose a “filament” as claimed. Ex. 1002 ('005 patent prosecution history excerpt) at 213. The Examiner’s dismissal of Wong is consistent with my understanding of “filament” from the '005 patent. Wong discloses two “sliders” 15 and 17 that can be formed from “a suitable generally non-elastic synthetic material.” Ex. 1010 (Wong) at [0042], [0053]. Wong’s slider 15 is “formed as an ashlar-shaped element having a rectangular cross-section, integrally formed with a circular stopper 15a at one end thereof, and including a limiting lever 15b on a middle portion 15c at another end thereof, and two triangle-shaped grooves 15d at two opposing sidewalls 15e in the middle portion 15c which form the ramp-shaped section 23a”:

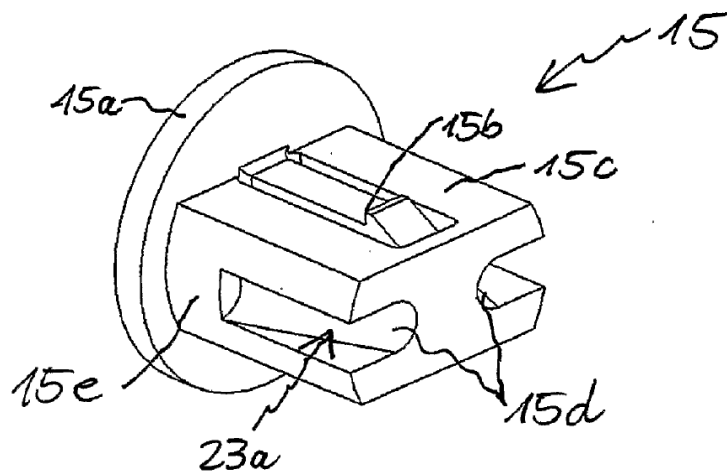


Fig. 3

Id. at [0051], Fig. 3. Wong's slider 17 "is a brake shoe-like element having a V-shaped groove 17a sandwiched between two opposing sidewalls 17b, the V-shaped groove 17a extending along the longitudinal axis of the second slider 17, two protrusions 17c extending in opposing directions out from the two sidewalls 17b, and a holder 17d":

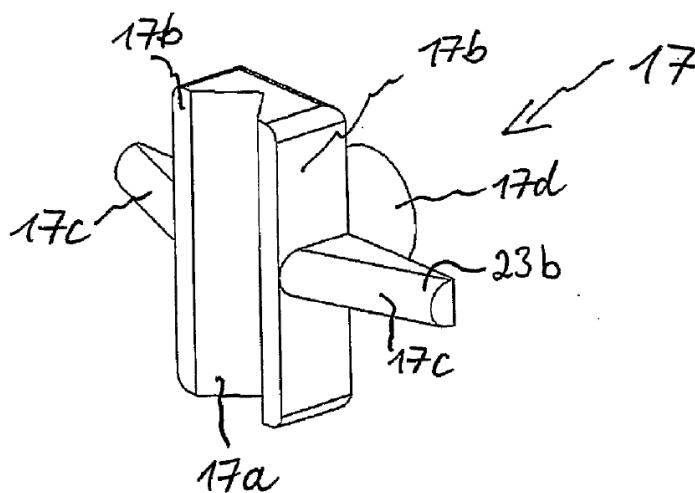


Fig. 4

Id. at [0052], Fig. 4. Thus, Wong's sliders are not "one or several threads, lines, cords, rope, ribbon, flat wire, sheet, or tape" as described in the '519 Application. Ex. 1017 ('519 Application) at [0047].

59. I also see that the Examiner found that Hartley discloses a "filament" as claimed in the '005 patent. Ex. 1002 ('005 Patent Pros. History) at 214. Hartley describes item 14 as a "string." Ex. 1006 (Hartley) at [0031]. Thus, the Examiner's analysis of Hartley is consistent with my claim construction because a string is "one or several threads, lines, cords, rope, ribbon, flat wire, sheet, or tape" as described in the '519 Application. Ex. 1017 ('519 Application) at [0047].

60. I note that in a related proceeding, Patent Owner has argued that "filament" should mean "a thin, flexible length of material formed by one or more strands of material." Patent Owner Preliminary Response re: '011 patent filed in *Imperative Care, Inc. v. Inari Medical Inc.*, IPR2024-01157, Paper 5 at 16 (P.T.A.B. Oct. 29, 2024). However, I have reviewed the '005 patent and the '519 Application, and neither describes the filaments as "thin" or "flexible." Moreover, as I explained above, neither the '005 patent nor the '519 Application provides any criteria for flexibility that would help a person of ordinary skill in the art determine whether a specific material was, in fact, "flexible." While the '519 Application identifies some potential dimensions for the "filament(s)," the application states that those dimensions are exemplary, not mandatory. I also believe that Patent Owner's

use of the phrase “material formed by one or more strands of material” would exclude several of the exemplary “filaments” identified in the ’519 Application. The ’519 Application explains that the filaments can be made of metal or polymers and form, for example, a sheet or tape. Ex. 1017 (’519 Application) at [0047]. A sheet of metal or polymer, or a tape made of metal or polymer, for example, would not include “one or more strands of material.” I have also seen in related patents, such as U.S. Patent No. 12,109,384 (Ex. 1016), that Patent Owner has expressly claimed a filament that is “flexible.” Ex. 1016 (’384 patent) at claim 1. I believe these claims confirm that not all filaments described in the ’519 Application are flexible. I also see that Patent Owner argues that the filament must be flexible to “circumferentially constrict” the lumen to create a seal. But Patent Owner’s own arguments in the related proceeding conflict with that argument. Schaffer’s actuating members circumferentially constrict the seal module and yet, according to Patent Owner, the actuating members are rigid. The U-shaped filaments disclosed in the ’519 Application operate just like Schaffer’s U-shaped actuating members so if Schaffer can circumferentially constrict a lumen with rigid members, then so can the valve in the ’519 Application. Finally, this debate about the meaning of “filament” does not impact my views on unpatentability. As explained below, Patent Owner’s attempts to characterize Schaffer’s actuating members as “rigid” is not supported by Schaffer and is inconsistent with how a person of ordinary skill in

the art would understand Schaffer. Further, Hartley’s and Eller’s string/wire member are unquestionably thin and flexible and meet either definition of “filament.” 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 August 2018 would have understood the term “filament” recited in the claims of the ’005 patent to mean at least: “one or more threads, lines, cords, ropes, ribbons, flat wires, sheets, or tapes.”

V. SUMMARY OF IPR GROUNDS

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

Ground	Claims Challenged	Basis	References
1	1-12, 14-15	35 U.S.C. § 103	Garrison + Schaffer
2	1-15	35 U.S.C. § 103	Garrison + Schaffer + Hartley
3	1-15	35 U.S.C. § 103	Garrison + Schaffer + Eller
4	1-3, 5-6, 9-15	35 U.S.C. § 103	Garrison + Hartley + Eller

VI. GROUNDS 1-3: GARRISON COMBINED WITH SCHAFFER AND OPTIONALLY HARTLEY OR ELLER

62. Garrison discloses an aspiration system for removing unwanted material, such as blood clots, from a patient’s vasculature. As I’ve annotated below, Garrison’s aspiration system includes a catheter [orange], an aspiration source [red],

a connector [green] placing the aspiration source in communication with a flow path through the device, an on/off control [purple], and a clot cannister [blue]:

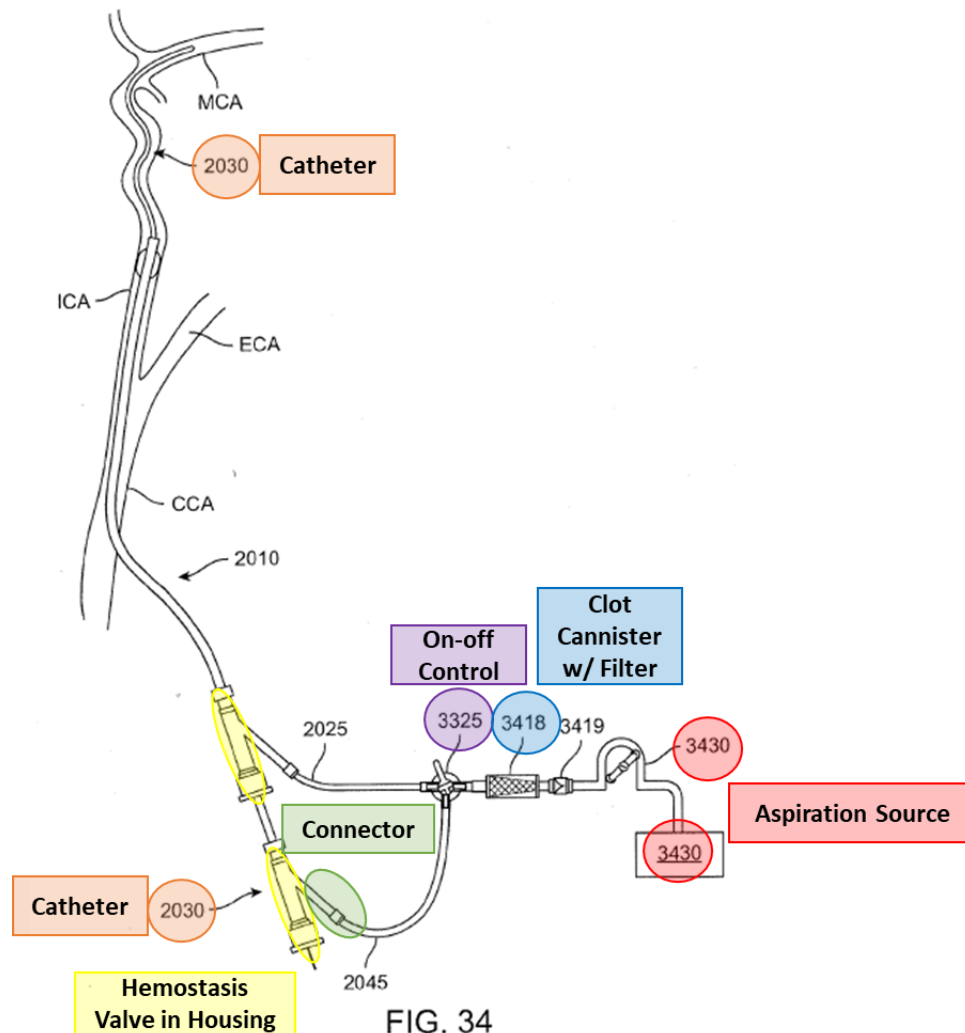
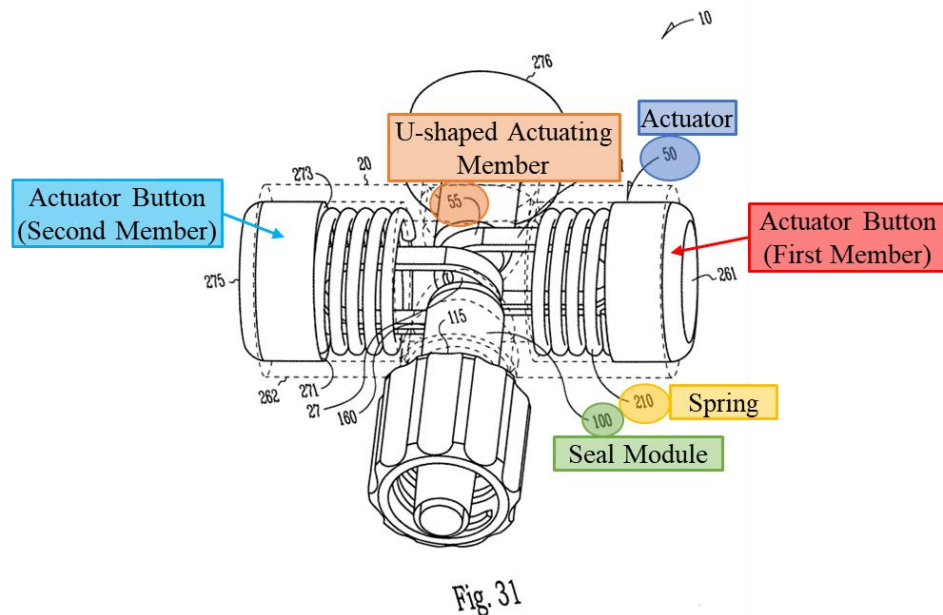


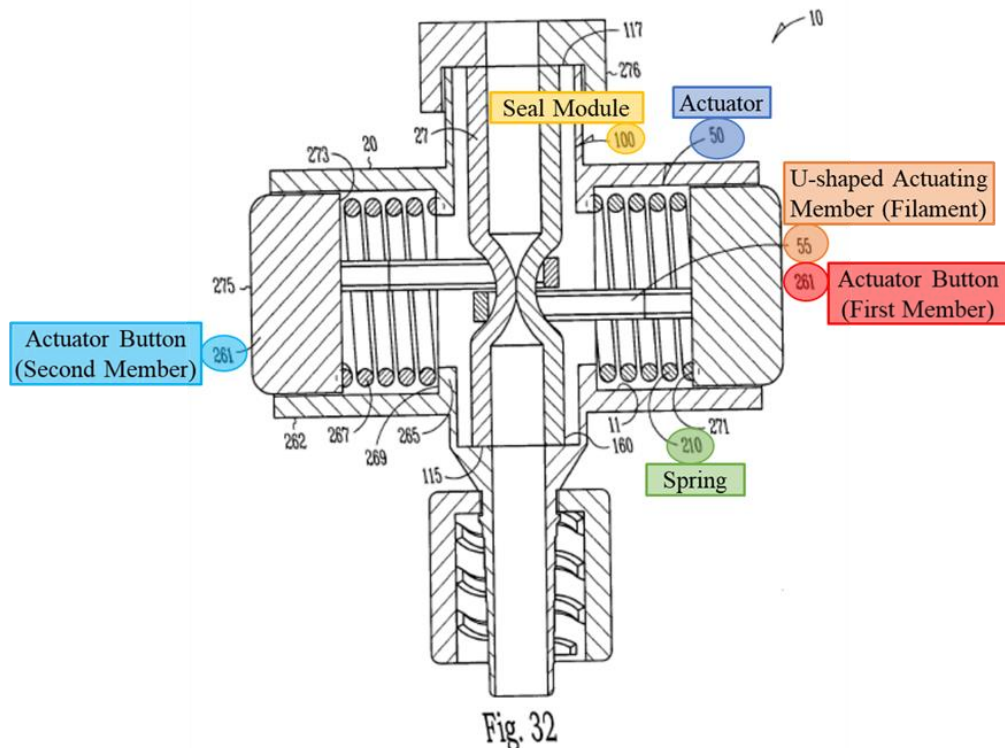
FIG. 34

Ex. 1011 (Garrison) at Fig. 34. Garrison also discloses that its system can include a hemostasis valve to “allow for the introduction of devices therein while preventing or minimizing blood loss via the internal lumen during the procedure.” *Id.* at [0062]. Garrison does not describe the detailed features of the hemostasis valve, and instead presumes that a POSITA would have been familiar with their structures. But Garrison does explain that a variety of hemostasis valves can be used, including

“a static seal-type passive valve, or an adjustable-opening valve such as a Tuohy-Borst valve 227 or rotating hemostasis valve (RHV) (see FIG. 6).” *Id.* at [0062].

63. Schaffer discloses a hemostasis 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. 1005 (Schaffer) at [0002], [0008]. As shown in Figure 32 below, Schaffer illustrates an example of a hemostasis valve that has a tubular seal module 100 extending through the center of the valve and an actuator comprising: (a) two actuator buttons 261 positioned on opposite sides of the seal module, (b) two compression springs 210/267 coupled to the actuator buttons, and (3) two actuating members 55 (which may be U-shaped) that compress the seal module when the actuating buttons are undepressed:





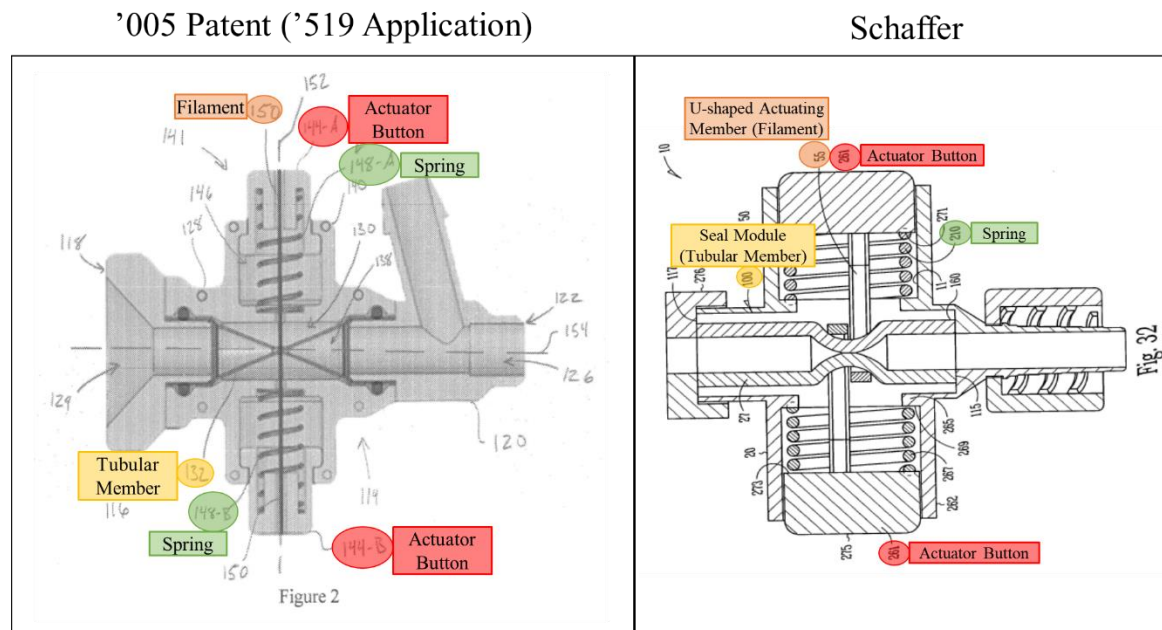
Id. at [0076]-[0077], Figs. 31-32.¹ Notably, the '519 Application also describes the filament in Figures 8 and 9 as U-shaped, stating:

“In some embodiments, the filament 150 can be configured to form a bight 800, which bight 800 can be a single bight or multiple bights. As used herein, a ‘bight’ refers to a U-shaped section between the two ends of the filament 150.”

Ex. 1017 ('519 Application) at [0067]. The example of Schaffer's hemostasis valve depicted in Figures 31-34 has the same components in the same arrangement as the valve described in the '519 Application and claimed in the '005 patent, which is

¹ In this declaration, I have used the versions of Schaffer's drawings that were submitted to the Patent Office during prosecution of the Schaffer application on June 18, 2003 (Ex. 1008) because they are clearer than the copies of the drawings in Schaffer's published application.

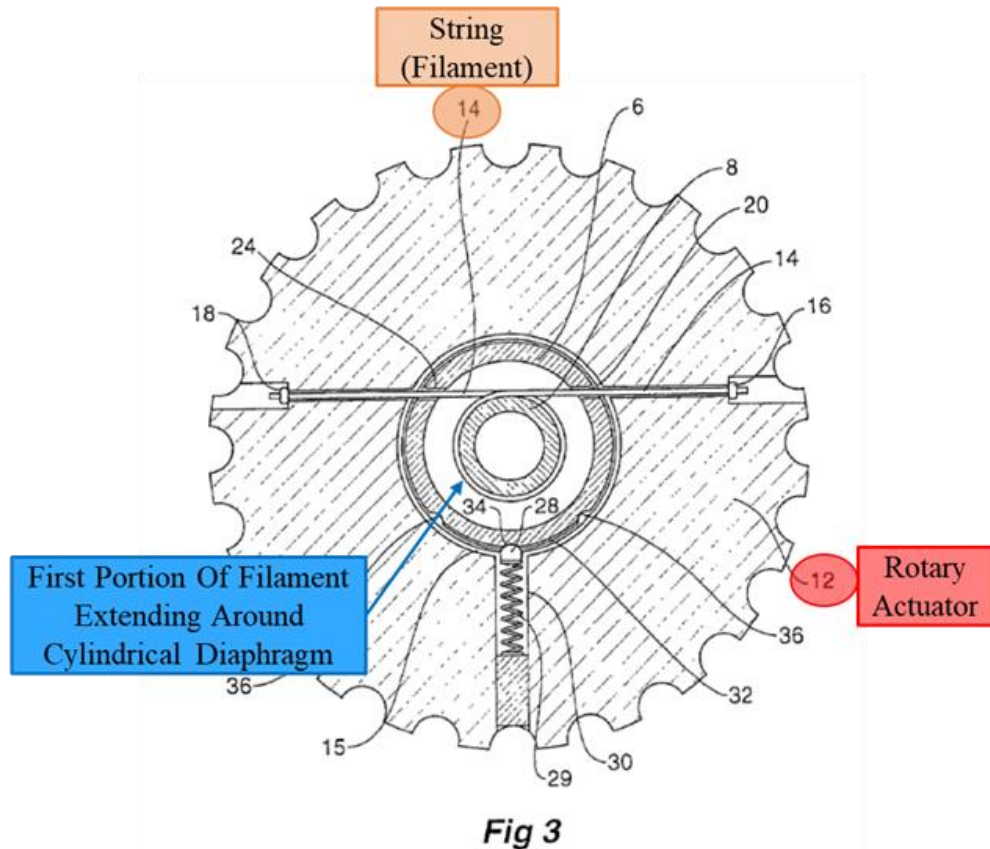
apparent from the side-by-side comparison of Figure 2 of the '519 Application (left) and Figure 32 of Schaffer (right):



Id. at Fig. 2 (left); Ex. 1005 (Schaffer) at Fig. 32 (right). Because Schaffer discloses all of the hemostasis valve limitations recited in the '005 patent, and Garrison discloses all of the remaining limitations (including an aspiration system having a hemostasis valve in a housing), it is my opinion that Claims 1-15 of the '005 patent would have been obvious to a person of ordinary skill in August 2018 in view of Garrison combined with Schaffer. As I explain in detail below, a person of ordinary skill in the art would have had ample motivation to combine Schaffer's hemostasis valve with Garrison's aspiration system and would have had a reasonable expectation of success in doing so.

64. As noted in the preceding paragraph, Schaffer's valve includes two actuating members (which may be U-shaped) that constrict the valve's central lumen to form a seal. Ex. 1005 (Schaffer) at [0076]-[0077]. As I explain in detail below, Schaffer's actuating members are a "filament," as that term is defined in the '519 Application and claimed in the '005 patent, because the described actuating members are at least "ribbons, flat wires, sheets, or tapes." *See supra* ¶¶54-60 (claim construction of "filament"). However, even if the Board concludes that Schaffer's U-shaped actuating members are not a "filament," using a filament (i.e., one or several threads, lines, cords, rope, ribbon, flat wire, sheet, or tape) to constrict the central lumen of a hemostasis valve was not a novel or nonobvious concept in August 2018.

65. Hartley and Eller each disclose hemostasis valves that use a filament to constrict the lumen of a tubular member to seal the valve. Hartley's "filament" is described as a string (or suture, band, or other suitable material) secured to a rotary actuator, which is shown in Hartley's Figure 3 below:



Ex.1006 (Hartley) at [0031], Fig. 3. Eller's "filament" is described as a wire member (or suture or cable) secured to the actuator and valve housing, illustrated in Eller's Figures 2 and 16-17 below:

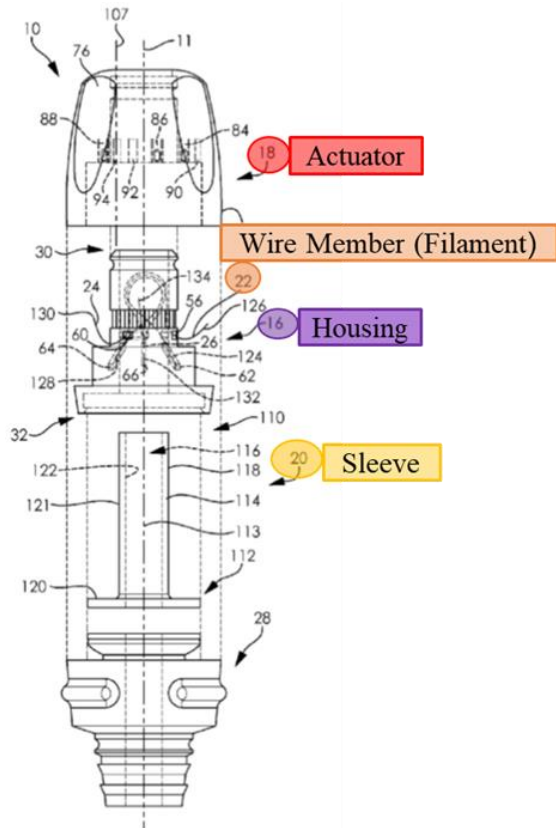


FIG. 2

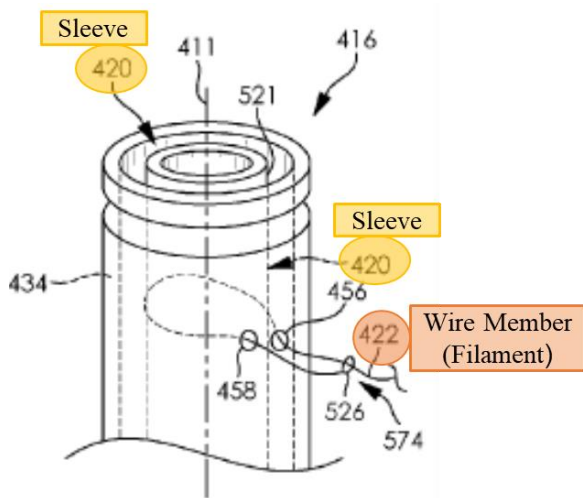


FIG. 16

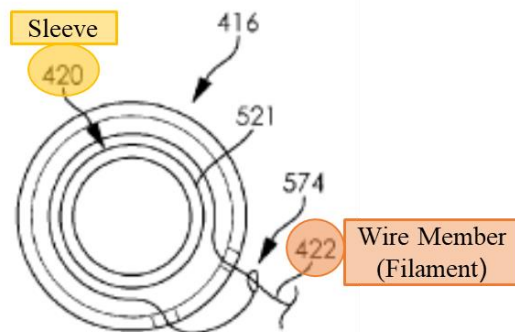


FIG. 17

Ex. 1007 (Eller) at 5:1-5, 16:5-6, Figs. 2, 16-17. Eller explains that the wire member “can be formed of any suitable material using any suitable manufacturing technique,

and skilled artisans will be able to select a suitable material and technique to form a wire member according to a particular embodiment based on various considerations, including the material(s) that forms the sleeve of an embodiment.” *Id.* at 15:41-47. Some of the exemplary materials identified in Eller include “metals,” “polymers,” “compliant materials,” and “flexible materials.” *Id.* at 15:47-60. Eller also explains that “a wire member can comprise a suture or a cable.” *Id.* at 16:5-6.

66. For the reasons I provide in detail below, a person of ordinary skill in the art would have been motivated and found it obvious to substitute Hartley’s string or Eller’s wire member for the actuating members in Schaffer’s hemostasis valves. Accordingly, based on my review of these references, I believe that the combination of Garrison and Schaffer with Hartley *or* Eller also renders Claims 1-15 obvious.

A. Claim 1

67. Based on my review of the prior art, it is my opinion that Garrison combined with Schaffer and optionally Hartley *or* Eller renders Claim 1 obvious.

1. Preamble

68. The preamble of Claim 1 recites: “A vacuum aspiration system.” If this preamble is limiting, Garrison discloses this limitation.

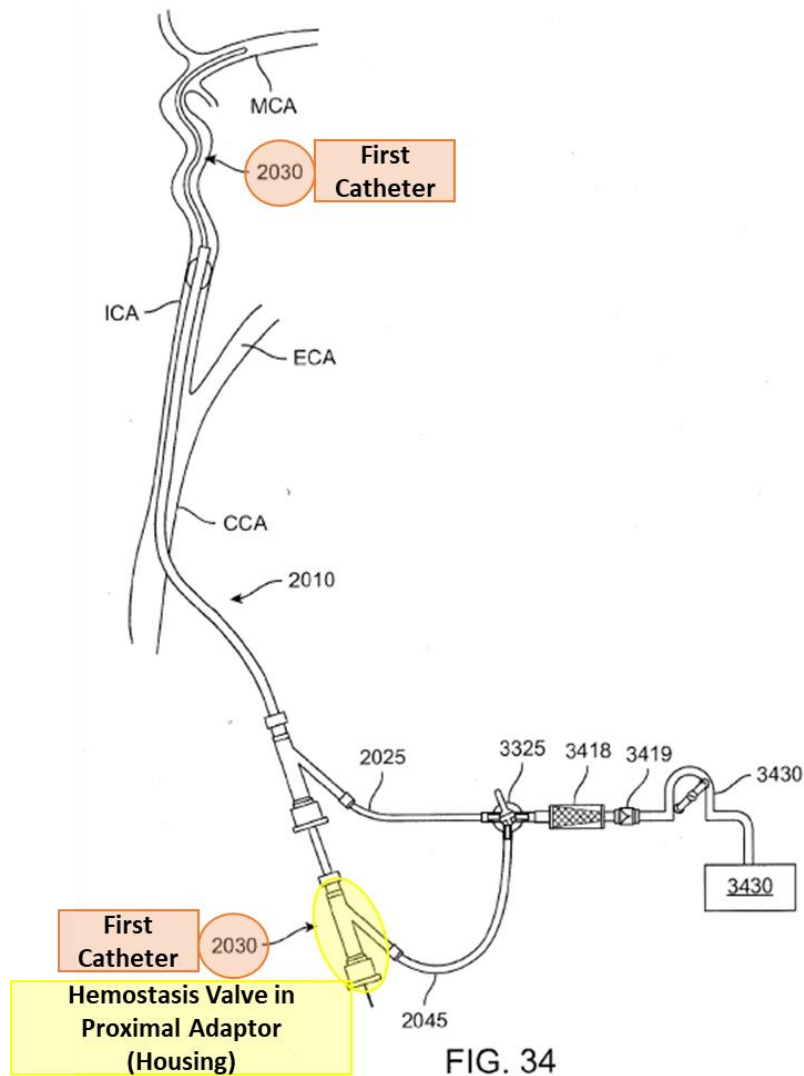
69. Garrison discloses a vacuum aspiration system “to provide aspiration and passive flow reversal for the purpose of facilitating removal of the occlusion as

well as minimizing distal emboli.” Ex. 1011 (Garrison) at [0007]; *see also id.* at [0029] (“FIGS. 32-35 showing examples of systems for treating an artery with active aspiration”); [0048] (“Disclosed also are methods and devices that optimize clot aspiration through either transfemoral or transcarotid access approaches.”).) Garrison’s system includes an aspiration source, for example a pump or syringe, that creates negative vacuum pressure which aspirates (i.e., suctions) material such as blood clots from a patient’s blood vessel. *See id.* at [0071], [0137] (describing aspiration sources). Garrison’s system is therefore a “vacuum aspiration system.”

2. Housing

70. Claim 1 next recites: “a housing” and additionally recites “a hemostasis valve in the housing.” Garrison discloses these limitations.

71. Garrison discloses that its system may include a first catheter 2030 having a “proximal hub 2065” or “proximal adaptor,” and Garrison further explains 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” or “the hemostasis valve may be integral to the catheter proximal adaptor”:



Ex. 1011 (Garrison) at [0098], Fig. 34. Garrison’s proximal hub/adaptor is a “housing” that includes an integral hemostasis valve housed within the hub/adaptor.

72. Figure 34 does not expressly label the proximal adaptor and hemostasis valve, but other, related figures do. Based on the many related disclosures discussed in the following paragraphs, a person of ordinary skill in the art would have understood that the proximal hub/adaptor on catheter 2030 depicted

in Figure 34 houses the described hemostasis valve as in, for example, Figures 1, 3, and 5.

73. For example, Garrison discloses that the access device 2010 includes “a proximal port 2015 with a hemostasis valve,” and explains that the catheter 2030 is “inserted into the internal lumen of the arterial access device 2010 via the port 2015”:

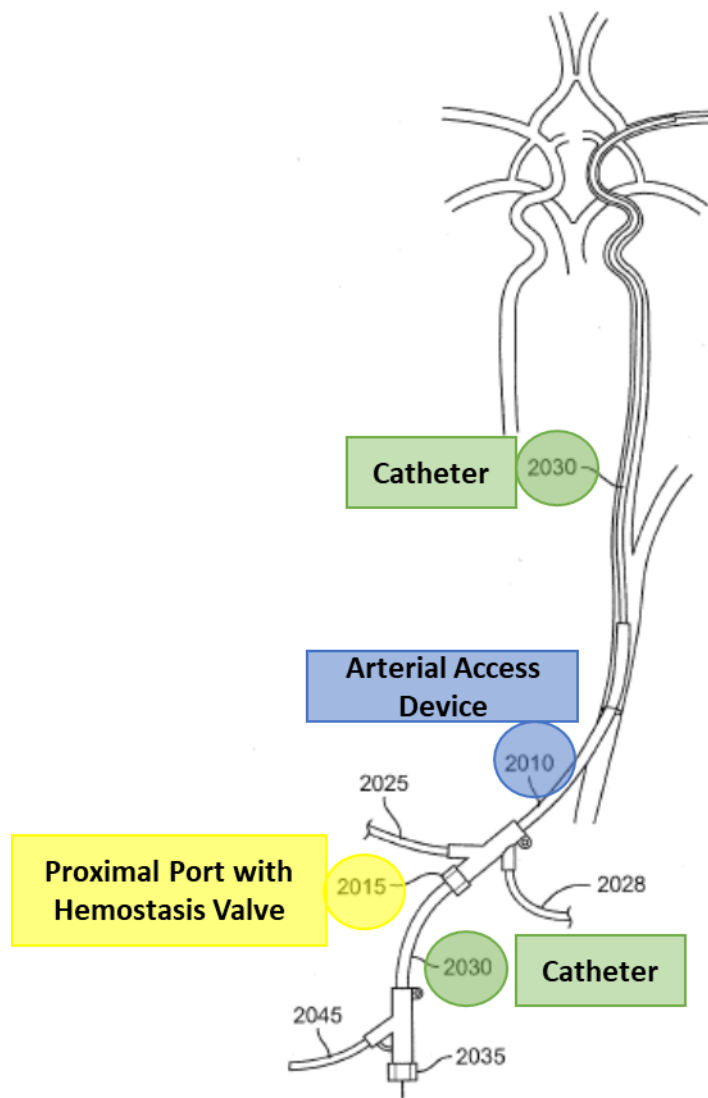


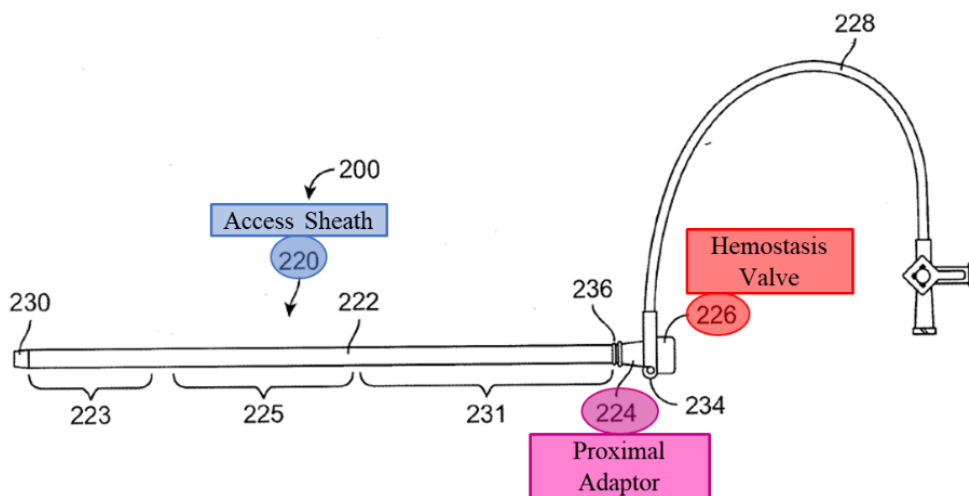
FIG. 1

74. Garrison also discloses an embodiment shown in Figure 3 below that includes a “guide catheter 2105 that is inserted through an arterial access sheath 2010 via the access device proximal hemostasis valve 2012”:



Id. at [00535], Fig. 3. As shown in Figure 3, the hemostasis valve 2012 is located in a housing on the proximal end of the catheter of the access device 2010. *Id.* Garrison further disclose that in this embodiment, “[t]he guide catheter 2105 includes 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.* As shown in Figure 3, the hemostasis valve in the port is located in a housing (i.e., proximal adapter) on the proximal end of the guide catheter 2105. *Id.*

75. Figure 5 of Garrison “shows an embodiment of a transcarotid access sheath system 200 of devices for inserting an access sheath into the carotid artery.” *Id.* at [0060]. The system 200 includes “[a] proximal adaptor 224 [that] can be positioned near a proximal end of an elongated sheath body 222,” and “[t]he proximal adaptor 224 can have a hemostasis valve 226 that communicates with the internal lumen of the sheath body 222”:



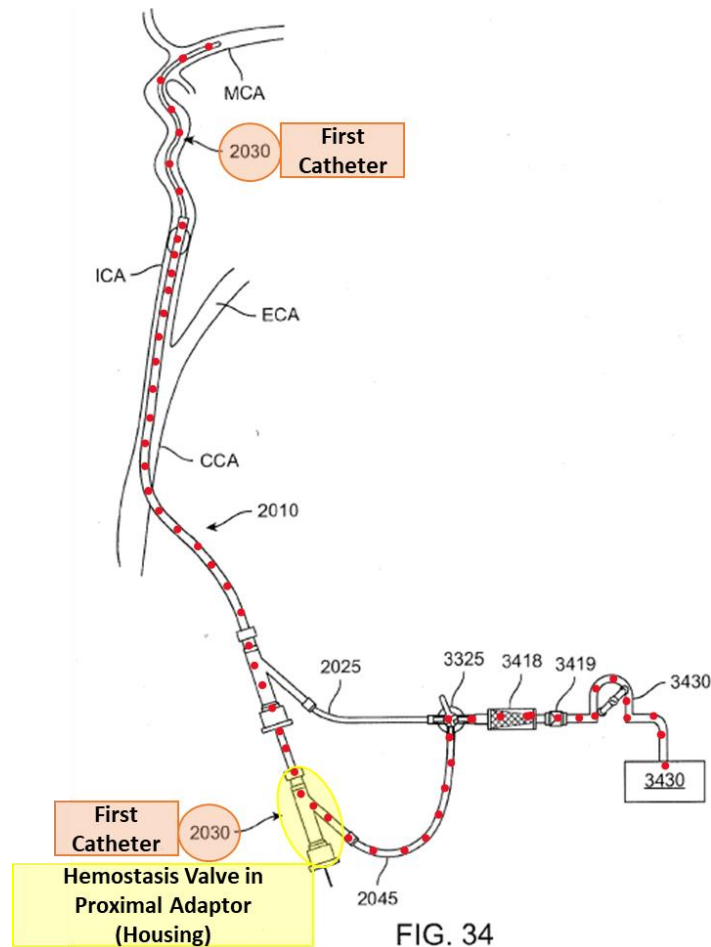
Id. at [0062], Fig. 5 (excerpt). As shown in Figure 5, the hemostasis valve 226 is located in a housing (proximal adaptor) on the proximal end of the catheter of the access sheath 220. *Id.*

76. Given these disclosures in Garrison, a person of ordinary skill in the art would have understood that the proximal hub/adaptor on the end of catheter 2030 in Figure 34 houses the described hemostasis valve.

3. Flow Path

77. Claim 1 next recites: “flow path extending through the housing.” Garrison discloses this limitation.

78. Garrison discloses that “the catheter 2030 may be connected to sources of passive or active aspiration via flow lines ... 2045 (Fig. 1) on the devices.” Ex. 1011 (Garrison) at [0130]; *see also id.*, [0059] (“the access device includes a proximal adaptor with a proximal port 2015 with a hemostasis valve and a connection to a flow line 2025 (or shunt) which may be connected to means for passive or active reverse flow.”). The flow line 2045 connects the catheter 2030 to the aspiration source and permits fluid to flow from the catheter 2030 through the system to the aspiration source/cannister during an aspiration procedure. *Id.* at [0133]. Thus, a person of ordinary skill in the art would have understood that a “flow path” extends through the housing (i.e., proximal hub/adaptor on catheter 2030), as illustrated by the dashed red line below:

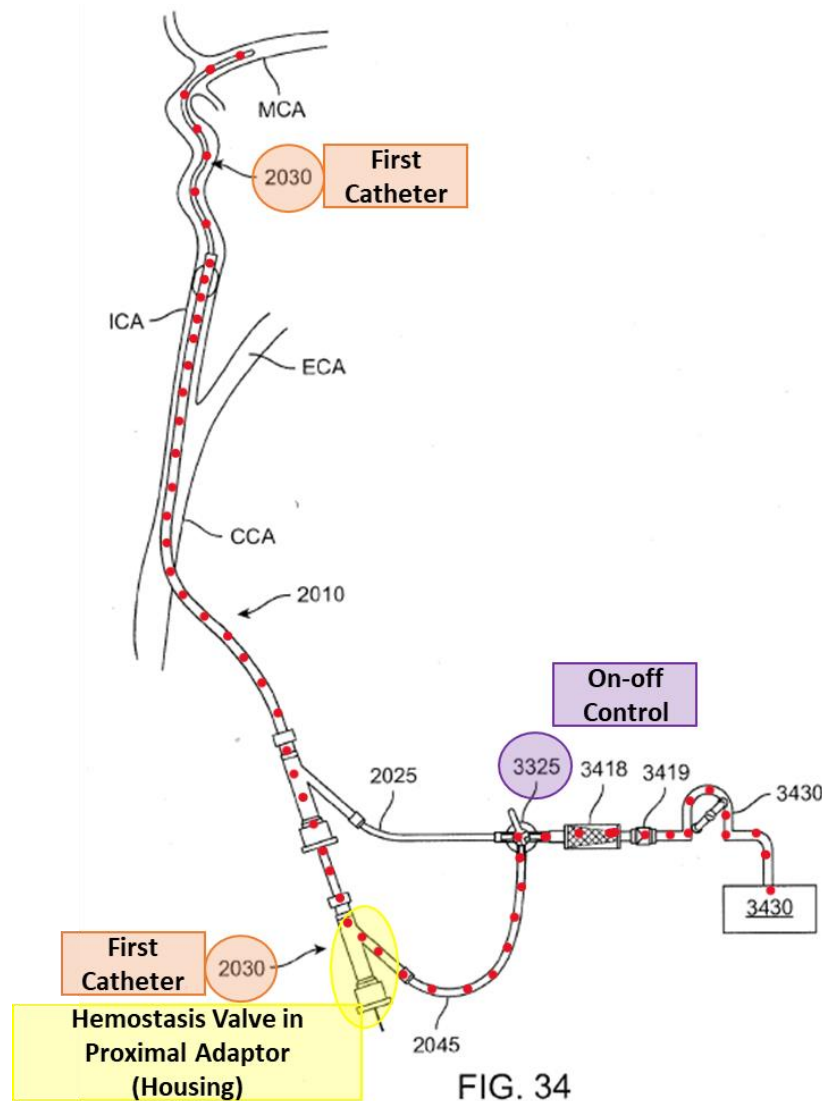


Id. at Fig. 34. This understanding is further confirmed by Garrison’s description of similar flow line 2025 attached to the access device as having “an internal lumen that communicates with an internal lumen of the arterial access device 2010 for shunting blood from the arterial access device.” *Id.* at [0059].

4. On-off Control

79. Claim 1 next recites: “an on-off control in the flow path.” Garrison discloses this limitation.

80. Garrison's vacuum aspiration system includes a "valve 3325" in the flow path (dashed red line) placed between the housing and the aspiration source, as illustrated in Figure 34:



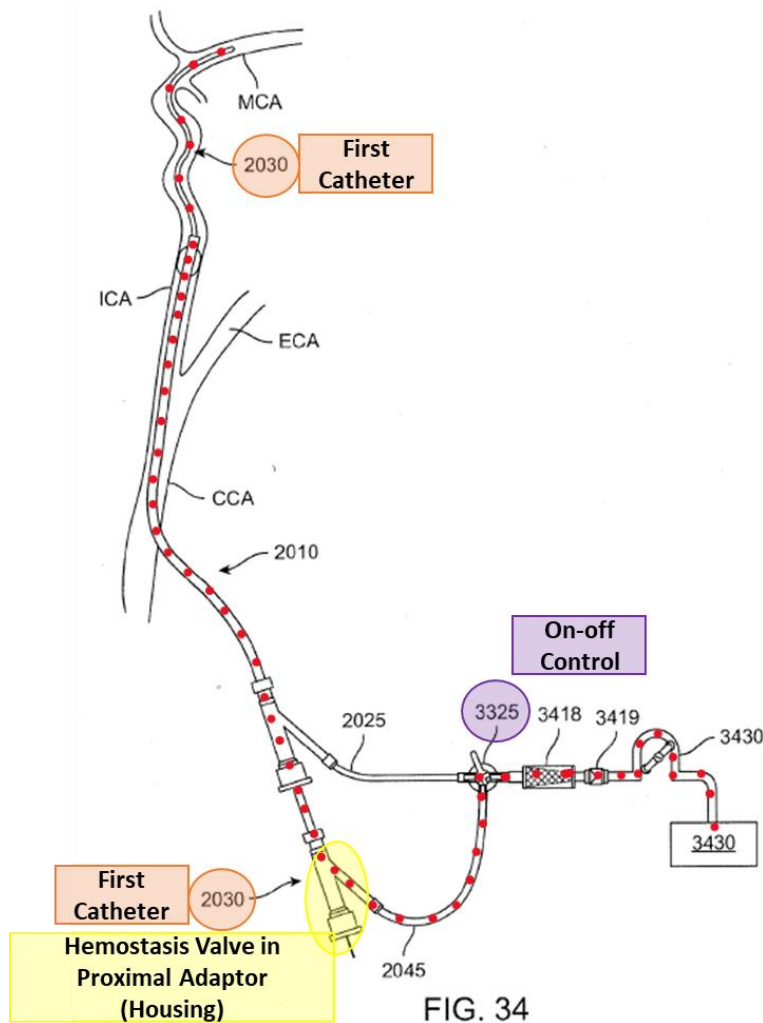
Ex. 1011 (Garrison) at [0132], Fig. 34. Garrison explains that the "valve 3325 controls which device is connected to the aspiration source 3430." *Id.* Garrison further explains that "[t]he valve may be a 3-way or 4-way stopcock" and may "enable one device, the other device, both devices, or neither device to be connected

to the aspiration source at any given time.” *Id.* The valve can also “be a flow controller with a simple actuation which selects the configuration as described above.” *Id.*; *see also id.* at [0133] (describing flow controller).) Thus, Garrison’s valve 3325 (e.g., stopcock or flow controller) is an on-off control in the flow path that controls the connection of the catheter 2030 to the aspiration source.

5. First Catheter

81. Claim 1 next recites: “a first catheter in fluid communication with the flow path.” Garrison discloses this limitation.

82. As I noted above, Garrison’s system includes a “catheter 2030 [that] may be connected to sources of passive or active aspiration via flow lines ... 2045 (Fig. 1) on the devices.” Ex. 1011 (Garrison) at [0130]. As I also explained above, the flow line 2045 permits fluid to flow from the catheter 2030 through the system to the aspiration source/cannister. *Id.* at [0133]. Therefore, a person of ordinary skill in the art would have recognized that catheter 2030 (i.e., the first catheter) is in fluid communication with the “flow path,” as I’ve illustrated with the dashed red line in Figure 34 below:

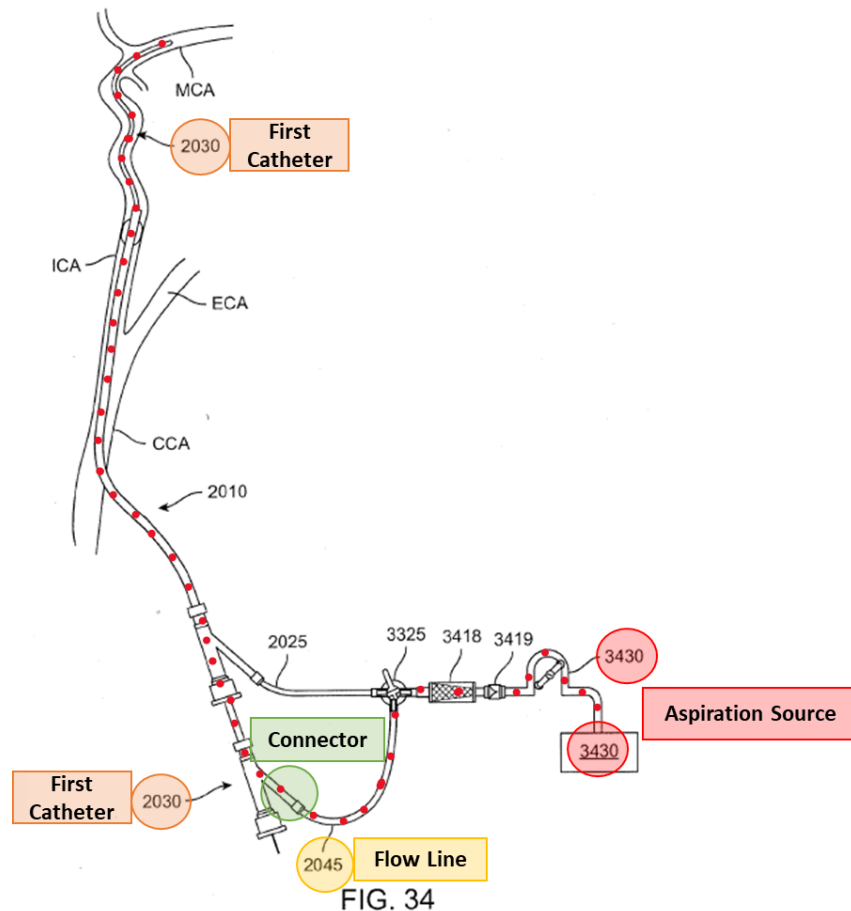


Id. at [0059], Fig. 34; *see also id.* (“flow line 2025 has an internal lumen that communicates with an internal lumen of the arterial access device 2010 for shunting blood from the arterial access device”).

6. Connector

83. Claim 1 next recites: “a connector configured to place a source of aspiration in communication with the flow path.” Garrison discloses this limitation in several ways.

84. First, Garrison discloses that “the catheter 2030 may be connected to sources of passive or active aspiration via flow line[] ... 2045.” Ex. 1011 (Garrison) at [0130]; *see also id.* at [0059] (“the access device includes a proximal adaptor with a proximal port 2015 with a hemostasis valve and a connection to a flow line 2025 (or shunt) which may be connected to means for passive or active reverse flow”).) As illustrated in Figure 34 below, the flow line 2045 is connected to the catheter 2030 via the Y-arm extending from the hub/adaptor:



Id. at Fig. 34. A person of ordinary skill in the art would have recognized that the Y-arm is a connector configured to place the aspiration source 3430 in communication with the flow path given the illustration in Figure 34 and the description of flow line 2045 as connecting the catheter 2030 to the aspiration source. *See id.* at [0130], Fig. 34. This understanding is further confirmed by Garrison’s reference to similar Y-arms as a “connector”:

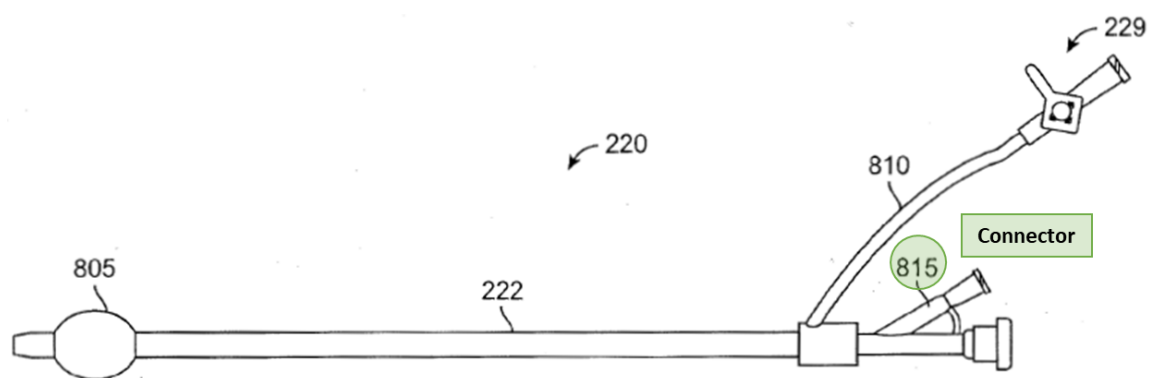


FIG. 9

Id. at Fig. 9; *see also id.* at [0067] (“a hemostasis valve is built into the connector 815 between the sheath body 222 and the proximal extension 805”).

85. Second, Garrison’s flow line 2045 itself is also a connector configured to place the aspiration source 3430 in communication with the flow path. As illustrated in Figure 34 above, the flow line 2045 connects the aspiration source to the catheter 2030 and enables fluid to flow between them.

86. Third, Garrison discloses that several components may be optionally coupled to the flow line 2045, such as the aspiration source 3430, the filter 3418,

and/or the check valve 3419. *Id.* at [0131]-[0132], Figs. 33-34. A person of ordinary skill in the art would have understood that each of these connections must have a connector joining the component to the flow line for the system to function. Moreover, the person of ordinary skill in the art in August 2018 would have known of several standard connectors that were commonly used in the field to connect flow lines to medical components, such as Luer connectors and slip-fit connectors. *Id.*; *see also* Ex. 1005 (Schaffer) at [0047] (describing Luer and slip-fit connectors); Ex. 1007 (Eller) at 16:65-17:4, Fig. 7 (describing type of slip fit connector); Ex. 1011 (Garrison) at [0062], [0065], Fig. 11 (illustrating stopcock with standard female connector); Ex. 1020 (Treretola) at 4:29-40 (describing the use of Luer type connectors for aspiration catheters); Ex. 1001 ('005 patent) at 7:54-58 (describing a “standard luer connector”), 33:32 (describing a “standard Luer or large bore connector”).

87. For example, Garrison explains that proximal hub 2065, which I discussed above, includes “a female Luer configuration for attachment of a syringe during prep and attachment of other components.” Ex. 1011 (Garrison) at [0098]. Garrison also incorporates by reference patents and patent publications that describe attaching catheter components using “a conventional luer fitting” or improvements to such fittings. Ex. 1021 (Garrison '118) at [0130]; *see also* Ex. 1022 (Gordon) at 8:45, 8:63 (describing an “auxiliary Luer port”); Ex. 1023 (Garrison '868) at

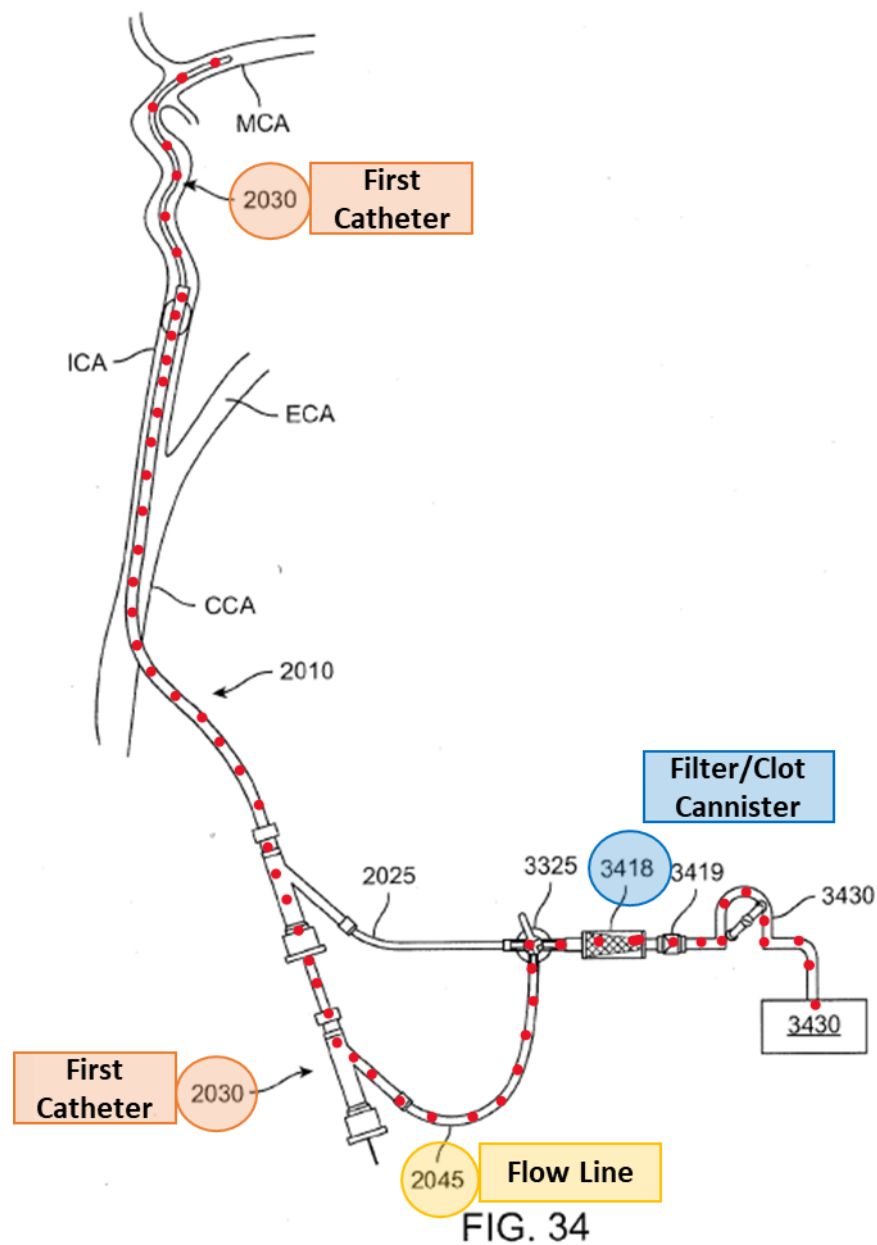
[0056]-[0059] (describing improvements to the “standardized ... locking Luer taper design”). Thus, the person of ordinary skill in the art would have understood that the standard connectors joining the components of Garrison’s system with flow line 2045 would be configured to place the aspiration source in communication with the flow path that extends through catheter 2030.

7. Clot Cannister

88. Claim 1 next recites: “a clot cannister fluidly coupled to the flow path.”

Garrison discloses this limitation in two ways.

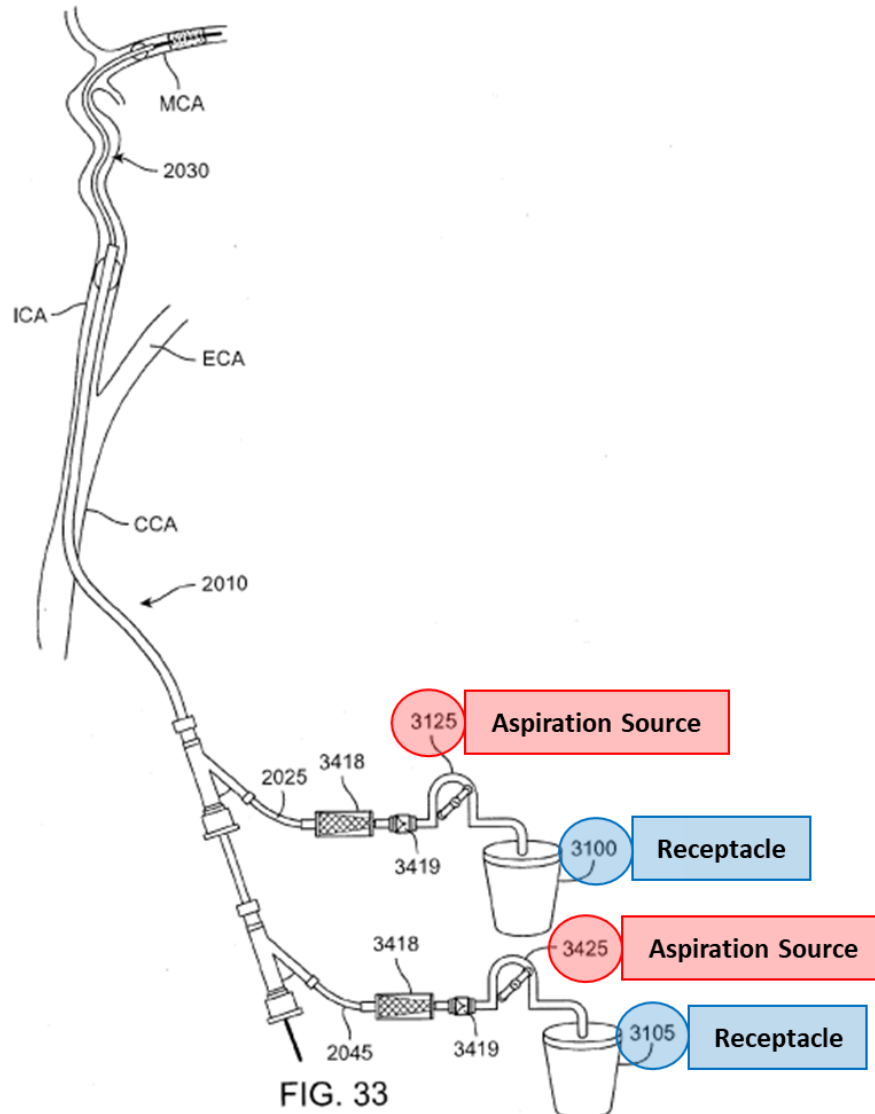
89. First, Garrison’s system includes a “filter 3418 ... [that] may also be coupled with flow line 2045”:



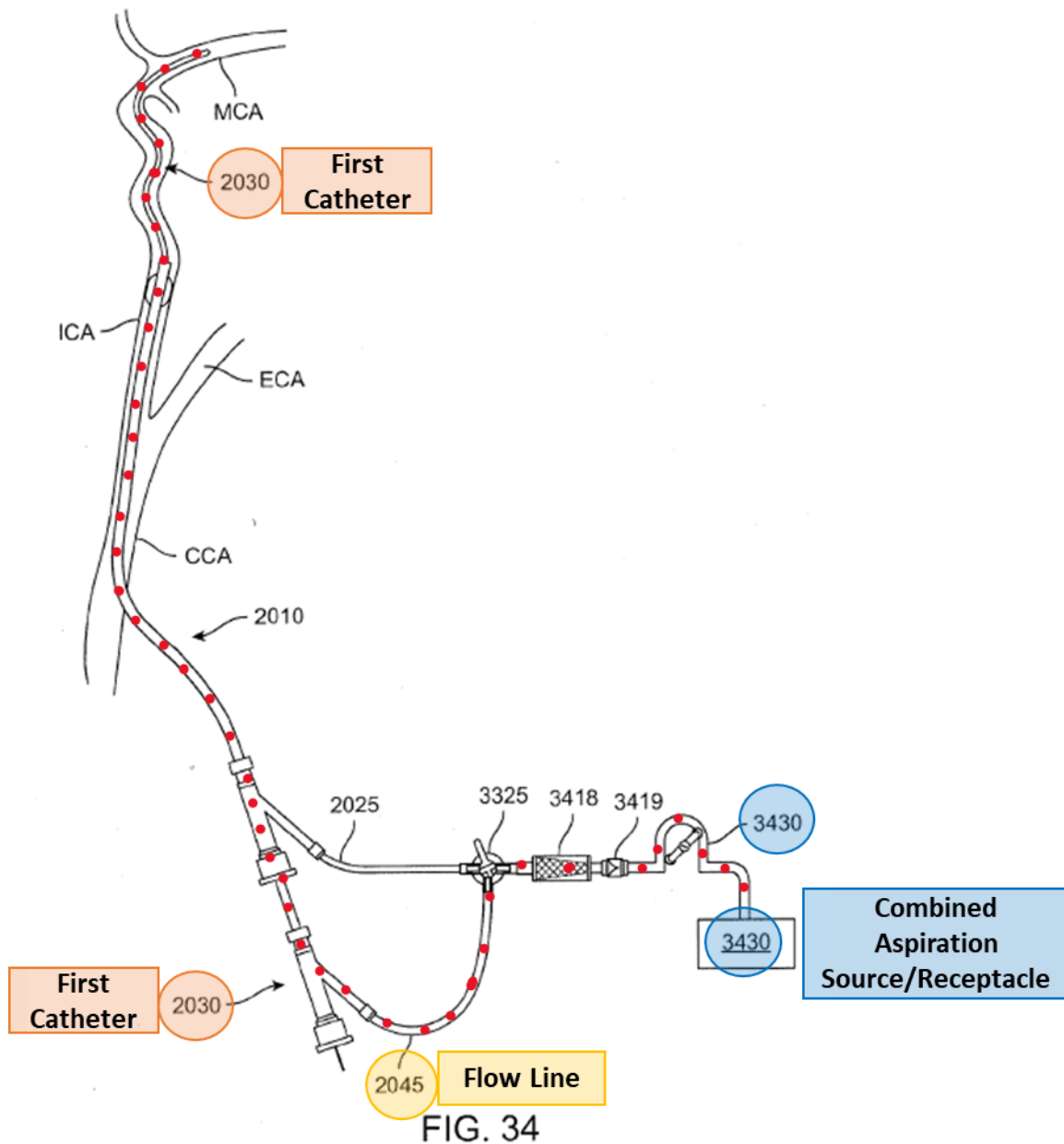
Ex. 1011 (Garrison) [0131], Fig. 34. A person of ordinary skill in the art would have understood that as blood passed through the filter during an aspiration procedure, the filter container would capture clot material and separate it from the aspirated blood. *See id.* at [0142] (“If desired, the blood could be filtered and

subsequently returned to the patient.”). Indeed, filters, like the filter disclosed in Garrison, were commonly used in prior-art aspiration systems to separate clot material from the aspirated blood. See Ex. 1024 (Goff) at [0025], Fig. 2. Garrison’s filter 3418 is therefore a “clot cannister fluidly coupled to the flow path.”

90. Second, Garrison discloses that the aspiration system may include receptacle(s) 3100/3105 that receive the aspirated blood and clot material after it is removed from the patient:



Ex. 1011 (Garrison) at [0131], Fig. 33. Garrison explains that the receptacle 3100/3105 and the source of aspiration “may be separate,” as in Figure 33 above, or they “may be combined into a single device such as a syringe,” as in illustrated in Figure 34:



Id. at [0131], Fig. 34. Given the arrangement of components described and illustrated in Garrison, the person of ordinary skill in the art would have recognized that any clot material that may pass through the filter would flow into the receptacle. Therefore, the receptacle is also a “clot cannister fluidly coupled to the flow path.”

8. Hemostasis Valve

91. Claim 1 next recites: “a hemostasis valve in the housing configured to receive a second catheter and direct the second catheter through the first catheter.” Claim 1 then goes on to recite several specific features of the hemostasis valve, including: a “tubular member,” a “constricting mechanism,” and a “biasing system.” Garrison in combination with Schaffer and optionally Hartley or Eller renders the hemostasis-valve limitations of claim 1 obvious.

92. As I explained previously, Garrison’s catheter 2030 (i.e., first catheter) includes a housing (i.e., the proximal hub/adaptor) containing a hemostasis valve:

arterial access device 2010.” *Id.* at [0054]. Garrison also specifically discloses that a “second, smaller diameter catheter may be inserted through the first catheter” *Id.* Accordingly, Garrison’s hemostasis valve located in the housing (i.e., proximal hub/adaptor) is configured to receive a second catheter and direct the second catheter through the first catheter.

93. Garrison discloses that different types of hemostasis valves can be used with the catheter 2030, such as, for example, “an adjustable-opening valve such as a Tuohy-Borst or rotating hemostasis valve (RHV).” *Id.* at [0098]. However, Garrison does not expressly describe the structure of the hemostasis valves used with its system. Instead, Garrison presumes that person of ordinary skill in the art would have been familiar with such valves.

94. Schaffer discloses embodiments of an adjustable-opening “fluid stasis valve” that is intended for use with catheters to prevent the flow of blood through the valve during medical procedures, and Schaffer discloses or renders obvious the hemostasis valve limitations of claim 1 as I explain in detail below. Ex. 1005 (Schaffer) [0002], [0046], [0055]; *infra* ¶¶103-147. A person of ordinary skill in the art in August 2018 would have been motivated, and found it obvious, to use Schaffer’s hemostasis valve, either with the U-shaped actuating members or with Hartley’s string or Eller’s wire member, as any or all of the hemostasis valves in

Garrison's system. A person of ordinary skill in the art would have been motivated to use Schaffer's valve in Garrison's system for several reasons.

95. First, as discussed above, Garrison expressly suggests combining catheter 2030 with "an adjustable-opening valve." Ex. 1011 (Garrison) at [0098]. Schaffer discloses a type of adjustable-opening hemostasis valve and, therefore, a person of ordinary skill in the art would have been motivated to combine, and reasonably expected success in combining, Schaffer's valve with Garrison's catheters.

96. 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. 1005 (Schaffer) at [0002], [0008]. Accordingly, a person of ordinary skill in the art would have understood that Schaffer's valve would perform the stated function of the "hemostasis valve" in Garrison's system—to "allow for the introduction of devices therein while preventing or minimizing blood loss via the internal lumen during the procedure." Ex. 1011 (Garrison) at [0062].

97. 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.

98. Fourth, combining Schaffer's valve with Garrison's aspiration catheters (such as catheter 2030) would merely entail the combination of known elements (Schaffer's valve and Garrison's aspiration catheter) according to known methods (attaching the valve to a proximal hub on the catheter or forming it integrally with the hub). This combination would yield the predictable result of preventing or minimizing blood loss and preventing the introduction of air into the catheter. Combining known elements in such a predictable fashion would have been well within the level of ordinary skill in the art in August 2018.

99. Fifth, a person of ordinary skill in the art in August 2018 had a finite number of predictable hemostasis valves to choose, including an "adjustable-opening valve" like Schaffer's valve, or "a passive seal hemostasis 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 catheter 2030. 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.

100. A person of ordinary skill in the art would have reasonably expected success in using Schaffer's hemostasis valve with Garrison's catheters in August 2018. Garrison broadly discloses that the hemostasis valves used with its system "can be a static seal-type passive valve, or an adjustable-opening valve such as a Tuohy-Borst valve 227 or rotating hemostasis valve (RHV) (see FIG. 6)." Ex. 1011 (Garrison) at [0062]. Schaffer's hemostasis valve is an "adjustable-opening valve," which Garrison describes as suitable for use with its system.

101. In addition, Schaffer discloses that its hemostasis valve is intended "for use with catheters" and that the seal module 100 of its valve is "proximally connected to the connecting member 35 ... [that is] sized and configured to attach in fluid communication to a fluid delivery supply or a body passage such as a blood vessel. Ex. 1005 at [0002], [0047], [0049]. Schaffer further explains that "a range of instruments [can be] used within the seal module," such as "a catheter, guidewire, needle, or fiber," and that "a guidewire and catheter may be placed into the same lumen 193 for extension into a body passage." *Id.* at [0056], [0074]. Given these disclosures in Schaffer, a person of ordinary skill in the art would have reasonably expected that Schaffer's valve would allow the tools in Garrison's system, such as

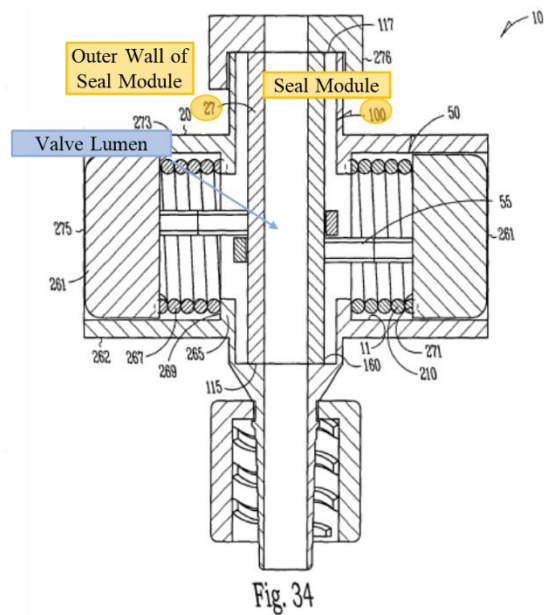
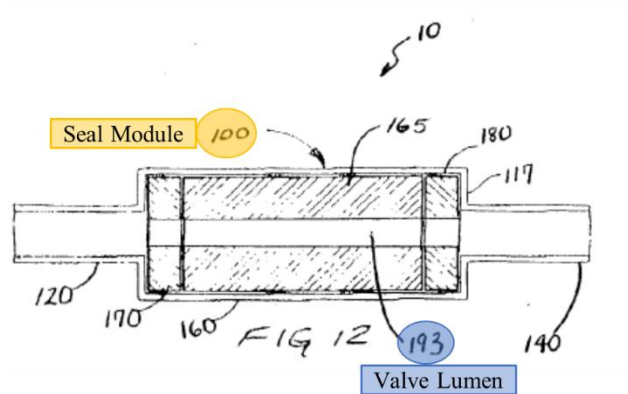
the catheter 2030 or a smaller catheter through catheter 2030, to pass through the valve into the patient's vasculature while also preventing blood from leaking around those tools.

102. For the reasons I explain in detail below, Schaffer discloses or renders obvious, both alone and combined with Hartley or Eller, the hemostasis valve recited in claim 1 of the '005 patent.

a. Tubular Member

103. Claim 1 next recites: "wherein the hemostasis valve comprises: a tubular member defining a lumen configured to slidably receive the second catheter." Schaffer discloses this limitation.

104. Schaffer's hemostasis valve includes a seal module 100 that "comprises an elongate tubular structure" and defines a "central lumen 193." Ex. 1005 (Schaffer) at [0049], [0051], [0054], [0075]. When the actuating members are disengaged from the opposing outer walls 27 of the seal module 100, the portion 108 of the seal module 100 can "retract to an uncollapsed configuration where gases and fluids can pass therethrough." *Id.* at [0077]. The seal module 100 defines a valve lumen 193 extending therethrough:



Id. at [0022, 0075], Figs. 12,² 34.

105. Schaffer explains that “a range of instruments [can be] used within the seal module,” such as “a catheter, guidewire, needle or fiber.” *Id.* at [0056]. Schaffer further explains that “a guidewire and catheter may be placed into the same lumen 193 for extension into a body passage.” *Id.* at [0074]. Schaffer’s seal module 100 is therefore “tubular member defining a lumen configured to slidably receive the second catheter.”

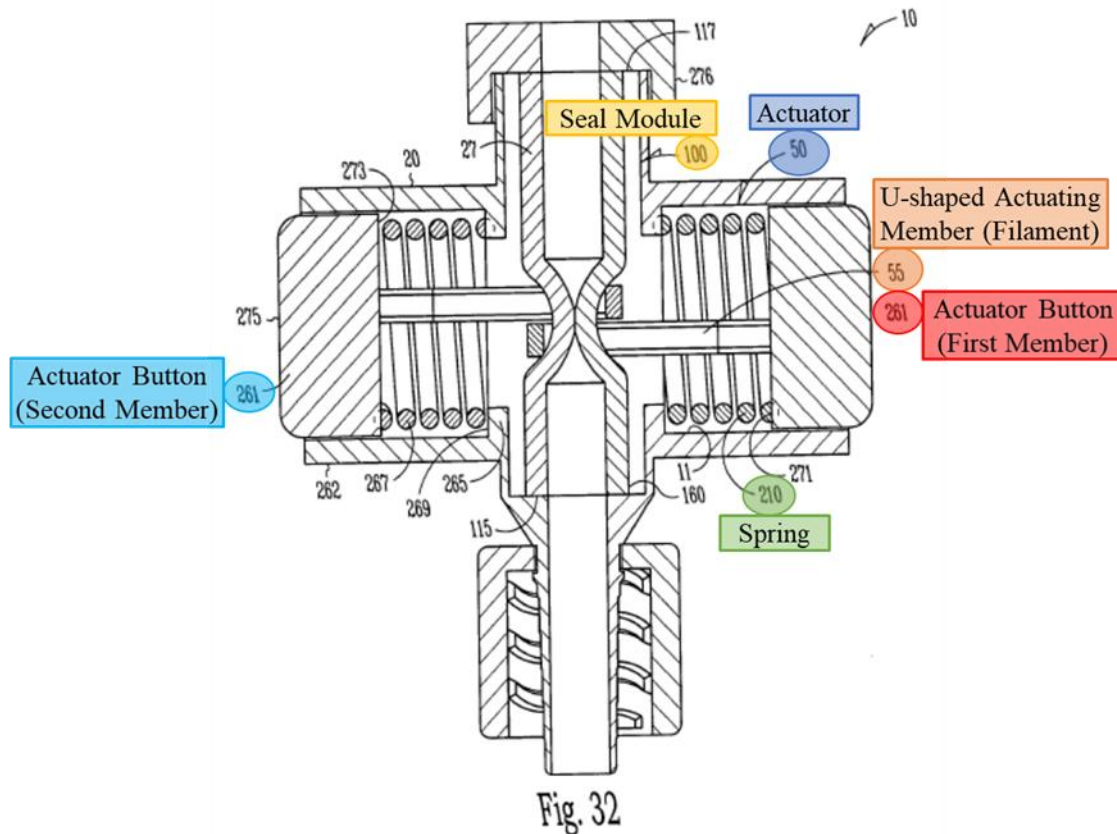
² While Figure 12 shows a seal module 100 comprised of three seal members 160, 170, and 180, Schaffer discloses that the “seal module 100 is formed of one or more seal members.” *Id.* at [0075], Figs. 32, 34. Thus, the seal module 100 may be formed from a single seal member.

b. Constricting Mechanism

106. Claim 1 next recites that the hemostasis valve comprises “a constricting mechanism including a filament and an actuator coupled to the filament, the filament comprising a first portion extending around at least a portion of the tubular member and a second portion having a first end extending from the first portion in one direction and a second end extending from the first portion in another direction, and the actuator comprises a first member coupled to the first end of the filament and a second member coupled to the second end of the filament, wherein the first member and the second member of the actuator are moveable between (a) a first position wherein the filament circumferentially constricts the lumen to create a seal and (b) a second position wherein the filament is moved to at least partially open the lumen.” Schaffer discloses the claimed constricting mechanism or renders it obvious in combination with Hartley or Eller.

i. Actuator

107. Schaffer discloses a hemostasis valve, depicted in Figures 31-34, that includes two spring-loaded actuators 50 that are “movable from a first position to a second position on opposing sides of the housing.” Ex. 1005 (Schaffer) at [0075]-[0076]. The actuators each include an actuator button 261 and a spring 210/267, as illustrated in Figure 32 below:



Id. at [0075]-[0076], Fig. 32.

108. Schaffer describes the embodiment in Figures 31-34 as including “two circular actuators 50,” and discloses that each of the two actuators includes a spring secured to an actuator button. *Id.* at [0076]. The ’519 Application calls the same structure a single actuator (i.e., a first button 144-A attached to spring 148-A (a “biasing mechanism”) and a second button 144-B attached to spring 148-B (a “biasing mechanism”). Ex. 1005 (’519 Application) at [0043]-[0045]. Schaffer’s description of its structure as two actuators (versus the ’519 Application’s description of its structure as a single actuator) is immaterial to my analysis because

Schaffer's valve has the same components, structure, and function as the actuator described in the '519 Application and claimed in the '005 patent. Thus, Schaffer has all the claimed components.

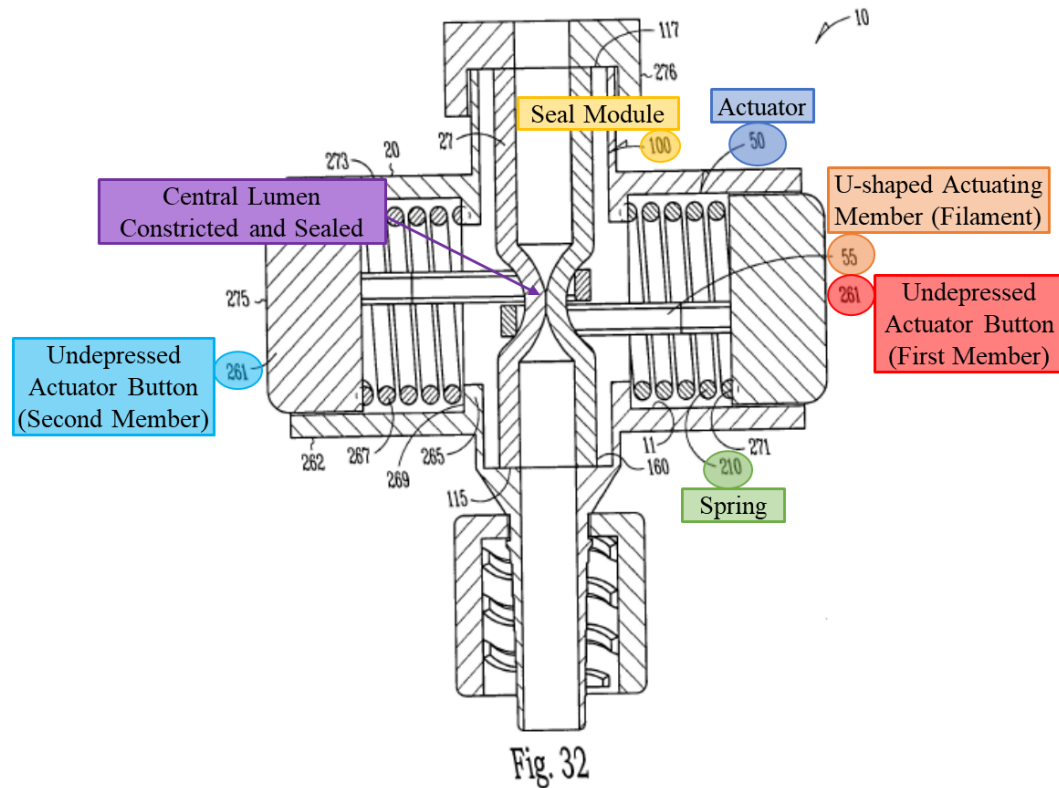
109. Schaffer's actuator buttons are a "first member" and a "second member" of the actuator as claimed in the '005 patent. Outside of the claims, '005 patent does not use the terms "first member" and "second member" to describe any portion of the actuator, nor does the '519 Application. The claims of the '005 patent say that the "first member" and "second member" possess the following attributes: (1) they are coupled to a first end and second end of the filament respectively and (2) they are movable between a first position where the filament creates a seal and a second position where the filament is moved to at least partially open the lumen. *See* Ex. 1001 ('005 patent) at Claim 1. Schaffer's actuator buttons have these attributes.

110. First, Schaffer's actuator buttons are coupled to the ends of Schaffer's actuating members, which can be U-shaped. Ex. 1005 (Schaffer) at [0076]-[0077], Figs. 31-34. As I discuss in the section below, Schaffer's U-shaped actuating members are the claimed "filament." Moreover, even if the U-shaped actuating members are not a "filament," a person of ordinary skill in the art would have been motivated to couple the ends of Hartley's string to Schaffer's actuator buttons when substituting Schaffer's U-shaped actuating members for Hartley's string. Similarly,

a person of ordinary skill in the art would have been motivated to couple Eller's wire member to Schaffer's actuator buttons when substituting Schaffer's U-shaped actuating members for Eller's wire member.

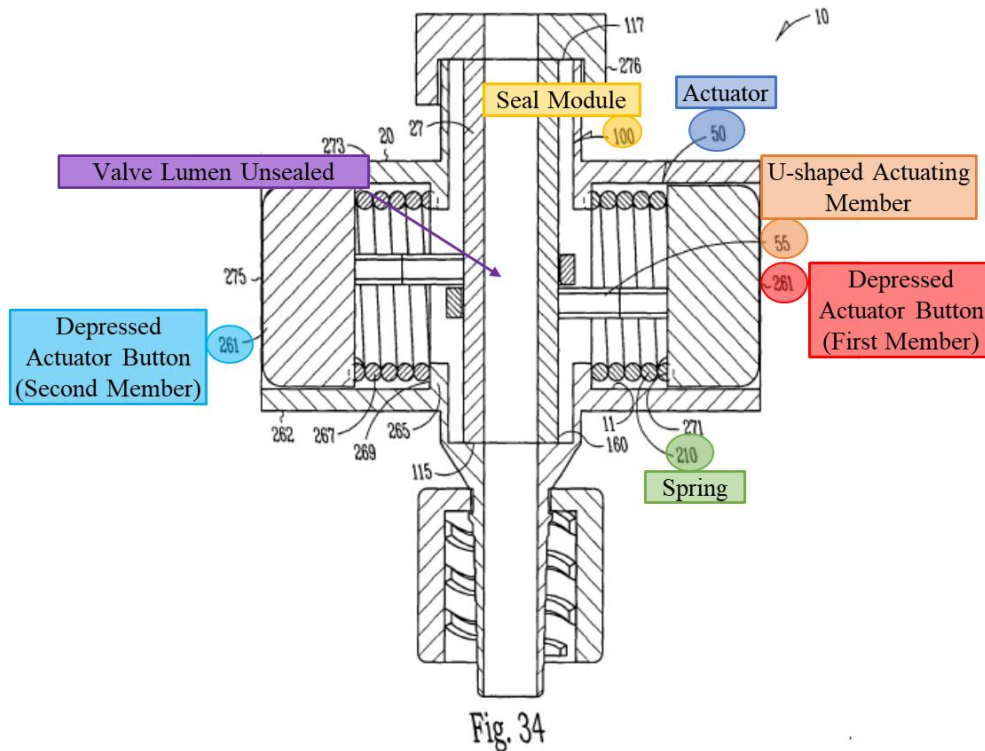
111. Second, Schaffer discloses that in a first position, the U-shaped actuating members are “at least partially circumferentially [sic] disposed about the portion 108 of the seal module 100 depressing and at least partially collapsing a portion 108 of the containment structure 160 by a compressive force 67 (e.g. by a spring 210).” Ex. 1005 (Schaffer) at [0077]. This position is depicted in Figure 32, which shows that the central lumen is completely constricted and sealed in the first position:

First Position – Actuator Buttons Undepressed



Id. at [0077], Fig. 32. Schaffer then explains that in a second position, the actuator buttons are depressed, which compresses the spring and allows the actuator members 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 where gases and fluids can pass therethrough.” *Id.* The second position is illustrated in Figure 34:

Second Position – Actuator Buttons Depressed



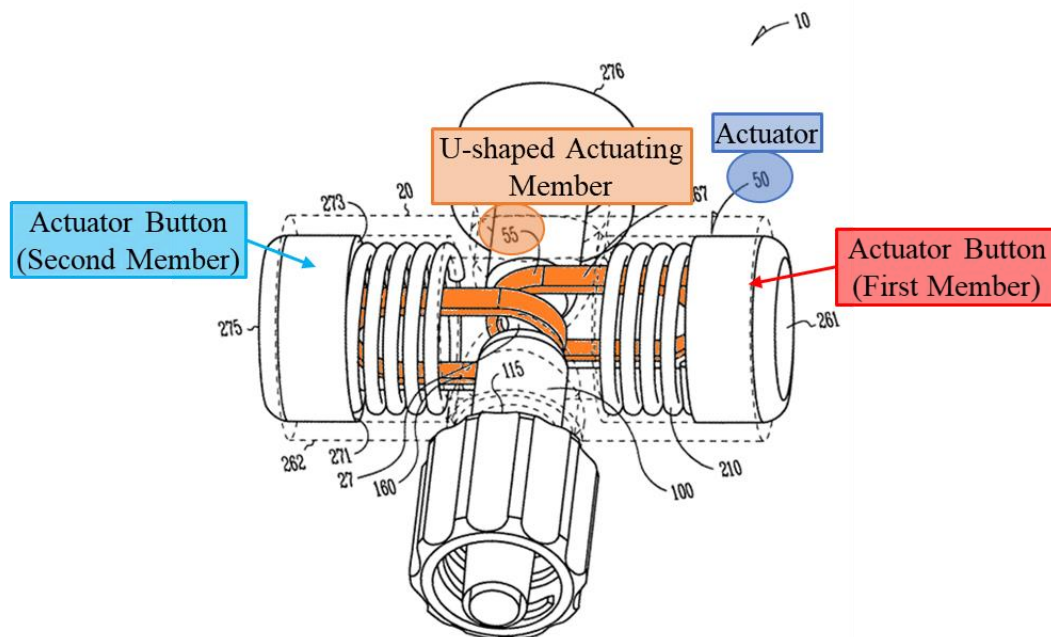
Id. at [0077], Fig. 34. The description in Schaffer that the actuating members “forcibly disengage opposing outer walls of the seal module 100” does not mean that the actuating members do not remain in contact with the seal module. As shown in Figure 34 above, the actuating members are still in contact 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.* Schaffer’s actuating members disengage from the seal module

in the exact same way that the '519 Application's filament disengages from the tubular member. Thus, either of Schaffer's actuator buttons are a "first member" and a "second member" as claimed in the '005 patent.

ii. Filament

(a) Schaffer

112. Schaffer discloses a "filament," as that term is claimed in the '005 patent. I addressed the meaning of "filament" in the claim construction section above. *Supra* ¶¶54-60. As I explained in the preceding section, Schaffer's valve includes two U-shaped actuating members that are coupled to the actuator buttons and constrict the valve when the buttons are undepressed:



Id. at [0076], Fig. 31. Schaffer's U-shaped actuating members are a "filament" as claimed in the '005 patent.

113. As I explained in section IV (Heading: "Claim Construction") above, a person of ordinary skill in the art would have understood "filament" to mean at least one or more threads, lines, cords, ropes, ribbons, flat wires, sheets, or tapes based on the description in the '519 Application. *Supra* ¶¶54-60. Schaffer's U-shaped actuating members meet this definition. Schaffer discloses that the U-shaped actuating members are formed from metals, such as aluminum, or plastic, which are consistent with the description of the filaments in the '519 Application (described as being metal or a polymer). Ex. 1005 (Schaffer) at [0081]. Schaffer does not describe the shape of the actuating members beyond stating that they are optionally U-shaped; however, Schaffer's figures depict the actuating members as resembling a ribbon, flat wire, sheet, or tape, as described in the '519 Application:

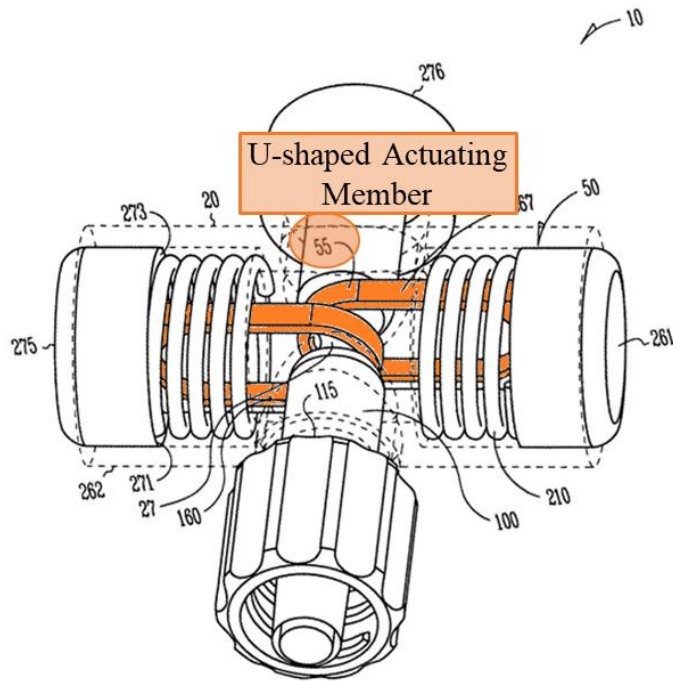


Fig. 31

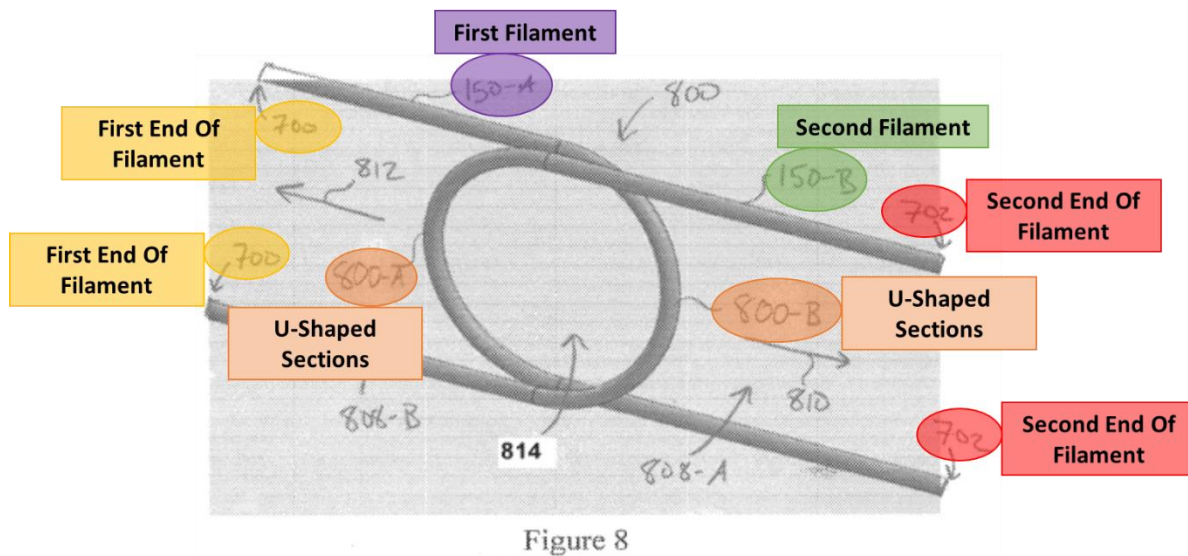
Id. at Fig. 31; *see also id.* at Figs. 32-34. I notice in related proceedings that Patent Owner characterizes Schaffer's actuating members as "rigid." Patent Owner Preliminary Response re: '011 patent filed in *Imperative Care, Inc. v. Inari Medical Inc.*, IPR2024-01157, Paper 5 at 3 (P.T.A.B. Oct. 29, 2024). 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. Thus, I see nothing in Schaffer that would require the actuating members to be "rigid." To the contrary, a person of ordinary skill in the art would have understood that Schaffer's U-shaped actuating members would have preferably been formed from a thin, flexible material. Such a material would have

permitted the actuating members to conform, as much as possible, to the outer surface of the seal module and tool inserted through the valve. For example, not all tools inserted through the valve would have a circular profile. In those cases, U-shaped actuating members having some flexibility would better seal around the irregular shapes. A thin metallic or plastic flat wire, sheet, ribbon, or tape would have provided the flexibility required for the actuating members to best seal around tools of various shapes and sizes. I also note that Patent Owner argues the actuating members in Schaffer are “rigid” based on the following description:

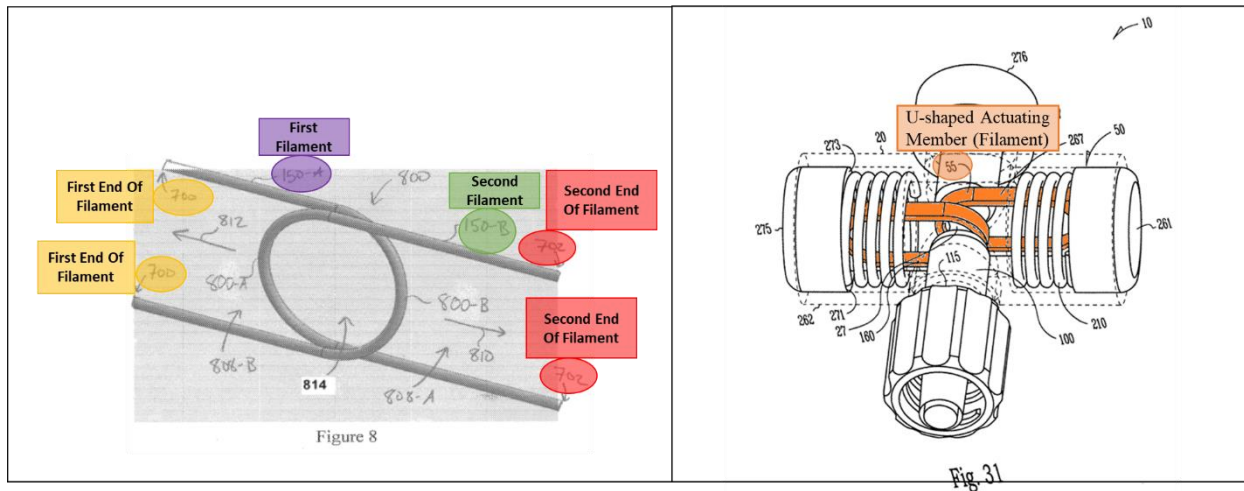
“The stasis valve 10, in one option, is made from machining pre-existing amounts of metals and/or plastics. For example, [t]he actuating member 55 and the actuating button 261 is machined from aluminum.”

Id. at [0082]. However, the description that a device is “made from machining” is not dispositive of whether the finished product is rigid or flexible. In the case of aluminum, for example, if enough material is removed during machining, then the final product would not be rigid. Moreover, the description of “machining” the parts is just “one option.” A person of ordinary skill in the art would have known that the U-shaped actuating members could be made using a variety of common manufacturing techniques, including extrusion and drawing. In fact, in 2018, a person of ordinary skill in the art could have simply purchased pre-made flat wire or plastic tapes or ribbons.

114. As I explained in section III.A (Heading: “Summary of the ’005 Patent”) above, the ’519 Application also discloses that the “**the filament 150** can comprise multiple filaments,” including two filaments that have “a U-shaped section between the two ends of the filament 150,” as shown in Figure 8 from the ’519 Application:



Ex. 1017 (’519 Application) at 12:61-13:16, Fig. 8 (emphasis added). Schaffer’s U-shaped actuating members have the same arrangement as that disclosed in Figure 8 of the ’519 Application:



Ex. 1017 ('519 Application) at Fig. 8 (left); Ex. 1005 (Schaffer) at Fig. 31 (right). The '519 Application's explanation that the two U-shaped filaments are "***the filament 150***" confirms that Schaffer's U-shaped actuating members collectively constitute "a filament" as claimed in the '005 patent. See Ex. 1017 ('519 Application) at [0064] ("With reference now to FIGS. 6 through 9, different embodiments and/or configurations of the filament 150 are shown."), [0065]-[0070], Figs. 6-9.

115. Schaffer discloses that the actuating members are "at least partially circumferentially [sic] disposed about the portion 108 of the seal module 100." Ex. 1005 (Schaffer) at [0077]. The section of the actuating members that are circumferentially disposed about the seal module is a "first portion [of the filament] extending around at least a portion of the tubular member" as highlighted below:

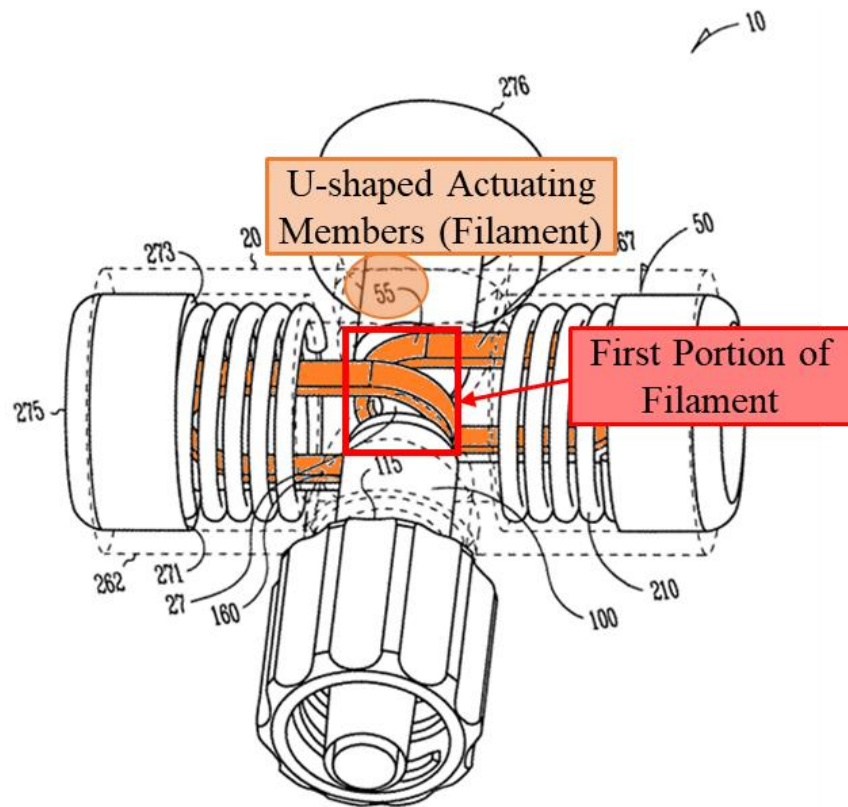
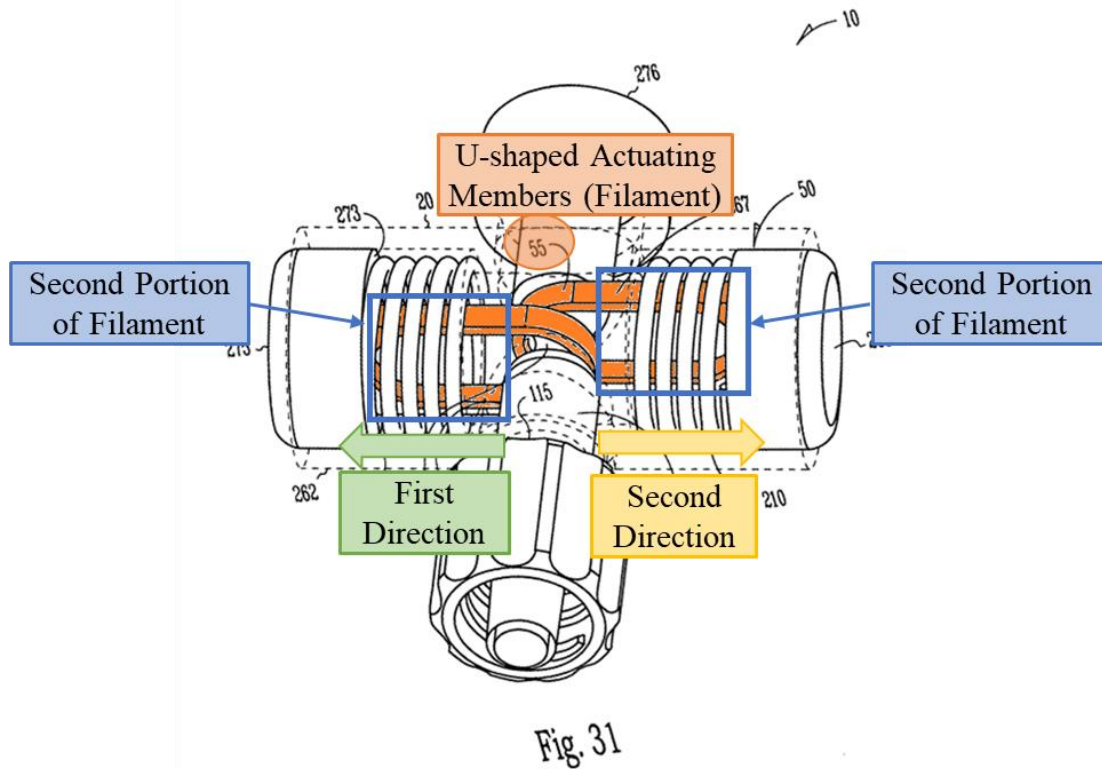


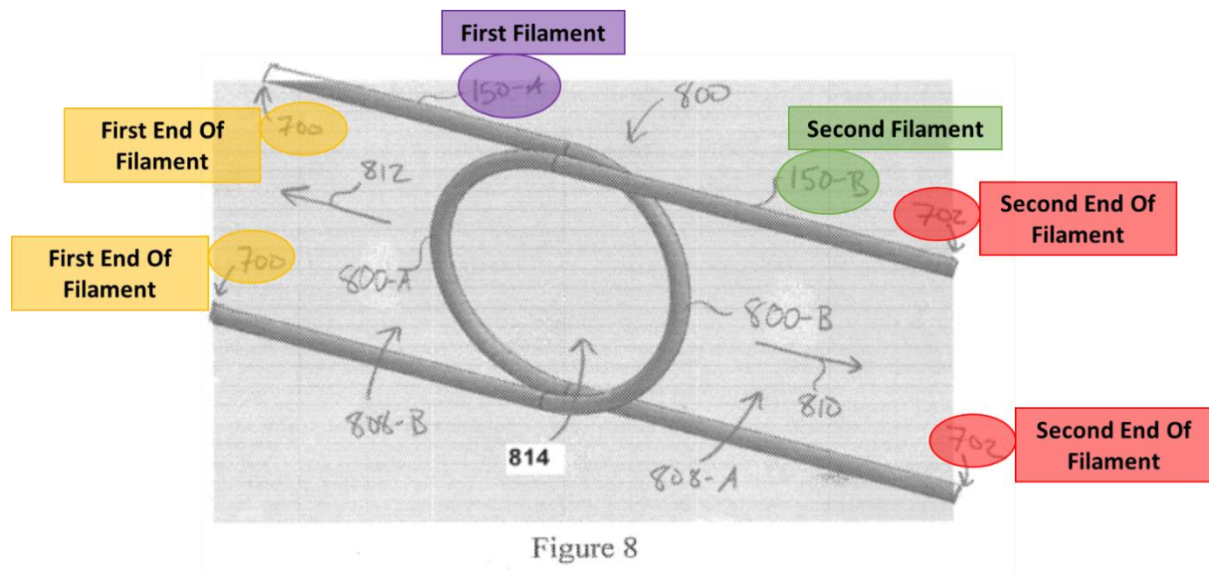
Fig. 31

Id. at [0076], Fig. 31. As shown in Figure 31 above, each of the U-shaped actuating members extends in opposing directions from the seal module 100. *Id.* The portions of the actuating members that are extending in those opposing directions are a “second portion [of the filament] having a first end extending from the first portion in one direction and a second end extending from the first portion in another direction”:



Id., Fig. 31.

116. The '519 Application states that “where **the filament 150** comprises multiple filaments, each of the multiple filaments can have a **first end 700** and a **second end 702**,” as shown in Figure 8 below:



Ex. 1017 ('519 Application) at [0065], Fig. 8 (emphasis added). Thus, as shown in Figure 8 above, when the filament comprises multiple filaments in a U-shaped configuration, the “first end” of the filament are the ends extending from a first direction from the center of the U-shaped arrangement, and the “second end” of the filament are the ends extending from a second direction from the center of the U-shaped arrangement. *Id.* Accordingly, Schaffer’s U-shaped actuating members have a “first end” that is coupled to the first actuator button and a “second end” coupled to the second actuator button as disclosed in the '519 Application and claimed in the '005 patent:



Ex. 1005 (Schaffer) at [0076], Figs. 31-32. Schaffer's U-shaped actuating members, therefore, disclose "a filament" as claimed in the '005 patent.

117. I note that Patent Owner argued in a related proceeding that the '011 patent, which has the same specification as the '519 Application, contains an "obvious typographical error." Patent Owner Preliminary Response re: '011 patent filed in *Imperative Care, Inc. v. Inari Medical Inc.*, IPR2024-01157, Paper 5 at 13 (P.T.A.B. Oct. 29, 2024). Patent Owner argued that the '011 patent "recites that for embodiments where the filament comprises multiple individual filaments, reference to a first end and a second end of the filament means the first and second end of a single continuous filament." *Id.* (citing '011 patent, 12:56-64 – equivalent disclosure in '519 Application at [0064]). However, the portion cited by Patent Owner describes "FIG. 6," not Figures 8-9, and uses different numbers to refer to the first and second ends "600" and "602." Ex. 1017 ('519 Application) at [0064]. When describing Figures 7-9, the '519 Application clearly states, "In embodiments in which the filament 150 comprises multiple filaments, each of the multiple filaments can have a first end 700 and a second end 702." *Id.* at [0065]. There is no indication in the '519 Application to suggest that this description is a typographical error or that Figures 8-9 contain a typographical error. Accordingly, Schaffer's U-shaped actuating members have a "first end" that extends away from

the first portion and is connected to the first member and a “second end” connected to the second member:

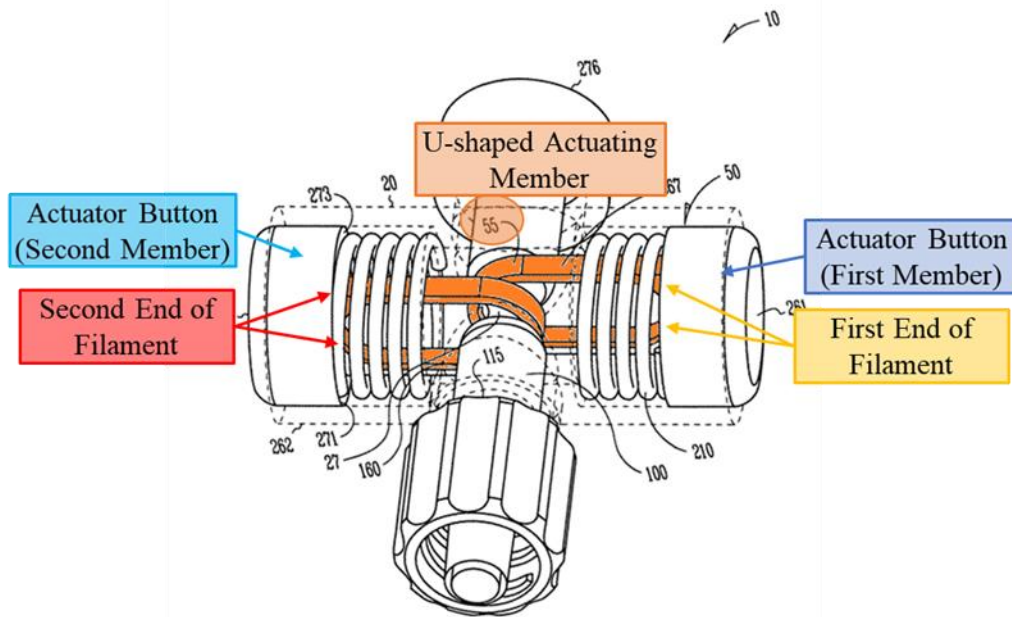


Fig. 31

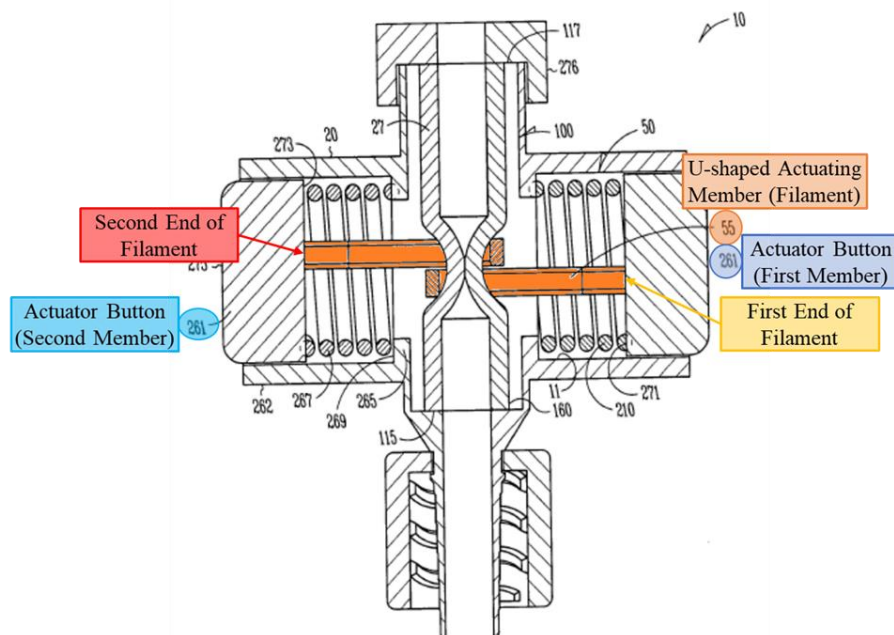


Fig. 32

Ex. 1005 (Schaffer) at [0076], Figs. 31-32. Schaffer's U-shaped actuating members, therefore, disclose a "filament" as claimed in the '005 patent.

118. As explained above with respect to the "actuator" limitation, Schaeffer's Fig. 32 illustrates the lumen of the valve being completely constricted and sealed when the actuator buttons are in the first, undepressed position, and therefore, Schaeffer's U-shaped actuating members "circumferentially constrict the lumen to create a seal." *Supra* §VI.A.8.b.i. However, even if the Board finds that that Schaffer's U-shaped actuating members do not "circumferentially constrict[] the lumen [of Schaffer's valve] to create a seal," a person of ordinary skill in the art would have found it obvious to modify the U-shaped actuating members to circumferentially constrict the lumen. Schaffer discloses that the actuating members are "at least partially circumferentially [sic] disposed about the portion 108 of the seal module 100." Ex. 1005 (Schaffer) at [0077]. The phrase "at least partially circumferentially [sic] disposed" strongly suggests that the U-shaped actuating members can also be **completely** circumferentially disposed around the seal module. A person of ordinary skill in the art would have been motivated to configure the U-shaped actuating members to circumferentially constrict the lumen to form a better seal and avoid the gaps I discuss below. *Infra* ¶¶119-132 (Section titled "Hartley"). The required adjustments, to the extent any adjustments were needed, would have been simple, including modifying the shape, material, and/or

dimensions of the U-shaped actuating members to better conform to the cylindrical shape of the seal module. For example, the actuating members could be formed from a thin, flexible sheet or flat ribbon of metal or plastic so that they have the flexibility to conform to the outer surface of the cylindrical seal module. A person of ordinary skill in the art would have reasonably expected success in making these simple and routine adjustments. Actuating members with this type of structure and flexibility would circumferentially constrict the lumen of Schaffer's seal module when pulled in opposite directions by the actuator buttons. For these reasons, if Schaffer does not disclose the "filament" limitation, it renders the limitation obvious.

(b) Hartley

119. Hartley discloses a fluid control valve that "can be controlled to vary the size of the aperture through the valve and be flexible so that a seal may be formed against an instrument or other object inserted through the access valve." Ex. 1006 (Hartley) at [0004]. As shown in Figure 1 below, Hartley's valve includes a cylindrical valve housing that houses a "cylindrical elastomeric diaphragm," and a rotary actuator mounted onto the housing:

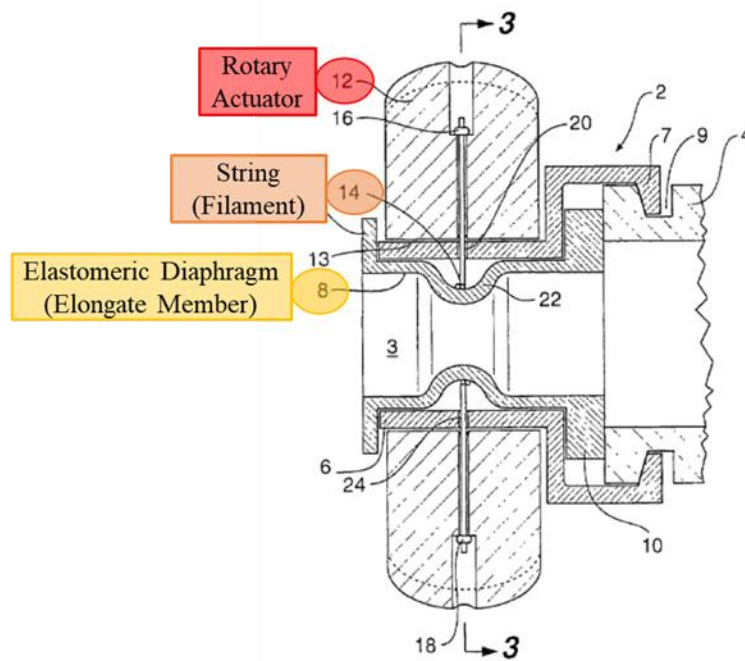


Fig 1

Id. at [0031], Fig. 1. Hartley's valve also includes a "flexible member," referred to as a "string" in the Detailed Description section, that is "mounted into the rotary actuator. *Id.* at [0005], [0031]. Hartley discloses that the flexible member "may be a string, suture or band or other suitable material." *Id.* at [0017]. Hartley's flexible member is therefore a "filament" as disclosed in the '519 Application and claimed in the '005 patent because a "string" is made of at least one or more threads, lines, or cords. *See* Ex. 1017 ('519 Application) at [0047] (disclosing that the filament can constitute "one or several threads, lines, cords, rope, ribbon, flat wire, sheet, or tape").

120. Hartley discloses that the “flexible member may be mounted at both of its ends to an actuator arrangement and hence the flexible member can be simultaneously pulled in substantially opposite directions to constrict the valve.” Ex. 1006 (Hartley) at [0010]. As shown in Figure 3 below, Hartley’s string is secured to the rotary actuator at a first end via knot 16 and “then passes through an aperture 20 in the cylindrical housing 6 and then is wound preferably twice around the cylindrical diaphragm 8 ... and then passes through a further aperture 24 in the cylindrical housing before being fixed by knot 18 again in the rotary actuator”:

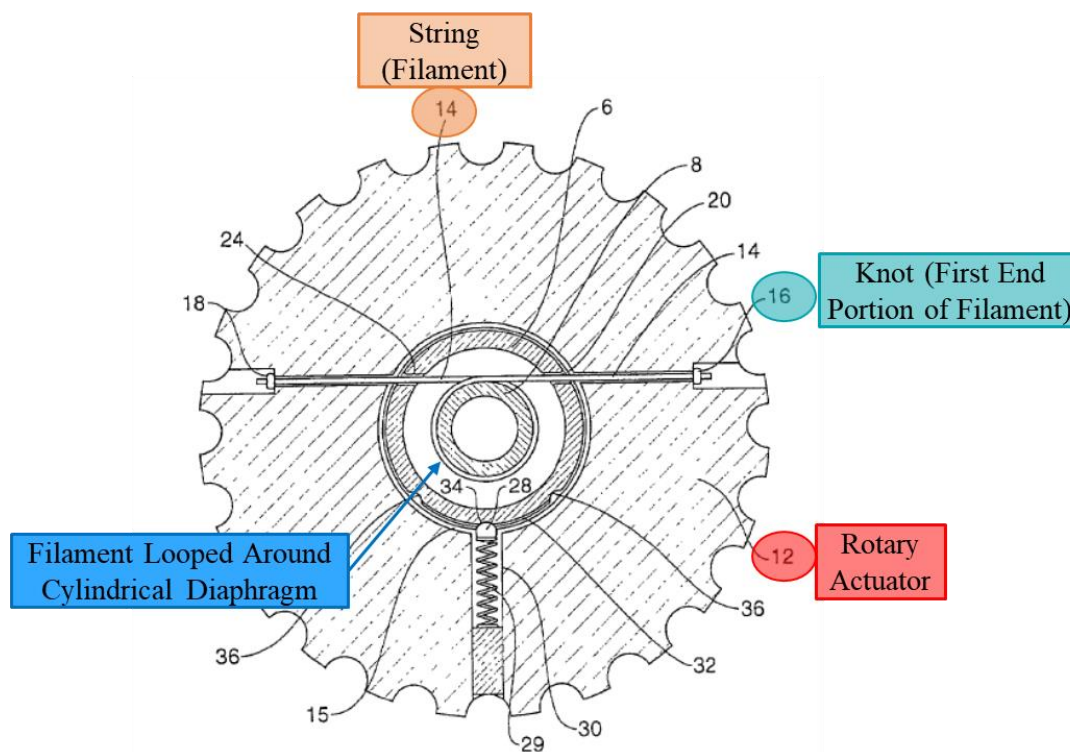


Fig 3

Id. at [0031], Fig. 3. Hartley’s string therefore includes “a first portion extending around at least a portion of the tubular member” as recited in Claim 1. The portion

of Hartley's string that "is wound preferably twice around the cylindrical diaphragm" is the claimed "first portion." *See id.* at [0031].

121. Hartley's string also includes a "a second portion having a first end extending from the first portion in one direction and a second end extending from the first portion in another direction." The portion of Hartley's string that extends away from the cylindrical diaphragm in opposite directions is the claimed "second portion":

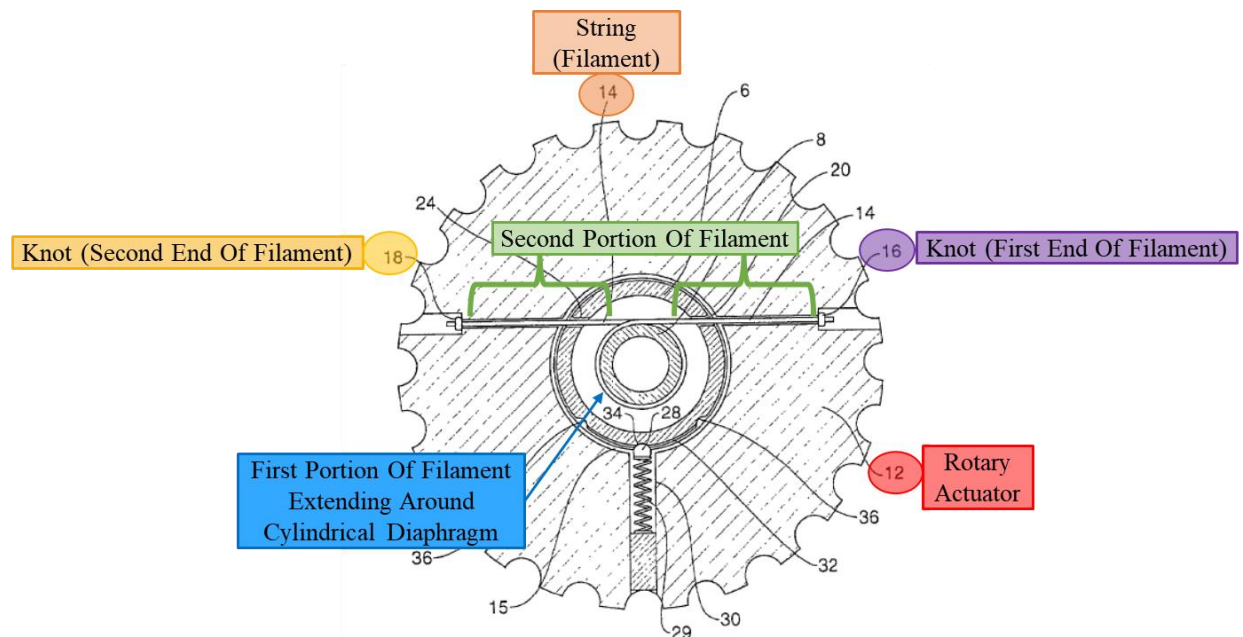


Fig 3

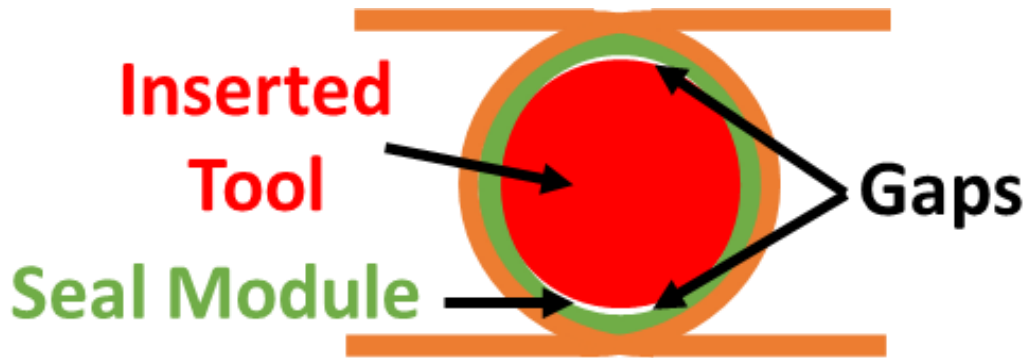
Id. at Fig. 3. The first end of second portion of Hartley's string is secured to the actuator at knot 16 and the second end of second portion is secured to the actuator at knot 18. *See id.* at [0031], Fig. 3.

122. 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.” *Id.* at [0031], [0034], Fig. 4. Hartley also discloses that its valve “will close over a range of diameters of devices passed through the valve or can close completely down to be self sealing.” *Id.* at [0037]. A person of ordinary skill in the art would have understood that Hartley’s ability to seal over a range of devices and to self seal when no device is passed through the valve is an important benefit for a hemostasis valve used during intravascular procedures, and it is important to minimize blood loss when a tool is inserted through the valve and before/after the tool is inserted. *See, e.g.*, Ex. 1005 (Schaffer) at [0008] (recognizing that “what is needed is a durable stasis valve that blocks the flow of gas or fluid completely and immediately with or without an instrument in place within the gas/fluid path”).

123. A person of ordinary skill in the art would have been motivated to replace Schaffer’s U-shaped actuating members with Hartley’s string/flexible member for several reasons. First, a person of ordinary skill in the art would have been motivated by Hartley’s disclosure that its valve with the string can “close over a range of diameters of devices passed through the valve or can close completely down to be self sealing.” Ex. 1006 (Hartley) at [0037]. A person of ordinary skill in the art would have known that multiple tools of varying sizes could be required

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

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



However, Hartley’s string encircles and, depending on the materials, may conform to the size and shape of a wider range of tools used with the valve. This ability to accommodate more tools would have been a highly desirable feature to a person of ordinary skill in August 2018. I note in related proceedings that Patent Owner argues a person of ordinary skill in the art would not have been motivated to modify Schaffer’s valve with Hartley’s string because Schaffer would not result in gaps. Patent Owner Preliminary Response re: ’011 patent filed in *Imperative Care, Inc. v. Inari Medical Inc.*, IPR2024-01157, Paper 5 at 28-29 (P.T.A.B. Oct. 29, 2024). However, even Schaffer recognizes it may not form a complete seal with the “gelatinous” and “sticky” valves identified by Patent Owner, stating the valves form a “**nearly** fluid/gas tight seal.” Ex. 1005 (Schaffer) at [0059]. Further, Patent Owner argues that Schaffer discloses a “gelatinous” or “sticky” valve with “selfclosing” properties. Patent Owner Preliminary Response re: ’011 patent filed in *Imperative Care, Inc. v. Inari Medical Inc.*, IPR2024-01157, Paper 5 at 29 (P.T.A.B. Oct. 29, 2024). But the portion of Schaffer that refers to a “sticky” or

“gelatinous” substance refers to embodiments of the valve having three portions where one of the portions can optionally be made from a “sticky” or “gelatinous” substance having a specific “shore hardness.” Ex. 1005 (Schaffer) at [0059]. Schaffer discloses many other materials that would not be “sticky” or “gelatinous” that could make up that same portion of the valve, such as modified vinyl, silicone, or polyurethane. *Id.* Nothing in Schaffer suggests that the third valve portion must be made with a “sticky” or “gelatinous” substance. Additionally, Schaffer makes clear that the valves in Figures 31-34 do not require the third portion stating: “The seal module 100 is formed of one or more seal members, as discussed above.” *Id.* at [0075]. Further, a person of ordinary skill in the art would have recognized that the “sticky” or “gelatinous” materials would not work well with the seal modules disclosed in Figures 31-34 because those seal modules must “retract to an uncollapsed configuration” when the tension on the module is released by the actuating members. A seal module made of the “sticky” or “gelatinous” materials would not easily return to its uncollapsed configuration.

125. Third, the combination of Hartley’s string and Schaffer’s valve would have merely entailed the substitution of one known element (Hartley’s string) for another (Schaffer’s U-shaped actuating members) and would have yielded the predictable results of constricting the central lumen of Schaffer’s valve to form a seal. I do not see any significant technical challenges that a person of ordinary skill

would have confronted in substituting Hartley's string for Schaffer's U-shaped actuating members, and I believe that the substitution would have been well within the level of ordinary skill in August 2018. I note in related proceedings that Patent Owner argues that a person of ordinary skill in the art would not have combined Hartley's string with Schaffer's valve because the combination would compromise Schaffer's "ease of manufacturing and durability." Patent Owner Preliminary Response re: '011 patent filed in *Imperative Care, Inc. v. Inari Medical Inc.*, IPR2024-01157, Paper 5 at 33 (P.T.A.B. Oct. 29, 2024). Notably, however, Schaffer does not claim to be easy to manufacture or durable. Further, as I explained during my deposition in the Litigation, Hartley's string would not have made Schaffer's valve so much more difficult to manufacture that it would have discouraged a person of ordinary skill in the art from making the combination. A person of ordinary skill in the art would have known of many ways to assemble the valve with the string. For example, a tapered fixture could be used to introduce the seal module through the looped strings that are already attached to the buttons. Alternatively, the seal module could be positioned in the valve and the strings could be looped around the module and connected to the buttons. Fundamentally, Schaffer's valve uses simple, predictable components and a person of skill would have had ample training and experience to manufacture the valve using Hartley's strings. Moreover, I see no basis for Patent Owner's argument that Hartley's strings

would “weaken the valve’s durability” as argued by Patent Owner. Hartley uses the strings for the same purpose they would be used in Schaffer’s valve and does not suggest any issues with durability. Based on the teachings in Schaffer, a person of ordinary skill in the art would reasonably expect success in using Hartley’s string in Schaffer’s valve.

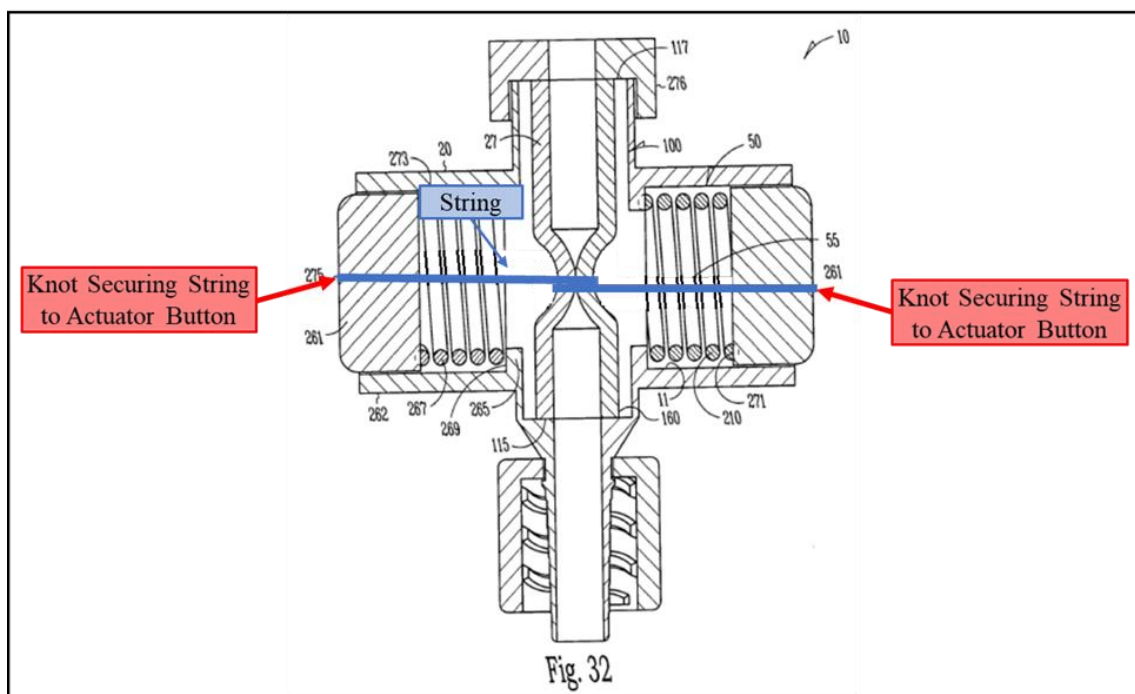
126. Fourth, as Schaffer recognizes, fluid stasis valves generally comprise “a resilient material in compression within a housing or clamping member.” Ex. 1005 (Schaffer) at [0003]. There were a finite number of ways to compress the resilient material in a hemostasis valve to create a seal in August 2018. Hartley and Schaffer disclose two such methods – Hartley’s single string and Schaffer’s two U-shaped actuating members formed from metal (e.g., aluminum) or plastic. As I discuss in the following section, Eller discloses a third option: one or more wire members. A person of ordinary skill in the art in August 2018 would have found it obvious to select from these finite, predictable options. And as I explain below, they would have had a reasonable expectation of success in implementing them.

127. Moreover, when replacing Schaffer’s actuating members with Hartley’s string, a person of ordinary skill in the art would have been motivated to loop Hartley’s string around Schaffer’s seal module (as in Hartley). Hartley discloses that looping the string around the cylindrical diaphragm will allow the diaphragm to “close over a range of diameters of devices passed through the valve

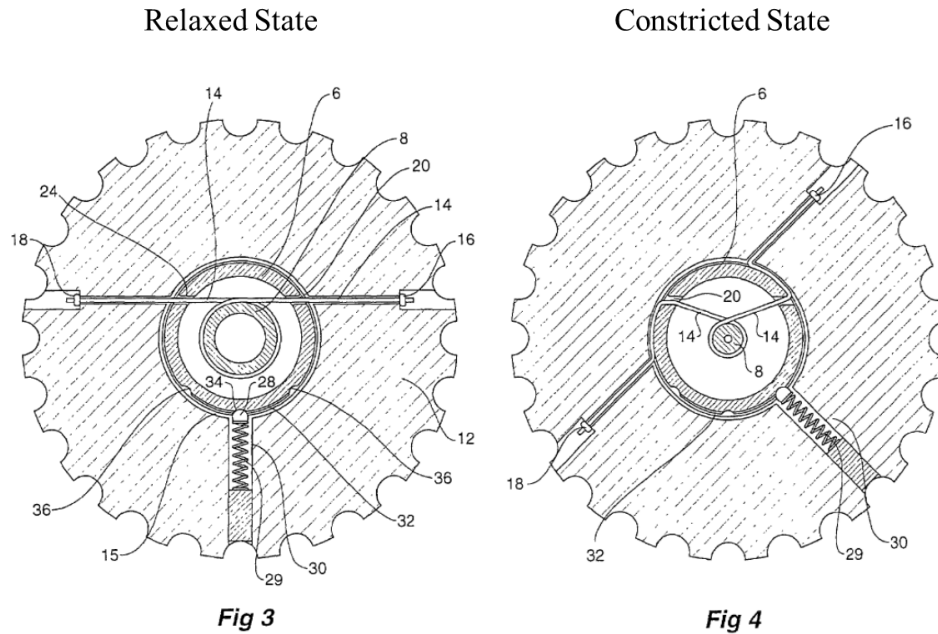
or can close completely down to be self sealing.” Ex. 1006 (Hartley) at [0031], [0037]. A person of ordinary skill in the art would have reasonably expected success in looping Hartley’s string around Schaffer’s seal module because Hartley discloses the configuration forms an effective seal.

128. A person of ordinary skill in the art would have had reasonably expected success in substituting Hartley’s string for Schaffer’s U-shaped actuating members for multiple reasons. First, Hartley teaches a simple method for attaching its string to an actuator – a knot at the terminal ends of the string. Ex. 1006 (Hartley) at [0031]. A person of ordinary skill in the art would have reasonably expected that this same method could be used to attach Hartley’s string to each of Schaffer’s actuator buttons. For example, small holes could be made in each of Schaffer’s actuator buttons, and each end of the string could be threaded through the hole on the opposite buttons and knotted on the other side. This would have been a very simple modification, and a person of ordinary skill in the art would have been fully capable of implementing it in August 2018. The demonstrative illustration that I provide below depicts a basic diagram of how this modification could be achieved. As shown, the first end of the string would be secured to the first actuator button (first actuator member), the string would loop at least once around the lumen of Schaffer’s valve, and then the second end of the string would be secured to the second actuator button (second actuator member) on the opposite side of the valve:

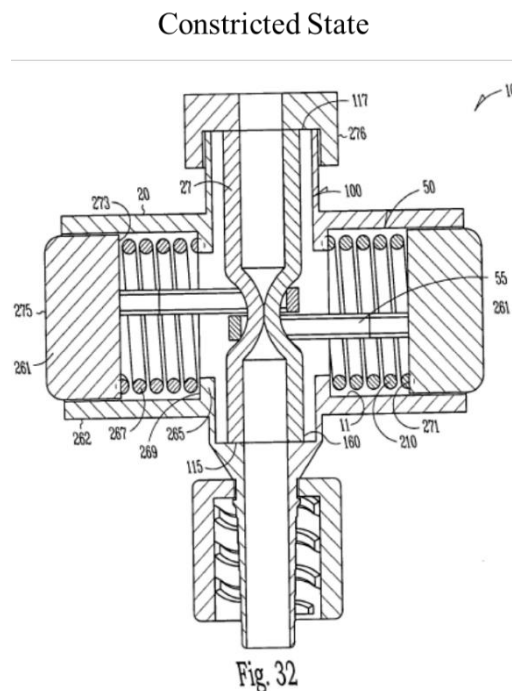
Demonstrative Illustration Schaffer + Hartley's String



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



Ex. 1006 (Hartley) at [0031], Figs. 3-4. Schaffer's U-shaped actuating members seal the central lumen when compressive forces supplied by the springs attached to the actuator buttons cause the U-shaped actuating members to constrict and collapse the seal module, as illustrated in Figure 32:



Ex. 1005 (Schaffer) at [0077], Fig. 32. Thus, both Hartley and Schaffer seal the central lumen of the valve by pulling the string/actuating members in opposite directions to constrict and compress the central lumen of the valve. *See* Ex. 1005 (Schaffer) at [0077], Ex. 1006 (Hartley) at [0031]. Moreover, both Hartley and Schaffer disclose a seal module/cylindrical diaphragm that is resilient and can resume its open position when tension is removed by pressing the buttons. For example, Schaffer discloses that its seal module is formed of a “resilient material” that will “retract to an uncollapsed configuration” when the compressive forces are removed. Ex. 1005 (Schaffer) at [0003], [0077]. Similarly, Hartley discloses that “the cylindrical diaphragm is formed from a resilient material so that after constriction and release of the flexible member the valve reopens.” Ex. 1006 (Hartley) at [0008].

130. In view of the similarities between the operation of Hartley and Schaffer’s valves, a person of ordinary skill in the art would have expected Hartley’s string to serve as a reasonable, if not superior, substitute for the U-shaped actuating members. In a first position, Schaffer’s undepressed actuator buttons would cause the “string 14 [attached to the buttons] to be pulled in both directions at once.” *See* Ex. 1005 (Schaffer) at [0077]; Ex. 1006 (Hartley) at [0031]. This would cause the string to constrict and collapse the lumen of Schaffer’s containment structure, sealing the valve.

131. Then, when Schaffer's actuator buttons are depressed and moved to the second position, the compressive forces from the springs would be relaxed, relieving the tension on the string, and causing the string to loosen around the central lumen so that the lumen at least partially opens. See Ex. 1005 (Schaffer) at [0077]; Ex. 1006 (Hartley) at [0031]. Schaffer discloses that the seal module is formed from a "highly deformable, non-compressible material 166 (e.g., plastic)" and is "configured to maintain an open lumen 193 when no compressive force 67 is applied." Ex. 1005 (Schaffer) at [0054]. Thus, a person of ordinary skill in the art would have expected that Schaffer's lumen would have the resilience to return to its open configuration when the actuator buttons are pressed inwardly, and the tension on the string is released such that "no compressive force [] is applied" to the lumen." *Id.*

132. Moreover, if the person of ordinary skill found that the resiliency of Schaffer's lumen required adjustment to function with Hartley's string, the person of skill would have possessed the skills and knowledge to select an appropriate material with the proper resiliency. There were a range of suitable materials disclosed in the prior art for forming the lumen of a hemostasis valve. For example, Schaffer discloses that the materials for the lumen can include "modified vinyl, silicone, polyurethane or a combination thereof," as well as modifications of those materials with "waxes and/or oils or un-cross-linked modifiers." Ex. 1005

(Schaffer) [0081]. Hartley discloses that “[p]referably the cylindrical diaphragm is formed from a resilient material so that after constriction and release of the flexible member the valve reopens” and further discloses that “[i]n a preferred form the cylindrical diaphragm of the valve may be constructed from an elastomeric material such as silicone rubber.” Ex. 1006 (Hartley) at [0008], [0016]. Eller discloses a variety of sleeves made from “NuSil MED-4755, NuSil MED-4765, and NuSil MED-4014.” Ex. 1007 (Eller) at 36:27-60. The components referred to as the “seal module” in Schaffer, the “cylindrical diaphragm” in Hartley, and the “sleeve” in Eller all correspond to the portion of the hemostasis valve that forms the central lumen of the valve. See Ex. 1005 (Schaffer) at [0049], [0051], [0054], [0075]; Ex. 1006 (Hartley) at [0031]; Ex. 1007 (Eller) at 11:60-64. Thus, the prior art would have provided a person of ordinary skill with a range of suitable options for selecting a suitable lumen material that was both deformable and possessed the resilience to return to its open state when constricting force is removed.

(c) Eller

133. Eller discloses a hemostasis valve that includes “a housing 16, an actuator 18, a sleeve 20, [and] a first wire member 22”:

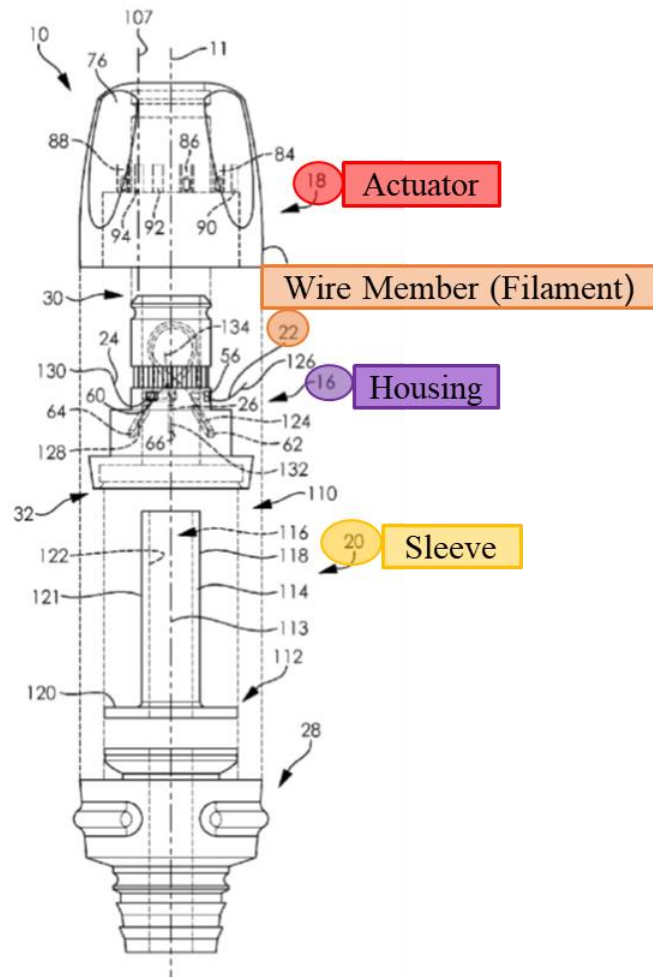


FIG. 2

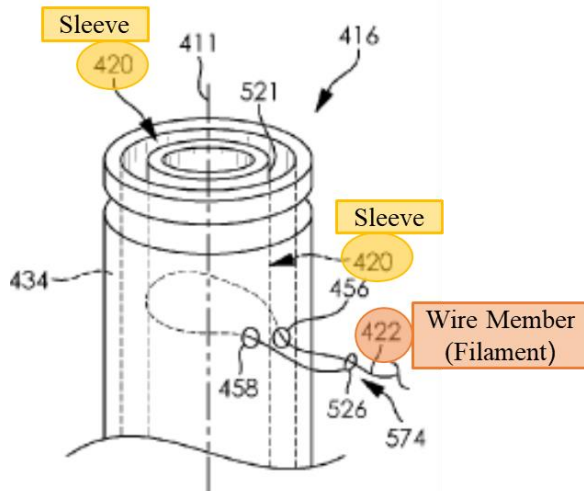


FIG. 16

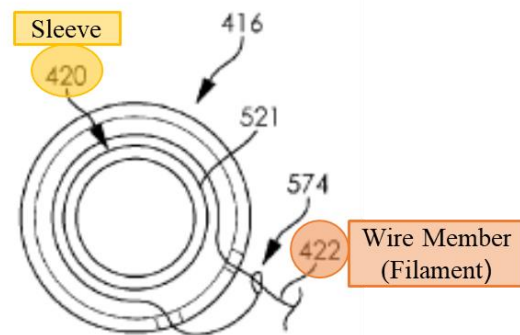


FIG. 17

Ex. 1007 (Eller) at 5:1-5, Figs. 2,³ 16-17. Some of Eller's examples, such as Figure 2 above, include three wire members: a first wire member, a second wire member, and a third wire member. *See* Ex. 1007 (Eller) at 5:1-5, Figs. 2, 8-10. However, Eller also discloses that "a selective fluid barrier device can include any suitable number of wire members," including only one wire member. *Id.* at 16:7-19. Eller depicts examples having only one wire member in Figures 15-17 and 20-22. *Id.* at 21:37-22:31, 23:50-25:9, Figs. 15-17, 20-22. Thus, Eller's disclosure of examples having more than one wire member does not affect my opinions on whether the claims of the '005 patent are patentable.

134. Eller says that its wire member "can have any suitable structure and comprise any suitable number of strands and/or fibers that are twisted, or otherwise interconnected to one another" and can comprise, for example, "a suture or a cable." Ex. 1007 (Eller) at 15:61-16:6. The wire member "can have a cross-sectional configuration that is round, substantially round, rectangular, square, oval, and any other configuration considered suitable for a particular embodiment." *Id.* at 15:65-16:2. Eller's wire member is therefore a "filament" as disclosed in the '519 Application and claimed in the '005 patent because the wire member is at least a

³ Eller's Figure 2 shows an exploded view of the device. Ex. 1007 (Eller) at 2:46-47. An un-exploded view is depicted in Figure 1. *Id.* at Fig. 1.

line, cord, ribbon, sheet, or flat wire. *See* Ex. 1017 ('519 Application) at [0047] (disclosing that the filament can constitute “one or several threads, lines, cords, rope, ribbon, flat wire, sheet, or tape”).

135. Eller's first wire member has a first end 124 attached to the housing 16 and a second end 126 attached to the actuator 18. Ex. 1007 (Eller) at 12:52-58. Eller discloses that first wire member extends from its first end attached to the housing 16 and “around a portion of the outer surface 121 of the sleeve 20” to the second end attached to the actuator 18. *Id.* at 12:58-64. Figure 21 below illustrates the arrangement of the wire member around the outer surface of the sleeve:

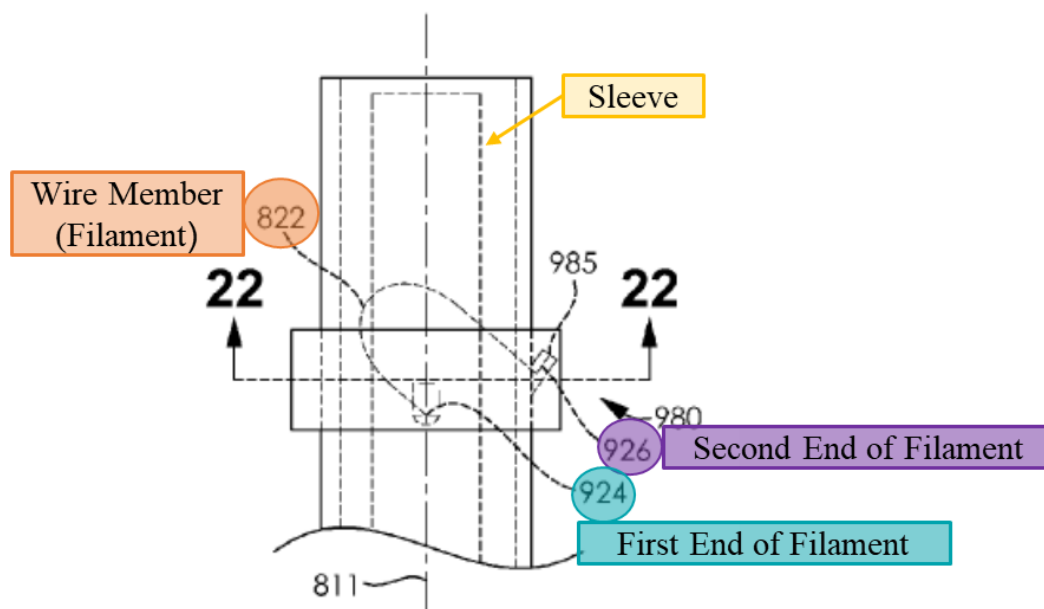
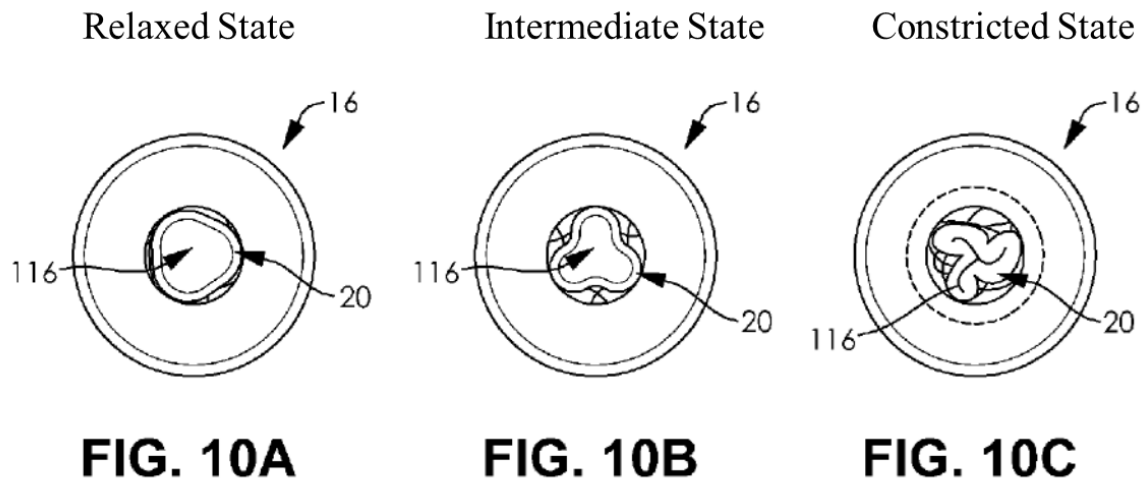


FIG. 21

Id. at 24:50-57, Fig. 21.

136. Eller's valve is “movable between a first configuration and a second configuration.” *Id.* at 15:21-25. Eller explains that in the first configuration, the

wire member is in a relaxed state and fluid is permitted to flow through the sleeve. *Id.* at 15:21-40, 17:38-43. Then, when the actuator is rotated, the valve is moved to the second configuration where the actuator places the wire member in a tensioned state, causing the wire member to constrict the sleeve and prevent fluid from passing therethrough. *Id.* at 15:21-40, 17:62-67. Figures 10A through 10C illustrate the valve transitioning from the first relaxed position (10A) to the second constricted position (10C):



Id. at 15:21-40, Figs. 10A-10C. Eller also discloses that “when one or more medical devices are passed through the passageway 116 defined by the sleeve 20, the material that forms the sleeve 20 contacts a portion of one or more of the medical devices to close the passageway 116 such that fluid is prevented from passing through the passageway 116.” *Id.* at 18:3-8.

137. A person of ordinary skill in the art would have found it obvious, and been motivated, to replace Schaffer’s U-shaped actuating members with Eller’s

wire member for several reasons. First, a person of ordinary skill in the art would have been motivated by Eller's description that the wire member can form a seal around one or more medical devices passed through the valve to prevent fluid from leaking around the device. Ex. 1007 (Eller) at 15:21-40, 17:38-43, 18:3-8. A person of ordinary skill in the art would have also recognized that a stasis valve should seal and prevent leakage of fluid when a tool is inserted through the valve during a procedure. Thus, Eller's ability to seal around such devices would have been beneficial to a person of ordinary skill.

138. Second, like I explained previously with respect to Hartley's string (the discussion of which I incorporate herein), a person of ordinary skill in the art would have recognized that Eller's wire member may seal more effectively than Schaffer's metallic/plastic U-shaped actuating members when constricting the valve lumen. The compliancy of Eller's wire member would allow it to conform to a wider range of tools of varying diameters and shapes than Schaffer's U-shaped members. A person of ordinary skill in the art would have recognized that if a tool did not fit the size of Schaffer's U-shaped members, small gaps could form between the tool and the valve's lumen. However, a more compliant constricting mechanism, like Eller's wire member, could conform to the size and shape of a wider range of tools. Thus, Schaffer's valve combined with Eller's wire member may accommodate a wider

range of tools/devices, which would have been a highly desirable feature to a person of ordinary skill in August 2018.

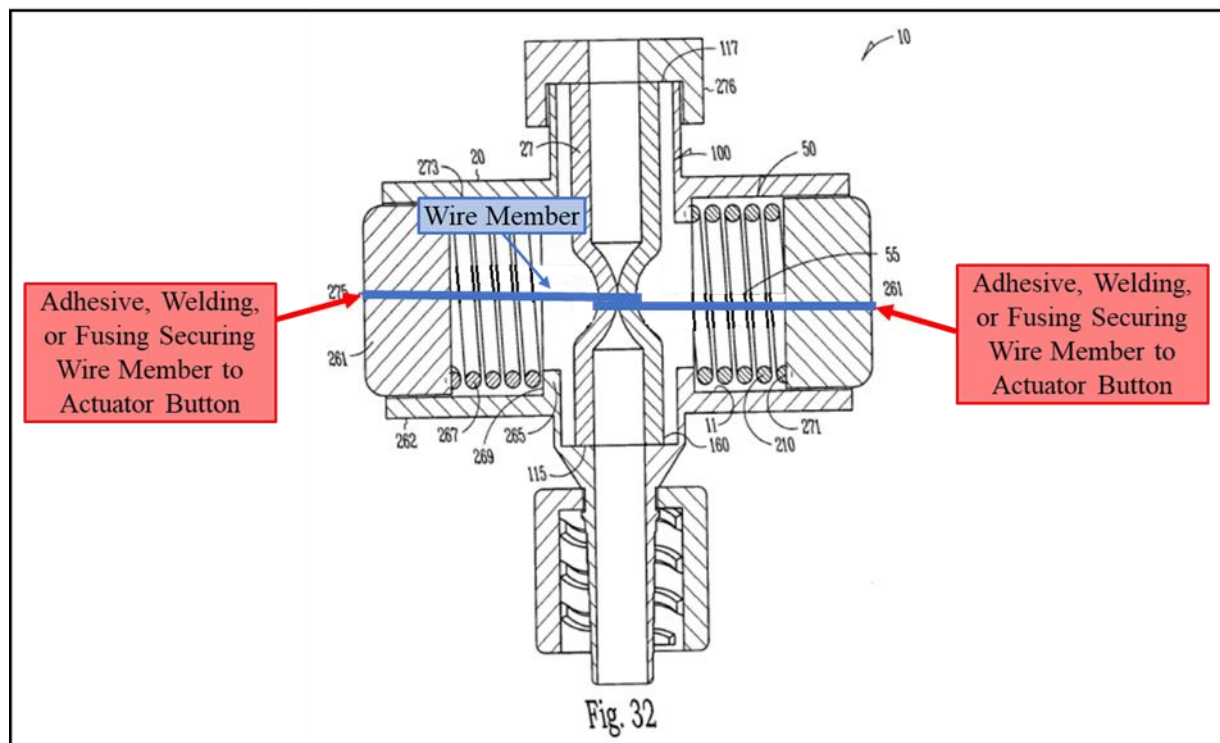
139. Third, the combination of Eller's wire member and Schaffer's valve would have merely entailed the substitution of one known element (Eller's wire member) for another (Schaffer's U-shaped actuating members) and would have yielded the predictable results of constricting the central lumen of Schaffer's valve to form a seal. I do not see any significant issues that would have prevented a person of ordinary skill in the art from combining Eller's wire member with Schaffer's valve. The substitution would have been well within the level of ordinary skill in August 2018.

140. Fourth, as Schaffer recognizes, fluid stasis valves generally comprise "a resilient material in compression within a housing or clamping member." Ex. 1005 (Schaffer) at [0003]. As I explained previously with respect to the Schaffer-Hartley combination, there were a finite number of methods to compress the resilient material in a stasis valve in August 2018. Eller and Schaffer disclose two such methods – Eller's wire member and Schaffer's U-shaped actuating members. A person of ordinary skill in the art in August 2018 would have found it obvious to select either of these finite, predictable options. And as I explain below, they would have had a reasonable expectation of success in implementing them.

141. A person of ordinary skill in the art would have had reasonably expected success in substituting Eller's wire member for Schaffer's U-shaped actuating members for multiple reasons. First, Eller states that the "[a]ttachment between a wire member and a housing and/or actuator can be accomplished using any suitable method or technique, and skilled artisans will be able to select a suitable method or technique to attach a wire member to a housing and/or an actuator according to a particular embodiment based on various considerations, including the material(s) that forms the wire member." Ex. 1007 (Eller) at 14:37-43. Eller then provides several exemplary ways to secure its wire member to an actuator, "including using adhesive, welding, fusing, providing a friction fit between the wire member and the ... actuator, and any other method or technique considered suitable for a particular embodiment." *Id.* at 14:43-49. Eller's examples would have been common and predictable to a person of ordinary skill in the art in August 2018, and a person of ordinary skill would have reasonably expected success in securing Eller's wire member to Schaffer's actuator buttons using one or more of those methods. The demonstrative illustration that I provide below depicts a basic diagram of how this could be achieved. As shown, the first end of the wire member would be secured to the first actuator button (first actuator member), the wire member would loop at least once around the lumen of Schaffer's valve, and then

the second end of the wire member would be secured to the second actuator button (second actuator member) on the opposite side of the valve:

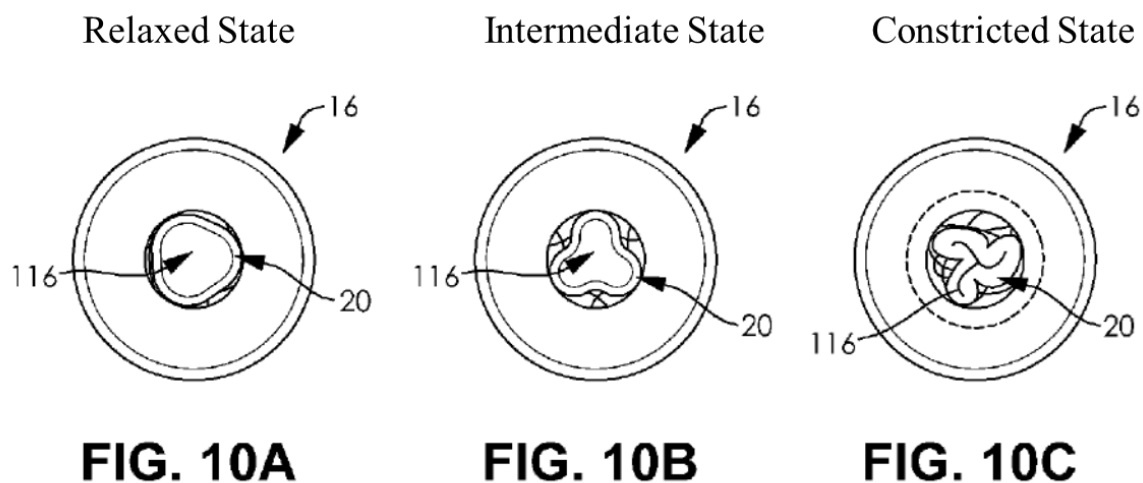
Demonstrative Illustration Schaffer + Eller's Wire Member



142. Second, Eller discloses that its wire member may be used with “any suitable actuator capable of moving the selective fluid barrier valve device between a first configuration and a second configuration” and that “[s]killed artisans will be able to select a suitable actuator to include on a selective fluid barrier valve device according to a particular embodiment based on various considerations, including the number of wire members included in the selective fluid barrier valve device and/or the structural arrangement of the housing.” *Id.* at 8:27–39. Eller discloses that suitable actuators include “rotatable actuators, linear actuators, slidable

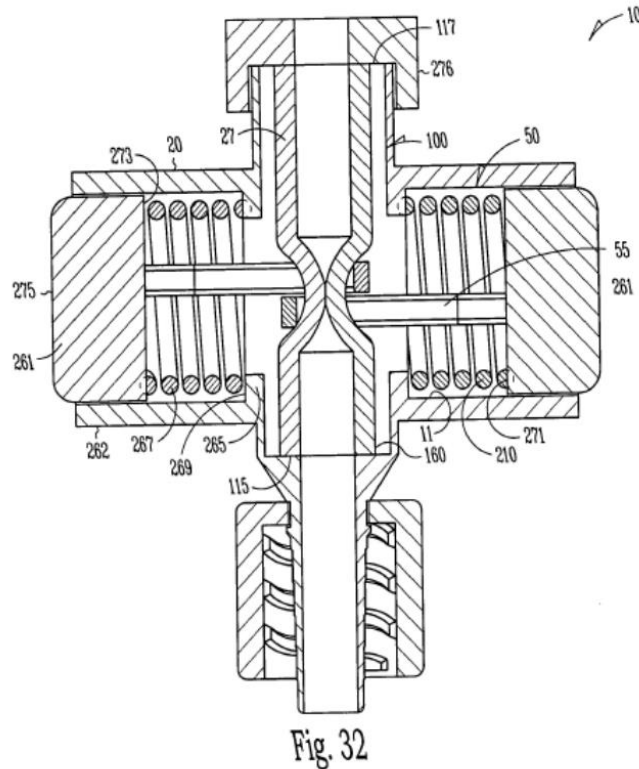
actuators, pivotable actuators, levers, and any other actuator considered suitable for a particular embodiment.” *Id.* at 8:39–44 (emphasis added). A person of ordinary skill in the art would have understood that Schaffer’s actuator is an example of a linear and slidable actuator. *See* Ex. 1005 (Schaffer) at [0076]–[0077]. Thus, Eller’s disclosure regarding the wide range of actuators suitable for use with its wire member would have reinforced the person of ordinary skill in the art’s reasonable expectation that Eller’s wire member could be successfully combined with Schaffer’s actuator buttons.

143. Third, a person of ordinary skill in the art would have recognized that Eller’s wire member and Schaffer’s U-shaped actuating members use similar mechanisms to compress and seal the central lumen of the valve. Eller’s wire member seals the valve when the actuator is placed in the second position, which creates tension in the wire member and causes the wire member to constrict the sleeve, as illustrated in Figures 10A-10C below:



Ex. 1007 (Eller) at 15:21-40, 17:47-18:3, Figs. 10A-10C. Schaffer's U-shaped actuating members seal the central lumen when the U-shaped actuating members constrict and collapse the containment structure, as illustrated in Figure 32:

Constricted State



Ex. 1005 (Schaffer) at [0077], Fig. 32. Thus, both Eller and Schaffer seal the central lumen of the valve by causing the wire/actuating members to constrict and compress the central lumen of the valve. See Ex. 1005 (Schaffer) at [0077]; Ex. 1007 (Eller) at 15:21-40, 17:47-18:3.

144. In view of the similarities between Eller and Schaffer's valves, a person of ordinary skill in the art would have expected that Eller's wire member

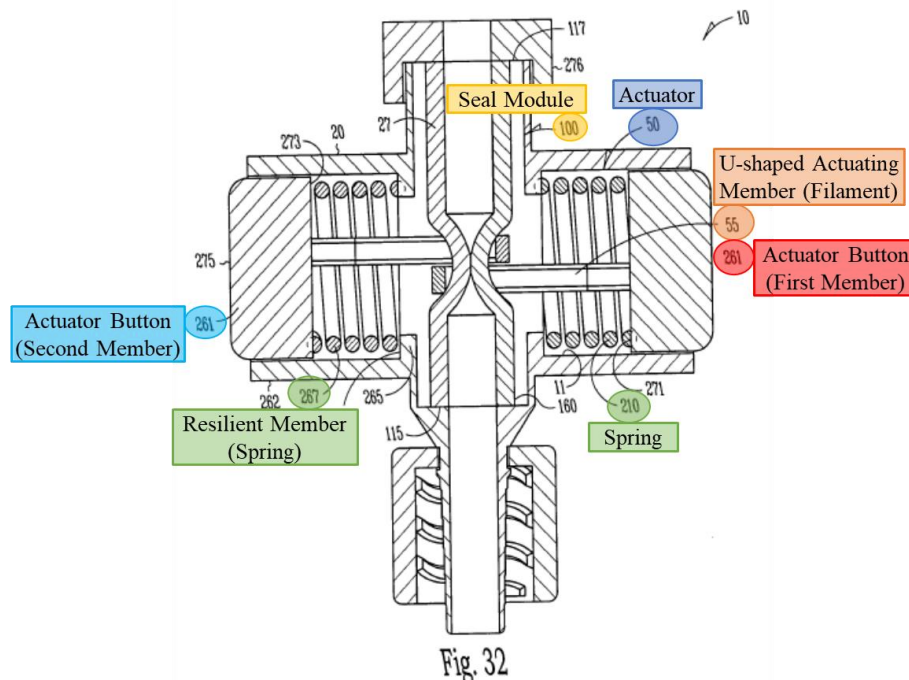
would serve as a reasonable, if not superior, substitute for the U-shaped actuating members. For example, in a first position Schaffer's undepressed actuator buttons would pull the wire member in opposing directions, placing tension on the wire member. *See* Ex. 1005 (Schaffer) at [0077]; Ex. 1007 (Eller) at 15:21-40, 17:47-18:3. This would cause the string to constrict and collapse the lumen of Schaffer's containment structure, sealing the valve. Then, when Schaffer's actuator buttons are depressed and moved to the second position, the compressive forces from the springs would be relaxed, relieving the tension on the wire member, and causing the wire member to loosen around the central lumen so that the lumen least partially opens. *See* Ex. 1005 (Schaffer) at [0077]; Ex. 1007 (Eller) at 15:21-40, 17:47-18:3. Schaffer discloses that the seal module is formed from a "highly deformable, non-compressible material 166 (e.g., plastic)" and is "configured to maintain an open lumen 193 when no compressive force 67 is applied." (Ex. 1005, [0054].) A person of ordinary skill in the art would have therefore expected that Schaffer's lumen would have the resilience to return to open configuration when the actuator buttons are pressed inwardly, and the tension on the wire member is released such that "no compressive force [] is applied" to the lumen." (*Id.*) Further, as I explained with respect to the Schaffer-Hartley ground, if the resiliency of Schaffer's lumen required adjustment to function with Eller's wire, a person of ordinary skill in the art would have possessed the skills and knowledge to select an appropriate material

with the proper resiliency. (*Supra* §VI.A.8.b.ii.b.) These similarities between Eller's wire member and Schaffer's U-shaped actuating members would have reinforced a person of ordinary skill in the art's reasonable expectation that Eller's wire member could be successfully implemented in Schaffer's valve.

c. Biasing System

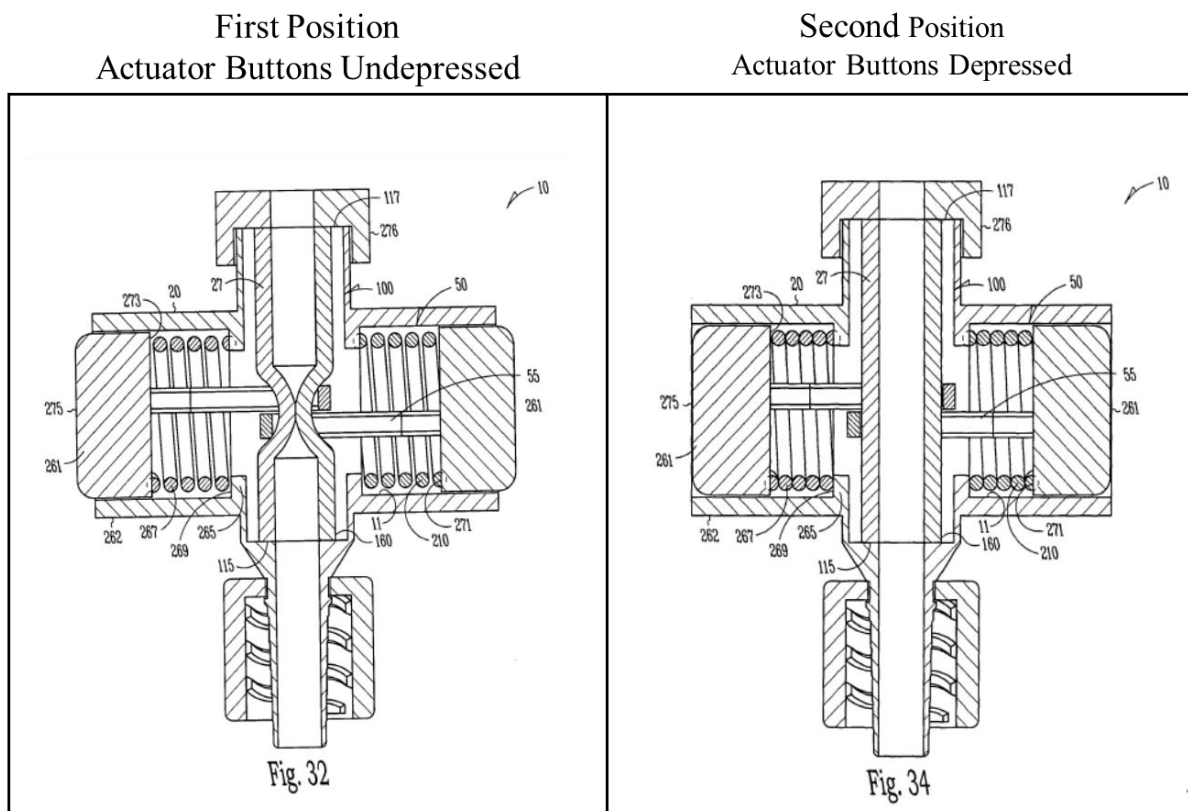
145. Claim 1 finally recites that the hemostasis valve comprises “a biasing system configured to bias the first member and the second member to the first position.” Schaffer discloses this limitation.

146. Schaffer's hemostasis valve includes “two resilient members 267 (e.g., spring 210) disposed within the actuating member 55”:



Ex. 1005 (Schaffer) at [0077], Fig. 31. Schaffer's resilient members/springs are a “biasing system configured to bias the first member and the second member to the first position.”

147. Schaffer's springs bias the actuator buttons (i.e., the first and second members of the actuator) toward the first (i.e., sealed) position by imposing a force on the actuator buttons when the buttons are undepressed. *Id.* at [0077]. The force supplied by the springs cause the actuating members coupled to the buttons to collapse and seal the seal module, preventing the flow of fluid through the valve. *Id.* The system remains biased towards this sealed stated until the actuator buttons are depressed, which relieves the force applied by the springs:



Id. at [0077], Figs. 32, 34.

B. Claim 2

148. Claim 2 recites: “The vacuum aspiration system of claim 1 wherein the tubular member is pliable.” Schaffer discloses the additional limitations in Claim 2, and therefore, Garrison in combination with Schaffer and optionally Hartley *or* Eller renders Claim 2 obvious.

149. Schaffer discloses that the seal module 100 (i.e., the tubular member) “includes a flexible, elongate tubular structure 101 having an outer wall 27 which includes a material 166 that is highly elastic, deformable, compliant and yet virtually non-compressible.” Ex. 1005 (Schaffer) [0054]. A “highly elastic, deformable, [and] compliant” material would be pliable. Thus, Schaffer’s tubular member is pliable.

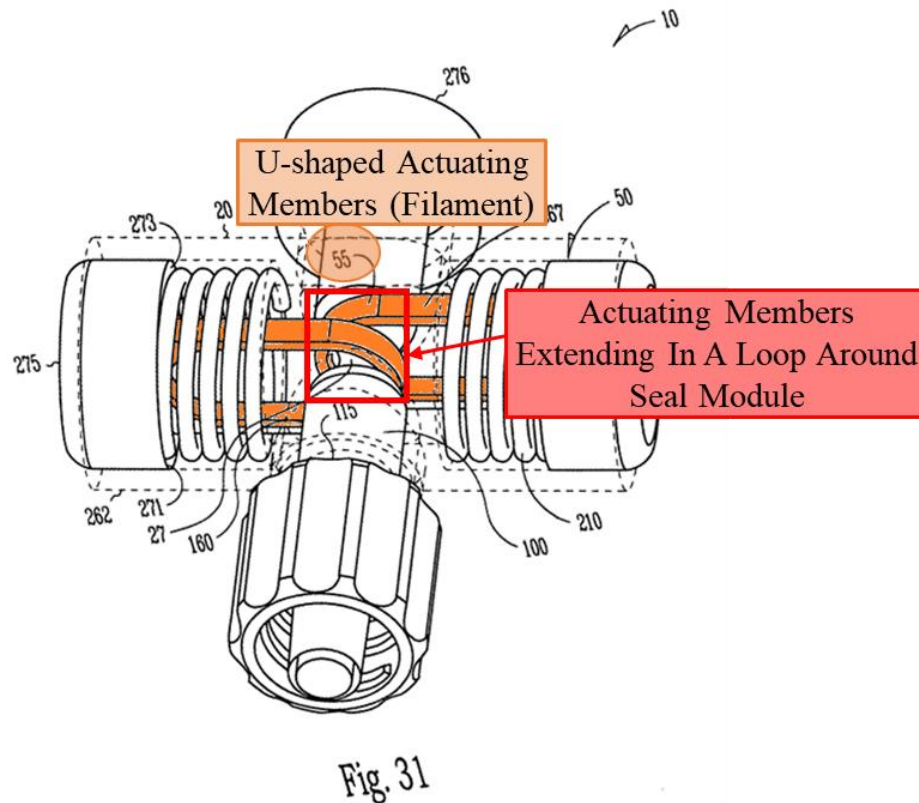
C. Claim 3

150. Claim 3 recites: “The vacuum aspiration system of claim 1 wherein the first portion of the filament extends in a loop completely around the tubular member.” Garrison in combination with Schaffer and optionally Hartley *or* Eller renders Claim 2 obvious.

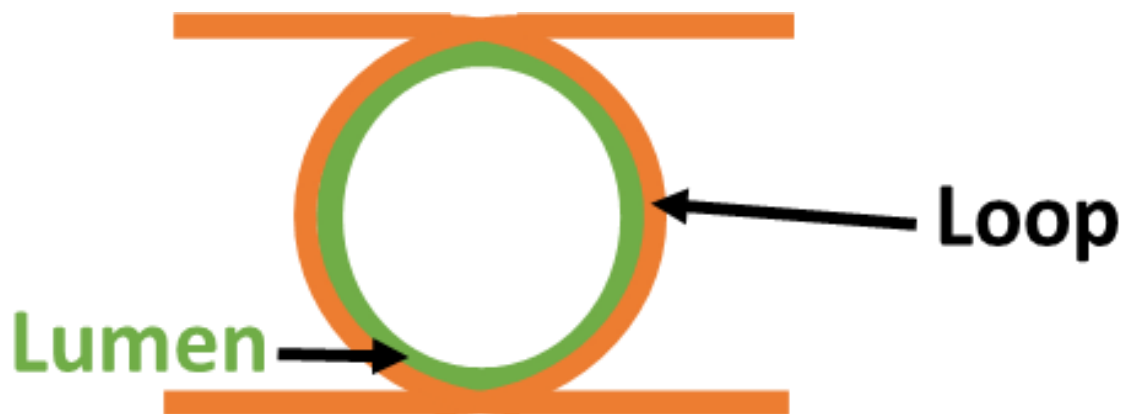
1. Schaffer

151. Schaffer discloses that the actuating members are “at least partially circumferentially [sic] disposed about the portion 108 of the seal module 100.” Ex.

1005 (Schaffer) at [0076]. As shown in Figure 31 below, the actuating members collectively encircle the seal module 100 to form a loop thereabout:



Id. at Fig. 31. The graphic below illustrates how Schaffer's U-shaped actuating members form a loop around the lumen:



152. This arrangement is similar to the arrangement of the filament depicted in Figures 8 and 9 of the '519 Application:

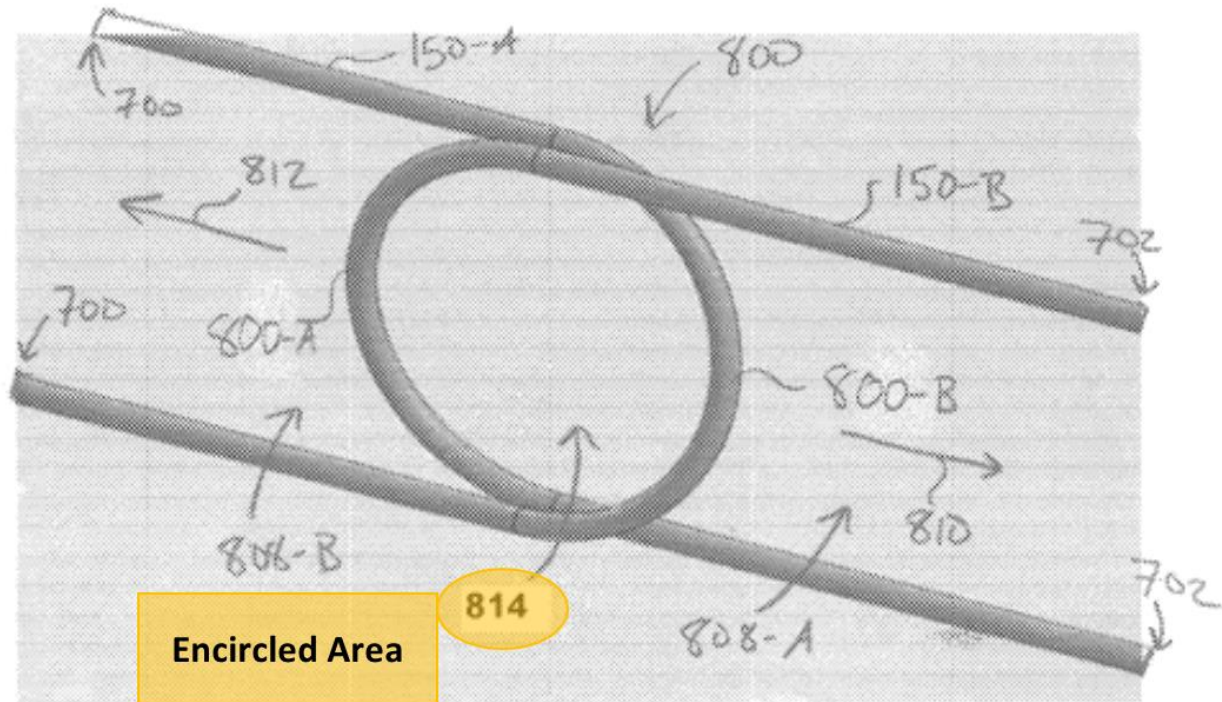


Figure 8

Ex. 1001 ('005 Application) at Figs. 8-9. The '519 Application explains that this configuration forms “an encircled area 814, also referred to herein as a constricting area 814” and that the “elongate member 132 can be received within the encircled area 814.” *Id.* at [0069]. Thus, the “encircled area” forms a loop around the elongate member 132. Schaffer’s actuating members form a similar loop.

2. Hartley

153. Hartley discloses that its string “is wound preferably twice around the cylindrical diaphragm” as shown in Figure 3 below:

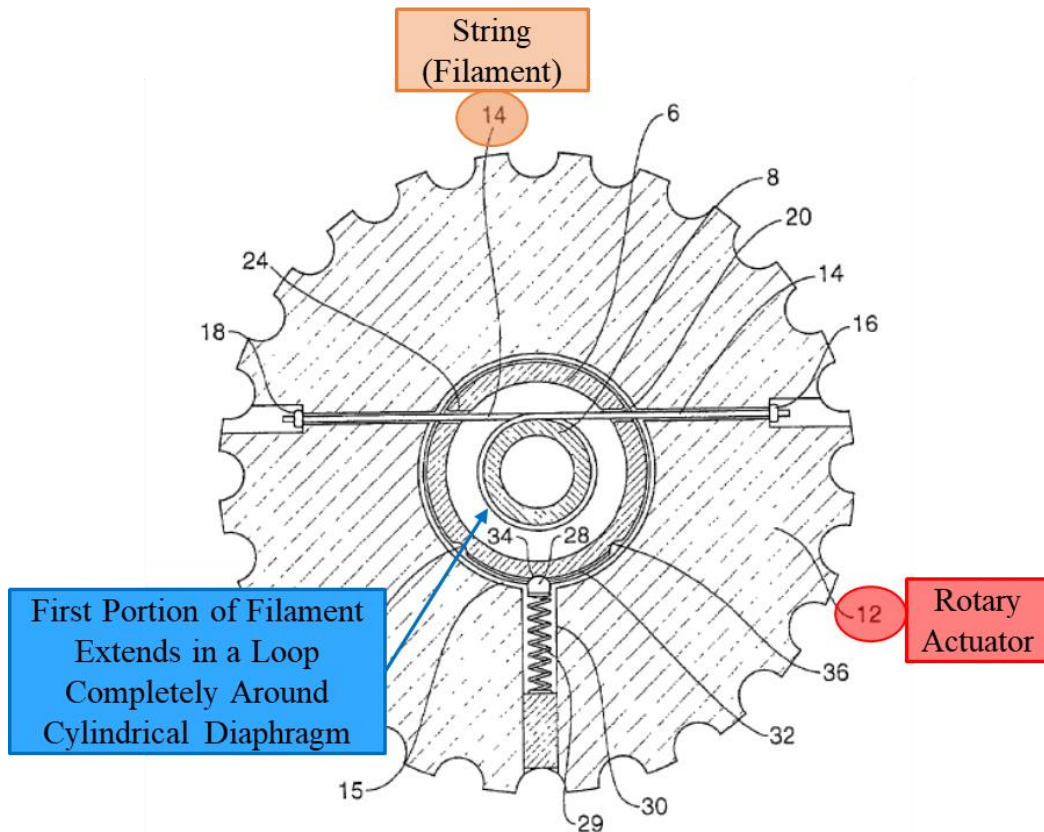


Fig 3

Ex. 1006 (Hartley) at [0031], Fig. 3. Hartley’s string therefore includes a first portion that “extends in a loop completely around the tubular member.” *Id.*

154. A person of ordinary skill in the art would have been motivated to loop Hartley’s string around Schaffer’s tubular member when replacing Schaffer’s U-shaped actuating members with Hartley’s string. Hartley discloses that looping the string around the tubular member is the preferred configuration for its string and that such a configuration “will close over a range of diameters of devices passed through the valve or can close completely down to be self sealing.” Ex. 1006 (Hartley) [0031], [0037]. This description of the benefits of the configuration

would have motivated a person of ordinary skill in the art to use the same configuration when implementing Hartley's string in Schaffer's valve.

155. A person of ordinary skill in the art would have reasonably expected success in winding Hartley's string around Schaffer's tubular member. As I explained in Claim 1 above, the mechanism of action of Schaffer's and Hartley's valves are similar. Basically, the valves are designed to pull the ends of the filaments to close the valve. The buttons/springs in Schaffer's valve would both pull the ends of Hartley's string in opposite directions to tighten the string around the tubular member. A person of ordinary skill in the art would have possessed the necessary skills to adjust the spring force and/or the resilience of the seal module so that Schaffer's valve operated effectively with Hartley's string.

3. Eller

156. Eller discloses that some versions of its valve "can include a single wire member that is disposed around more than 75% of the outer surface of the sleeve or that is disposed around more than 100% of the outer surface of the sleeve. For example, the wire member can be positioned such that it extends at least one full revolution around the outer surface of the sleeve." Ex. 1007 (Eller) at 22:18-24. In a configuration where the wire member is "positioned such that it extends at least one full rotation around the outer surface of the sleeve," the wire member

includes a first portion that “extends in a loop completely around the tubular member.” *Id.*

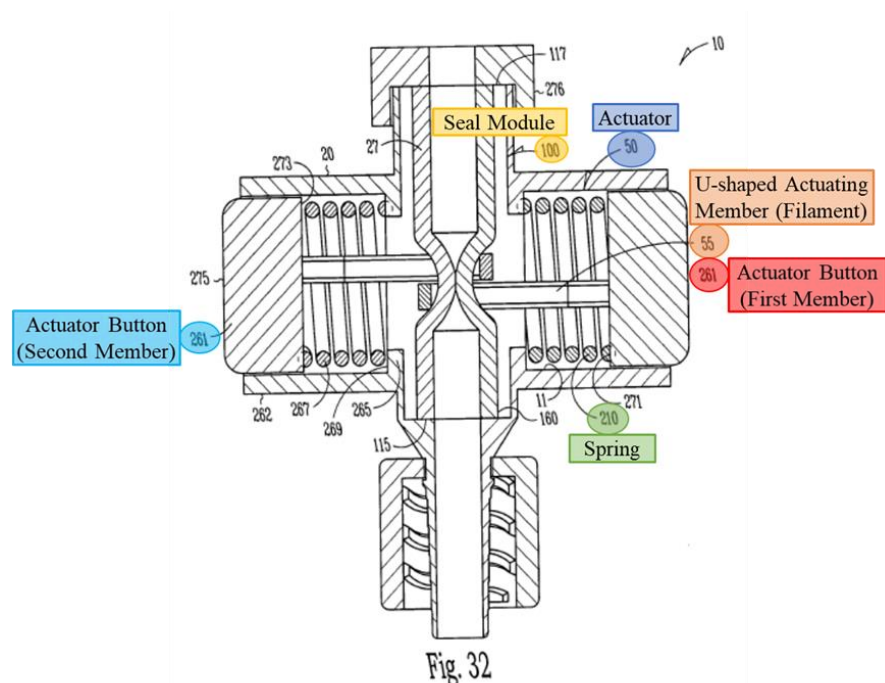
157. A person of ordinary skill in the art would have been motivated to use the looped configuration for Eller’s wire member when replacing Schaffer’s U-shaped actuating members with Eller’s wire member. A person of ordinary skill in the art would have recognized that looping the wire member around the entire circumference of Schaffer’s seal module would maximize the constrictive seal of the wire member around Schaffer’s seal module and any tools inserted therethrough because it would ensure that the entire outer circumference of tools would be constricted against the seal module, eliminating any gaps that might otherwise exist.

158. A person of ordinary skill in the art would have reasonably expected success in looping Eller’s wire member around Schaffer’s seal module much for the same reasons the person would have expected success looping Hartley’s string around Schaffer’s seal module. The mechanisms of action are similar between Schaffer and Eller – namely, pulling the ends of the filament in opposite directions to close the tubular member. A person of ordinary skill in the art would have expected Eller’s wire member to close around the seal module when Schaffer’s springs exert force on the wire member.

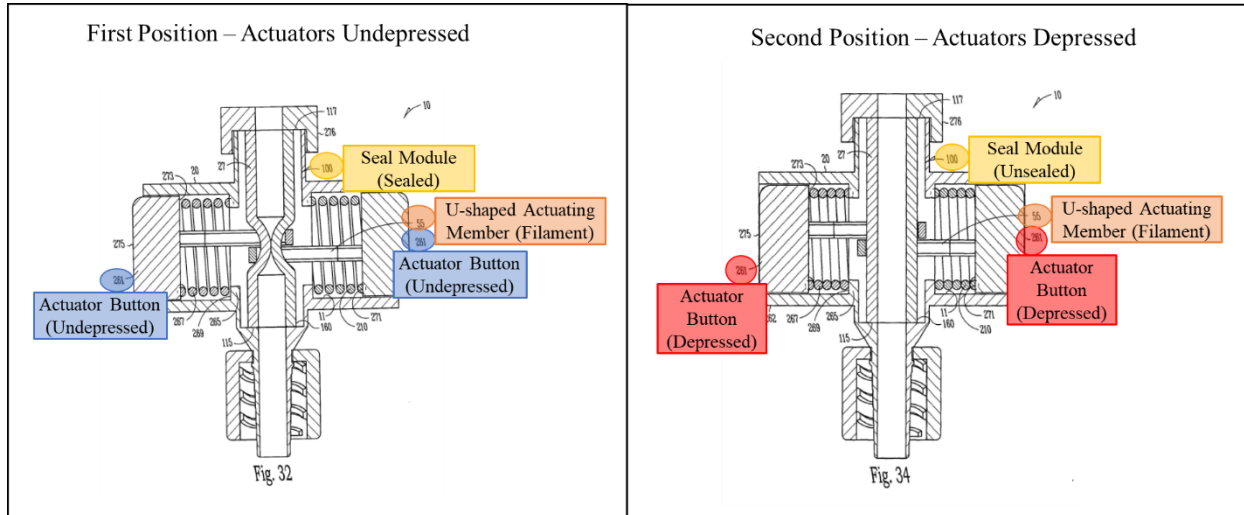
D. Claim 4

159. Claim 4 recites: “The vacuum aspiration system of claim 1 wherein the first member of the actuator comprises a first button and the second member of the actuator comprises a second button, wherein the first button and the second button are undepressed in the first position, and wherein the first button and the second button are depressed in the second position.” Garrison in combination with Schaffer and optionally Hartley or Eller renders claim 4 obvious.

160. As I explained for Claim 1 previously, 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”:

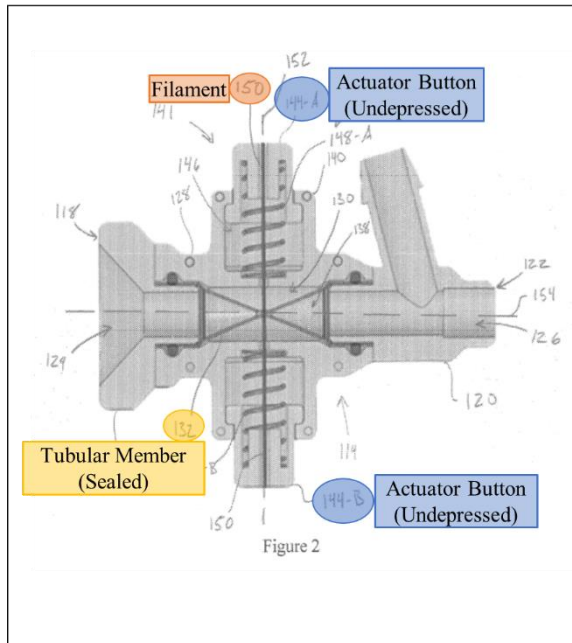


Ex. 1005 (Schaffer) at [0075]-[0076], Figs. 31-32. Schaffer discloses that the actuator buttons are undepressed when the valve is in the first (closed) position, shown in figure 32 below, and are depressed when the valve is in the second (open) position, shown in Figure 34 below:

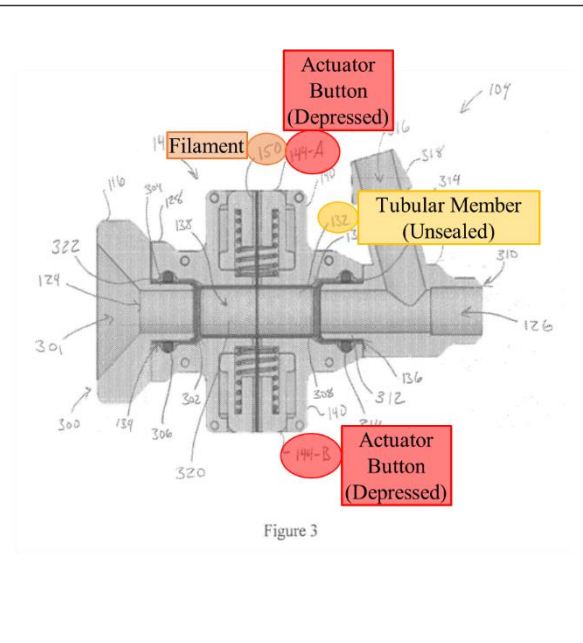


Id., [0077], Figs. 32, 34. This is the same configuration disclosed for the first position and second position of the hemostasis valve in the '519 Application:

First Position – Actuators Undepressed



Second Position – Actuators Depressed



Ex. 1017 ('519 Application) at Figs. 2-3.

E. Claim 5

161. Claim 5 recites: “The vacuum aspiration system of claim 1 wherein, when the first member and the second member of the actuator are in the first position, the lumen of the tubular member is configured to remain constricted and sealed when a pressure differential exists between (a) a first volume outside the lumen and adjacent to a first end of the tubular member and (b) a second volume outside the central lumen and adjacent to a second end of the tubular member.” Garrison in combination with Schaffer and optionally Hartley or Eller renders Claim 5 obvious.

162. As an initial matter, I note that Claim 5 merely requires that the valve is configured to remain sealed when “a pressure differential exists” between a

volume outside the first end of the tubular member and a volume outside the second end of the tubular member. In other words, Claim 5 encompasses **any** level of pressure differential between the first and second ends of the tubular member. A person of ordinary skill in the art would have recognized that such a pressure differential would necessarily exist between the outside of the first end of a catheter and the second end the catheter during any procedure where the catheter is inserted into a patient's vasculature. That is because the patient's blood pressure is higher than the air pressure outside of the patient's body. Indeed, the difference in pressure is the primary reason that hemostasis valves are necessary to prevent the patient's blood from leaking through the catheter once it is inserted into the vasculature. Accordingly, a person of ordinary skill in the art would have understood that any hemostasis valve for intravascular procedures must remain constricted and sealed when such a pressure difference exists. Notably, Schaffer, Hartley, and Eller all disclose that their hemostasis valves are intended for intravascular procedures, as I explain below.

1. Schaffer

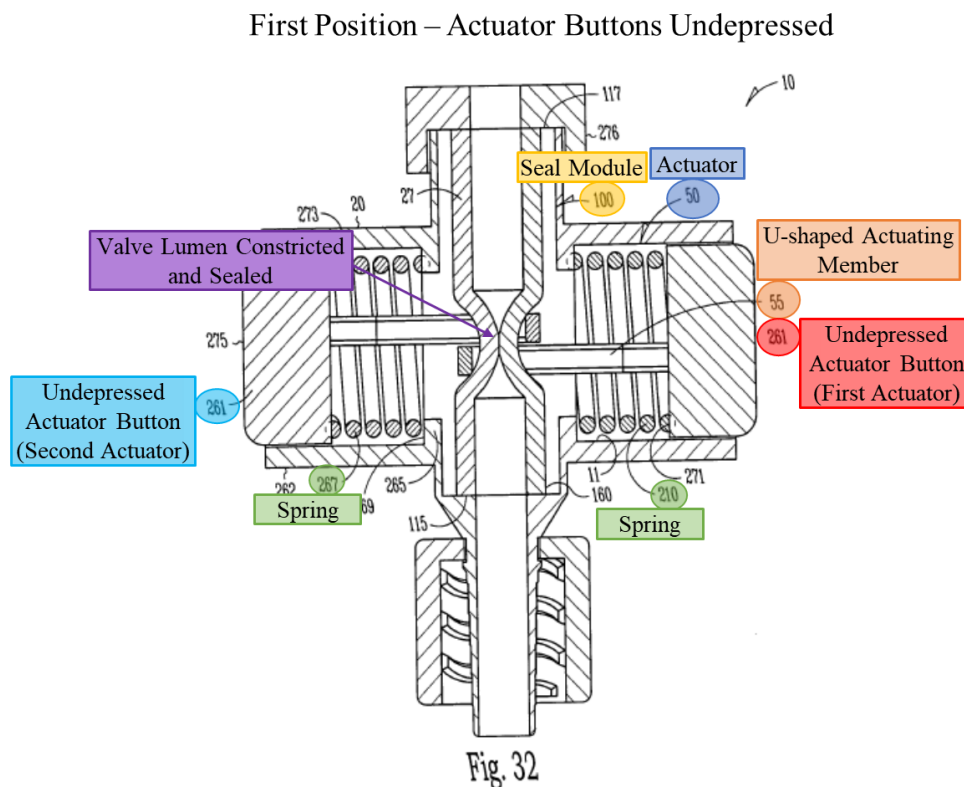
163. Schaffer's discloses that its patent application relates to "a composite fluid-stasis valve for use with catheters" such as the catheters disclosed in U.S. Patent No. 5,429,616 ("Schaffer '616") which Schaffer incorporates by reference. Ex. 1005 (Schaffer) at [0002]. Schaffer '616 discloses "catheters for venous or

Second End Subject to Air Pressure



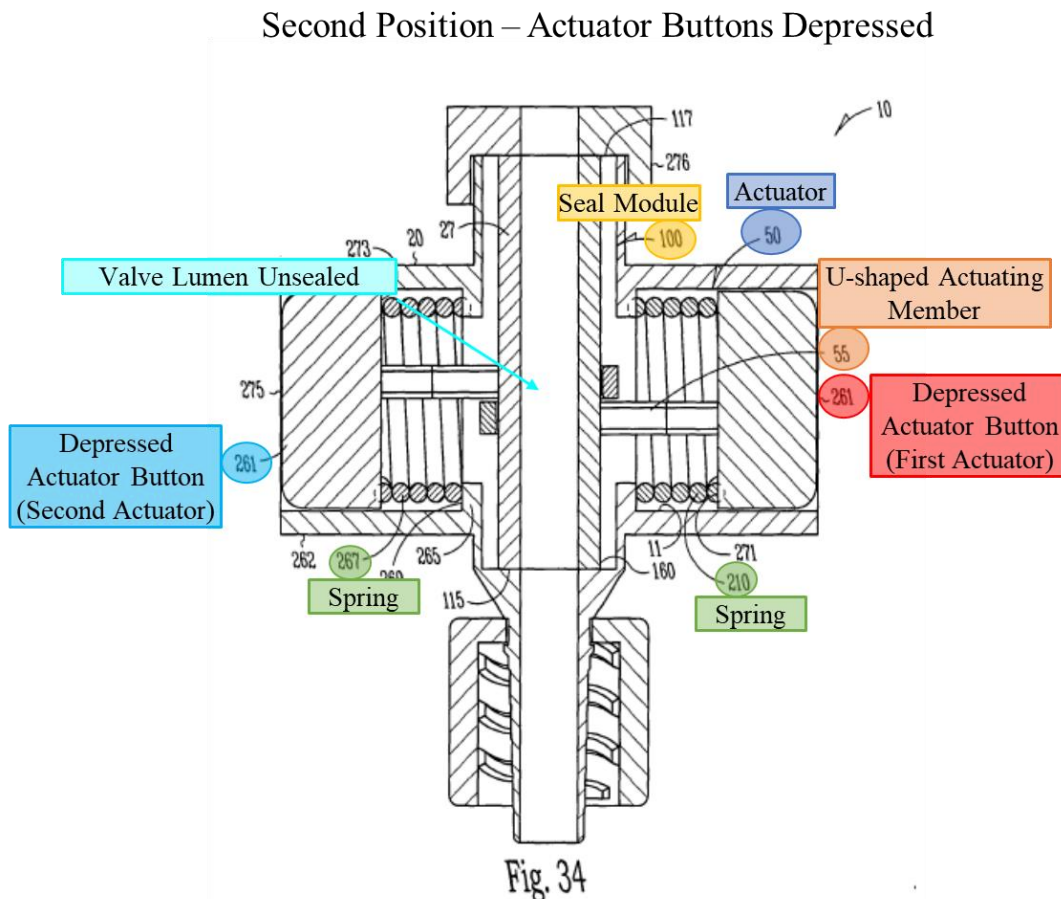
Id. at [0075], Fig. 32.

164. Schaffer also discloses that when the actuator buttons are undepressed (i.e., in the first position), “the actuating members 55 of the actuators 50 are, in one option, disposed and 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)” so that the “lumen 193 of the third seal member 165 is at least partially collapsed by the compressive force 67”:



Ex. 1005 (Schaffer) at [0077], Figs. 31-32. Thus, in the first position, Schaffer’s valve is constricted to form a seal that prevents fluid or gas from passing through

the valve. Schaffer then discloses that the valve is unsealed when the actuator buttons are depressed into the second position, which disengages the actuating members from the tubular member:



Id. at [0077], Figs. 33-34.

165. Accordingly, a person of ordinary skill in the art would have recognized that Schaffer's valve is configured to remain sealed so long as the actuator buttons are in the first, undepressed position. That would have included situations where a pressure differential existed between the distal and proximal ends of the lumen, such as during an intravascular procedure. Schaffer's disclosure that

its valve is intended to “block[] the flow of gas or fluid completely and immediately” during intravascular procedures confirms that understanding, as do Schaffer’s descriptions on the sealed state of the valve when the actuator buttons are in the first (undepressed) position. *Id.* at [0008], [0077].

166. Moreover, if a person of ordinary skill in the art found that Schaffer’s valve did not maintain its seal when a pressure differential existed, the person of ordinary skill would have found it obvious to adjust Schaffer’s valve to ensure that it could maintain a seal in the presence of a pressure differential – after all, maintaining a seal in such conditions is the purpose of a hemostasis valve. For example, the person of ordinary skill in the art had several simple options to adjust the seal, including adjusting Schaffer’s spring strength to apply additional force to seal the valve, adjusting the resilience and compressibility of the seal module that forms the valve’s lumen, or adjusting the shape, flexibility, and/or dimensions of the U-shaped actuating members to more closely conform to the shape of the seal module and any tool(s) inserted through the valve. A person of ordinary skill in the art would have been motivated to do so because the purpose of Schaffer’s hemostasis valve is to prevent leakage when a catheter or medical device is inserted into a patient, which would necessarily involve a pressure differential. A person of ordinary skill in the art would have reasonably expected success in adjusting the spring strength to exert more tension on the filament by, for example, changing the

spring material or adjusting the springs coils. Springs are simple, predictable mechanical devices that would have been well understood by a person of ordinary skill in the art in August 2018. As I explained previously, a person of ordinary skill in the art would have reasonably expected success in selecting an appropriate material for the seal module in view of the range of suitable seal module materials disclosed in the prior art.

167. To the extent it was necessary, a person of ordinary skill in the art would have also found it obvious to modify the U-shaped actuating members to maintain a seal in the presence of a pressure differential. Schaffer discloses that the actuating members are “at least partially circumferentially [sic] disposed about the portion 108 of the seal module 100.” Ex. 1005 (Schaffer) at [0077]. The phrase “at least partially circumferentially [sic] disposed” strongly suggests that the U-shaped actuating members can also be **completely** circumferentially disposed around the seal module. A person of ordinary skill in the art would have been motivated to configure the U-shaped actuating members to circumferentially constrict the lumen to form a better seal and avoid any potential gaps I discussed previously. The required adjustments, to the extent any adjustments were needed, would have been simple, including modifying the shape, material, and/or dimensions of the U-shaped actuating members to better conform to the cylindrical shape of the seal module. For example, the actuating members could be formed from a thin, flexible sheet or

flat ribbon of metal or plastic so that they have the flexibility to conform to the outer surface of the cylindrical seal module. A person of ordinary skill in the art would have reasonably expected success in making these simple and routine adjustments. Actuating members with this type of structure and flexibility would circumferentially constrict the lumen of Schaffer's seal module when pulled in opposite directions by the actuator buttons and would be able to maintain a seal even in the presence of a pressure differential.

2. Hartley

168. A person of ordinary skill in the art would have reasonably expected that Schaffer's valve would be configured to maintain its sealed state in the presence of a pressure differential when the U-shaped actuating members are replaced with Hartley's string. Like Schaffer, Hartley's valve is intended for use during intravascular procedures, where such a pressure differential will necessarily exist. Hartley explains that its valve is intended to "permit[] [a] catheter or other instrument to be passed through the access valve and the valve to form a seal against the walls of the catheter or other instrument to prevent loss of blood or other fluid." Ex. 1006 (Hartley) [0003]. To do so, Hartley's valve must be configured to maintain the seal in the presence of a pressure differential. *Supra* ¶146. Hartley also discloses that "[d]epending on how much the flexible member [i.e., string] is pulled radially and/or tangentially the cylindrical diaphragm can be completely

constricted to prevent fluid flow through the valve or can be constricted to the extent that it closes around an instrument, for instance a catheter, passed through the valve.” Ex. 1006 (Hartley) at [0006].

169. In view of Hartley’s disclosures and Schaffer’s disclosures that I discussed in the preceding section, a person of ordinary skill in the art would have reasonably expected that Hartley’s string would constrict and seal the lumen of Schaffer’s stasis valve during an intravascular procedure. Accordingly, a person of ordinary skill in the art would have reasonably expected that Hartley’s string would maintain Schaffer’s tubular member in a constricted and sealed state when Schaffer’s actuator buttons are in the first, undepressed position, even when a pressure differential exists between the proximal and distal ends of the lumen.

170. In addition, to the extent Schaffer’s valve and Hartley’s string did not maintain its seal when a pressure differential existed, a person of ordinary skill in the art would have found it obvious to adjust Schaffer’s spring strength to apply additional force to seal the valve, adjust the resilience of Schaffer’s seal module, and/or adjust Hartley’s string to improve the sealing of the valve for the reasons I explained previously with respect to Schaffer.

3. Eller

171. A person of ordinary skill in the art would have reasonably expected that Schaffer’s valve would be configured to maintain its sealed state in the presence

of a pressure differential when the U-shaped actuating members are replaced with Eller's wire member. Like Schaffer's valve, Eller's hemostasis valve is intended for use in procedures "that require the percutaneous insertion of one or more interventional devices into a bodily passage, such as a portion of the vascular system." Ex. 1007 (Eller) at 1:20-23. Eller's valve is designed to prevent the flow of fluid through the central sleeve when the actuator is in the second (closed) position, causing the wire member to constrict the sleeve and create a seal. *Id.* at Abstract, 12:14-17, 15:21-40, 17:47-18:8, Figs. 10A-10C. Thus, a person of ordinary skill in the art would have recognized that Eller's valve is configured to remain sealed when placed in the second (closed) position during an intravascular procedure, when a pressure differential would exist between the first and second ends of the lumen.

172. Eller also describes a quantitative analysis performed on different versions of its valve having six different sleeve materials "included in a selective fluid barrier valve device that was constructed to be similar to the embodiment illustrated in" Figures 1-10C. *Id.* at 36:46-53. Eller explains that the valves were "attached to a gravity flow rig and pressurized for 30 seconds per test at a pressure of 2.9 PSI +/- 0.1 PSI (e.g., systolic pressure)" and were measured for fluid leak "in the second configuration with no device disposed through the sleeve passageway and with the devices described in the table disposed through the sleeve

passageway.” *Id.* at 36:53-60. A person of ordinary skill in the art would have understood that Eller’s described test setup would have created a pressure differential between the first and second ends of the valve’s lumen.

173. Eller discloses the results of the testing in the following table:

Material of Sleeve	Empty Sleeve Passageway	0.018"Wire disposed within sleeve passageway	0.035" Wire disposed within sleeve passageway	14 French dilator disposed within sleeve passageway	Rating:
80% - 4755	3 g	5.4 g	50 g	4.9 g	+
20% - 4765					
100% - 4755	14.3 g	2.8 g	25.4 g	11 g	+
90% - 4755	0	0	1.4 g	0	++
10% - 4014					
80% - 4755	0	0	0	0	++++
20% - 4014					
70% - 4755	0	0	0	0	++++
30% - 4014					
60% - 4755	0	0	Trace	0	+++
40% - 4014					

Id. at 36:26-44. As reported in the table above, two of the six valves demonstrated no leaks regardless of the tool inserted through the valve, and one of the six devices demonstrated only trace leakage when a 0.035” wire was placed within the passageway. *Id.* at 36:64-37:3. Moreover, four of the valves reported no leaks when the sleeve passageway was empty, filled with a .018” wire, and filled with a 14 French dilator. These test results confirm that Eller’s wire member is suitable for constricting and sealing the lumen of a stasis valve, even when a pressure differential exists between the proximal and distal ends of the lumen.

174. In view of Eller's disclosures and Schaffer's disclosures that I discussed previously, a person of ordinary skill in the art would have reasonably expected that Eller's wire member would constrict and seal the lumen of Schaffer's stasis valve during an intravascular procedure. Accordingly, a person of ordinary skill in the art would have reasonably expected that Eller's wire member would maintain Schaffer's tubular member in a constricted and sealed state when Schaffer's actuator buttons are in the first, undepressed position, even when a pressure differential exists between the proximal and distal ends of the lumen, with or without devices inserted through the valve.

175. In addition, to the extent Schaffer's valve and Eller's wire member do not maintain a seal when a pressure differential exists, a person of ordinary skill in the art would have found it obvious to adjust Schaffer's spring strength to apply additional force to seal the valve, adjust the resilience of Schaffer's seal module, and/or adjust Eller's wire member to improve the sealing of the valve for the reasons I explained previously with respect to Schaffer.

F. Claim 6

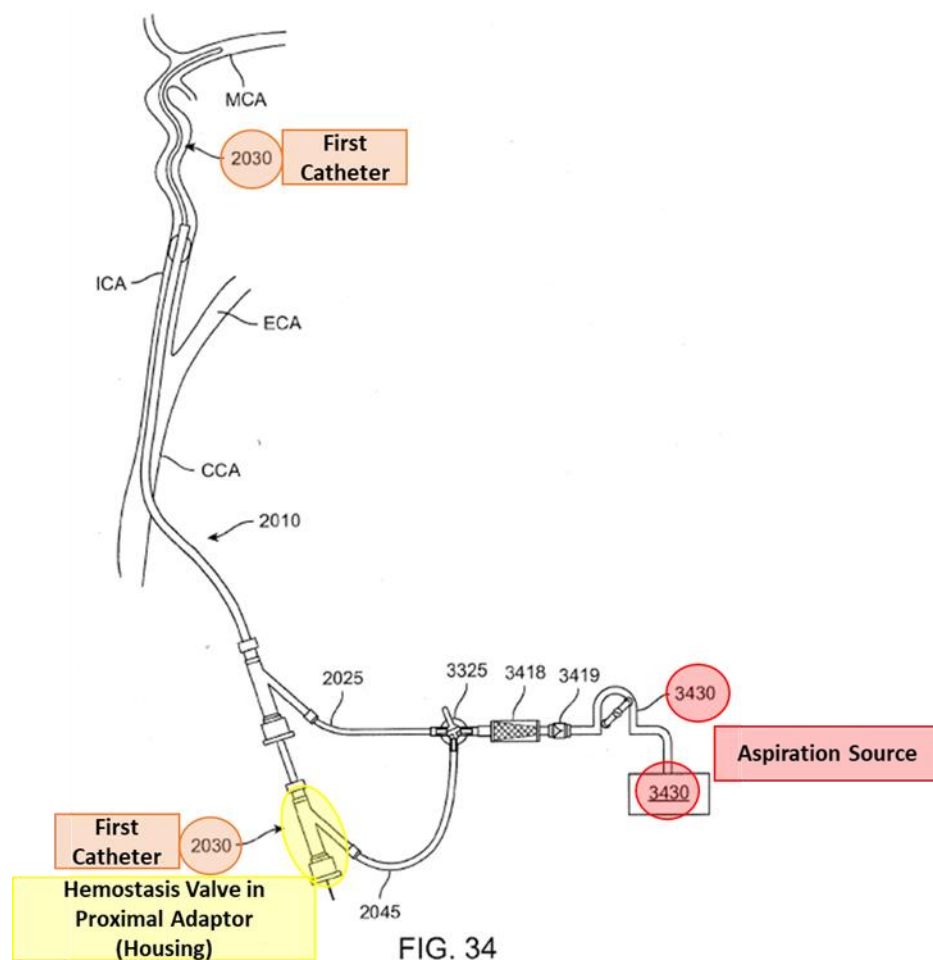
176. Claim 6 recites: "The vacuum aspiration system of claim 1 wherein, when the first member and the second member of the actuator are in the first position, the lumen of the tubular member is configured to remain constricted and sealed when vacuum pressure is applied to a volume outside the lumen and adjacent

to either a first end or a second end of the tubular member.” Garrison combined with Schaffer and optionally Hartley or Eller renders claim 6 obvious.

177. As I explained previously for Claim 5, Schaffer, Hartley, and Eller all disclose hemostasis valves that create a seal to prevent the leakage of blood or fluid during intravascular medical procedures. Schaffer further discloses that its valve is configured to connect to “a fluid or gas delivery system or device such as a syringe, or intravenous system or the like.” Ex. 1005 (Schaffer) at [0049]. A person of ordinary skill in the art in August 2018 would have understood that syringes could be used to generate negative pressure for aspiration. *See e.g.*, Ex. 1011 (Garrison) [0071] (“The flow line 905 may also be connected to an aspiration source such as a pump or syringe.”).

178. Schaffer also discloses that its valve prevents leakage across “a range of instruments,” such as “a catheter, guidewire, needle, or fiber.” Ex. 1005 (Schaffer) at [0056]. Aspiration catheters were commonly used with hemostasis valves prior to August 2018 to apply vacuum pressure through the catheter, often using syringes. For example, Garrison discloses an aspiration catheter 2030 having a proximal hub 2065 that may include a “separate hemostasis valve ... attached to proximal hub, to allow introduction of devices such as a microcatheter, guide wire, or thrombectomy device while preventing or minimizing blood loss during the

procedure. Alternately, the hemostasis valve may be integral to the catheter proximal adaptor”:



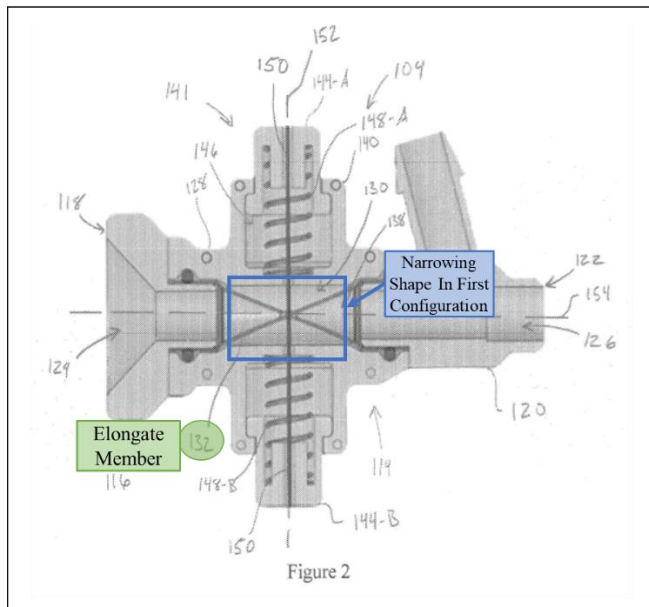
Ex. 1011 (Garrison) at [0098], Fig. 34; *see also id.* at [0130]-[0142]. Garrison’s system includes an aspiration source, such as a pump, that creates a vacuum to aspirate material from the patient’s vasculature through the flow path. (*Id.* at [0136]-[0137].)

179. I do not see anything about the design of Schaffer’s valve that would lead a person of ordinary skill in the art to believe the valve would open when exposed to negative pressure or be otherwise unsuitable for use with a device that

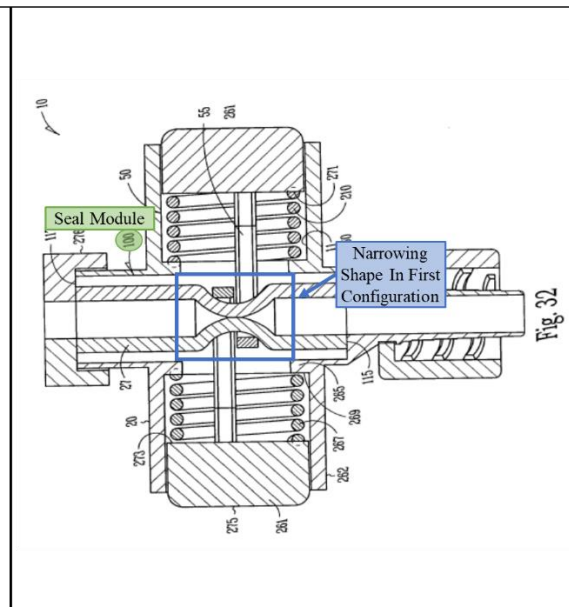
creates vacuum pressure, such as an aspiration catheter. Schaffer's U-shaped actuating members are pulled perpendicular to the lumen of the catheter with the springs. The suction force from the aspiration catheter would not be applied in the correct direction to move the U-shaped actuating members but may, in fact, help to pull the valve inward and even increase the strength of the seal. Thus, Schaffer's valve is configured to remain constricted and sealed when vacuum pressure is applied to a volume outside the lumen and adjacent to either a first end or a second end of the tubular member.

180. In addition, the only description I see in the '519 Application regarding the valve's ability to seal in the presence of vacuum pressure is the following statement: "due to the narrowing shape of the elongate member 132 when the constricting mechanism 141 is in the first configuration, a vacuum applied to the portions of the delivery device 100 distal to the axis 152 draws the elongate member 132 towards the first configuration and can, in some embodiments, increase the strength, robustness, and/or strength of the seal of the valve 104." Ex. 1017 ('519 Application) at [0055]. Notably, Schaffer's elongate member (i.e., the seal module 100) also has a "narrowing shape" when the actuator buttons are in the first, undepressed configuration:

'519 Application



Schaffer



Id. at Fig. 2 (left); Ex. 1005 (Schaffer) at [0077], Fig. 32 (right). Thus Schaffer's valve has the same structure, features, and function as those that the '519 Application describes as enabling the valve to seal in the presence of vacuum pressure. A person of ordinary skill in the art would have expected the narrowing shape of Schaffer's lumen to further seal in the face of negative pressure, just as the '519 Application describes.

181. In addition, for similar reasons as I explained above and for Claim 5, a person of ordinary skill in the art would also have reasonably expected that Hartley's string or Eller's wire member would maintain Schaffer's tubular member in a constricted and sealed state when Schaffer's actuator buttons are in the first, undepressed position, even when a vacuum pressure is applied to a volume outside of the valve's lumen. Ex. 1005 (Schaffer) at [0008], [0077]; Ex. 1006 (Hartley) at

[0003], [0006]; Ex. 1007 (Eller) at 27:44-50, 36:46-37:3. Again, Schaffer's buttons/springs pull the strings/wire members perpendicular to the forces caused by any vacuum pressure and may, in fact, help to pull the valve inward and even increase the strength of the seal.

182. To the extent Schaffer's valve did not maintain its seal under vacuum pressure (either with the U-shaped members, or the string/wire member), a person of ordinary skill in the art would have found it obvious to adjust Schaffer's valve to ensure that it could maintain a seal in the presence of vacuum pressure. For example, the person of ordinary skill in the art could have made one or more simple adjustments to Schaffer's valve to maintain the seal, including adjusting the spring strength to apply additional force to seal the valve, adjusting the resilience and compressibility of the seal module that forms the valve's lumen, and/or adjusting the shape, flexibility, and/or dimensions of the U-shaped actuating members to more closely conform to the shape of the seal module and any tool(s) inserted through the valve. A person of ordinary skill in the art would have been motivated to do so because the purpose of Schaffer's hemostasis valve is to prevent leakage when other devices, or no devices, are inserted, and whether the valve is exposed to positive pressure or vacuum pressure. Adjusting the spring strength would have been a simple modification that could have been accomplished by, for example, selecting a spring made of different materials or with tighter windings. The

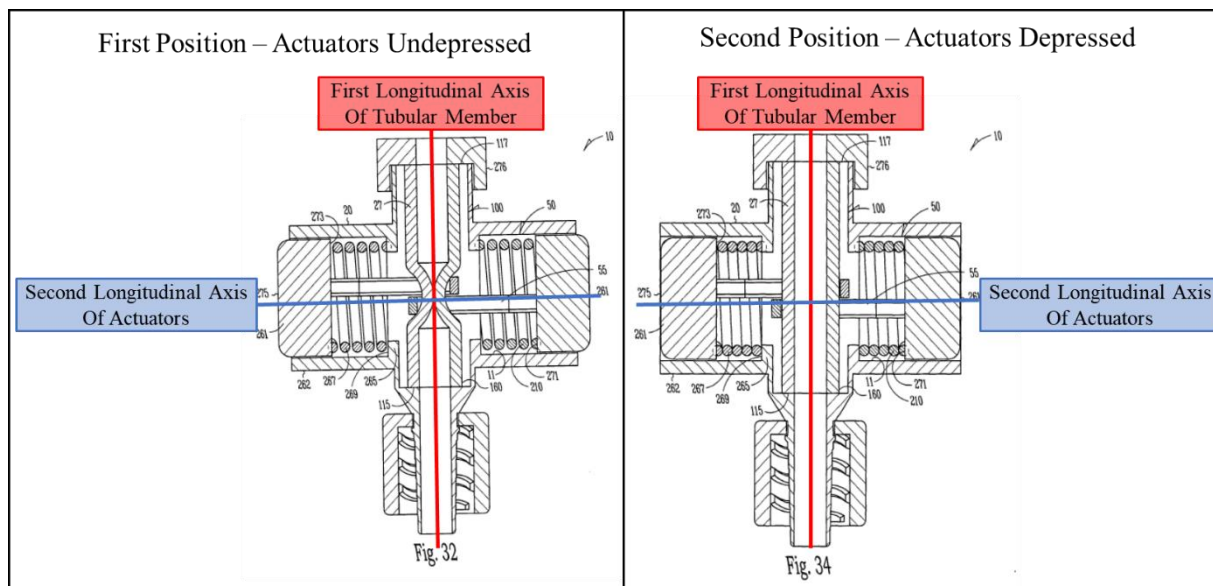
selection of springs would have been something commonly done by persons of ordinary skill in the art and well within their skill level. As I explained previously, a person of ordinary skill in the art would have reasonably expected success in selecting an appropriate material for the seal module in view of the range of suitable lumen materials disclosed in the prior art. *Supra* ¶132. As I also explained previously, a person of ordinary skill in the art would have reasonably expected success in adjusting the size, shape, and/or dimensions of Schaffer's U-shaped actuating members to modify their flexibility and improve the seal around the cylindrical seal module. *Supra* ¶118.

G. Claim 7

183. Claim 7 recites: "The vacuum aspiration system of claim 1 wherein the lumen of the tubular member extends a long a first longitudinal axis, wherein the first member and the second member of the actuator are movable between the first and second positions along a second longitudinal axis, and wherein the first longitudinal axis is orthogonal to the second longitudinal axis." Schaffer discloses the additional limitations recited in Claim 7, and therefore, Garrison in combination with Schaffer and optionally Hartley or Eller renders Claim 7 obvious.

184. Schaffer's actuator buttons (i.e., the first and second members) are movable between a first (undepressed) position shown in Figure 32 below and

second (depressed) position shown in Figure 34 below along a longitudinal axis that is orthogonal to the longitudinal axis of the tubular member (seal module 100):

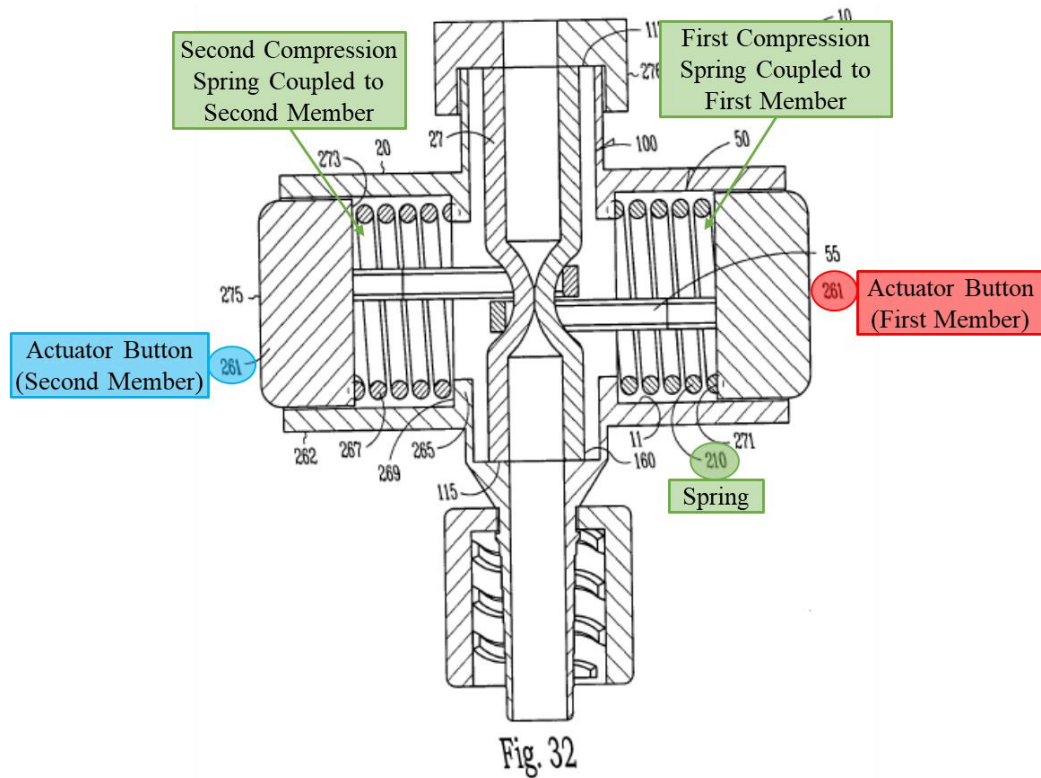


Ex. 1005 (Schaffer) at [0077], Figs. 31-34.

H. **Claim 8**

185. Claim 8 recites: “The vacuum aspiration system of claim 1 wherein the biasing system comprises a first compression spring coupled to the first member and a second compression spring coupled to the second member.” Schaffer discloses the additional limitations recited in Claim 8, and therefore, Garrison in combination with Schaffer and optionally Hartley or Eller renders Claim 8 obvious.

186. As I explained previously for Claim 1, Schaffer’s valve includes two springs (also referred to as resilient members), and Schaffer discloses that “the distal end 271 of the resilient members 267 each abut the proximal end 273 of an actuator button 261”:

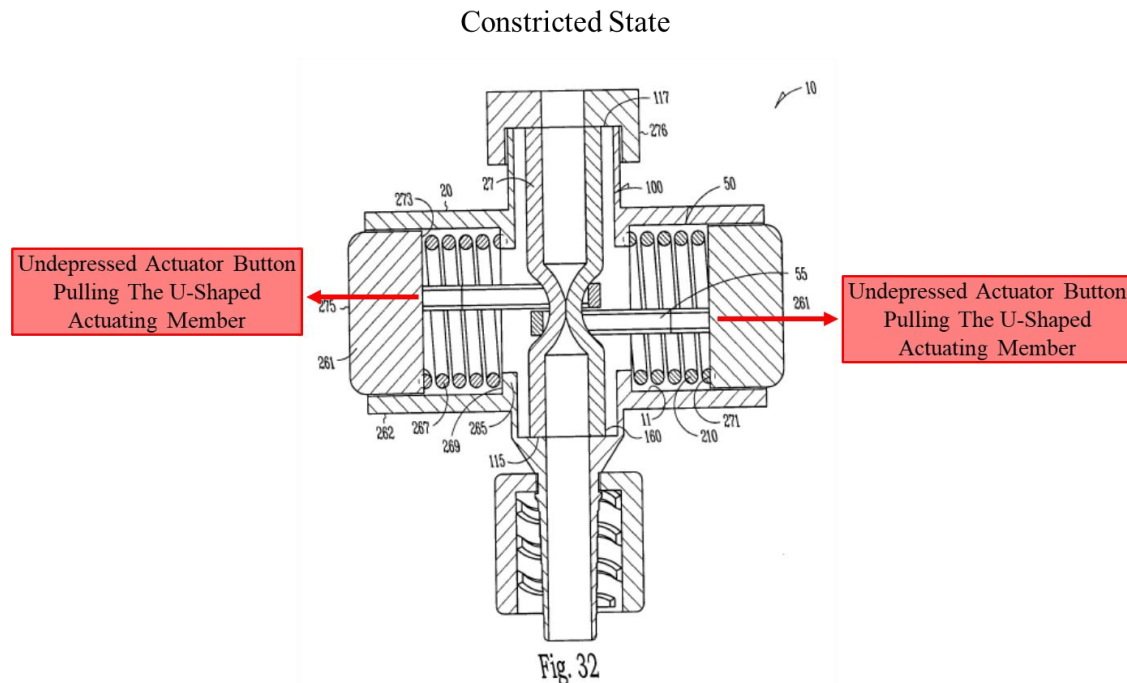


Ex. 1005 (Schaffer) at [0076], Figs. 31-34. Thus, Schaffer’s valve has a “first spring [that] comprises a first compression spring coupled to the first member and [a] second spring [that] comprises a second compression spring coupled to the second member.”

I. Claim 9

187. Claim 9 recites: “The vacuum aspiration system of claim 1 wherein, in the first position, the first member and the second member of the actuator pull the filament to circumferentially constrict the tubular member such that the lumen is constricted and sealed.” Schaffer discloses the additional limitations recited in Claim 9, and therefore, Garrison in combination with Schaffer and optionally Hartley or Eller renders Claim 9 obvious.

188. As I explained previously for Claim 1, when Schaffer's actuator buttons are in the first, undepressed position, the springs coupled to Schaffer's actuator buttons impart forces on the actuator buttons causing the buttons to pull the U-shaped actuating members in opposite directions to circumferentially constrict the seal module 100:



Ex. 1005 (Schaffer) at [0076]-[0077]. Alternatively, when Schaffer's U-shaped actuating members are replaced with Hartley's string or Eller's wire member, Schaffer's actuator buttons would pull the string/wire member, rather than the U-shaped actuating members, to circumferentially constrict the seal module 100.

J. Claim 10

189. Claim 10 is an independent claim that recites:

A vacuum aspiration system, comprising:

- a housing;
- a flow path extending through the housing;
- an on-off control in the flow path;
- a first catheter in fluid communication with the flow path and a connector configured to place a source of aspiration in communication with the flow path;
- a clot cannister fluidly coupled to the flow path; and
- a hemostasis valve in the housing configured to receive a second catheter and direct the second catheter through the first catheter, wherein the hemostasis valve comprises
 - (a) a support;
 - (b) an actuator having at least a first member movably coupled to the support;
 - (c) a collapsible tubular sidewall defining a lumen carried by the support;
 - (d) a filament formed in a loop around the tubular sidewall, the filament having at least a first end portion extending away from the loop to the first member; and
 - (e) a first spring configured to move the first member in a direction that pulls the first end portion such that a diameter of the lumen decreases in response to reducing a diameter of the loop.

Thus, the only differences between claims 1 and 10 of the '005 patent are with respect to the hemostasis-valve limitations. Garrison discloses the recited housing, flow path, on-off control, first catheter, and clot cannister limitations for the reasons I explained previously for claim 1. *Supra* §§VI.A.1-7.

1. Hemostasis Valve

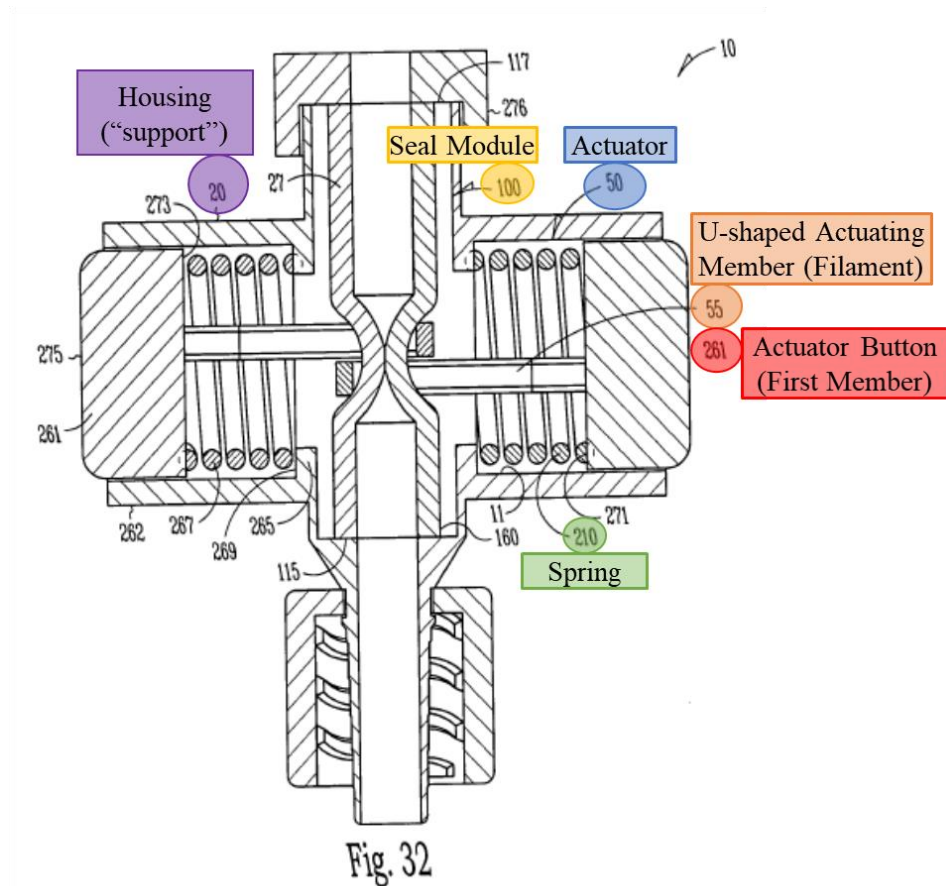
190. Claim 10 recites “a hemostasis valve in the housing configured to receive a second catheter and direct the second catheter through the first catheter.” Garrison discloses this limitation for the reasons I explained previously for Claim

1. *Supra* §VI.A.8. Claim 10 also recites several features of the hemostasis valve. For the reasons explained previously for Claim 1, 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 or Eller's filaments) as the hemostasis valve on Garrison's catheters (including catheter 2030). *Id.* Thus, Garrison in combination with Schaffer and optionally Hartley or Eller renders the hemostasis-valve limitations of claim 10 obvious.

a. Support

191. Claim 10 recites that the hemostasis valve comprises “a support.” Schaffer discloses this limitation.

192. First, I note that the term “support” does not appear in the specification of the '005 patent or the '519 Application. A person of ordinary skill in the art would have understood that in the context of a hemostasis valve, a component can be characterized as “a support” if it provides some sort of mechanical support to another component in the hemostasis valve. Schaffer's hemostasis valve includes a housing 20:

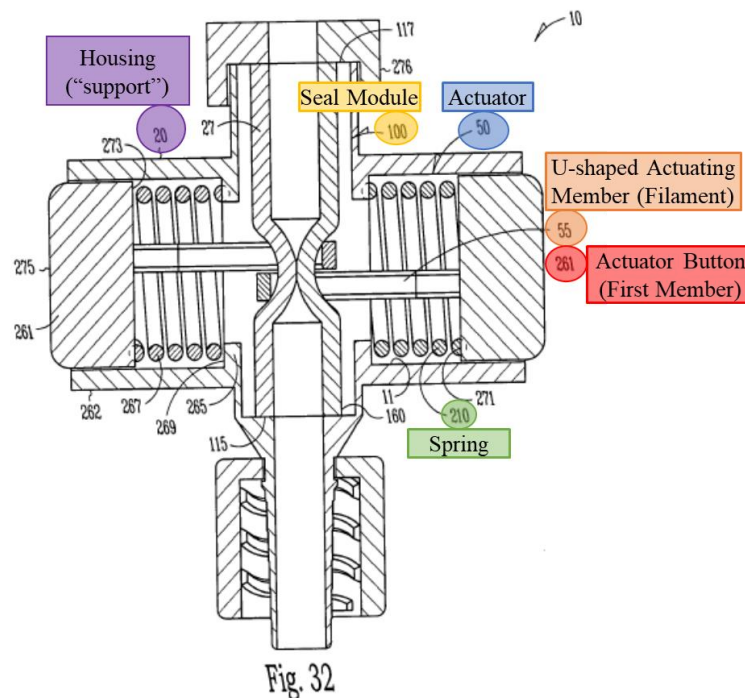


Ex. 1005 (Schaffer) at [0076], Fig. 32. Schaffer explains that “the housing 20 is sized and configured to hold and control a composite seal module 100, a portion of an actuator 50, and an actuating member.” *Id.* at [0046]. Based on this disclosure, a person of ordinary skill in the art would have recognized that the housing 20 supports (i.e., holds and controls) the other components of the hemostasis valve and is a “support” as recited in Claim 10.

b. Actuator

193. Claim 10 next recites that the hemostasis valve comprises “an actuator having a least a first member movably coupled to the support.” Schaffer discloses this limitation.

194. As I explained previously for Claim 1, Schaffer's valve includes "two circular actuators 50 [that] are at least partially circumferentially [sic] disposed about a portion of the seal module 100 movable from a first position to a second position on opposing sides of the housing 20." Ex. 1005 (Schaffer) at [0076]. Schaffer discloses that "the actuators 50 are configured cylindrically to slide along the cylindrical interior wall 11 of the housing 20 from a first position to a second position."



Id. at [0076], Fig. 32. Schaffer’s actuator button is a “first member” for the same reasons I explained previously for Claim 1. *Supra* §VI.A.8.b.i. The actuator button is movably coupled to the support (i.e., housing) because it is held within the housing and is “configured cylindrically to slide along the cylindrical interior wall 11 of the housing 20 from a first position to a second position.” Ex. 1005 (Schaffer) at [0046], [0076].

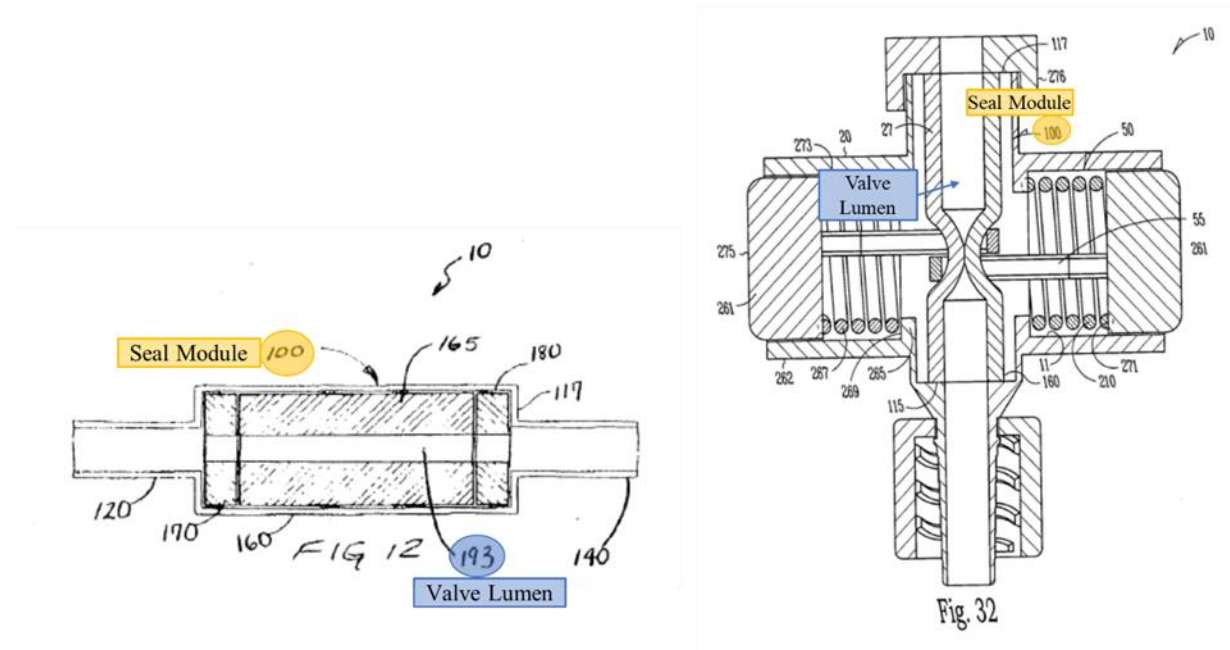
c. Tubular Sidewall

195. Claim 10 next recites that the hemostasis valve comprises “a collapsible tubular sidewall defining a lumen carried by the support.” Schaffer discloses this limitation.

196. The term “collapsible tubular sidewall” does not appear in the ’005 patent specification or the ’519 Application and, therefore, it is not identified in any figures. Instead, the ’519 Application describes valves having “an elongate member 132” or “tubular member 132” with a “central lumen 138.” Ex. 1017 (’519 Application patent) at [0039]. Therefore, I understand the term “collapsible tubular sidewall” includes at least the “tubular members” described in the ’519 Application.

197. As I explained previously, Schaffer’s hemostasis valve includes a “seal module 100” that comprises “a flexible, elongate tubular structure 101.” Ex. 1005 (Schaffer) at [0049], [0051], [0054]. Schaffer explains that the seal module can be “at least partially collapse[ed] ... by a compressive force” in order to seal the valve.

Id. at [0077]. The seal module 100 defines a valve lumen 193 extending therethrough:

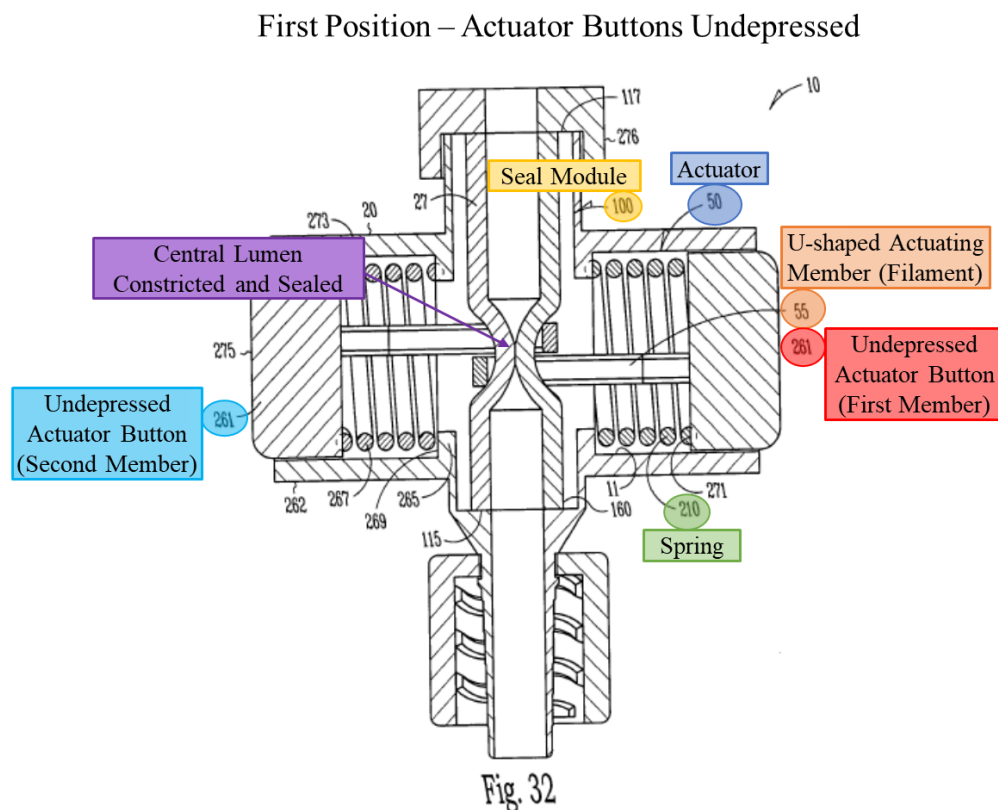


Id. at [0058], Fig. 12, 32. Schaffer also discloses that the housing (i.e., the support) “is sized and configured to hold and control a composite seal module 100, a portion of an actuator 50, and an actuating member.” *Id.* at [0046]. Accordingly, the seal module 100 (i.e., collapsible tubular sidewall) is carried by the housing (i.e., support). Therefore, Schaffer’s seal module is “a collapsible tubular sidewall defining a lumen carried by the support.”

d. Filament

198. Claim 10 next recites that the hemostasis valve comprises “a filament formed in a loop around the tubular sidewall, the filament having at least a first end portion extending away from the loop to the first member.” Schaffer discloses this

201. As I explained previously for Claim 1, Schaffer’s actuator buttons are “movable from a first position to a second position.” Schaffer discloses that in the first position, shown in Figure 32, the actuating members are “at least partially circumferentially disposed about the portion 108 of the seal module 100 depressing and at least partially collapsing a portion 108 of the containment structure 160 by a compressive force 67 (e.g. by a spring 210)”:



Id. at [0077], Fig. 32. Schaffer’s Figure 32 shows that the valve lumen is completely sealed in the first position. *Id.*; see also *id* at [0008] (disclosing Schaffer’s valve “blocks the flow of gas or fluid completely and immediately with or without an instrument in place within the gas/fluid path”).

202. Like I explained previously for Claim 1, Schaffer's spring biases Schaffer's actuator button toward the first (closed) position by pulling the first end portion of the actuating member (filament) away from the seal module 100, which is illustrated in Figure 32 above. Ex. 1005 (Schaffer) [0077], Fig. 32. This causes the actuating members (i.e., filament) attached to the buttons to circumferentially constrict around and collapse the seal module, preventing the flow of fluid through the valve, which is again illustrated in Figure 32. *Id.* The loop formed by the actuating members decreases in diameter as the first end portion of the actuating member is pulled by the spring. *Id.* at [0077], Figs. 31-34. Schaffer's spring would have the same effect on the loop formed by Hartley's string or Eller's wire member when either is used with Schaffer's valve. Schaffer's resilient member is therefore "a first spring configured to move the first actuator in a direction that pulls the first end portion such that a diameter of the valve lumen decreases in response to reducing a diameter of the loop."

K. Claim 11

203. Claim 11 recites: "The vacuum aspiration system of claim 10, further comprising a second member movably coupled to the support." Schaffer discloses the additional limitations recited in Claim 11 for the same reasons I explained previously for claim 1. *Supra* §VI.A.8.b.i. Therefore, Garrison in combination with Schaffer and optionally Hartley or Eller renders Claim 11 obvious.

L. Claim 12

204. Claim 12 recites: “The vacuum aspiration system of claim 11 wherein the filament further comprises a second end portion extending away from the loop to the second member.” Schaffer discloses the additional limitations recited in Claim 12 or renders them obvious in combination with Hartley and Eller for the same reasons I explained previously for Claim 1. *Supra* §VI.A.8.ii. Therefore, Garrison in combination with Schaffer and optionally Hartley or Eller renders Claim 12 obvious.

M. Claim 13

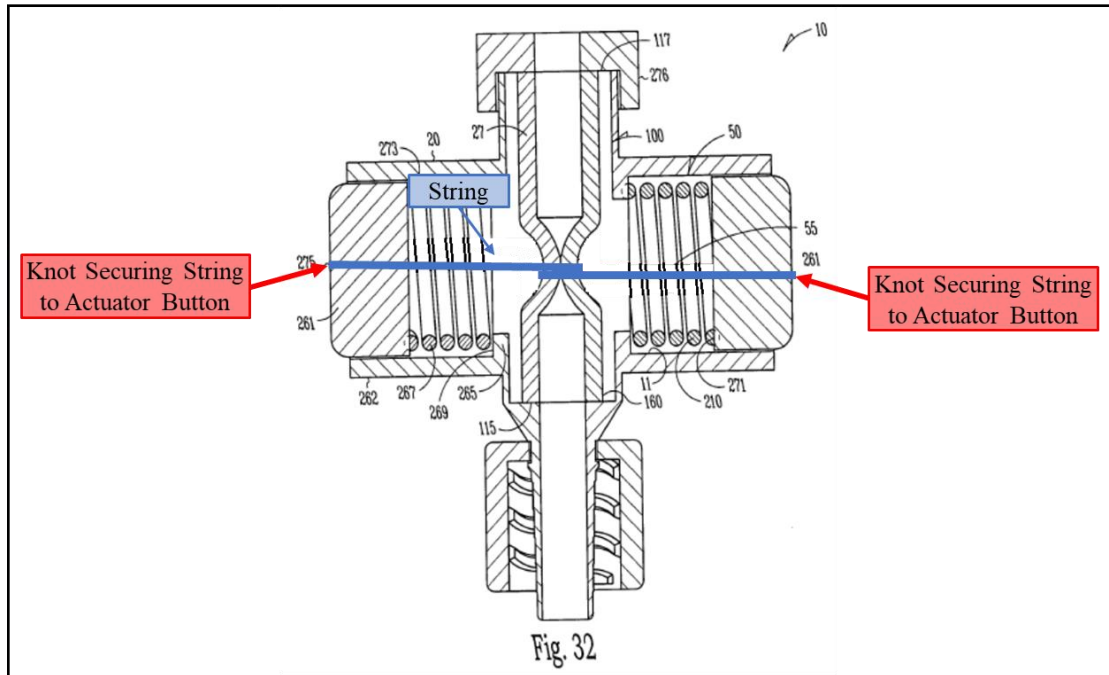
205. Claim 13 recites: “The vacuum aspiration system of claim 12 first end portion, the loop, and the second end portion are one continuous filament.” Garrison in combination with Schaffer and Hartley or Eller renders claim 13 obvious.

1. Schaffer-Hartley

206. As I explained previously for Claim 1, Hartley discloses a single string (i.e., filament) that forms a loop around the outer surface of the valve lumen. *Supra* §VI.A.8.ii.b. When substituting Hartley’s string for Schaffer’s U-shaped actuating members, a person of ordinary skill in the art would have secured the first end of Hartley’s string to the first actuator button (i.e., the first actuator member), looped the string at least once around the lumen of Schaffer’s valve, and then secured the

second end of the string to the second actuator button (i.e., the second actuator member) on the opposite side of the valve, as I illustrated in the demonstrative below:

Demonstrative Illustration Schaffer + Hartley's String

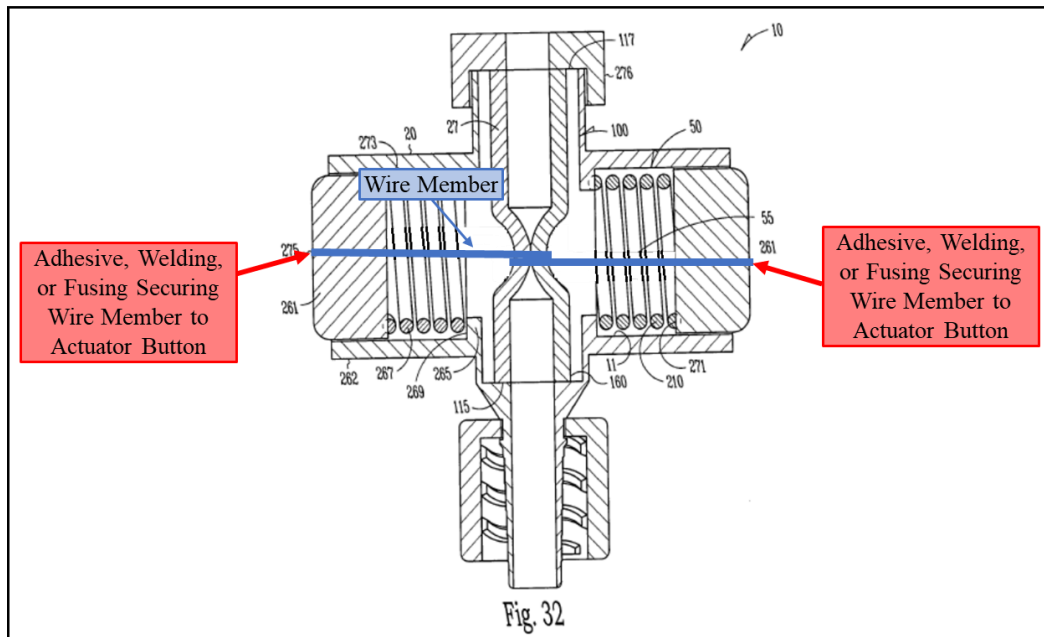


A person of ordinary skill in the art would have found this to be the simplest configuration for implementing Hartley's string into Schaffer's valve, and it would have required little, if any, modification to Schaffer's valve. In this configuration, the entirety of the filament, including the loop, the first end portion, and the second end portion, would constitute a single, continuous filament. Therefore, Garrison in combination with Schaffer and Hartley renders claim 13 obvious.

2. Schaffer-Eller

207. As I explained previously for Claim 1, Eller discloses a single wire member (i.e., filament) that can form a loop around the outer surface of the valve lumen. *Supra* §VI.A.8.ii.c. When substituting Eller's wire member for Schaffer's U-shaped actuating members, a person of ordinary skill in the art would have secured the first end of Eller's wire member to the first actuator button (i.e., the first actuator member), looped the wire member at least once around the lumen of Schaffer's valve, and then secured the second end of the wire member to the second actuator button (i.e., the second actuator member) on the opposite side of the valve, as I illustrated in the demonstrative below:

Demonstrative Illustration
Schaffer + Eller's Wire Member



A person of ordinary skill in the art would have found this to the simplest configuration for implementing Eller's wire member into Schaffer's valve, and it would have required little, if any, modification to Schaffer's valve. In this configuration, the entirety of the filament, including the loop, the first end portion, and the second end portion, would constitute a single, continuous filament. Therefore, Garrison in combination with Schaffer and Eller renders claim 13 obvious.

N. Claim 14

208. Claim 14 recites: "The vacuum aspiration system of claim 12 wherein first member and the second member are biased in a direction that places the first end portion and the second end portion under sufficient tension to reduce the diameter of the lumen and provide a seal around a device extending through the lumen." Schaffer discloses the additional limitations recited in claim 14 for the same reasons I explained previously for Claim 1. *Supra* §VI.A.8.c. Therefore, Garrison in combination with Schaffer and optionally Hartley or Eller renders claim 14 obvious.

O. Claim 15

209. Claim 15 recites: "The vacuum aspiration system of claim 12 wherein the first member and the second member are biased in a direction that places the first end portion and the second end portion under sufficient tension to close the

lumen.” Schaffer discloses the additional limitations recited in claim 15 for the same reasons explained previously for Claim 1. *Supra* §VI.A.8.c. Therefore, Garrison in combination with Schaffer and optionally Hartley or Eller renders claim 15 obvious.

VII. GROUND 4: GARRISON COMBINED WITH HARTLEY AND ELLER

210. As I explained in Grounds 1-3 above, Garrison discloses a vacuum aspiration system that discloses every limitation of the independent claims of the ’005 patent except for the limitations reciting specific features of the hemostasis valve. *Supra* §VI. While Garrison discloses hemostasis valves as part of its aspiration system, it does not describe the specific features of those valves and instead presumes that a person of ordinary skill in the art would have been familiar with such valves. *Supra* ¶62.

211. As I discussed in Grounds 1-3 above, Hartley discloses a hemostasis valve that “can be controlled to vary the size of the aperture through the valve and be flexible so that a seal may be formed against an instrument or other object inserted through the access valve.” Ex. 1006 (Hartley) at [0004]. As illustrated in Figure 1 of Hartley below, the valve includes an elastomeric diaphragm extending through the center of the valve, a rotary actuator, and a string extending around the outer surface of the diaphragm for constricting and sealing the valve:

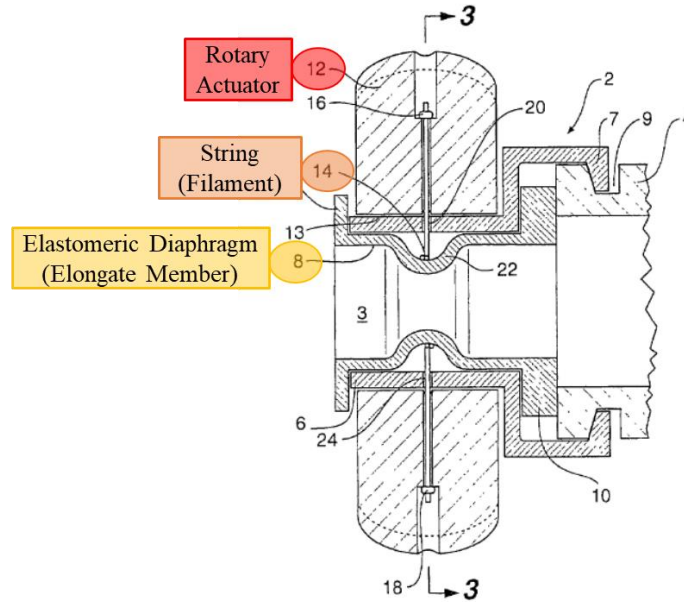


Fig 1

Id. at [0031], Fig. 1.

212. During prosecution of the '005 patent, the Examiner found in the Notice of Allowance that Hartley discloses every limitation of pending Claims 2 and 11 except for “an actuator having a first member movable [sic] coupled to the support and the first spring configured to move the first member.” Ex. 1002 ('005 patent prosecution history excerpt) at 214-215. I agree with the Examiner’s conclusion. However, I believe that the Examiner erred in failing to recognize that springs used to bias hemostasis valves toward their closed position were well known in the prior art as of August 2018 and would have been obvious to a person of ordinary skill in the art.

213. For example, as I explain in detail below, Eller discloses a system for biasing a hemostasis valve toward the closed position. In one example, Eller

describes a torsion spring secured to the valve's housing and actuator such that "when no outside forces are applied to the . . . valve device, the spring positions the actuator" in the closed position. Ex. 1007 (Eller) at 19:22-30. A person of ordinary skill in the art would have found it obvious to combine Eller's torsion spring with Hartley's rotary actuator to bias Hartley's valve closed when no outside forces were applied.

214. For the reasons I provide in detail below, a person of ordinary skill in the art would have been motivated and found it obvious to use Hartley's hemostasis valve, with Eller's torsion spring, as the proximal hemostasis valve in the system disclosed by Garrison. Accordingly, it is my opinion that a person of ordinary skill in the art would have found Claims 1-3, 5-6, and 9-15 obvious over Garrison in combination with Hartley and Eller.

A. Claim 1

215. Based on my review of the prior art, it is my opinion that Garrison in combination with Hartley and Eller renders Claim 1 obvious.

1. Preamble and Limitations 2-7

216. As I explained previously in Grounds 1-3, if the preamble of Claim 1 is limiting, Garrison discloses a "vacuum aspiration system." *Supra* §VI.A1. Similarly, Garrison also discloses the housing, flow path, on-off control, first

catheter, connector, and clot cannister limitations for the same reasons I explained in Grounds 1-3. *Supra* §§VI.A.2-7.

2. Hemostasis Valve

217. Garrison in combination with Hartley and Eller renders the hemostasis-valve limitations of Claim 1 obvious.

218. As I explained previously in Grounds 1-3, Garrison's catheter 2030 (i.e., the first catheter) includes a hemostasis valve in a housing. Ex. 1011 (Garrison) at [0098]; *supra* §§VI.A.2, VI.A.8. Garrison also discloses that different types of hemostasis valves can be combined with the catheter. Ex. 1011 (Garrison) at [0098].

219. Hartley discloses an "access valve which can be controlled to vary the size of the aperture through the valve and be flexible so that a seal may be formed against an instrument or other object inserted through the access valve." Ex. 1006 (Hartley) at [0004]. A person of ordinary skill in the art would have been motivated, and found it obvious, to use Hartley's hemostasis valve as the hemostasis valve in Garrison's system for several reasons.

220. First, Garrison expressly suggests combining catheter 2030 with a "rotating hemostasis valve." Ex. 1011 (Garrison) at [0062], [0098]. Hartley discloses a rotating hemostasis valve and, therefore, a person of ordinary skill in the

art would have been motivated to combine, and reasonably expected success in combining, Hartley's valve with Garrison's catheters.

221. Second, combining Hartley's valve with Garrison's aspiration catheters (such as catheter 2030) would merely entail the combination of known elements (Hartley's valve and Garrison's aspiration catheter) according to known methods (attaching the valve to a proximal hub on the catheter or forming it integrally with the hub). This combination would yield the predictable result of preventing or minimizing blood loss and preventing the introduction of air into the catheter. Combining known elements in such a predictable fashion would have been well within the level of ordinary skill in the art in August 2018.

222. Third, a person of ordinary skill in the art in August 2018 had a finite number of predictable hemostasis valves to choose, including a "rotating hemostasis valve" like Hartley's valve, or "a passive seal hemostasis 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 catheter 2030. Moreover, the known valves, including Hartley's rotating 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 Hartley'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.

223. Fourth, Hartley discloses that its hemostasis valve can “close over a range of diameters of devices passed through the valve or can close completely down to be self sealing.” Ex. 1006 (Hartley) at [0037]. Hartley further discloses that its hemostasis valve can be “constricted around [an inserted device] to prevent loss of blood or inflation gas from within a body cavity during operation of the device.” *Id.* at [0011]-[0012]. Accordingly, a person of ordinary skill in the art would have understood that Hartley’s valve would perform the stated function of the “hemostasis valve” in Garrison’s system—to “allow for the introduction of devices therein while preventing or minimizing blood loss via the internal lumen during the procedure.” Ex. 1011 (Garrison) at [0062].

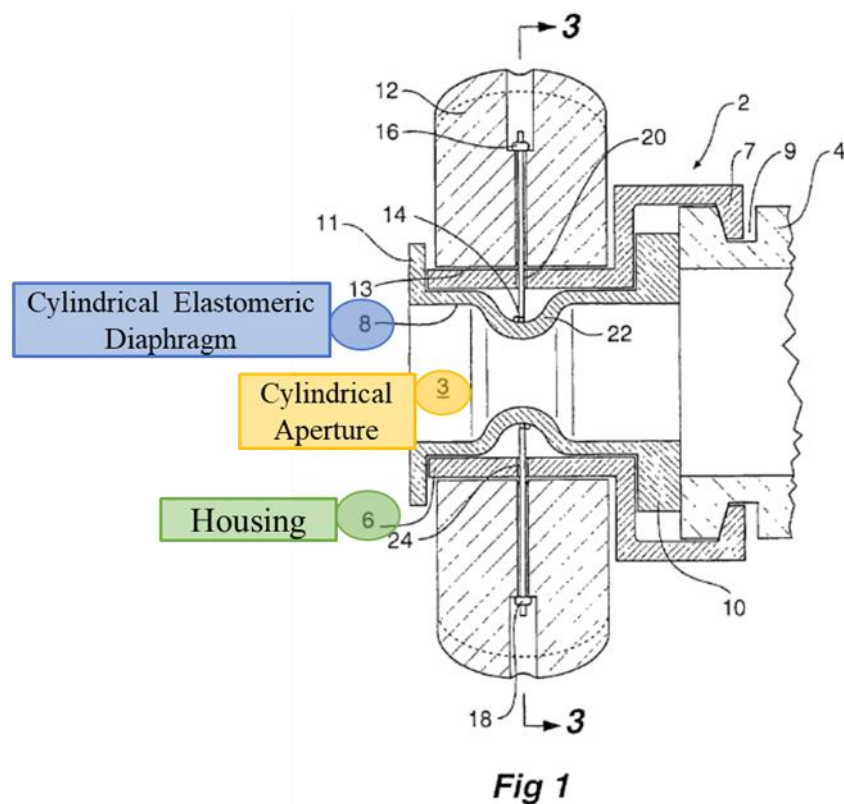
224. A person of ordinary skill in the art would have reasonably expected success in using Hartley’s hemostasis valve with Garrison’s catheters in August 2018. Garrison broadly discloses that the hemostasis valves used with its system “can be a static seal-type passive valve, or an adjustable-opening valve such as a Tuohy-Borst valve 227 or rotating hemostasis valve (RHV) (see FIG. 6).” Ex. 1011 (Garrison) at [0062]. Hartley’s hemostasis valve is a “rotating hemostasis valve” which Garrison describes as suitable for use with its system.

225. In addition, Hartley discloses that its “cylindrical housing may be mounted for instance onto an access point on a laparoscopic device. When it is required to insert a laparoscopic device through the valve the valve can be opened sufficiently to allow insertion of the device and then the access valve can be constricted around the device to prevent loss of blood or inflation gas from within a body cavity during operation of the device.” Ex. 1006 (Hartley) at [0011]; *see also id.* at [0021] (disclosing that the hemostasis valve may “reside in an access port on a laparoscopic catheter”). Hartley also discloses that “the cylindrical housing may be mounted on a prosthesis delivery catheter and the access valve be adapted to close around a prosthesis delivery device.” *Id.* at [0012]. Given these disclosures in Hartley, a person of ordinary skill in the art would have reasonably expected that Hartley’s valve could be attached to or formed integrally with the proximal hub/adaptor in Garrison’s aspiration system and would allow the tools in Garrison’s system, such as the catheter 2030 or a smaller catheter through catheter 2030, to pass through the valve into the patient’s vasculature while also preventing blood from leaking around those tools.

226. As I explain in detail below, Hartley combined with Eller renders each of the claimed features of the hemostasis valve recited in Claim 1 obvious.

a. **Tubular Member**

227. Hartley discloses an “access valve which can be controlled to vary the size of the aperture through the valve and be flexible so that a seal may be formed against an instrument or other object inserted through the access valve.” Ex. 1006 (Hartley) at [0004]. As shown in Figure 1 below, Hartley’s valve includes a “cylindrical housing 6 into which is received a cylindrical elastomeric diaphragm 8 ... [that] defines a cylindrical aperture 3 therethrough”:



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

through the valve.” *Id.* at [0006]. Thus, Hartley’s cylindrical diaphragm is “a tubular member defining a lumen configured to slidably receive the second catheter.”

b. Constricting Mechanism

i. Actuator

228. Hartley’s valve includes a cylindrical housing that holds a “cylindrical elastomeric diaphragm” and a rotatory actuator mounted onto the housing:

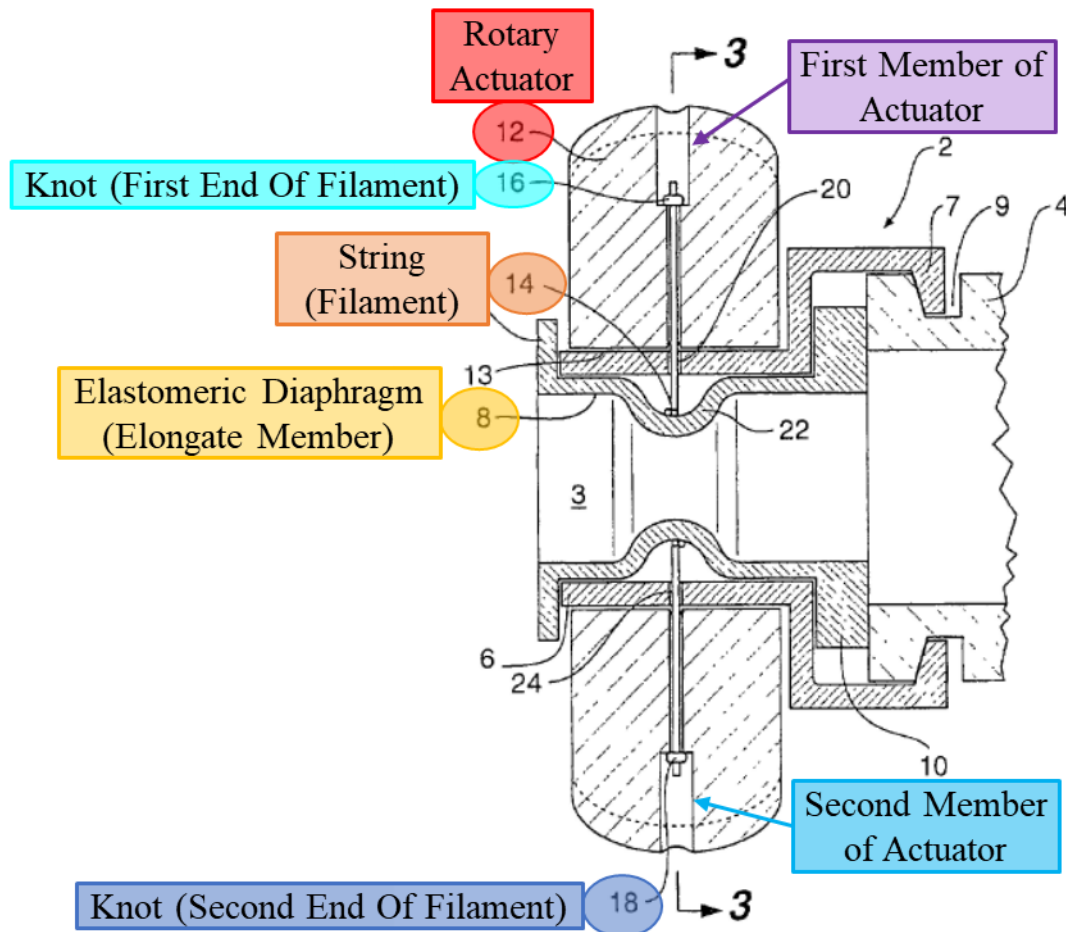


Fig 1

Ex. 1006 (Hartley) at [0031], Fig. 1.

229. The portions of the rotary actuator secured to the ends of the string 14 are the first and second members of the actuator as claimed in the '005 patent because those portions of the actuator satisfy the requirements for the first and second members.

230. First, those portions of Hartley's actuator are coupled to the first and second ends of the string 14 (i.e., filament) via the knots 16 and 18. *Id.* at [0031].

231. Second, those portions of Hartley's actuator are “moveable between (a) a first position wherein the filament circumferentially constricts the lumen to create a seal and (b) a second position wherein the filament is moved to at least partially open the lumen.” 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”:

Constricted State

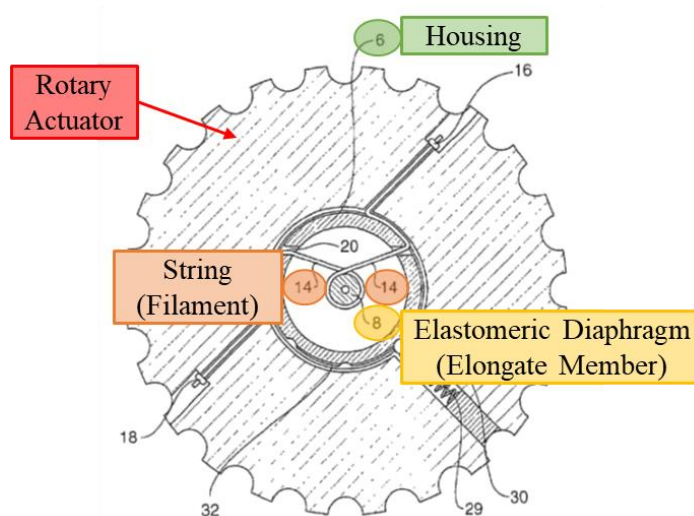
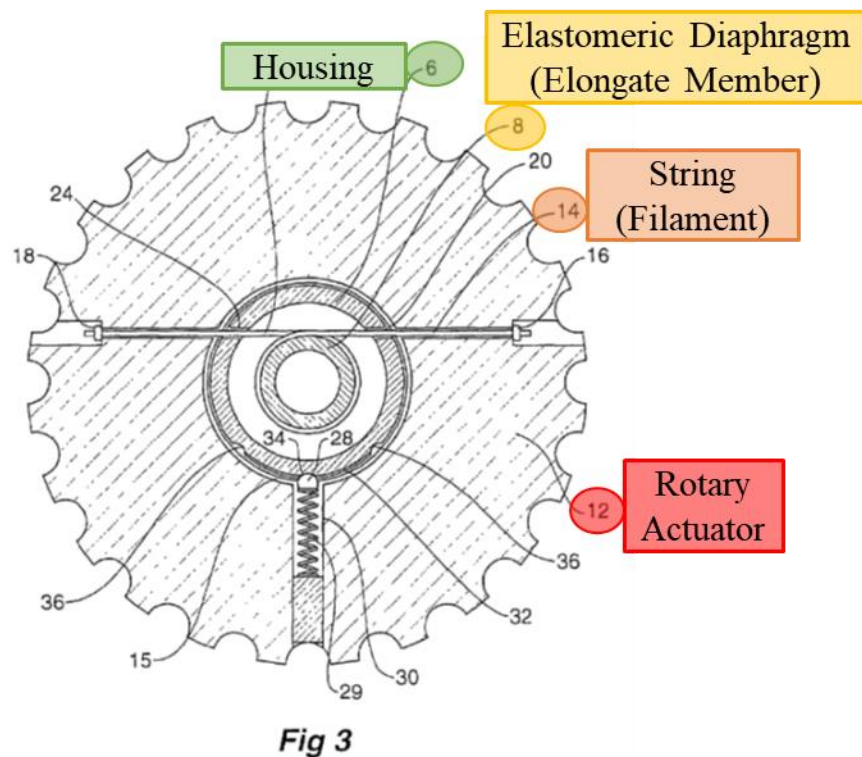


Fig 4

Id. at [0031], [0034], Fig. 4. Hartley further discloses that “[r]otation of the rotary actuator back to the central position where the detent ball 28 is received in depression 34 will cause the sutures to loosen again so that the resilient cylindrical diaphragm will retain its original shape as shown in FIGS. 1 and 3”:

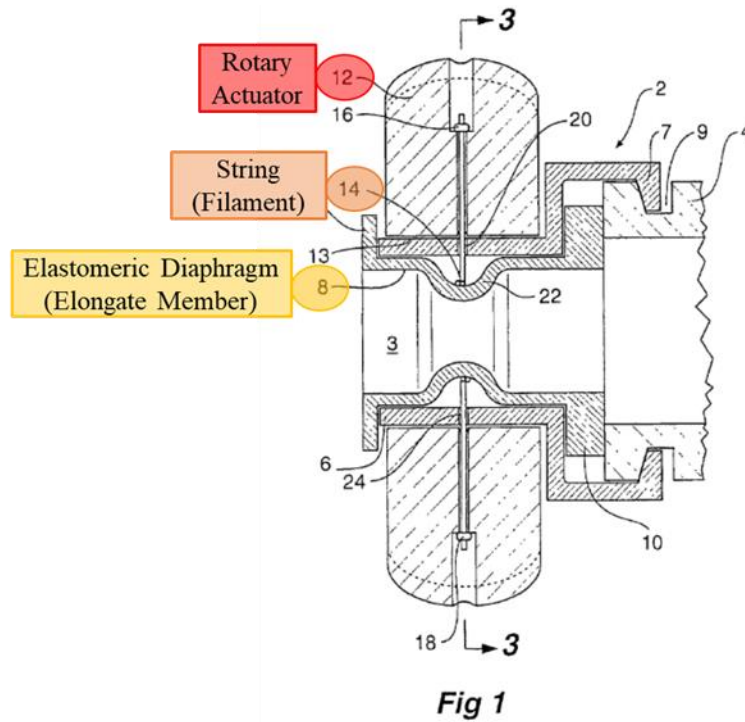
Relaxed State



Id. at [0034], Fig. 3.

ii. Filament

232. Hartley’s valve includes a “flexible member,” referred to as a “string” in the Detailed Description section, that is “mounted into the rotary actuator” as illustrated in Figure 1 below:



Id. at [0005], [0031], Fig. 1. Hartley also describes that the flexible member “may be a string, suture or band or other suitable material.” *Id.* at [0017]. Hartley’s flexible member is therefore a “filament” as disclosed in the ’519 Application and claimed in the ’005 patent. *See* Ex. 1017 (’519 Application patent) at [0047] (disclosing that the filament can constitute “one or several threads, lines, cords, rope, ribbon, flat wire, sheet, or tape”). I refer to Hartley’s “string” herein; however, a suture or band would also meet the claim limitations as they would be at least a thread, line, cord, rope, ribbon, flat wire, sheet, or tape.

233. Hartley discloses that the “flexible member may be mounted at both of its ends to an actuator arrangement and hence the flexible member can be simultaneously pulled in substantially opposite directions to constrict the valve.”

Ex. 1006 (Hartley) at [0010]. As illustrated in Figure 3 below, Hartley's string is secured to the rotary actuator at a first end via knot 16 and "then passes through an aperture 20 in the cylindrical housing 6 and then is wound preferably twice around the cylindrical diaphragm 8 ... and then passes through a further aperture 24 in the cylindrical housing before being fixed by knot 18 again in the rotary actuator":

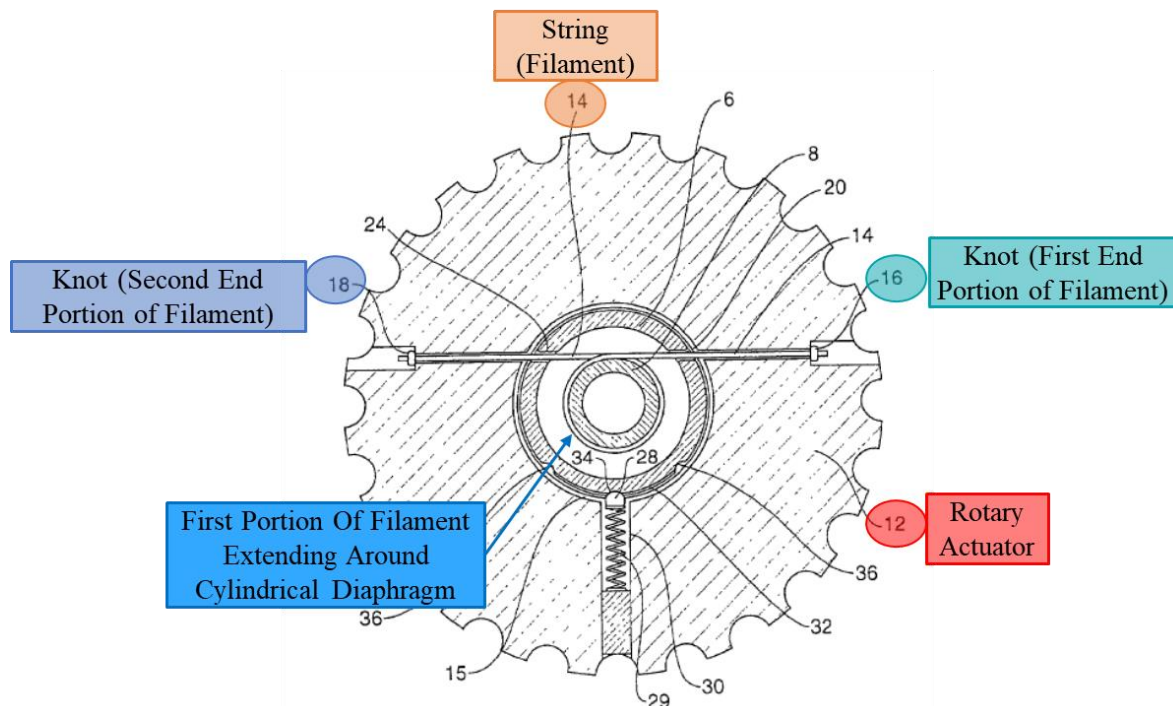


Fig 3

Id. at [0031], Fig. 3. Hartley's string therefore includes "a first portion extending around at least a portion of the tubular member" as recited in Claim 1. The portion of Hartley's string that "is wound preferably twice around the cylindrical diaphragm" is the claimed "first portion." See *id.* at [0031].

234. Hartley's string also includes a "a second portion having a first end extending from the first portion in one direction and a second end extending from

the first portion in another direction.” The portion of Hartley’s string that extends away from the cylindrical diaphragm in opposite directions is the claimed “second portion”:

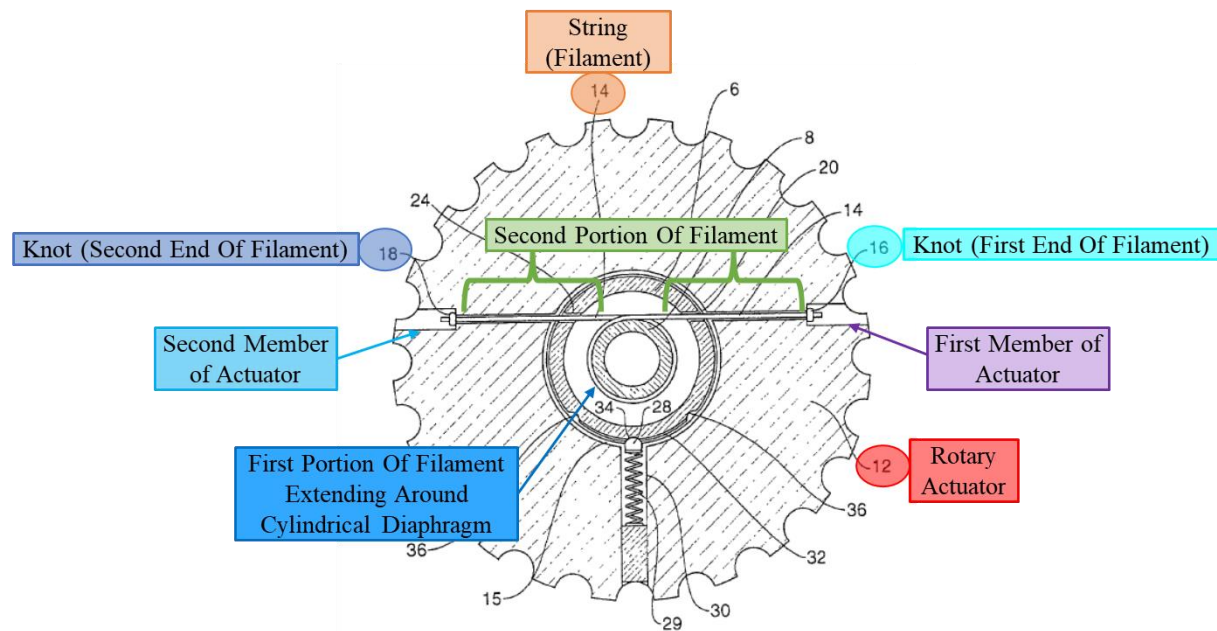


Fig 3

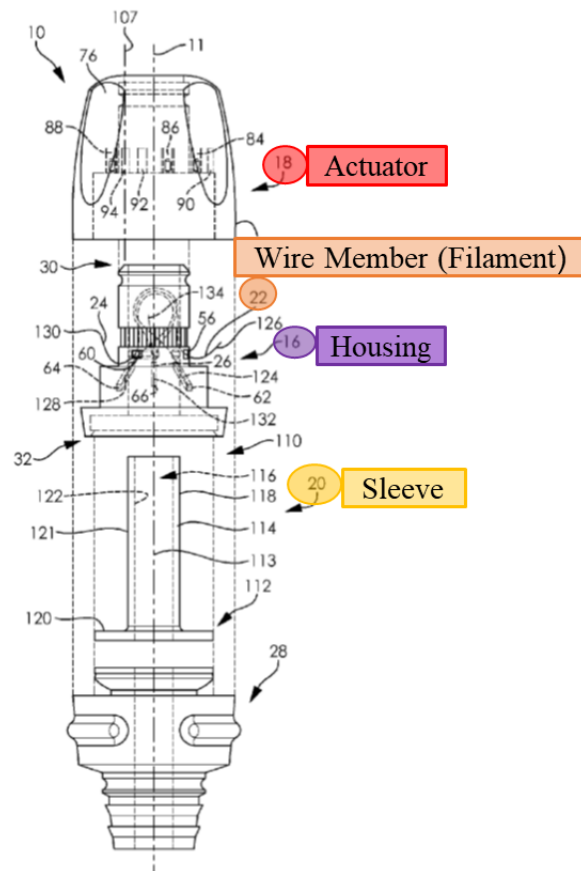
Id. at Fig. 3. The first end of second portion of Hartley’s string is secured to the actuator at knot 16 and the second end of second portion is secured to the actuator at knot 18. *See id.* at [0031], Fig. 3.

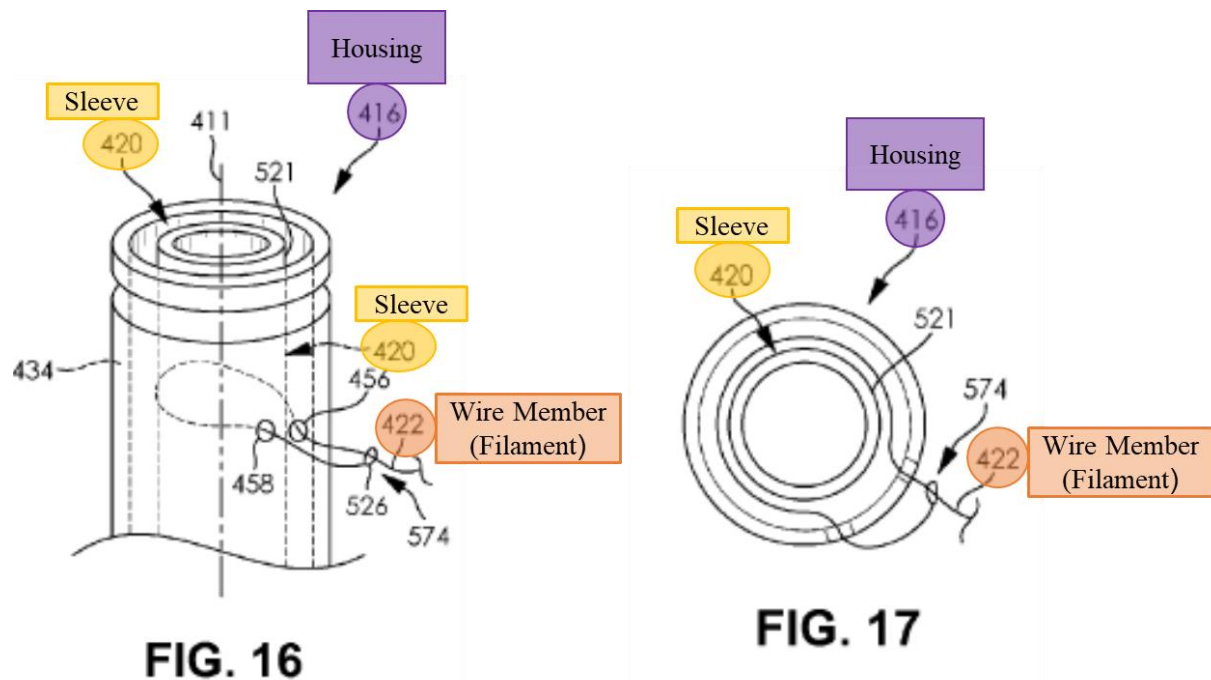
235. Hartley discloses that “[r]otation of the rotary actuator 12 with respect to the cylindrical housing 6 will cause the string 14 to be pulled in both directions at once and hence the cylindrical diaphragm 8 to be constricted.” *Id.* at [0031], [0034], Fig. 4. Hartley also discloses that its valve “will close over a range of diameters of devices passed through the valve or can close completely down to be self sealing.” *Id.* at [0037].

c. **Biasing System**

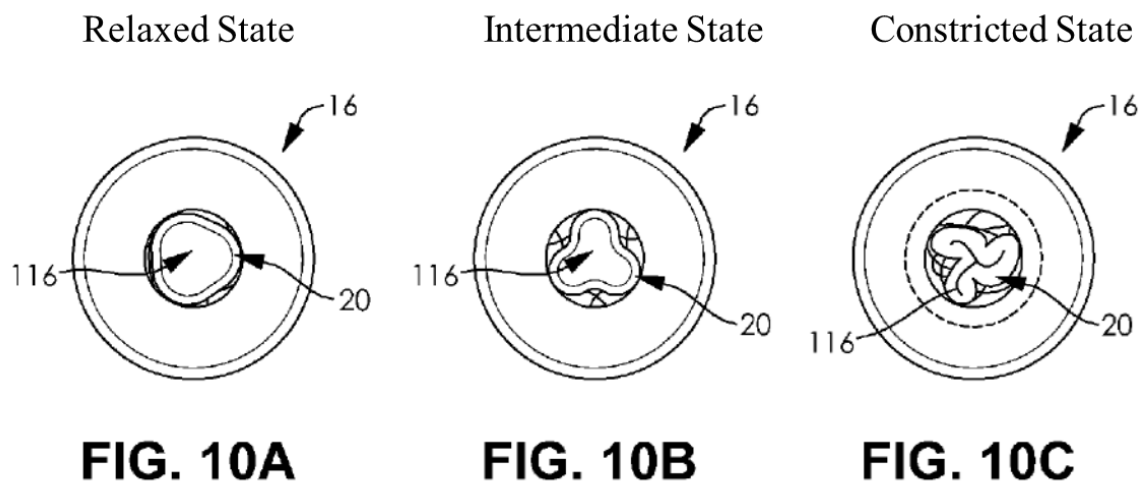
236. Hartley in combination with Eller renders the “biasing system” recited in Claim 1 obvious.

237. Eller discloses a hemostasis valve that includes “a housing 16, an actuator 18, a sleeve 20, [and] a first wire member 22”:





Ex. 1007 (Eller) at 5:1-5, Figs. 2, 16-17. Eller explains that its valve has two configurations. “In a first configuration, the passageway 116 defined by the sleeve 20 is open such that fluid can pass through the passageway. In the second configuration, the passageway 116 defined by the sleeve 20 is closed such that fluid is prevented from passing through the passageway 116”:



Id. at 12:13-18, Figs. 10A-10C. Eller further explains that its valve can include a biasing systems for biasing the valve toward the closed configuration:

Optionally, a selective fluid barrier valve device can be **biased to the second configuration** such that the **actuator is biased to the second position**. This can be accomplished using any suitable structural configuration or component. For example, a **torsion spring** can be positioned between the housing and the actuator and can be attached to the housing and the actuator such that **when no outside forces are applied to the selective fluid barrier valve device, the spring positions the actuator in the second position**.

Id. at 19:22-30 (emphasis added). A person of ordinary skill in the art would have recognized that Eller's exemplary torsion spring biasing system would be particularly suitable for use with a rotary actuator, like that disclosed in Hartley.

238. A person of ordinary skill in the art would have been motivated to combine Eller's torsion spring biasing system with Hartley's valve for several reasons. First, the person of ordinary skill in the art would have recognized that Eller's biasing system would help ensure that Harley's valve is sealed as quickly as possible when a catheter or other tool is removed through the valve during a medical procedure. Specifically, the torsion spring would maintain Hartley's actuator/string in the constricted position as the tool is withdrawn through the valve lumen and would then quickly seal the valve completely once the tool is fully withdrawn from the valve lumen without requiring additional intervention from the operator. This would help to minimize blood loss during the procedure, which is the primary purpose for the hemostasis valve.

239. Second, the person of ordinary skill in the art would have recognized that Eller's biasing system would simplify the use of Hartley's valve and the steps required to seal the valve to prevent blood loss. For example, the torsion spring biasing system would eliminate the need for the operator to manually seal the valve before or during the procedure. The valve would be set to the closed position by default, which would minimize the possibility that operator error could allow unwanted blood leakage.

240. Third, the person of ordinary skill in the art would have recognized that adding Eller's biasing system to Hartley's valve would merely entail the combination of known elements (Hartley's valve and Eller's biasing system) according to known methods (positioning a torsion spring between the valve housing and actuator) to yield the predictable result of reducing leakage of fluid through the valve. Combining such known elements in such a predictable manner would have been well within the level of ordinary skill in August 2018.

241. A person of ordinary skill in the art would have reasonably expected success in combining Eller's torsion spring biasing system with Hartley's valve. Hartley and Eller are from the same field of endeavor and share the same objective, which is providing a hemostasis valve that can seal around a range of tools inserted through the valve during intravascular medical procedures to minimize the leakage of blood or other fluids. Ex. 1006 (Hartley) at [0004]; Ex. 1007 (Eller) at Abstract,

12:15-18, 15:21-40, 17:47-18:8. The person of ordinary skill in the art would have therefore naturally turned to Eller when seeking to improve Hartley's hemostasis valve.

242. In addition, the person of ordinary skill in the art would have recognized that Hartley's valve shares many common features with Eller's valve, such as: a housing, a rotational actuator mounted to the housing, a tubular sleeve/diaphragm extending through the actuator, and a constricting string/wire extending circumferentially around the sleeve/diaphragm. *See, e.g.*, Ex. 1006 (Hartley) at [0031], Figs. 1-3; Ex. 1007 (Eller) at 5:1-12, Figs. 1-10. These similarities would have suggested to a person of ordinary skill in the art that Eller's torsion spring biasing system could successfully be added to Hartley's similarly structured valve.

243. In addition, Eller explains that the torsion spring "can be positioned between the housing and the actuator and can be attached to the housing and the actuator such that when no outside forces are applied to the selective fluid barrier valve device, the spring positions the actuator in the second position." Ex. 1007 (Eller) at 19:26-30. A person of ordinary skill in the art would have recognized that a similar arrangement could be used for Hartley's valve. Specifically, the person of ordinary skill in the art would have reasonably expected success in attaching the torsion spring to Hartley's housing 6 and rotational actuator 12 in a position that

would cause the actuator to be biased toward the closed position when no outside force is applied to the actuator:

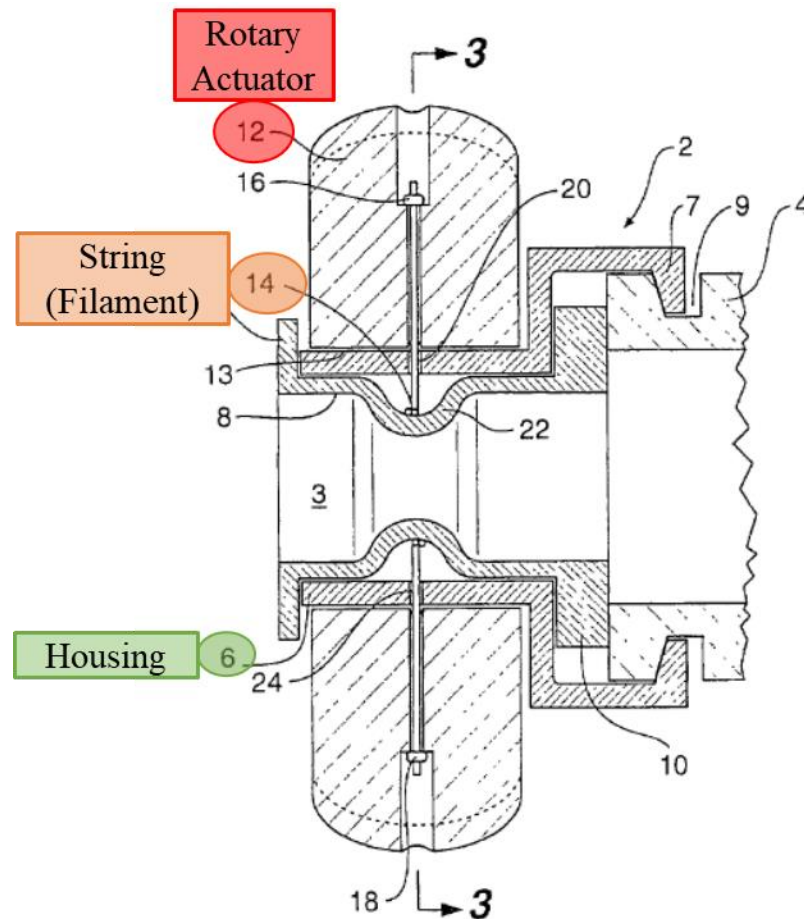


Fig 1

Ex. 1006 (Hartley) at Fig. 5. Therefore, Hartley in combination with Eller renders the “biasing system” recited in claim 1 obvious.

B. Claim 2

244. Claim 2 recites: “The vacuum aspiration system of claim 1 wherein the tubular member is pliable.” Hartley discloses the additional limitations recited

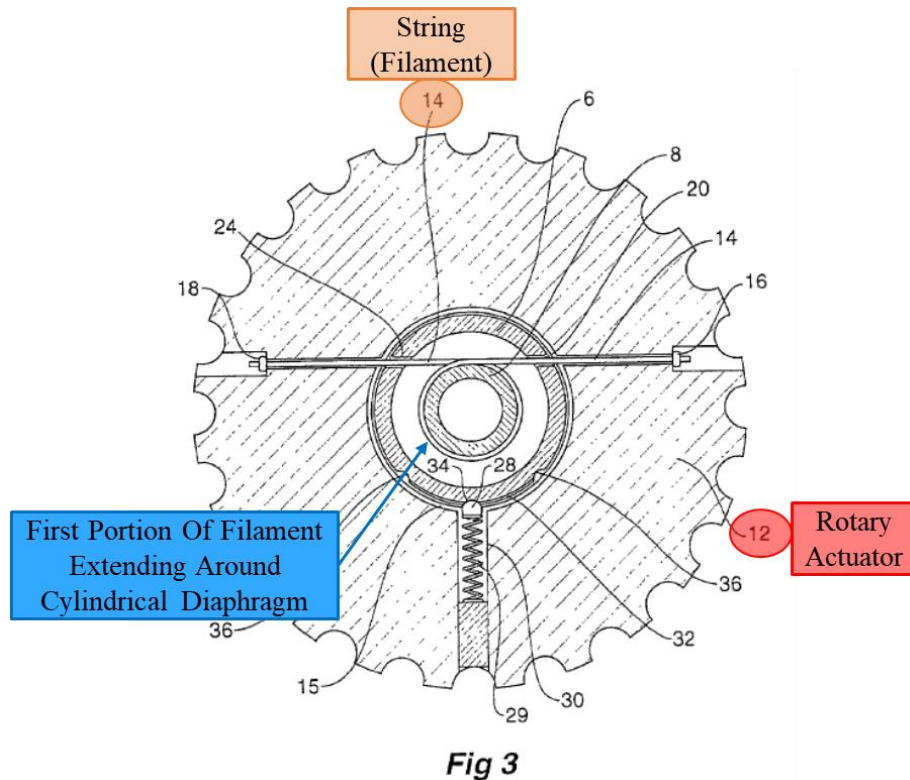
in Claim 2, and therefore, Garrison combined with Hartley and Eller renders claim 2 obvious.

245. Hartley discloses that its cylindrical diaphragm (i.e., the tubular member) “may be constructed from an elastomeric material such as silicone rubber.” Ex. 1006 at [0016]. Elastomeric materials are pliable. Additionally, Hartley also discloses that the cylindrical diaphragm can be constricted and then spring back to its original, open configuration when the constricting element is loosened. *See id.* at [0008] (Hartley disclosing that “[p]referably the cylindrical diaphragm is formed from a resilient material so that after constriction and release of the flexible member the valve reopens”). Thus, Hartley’s cylindrical diaphragm is pliable.

C. Claim 3

246. Claim 3 recites: “The vacuum aspiration system of claim 1 wherein the first portion of the filament extends in a loop completely around the tubular member.” Hartley discloses the additional limitations recited in Claim 3, and therefore, Garrison combined with Hartley and Eller renders claim 3 obvious.

247. Hartley discloses that its string “is wound preferably twice around the cylindrical diaphragm” as illustrated in Figure 3 below:



Ex. 1006 (Hartley) at [0031], Fig. 3. Hartley’s string therefore includes a first portion that “extends in a loop completely around the tubular member.” *Id.*

D. Claim 5

248. Claim 5 recites: “The vacuum aspiration system of claim 1 wherein, when the first member and the second member of the actuator are in the first position, the lumen of the tubular member is configured to remain constricted and sealed when a pressure differential exists between (a) a first volume outside the lumen and adjacent to a first end of the tubular member and (b) a second volume outside the central lumen and adjacent to a second end of the tubular member.” Garrison combined with Hartley and Eller renders claim 5 obvious.

249. First, as I explained in Grounds 1-4 previously, Claim 5 encompasses **any** level of pressure differential between the first and second ends of the tubular member, and a person of ordinary skill in the art would have recognized that such a pressure differential would necessarily exist between the outside of the first end of a catheter and the second end the catheter during any procedure where the catheter is inserted into a patient's vasculature. *Supra* ¶118.

250. As I further explained in Grounds 1-4, Hartley's valve is intended for use during intravascular procedures, where such a pressure differential will necessarily exist, and Hartley discloses that its valve is intended to "permit[] [a] catheter or other instrument to be passed through the access valve and the valve to form a seal against the walls of the catheter or other instrument to prevent loss of blood or other fluid." Ex. 1006 (Hartley) at [0003]. To do so, Hartley's valve must be configured to maintain the seal in the presence of a pressure differential. *Supra* ¶118.

251. Hartley also discloses that "[d]epending on how much the flexible member [i.e., string] is pulled radially and/or tangentially the cylindrical diaphragm can be completely constricted to prevent fluid flow through the valve or can be constricted to the extent that it closes around an instrument, for instance a catheter, passed through the valve." Ex. 1006 (Hartley) at [0006]. A person of ordinary skill in the art would have recognized that when Hartley's valve is "completely

constricted” or “constricted to the extent that it closes around an instrument, for instance a catheter, passed through the valve,” the valve would be configured to remain constricted and sealed, even in the presence of a pressure differential between the two ends of the valve lumen.

E. Claim 6

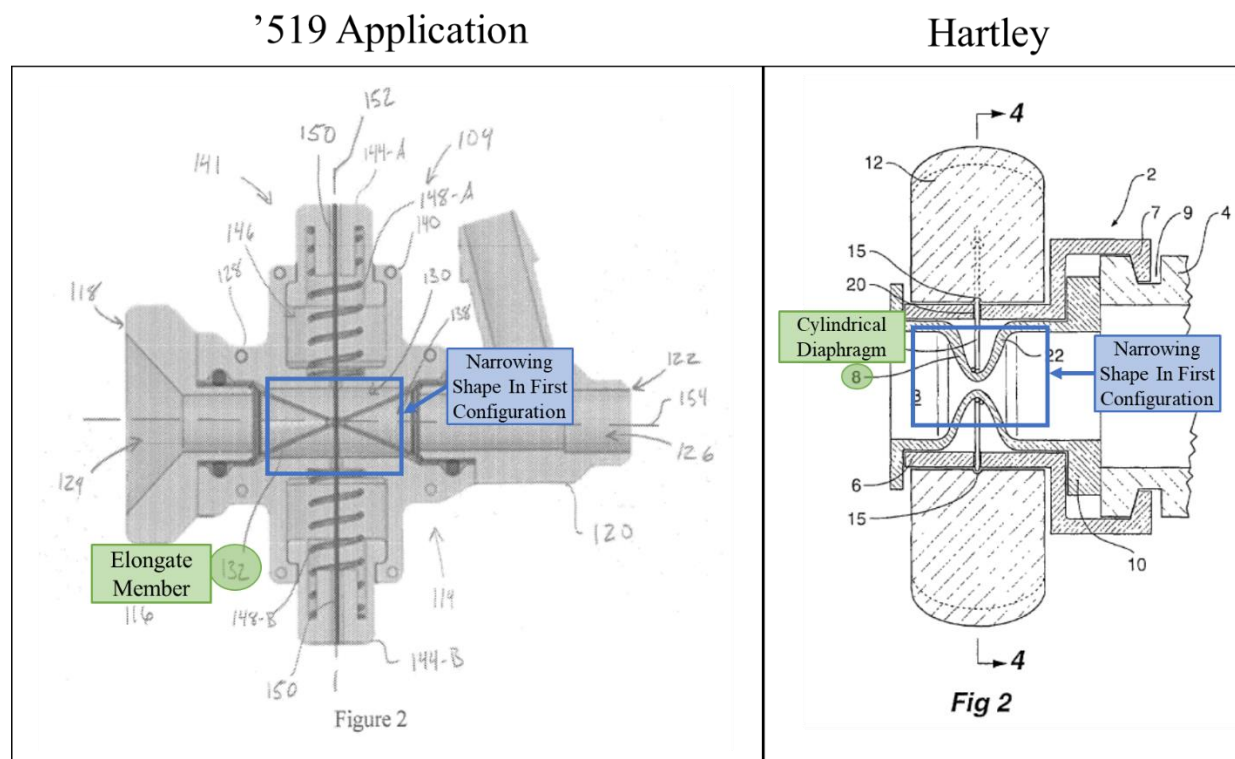
252. Claim 6 recites: “The vacuum aspiration system of claim 1 wherein, when the first member and the second member of the actuator are in the first position, the lumen of the tubular member is configured to remain constricted and sealed when vacuum pressure is applied to a volume outside the lumen and adjacent to either a first end or a second end of the tubular member.” Garrison combined with Hartley and Eller renders claim 6 obvious.

253. As I explained previously in Grounds 1-3, a person of ordinary skill in the art in August 2018 would have recognized that some intravascular procedures included suction devices, such as aspiration catheters, which would apply vacuum pressure outside of the lumen of the hemostasis valve. A person of ordinary skill in the art would have understood that a hemostasis valve used with a suction device should be configured to maintain its seal in the presence of a vacuum pressure to effectively prevent air from being drawing into and through the valve during the procedure. *Supra* ¶¶176-182.

254. Accordingly, a person of ordinary skill in the art would have been motivated to ensure that Hartley's valve is configured to remain sealed when the rotary actuator is in the first position, even when a vacuum pressure is applied to a volume outside of the valve's lumen. *See, e.g.*, Ex. 1006 (Hartley) at [0003], [0006]. A person of ordinary skill in the art would have accomplished such a seal by ensuring that the torsion spring coupled to the rotary actuator was strong enough to resist any forces caused by the negative pressure. The suction force from the aspiration catheter would not be applied in the correct direction to move the string but may, in fact, help to pull the valve inward and even increase the strength of the seal. Thus, Hartley's valve is configured to remain constricted and sealed when vacuum pressure is applied to a volume outside the lumen and adjacent to either a first end or a second end of the tubular member.

255. In addition, the only description in the '519 patent that I see regarding the valve's ability to seal in the presence of vacuum pressure is the following statement: "due to the narrowing shape of the elongate member 132 when the constricting mechanism 141 is in the first configuration, a vacuum applied to the portions of the delivery device 100 distal to the axis 152 draws the elongate member 132 towards the first configuration and can, in some embodiments, increase the strength, robustness, and/or strength of the seal of the valve 104." Ex. 1017 ('519 Application) at [0055]. Notably, Hartley's elongate member (i.e., the cylindrical

diaphragm 8) also has a “narrowing shape” when the actuator is in the first (i.e., constricted) configuration:



Id. at Fig. 2 (left); Ex. 1006 (Hartley) at [0031], Fig. 2⁴ (right). Thus Hartley’s valve has the same structure, features, and function as those that the ’519 Application

⁴ Figure 2 of Hartley shows the valve in a “partially constricted position.” Ex. 1006 (Hartley) [0026]. However, a person of ordinary skill in the art would have recognized that the cylindrical diaphragm would have an even more narrowing shape in the fully constricted position, where the diaphragm is completely constricted. *See id.* at [0037] (Hartley disclosing that the valve “can close completely down to be self sealing”).

describes as enabling the valve to seal in the presence of vacuum pressure. A person of ordinary skill would have expected Hartley's valve to remain closed even when subjected to negative pressure on one side of the valve due to the shape of the valve and due to the elastomeric properties of the diaphragm.

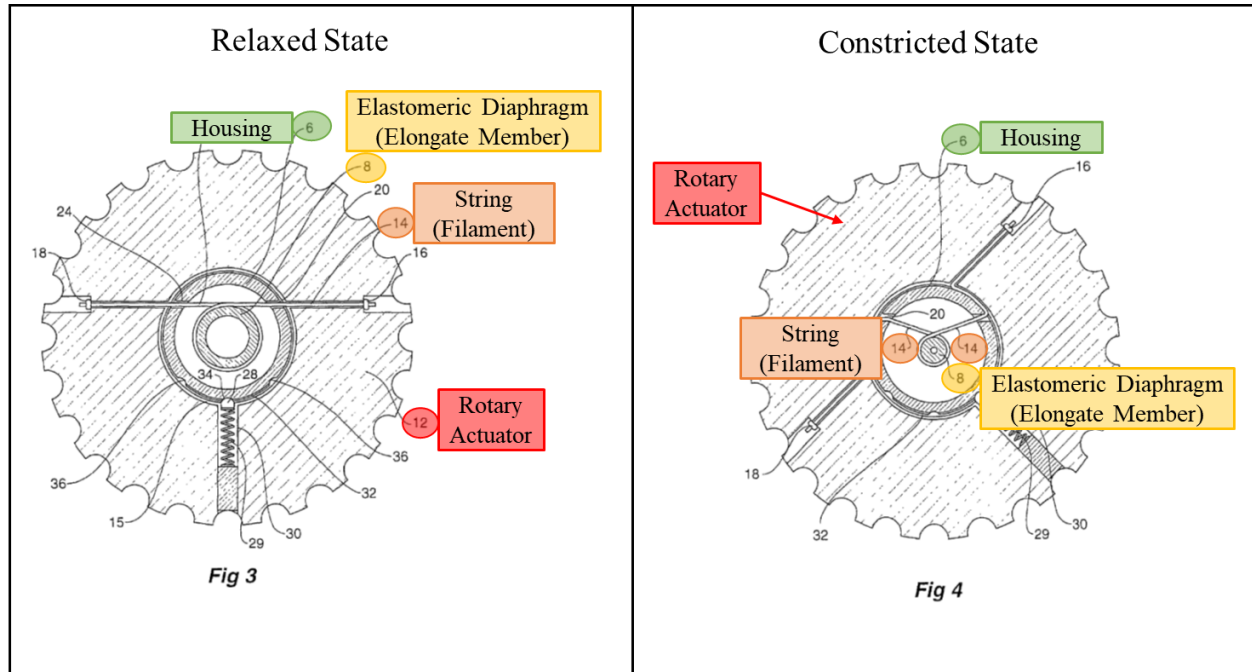
256. If Hartley's valve did not maintain its seal under vacuum pressure, it would have been obvious for a person of ordinary skill in the art to adjust Hartley's valve to ensure that it could maintain a seal in the presence of vacuum pressure. For example, the person of ordinary skill in the art could have adjusted the spring strength of the torsion spring added from Eller to apply additional force to seal the valve, they could have adjusted the resilience and compressibility of the cylindrical diaphragm that forms the valve's lumen, and/or they could have adjusted the shape, flexibility, and/or dimensions of the string to more closely conform to the shape of the seal module and any tool(s) inserted through the valve. A person of ordinary skill in the art would have been motivated to do so because the purpose of Hartley's hemostasis valve is to prevent leakage when other devices, or no devices, are inserted, and whether the valve is exposed to positive pressure or vacuum pressure. A person of ordinary skill in the art could have simply adjusted the strength of the torsion spring in several ways, including selecting a different material, modifying its dimensions, or winding the spring more tightly. These simple changes were well within the skill of a person of ordinary skill in the art and these adjustments in

material or configuration would have had predictable results. As I explained previously, a person of ordinary skill in the art would have reasonably expected success in selecting an appropriate material for the valve lumen in view of the range of suitable lumen materials disclosed in the prior art. *Supra* ¶132. A person of ordinary skill in the art would have reasonably expected success in adjusting the size, shape, and/or dimensions of Hartley's string to improve the sealing of the valve lumen. A person of ordinary skill could have adjusted the string in several ways, including selecting a different material or dimensions for the string and/or shortening or lengthening the string to adjust the amount of tension applied by rotation of the actuator. These simple changes were well within the skill of a person of ordinary skill in the art and these adjustments in material or configuration would have had predictable results. Therefore, Hartley in combination with Eller renders claim 6 obvious.

F. Claim 9

257. Claim 9 recites: "The vacuum aspiration system of claim 1 wherein, in the first position, the first member and the second member of the actuator pull the filament to circumferentially constrict the tubular member such that the lumen is constricted and sealed." Hartley discloses the additional limitations recited in Claim 9, and therefore, Garrison combined with Hartley and Eller renders claim 9 obvious.

258. 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. 1006 at [0031], Figs. 3-4. In other words, when Hartley’s actuator is in the in first (i.e., constricted) position, the portions of the actuator that are secured to the string at knots 16 and 18 (i.e., the first and second actuator members) “pull the [string] to circumferentially constrict the tubular member such that the lumen is constricted and sealed.” Hartley therefore discloses the additional limitations of Claim 9.

G. Claim 10

1. Preamble and Limitations 2-7

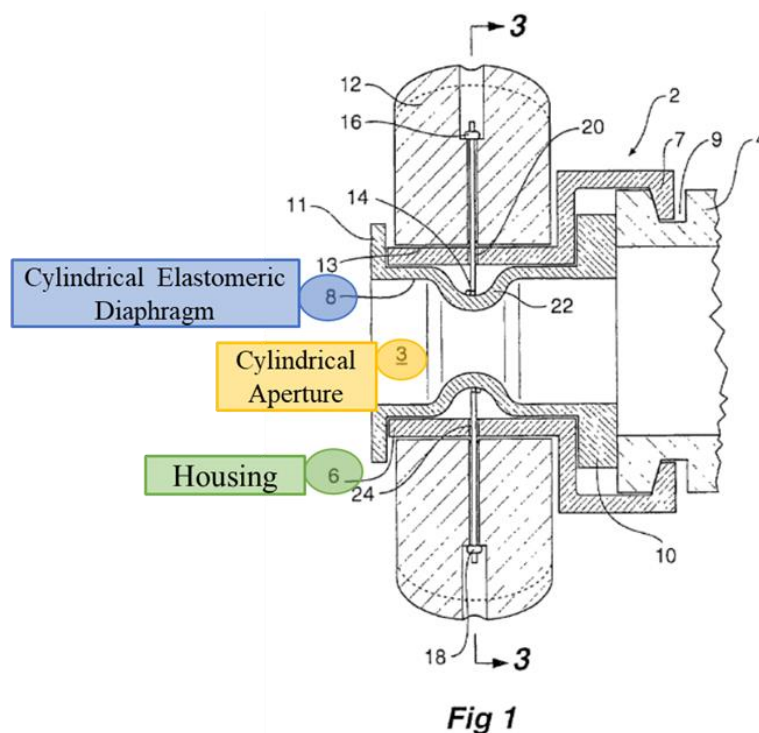
259. If the preamble of claim 10 is limiting, Garrison discloses that limitation for the same reasons I explained in Grounds 1-3. *Supra* §VI.A.1. Garrison discloses the recited housing, flow path, on-off control, first catheter, and clot cannister limitations of Claim 10 for the reasons I explained previously in Grounds 1-3. *Supra* §§VI.A.1-7.

2. Hemostasis Valve

260. Claim 10 recites “a hemostasis valve in the housing configured to receive a second catheter and direct the second catheter through the first catheter.” Garrison discloses this limitation for the reasons I explained previously in Grounds 1-3. *Supra* §VI.A.8. Claim 10 also recites several features of the hemostasis valve. For the reasons explained previously for Claim 1, a person of ordinary skill in the art would have been motivated, and found it obvious, to use Hartley’s valve (with Eller’s torsion spring) as the hemostasis valve on Garrison’s catheters (including catheter 2030). *Id.* Thus, Garrison in combination with Hartley and Eller renders the hemostasis-valve limitations of claim 10 obvious.

a. **Support**

261. Hartley's valve includes a "cylindrical housing 6 into which is received a cylindrical elastomeric diaphragm 8 ... [that] defines a cylindrical aperture 3 therethrough":



Ex. 1006 (Hartley) at [0031], Fig. 1. Hartley explains that the “rotary actuator 12 is mounted onto the cylindrical housing 6.” *Id.* A person of ordinary skill in the art would have therefore understood that Hartley’s housing 6 “supports” the other components of the valve, such as the elastomeric diaphragm and the rotary actuator, and is thus a “support” as claimed in the ’005 patent.

b. Actuator

262. Claim 10 next recites that the hemostasis valve comprises “an actuator having a least a first member movably coupled to the support.” Hartley discloses this limitation.

263. Hartley’s valve includes a “rotary actuator 12 [that] is mounted onto the cylindrical housing 6”:

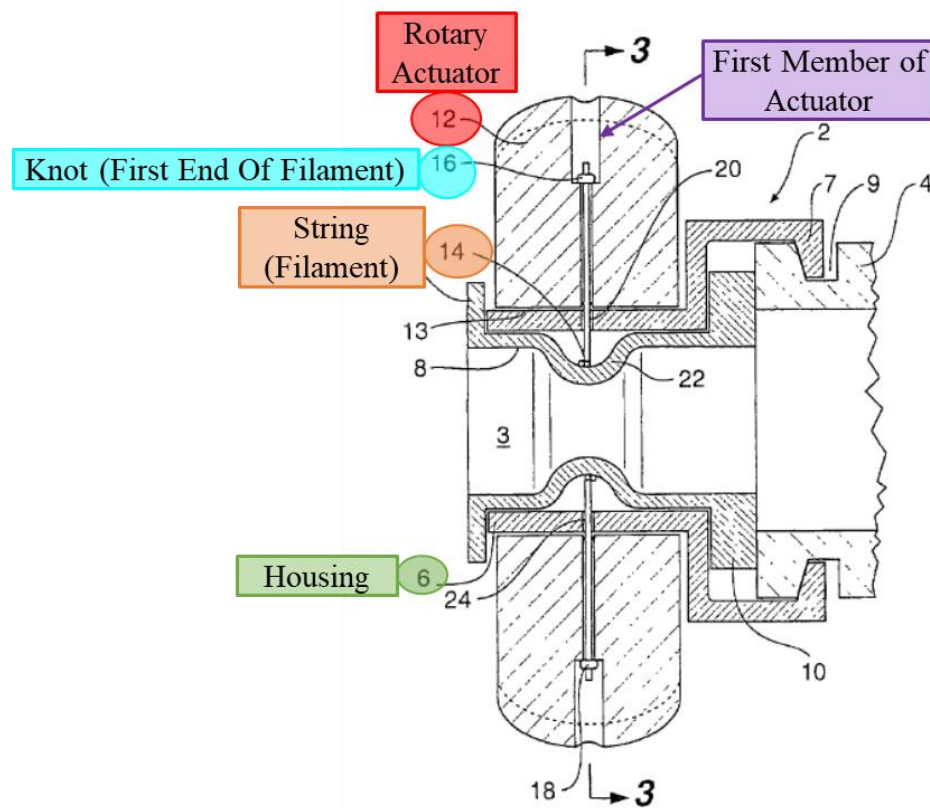


Fig 1

Ex. 1006 (Hartley) [0031], Fig. 1. As I explained previously for Claim 1 Hartley’s actuator has a “first member” where the first end of the string is secured to the

actuator. *Supra* §VII.A.2.b.i. 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. 1006 (Hartley) at [0031]. The first member of Hartley’s actuator is therefore “movably coupled to the support.”

c. Tubular Sidewall

264. Claim 10 next recites that the hemostasis valve comprises “a collapsible tubular sidewall defining a lumen carried by the support.” Hartley discloses this limitation.

265. Hartley’s valve includes a “cylindrical housing 6 into which is received a cylindrical elastomeric diaphragm 8 ... [that] defines a cylindrical aperture 3 therethrough”:

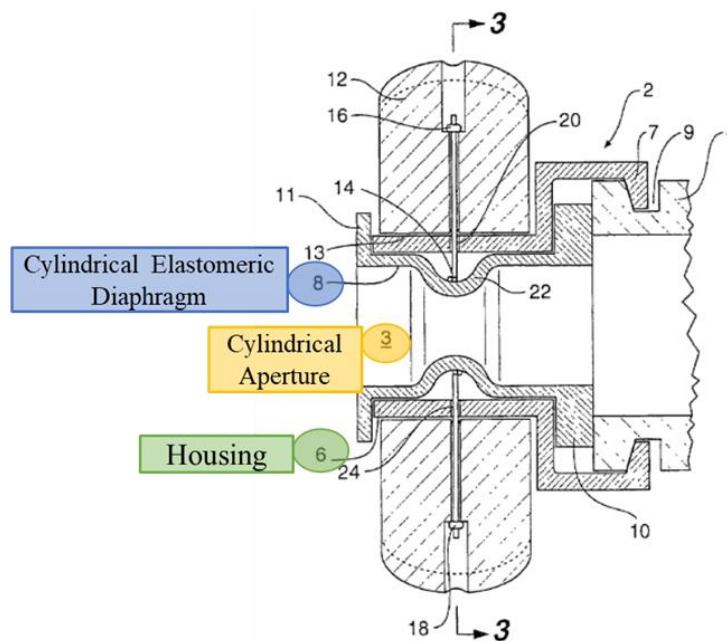


Fig 1

Ex. 1006 (Hartley) at [0031], Fig. 1. Hartley's elastomeric diaphragm therefore defines a lumen that is "carried" by the housing 6 (i.e., support). *Id.* Hartley discloses that the "cylindrical diaphragm can be completely constricted to prevent fluid flow through the valve or can be constricted to the extent that it closes around an instrument, for instance a catheter, passed through the valve." *Id.* at [0006]. Hartley's elastomeric diaphragm is therefore "collapsible." *Id.* Accordingly, Hartley's elastomeric diaphragm is "a collapsible tubular sidewall defining a lumen carried by the support."

d. Filament

266. Claim 10 next recites that the hemostasis valve comprises "a filament formed in a loop around the tubular sidewall, the filament having at least a first end portion extending away from the loop to the first member." Hartley discloses this limitation for the same reasons I explained previously for claims 1 and 3. *Supra* §VII.A, C.

e. First Spring

267. Claim 10 finally recites that the hemostasis valve comprises "a first spring configured to move the first member in a direction that pulls the first end portion such that a diameter of the lumen decreases in response to reducing a diameter of the loop." Hartley in combination with Eller renders this limitation

obvious for the same reasons I explained previously with respect to the “biasing system” limitation of Claim 1. *Supra* §VII.A.2.c.

H. Claim 11

268. Claim 11 recites: “The vacuum aspiration system of claim 10, further comprising a second member movably coupled to the support.” Hartley discloses the additional limitations recited in Claim 11 for the same reasons I explained previously for Claim 1. *Supra* §VII.A.2.b.i. Therefore, Garrison in combination with Hartley and Eller renders Claim 11 obvious.

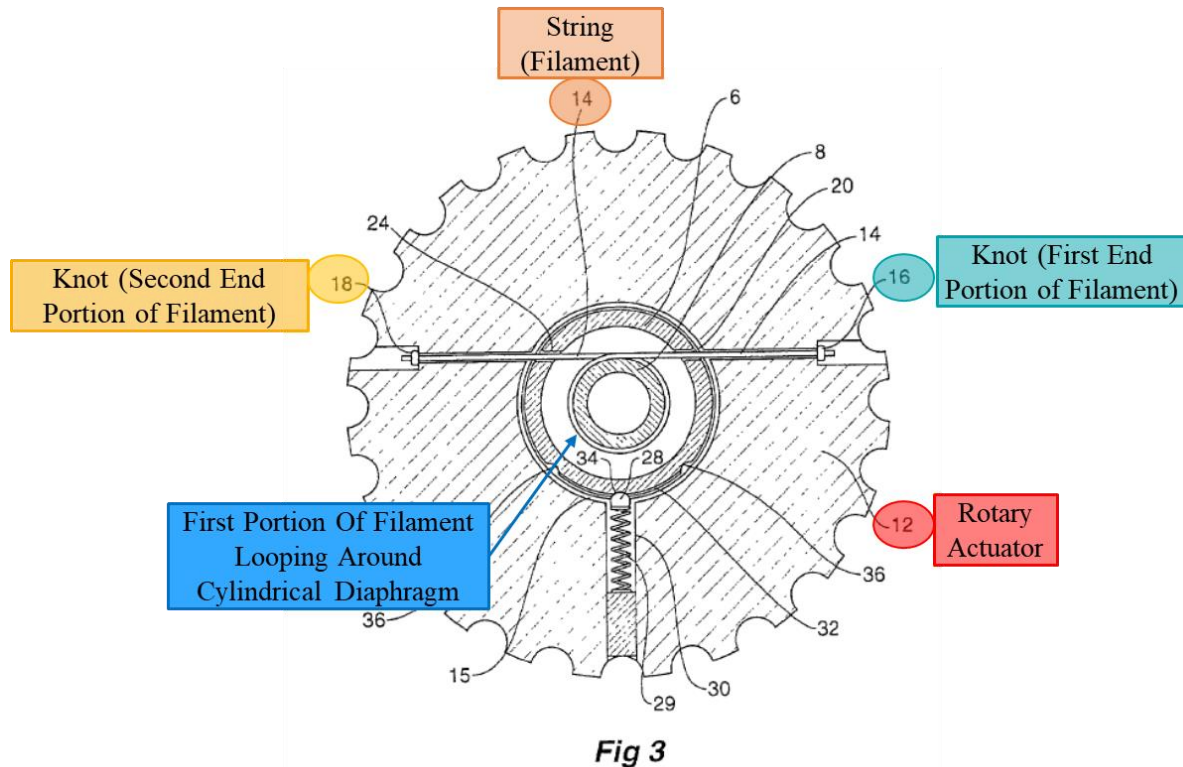
I. Claim 12

269. Claim 12 recites: “The vacuum aspiration system of claim 11 wherein the filament further comprises a second end portion extending away from the loop to the second member.” Hartley discloses the additional limitations recited in Claim 12 for the same reasons I explained previously for Claim 1. *Supra* §VII.A.2.b.ii. Therefore, Garrison in combination with Hartley and Eller renders Claim 12 obvious.

J. Claim 13

270. Claim 13 recites: “The vacuum aspiration system of claim 12 first end portion, the loop, and the second end portion are one continuous filament.” Hartley discloses the additional limitations recited in Claim 13 and therefore, Garrison in combination with Hartley and Eller renders Claim 13 obvious.

271. As I explained previously for Claim 3, Hartley discloses that its single string “is wound preferably twice around the cylindrical diaphragm” as illustrated in Figure 3 below:



Ex. 1006 (Hartley) at [0031], Fig. 3. Thus, the entirety of Hartley’s filament (i.e., the string), including the loop, the first end portion, and the second end portion constitutes a single, continuous filament.

K. Claim 14

272. Claim 14 recites: “The vacuum aspiration system of claim 12 wherein first member and the second member are biased in a direction that places the first end portion and the second end portion under sufficient tension to reduce the diameter of the lumen and provide a seal around a device extending through the

lumen.” Hartley in combination with Eller renders the additional limitations recited in claim 14 obvious for the same reasons I explained previously for Claim 1. *Supra* §VII.A.2.c. Therefore, Garrison in combination with Hartley and Eller renders Claim 14 obvious.

L. Claim 15

273. Claim 15 recites: “The vacuum aspiration system of claim 12 wherein the first member and the second member are biased in a direction that places the first end portion and the second end portion under sufficient tension to close the lumen.” Hartley in combination with Eller renders the additional limitations recited in claim 15 obvious for the same reasons I explained previously for Claim 1. *Supra* §VII.A.2.c. Therefore, Garrison in combination with Hartley and Eller renders Claim 15 obvious.

VIII. SECONDARY CONSIDERATIONS

274. I am not aware of any secondary considerations of nonobviousness relating to the claims of the ’005 patent.

275. The devices claimed in the ’005 patent are not new, and were invented long before August 2018. Therefore, I am not aware of any long-felt need in the industry, unexpected results, skepticism of the invention, or teaching away from the invention. I am also not aware of any praise for the alleged inventions or copying of the alleged inventions by other companies. Many aspiration systems were available on the market by August 2018, and many of those systems included the

conventional components recited in the claims of the '005 patent, including a housing, a flow path, an on-off control, a first catheter, a connector, a clot cannister, and hemostasis valve. *See, e.g., supra* §§VII.A (discussing Garrison). In addition, many aspiration systems and hemostasis valves were available on the market by August 2018, and they all generally accomplished their purpose of sealing the end of a catheter so that blood could not flow out of the catheter. Moreover, the different hemostasis valves were largely interchangeable as evidenced by, for example, Garrison, which explains that various types of hemostasis valves could be used with the aspiration catheters (e.g., “static seal-type passive valve,” “a Tuohy-Borst valve,” or “rotating hemostasis valve”). Ex. 1011 (Garrison) at [0065]. Thus, there was no long-felt need for a better hemostasis valve, let alone one with the specific features required by the '005 patent, for example a “filament.” In fact, in my experience, the users of the valves, physicians, do not know how the hemostasis valves work or what components are inside the valve, so those features would not be the subject of praise or commercial success.

276. I am aware that Patent Owner argued in the related Litigation that the valve described in the '005 patent improved on the prior art hemostasis valves because it could be operated with one hand. However, almost all prior art hemostasis valves could be, and often were, operated with one hand. For example, a static valve required no manipulation by the physician and was always one

handed. Similarly, physicians would typically twist the operable portion of a rotating hemostasis valve with one hand to open and close the valve. Simply put, a hemostasis valve that could be operated with one hand was already known and being sold so there was no long-felt need for such a valve. If Patent Owner identifies any alleged evidence of secondary considerations in the future, I reserve the right to respond to that information.

IX. CONCLUSION

277. For the foregoing reasons, it is my opinion that Claims 1-15 of the '005 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.

278. 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.

279. 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, 2024 in Glen Ellen, CA.

troy thornton

Troy Thornton