UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

IMPERATIVE CARE, INC.,
Petitioner,

v.

INARI MEDICAL, INC.,
Patent Owner.

Patent No. 11,697,012

DECLARATION OF TROY L. THORNTON IN SUPPORT OF PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 11,697,012

IMPERATIVE Ex. 1003
IPR Petition - US 11,697,012

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TABLE OF EXHIBITS

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1002	’012 Patent Prosecution History Excerpt
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 US 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
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1014	U.S. Patent No. 4,723,550 to Bales et al.
1015	U.S. Patent No. 5,895,376 to Schwartz et al.
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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 1-9 of U.S. Patent No. 11,697,012 ("the '012 patent"). For the reasons discussed herein, I have concluded that Claims 1-9 of the '012 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 '012 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 '012 patent, Inari Medical, Inc. ("Inari" or "Patent Owner").

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

B. Experience and Qualifications

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

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

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

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

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

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

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

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

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

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

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

14. In summary, I have more than 35 years of experience in the cardiovascular medical device field, including significant experience designing, developing, testing, and manufacturing catheters and catheter systems for minimally invasive cardiovascular procedures. I am therefore very familiar with the concepts of catheters, catheter systems, and hemostasis valves, and I believe I am well placed to comment on the understanding of a person of ordinary skill in the art in the context of the ’012 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 ’012 patent;
- The level of ordinary skill in the art pertaining to the ’012 patent;
- The teachings of the prior art; and
- Whether Claims 1-9 of the ’012 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 ’012 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 ’012 patent.

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

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

A. Claim Construction

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

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

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

B. Anticipation

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

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

C. Obviousness

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

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

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

26. The prior art references applied in this Declaration are analogous art that is usable in an obviousness combination. The references are from the same field as the '012 patent, e.g., hemostasis valves for use during intravascular procedures. The references are also pertinent to the problem the inventor was focused on, e.g., sealing a catheter during intravascular procedures to minimize blood leaks.

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 1-9 of the ’012 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 ’012 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 ’012 patent is September 6, 2017. 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 ’012 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 ’012 PATENT

A. Summary of the ’012 Patent

37. The ’012 patent describes a delivery system that includes a catheter and a hemostasis (or “garrote”) valve for use during minimally invasive intravascular procedures, as illustrated below in Figure 1:

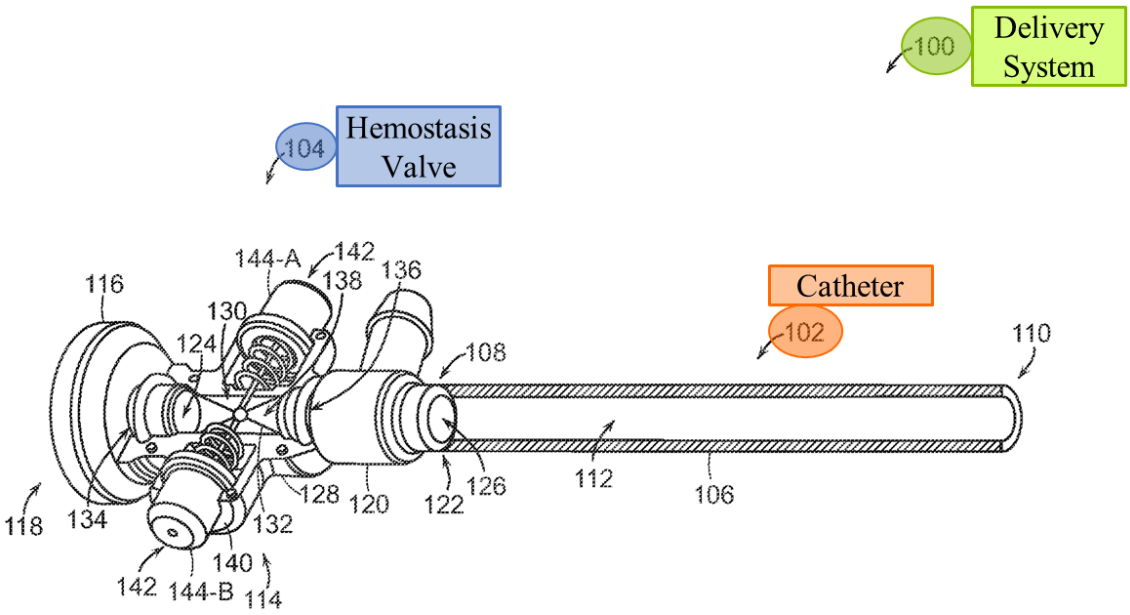


FIG. 1

Ex. 1 ('012 patent) at 6:26-47, Fig. 1. The hemostasis valve is used with a catheter that is inserted into the patient's vasculature and prevents blood from passing through the valve. In this way, the valve helps provide a seal to minimize blood loss, prevent the introduction of air into the vasculature, and maintain sterility during the procedure. *Id.* at 1:41-44. The '012 patent states that the hemostasis valve "can seal with or without a tool extending through the valve." *Id.* at 5:55-58.

38. As illustrated in Figure 2 of the '012 patent below, the hemostasis valve described in the '012 patent includes a "housing 128" that defines a "interior

channel 130," and a collapsible "elongate member 132" that extends through the housing 128:

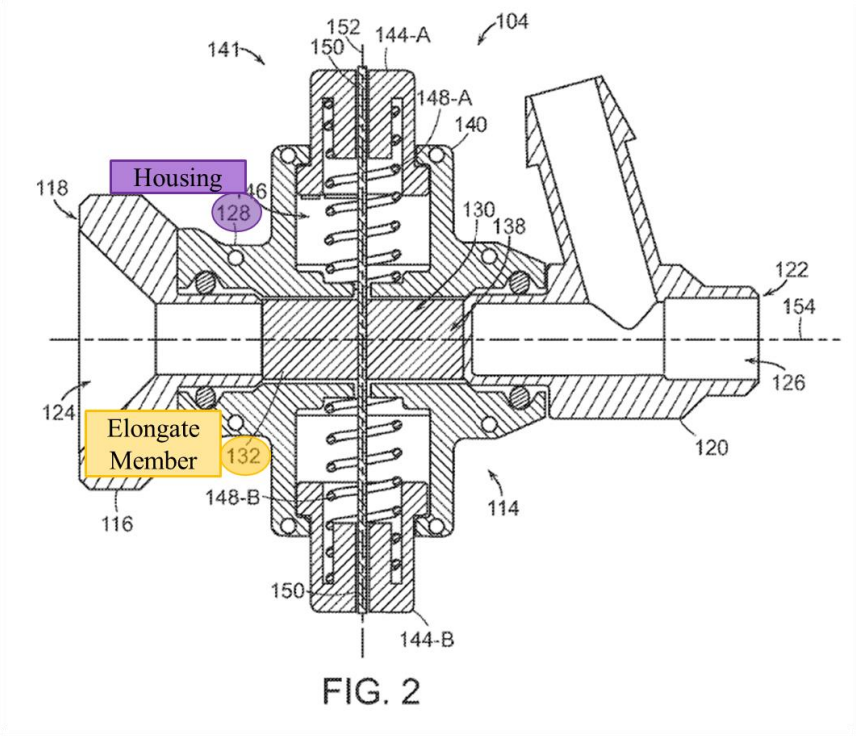


FIG. 2

Id. at 7:1-31, Fig. 2. The '012 patent explains that the elongate member 132 has a "thin-walled compliant tubular structure," which helps facilitate "the uniform collapse of the elongate member 132 and the sealing of the elongate member 132." *Id.* at 7:17-20.

39. The '012 patent describes that the elongate member is sealed by a "constricting mechanism," which can "collapse and seal the elongate member 132 via compression and/or constriction, and specifically via constriction with at least one filament 150." *Id.* at 8:5-8. The '012 patent explains that the filament "can extend at least partially around the elongate member." *Id.* at 8:11-12. The

constricting mechanism also includes an actuator, which the ’012 patent states “can be a manual actuator such as one or several buttons 144”:

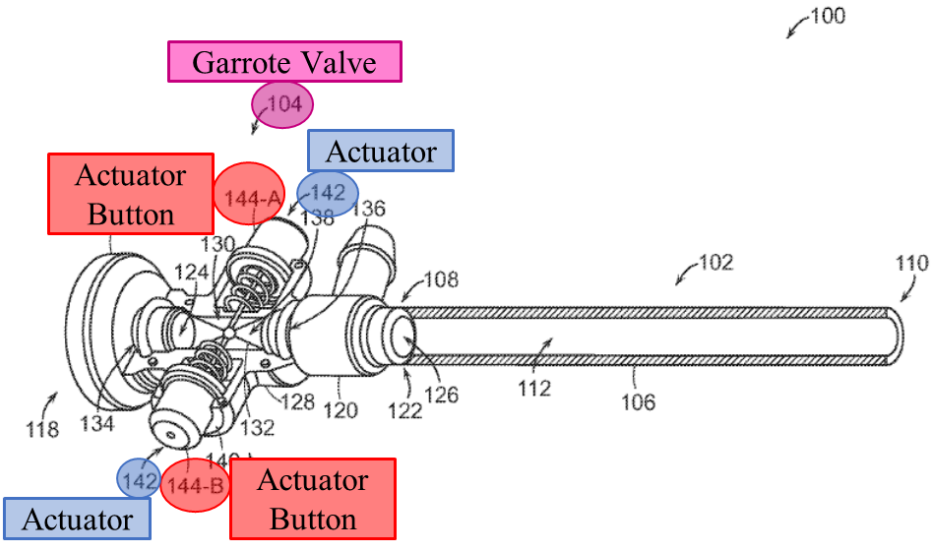


FIG. 1

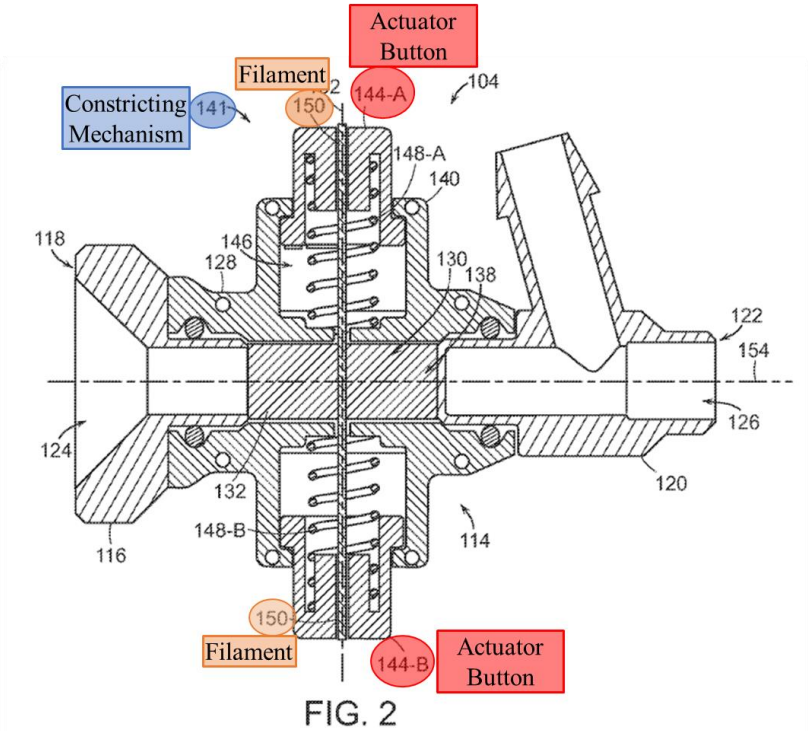


FIG. 2

Id. at 8:8-10, Figs. 1-2. The filament is "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 9:24-28.

40. The '012 patent 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 8:38-56. Figure 4 shows the valve biased toward the first, closed position:

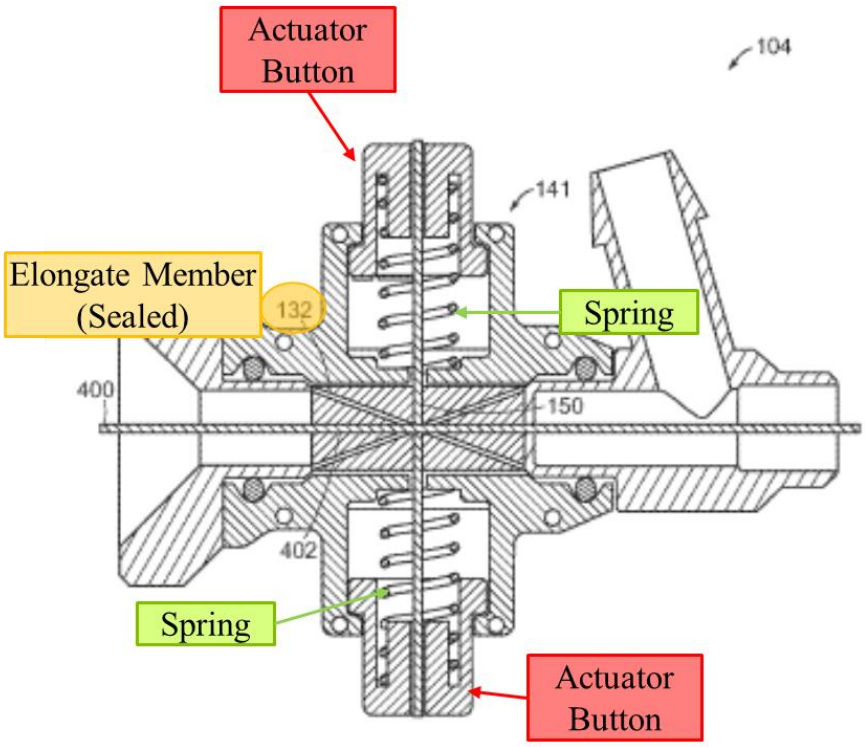


FIG. 4

Id. at 8:38-56, Fig. 4. The '012 patent 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 9:54-62. Figure 3 below depicts the valve in the second, opened position when the actuator buttons are depressed:

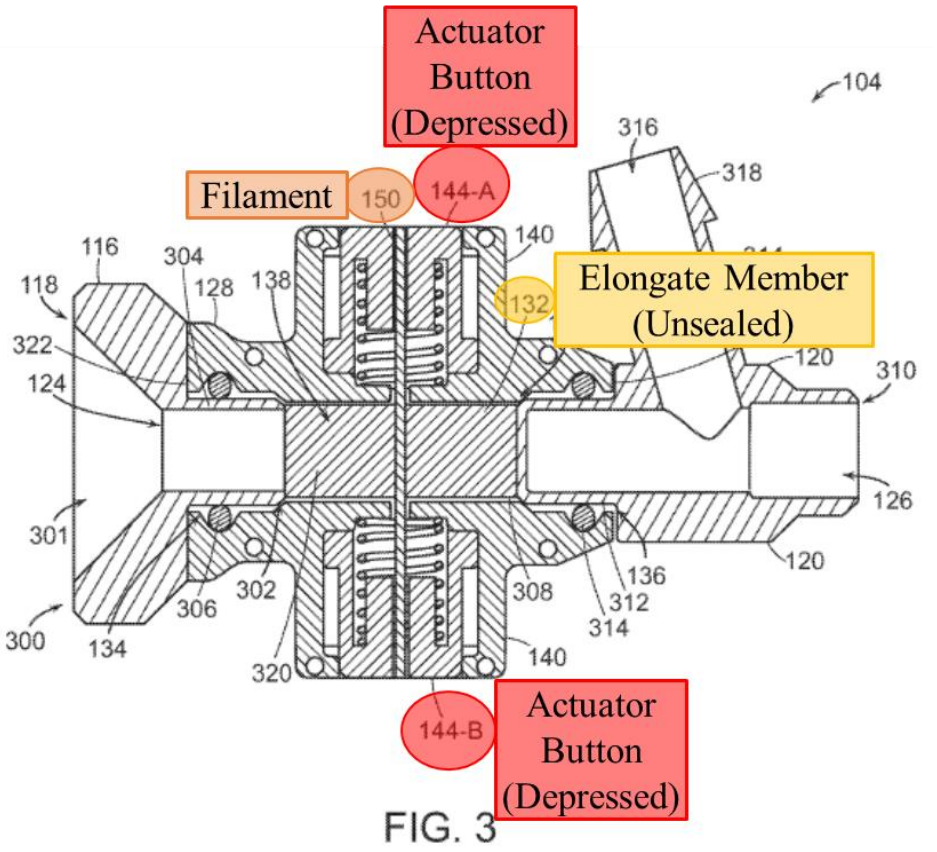


FIG. 3

Id. at 5:32-32, Fig. 3.

41. The '012 patent explains that its constricting mechanism, including the filament, can constrict the elongate member around a tool that is inserted through the central lumen of the elongate member to "seal the valve 104 around

the tool." *Id.* at 11:64-12:15. Figure 4 below depicts the valve in the first, closed position, with a tool 400 inserted through the central lumen of the elongate member:

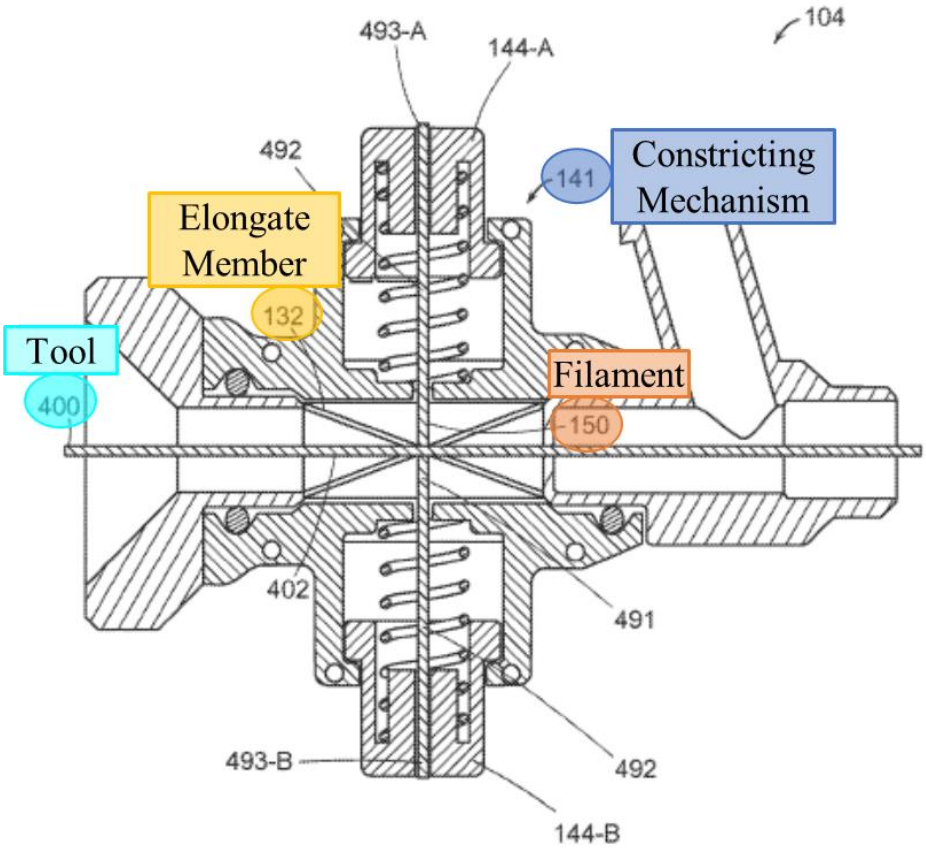


FIG. 4

Id. at 5:33-35, Fig. 4.

42. The '012 patent discloses that the "filament 150 can be arranged in a variety of configurations" including a single loop 604 that can extend around the elongate member 132 as shown in Figure 6, multiple loops that can extend around

the elongate member as shown in Figure 7, or a "U-shaped section between the two ends of the filament 150" (i.e., a bight) that can extend around the elongate member as shown in Figures 8 and 9:

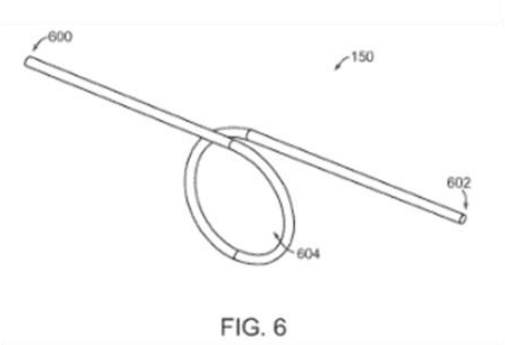


FIG. 6

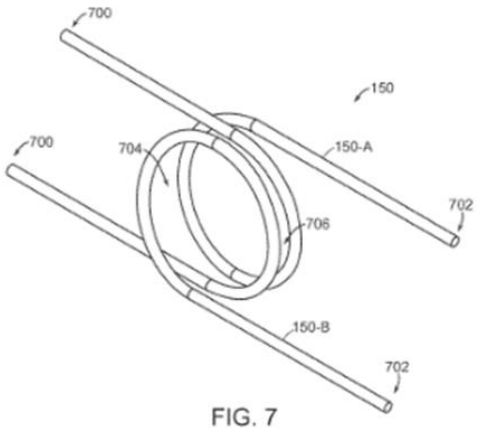


FIG. 7

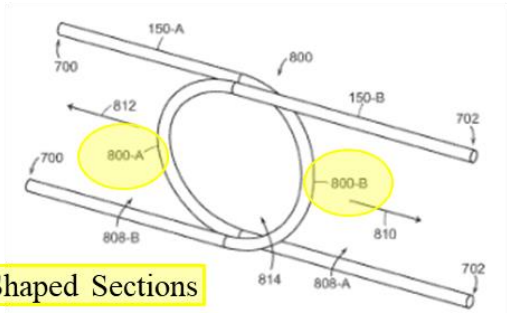


FIG. 8

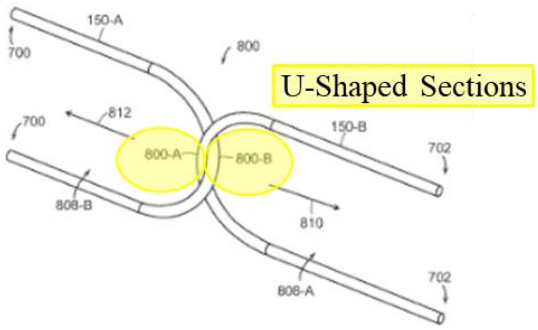


FIG. 9

Id. at 13:17-14:34, Figs. 6-9. The '012 patent also discloses that the filament can be formed from a range of materials "including, for example, a polymer, a synthetic, and/or a metal." *Id.* at 9:13-15. The filament can also "comprise a single strand such as, for example, a monofilament" or it "can comprise a plurality of strands that can be, for example, twisted, woven, grouped, and/or fused to form the filament." *Id.* at 9:16-20. Accordingly, "the filament 150 can comprise one or several threads, lines, cords, rope, ribbon, flat wire, sheet, or tape." *Id.* at 9:21-23.

Additionally, "in some embodiments, each of the first end 700 and the second end 702 of one or more of the multiple filaments 150 can be coupled to different buttons 144":

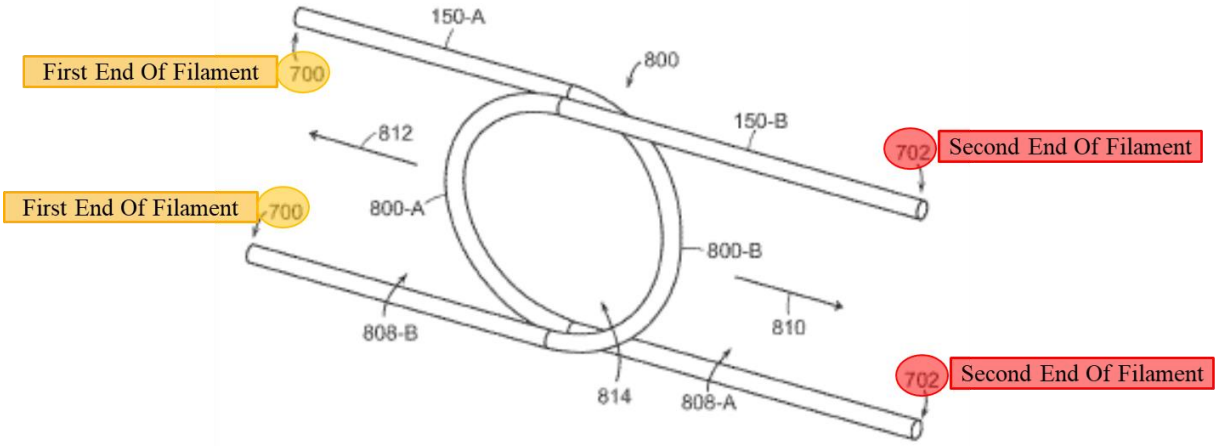


FIG. 8

Id. at 13:8-11, Fig. 8.

B. The Challenged Claims

43. The challenged claims include Claims 1-9 of the '012 patent. Claim 1 is the only independent claim.

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

> 1. An aspiration catheter, comprising:
> an elongate, flexible tubular body, having a proximal end, a distal end and a central lumen;
> a hemostasis valve on the proximal end of the catheter, the hemostasis valve comprising
> (a) a collapsible tubular sidewall defining a valve lumen in communication with the central lumen; and

(b) a constricting mechanism having at least a first actuator, a first filament formed into a loop around the collapsible tubular sidewall, the filament having at least a first end portion extending away from the loop and connected to the first actuator, and 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.

Ex. 1001 ('012 patent) at Claim 1.

C. Prosecution History

45. I have reviewed the '012 patent's prosecution history. I see that the Patent Examiner issued a single non-final office action that did not include any prior-art based rejections. Ex. 1002 ('012 patent prosecution history excerpt) at 81-87. 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.

46. I see that in a notice of allowance issued on November 23, 2022, the Examiner stated the following regarding the Hartley prior art reference that I discuss herein:

Hartley discloses a catheter is capable for aspiration therefore, it can be called as an aspiration catheter, comprising: an elongate, flexible tubular body 4, having a proximal end (adjacent to element 7), a distal end (opposite end of the proximal end, the distal end being inserted into a patient) and a central lumen (catheter lumen); a hemostasis valve 8 on the proximal end of the catheter, the hemostasis valve 8 comprising - (a) a collapsible tubular sidewall 22 defining a valve lumen 3 in communication with the central lumen; and (b) a

> constricting mechanism 12 & 20 having at least a first actuator 12, a first filament 14 formed into a loop around the collapsible tubular sidewall 8, see Figs. 3-4, the filament 14 having at least a first end portion 16 extending away from the loop and connected to the first actuator 12.
>
> Harley fails to disclose that and [sic] a first spring configured to move the first actuator in a direction that pulls the first end portion such that the diameter of the valve lumen decreases in response to reducing a diameter of the loop.

Id. at 85. In other words, the Examiner found that Hartley disclosed every limitation in Claim 1 of the '012 patent except for "a first spring configured to move the first actuator in a direction that pulls the first end portion such that the diameter of the valve lumen decreases in response to reducing a diameter of the loop." *Id.*

47. I see that the Examiner also concluded that two additional references, Wong (attached as Exhibit 1010) and Myers (attached as Exhibit 1012), described "a missing limitation of Hartley (i.e. a spring), however, the spring in Wong or Myers is inapplicable to add into the device of Hartley." *Id.* at 85-86. The examiner did not provide further information regarding this conclusion.

IV. CLAIM CONSTRUCTION

A. Filament

48. Claim 1 requires "a first ***filament*** formed into a loop around the collapsible tubular sidewall." I have reviewed the claims, specification, and prosecution history of the '012 patent, and in my opinion, a person of ordinary

skill in the art in September 2017 would have understood the term "filament" in the claims of the '012 patent to mean at least: "one or more threads, lines, cords, ropes, ribbons, flat wires, sheets, or tapes."

49. 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 '012 patent says that the constricting mechanism includes "at least a first actuator [and] a first filament formed into a loop around the collapsible tubular sidewall." Ex. 1001 ('012 patent) at Claim 1. Claim 1 goes on to say that the "filament" has at least "a first end portion extending away from the loop and connected to the first actuator." *Id.* Claim 2 says that the "filament" further comprises a second end portion extending away from the loop in a different direction than the first end portion and connected to the second actuator." While this language identifies some features that the filament must have (e.g., a first end portion, second end portion), the claim language does not identify the structures or materials that form a "filament."

50. The specification of the '012 patent does identify structures and materials that may form the "filament." The specification discloses that the filament can be formed from a range of materials "including, for example, a polymer, a synthetic, and/or a metal." *Id.* at 9:13-15. The specification 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.* at 9:16-21. The '012 patent also states that "***the filament 150 can comprise one or several threads, lines, cords, rope, ribbon, flat wire, sheet, or tape***." *Id.* 9:21-23 (emphasis added). I have used this specific description of "filament" for my construction.

51. The specification of '012 patent 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 12:61-64. 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):

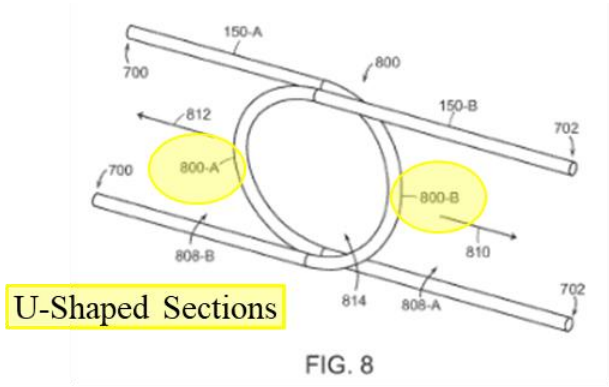


FIG. 8

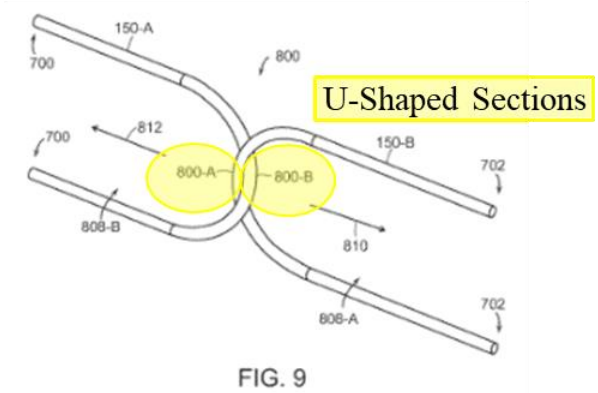


FIG. 9

Id. at 13:17-14:34, Figs. 7-9. Focusing specifically on the embodiments having the "U-shaped section," the specification explains that the filaments can have "any

desired cross-sectional shape." *Id.* at 14:29-34. The specification also identifies some exemplary dimensions for the filaments but does not specify any mandatory diameter or thickness for the filament. *Id.* at 14:11-19. The specification also does not require the filament to have a specific amount of flexibility or hardness (or provide any guidance regarding those properties).

52. 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 '012 patent, the Examiner concluded that the prior art reference Wong, U.S. Patent Publication No. 2011/0144592 (Ex. 1010), "fails to disclose a constricting mechanism having a first filament formed into a loop around the collapsible tubular sidewall." Ex. 1002 ('012 patent prosecution history excerpt) at 86. The Examiner's dismissal of Wong is consistent with my understanding of "filament" from the '012 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":

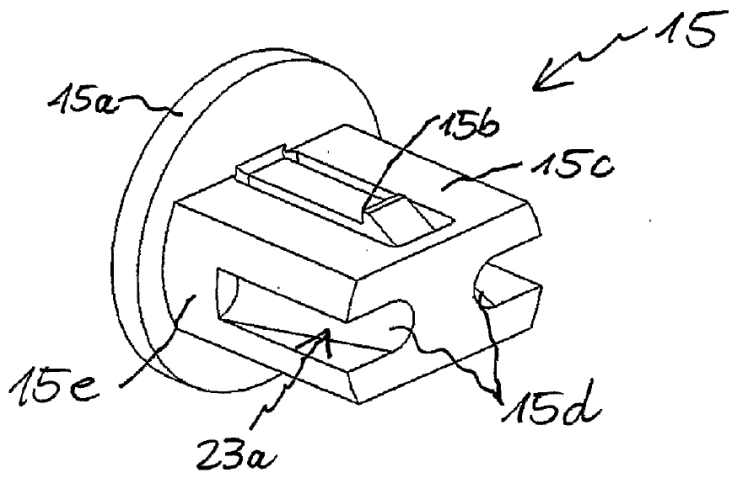


Fig. 3

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":

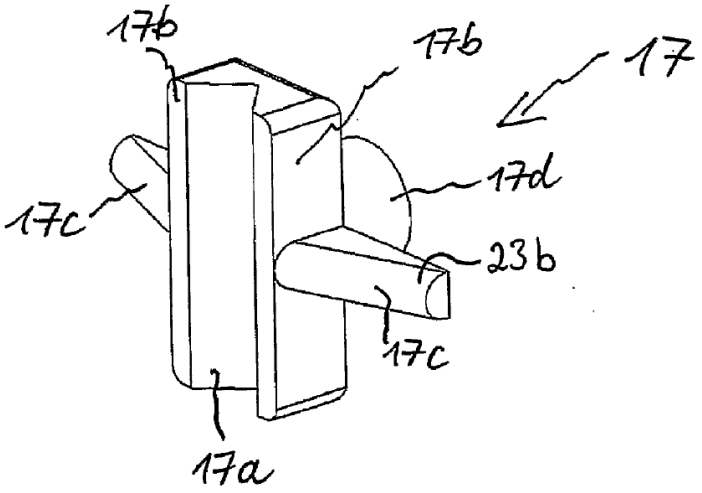


Fig. 4

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 for the "filament" claimed in the '012 patent. Ex. 1001 ('012 patent) at 9:13-23.

53. I also see that the Examiner found that Hartley discloses "a constricting mechanism 12 & 20 having at least a first actuator 12, ***a first filament 14*** formed into a loop around the collapsible tubular sidewall 8, see Figs. 3-4, the filament 14 having at least a first end portion 16 extending away from the loop and connected to the first actuator." Ex. 1002 ('012 Patent Pros. History) at 85 (emphasis added). 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 for the "filament" claimed in the '012 patent. Ex. 1001 ('012 patent) at 9:13-23.

54. 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 '012 patent and it does not describe the filaments as "thin" or "flexible." Moreover, as I explained above, the specification does not provide any measurements for flexibility that would

help a person of ordinary skill in the art determine whether a specific material was, in fact, "flexible." While the '012 patent identifies some potential dimensions for the "filament(s)," the patent 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 '012 patent. The '012 patent explains that the filaments can be made of metal or polymers and form, for example, a sheet or tape. A sheet of metal, 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 '012 patent 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 '012 patent 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 '012 patent. 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 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 September 2017 would have understood the term "filament" recited in the claims of the '012 patent to mean at least: "one or more threads, lines, cords, ropes, ribbons, flat wires, sheets, or tapes."

B. <u>The "Aspiration Catheter" in the Preamble</u>

55. I understand from counsel that the Board may find that the term "aspiration" in the preamble of the claims is not limiting. I understand that if the Board finds the term "aspiration" not limiting, then the claims would not require an "aspiration catheter." I have reviewed the claims and specification of the '012 patent and I do not see any reference to aspiration outside of the preamble. I also do not see any description of special catheter or valve features required specifically for aspiration. However, I do not have an opinion regarding whether the preamble is legally limiting. I believe the claims are invalid regardless of whether the preamble is limiting, and I have identified prior art below to support my opinions.

V. SUMMARY OF IPR GROUNDS

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

Ground	Claims Challenged	Basis	References
1	1-9	35 U.S.C. § 102	Schaffer
2	1-9	35 U.S.C. § 103	Schaffer
3	1-9	35 U.S.C. § 103	Schaffer + Hartley
4	1-9	35 U.S.C. § 103	Schaffer + Eller
5	1-9	35 U.S.C. § 103	Schaffer + Garrison
6	1-9	35 U.S.C. § 103	Schaffer + Hartley + Garrison
7	1-9	35 U.S.C. § 103	Schaffer + Eller + Garrison

VI. GROUNDS 1-4: CLAIMS 1-9 ANTICIPATED BY SCHAFFER OR OBVIOUS OVER SCHAFFER ALONE OR IN COMBINATION WITH HARTLEY OR ELLER

57. 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:

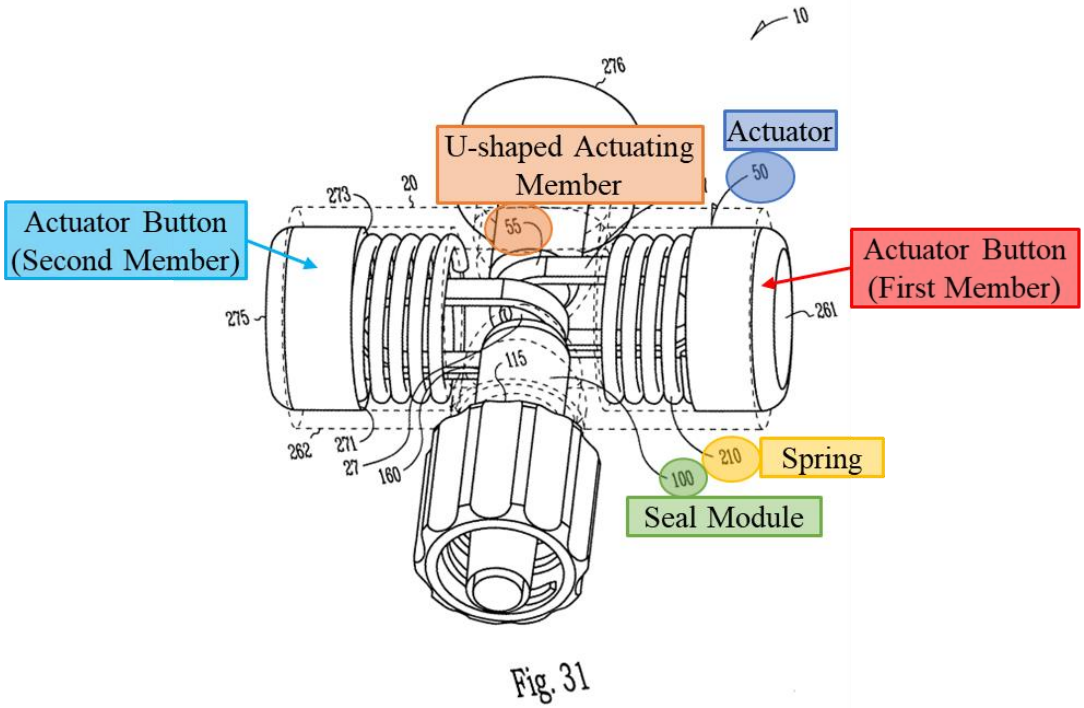


Fig. 31

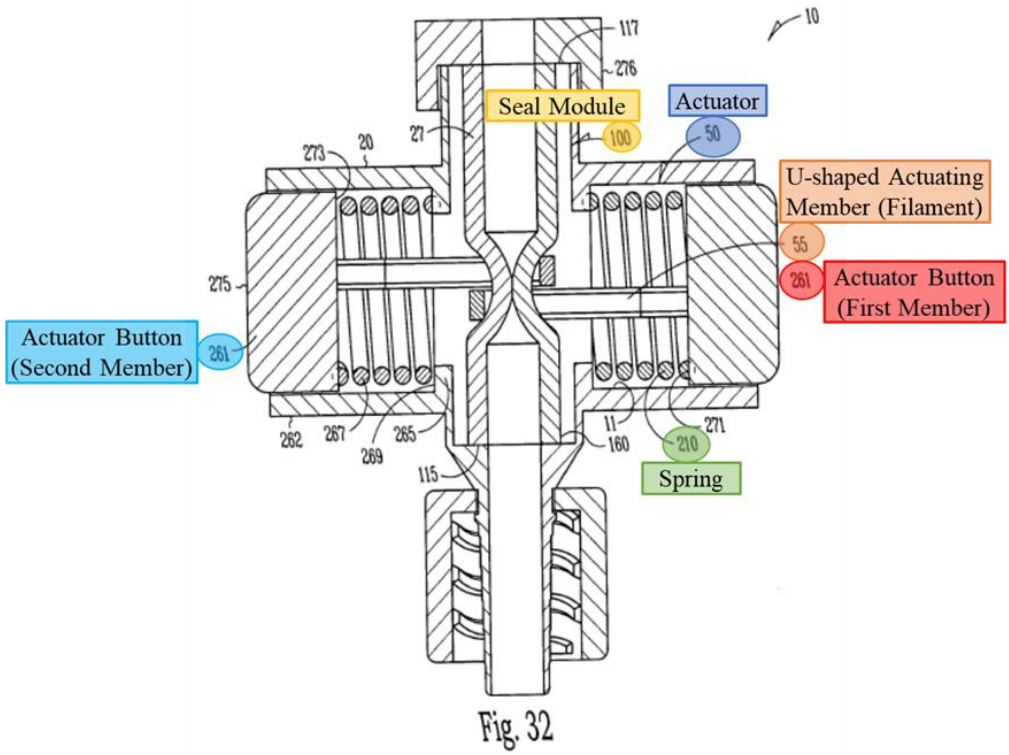


Fig. 32

Id. at [0076]-[0077], Figs. 31-32.[1] Notably, the '012 patent 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. 1001 ('012 patent) at 13:30-33. The example of Schaffer's hemostasis valve depicted in Figures 31-34 has the same components in the same arrangement as the valve described and claimed in the '012 patent, which is apparent from the side-by-side comparison of Figure 2 of the '012 patent (left) and Figure 32 of Schaffer (right):

'012 Patent

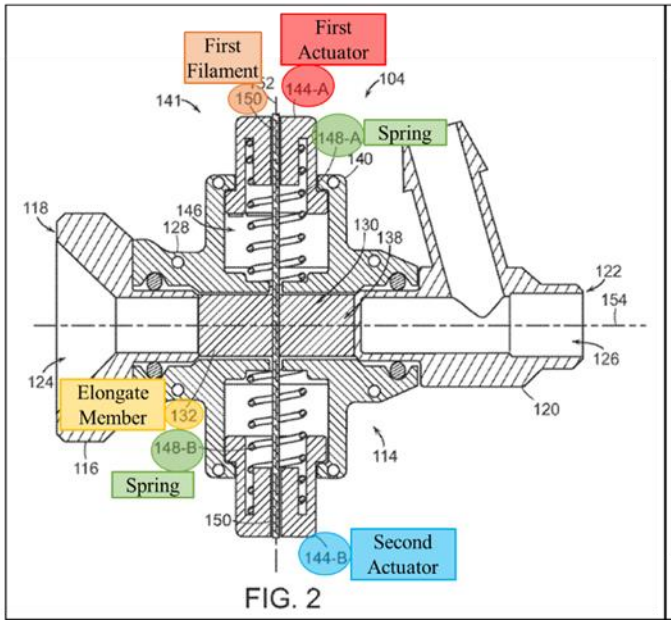


FIG. 2

Schaffer

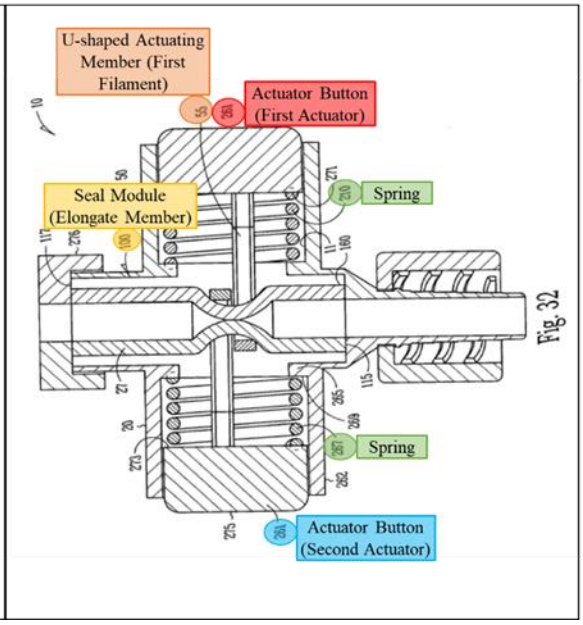


Fig. 32

[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.

Ex. 1001 (’012 patent) at Fig. 2 (left); Ex. 1005 (Schaffer) at Fig. 32 (right). Because Schaffer discloses all of the components claimed in the ’012 patent, it is my opinion that Schaffer anticipates Claims 1-9 of the ’012 patent. It is also my opinion that if the Board finds that Schaffer does not anticipate any of Claims 1-9, Claims 1-9 would have been obvious to a person of ordinary skill in September 2017 in view of Schaffer’s disclosures.

58. 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 and claimed in the ’012 patent, because the described actuating members are at least “ribbons, flat wires, sheets, or tapes.” *See supra* ¶¶48-54 (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 September 2017.

59. 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:

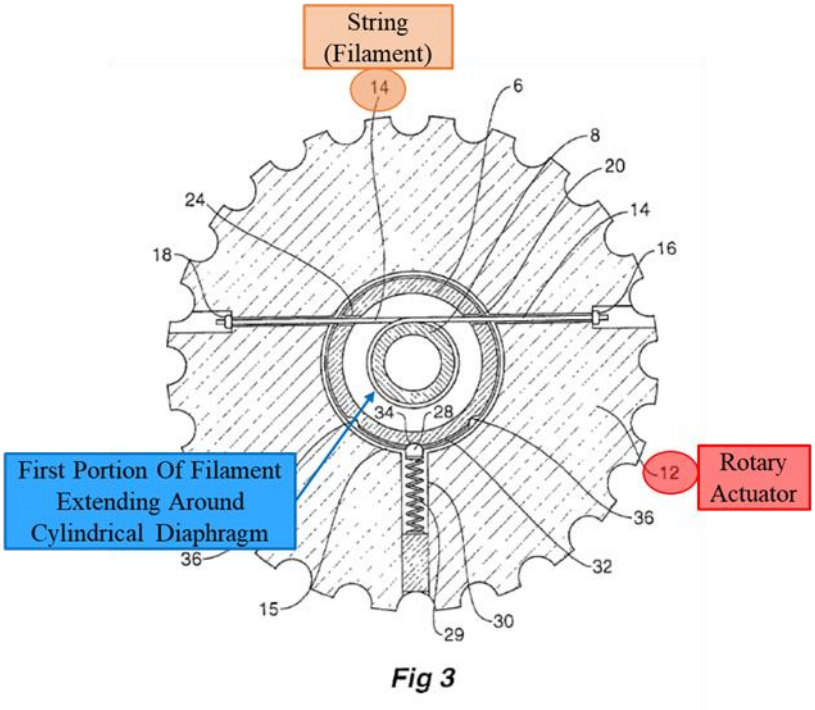


Fig 3

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:

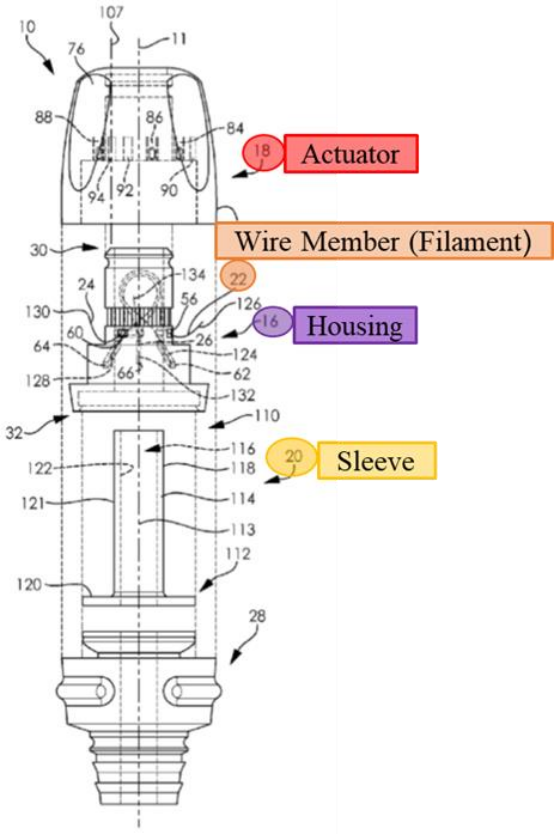


FIG. 2

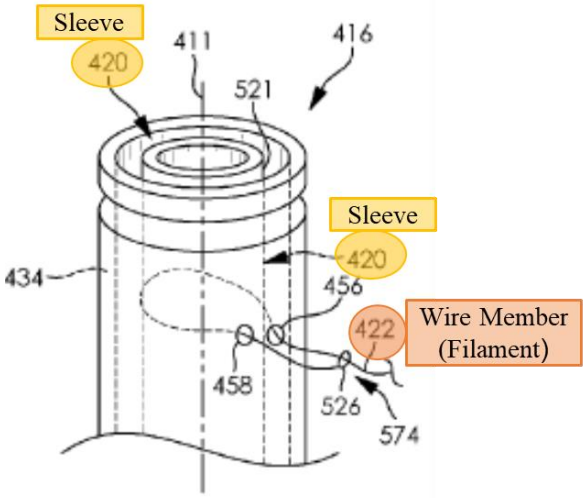


FIG. 16

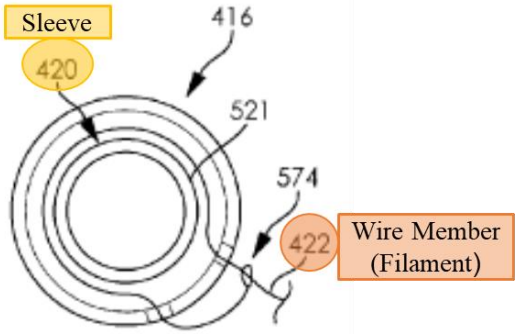


FIG. 17

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.

60. 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 Schaffer with Hartley ***or*** Eller also renders Claims 1-9 obvious.

A. Claim 1

61. Based on my review of the prior art, it is my opinion that Schaffer anticipates Claim 1 or renders Claim 1 obvious alone or in combination with Hartley ***or*** Eller.

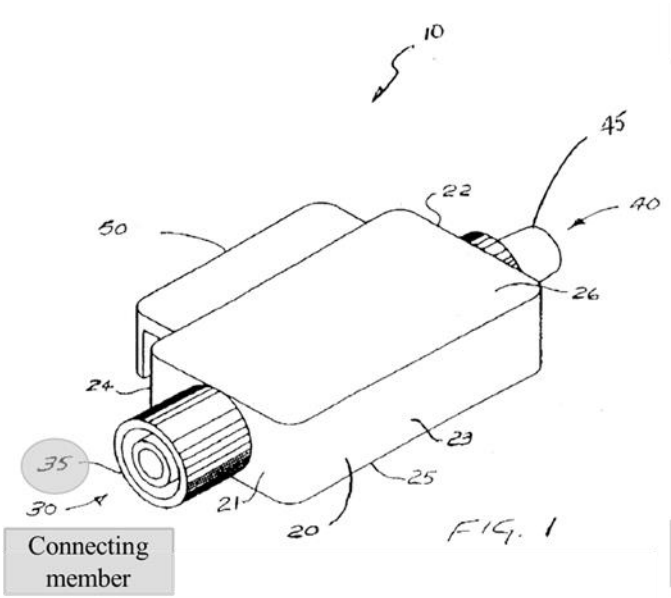
1. Preamble

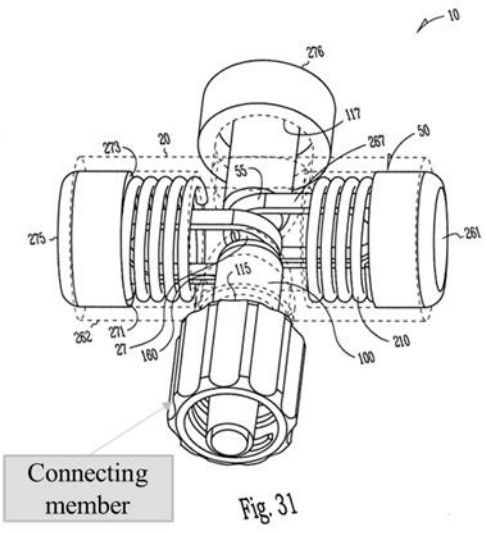
62. The preamble of Claim 1 recites: "An aspiration catheter." If the term "aspiration" in the preamble is not limiting, I understand that Schaffer does

not need to disclose an "aspiration catheter." In that circumstance, Schaffer discloses or renders obvious a "catheter" having the described hemostasis valve.

63. Schaffer says that the application "relates to catheters, in particular to a composite fluid-stasis valve for use with catheters." Ex. 1005 (Schaffer) at [0002]. Schaffer also explains, "Fluid stasis mechanisms are commonly used to prevent loss of fluids from the insertion site of a catheter or interventional system." *Id.* at [0003]. In my experience, this statement was correct in September 2017. A person of ordinary skill in the art in September 2017 would have understood that Schaffer's hemostasis valve would be attached to the end of a catheter because the valve is "for use with catheters" and, as discussed below, includes connectors commonly used to attach hemostasis valves to catheters.

64. Schaffer's valve includes a "connecting member 35" that enables the attachment of a catheter. *Id.* at [0047].





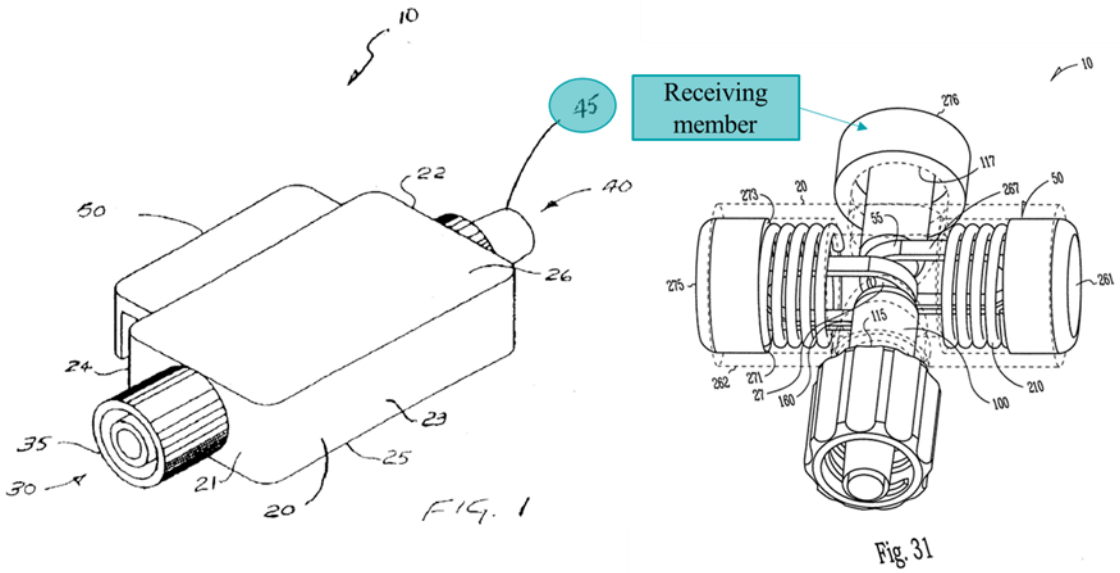
Id. at Figs. 1 and 31. Schaffer explains that the connecting member 35 is "sized and configured to attach in fluid communication to a fluid delivery supply or a body passage such as a blood vessel." *Id*. at [0047]. Again, a person of ordinary skill in the art in September 2017 would have understood that the connecting member 35 attaches to a body passage through a catheter attached to the valve. Several references I rely upon in this Declaration show that hemostasis valves were commonly added to the end of a catheter. *See e.g.*, Ex. 1006 (Hartley) at [0031], Fig. 1 (describing valve "mounted onto catheter body"); Ex. 1007 (Eller) at 16:65-17:4, Fig. 7 (describing valve connector for "releasably attaching another component (e.g., medical device, tubular member) to the connector").

65. Schaffer explains that "the connecting member 35 is a common male thread 'Luer' type fitting or a common 'slit-fit' [sic] tube connector or the like." Ex. 1005 (Schaffer) at [0047]. I believe that the term "slit-fit" in Schaffer is a mistake and that the patentee meant to say a "slip fit" tube connector. A "slip fit" connector was a common type of connector for tubes prior to September 2017. A person of ordinary skill in the art would have known that Luer type fittings and slip fittings were commonly used to attach hemostasis valves to catheters in September 2017. I have identified several prior art references that teach connecting a catheter to a hemostasis valve using a Luer or slip fit connector. *See e.g.*, Ex. 1007 (Eller) at 16:65-17:4, Fig. 7 (describing type of slip fit connection);

Ex. 1014 (U.S. Patent No. 4,723,550) at 4:5-10 ("hemostasis valve 10 is shown to be attached to the end of a catheter 12 by means of a luer lock connector 14 of conventional design"); Ex. 1015 (U.S. Patent No. 5,895,376) at ("a standard luer lock 17 is shown at distal end 16 for connection to guide catheter 18") at 3:16-17. Schaffer's description of the connecting member would have further confirmed for a person of ordinary skill in the art that Schaffer describes attaching the hemostasis valve to a catheter using the connecting member.

66. Even if Schaffer does not disclose this limitation, a person of ordinary skill in the art would have found it obvious to attach a catheter to Schaffer's hemostasis valve because Schaffer expressly explains that the valve is for use with catheters. Moreover, as demonstrated in the paragraphs above, hemostasis valves were routinely attached to catheters in September 2017.

67. If this preamble is limiting, Schaffer discloses or renders obvious an "aspiration catheter" having the described hemostasis valve. Schaffer explains that the valve also includes a "receiving member 45." Ex. 1005 (Schaffer) at [0047].



Id. at Figs. 1, 31. Schaffer says, "The receiving member 45 is, in one option, configured to connect to a fluid or gas delivery system or device such as a syringe, intravenous system or the like." *Id.* at [0049]. As demonstrated by, for example, the Garrison reference discussed in this Declaration, syringes were commonly used to generate suction for aspiration catheters by September 2017. *See*, *e.g.*, Ex. 1011 (Garrison) at [0060], [0111], [0123], [0125]. Consequently, a person of ordinary skill in the art would have understood that a syringe may act as the aspiration source for an aspiration catheter.

68. Further, I agree with the Examiner of the '012 patent who determined that any catheter can be attached to a source of negative pressure and, therefore, can be called an aspiration catheter. Schaffer's valve is configured for use with an aspiration catheter because it is configured to attach to a catheter at one end and a negative pressure source, such as a syringe, at the other.

69. Moreover, Garrison demonstrates that aspiration catheters were a common type of catheter used with hemostasis valves in September 2017. Ex. 1011 (Garrison) at [0054], [0059], Fig. 1. Garrison expressly discloses the purpose and benefits of a hemostasis valve. *Id.* at [0098] ("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"). Therefore, a person of ordinary skill in the art would have been motivated to use Schaffer's system, which includes the catheter, valve, and syringe, as an aspiration catheter.

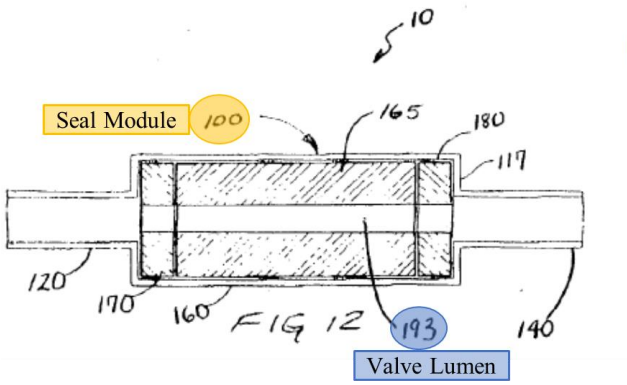
70. Further, Schaffer's hemostasis valve is a part of a system that is inserted into the patient's vasculature, and the hemostasis valve helps prevent blood and air leaks in the device by "block[ing] the flow of gas or fluid completely and immediately with or without an instrument in place within the gas/fluid path." Ex. 1005 (Schaffer) at [0002], [0008]; *see also* Ex. 1009 (Schaffer '616) at Abstract, 1:1-9 (disclosing catheter systems for insertion into a blood vessel). Schaffer also discloses that its hemostasis valve can prevent leaks even when "a range of instruments," such as "a catheter, guidewire, needle, or fiber," are inserted through the valve. Ex. 1005 at [0056]. Thus, a person of ordinary skill in the art would have reasonably expected that Schaffer's hemostasis valve could be used to prevent leaks around an aspiration catheter

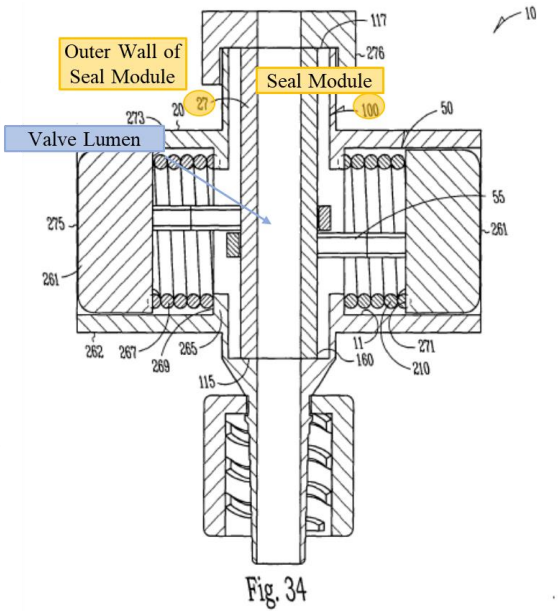
inserted through the valve. A person of ordinary skill in the art would have also reasonably expected success based on the many references, like Garrison, disclosing the effectiveness of aspiration catheters. Ex. 1011 (Garrison) at [0060].

2. <u>Tubular Body</u>

71. Claim 1 next recites: "an elongate, flexible tubular body, having a proximal end, a distal end and a central lumen." Schaffer discloses this limitation.

72. 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]. Figure 34 below depict examples of the seal module 100:





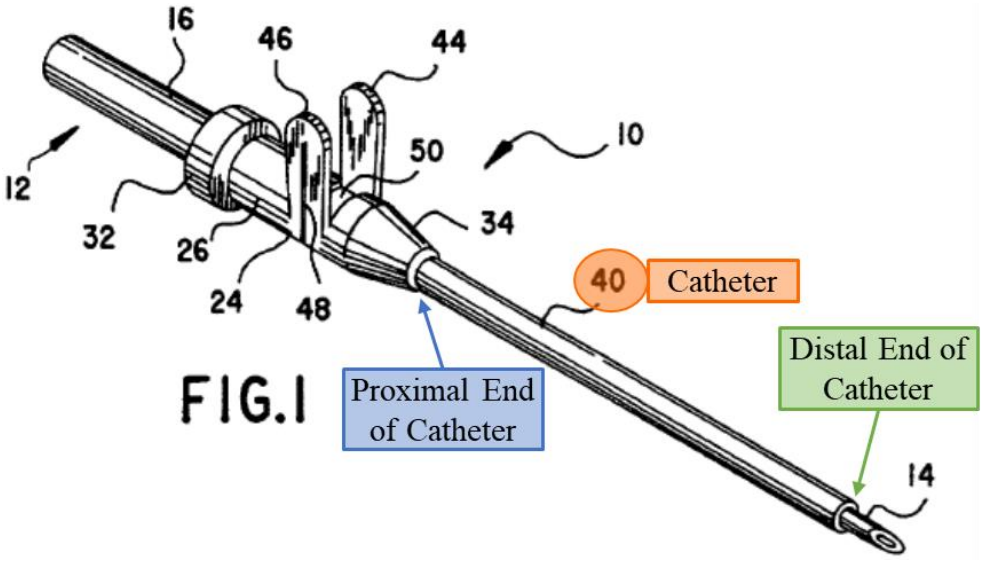
Id. at [0022, 0075], Figs. 12,[2] 34.

73. 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]. A "catheter" inserted into Schaffer's seal module 100 satisfies this limitation. A person of ordinary skill in the art would have known that a catheter has an "elongate, flexible tubular body, having a proximal end, a distal end and a central lumen." Indeed, a person of ordinary skill in the art would have known that all catheters used for intravascular procedures have an "elongate, flexible tubular body, having a proximal end, a distal end and a central lumen." As evidence of this general understanding, Dorland's Medical Dictionary defines "catheter" to mean "a tubular, flexible, surgical instrument that is inserted into a cavity of the body to withdraw or introduce fluid." Ex. 1013 (Dorland) at 306.

74. Similarly, Schaffer incorporates the material of another patent, U.S. Patent No. 5,429,616 ("Schaffer '616"). Ex. 1005 (Schaffer) at [0002]. Schaffer

[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.

'616 discloses "catheters for venous or arterial cannulation …." Ex. 1009 (Schaffer '616) 1:6-9. The catheters illustrated and described in Schaffer '616 include features common to all catheters, including a central lumen, which in the case of Schaffer '616 is for "permitting receipt of needle 14."



Id. at 4:52-56, Fig. 1. As shown in Figure 1 from Schaffer '616 above, the catheter includes an elongate, tubular body, a proximal end, and a distal end. *Id.* Schaffer '616 also discloses that the catheter is "advanced into the lumen of the vessel" during use. *Id.* at 5:5-12. Almost all blood vessels have some tortuosity, requiring any catheter inserted into those vessels to have some flexibility. A person of ordinary skill in the art would have understood that the catheter described in Schaffer '616 (as well as Schaffer) would have a flexible body to enable the catheter to conform to the vessel and avoid damaging the patient's tissue during insertion. Thus, Schaffer '616 further confirms the general

understanding in the art that the "catheters" in Schaffer would have an elongate, flexible tubular body, having a proximal end, a distal end and a central lumen.

75. Accordingly, Schaffer's disclosure of a catheter inserted through the hemostasis valve discloses an "elongate, flexible tubular body, having a proximal end, a distal end and a central lumen" as recited in claim 1.

76. If Schaffer's and Schaffer '616's catheters were not flexible, a person of ordinary skill in the art would have found it obvious to use a flexible catheter. As explained above, virtually every catheter inserted into a patient's vasculature requires flexibility to navigate the tortuous vessels and avoid damaging the patient's vasculature. As an example, Garrison discloses many flexible catheters advanced into a patient's vasculature. See e.g., Ex. 1011 (Garrison) at Figs. 1-3. Given the ubiquity of flexible catheters in the field by September 2017, a person of ordinary skill in the art would have been motivated to use such catheters, and reasonably expected success in doing so.

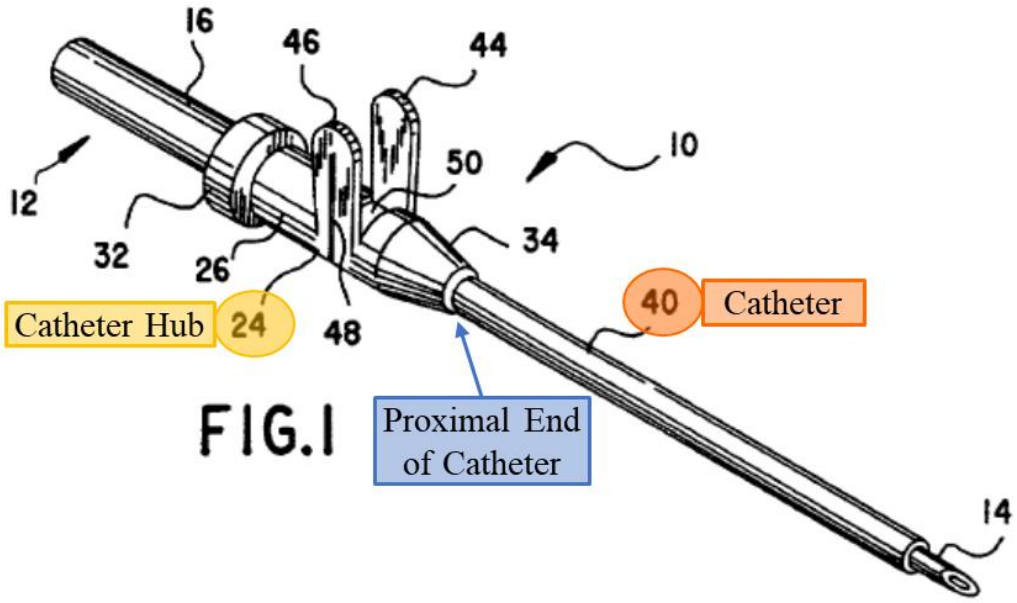
3. Hemostasis Valve

77. Claim 1 next recites "a hemostasis valve on the proximal end of the catheter." Schaffer discloses this limitation or renders the limitation obvious.

78. Schaffer discloses embodiments of a "fluid stasis valve" (e.g., hemostasis valve) that is intended for use with catheters to prevent the flow of fluid and/or blood through the valve during medical procedures. Ex. 1005

(Schaffer) at [0002], [0046], [0055]. As I explained in the preceding section, Schaffer's hemostasis valve includes a seal module 100 having a central lumen extending therethrough. Schaffer discloses that the seal module 100 is "proximally connected to the connecting member 35" and that the "connecting member 35 [is] sized and configured to attach in fluid communication to a fluid delivery supply or a body passage such as a blood vessel." *Id.* at [0047], [0049]. A person of ordinary skill in the art would have recognized that Schaffer's hemostasis valve would be attached in "fluid communication to … a body passage such as a blood vessel" via a catheter. Because the catheter is inserted into a "body passage such as a blood vessel," the hemostasis valve must be positioned at the catheter's proximal end because the rest of the catheter is inserted into the patient's vasculature. In other words, the proximal end of the catheter is the only exposed portion of the catheter. Numerous references demonstrate that hemostasis valves were traditionally attached to the proximal end of the catheter, including Hartley, Eller, and Garrison. Ex. 1006 at [0031], Fig. 1 (valve mounted to catheter's proximal end); Ex. 1007 at 16:65-17:4, Fig. 7 (same); Ex. 1011 at Figs. 1-3. Further, the purpose of the hemostasis valve is to prevent blood from leaking out of the proximal end of the catheter. Thus, the most natural place to position the valve is at the proximal end of the catheter.

79. In addition, Schaffer discloses that its "fluid-stasis valve [is intended] for use with catheters" and Schaffer expressly incorporates U.S. Patent No. 5,429,616 ("Schaffer '616") by reference. *Id.* at [0002]. Schaffer '616 discloses a catheter apparatus having a "catheter hub 24" at the proximal end of the catheter 40:



Ex. 1009 (Schaffer '616) at 4:20-56, Fig. 1. Schaffer '616 discloses that the catheter hub 24 includes a deformable portion (i.e., valve) that can be collapsed to occlude the lumen of the hub and prevent blood or fluid from leaking during intravascular procedures. *Id.* at 4:20-49, 5:5-24. As shown above, the catheter hub, including the valve, is attached to the catheter's proximal end. *See id.*, 4:34-35 ("A catheter 40 extends axially outward from distal end 34."). Thus, Schaffer '616 (and therefore Schaffer) discloses positioning a hemostasis valve on the proximal end of a catheter.

80. If the Board finds Schaffer does not disclose this limitation, Schaffer renders the limitation obvious. As shown in the paragraph above, Schaffer '616 discloses a valve positioned on the catheter's proximal end. As also explained above, the positioning of a hemostasis valve on the proximal end of a catheter was the conventional location for a hemostasis valve well before September 2017. Ex. 1011 (Garrison) at Figs. 1-2; Ex. 1014 at Fig. 1. The purpose of a hemostasis valve is to prevent blood flow out the catheter's proximal end and into the operating room, and to permit the introduction of other devices through the catheter's proximal end. Because the catheter body is in the patient, the hemostasis valve must be attached to the catheter's proximal end. Therefore, I believe this claim limitation merely combines prior art elements (hemostasis valve and catheter) according to known methods (attaching the hemostasis valve to the proximal end of the catheter) to yield predictable results.

81. A person of ordinary skill in the art would have been motivated to attach Schaffer's hemostasis valve to the proximal end of the catheter to prevent blood from flowing out of the catheter because (1) the proximal end of the catheter is the exposed portion of the catheter that the doctor can access, (2) hemostasis valves were conventionally positioned on the proximal end of the catheter, and (3) by positioning the hemostasis valve on the proximal end of the catheter, the user can introduce other devices through the valve. A person of

ordinary skill in the art would have recognized that the catheter hub 24 disclosed in Schaffer ’616 provides a similar function as Schaffer’s hemostasis valve. Accordingly, a person of ordinary skill in the art would have reasonably expected success in attaching Schaffer’s hemostasis valve to the proximal end of a catheter, as taught in Schaffer ’616.

4. <u>Collapsible Tubular Sidewall</u>

82. Claim 1 next recites “the hemostasis valve comprising (a) a collapsible tubular sidewall defining a valve lumen in communication with the central lumen.” Schaffer discloses this limitation.

83. The term “collapsible tubular sidewall” does not appear in the ’012 patent specification and, therefore, it is not identified in any figures. Instead, the specification describes valves having “an elongate member 132” or “tubular member 132” with a “central lumen 138.” Ex. 1001 (’012 patent) at 7:11-45. I see that dependent claim 2 of the ’012 patent recites that “the collapsible tubular sidewall comprises a tubular member defining a valve lumen.” *Id.* at claim 2. Therefore, I understand the term “collapsible tubular sidewall” includes at least the “tubular members” described in the specification. I also note that claim 2 of the ’012 patent recites that the “collapsible tubular sidewall … [is] configured to slidably receive the elongate, flexible tubular body” and that the “filament circumferentially constricts the valve lumen to create a seal about the elongate,

flexible tubular body." *Id.* In other words, claim 2 requires that the "elongate, flexible tubular body," including the "central lumen," is "slidably receive[d]" within the "valve lumen." Therefore, the phrase "valve lumen in communication with the central lumen" recited in claim 1 means that the central lumen of the elongate, flexible tubular body is placed coaxially within the valve lumen.

84. 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:

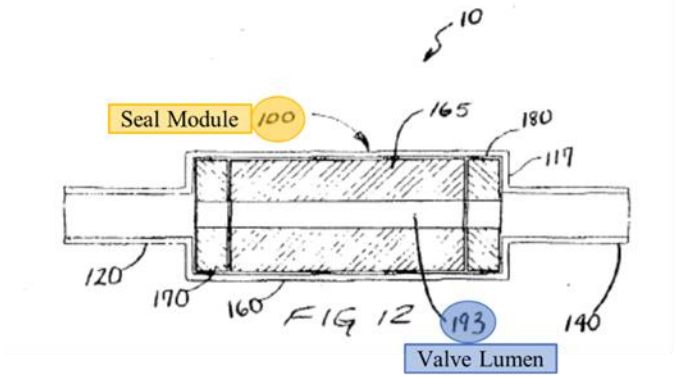


FIG 12

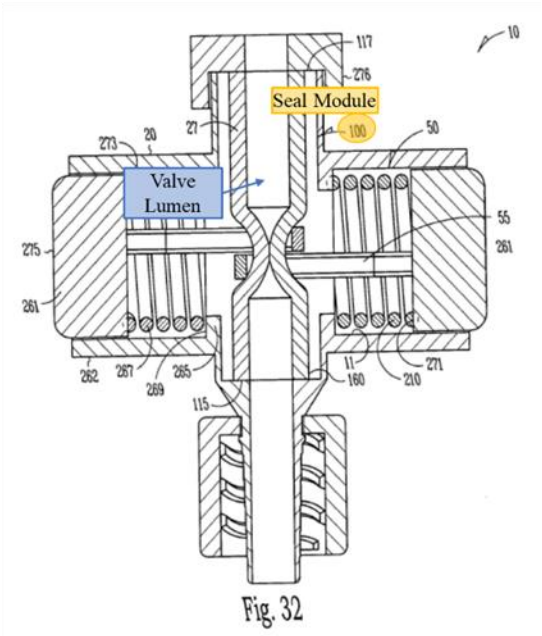


Fig. 32

Id. at [0058], Fig. 12, 32.

85. Schaffer discloses that "a range of instruments [can be] used within the seal module," such as "a catheter, guidewire, needle, or fiber." *Id.* at [0056]. Schaffer also discloses that "a guidewire and catheter may be placed into the same lumen 193 for extension into a body passage." *Id.* at [0074].) As I explained previously, the catheter placed into Schaffer's lumen 193 of the seal module would define a "central lumen" extending through the catheter. Thus, the lumen 193 of Schaffer's hemostasis valve would be "in communication with" the central lumen of the catheter extending through the valve as recited in claim 1. Schaffer's seal module 100 is therefore "a collapsible tubular sidewall defining a valve lumen in communication with the central lumen."

5. <u>Constricting Mechanism</u>

86. Claim 1 next recites: "the hemostasis valve comprising . . . (b) a constricting mechanism having at least a first actuator, a first filament formed into a loop around the collapsible tubular sidewall, the filament having at least a first end portion extending away from the loop and connected to the first actuator, and 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." Schaffer discloses these limitations or renders them obvious in combination with Hartley or Eller.

a. First Actuator

87. Schaffer discloses a "constricting mechanism having at least a first actuator." 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:

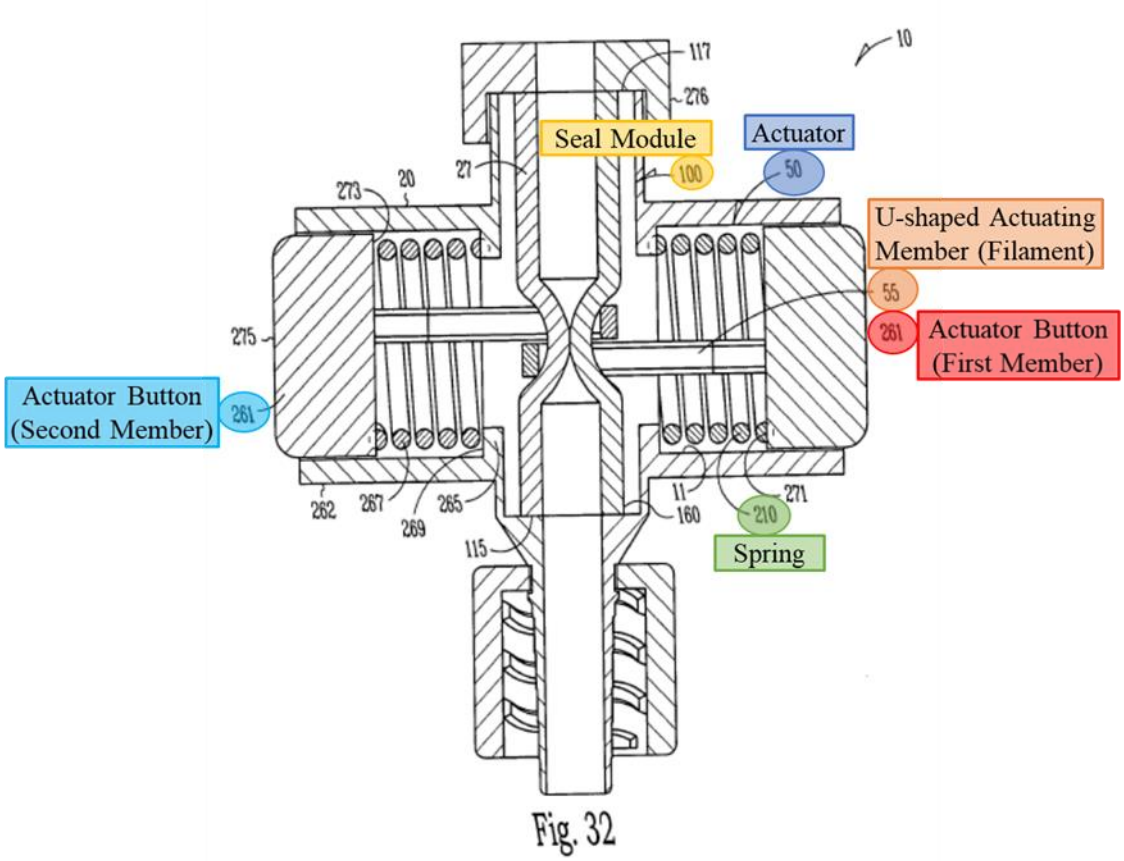


Fig. 32

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

88. 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.

89. Schaffer discloses that in a first position, the U-shaped actuating members are "at least partially circumferencially [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

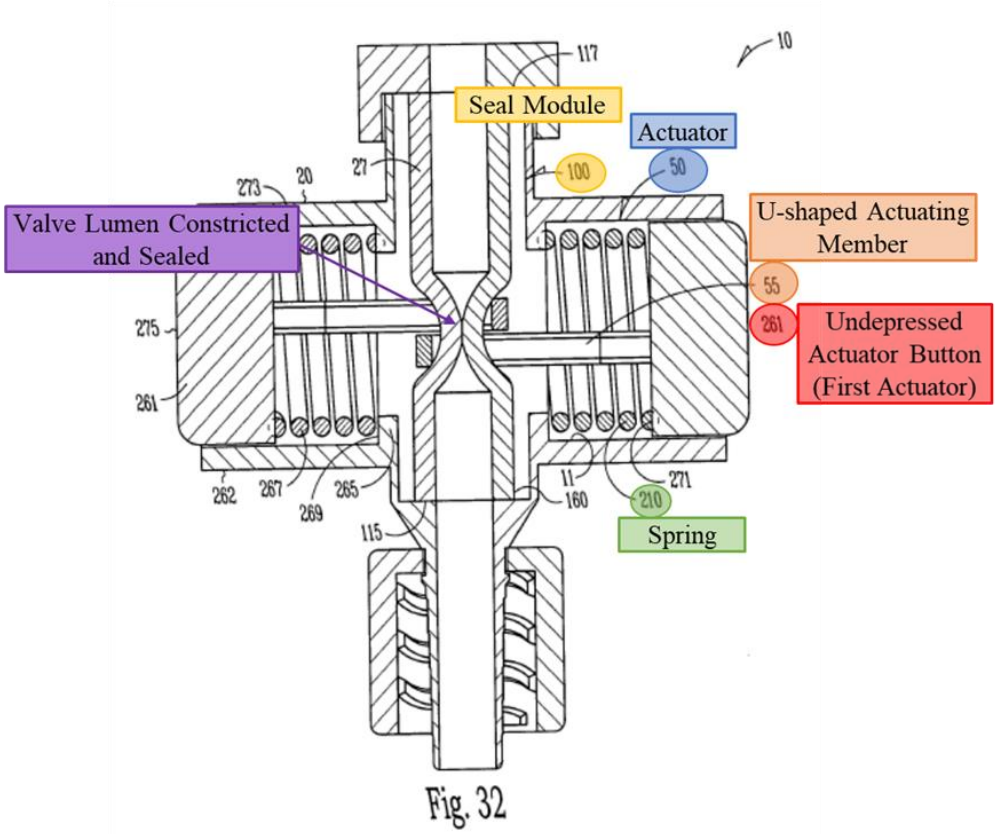


Fig. 32

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

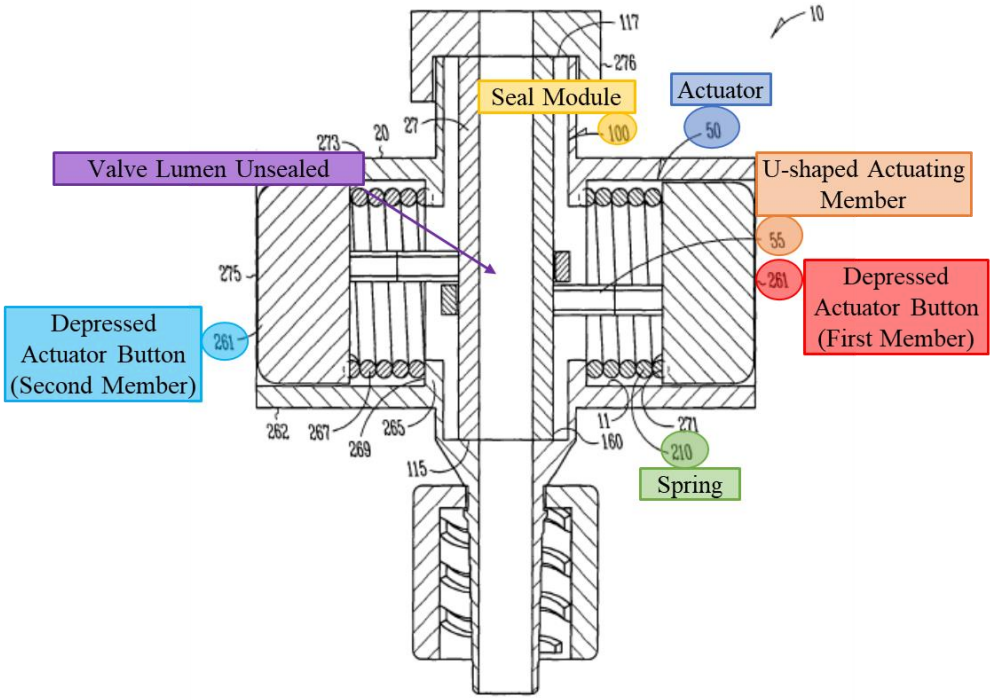


Fig. 34

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 ’012 patent’s filament disengages from the tubular member. Thus, either of Schaffer’s actuator buttons are a “first actuator” as claimed in the ’012 patent.

b. Filament

i. Schaffer

90. Schaffer discloses a “filament,” as that term is used in the ’012 patent. I addressed the meaning of “filament” in the claim construction section above. *Supra* ¶¶48-54. 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:

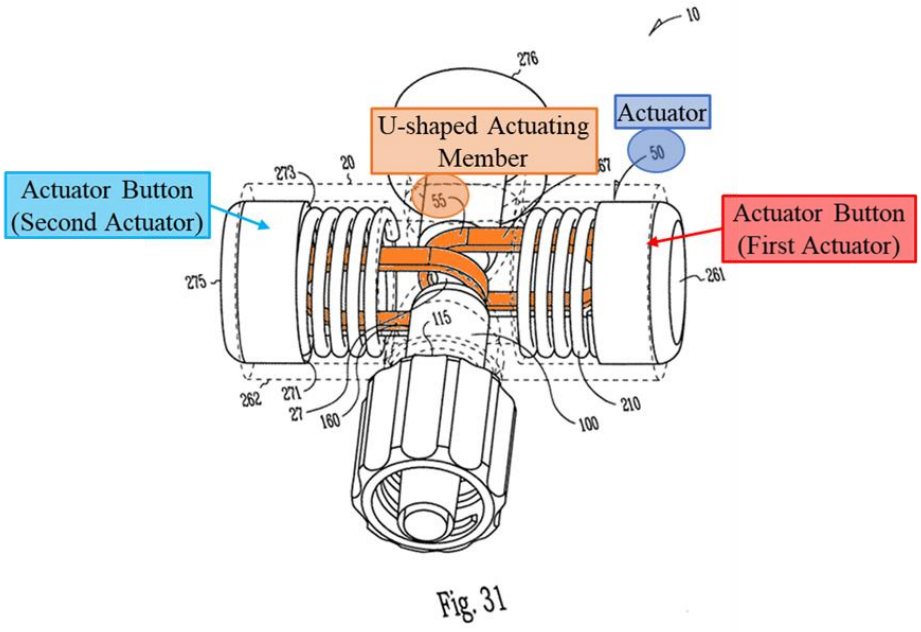


Fig. 31

Id. at [0076], Fig. 31. Schaffer’s U-shaped actuating members are a “filament” as claimed in the ’012 patent.

91. 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 '012 patent. *Supra* ¶¶48-54. 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 '012 patent (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 '012 patent:

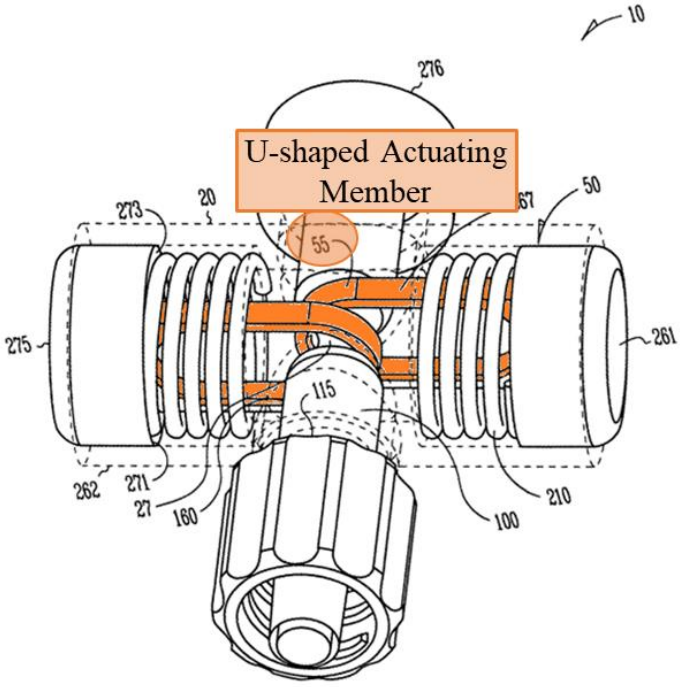


Fig. 31

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 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 2017, a person of ordinary skill in the art could have simply purchased pre-made flat wire or plastic tapes or ribbons.

92. As I explained in section III.A (Heading: "Summary of the '012 Patent") above, the '012 patent 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 '012 patent:

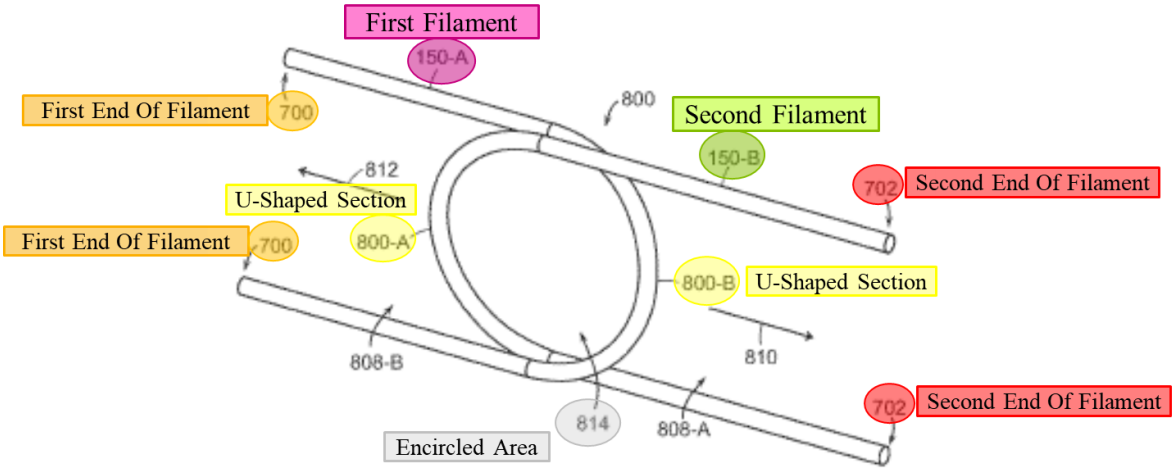


FIG. 8

Ex. 1001 (’012 patent) 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 ’012 patent:

’012 Patent

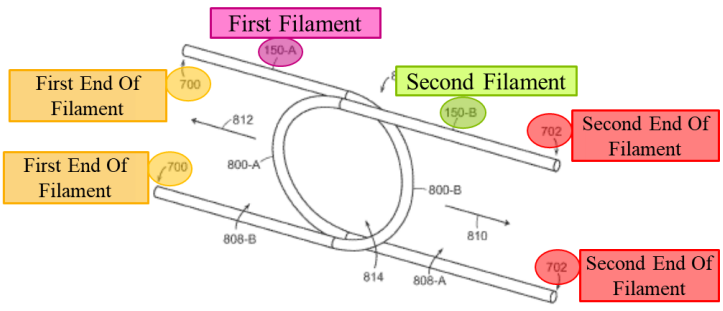


FIG. 8

Schaffer

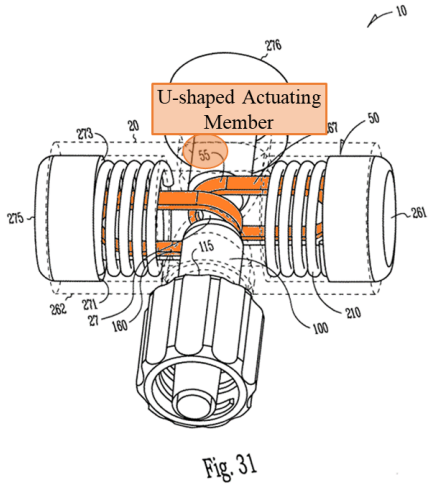


Fig. 31

Ex. 1001 (’012 patent) at Fig. 8 (left); Ex. 1005 (Schaffer) at Fig. 31 (right). The ’012 patent’s explanation that the two U-shaped filaments are “***the filament 150***”

confirms that Schaffer's U-shaped actuating members collectively constitute "at least one filament" as claimed in the '012 patent. *See* Ex. 1001 ('012 patent) at 12:44-46 ("With reference now to FIGS. 6 through 9, different embodiments and/or configurations of the filament 150 are shown."), 12:61-14:34, Figs. 8-9.

93. Schaffer also discloses that the actuating members are "at least partially circumferencially [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:

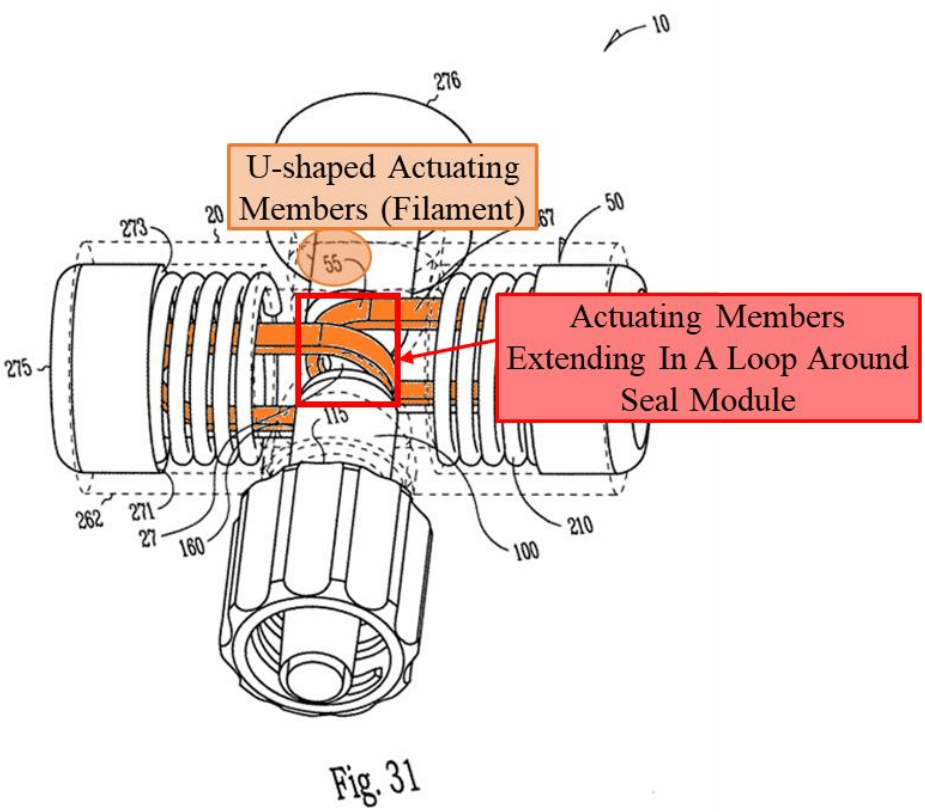
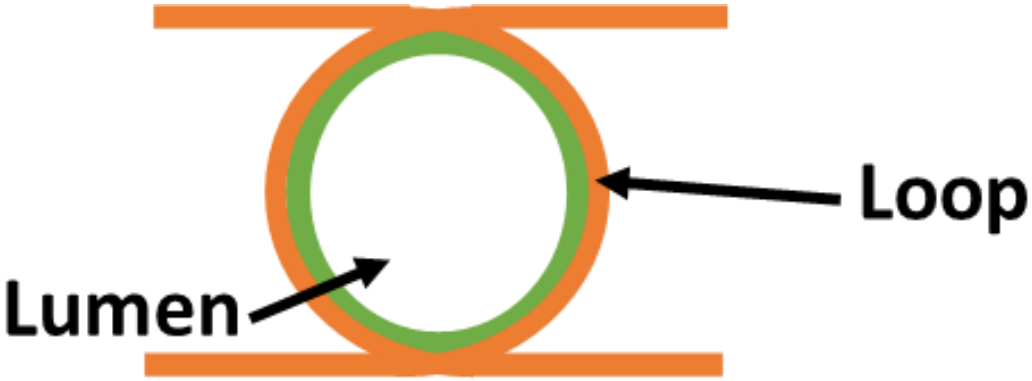


Fig. 31

Id. at Fig. 31. The demonstrative graphic below illustrates how Schaffer's U-shaped actuating members (orange) form a loop around the seal module (green):



This arrangement is similar to the arrangement of the filament depicted in Figures 8 and 9 of the ’012 patent:

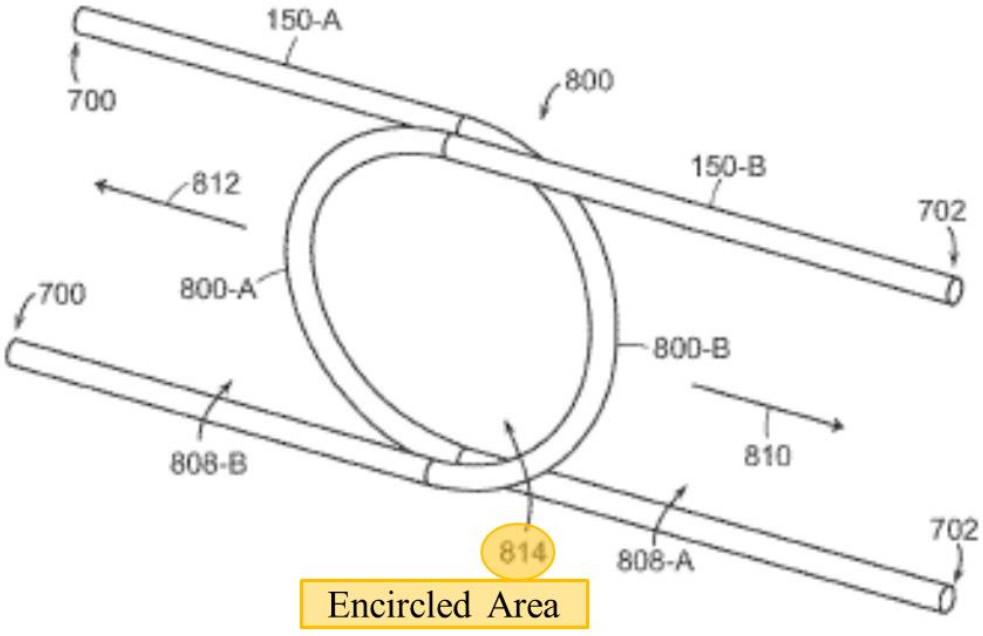


FIG. 8

Ex. 1001 (’012 patent) at Figs. 8-9. The ’012 patent 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 13:57-14:5. Thus, the “encircled area” forms a

loop around the elongate member 132. Schaffer's actuating members form a similar loop.

94. The portion of the actuating members that extends away from the seal module 100 is a "first end portion" of the filament "extending away from the loop:

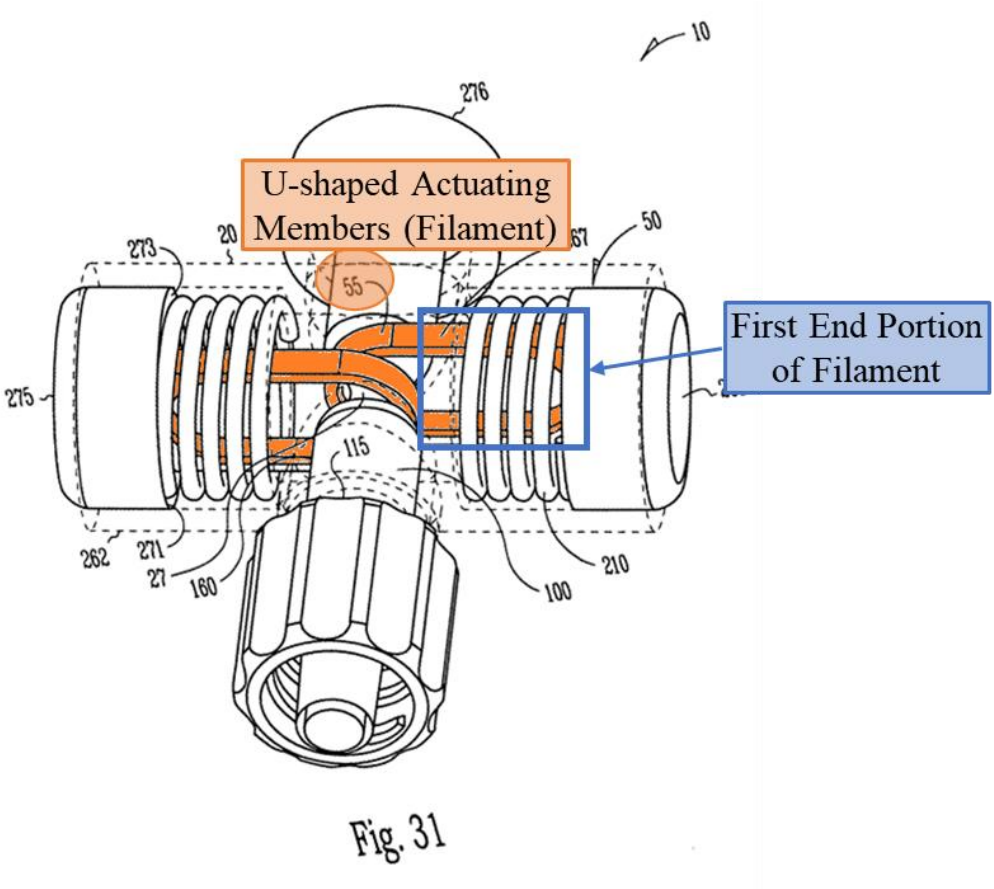


Fig. 31

Ex. 1005 (Schaffer) at Fig. 31. The '012 patent 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:

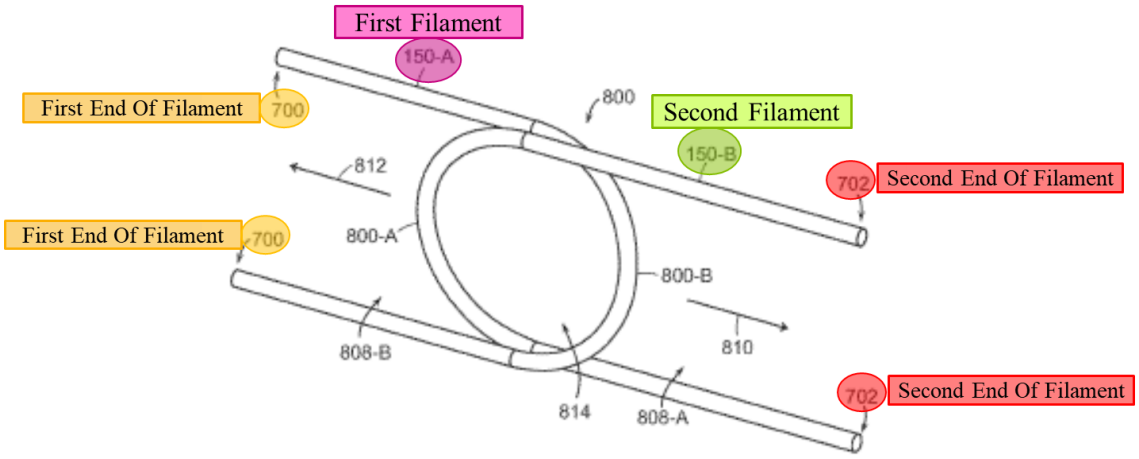


FIG. 8

Ex. 1001 ('012 patent) at 12:64-67, Fig. 8 (emphases 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.*

95. I note that Patent Owner argued in a related proceeding that the '012 patent (and related patents) 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 '012 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 '012 patent

at 12:44-53). 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. 1001 ('012 patent), 12:47-48. When describing Figures 7-9, the patent 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 12:61-67. There is no indication in the patent 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 loop and is connected to the first actuator:

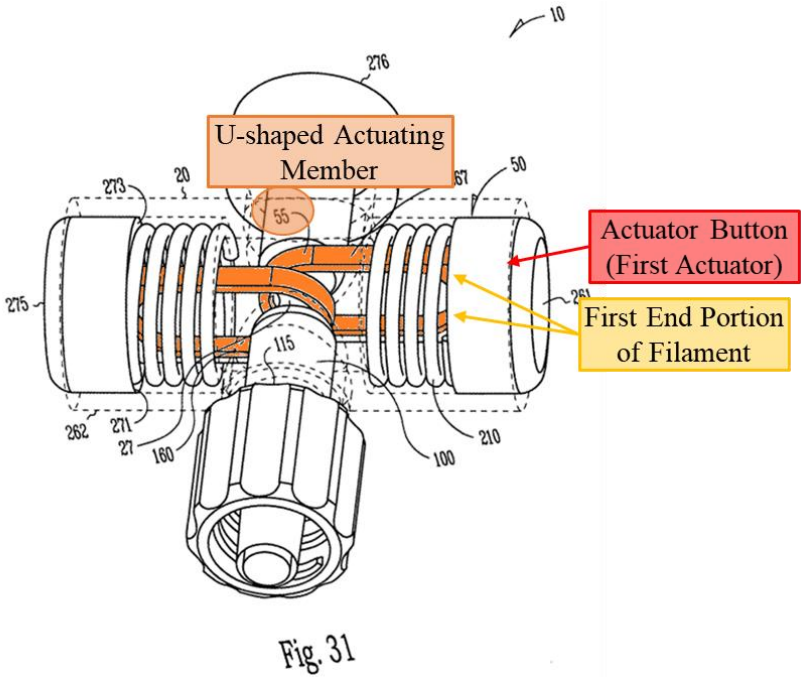


Fig. 31

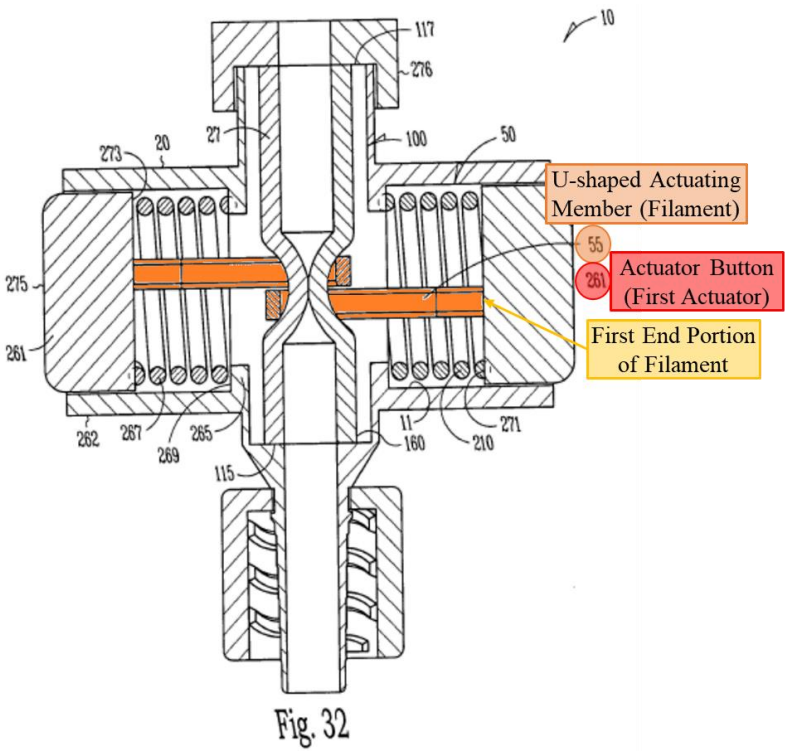


Fig. 32

Ex. 1005 (Schaffer) at [0076], Figs. 31-32. Schaffer's U-shaped actuating members, therefore, disclose the "filament" as claimed in the '012 patent.

ii. Hartley

96. 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:

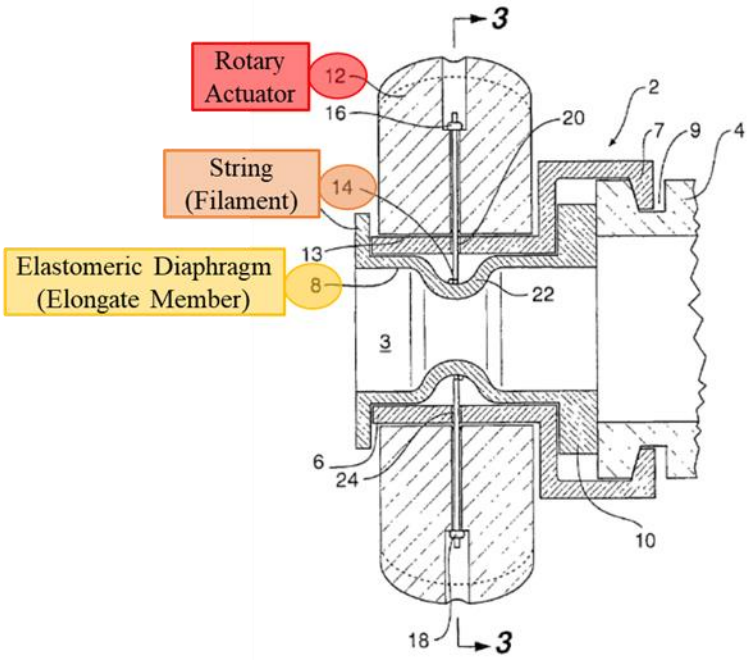


Fig 1

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 and claimed in the '012 patent because a "string" is made of at least one or more threads, lines, or cords. *See* Ex. 1001 ('012 patent) at 9:21-23 (disclosing that the filament can constitute "one or several threads, lines, cords, rope, ribbon, flat wire, sheet, or tape").

97. 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":

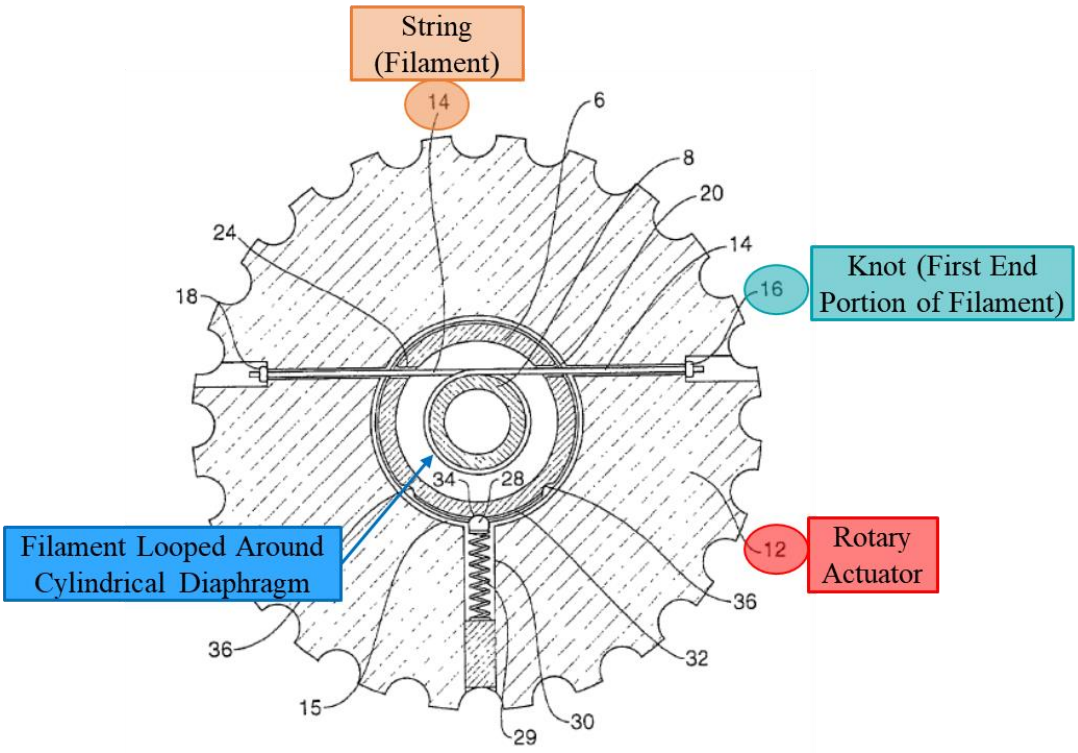


Fig 3

Id. at [0031], Fig. 3. Hartley's string is therefore formed into a loop around the "collapsible tubular sidewall" (i.e., cylindrical diaphragm). As shown in Figure 3

above, the string also has "a first end portion extending away from the loop and connected to the first actuator." *Id.*

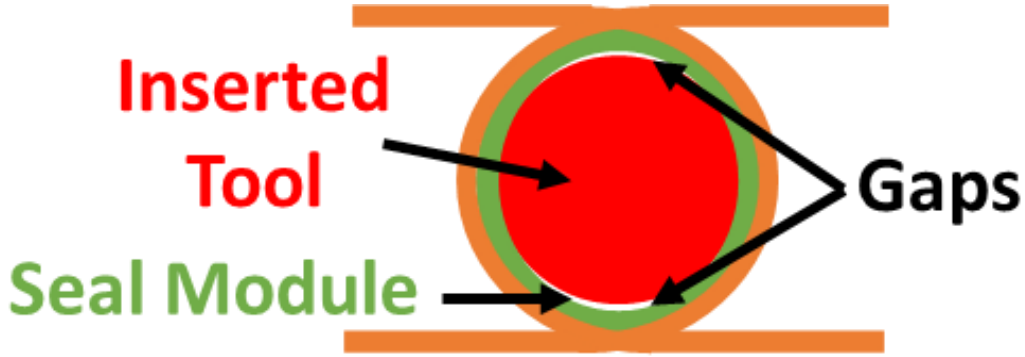
98. Hartley discloses that "[r]otation of the rotary actuator 12 with respect to the cylindrical housing 6 will cause the string 14 to be pulled in both directions at once and hence the cylindrical diaphragm 8 to be constricted." *Id.* at [0031], [0034], Fig. 4. Hartley also discloses that its valve "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").

99. 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 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.

100. 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 September 2017. 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.

101. 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 September 2017. 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.

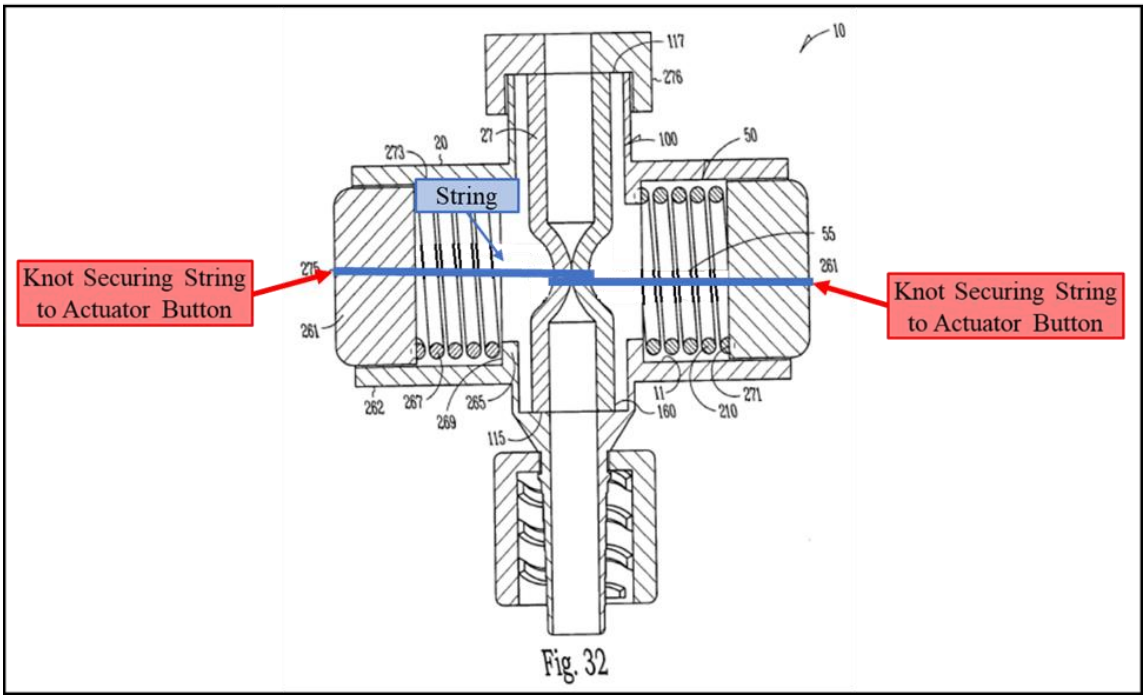
102. Fourth, as Schaffer recognizes, fluid stasis valves generally comprise "a resilient material in compression within a housing or clamping member." Ex. 1005 (Schaffer) at [0003]. There were a finite number of ways to compress the resilient material in a hemostasis valve to create a seal in September 2017. 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 September 2017 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.

103. 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.

104. 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 September 2017. 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



105. 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):

Relaxed State

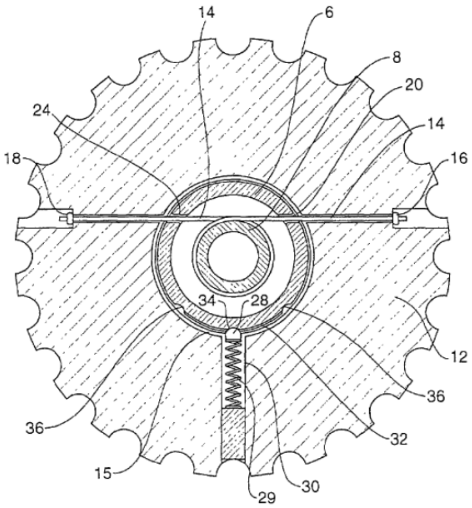


Fig 3

Constricted State

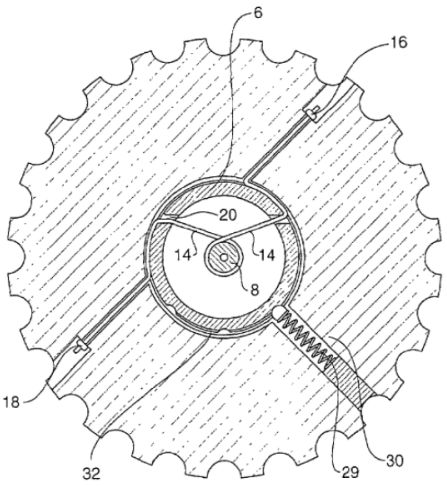


Fig 4

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:

Constricted State

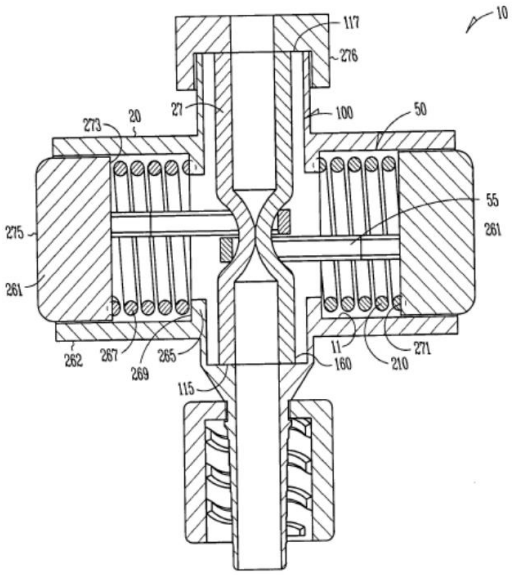


Fig. 32

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].

106. 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.

107. 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.*

108. 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 a 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.

iii. Eller

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

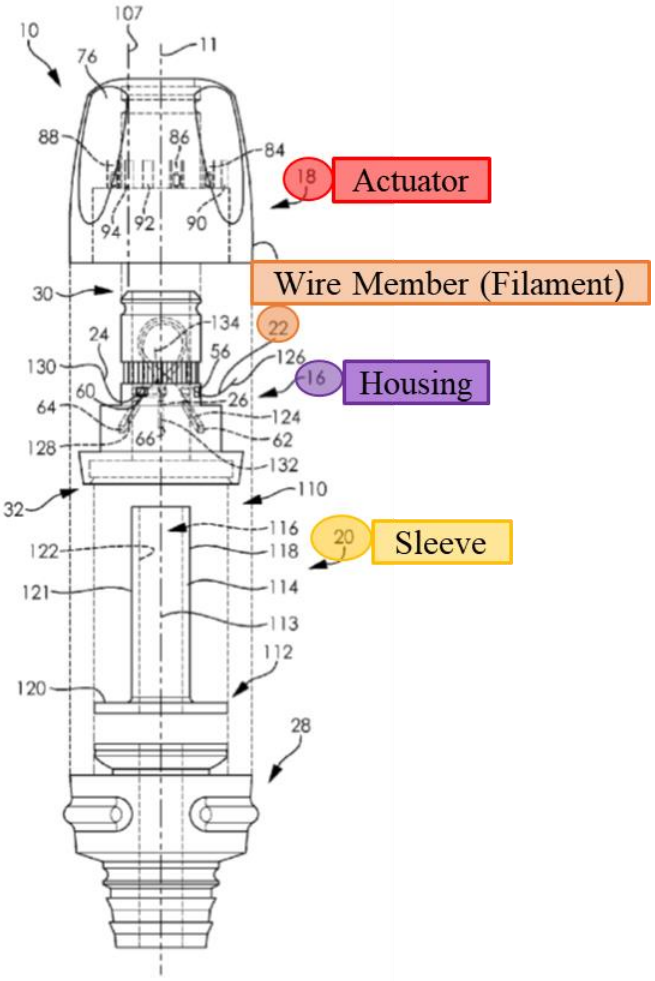


FIG. 2

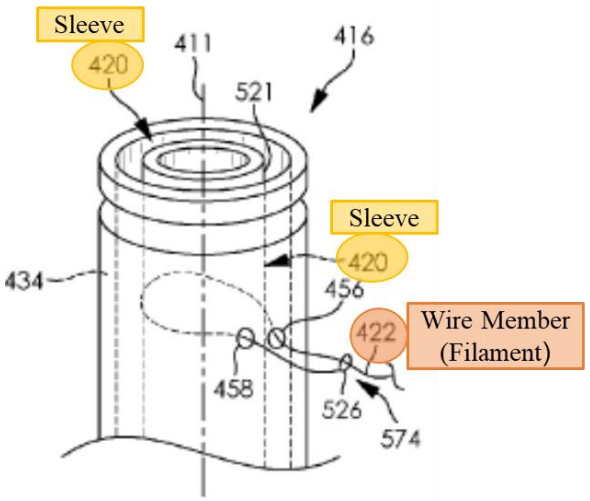


FIG. 16

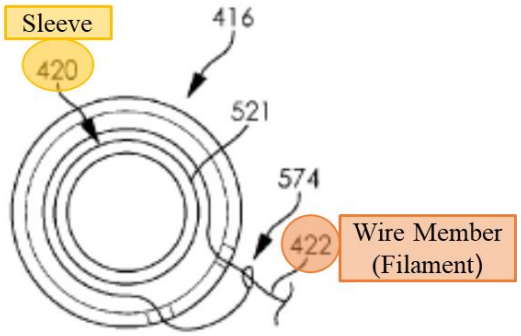


FIG. 17

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. I also note that Claim 1 of the '012 patent recites that the valve includes "at least … a first filament," meaning that the claims contemplate a valve having more than one filament. Ex. 1001 ('012 patent) at Claim 1. Thus, Eller's disclosure of examples having more

[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.

than one wire member does not affect my opinions on whether the claims of the ’012 patent are patentable.

110. 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 and claimed in the ’012 patent because the wire member is at least a line, cord, ribbon, sheet, or flat wire. *See* Ex. 1001 (’012 patent) at 9:21-23 (disclosing that the filament can constitute “one or several threads, lines, cords, rope, ribbon, flat wire, sheet, or tape”).

111. 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:

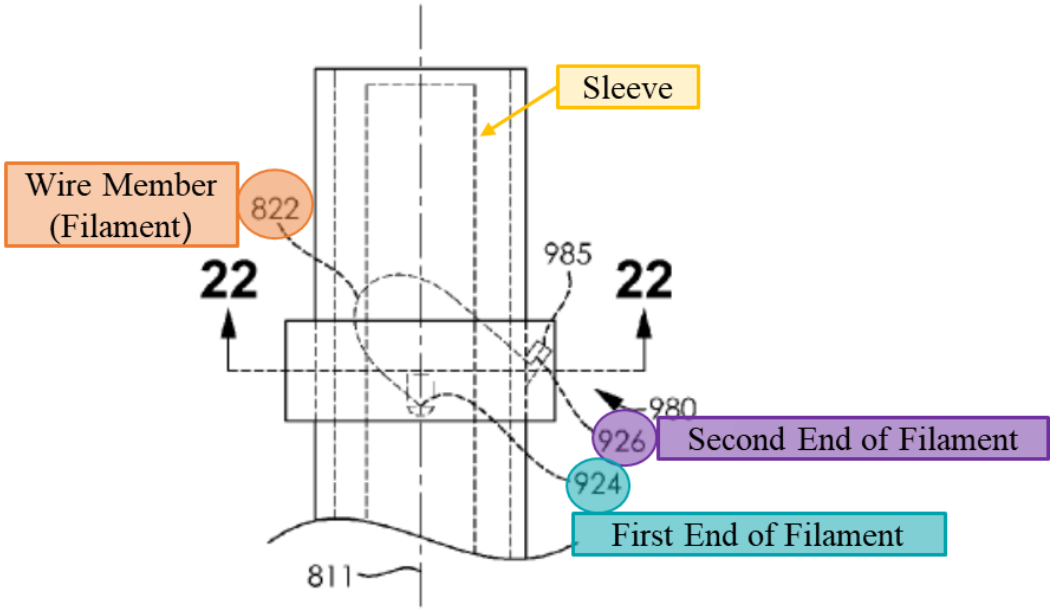


FIG. 21

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

112. 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):

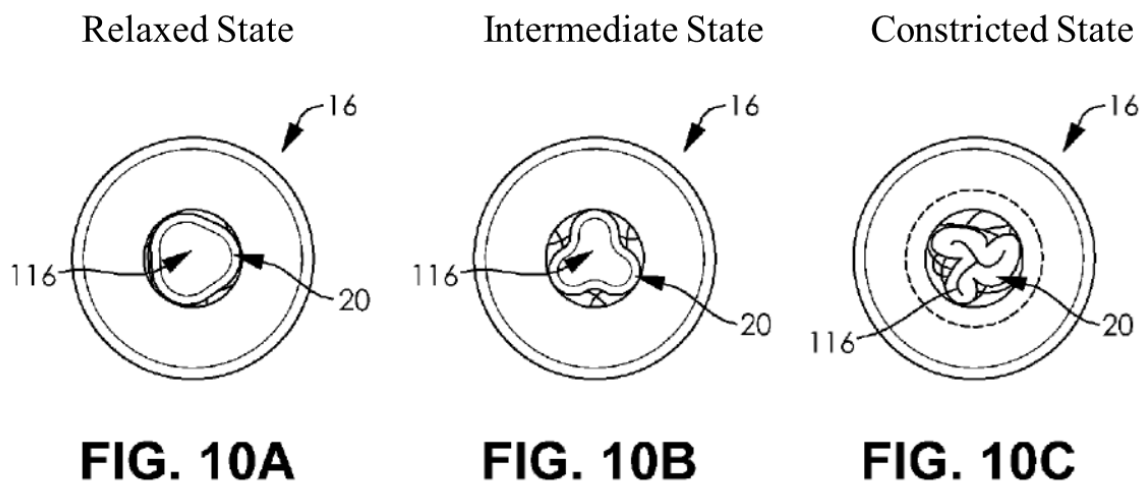


FIG. 10A FIG. 10B FIG. 10C

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.

113. Eller also discloses embodiments that "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 this configuration, Eller's wire member is a filament formed into a loop around the collapsible tubular sidewall. When replacing Schaffer's U-shaped actuating members with Eller's wire member, a person of ordinary skill in the art would have been motivated to loop Eller's wire at least one full revolution around

Schaffer's seal module to ensure the wire formed a constrictive seal against any devices inserted through the valve. A person of ordinary skill in the art would have reasonably expected success because Eller encourages looping the wire one revolution around the sleeve and discloses that such a configuration forms a seal.

114. 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.

115. 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 September 2017.

116. 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 September 2017.

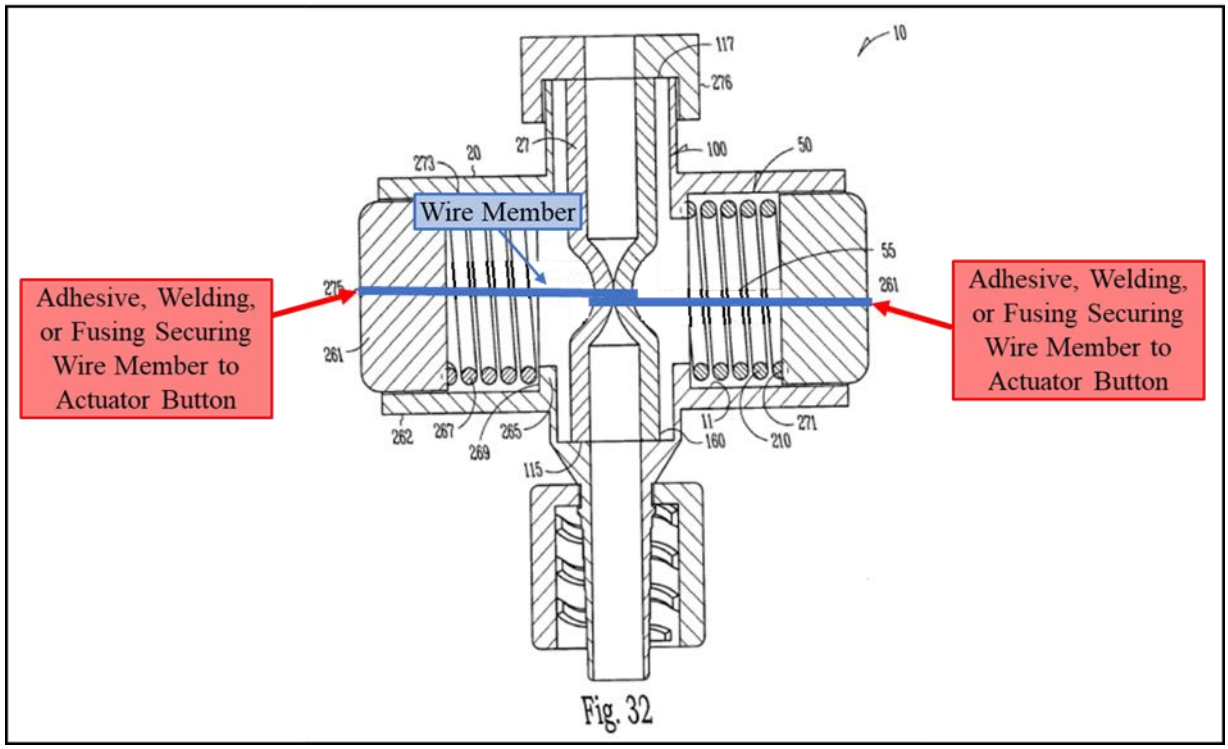
117. Fourth, as Schaffer recognizes, fluid stasis valves generally comprise "a resilient material in compression within a housing or clamping member." Ex. 1005 (Schaffer) at [0003]. As I explained previously with respect to the Schaffer-Hartley combination, there were a finite number of methods to compress the

resilient material in a stasis valve in September 2017. 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 September 2017 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.

118. 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 September 2017, 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



119. 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.

120. 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:

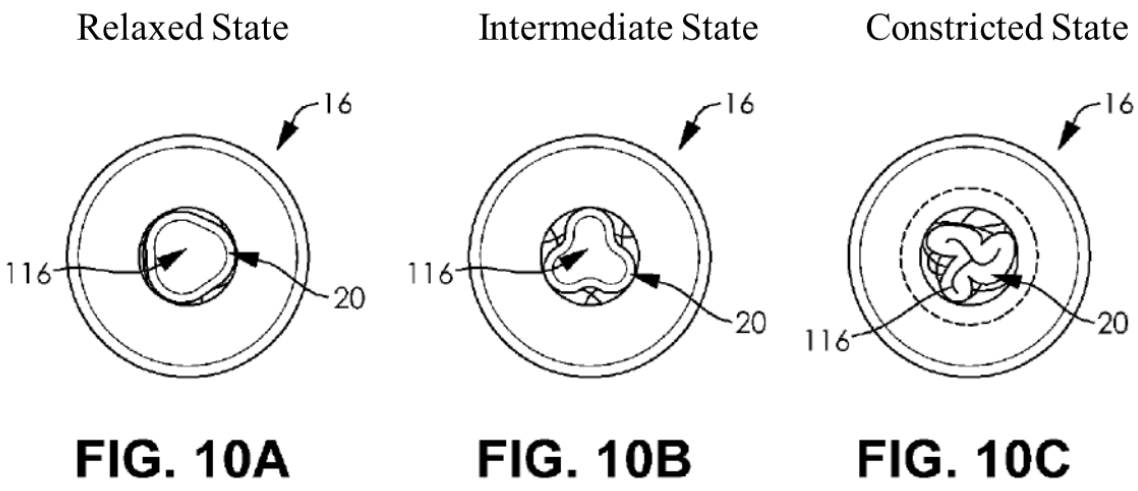


FIG. 10A FIG. 10B FIG. 10C

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:

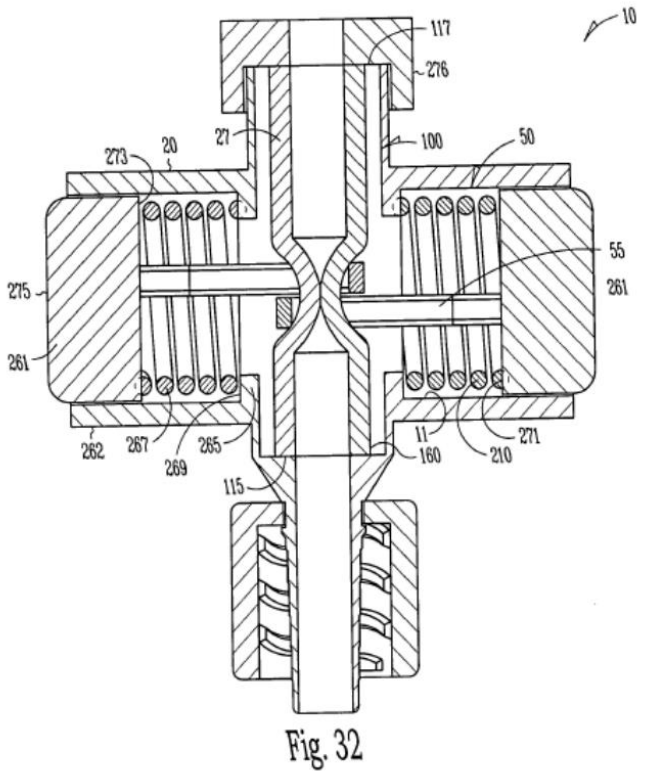


Fig. 32

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.

121. 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.3.b.ii.) 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. <u>First Spring</u>

122. Schaffer discloses the "first spring" recited in claim 1.

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

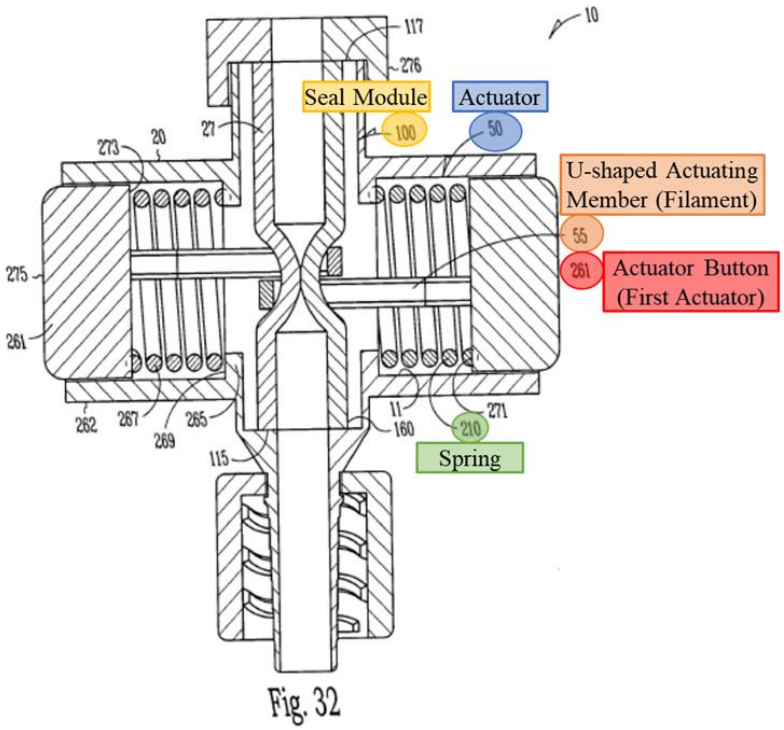


Fig. 32

Ex. 1005 (Schaffer) at [0077], Fig. 31.

124. As I explained previously, Schaffer discloses that the actuator buttons are "movable from a first position to a second position." *Id.* at [0076]. 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)":

First Position – Actuator Buttons Undepressed

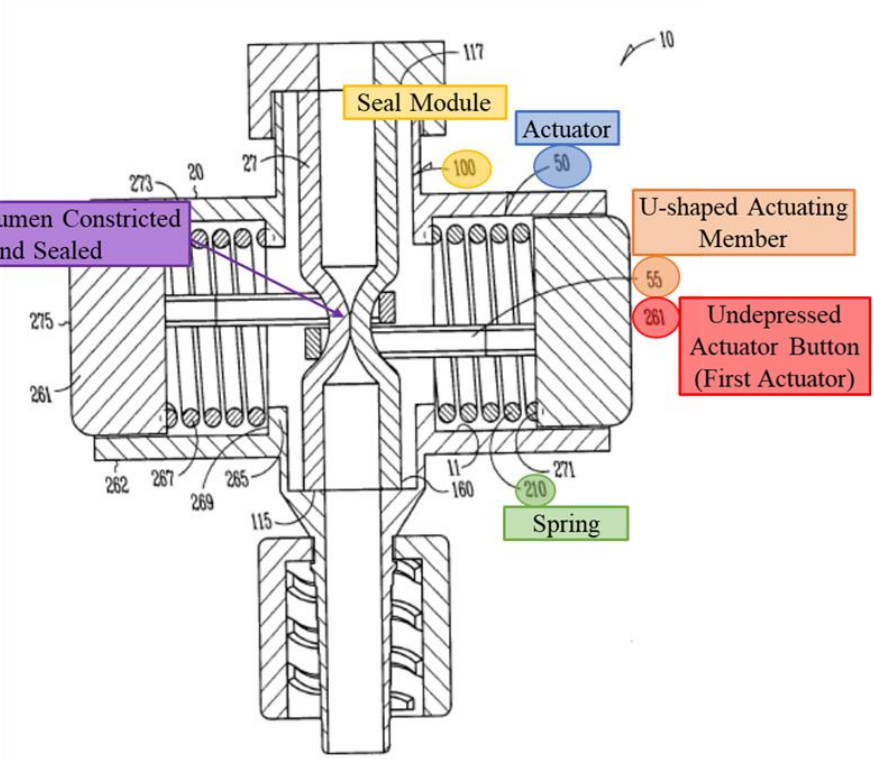


Fig. 32

Id. at [0077], Fig. 32. As illustrated in Figure 32 above, the lumen of Schaffer's valve is completely constricted and sealed when the actuator buttons are in the first position. *Id.* This is consistent with Schaffer's disclosure that the valve "blocks the flow of gas or fluid completely and immediately with or without an instrument in place within the gas/fluid path." *Id.* at [0008].

125. Schaffer's spring biases the actuator button (first actuator) toward the first (closed) position by pulling the first end portion of the actuating member (filament) away from the seal module 100. *Id.* at [0077]. This causes the U-shaped actuating members attached to the buttons to circumferentially constrict

around and collapse the seal module, preventing the flow of fluid through the valve. *Id.* As illustrated in Figures 31-34 of Schaffer, the loop formed by the actuating members around the valve lumen 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 resilient member/spring 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."

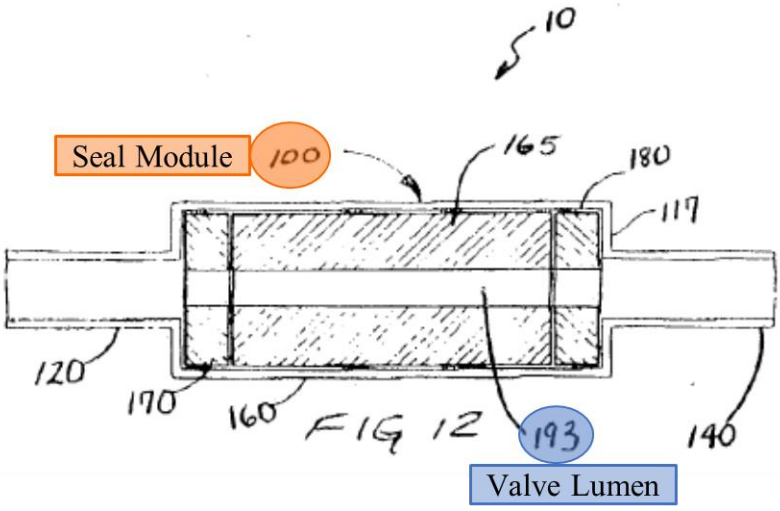
B. Claim 2

126. Claim 2 recites: "The aspiration catheter of claim 1 wherein: the collapsible tubular sidewall comprises a tubular member defining the valve lumen configured to slidably receive the elongate, flexible tubular body; the constricting mechanism further comprises a second actuator and a second spring coupled to the second actuator; and the filament further comprises a second end portion extending away from the loop in a different direction than the first end portion and connected to the second actuator, and wherein the first actuator and the second actuator are moveable between (a) a first position wherein the filament circumferentially constricts the valve lumen to create a seal about the elongate, flexible tubular body and (b) a second position wherein the filament is moved to open the valve lumen at least partially." Schaffer anticipates claim 2 or renders it obvious either alone or in combination with Hartley ***or*** Eller.

1. Tubular Member

127. Schaffer discloses that "the collapsible tubular sidewall comprises a tubular member defining the valve lumen configured to slidably receive the elongate, flexible tubular body."

128. As I explained previously for claim 1, Schaffer's hemostasis valve includes a "seal module 100" that comprises "a flexible, elongate tubular structure 101." Ex. 1005 (Schaffer) at [0049], [0051], [0054]. The elongate tubular structure 101 defines a lumen 193:



Id. at [0058], Fig. 12. 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 also discloses that "a guidewire and catheter may be placed into the same lumen 193 for extension into a body passage." *Id.* at [0074]. As I explained previously for claim 1, the catheter placed into Schaffer's lumen 193 is a "tubular body" as claimed in the '012 patent. *Supra* ¶¶71-76. Accordingly,

Schaffer's seal module 100 is a collapsible tubular sidewall comprising "a tubular member defining the valve lumen configured to slidably receive the elongate, flexible tubular body."

2. Constricting Mechanism

129. Schaffer discloses "a second actuator and a second spring coupled to the second actuator."

130. The embodiment depicted in Figures 31-34 of Schaffer includes "two circular actuators 50" on opposite sides of the housing that are "movable from a first position to a second position." Ex. 1005 (Schaffer) at [0075]-[0076], Figs. 31-34. Each actuator 50 includes "an actuator button 261":

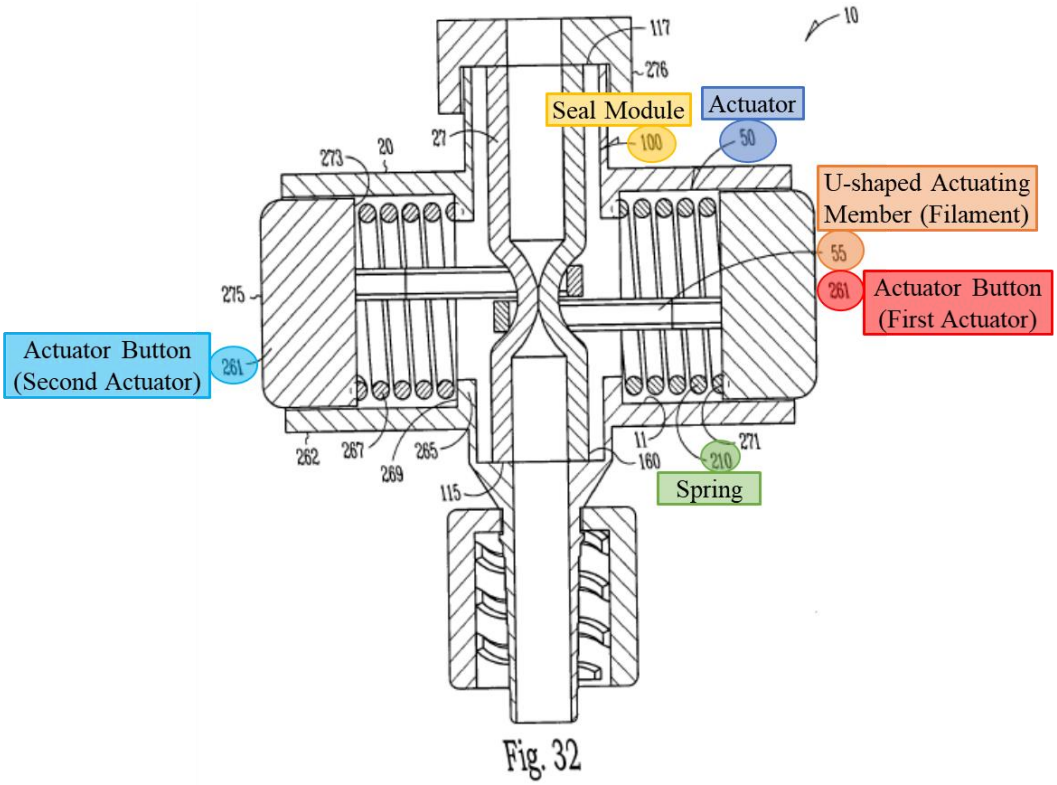


Fig. 32

Id. at [0076], Fig. 32. Schaffer's valve also includes "two resilient members 267 (e.g., spring 210) disposed within the actuating member 55":

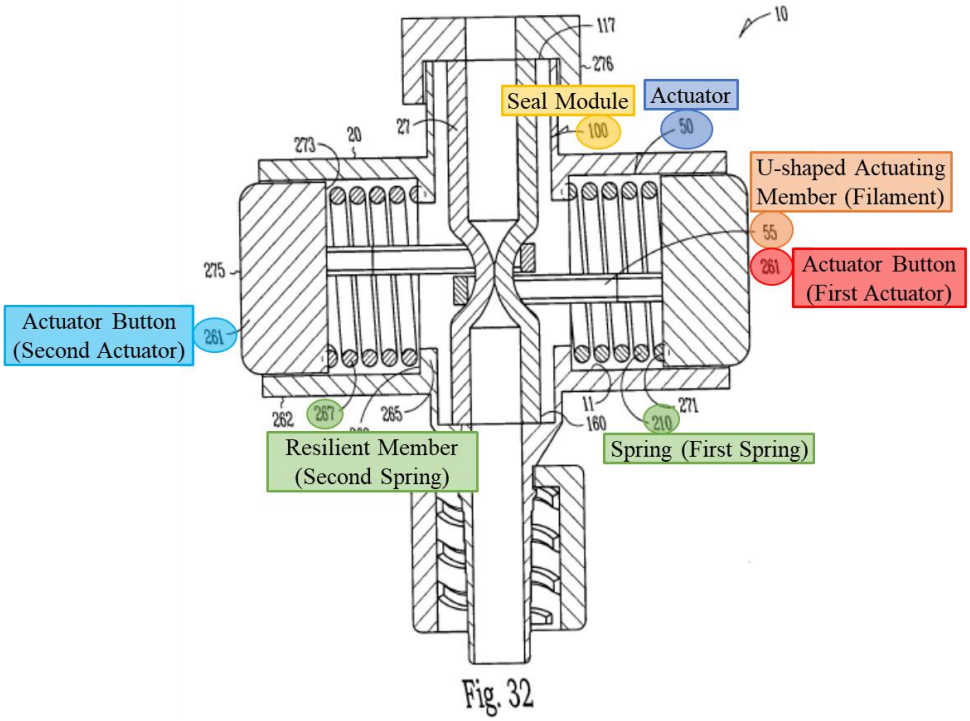


Fig. 32

Id. "[T]he resilient members 267 each abut the proximal end 273 of an actuator button 261." *Id*.

131. Therefore, as depicted in Figure 32 above and described in Schaffer, Schaffer's valve has a first spring coupled to a first actuator (the first actuator button 261) and a second spring coupled to a second actuator (the second actuator button 261).

3. <u>Filament</u>

132. Claim 2 finally recites that "the filament further comprises a second end portion extending away from the loop in a different direction than the first end

portion and connected to the second actuator, and wherein the first actuator and the second actuator are moveable between (a) a first position wherein the filament circumferentially constricts the valve lumen to create a seal about the elongate, flexible tubular body and (b) a second position wherein the filament is moved to open the valve lumen at least partially." Schaffer discloses these limitations or renders them obvious in view of Hartley ***or*** Eller.

a. <u>Schaffer</u>

133. As I explained for claim 1, Schaffer's actuator buttons are each coupled to "an actuating member 55 which, in one option, is U-shaped." Ex. 1005 (Schaffer) at [0076]. As I also explained for claim 1, the U-shaped actuating members are the claimed "filament." Also relevant to this limitation, the '012 patent expressly identifies the first and second ends when the filament includes multiple filaments having "a U-shaped section." Ex. 1001 ('012 patent) at 13:30-34, Fig. 8.

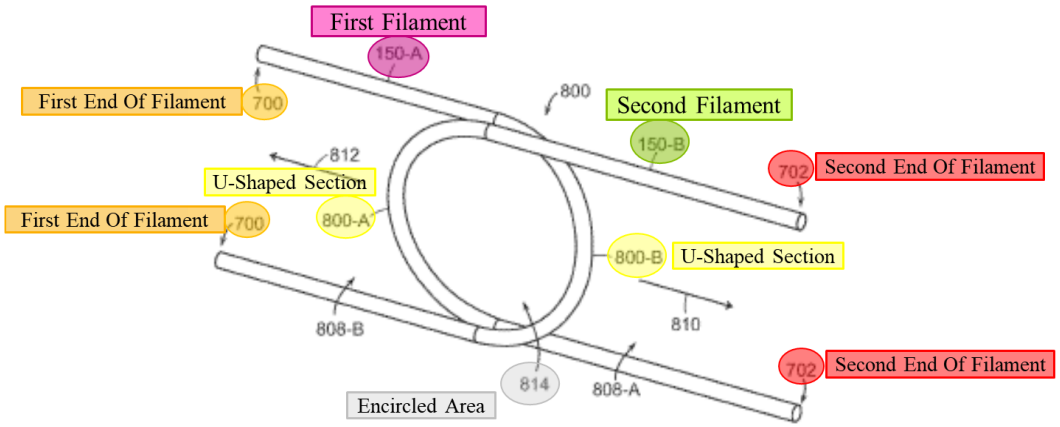


FIG. 8

As shown in Figure 31 below, Schaffer's U-shaped actuating members have a first end portion that extends away from the seal module 100 in a first direction and a second end portion that extends away from the seal module 100 in an opposite direction:

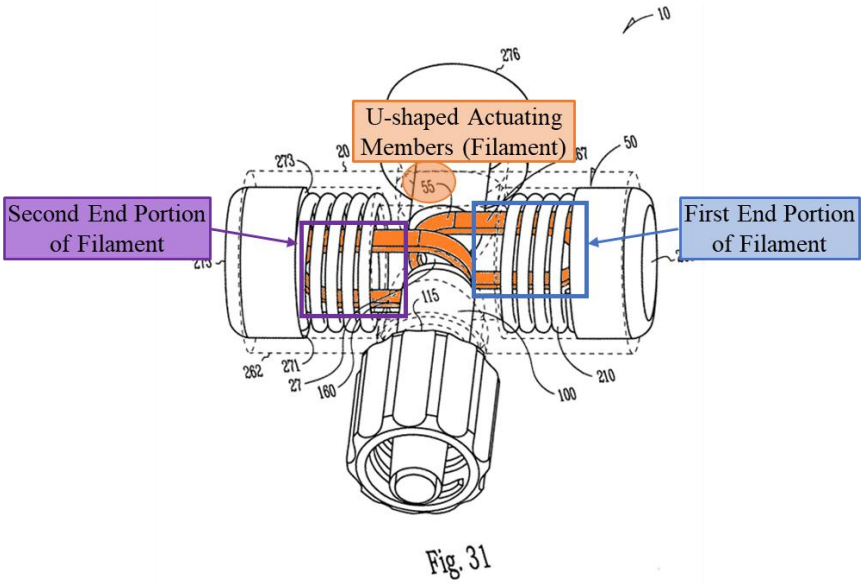


Fig. 31

Id. at Fig. 31. The second end portion of the U-shaped actuating members extends away from the loop formed by the actuating members and is connected to the second actuating button (i.e., the second actuator):

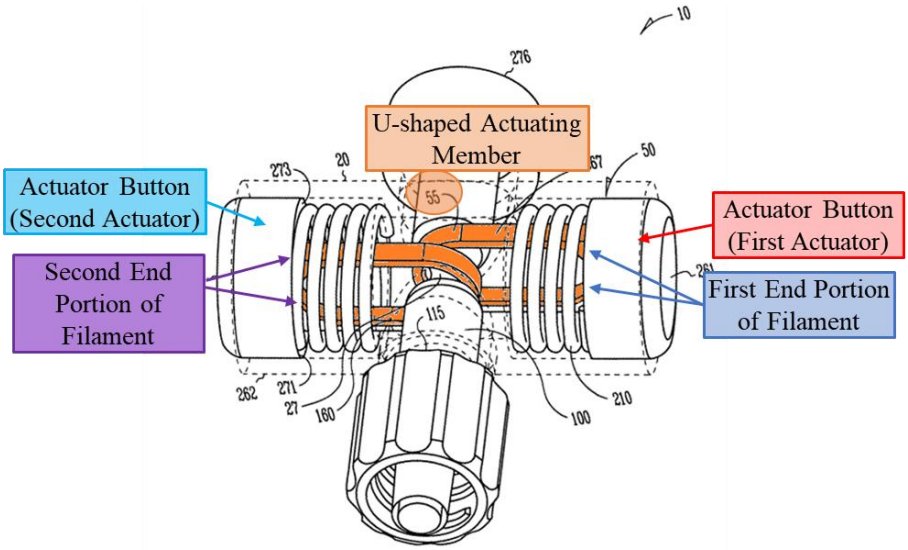


Fig. 31

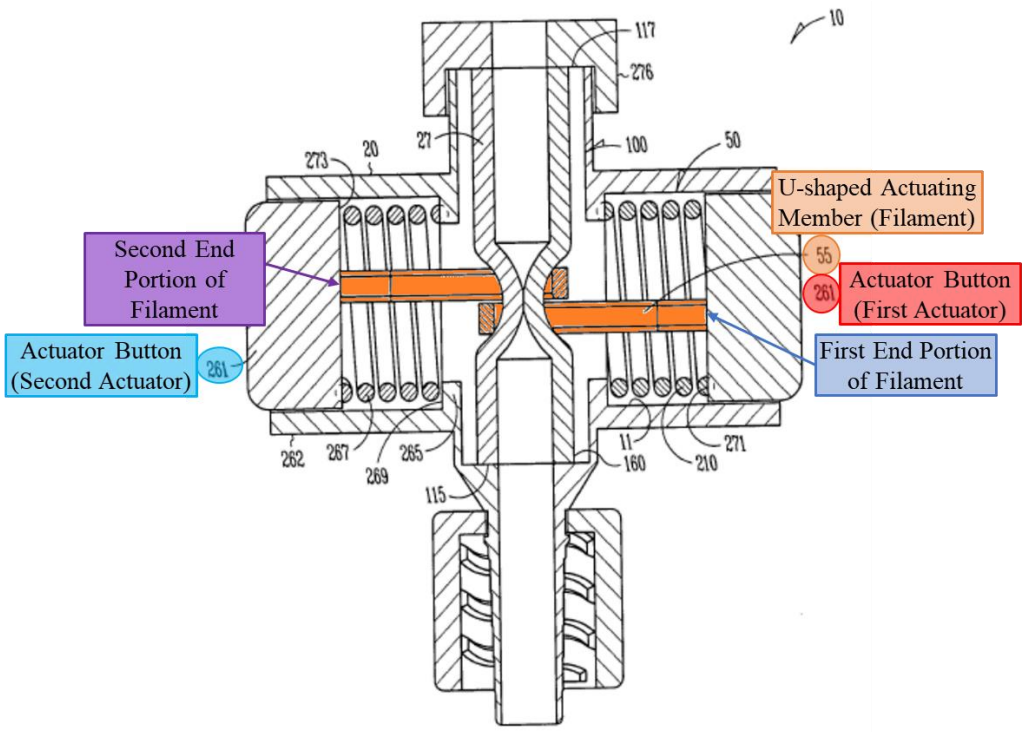


Fig. 32

Id. at [0075]-[0076], Figs. 31-32. Schaffer's actuator buttons are movable between a first position wherein the lumen is constricted to create a seal around the tubular body and a second position wherein the lumen is at least partially

open. As I explained for claim 1, 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)":

First Position – Actuator Buttons Undepressed

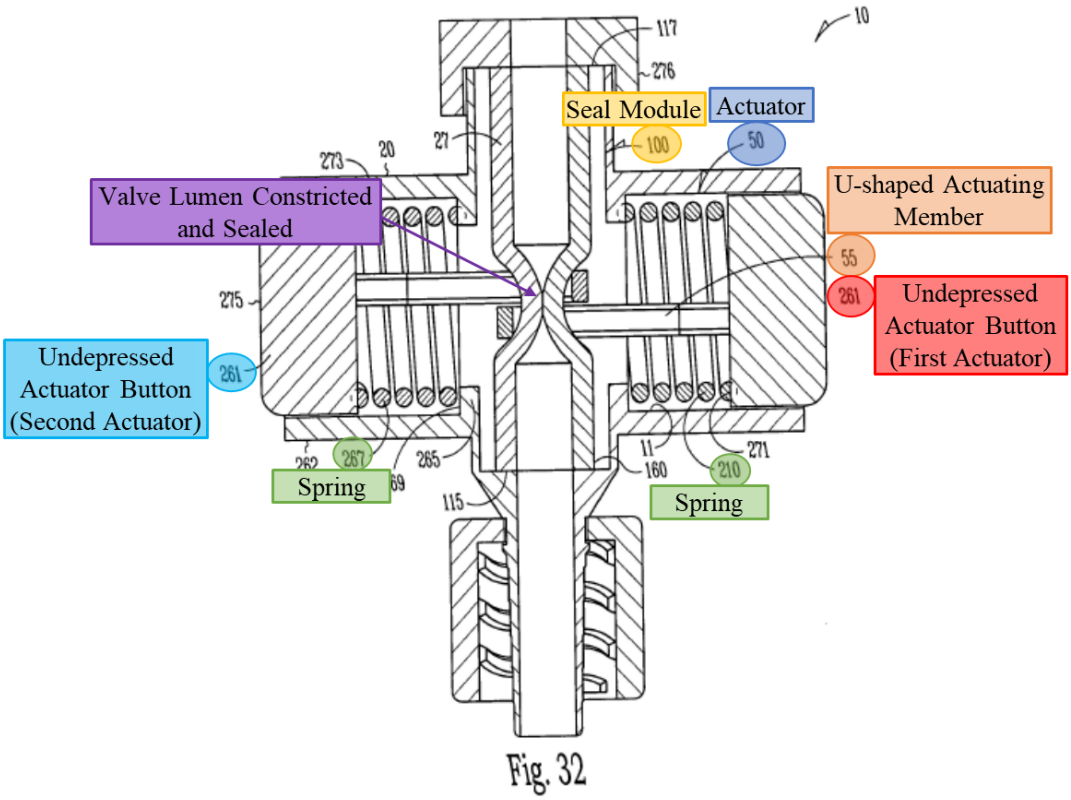


Fig. 32

Id. at [0077], Fig. 32. As illustrated in Figure 32 above, the lumen of Schaffer's valve is completely constricted and sealed when the actuator buttons are in the first position. *Id.* This is consistent with Schaffer's disclosure that the valve

"blocks the flow of gas or fluid completely and immediately with or without an instrument in place within the gas/fluid path." *Id.* at [0008].

134. In the second position, shown in Figure 34, Schaffer's actuator buttons are depressed, compressing the springs and allowing the actuator members to "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 gasses and fluids can pass therethrough":

Second Position – Actuator Buttons Depressed

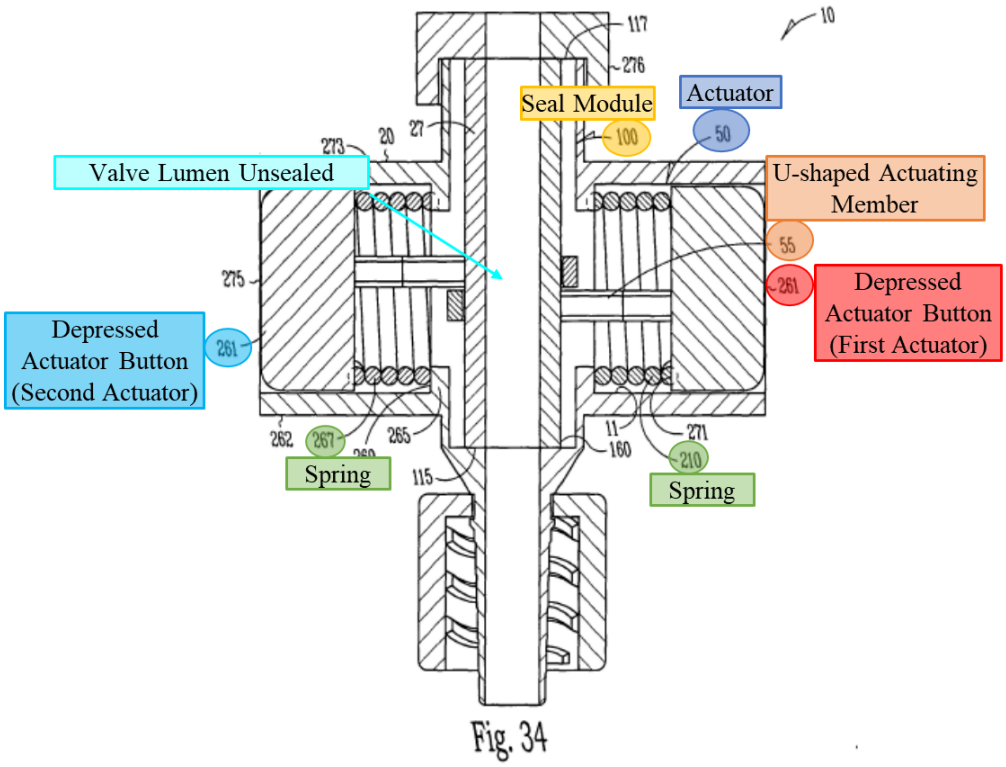


Fig. 34

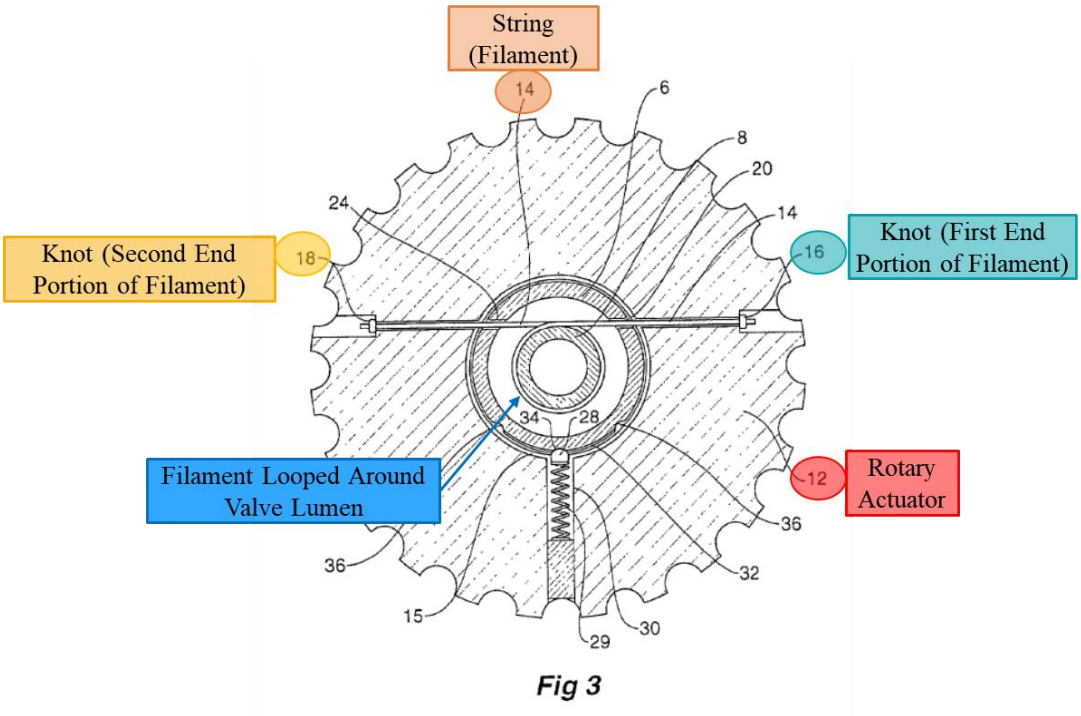
Id. at [0077], Fig. 34.

135. Schaffer discloses that its hemostasis valve "blocks the flow of gas or fluid completely and immediately with or without an instrument in place within

the gas/fluid path." *Id.* at [0008]. Schaffer also discloses 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]. Therefore, when Schaffer's valve is in the first, sealed position, the U-shaped actuating members would "constrict[] the valve lumen to create a seal about the elongate, flexible tubular body" of a catheter inserted through the valve. Accordingly, because Schaffer discloses every limitation recited by claim 2, it is my opinion that Schaffer anticipates claim 2 or renders claim 2 obvious.

b. <u>Hartley</u>

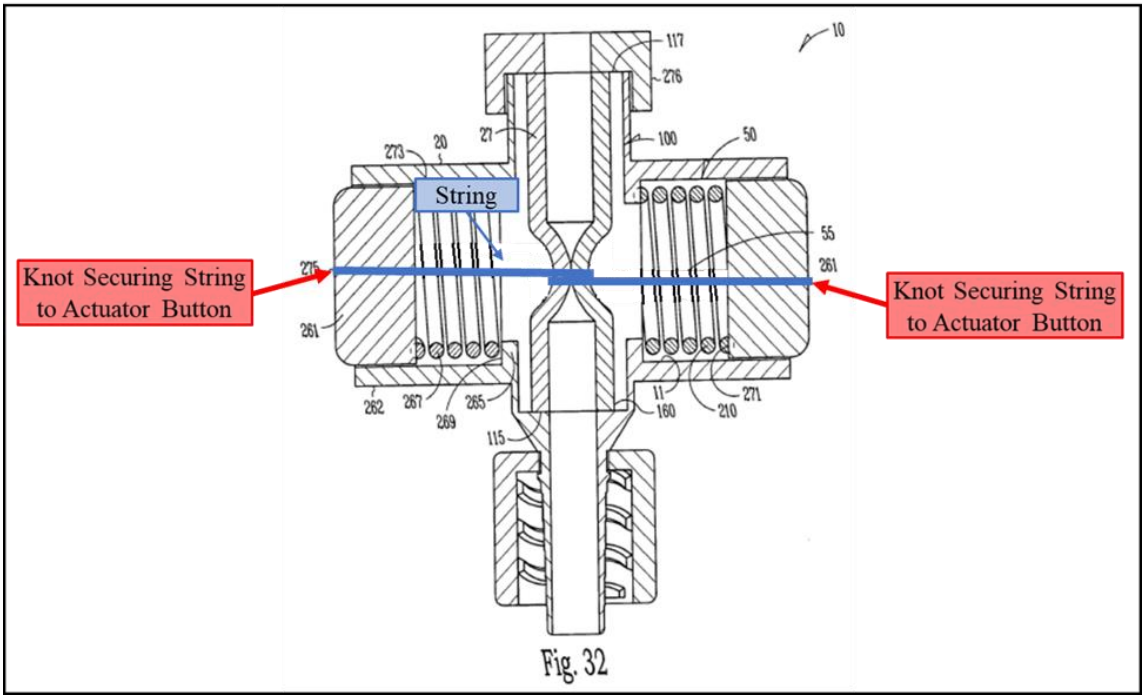
136. As illustrated in Figure 3 of Hartley below, Hartley's string is secured to the rotary actuator at a first end via a knot 16 and "then passes through an aperture 20 in the cylindrical housing 6 and then is wound preferably twice around the cylindrical diaphragm 8 … and then passes through a further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



Ex. 1006 (Hartley) at [0031], Fig. 3. Hartley's string thus has a first end portion that extends away from the valve lumen in a first direction (i.e., knot 16) and a second end portion that extends away from the valve lumen in an opposite direction (i.e., knot 18).

137. As I explained previously for claim 1, when a person of ordinary skill in the art replaced Schaffer's U-shaped actuating members with Hartley's string, each of the first and second ends of Hartley's string would be secured to one of Schaffer's actuator buttons (the first and second actuators) by, for example, a knot:

Demonstrative Illustration
Schaffer + Hartley's String



The first and second ends of Hartley's string would therefore extend in opposite directions from Schaffer's seal module 100. Schaffer's actuator buttons would be movable between a first position wherein Hartley's string constricts the valve lumen to create a seal around the tubular body and a second position wherein the lumen is at least partially open for the same reasons I explained above for Schaffer (which I incorporate herein). *Supra* ¶¶133-135. A person of ordinary skill in the art would have been motivated to combine Hartley's string with Schaffer's valve, and reasonably expected success in doing so, for the reasons provided in claim 1 (which I incorporate herein). *Supra* ¶¶96-108. The valve in Schaffer includes the remaining limitations of Claim 2, including, for example, "the collapsible tubular

sidewall" and the "constricting mechanism" as outlined in the previous sections. Therefore, it is my opinion that Schaffer in combination with Hartley renders claim 2 obvious.

c. Eller

138. As I explained previously for claim 1, Eller discloses that its 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. As illustrated in Figure 21 below, Eller's wire member extends from its first end, around the outer surface of the sleeve 20, to its second end in a direction that differs from the direction of the first end:

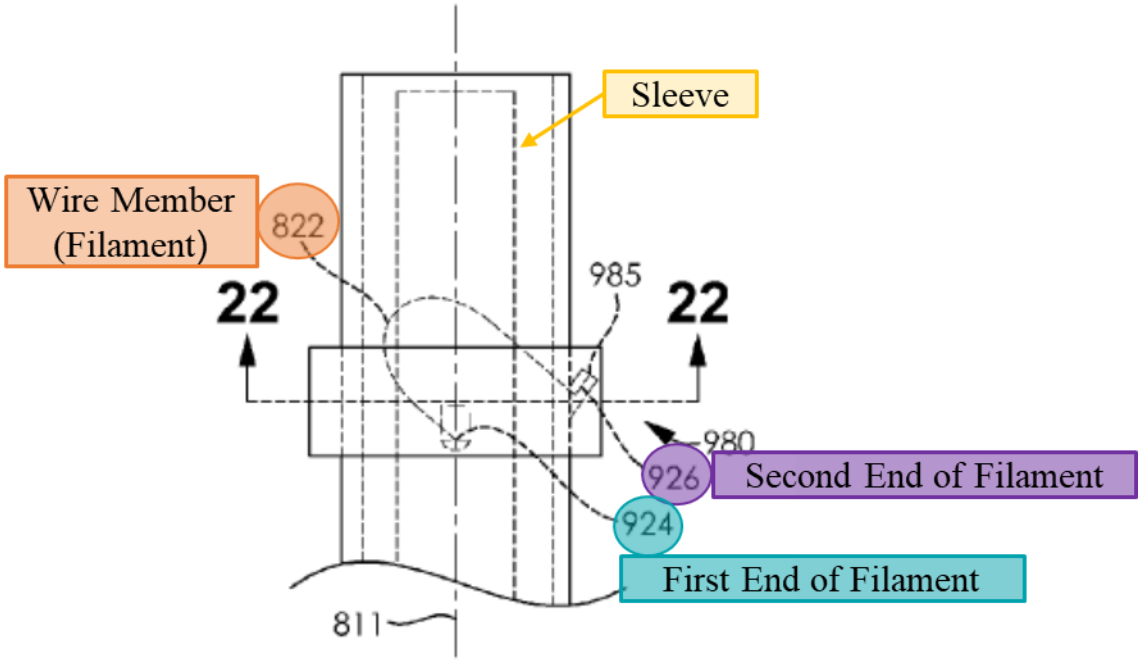
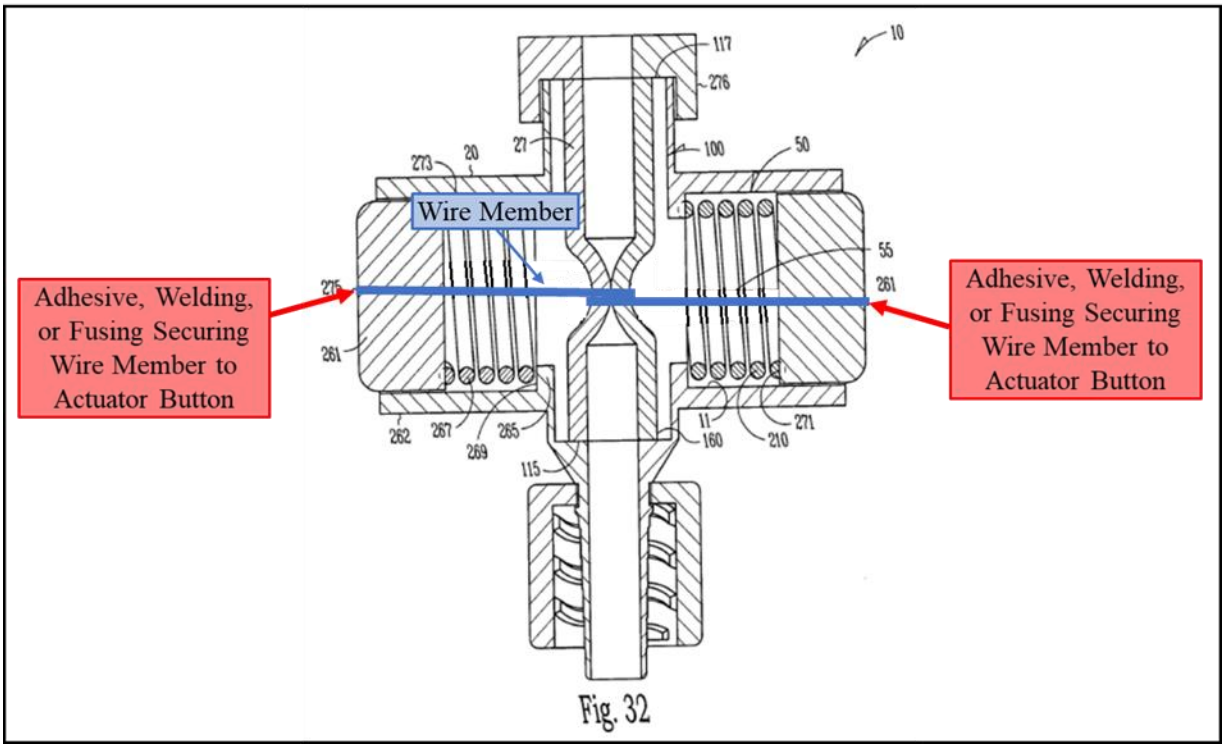


FIG. 21

Id., 12:58-64, 24:50-57, Fig. 21.

139. As I explained previously for claim 1, when a person of ordinary skill in the art replaced Schaffer's U-shaped actuating members with Eller's wire member, each of the first and second ends of Eller's wire member would be secured to one of Schaffer's actuator buttons (the first and second actuators) by, for example, adhering, welding, or fusing the wire member to the button:

Demonstrative Illustration
Schaffer + Eller's Wire Member



The first and second ends of Eller's wire member would therefore extend in opposite directions from Schaffer's seal module 100. Schaffer's actuator buttons would be movable between a first position wherein Eller's wire member constricts the valve lumen to create a seal around the tubular body and a second position wherein the lumen is at least partially open for the same reasons I explained

previously for Schaffer (which I incorporate herein). *Supra* ¶¶133-135. A person of ordinary skill in the art would have been motivated to combine Eller's wire member with Schaffer's valve, and reasonably expected success in doing so, for the reasons provided in claim 1 (which I incorporate herein). *Supra* ¶¶109-121. The valve in Schaffer includes the remaining limitations of Claim 2, including, for example, "the collapsible tubular sidewall" and the "constricting mechanism" as outlined in the previous sections. Therefore, it is my opinion that Schaffer in combination with Eller renders claim 2 obvious.

C. <u>Claim 3</u>

140. Claim 3 recites: "The aspiration catheter of claim 2 wherein the tubular member is pliable." Schaffer discloses the additional limitations in Claim 2, and therefore, Schaffer anticipates Claim 2 or renders it obvious alone or in combination with Hartley ***or*** Eller.

141. 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.

D. Claim 4

142. Claim 4 recites: "The aspiration catheter of claim 2 wherein the first actuator comprises a first button and the second 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." Schaffer discloses the additional limitations recited in Claim 4, and therefore, Schaffer anticipates Claim 4 or renders it obvious alone or in combination with Hartley ***or*** Eller.

143. 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":

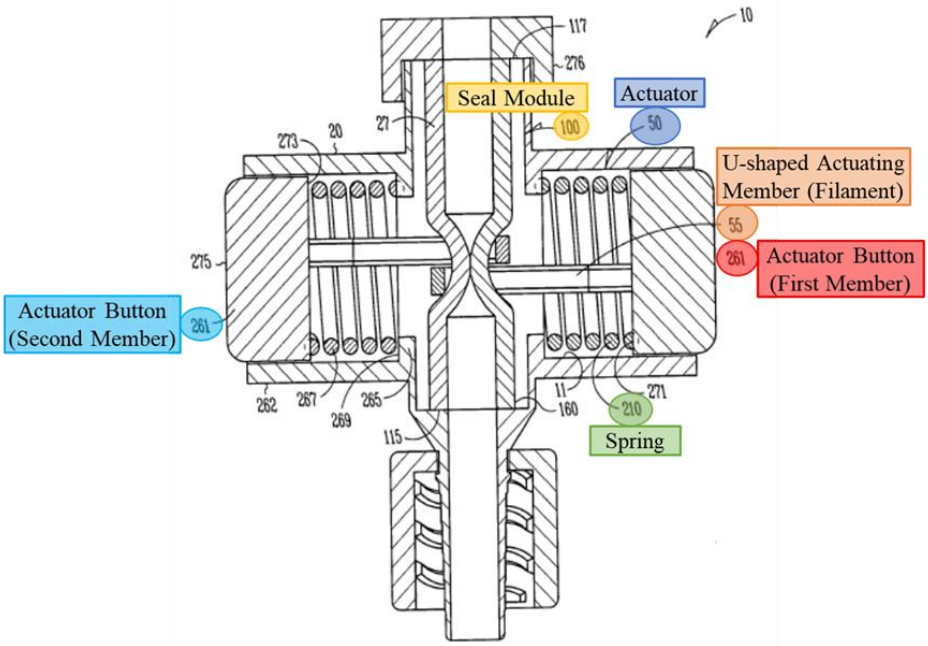
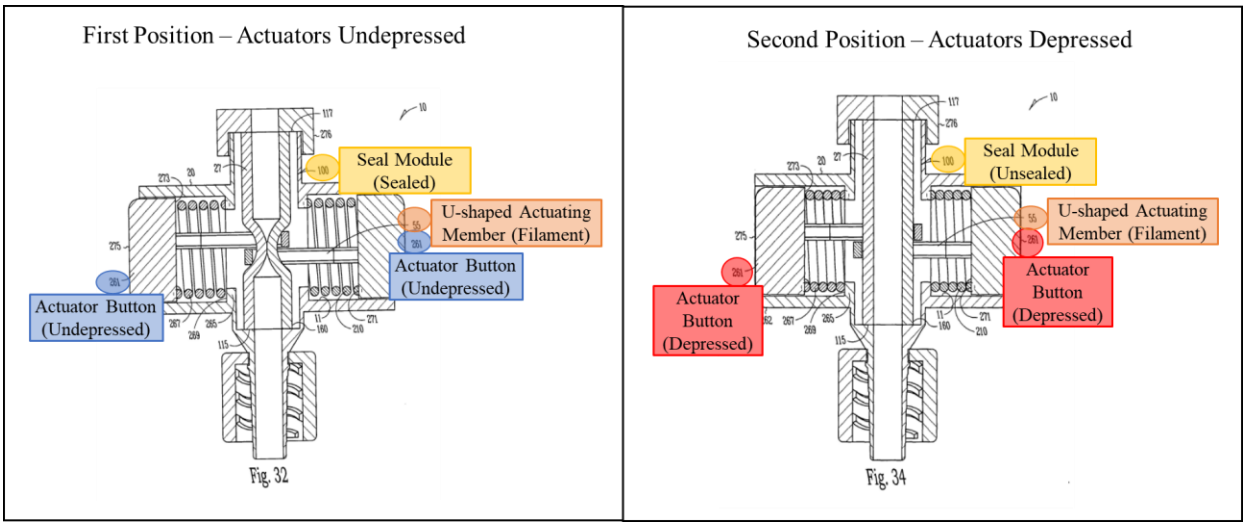
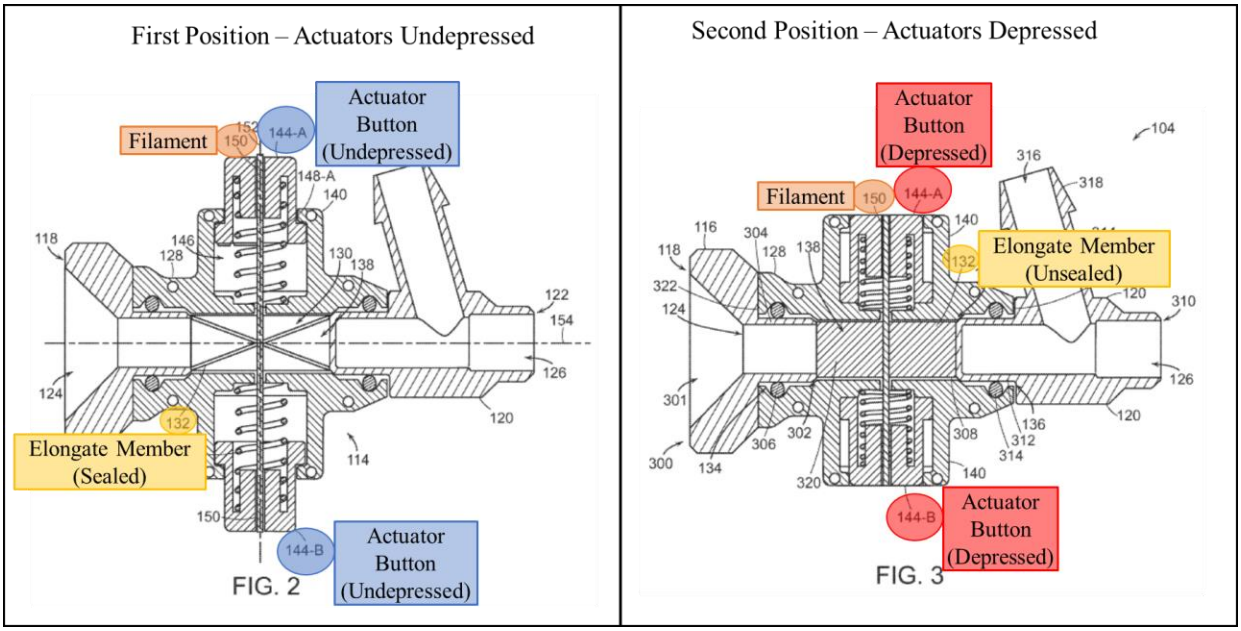


Fig. 32

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 '012 patent:



Ex. 1001 (’012 patent) at Figs. 2-3.

E. Claim 5

144. Claim 5 recites: “The aspiration catheter of claim 2 wherein, when the first actuator and the second actuator are in the first position, the valve lumen of the tubular member is configured to remain constricted and sealed when a pressure differential exists between (a) a first volume outside the valve 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.” Schaffer anticipates Claim 5 or renders it obvious alone or in combination with Hartley ***or*** Eller.

145. 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. <u>Schaffer</u>

146. 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 arterial cannulation, which are inserted into a blood vessel." Ex 1009 (Schaffer 616) at 1:1-9; *see also id.* at Abstract. Thus, Schaffer's hemostasis valve is intended for use with catheters inserted into a patient's blood vessels and "blocks the flow of gas or fluid completely and immediately with or without an instrument in place within the gas/fluid path" during those procedures. Ex. 1005 (Schaffer) [0008]. A person of ordinary skill in the art would have recognized that for Schaffer's valve to fulfill its purpose, the valve remains sealed when a pressure differential exists between the first end (i.e., adjacent the proximal end of a

catheter inserted into the patient and subject to intravascular pressure) and second end (i.e., subject to air pressure) of the tubular member.

Second End Subject to Air Pressure

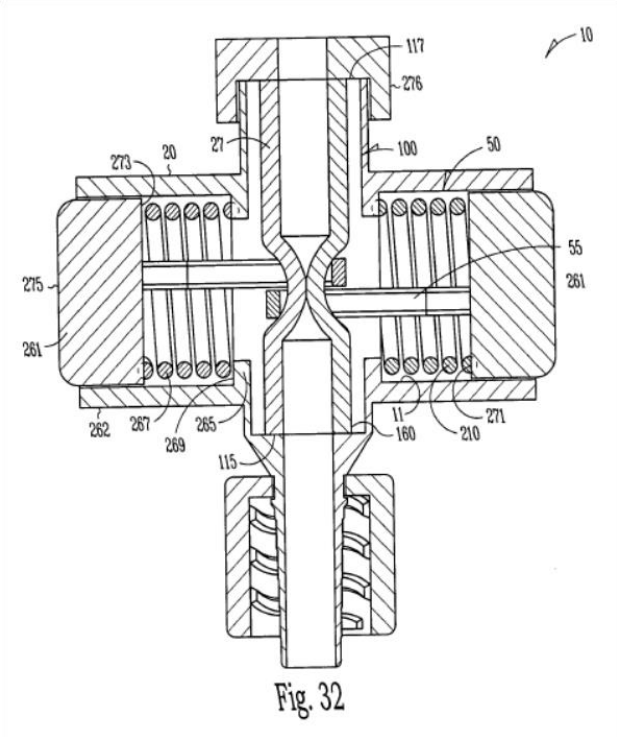


Fig. 32

First End Subject to Blood Pressure

Id. at [0075], Fig. 32.

147. 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 circumferencially [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":

First Position – Actuator Buttons Undepressed

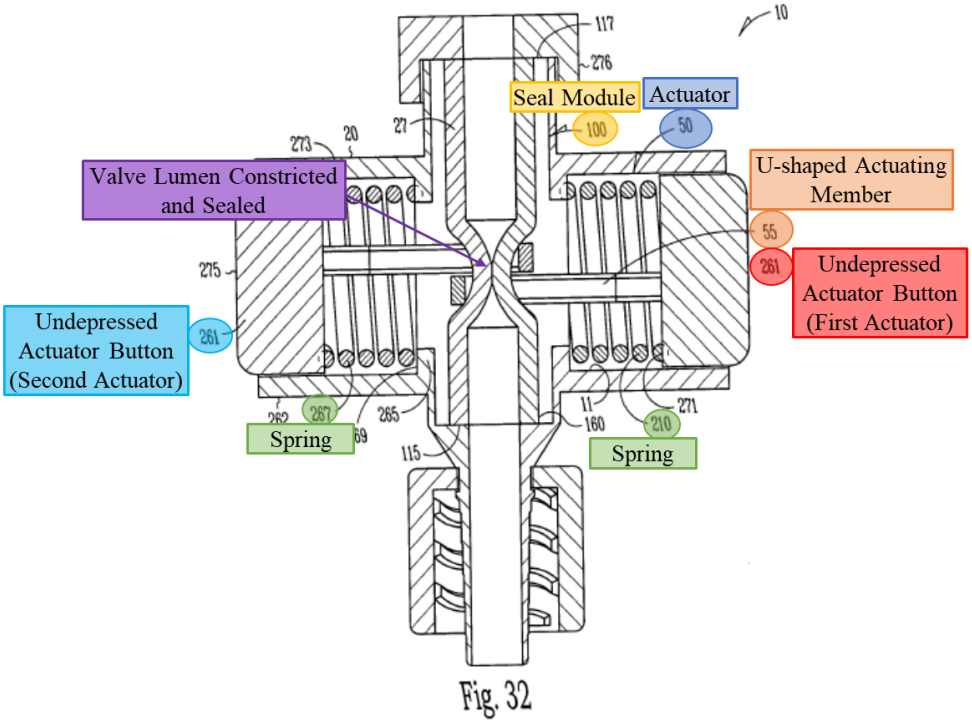


Fig. 32

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:

Second Position – Actuator Buttons Depressed

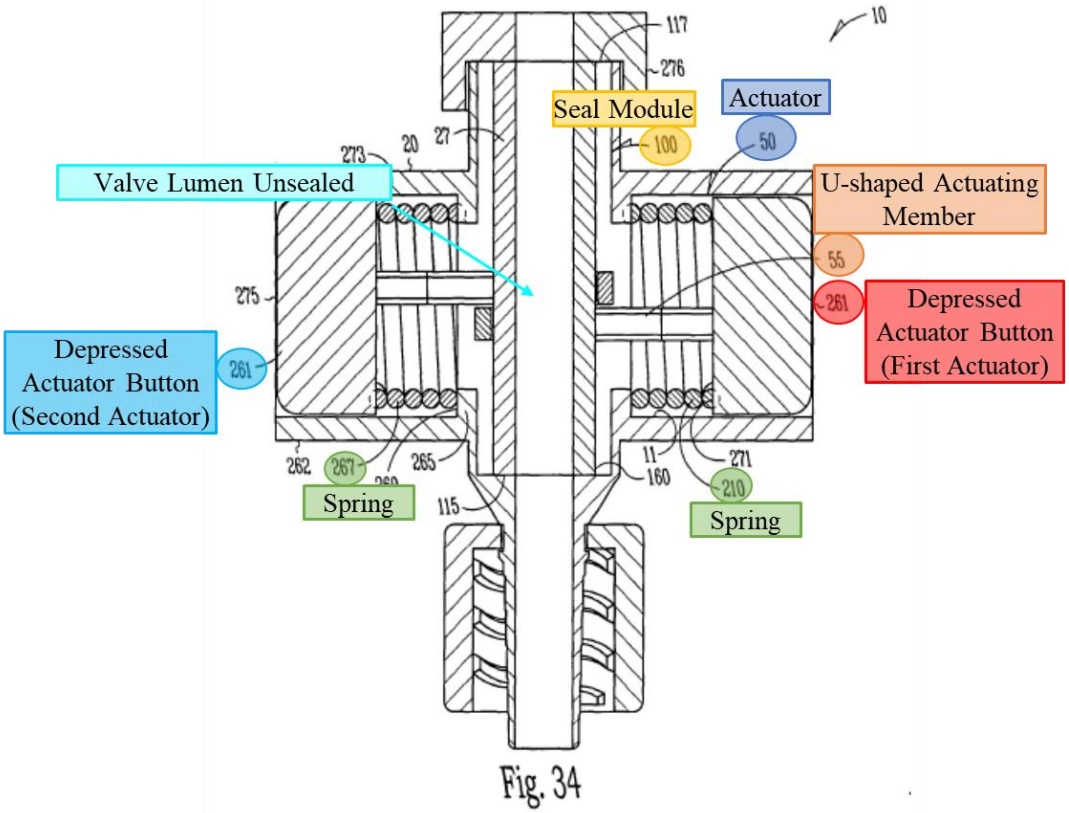


Fig. 34

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

148. 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].

149. 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 September 2017. 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.

150. 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 circumferencially [sic] disposed about the portion 108 of the seal module 100." Ex. 1005 (Schaffer) at [0077]. The phrase "at least partially circumferencially [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

151. 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].

152. 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.

153. 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. <u>Eller</u>

154. 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.

155. 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.

156. 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 20% - 4765	3 g	5.4 g	50 g	4.9 g	+
100% - 4755	14.3 g	2.8 g	25.4 g	11 g	+
90% - 4755 10% - 4014	0	0	1.4 g	0	++
80% - 4755 20% - 4014	0	0	0	0	++++
70% - 4755 30% - 4014	0	0	0	0	++++
60% - 4755 40% - 4014	0	0	Trace	0	+++

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.

157. 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.

158. 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. <u>Claim 6</u>

159. Claim 6 recites: "The aspiration catheter of claim 2 wherein, when the first actuator and the second actuator are in the first position, the valve lumen of the tubular member is configured to remain constricted and sealed when vacuum pressure is applied to a volume outside the valve lumen and adjacent to either a first end or a second end of the tubular member." Schaffer anticipates Claim 6 or renders it obvious alone or in combination with Hartley ***or*** Eller.

160. 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 September 2017 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.").

161. 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 September 2017 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":

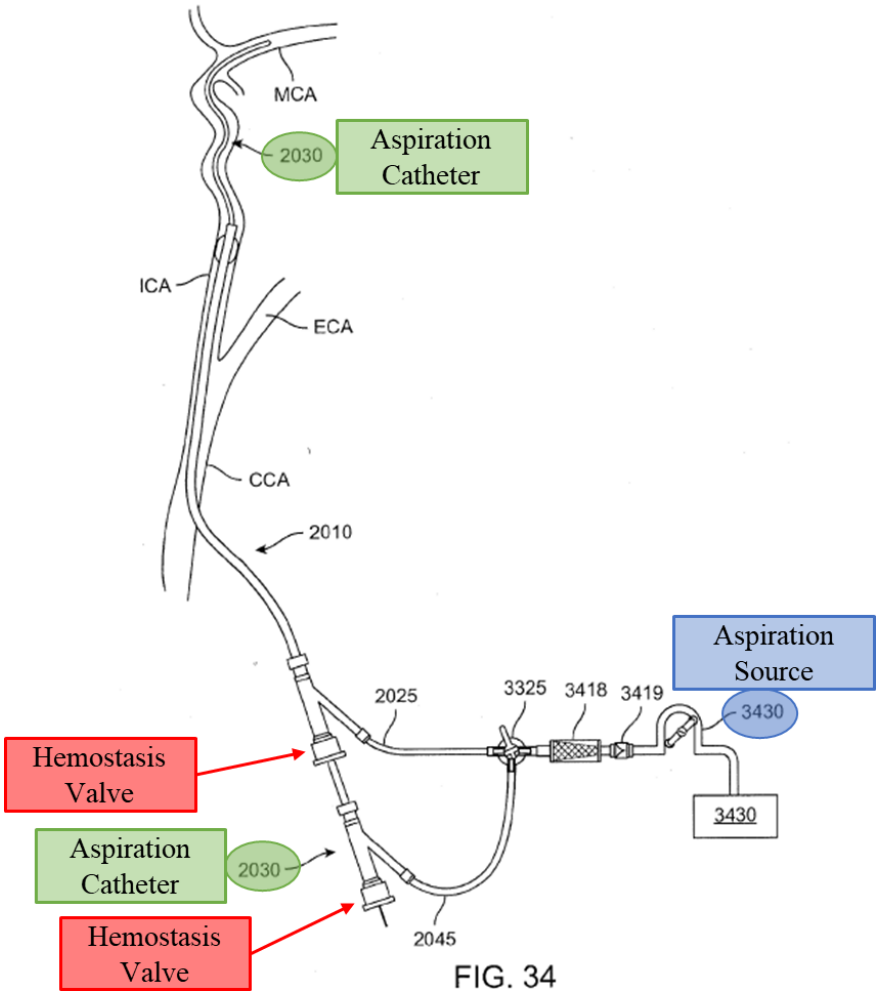


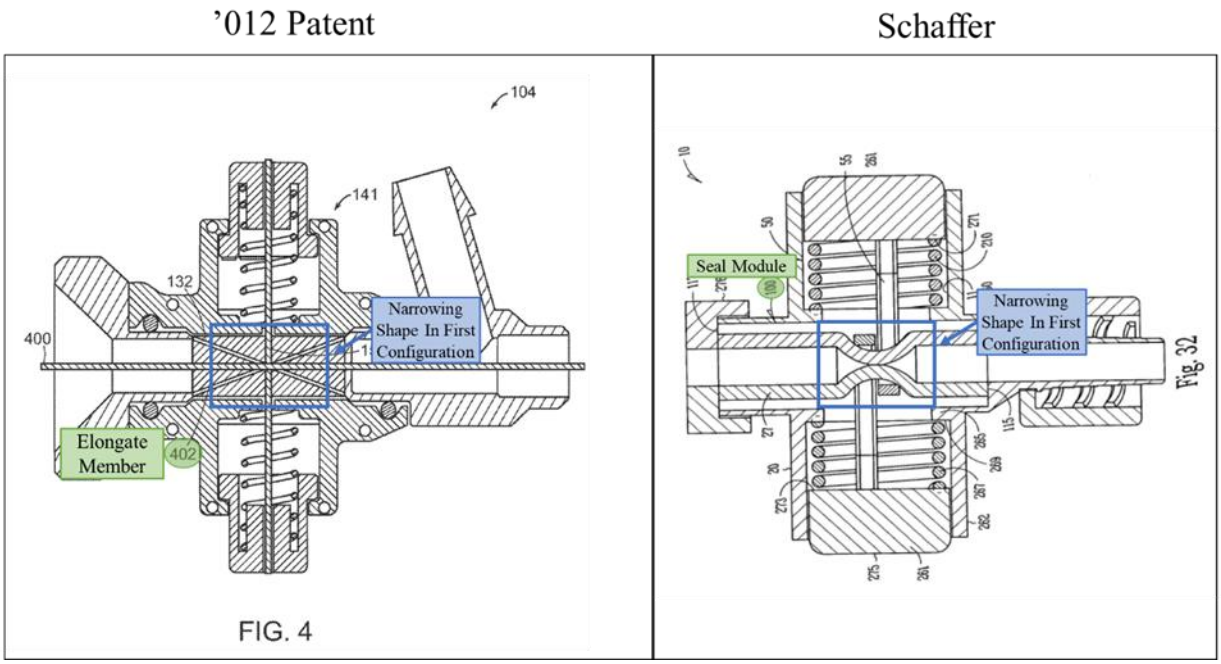
FIG. 34

Ex. 1011 (Garrison) at [0098], Fig. 34; *see also id.* at [0130]-[0142].

162. 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.

163. In addition, the only description I see in the '012 patent 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. 1001 ('012 patent) at 10:57-67. 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:



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 '012 patent 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 '012 patent describes.

164. 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.

165. 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

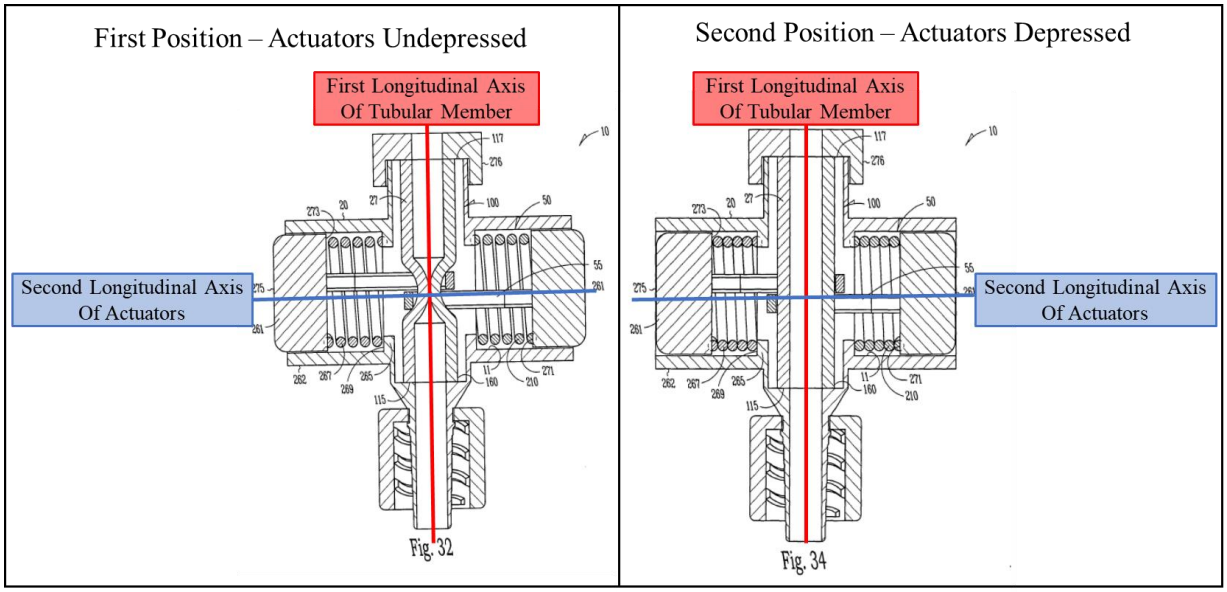
with tighter windings. The selection of springs would have been something commonly done by persons of ordinary skill in the art and well within their skill level. As I explained previously, a person of ordinary skill in the art would have reasonably expected success in selecting an appropriate material for the seal module in view of the range of suitable lumen materials disclosed in the prior art. *Supra* ¶108. 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 increase their flexibility and improve the seal around the cylindrical seal module. *Supra* ¶150.

G. Claim 7

166. Claim 7 recites: "The aspiration catheter of claim 2 wherein the valve lumen of the tubular member extends a long [sic] a first longitudinal axis, wherein the first actuator and the second 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, Schaffer anticipates Claim 7 or renders it obvious alone or in combination with Hartley ***or*** Eller.

167. 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

168. Claim 8 recites: "The aspiration catheter of claim 2 wherein the first spring comprises a first compression spring coupled to the first member and the second spring comprises a second compression spring coupled to the second member."[4] Schaffer discloses the additional limitations recited in Claim 8, and therefore, Schaffer anticipates Claim 8 or renders it obvious alone or in combination with Hartley ***or*** Eller.

[4] I note that the terms "first member" and "second member" recited in claim 8 lack antecedent basis. For purposes of my Declaration, I have interpreted the "first member" and "second member" recited in claim 8 to correspond with the "first actuator" and "second actuator" recited in claims 1 and 2.

169. 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":

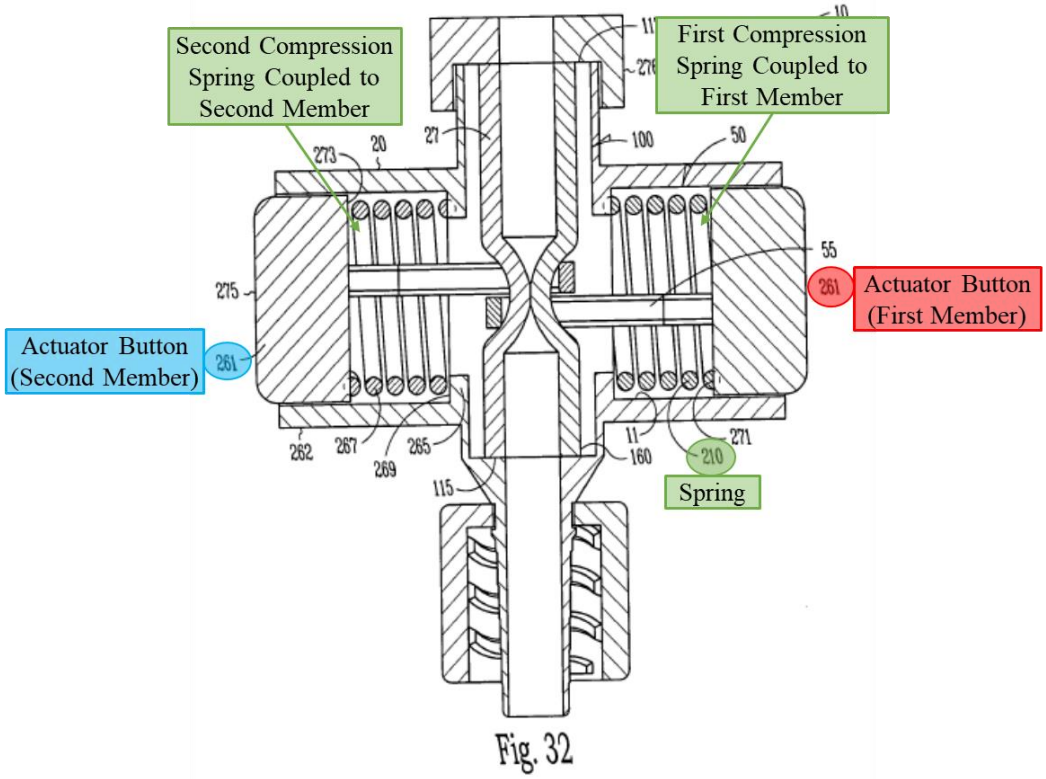


Fig. 32

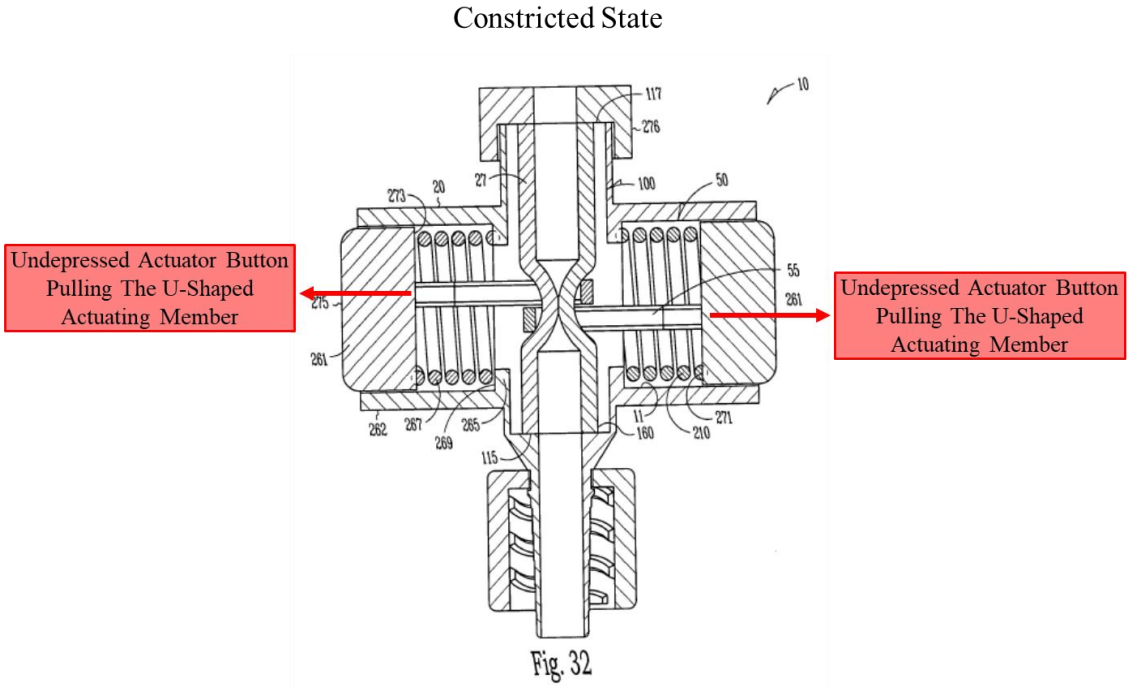
Ex. 1005 (Schaffer) at [0076], Figs. 31-34. Thus, Schaffer's valve has a "first spring [that] comprises a first compression spring coupled to the first member and [a] second spring [that] comprises a second compression spring coupled to the second member."

I. Claim 9

170. Claim 9 recites: "The aspiration catheter of claim 2 wherein, in the first position, the first actuator and the second actuator pull the filament to

circumferentially constrict the collapsible tubular member such that the valve lumen is constricted and sealed." Schaffer discloses the additional limitations recited in Claim 9, and therefore, Schaffer anticipates Claim 9 or renders it obvious alone or in combination with Hartley ***or*** Eller.

171. 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.

VII. GROUNDS 5-7: CLAIMS 1-9 OBVIOUS OVER SCHAFFER IN COMBINATION WITH GARRISON AND OPTIONALLY HARTLEY OR ELLER

172. As I explained in Grounds 1-4 above, using a hemostasis valve with an aspiration catheter to prevent the leakage of blood and air during intravascular procedures was not a novel concept in September 2017. Garrison's system includes 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":

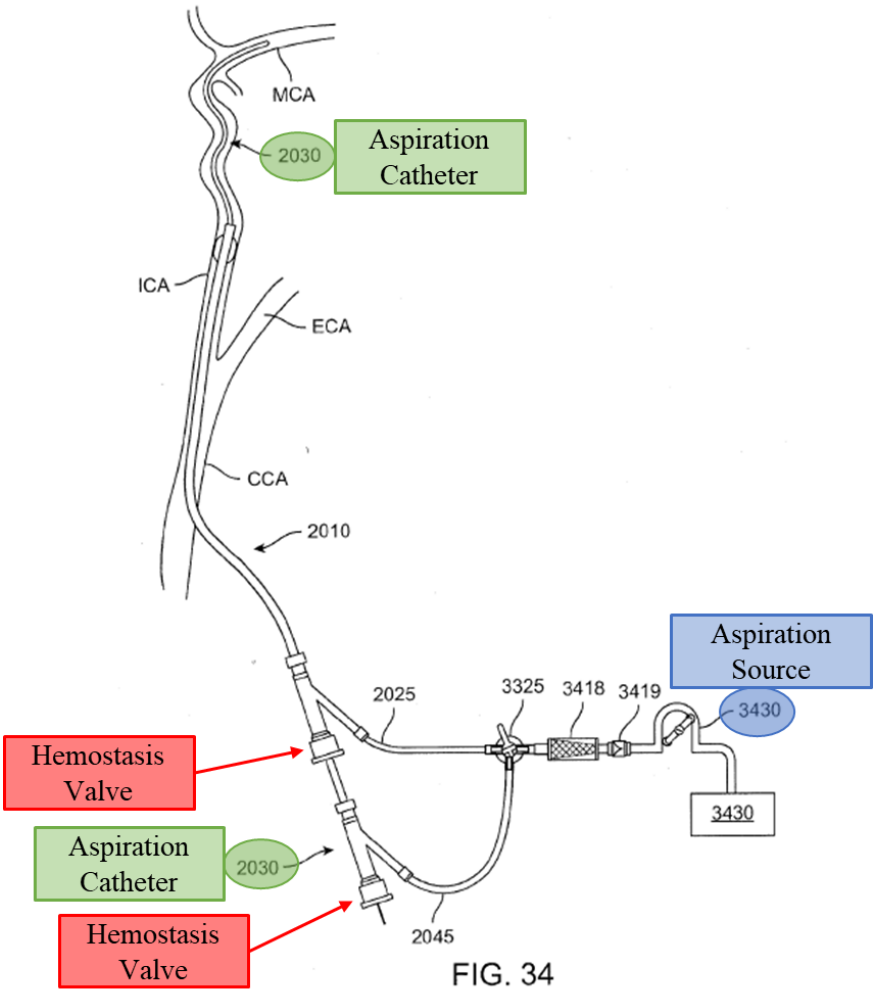


FIG. 34

Ex. 1011 (Garrison) at Abstract, [0098]; *see also id.*, [0130]-[0132], Fig. 34.

173. 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 Schaffer's hemostasis valve 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 1-9 obvious over Schaffer in combination Garrison and optionally Hartley ***or*** Eller.

A. Claim 1

174. Based on my review of the prior art, it is my opinion that Schaffer in combination with Garrison and optionally Hartley ***or*** Eller renders claim 1 obvious.

1. Preamble

175. The preamble of Claim 1 recites: "An aspiration catheter." If this preamble is limiting, Garrison discloses an aspiration catheter.

176. Garrison discloses "a system of devices for treating an artery" that includes "an arterial access device 2010 (sometimes referred to herein as an arterial access sheath) having an internal lumen and a port 2015." Ex. 1011 (Garrison) at Abstract, [0050]. Garrison's devices "provide aspiration and passive flow reversal either from the access sheath, a guide catheter, or a catheter for the purpose of minimizing distal emboli." *Id*. at [0048]. Garrison further discloses that "[a]ny or all of the arterial access device 2010 and the catheter 2030 may be connected to sources of passive or active aspiration via flow lines 2025 or 2045 (FIG. 1) on the devices":

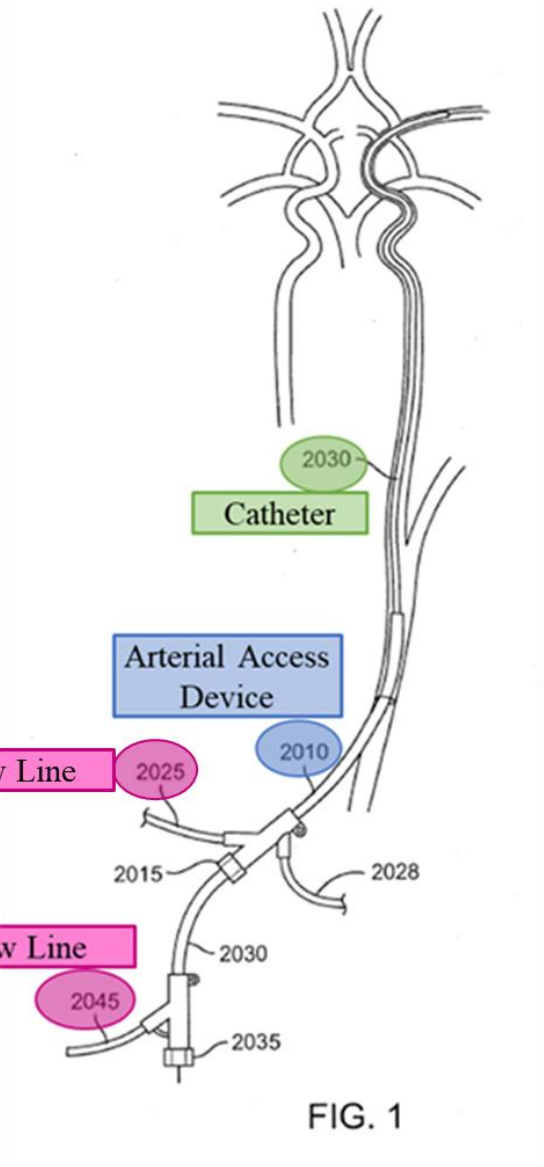
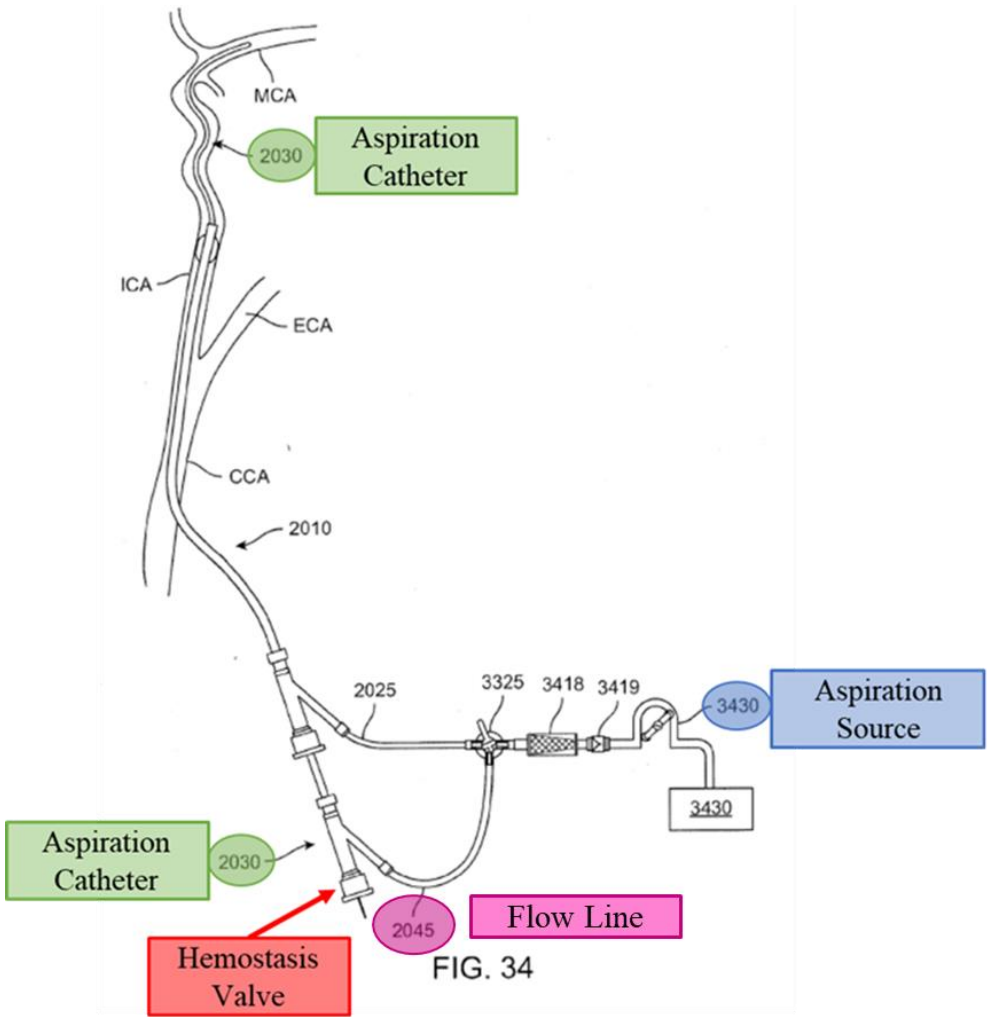


FIG. 1

Id. at [0130], Fig. 1; *see also id.* at [0071] ("The flow line 905 may also be connected to an aspiration source such as a pump or a syringe."). Accordingly, Garrison's access device 2010 and catheter 2030 are each an aspiration catheter.

177. Garrison discloses additional examples of aspiration systems, including the system below having an aspiration catheter [green], an aspiration source (e.g., aspiration pump) [blue], and at least one hemostasis valve [red]:



Ex. 1011 (Garrison) at Fig. 34; *see also id.* at [0098], [0131]-[0134] (describing Figure 34 and related figures). Garrison explains that the catheter 2030 may be connected to sources of passive or active aspiration via flow line[] … 2045." *Id.* at [0130]. Garrison further disclose that the "catheter 2030 may then be used to apply aspiration to the occlusion." *Id.* at [0054]. Again, Garrison's catheter 2030 is an "aspiration catheter."

2. Tubular Body

178. Claim 1 next recites: "an elongate, flexible tubular body, having a proximal end, a distal end and a central lumen." Garrison describes several "tubular bod[ies]" that meet the limitations of claim 1.

179. First, Garrison discloses "one or more catheters 2030 to provide distal access for additional devices, localized fluid or contrast delivery, or localized aspiration at a location distal of the distal-most end of the arterial access device 2010." Ex. 1011 (Garrison) at [0054]. Garrison explains that the "catheter 2030 … may also be used to deliver additional catheters and/or interventional devices to the stie of the occlusion. *Id.* Such an arrangement is shown in, for example, Garrison's Figure 2, which illustrates a device (4100) extending through catheter 2030. *Id.* at Fig. 2.

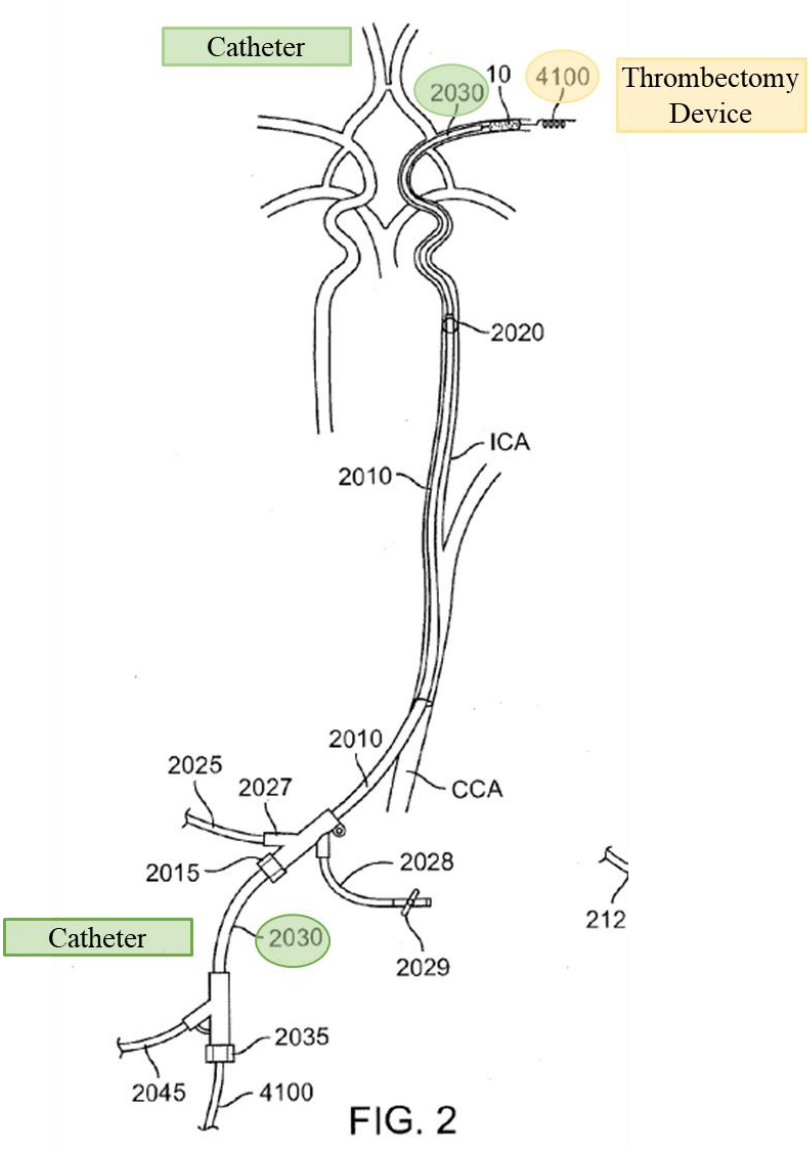


FIG. 2

Thus, catheter 2030 includes a central lumen extending through the catheter to allow for "distal access for additional devices, localized fluid or contrast delivery, or localized aspiration" through the catheter. *Id.* As illustrated in Figure 1 below, Garrison's catheter is passed through a hemostasis valve, into the lumen of the arterial access device 2010, and ultimately to the treatment site in the patient's body:

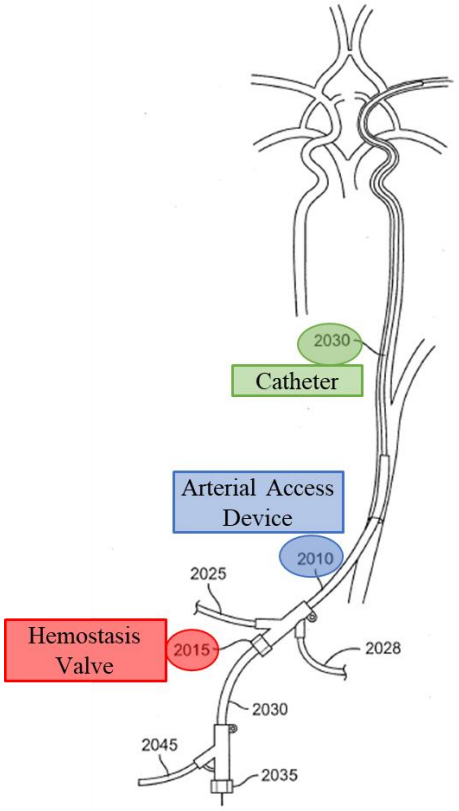


FIG. 1

Id. at [0054], [0100], Fig. 1. The catheter 2030 is elongate and includes a proximal and distal end. The catheter 2030 is also flexible as illustrated by the catheter's ability to track through the tortuous anatomy. Likewise, a smaller catheter placed through catheter 2030 also has an elongate, flexible tubular body, having a proximal end, a distal end and a central lumen. As shown in Figure 1 above, a guidewire is placed through the catheters. A smaller catheter inserted through the hemostasis valve in catheter 2030 would travel over the guidewire and, therefore, also has an internal lumen (consistent with all catheters). The smaller catheter must travel the same path as catheter 2030 and, therefore, must also be flexible.

180. Garrison describes many other catheters having similar features. For example, Garrison explains that Figure 22, shown below, "shows a schematic view of an exemplary catheter 105" with "an external dimension that is sized and shaped for insertion into a blood vessel":

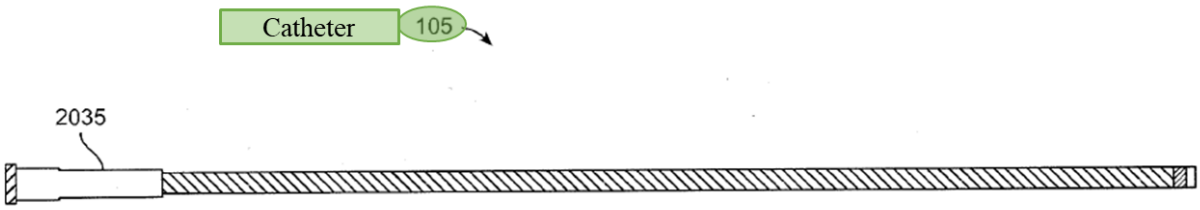


FIG. 22

Id. at [0098], Fig. 22. As shown in Figure 22 above, the catheter has an elongate, tubular body with a proximal end and a distal end. *Id.* Garrison discloses that the catheter includes a "distal-most portion [that] is constructed to be more flexible than the proximal portion, with **one or more flexible sections, to successfully navigate the internal carotid artery curvature to reach target sites in the distal ICA or cerebral arteries**." *Id.* at [0101] (emphasis added). Consequently, Garrison's catheters 2030/105 (and any smaller catheter inserted through these catheters) are "an elongate, flexible tubular body, having a proximal end, a distal end and a central lumen" as claimed in the '012 patent.

181. Garrison discloses additional embodiments of smaller diameter catheters, such as "a tapered co-axial inner member 2652 … sized and shaped to be inserted through the internal lumen of the catheter":

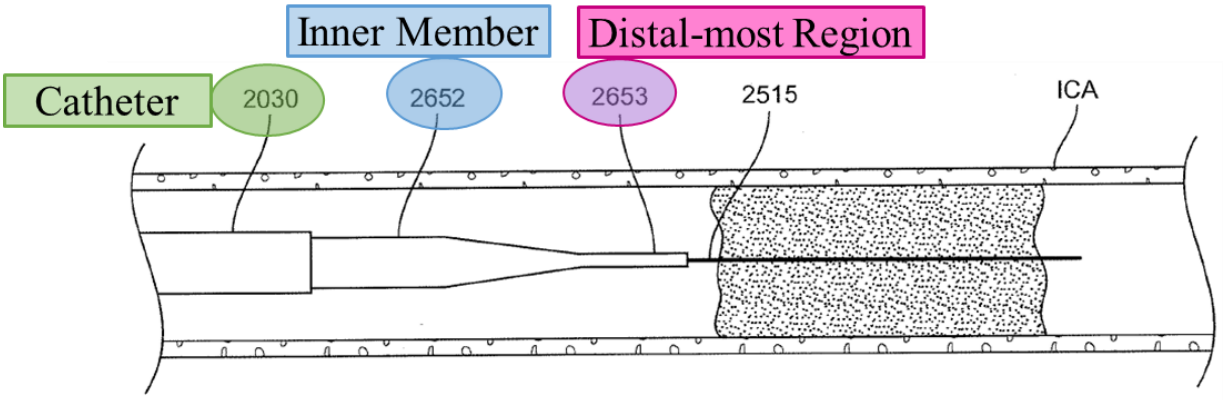


FIG. 25B

Id. at [0112], Fig. 25B. The inner member 2652 extends from a proximal end (not shown in Figure 25B) to a distal end that has a "distal-most region 2653 that extends distally past the tapered portion." *Id.* at [0113]. Garrison discloses that the inner member includes "an internal lumen" through which "a guidewire 2515 or microcatheter" can extend." *Id.*, [0112]. Thus, the inner member has an elongate, tubular body, a proximal and distal end, and a central lumen. Garrison states that "[t]he material of the dilator (inner member 2652) is flexible enough and the taper is long enough to create a smooth transition between the flexibility of the guide wire and the catheter" which helps "facilitate advancement of the catheter through the curved anatomy and into the target cerebral vasculature." *Id.*, [0114]. Garrison's inner member 2652 is therefore "an elongate, flexible tubular body, having a proximal end, a distal end and a central lumen" as claimed in the '012 patent.

182. Garrison also discloses an embodiment that includes "an anchor device which is configured to be easily navigable through the vasculature to a location distal to the cerebral occlusion." *Id.* at [0115]. "[T]he anchor is a microcatheter 2505 with a distal balloon 2510":

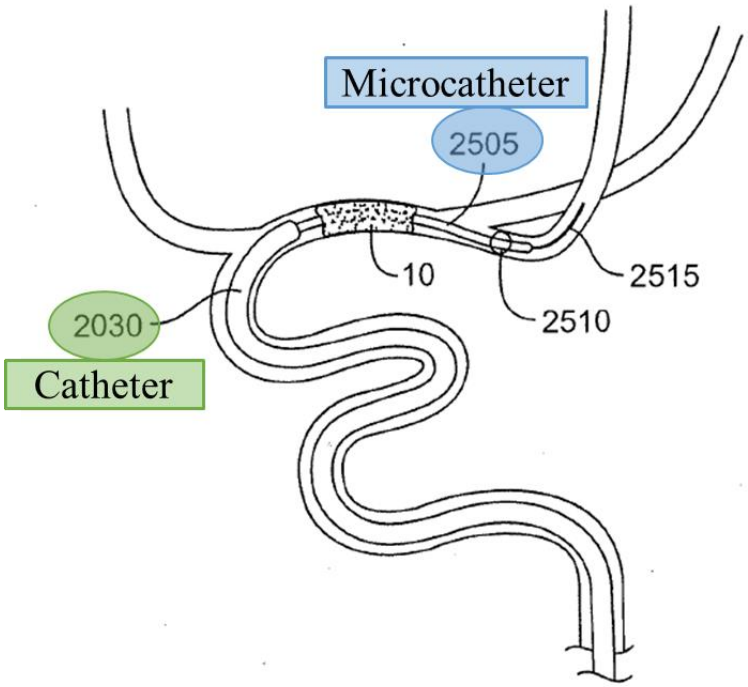


FIG. 26

Id. at Fig. 26. Garrison explains that the "microcatheter 2505 is placed over a guidewire 2515 to a site distal of the target treatment area, for example a thrombus 10." *Id.* at [0115]. The microcatheter therefore includes a central lumen through which the guidewire 2515 can be placed. As shown in Figure 26 above, the microcatheter is flexible and has an elongate, tubular body with a proximal end and a distal end. Garrison's microcatheter 2505 is therefore "an elongate, flexible

tubular body, having a proximal end, a distal end and a central lumen" as claimed in the '012 patent.

3. Hemostasis Valve

183. Claim 1 next recites "a hemostasis valve on the proximal end of the catheter." Garrison discloses this limitation.

184. Garrison's arterial access system includes several hemostasis valves that are located on the proximal end of a catheter. For example, Garrison discloses that the catheter 2030 (i.e., aspiration catheter discussed above) has a "proximal hub 2065" and 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":

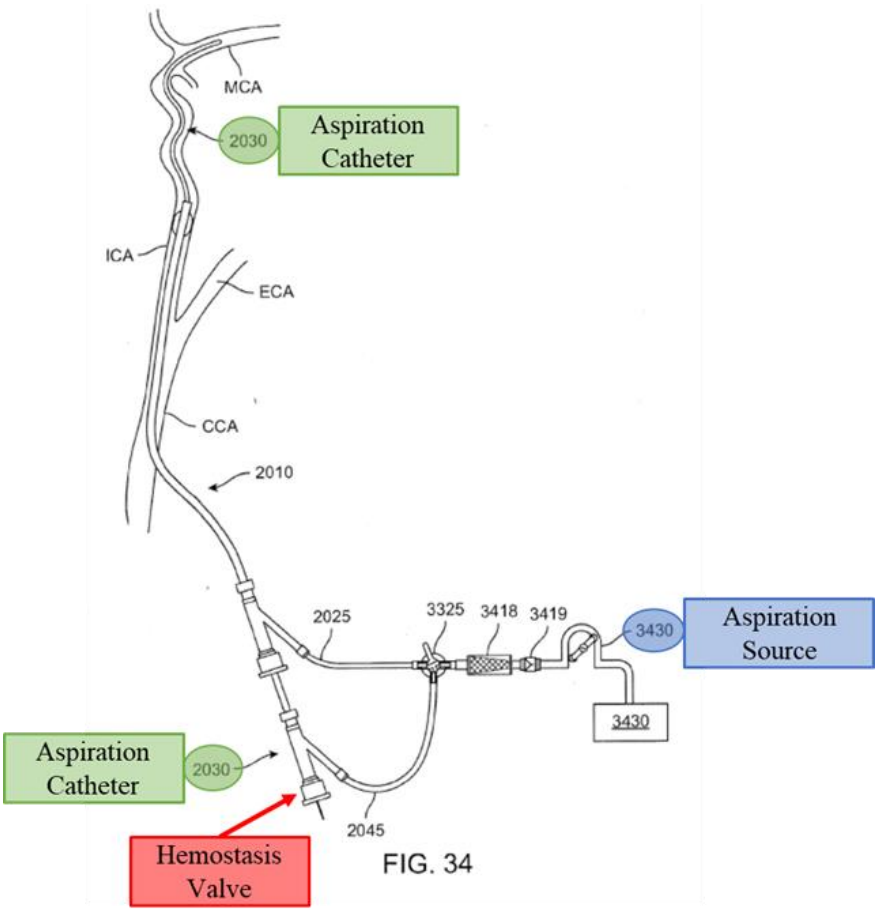


FIG. 34

Ex. 1011 (Garrison) at [0098], Fig. 34. 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 catheter 2030's hemostasis valve in Figure 34 is located at the end of the proximal adaptor as in, for example, Figures 1, 3, and 5.

185. 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":

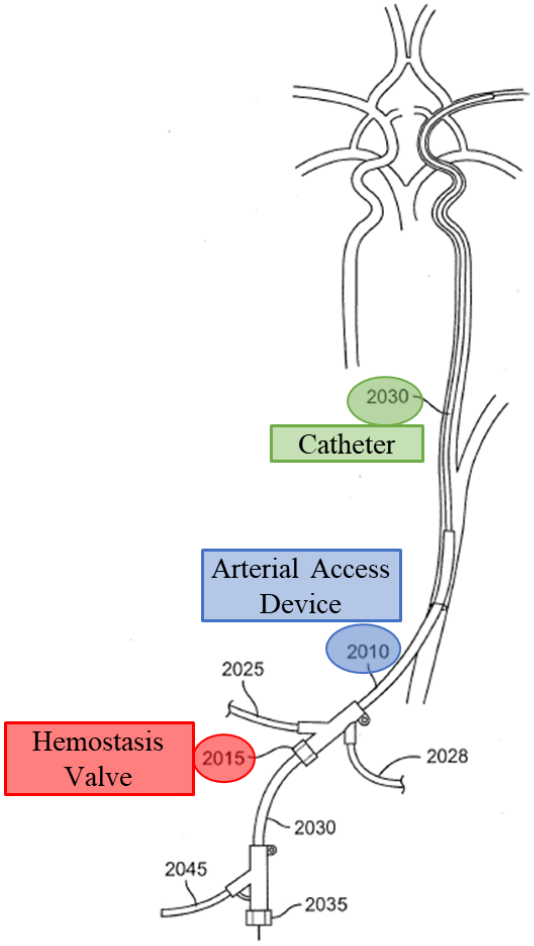


FIG. 1

Ex. 1011 (Garrison) at [0054], [0059], Fig. 1. As shown in Figure 1 above, the hemostasis valve in the port 2015 is located on the proximal end of the catheter of the access device 2010. *Id.*

186. 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":

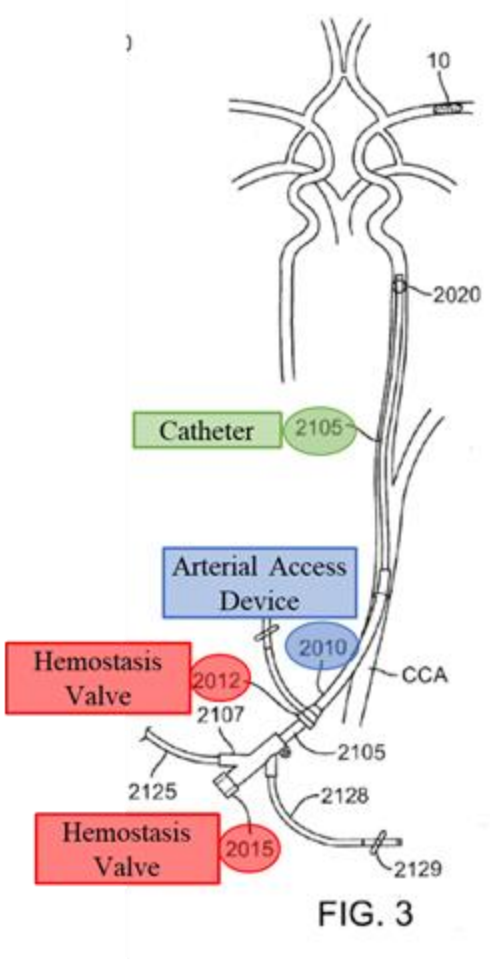
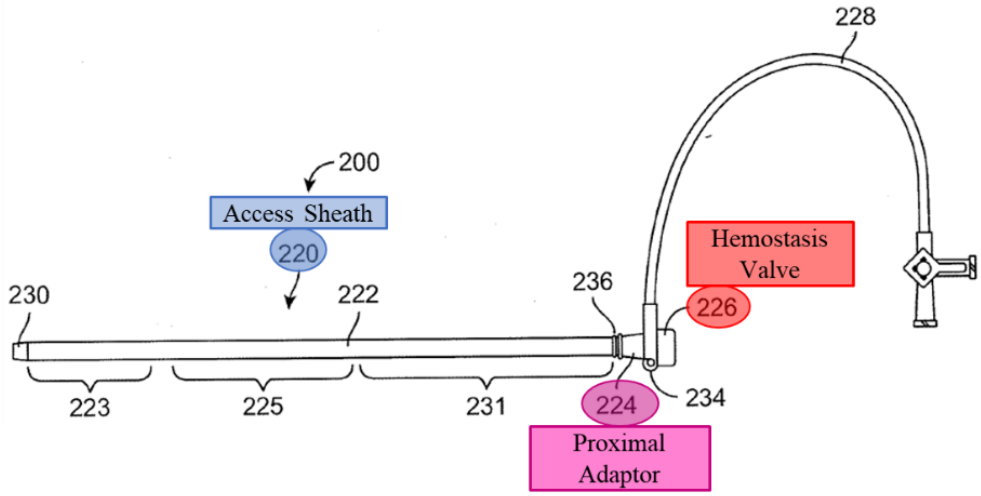


FIG. 3

Id. at [00535], Fig. 3. As shown in Figure 3, the hemostasis valve 2012 is located 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 2015 is located on the proximal end of the guide catheter 2105. *Id.*

187. 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 on the proximal end of the catheter of the access sheath 220. *Id.*

188. Garrison explains that the hemostasis valves in its system "allow for the introduction of devices therein while preventing or minimizing blood loss via the internal lumen during the procedure." *Id.* at [0062]. Garrison also discloses that "[t]he hemostasis valve 226 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)." *Id.*

189. Schaffer discloses the limitations of the hemostasis valve recited in claim 1 or renders those limitations obvious alone or in combination with Hartley or Eller, for the reasons that I explained previously in Grounds 1-4. *Supra* ¶¶57-171. A person of ordinary skill in the art September 2017 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.

190. 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.

191. 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].

192. 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.

193. Fourth, combing 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 September 2017.

194. Fifth, a person of ordinary skill in the art in September 2017 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.

195. A person of ordinary skill in the art would have reasonably expected success in using Schaffer's hemostasis valve with Garrison's catheters in September 2017. 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.

196. 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.

197. When Schaffer's valve, either as described in Schaffer or as combined with Hartley's string or Eller's wire member, is used as the hemostasis valve in Garrison's artery treatment system, each of the "tubular bod[ies]" disclosed in Garrison would pass through the lumen of Schaffer's hemostasis valve prior to being inserted into the patient's vasculature. *Supra* ¶¶178-182 (section titled Tubular Body); Ex. 1011 (Garrison) at [0054], [0090], [0100], [0112]-[0115]], Figs. 1-3, 26. Accordingly, the "central lumen" defined by

Garrison's tubular bodies would be placed coaxially within the valve lumen of Schaffer's hemostasis valve. Schaffer's valve lumen would therefore be "in communication with the central lumen" as claimed in the '012 patent.

198. For the above reasons, it is my opinion that claim 1 of the '012 patent would have been obvious to a person of ordinary skill in the art in view of Schaffer combined with Garrison and optionally Hartley ***or*** Eller.

4. Remaining Limitations In Claim 1

199. Schaffer alone or in combination with Hartley or Eller disclose or render obvious the remaining limitations of claim 1 (e.g., collapsible tubular sidewall and constricting mechanism) for the reasons I provided in Grounds 1-4. *See* ¶¶82-125 (explaining how Schaffer, Hartley, and Eller meet the "collapsible tubular sidewall" and "constricting mechanism" limitations). I incorporate those prior portions of this Declaration here.

B. Claims 2-9

200. Schaffer discloses the additional limitations recited by claims 2-9 of the '012 patent or renders those limitations obvious alone or in combination with Hartley ***or*** Eller for the reasons I explained previously in Grounds 1-4. *Supra* ¶¶126-171 (explaining how Schaffer, Hartley, and Eller disclose or render obvious). I incorporate those prior portions of this Declaration here. A person of ordinary skill in the art September 2017 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 for the reasons I explained in the preceding section for claim 1. For these reasons, it is my opinion that claims 2-9 of the '012 patent would have been obvious to a person of ordinary skill in the art in view of Schaffer combined with Garrison and optionally Hartley ***or*** Eller.

VIII. SECONDARY CONSIDERATIONS

201. I am not aware of any secondary considerations of nonobviousness relating to the claims of the '012 patent.

202. The devices claimed in the '012 patent are not new, and were invented long before September 2017. 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 hemostasis valves were available on the market by September 2017, 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 '012 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.

203. I am aware that Patent Owner argued in the related Litigation that the valve described in the '012 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

204. For the foregoing reasons, it is my opinion that Claims 1-9 of the '012 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.

205. 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.

206. 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 November 8, 2024 in San Francisco, CA.

troy thornton

Troy Thornton