

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. 11,865,291

**DECLARATION OF TROY L. THORNTON
IN SUPPORT OF PETITION FOR *INTER PARTES* REVIEW OF
U.S. PATENT NO. 11,865,291**

<i>Imperative Care v. Inari Medical</i> US Patent 11,865,291 Imperative Care Ex. 1003

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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”)
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1007	U.S. Patent No. 9,980,813 B1 to Eller (“Eller”)
1008	Certified File History of U.S. Patent Application 10/371,190 (Schaffer File History)
1009	U.S. Patent No. 5,429,616 to Schaffer (“Schaffer ’616”)
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1011	U.S. Patent Publication No. 2015/0173782 A1 to Garrison et al. (“Garrison”)
1012	U.S. Patent No. 11,697,011 (“the ’011 patent”)
1013	Inari’s Supplemental Infringement Contentions (without claim charts) from <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , No. 24-cv-3117 (N.D. Cal.) (served February 7, 2025).
1014	New Oxford American Dictionary, 3rd ed. (2010) – definitions of “diameter,” “filament,” and “loop”
1015	RESERVED

Exhibit No.	Description
1016	U.S. Patent No. 12,109,384 B2 to Merritt et al.
1017	Decision Granting Institution of <i>Inter Partes</i> Review for U.S. Patent No. 11,697,011 (Paper 7) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2024-01157 (P.T.A.B. Jan. 23, 2025)
1018	PCT Patent Publication WO 2018/019829 A1 to Brady et al.
1019	Inari’s Notice of Motion and Motion for Leave to File Third Amended Complaint (Dkt. #88) in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 24-cv-03117-EKL (N.D. Cal.) (filed March 5, 2025)
1020	U.S. Patent No. 6,776,770 B2 to Trerotola
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1024	Imperative Care’s Opposition to Inari’s Motion for Leave to File Third Amended Complaint (Dkt. #98) in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 24-cv-03117-EKL (N.D. Cal.) (filed March 26, 2025)
1025	Imperative Care’s Notice of Motion and Motion to Stay Pending Inter Partes Review (Dkt. #100) in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 24-cv-03117-EKL (N.D. Cal.) (filed April 2, 2025)
1026	Patent Owner’s Exhibit 2002 filed in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-00289 (P.T.A.B.)
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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 1-8, and 12-19 of U.S. Patent No. 11,865,291 (“the ’291 patent,” Ex. 1001). For the reasons discussed herein, I have concluded that Claims 1-8 and 12-19 of the ’291 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 ’291 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 ’291 patent, Inari Medical, Inc. (“Inari” or “Patent Owner”).

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

B. Experience and Qualifications

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

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

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

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

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

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

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

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

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

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

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

14. In summary, I have more than 35 years of experience in the cardiovascular medical device field, including significant experience designing, developing, testing, and manufacturing catheters and catheter systems for minimally invasive cardiovascular procedures. I am therefore very familiar with the concepts of catheters, catheter systems, and hemostasis valves, and I believe I am well placed to comment on the understanding of a person of ordinary skill in the art in the context of the '291 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 '291 patent;
- The level of ordinary skill in the art pertaining to the '291 patent;
- The teachings of the prior art; and
- Whether Claims 1-8 and 12-19 of the '291 patent are anticipated by the prior art or would have been obvious to a person of ordinary skill in the art at the time of the alleged invention in view of the prior art.

D. Materials Considered

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

17. I have also prepared Declarations in support of other IPR petitions filed by Imperative Care challenging patents owned by Inari Medical. I have considered the arguments made by Inari Medical in those IPRs and any institution decisions issued by the Board.

18. I have also relied on my education, training, and experience, and my knowledge of pertinent literature in the field of the '291 patent.

II. APPLICABLE LEGAL STANDARDS

19. 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 '291 patent.

20. 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

21. 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.

22. 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

23. 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 6, 2017).

24. 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

25. 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.

26. 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.

27. 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 ’291 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.

28. 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.

29. 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.

30. 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.

31. 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.

32. 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 1-8 and 12-19 of the '291 patent would have been non-obvious, as further explained in Section § VIII (Heading: "Secondary Considerations") below.

D. Person of Ordinary Skill in the Art

33. It is my understanding that when interpreting the claims of the '291 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 '291 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.

34. 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.

35. 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.

36. Based on my review of the specification and claims of the '291 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.

37. 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 '291 PATENT

A. Summary of the '291 Patent

38. The '291 patent describes embodiments of a hemostasis valve (also referred to in the '291 patent as a “garrote” valve) for use with a catheter during minimally invasive intravascular procedures. Ex. 1001 ('291 patent) at 5:55-6:6.

39. As illustrated in Figure 2 of the '291 patent below, the valve described in the '291 patent includes a “housing 128” that defines an “interior channel 130,” and a collapsible “elongate member 132” that extends through the housing:

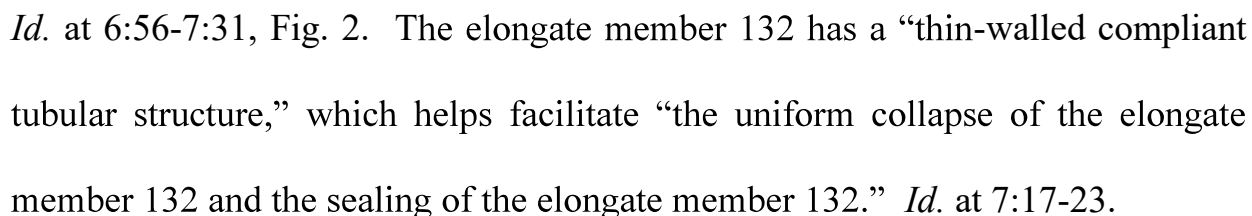
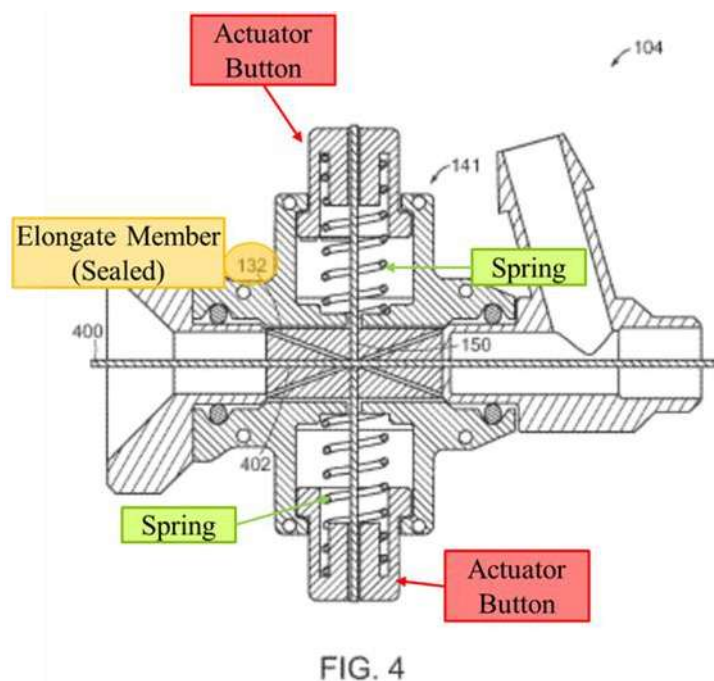


FIG. 1



150 that can extend at least partially around the elongate member 132.” *Id.* at 8:8-12. The “filament 150 can be coupled to the actuator 142 such that the filament 150 selectively constricts, collapses, and/or seals the elongate member 132 ... based on the movement and/or position of the actuator 142.” *Id.* at 9:24-28.

41. The valve also includes a “bias feature,” such as a spring (148-A and 148-B), which biases the actuator toward the open or closed configuration. *Id.* at 8:38-56. Figure 4 shows the valve biased toward a first, closed position:



Id. at 8:38-56, Fig. 2.

42. Depressing the actuator buttons releases tension on the filament, “thereby allowing the expansion of the elongate member 132 and the unsealing of the central lumen 138 of the elongate member 132”:

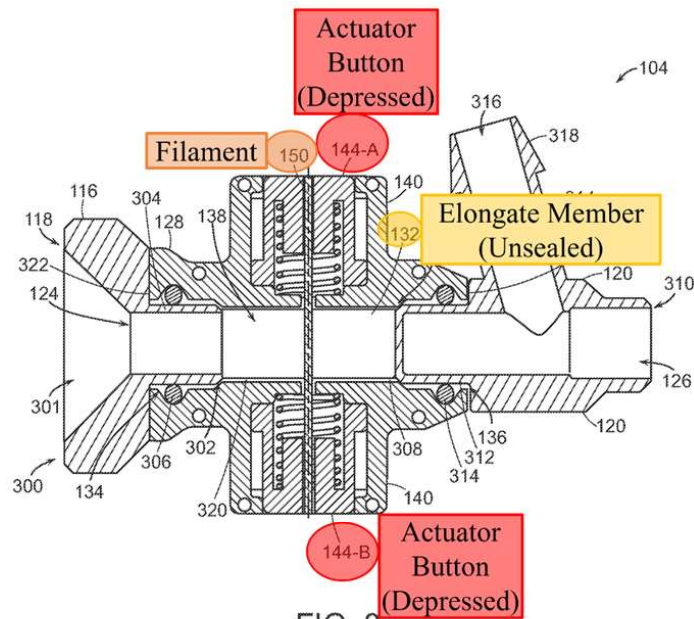


FIG. 3

Id. at 9:54-62, Fig. 3.

43. The filament 150 can constrict the elongate member around a tool 400 inserted through the central lumen of the elongate member, “create[ing] a seal between the elongate member 132 and the tool,” as illustrated in Figure 4:

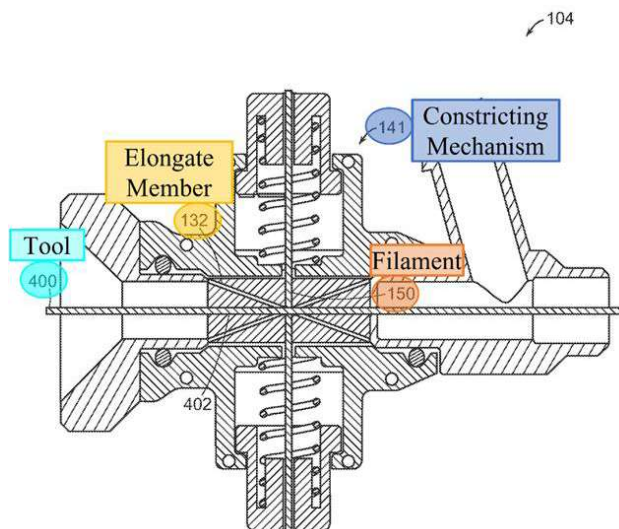


FIG. 4

Id. at 12:4-15, Fig. 4.

44. 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 as shown in Figure 7, or a “U-shaped section between the two ends of the filament 150” as shown in Figures 8-9:

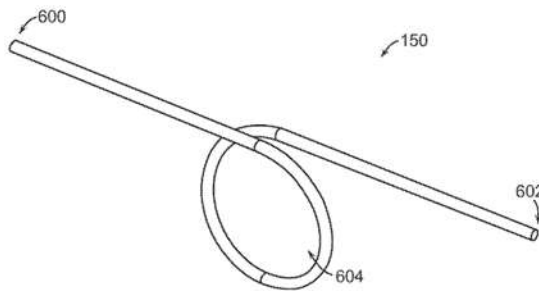


FIG. 6

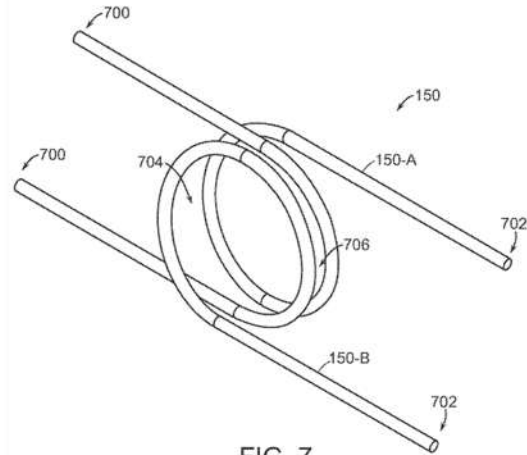


FIG. 7

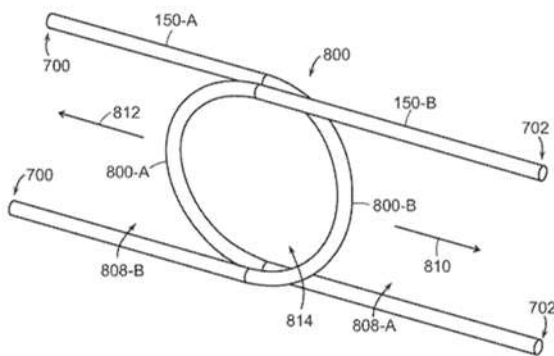


FIG. 8

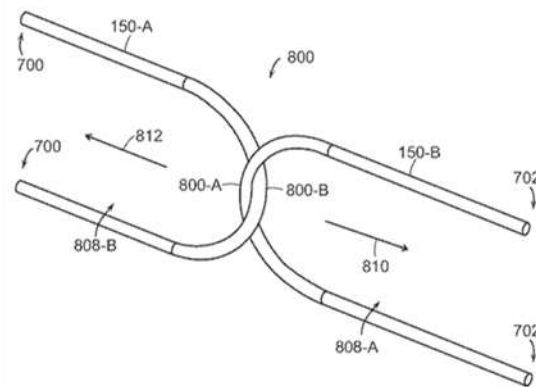


FIG. 9

Id. at 13:16-14:34, Figs. 6-9.

45. The patent also discloses that “[t]he filament can be made from a variety of materials including, for example, a polymer, a synthetic, and/or a metal.” *Id.* at 9:13-15. The filament may also “comprise multiple filaments,” such as in

Figures 7-9, where “each of the multiple filaments can have a first end 700 and a second end 702”:

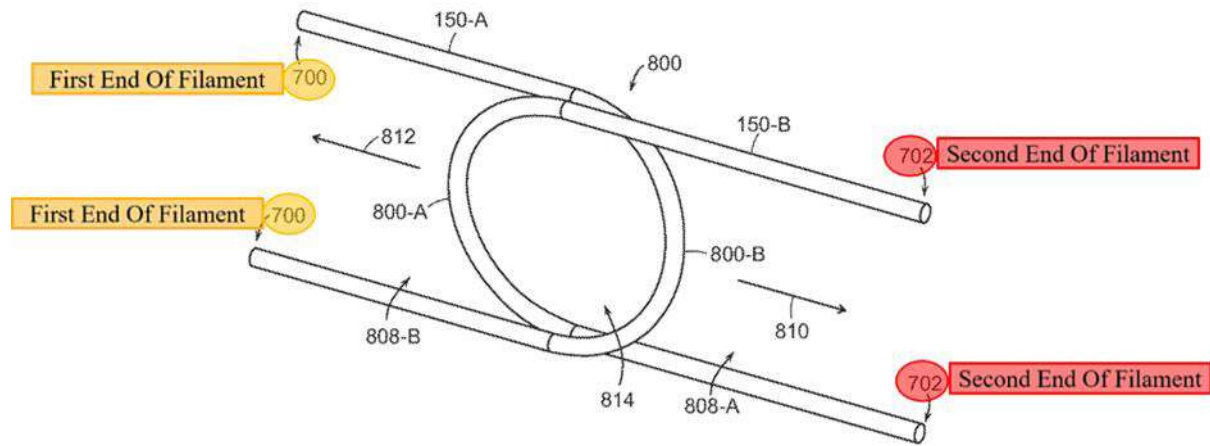


FIG. 8

Id. at 12:61-67, Fig. 8.

B. The Challenged Claims

46. The challenged claims include Claims 1-8 and 12-19 of the '291 patent. Claims 1 and 18 are independent claims.

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

1. A hemostasis valve, comprising:

- a support;
- an actuator having at least a first member movably coupled to the support;
- an collapsible tubular sidewall defining a lumen carried by the support;
- a filament formed in a loop around the tubular sidewall, the filament having at least a first end portion extending away from the loop to the first member and;
- a spring configured to move the first member in a direction that pulls the first end portion away from the tubular sidewall, reducing a diameter of the lumen in response to reducing a diameter of the loop.

Ex. 1001 ('291 patent) at Claim 1.

C. Prosecution History

48. I have reviewed the '291 patent's prosecution history. I see that the Patent Examiner did not offer any rejections of the claims in an Office Action. Ex. 1002 ('291 patent prosecution history). I see from the front of the patent that the examiner did not have Schaffer (Ex. 1005) during prosecution, and therefore did not consider the unpatentability arguments presented in this Declaration based on Schaffer. I also do not see that the examiner ever mentioned Eller (Ex. 1007) during prosecution.

49. The Examiner issued a Notice of Allowability. Ex. 1002 at 392-395. In the Notice of Allowance, the Examiner stated that Hartley (Ex. 1006) was the "closest prior art of record." *Id.* at 393. The Examiner found that Hartley disclosed every limitation of the claims except a spring that "perform[s] a function required in the claimed invention, i.e. the spring configured to move the first member in a direction that pulls the first end portion away from the tubular sidewall, reducing a diameter of the lumen in response to reducing a diameter of the loop." *Id.* at 393-394. The Examiner did not address the combination of any references.

IV. CLAIM CONSTRUCTION

50. Independent claims 1 and 18 require a "filament." I have offered a construction for "filament" in previous IPRs involving related patents, including

IPRs for U.S. Patent Nos. 11,697,011 and 11,697,012. I understand that the '011 and '012 patents have the same specification as the '291 patent (the subject of this IPR). Consistent with my previous analysis, it is my opinion that a person of ordinary skill in the art in September 2017 would have understood the term “filament” in the claims of the '291 patent to mean at least: “one or more threads, lines, cords, ropes, ribbons, flat wires, sheets, or tapes.”

51. In the previous IPRs, Patent Owner has argued that my construction of “filament” is incomplete because I did not limit the claims to “flexible” filaments. However, the debate about whether the term “filament” is limited to “flexible” filaments does not impact my views on unpatentability. If the Board decides that “filament” is limited to “flexible” filaments, that decision is relevant only to Inari’s arguments about Schaffer. The meaning of “filament” does not have any impact on my opinions regarding Schaffer in combination with Hartley and Eller because Inari has never disputed that Hartley and Eller describe “flexible” filaments. As the Board preliminarily found in the Institution Decisions for the '011 and '012 Patents, Hartley and Eller include a “filament,” regardless of whether the claims are limited to “flexible” filaments. The Board specifically found that Patent Owner “does not dispute that Hartley and/or Eller disclose a flexible filament (e.g., flexible string or flexible wire).” Ex. 1023 ('012 Institution Decision) at 21, n.13. The Board also preliminarily found that a person of ordinary skill in the art would have found it

obvious to combine Hartley's or Eller's filament with Schaffer's valve. Therefore, Schaffer in combination with Hartley or Eller renders the claims obvious regardless of the construction of "filament."

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

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

1. The '011 Patent IPR

53. In the '011 patent IPR, I understand that the Institution Decision was Paper 7. In the Institution Decision, the Board found that it did not need to "expressly construe the term 'filament' in the manner urged by Petitioner." Ex. 1017 at 13 (Imperative Care was the Petitioner). However, the Board agreed with "Petitioner that a filament as claimed *encompasses* one or more threads, lines, cords, ropes, ribbons, flat wires, sheets, or tapes." *Id.* (emphasis in original). The Board observed that the '011 patent "lists those structures explicitly, but suggests that those are only examples and, thus, the term 'filament' may be broader than those structures." *Id.* I agree with the Board that '011 patent identifies those structures as examples of "filament" and that additional structures could fall within the meaning of a filament. However, I understand that the Board needs to construe the terms only to the extent necessary to resolve the issues presented in the IPR. In this

IPR, I believe my construction of “filament” resolves the issues presented because the structures identified in the construction (e.g., threads, lines, cords, ropes, ribbons, flat wires, sheets, or tapes) are found in the prior art (as I explain below).

54. I see that the Board also addressed Patent Owner’s argument that “filament” should mean “a thin, flexible length of material formed by one or more strands of material.” The Board did not adopt Patent Owner’s construction. *Id.* at 15 (Inari was the Patent Owner). The Board observed that “the ’011 patent never uses the words ‘thin’ or ‘flexible’ to describe the ‘filament.’” *Id.* The Board also observed that “the words ‘thin’ and ‘flexible’ inject potential ambiguities as a relative term” because “flexibility and rigidity exist along a spectrum” *Id.*

55. I see the Board also addressed Patent Owner’s argument that the filament must be flexible to “circumferentially constrict” the lumen to create a seal. The Board stated, “Wanting for further explanation, however, is why two bights like shown in Figures 8-9 that cooperatively receive an elongate member in ‘encircled area 816’ cannot ‘circumferentially constrict’ the elongate member and lumen when pulled in opposite directions (810-812) even if those bights are substantially rigid.” Ex. 1017 at 18.

2. The ’012 Patent IPR

56. I see that the Board adopted a different preliminary construction of the term “filament” in the ’012 patent IPR. There, the Board found that the “claims, as

understood by the POSA, suggest that the filament must be flexible.” Ex. 1023 (’012 Patent Institution Decision) at 15. The Board focused on the specific language in the claims of the ’012 patent to reach this conclusion. The Board specifically focused on the limitations, “a first filament formed into a loop around the collapsible tubular sidewall” and that the “diameter of the valve lumen decreases in response to reducing a diameter of the loop.” *Id.* Additionally, the Board credited Patent Owner’s expert testimony that the loop must be flexible to have its diameter reduced. *Id.*

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

58. The Board also addressed the interplay between the ’011 and ’012 patents. The Board said, “[t]here is no irreconcilable inconsistency” between its preliminary constructions in the ’011 and ’012 patent IPRs. *Id.* at 18. The Board explained that claim 1 of the ’011 patent “does not require that the ‘filament forms into a loop’ where the ‘diameter of the loop’ reduces when the end portions of the filament are pulled,” unlike the challenged claims in the ’012 patent. *Id.* Thus, the

Board found that “Claim 1 in the [’011 patent IPR] is arguably broader concerning the ‘filament’ and would purport to encompass, for example, both loop and bight embodiments.” *Id.*

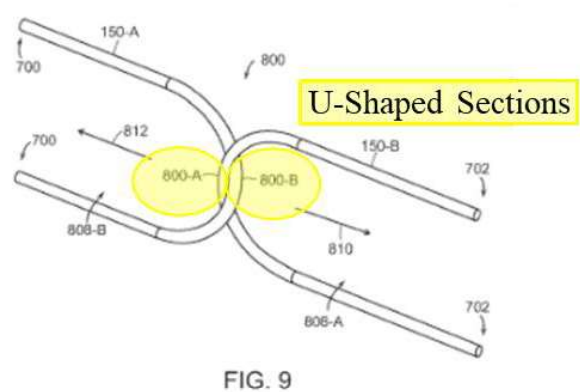
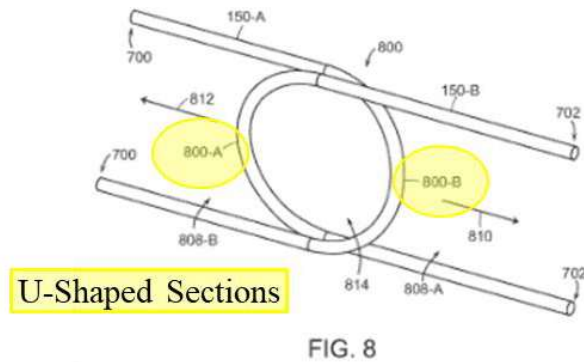
B. Construction of “Filament”

59. As explained above, I have previously construed “filament” in related IPRs. Below, I substantially repeat the analysis I previously provided. I understand from counsel that the claim construction analysis should begin with the language of the claims. Here, the claims provide little information regarding the structure forming the “filament.” For example, claims 1 and 18 recite “a filament formed in a loop around the tubular sidewall, the filament having at least a first end portion extending away from the loop to the first member.” Dependent claim 3 adds that the filament can optionally include a second end portion extending away from the loop to a second member. Dependent claim 4 adds that “the first end portion, the loop, and the second end portion are one continuous filament.” While this language identifies some features that the filament must have (e.g., having at least a first end portion), the claim language does not identify the structures, materials, or material properties that form a “filament.”

60. The specification of the ’291 patent identifies structures and materials that may form a “filament.” The ’291 patent states, “the filament 150 can comprise one or several threads, lines, cords, rope, ribbon, flat wire, sheet, or tape.” Ex. 1001

at 9:21-23. I have adopted this description for my construction of “filament.” The ’291 patent also discloses that “[t]he filament can be made from a variety of materials including, for example, a polymer, a synthetic, and/or a metal.” *Id.*, at 9:15-17. The specification also discloses, “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. Additionally, the specification 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.

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



Id. at 13:17-14:36, Figs. 8-9. Focusing specifically on the embodiments having the “U-shaped section,” the ’291 patent 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, thickness, or cross-sectional dimensions 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).

62. I understand that the prosecution history can also be relevant in construing patent claims because it can provide insight into how the applicant and the Patent Examiner understood the claims. I see that the Examiner found that Hartley discloses a “filament” as claimed in the ’291 patent. Ex. 1002 (’291 Patent Pros. History) at 393. Hartley describes a “string” for constricting Hartley’s cylindrical elastomeric diaphragm. Ex. 1006 (Hartley) at [0031]. Thus, the Examiner’s analysis of Hartley is consistent with my claim construction because a string is “one or several threads, lines, cords, rope, ribbon, flat wire, sheet, or tape” as described in the ’291 patent. Ex. 1001 (’291 patent) at 9:21-23.

63. 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 ’291 patent to mean at least: “one or more threads, lines, cords, ropes, ribbons, flat wires, sheets, or tapes.”

C. The Claims of the '291 Patent Are Not Limited to “Flexible” Filaments

64. I do not believe the claims of the '291 patent should be limited to only “flexible” filaments. For clarity, I agree that the term “filament” in the '291 patent encompasses “flexible” filaments. However, I do not see any language or descriptions in the patent that would limit the claims to only “flexible” filaments. The '291 patent does not use the word “flexible” to describe the filament. And the '291 patent does not provide any criteria for flexibility that would help a person of ordinary skill in the art determine whether a specific material was “flexible.” While the patent identifies some potential dimensions for the “filament(s),” the application states that those dimensions are exemplary, not mandatory. Because flexibility exists along a spectrum, I would not be able to tell whether a material was “flexible” enough to qualify as a filament based on the information in the '291 patent.

65. As summarized above, I am aware that the Board preliminarily construed “filament” in the claims of the '012 patent to require *only* “flexible” filaments. However, I see some differences in the claims that I think impact the Board’s analysis.¹ The claims of the '012 patent and the '291 patent both require “a filament formed into a loop around the tubular sidewall” and that pulling on the first end of the filament results in “reducing a diameter of the lumen in response to

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

reducing a diameter of the loop.” But, dependent claim 4 of the ’291 patent requires, “the first end portion, the loop, and the second end portion are one continuous filament.” So, dependent claim 4 establishes that “one continuous filament” is only optional, not mandatory. I do not see this claim in the ’012 patent.

66. Looking at the ’291 patent, I see that the embodiment in Figure 6 shows a filament made of “one continuous filament”:

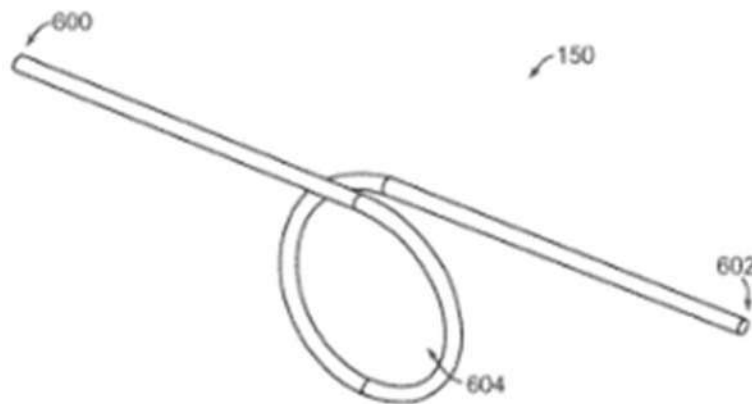


FIG. 6

The only embodiments in the ’291 patent that do not include “one continuous filament” are the “bight” embodiments in Figures 8 and 9:

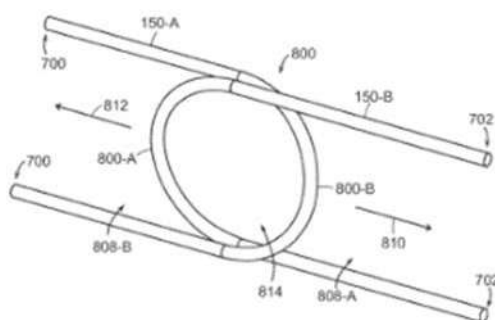


FIG. 8

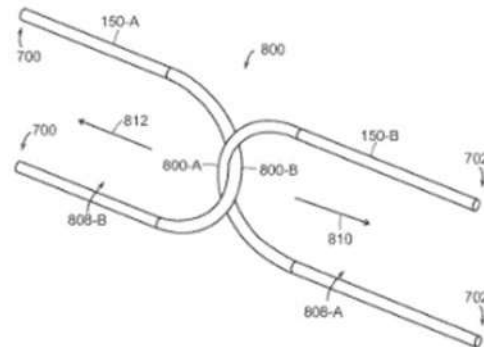
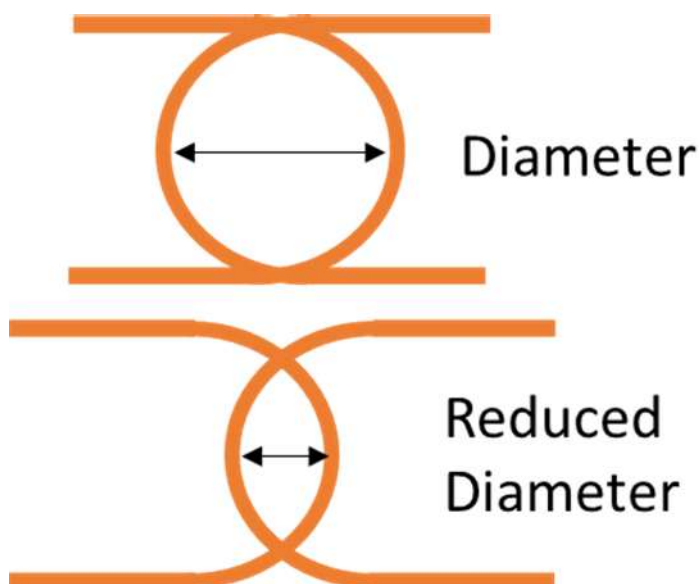


FIG. 9

So, the filament in claim 1 must include the embodiments in Figures 8 and 9 because the claim is not limited to the embodiment in Figure 6.

67. I also believe that the filaments in Figures 8 and 9 meet the claim limitations because the “bights” collectively form a loop and pulling the ends (700 and 702) of the bights reduces the diameter of the loop. The below demonstrative figure shows how the diameter of the “encircled area” between the bights is reduced when the ends of the filament are pulled:



While the term “diameter” often refers to circular objects, a diameter is not limited to a circular object. For example, two definitions for “diameter” in the New Oxford American Dictionary (3rd edition) is “a straight line passing from side to side through the center of a body or figure, esp. a circle or sphere” and “a transverse measurement of something; width or thickness.” Ex. 1014 at 480. Thus, noncircular objects, like an ellipse, can have a diameter. Further, I notice that PO

equates “diameter” with “size” in the ’291 patent, which is consistent with my understanding of “diameter.” For example, the ’291 patent says that the “a diameter of size of the loop 604” Ex. 1001 at 13:26-27. The patent also references “decreasing the size and/or diameter of one or several loops formed by the filament” *Id.* at 15:30-32.

68. I also see that the Board construed “filament” in the ’012 patent IPR based on the portion of the specification describing Figure 6 as having a “loop” and Figure 8 as having an “encircled area.” The Board suggested that the use of these different terms to describe the figures suggested that a “loop” is distinct from an “encircled area.” Ex. 1023 (’012 patent Institution Decision) at 18-19. While the words are different, loop is synonymous with encircle. For example, the New Oxford American Dictionary defines the verb “loop” to mean “form (something) into a loop or loop; encircle.” Ex. 1014 at 1031.

69. I also see that the ’291 patent specification describes the filaments in Figures 6 and 8-9 as behaving the same way. The specification explains that “a diameter or *size* of the loop ... can *decrease* when the constricting mechanism is moved” Ex. 1001 at 13:24-29 (emphasis added). Similarly, the ’291 patent specification explains movement of the constricting mechanism “*decreases* the *size* of the encircled area 814” *Id.* at 14:2-5 (emphasis added). Therefore, I do not believe that the use of different words in the specification for “loop” and “encircled”

means that the term “filament” in the claims of the ’291 patent must be limited to “flexible” filaments.

70. I also see that the Board preliminarily limited the ’012 patent claims to “flexible” filaments based, in part, on the ’012 patent prosecution history. Ex. 1023 at 19-20. However, the ’291 patent prosecution is different and does not include any restriction requirement response like the one provided in the ’012 patent. *See* Ex. 1002 (does not include restriction). Thus, the ’291 patent prosecution history does not support a construction of “filament” that is limited only “flexible” filaments.

71. I also know that Patent Owner has obtained patent claims in related patents that specifically require a “flexible” filament. For example, Patent Owner’s U.S. Patent No. 12,109,384 includes claims reciting, “a first filament extending in a first loop around the tubular member, wherein the first filament *is flexible*.” Ex. 1016 at claim 1 (emphasis added). The claim further recites that the actuator can apply tension to the filament to “decrease the dimension of the first loop.” *Id.* I have been informed that each term in a claim has meaning. Therefore, the limitation that the filament is “flexible” in the ’384 patent suggests that some filaments in the patent are not “flexible,” otherwise the words “is flexible” in the claims would be superfluous.

72. I also see in the '005 Patent IPR that Patent Owner has argued that the description of the embodiment in Figure 3 of the hemostasis valve patents requires a “flexible” filament. The specification states that when the buttons in the embodiment are depressed, “the filament 150 is loosened, thereby allowing the expansion of the elongate member 132” Ex. 1001 at 9:58-62, Fig. 3. I see that Patent Owner tries to equate “loosened” with “flexible.” But, the word “loosened” is not synonymous with “flexible.” The term “loosen” in the dictionary submitted by Patent Owner means “to release from restraint.” Ex. 1026. The term “loosen” does not have any relationship to flexibility because many relatively inflexible items can be loosened, such as screws and u-bolts. The filaments in the embodiments in Figures 8 and 9 of the '291 patent are “loosened” to allow expansion of the elongate member, even if they are determined by the Board to be relatively inflexible. Therefore, I don’t see the patent’s use of “loosened” to require only “flexible” filaments.

V. SUMMARY OF IPR GROUNDS

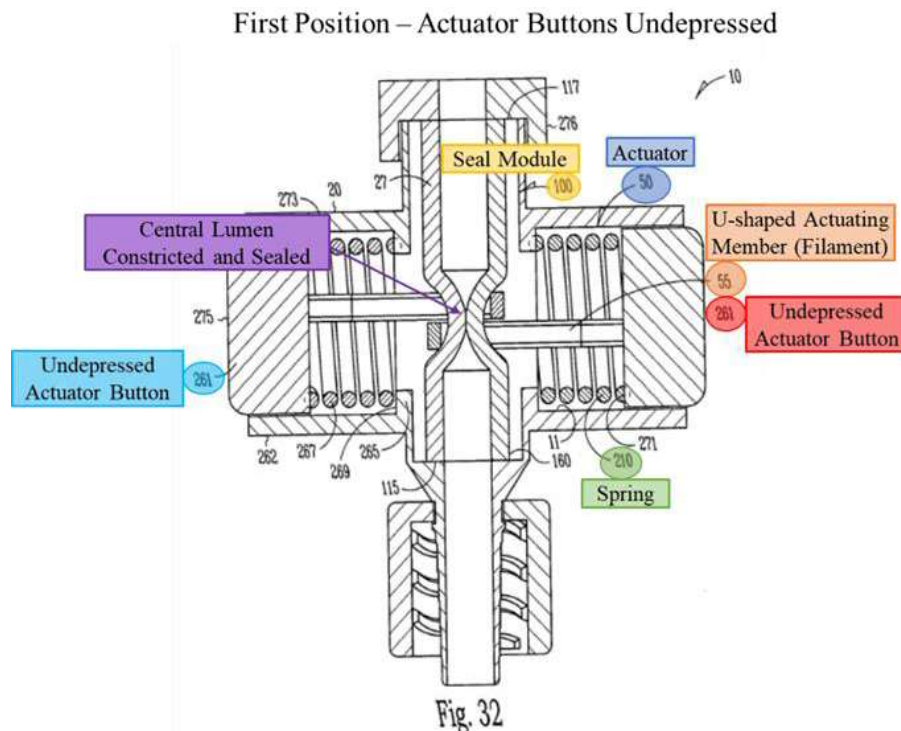
73. I have identified the following grounds of unpatentability in this Declaration:

Ground	Prior Art References	Basis	Claims Challenged
1	Schaffer	35 U.S.C. § 102	1-3, 5-8, 12-17, 19
2	Schaffer	35 U.S.C. § 103	1-3, 5-8, 12-17, 19
3	Schaffer + Hartley	35 U.S.C. § 103	1-8, 12-17, 19
4	Schaffer + Eller	35 U.S.C. § 103	1-8, 12-17, 19
5	Garrison + Schaffer	35 U.S.C. § 103	18-19
6	Garrison + Schaffer + Hartley	35 U.S.C. § 103	18-19
7	Garrison + Schaffer + Eller	35 U.S.C. § 103	18-19

VI. GROUNDS 1-4: CLAIMS 1-8, 12-17, AND 19 ANTICIPATED BY SCHAFFER OR OBVIOUS OVER SCHAFFER ALONE OR IN COMBINATION WITH HARTLEY OR ELLER

74. I believe that Schaffer anticipates claims 1-3, 5-8, 12-17, and 19 of the '291 patent or renders them obvious. Schaffer discloses a hemostasis valve “that blocks the flow of gas or fluid completely and immediately with or without an instrument in place within the gas/fluid path.” Ex. 1005 (Schaffer) at [0002], [0008]. As shown in Figure 32 below, Schaffer illustrates an example of a hemostasis valve that has a tubular seal module 100 extending through the center

of the valve and an actuator comprising: (a) two actuator buttons 261 positioned on opposite sides of the seal module, (b) two compression springs 210/267 coupled to the actuator buttons, and (3) two actuating members 55 (which may be U-shaped) that compress the seal module when the actuating buttons are undepressed:

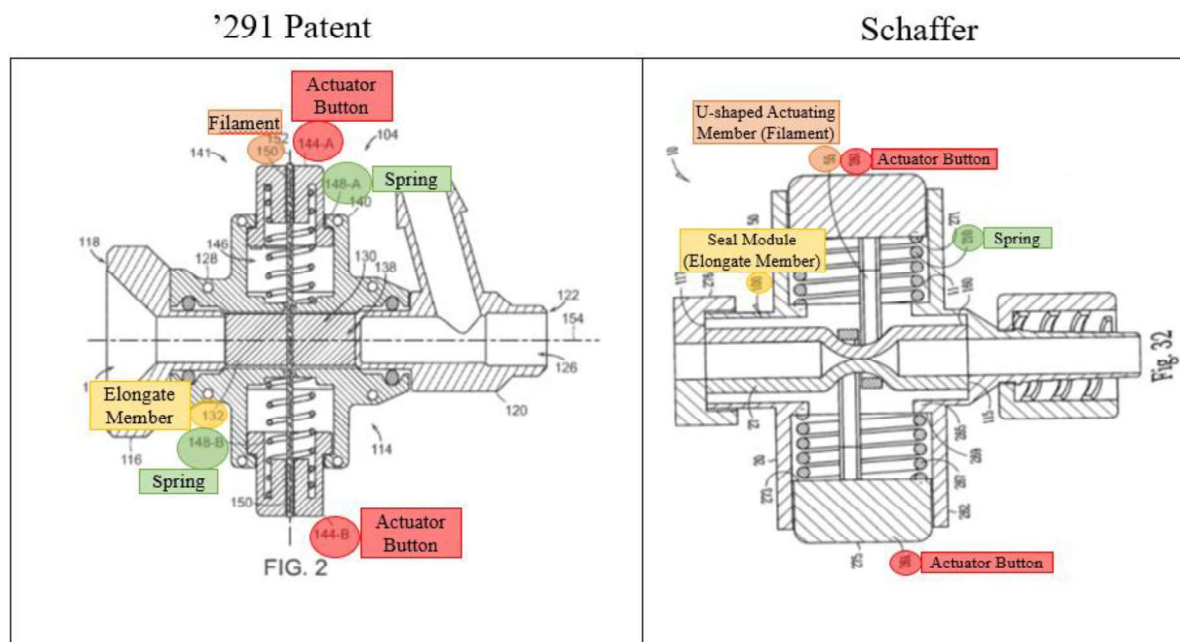


Id. at [0076]-[0077], Figs. 31-32.² Notably, the '291 patent also describes the filaments in Figures 8 and 9 as U-shaped, stating:

“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.”

² 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 ('291 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 claimed in the '291 patent, which is apparent from the side-by-side comparison of Figure 2 of the '291 patent (left) and Figure 32 of Schaffer (right):



Id. at Fig. 2 (left); Ex. 1005 (Schaffer) at Fig. 32 (right).

75. As explained 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 used in the '291 patent, because the described actuating members are at least "ribbons, flat wires, sheets, or tapes." *See supra* §IV (claim construction of "filament"). Moreover, if Schaffer's U-shaped actuating members were not sufficiently flexible

to form a “filament,” a person of ordinary skill in the art would have found it obvious to make the filaments more flexible, as described below. Further, 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.

76. 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:

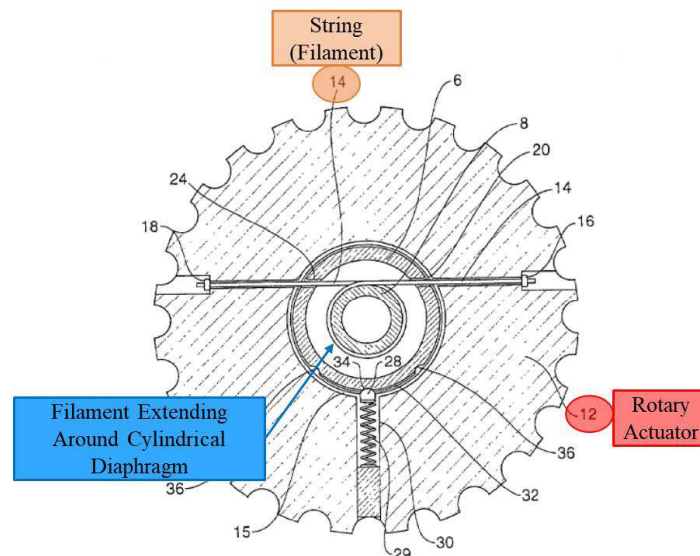


Fig 3

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:

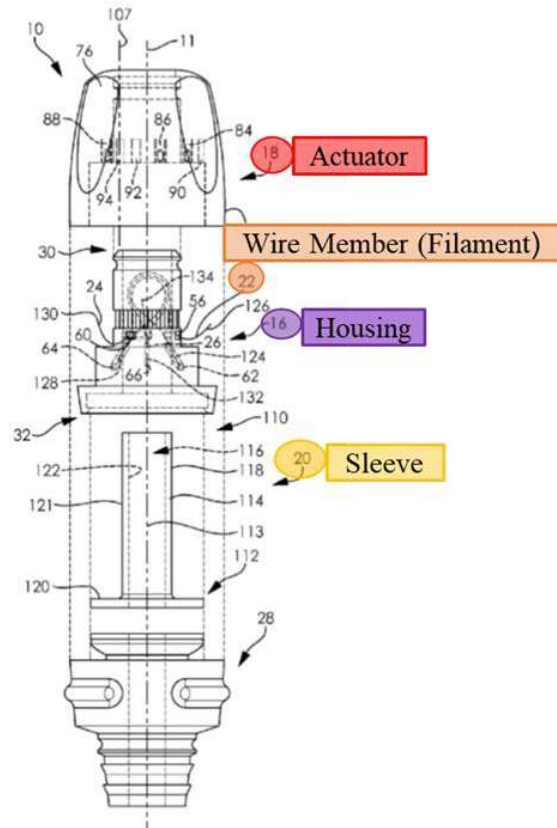


FIG. 2

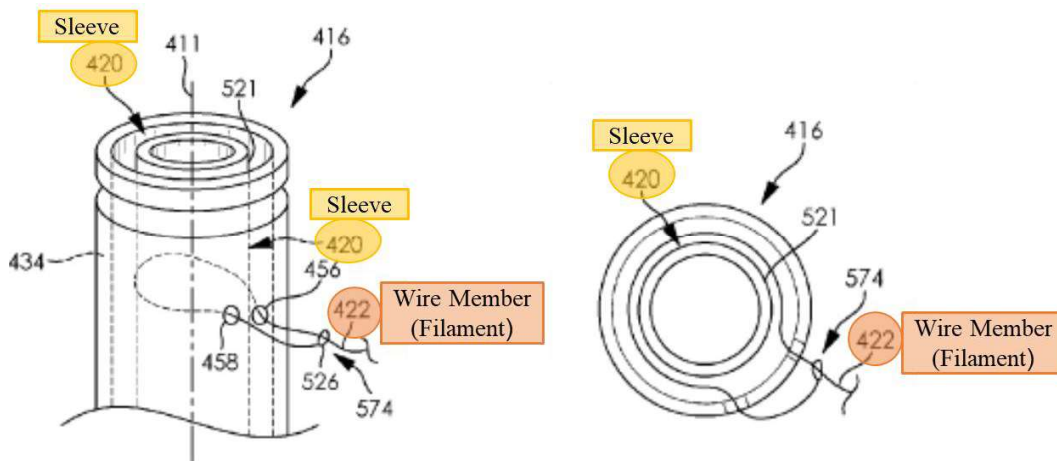


FIG. 16

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.

77. 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 1-8, 12-17, and 19 obvious.

A. Claim 1

78. 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 view of Hartley *or* Eller.

1. Preamble

79. The preamble of Claim 1 recites: “A hemostasis valve.” If this preamble is limiting, Schaffer, Hartley, and Eller disclose this limitation.

80. Schaffer discloses embodiments of a “fluid stasis valve” 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].

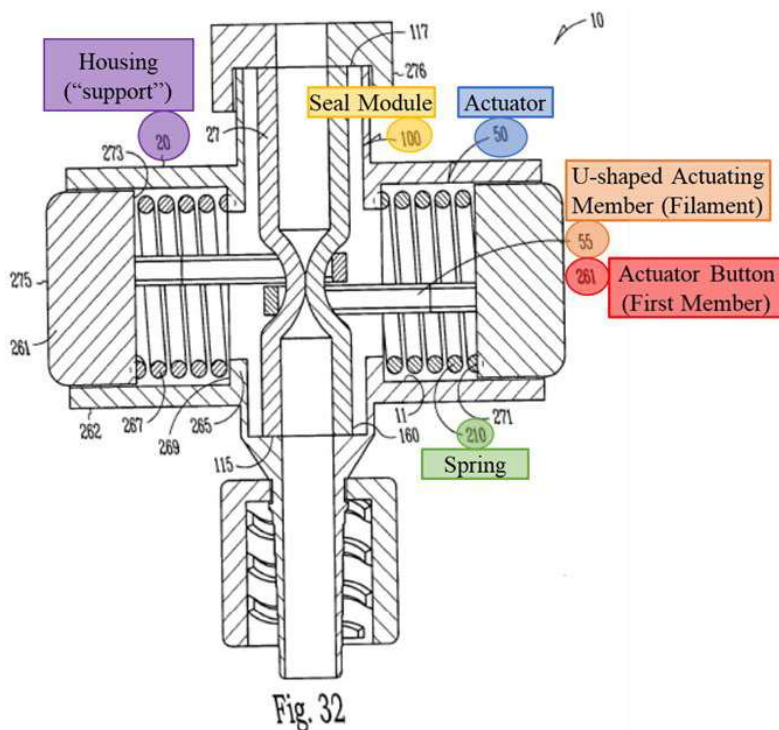
81. Hartley discloses “an access valve” for use in “medical applications ... where it is desired to seal around a catheter or other instrument ... to prevent loss of blood or other fluid.” Ex. 1006 (Hartley) at [0002]-[0004].

82. Eller discloses “selective fluid barrier valve devices” for 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 1:14-23.

2. Support

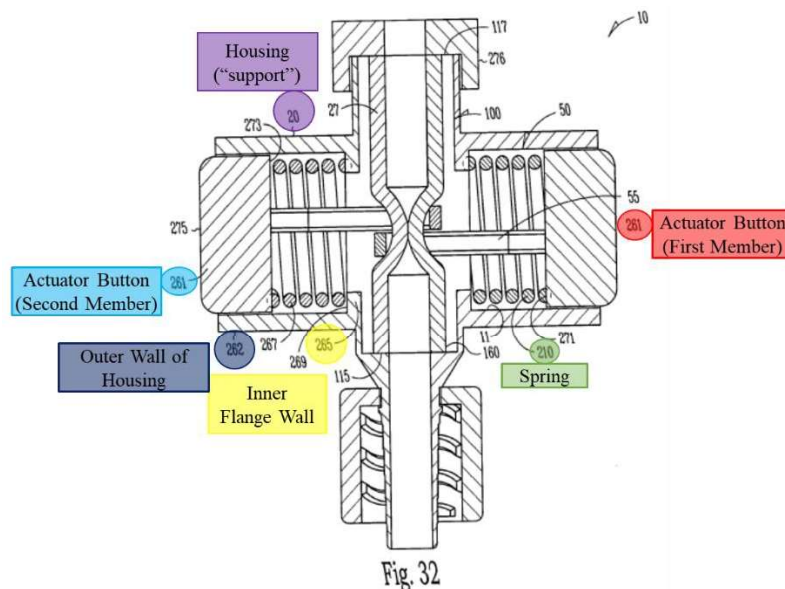
83. Claim 1 next recites: “a support.” Schaffer discloses “a support.”

84. Schaffer’s hemostasis valve includes a “housing 20”:



Ex. 1005 (Schaffer) at [0076], Fig. 32. Schaffer explains that the “outer wall 262 of the housing 20 and the inner flange wall 265 of the housing 20 provides opposing

support for two resilient members 267 (e.g., spring 210) disposed within the actuating member 55.” *Id.* at [0076] (emphasis added). Thus, the “housing” is a support. Also, Schaffer’s housing meets the other limitations in claim 1 that reference the “support.” Schaffer’s first member (i.e., button) is “movably coupled to the support [i.e., housing].” Schaffer’s collapsible tubular member (i.e., seal module) is “carried by the support [i.e., housing].” Schaffer’s housing also meets the limitation in Claim 9 that requires: “the spring is positioned between the first member and the support.” As shown in Figure 32 below, Schaffer’s springs are positioned between the first/second members (actuator buttons) and the inner flange wall 265 of the housing 20:



85. Also, in reviewing the prosecution history, I see that the Examiner found that Hartley’s hemostasis valve had a “support.” In fact, the Examiner

pointed to multiple components in Hartley's valve as forming a "support," including Hartley's housing 6, Hartley's flange 7, and Hartley's radial flange 10.

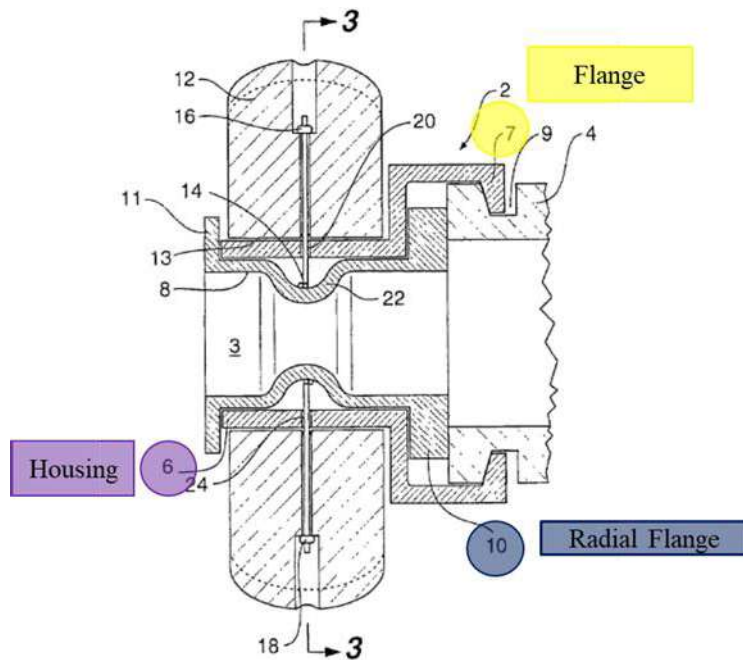


Fig 1

Ex. 1002 at 393-395. Schaffer's valve has a "housing" and a "flange" similar to the housing and flange in Hartley. For example, Schaffer's housing also surrounds the collapsible tubular member and provides support for the other components of the valve. Therefore, Schaffer discloses a "support."

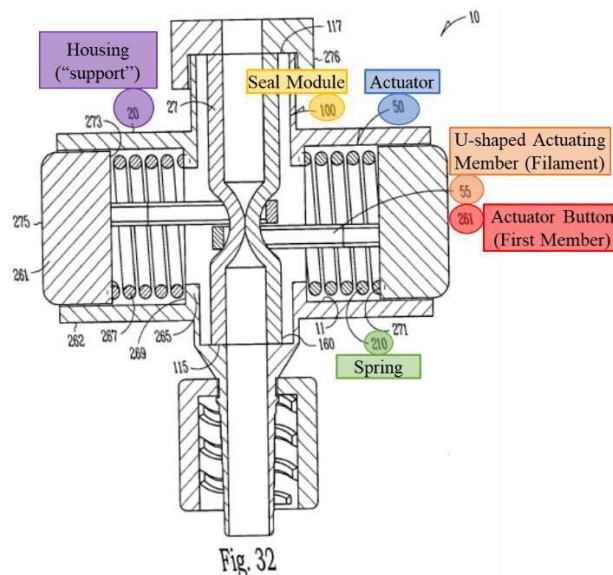
86. In the litigation pending in district court, I submitted an expert report where I explained that the term "support" is not defined with reasonable certainty in the '291 patent. Ex. 1027 (my expert declaration). For example, the '291 patent does not use the term "support" to describe any features of the hemostasis valve. While the prosecution history describes some features that fall within the scope of a "support," such as Schaffer's housing, it does not describe the boundaries of a

support. However, I understand that because Schaffer describes a “support” like the one the examiner identified in the prosecution history, the Board does not need to decide whether the term “support” is indefinite.

3. Actuator

87. Claim 1 recites “an actuator having at least a first member movably coupled to the support.” Schaffer discloses this limitation.

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



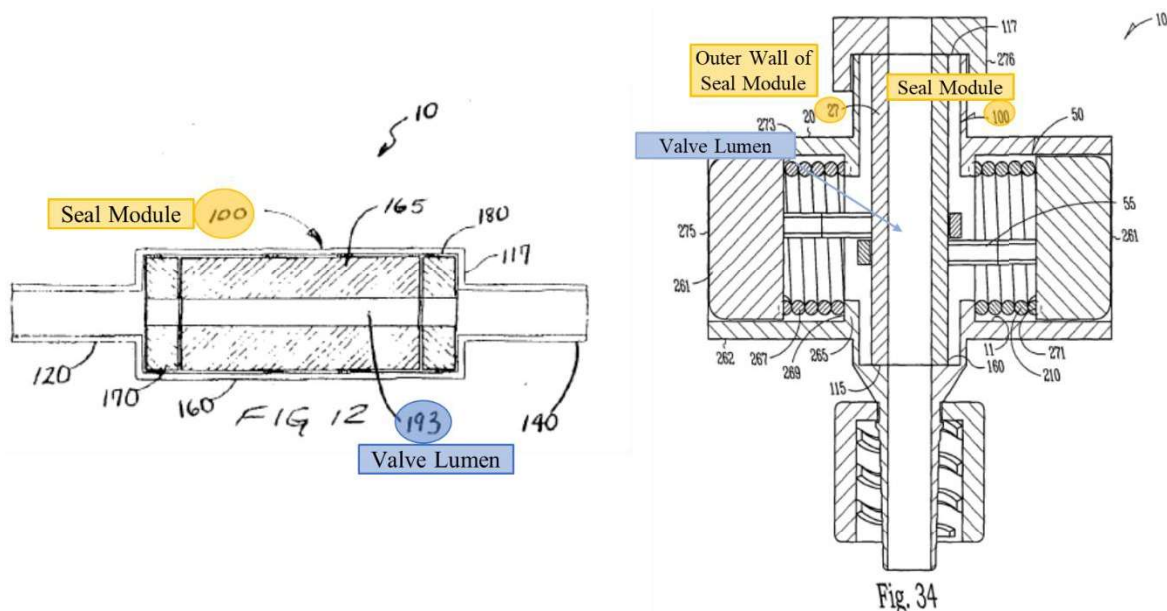
Id. at [0075]-[0076], Fig. 32. I refer to the right actuator button as the “first member,” although I recognize that the left actuator button could also be designated as the “first member.”

89. As shown in the figure above and described in Schaffer, the “actuators 50 are configured cylindrically to slide along the cylindrical interior wall 11 of the housing 20 from a first position to a second position.” *Id.* at [0076], Figs. 32 and 34; *see also id.* at [0083] (the actuator button 261 is inserted into the housing during assembly). Therefore, the actuator buttons are movably coupled to the Schaffer’s housing (the “support”).

4. Collapsible Tubular Sidewall

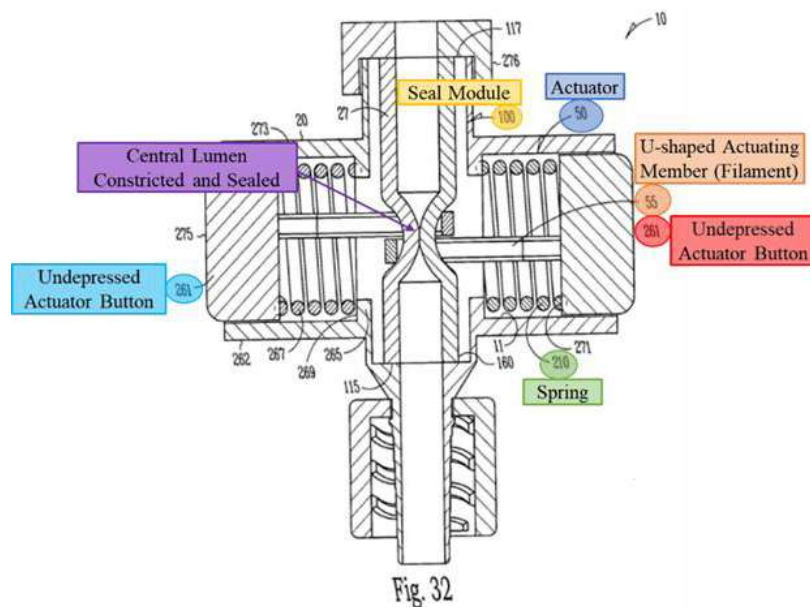
90. Claim 1 next recites: “a collapsible tubular sidewall defining a lumen carried by the support.” Schaffer discloses this limitation.

91. Schaffer’s hemostasis valve includes a “seal module 100” having “a flexible, elongate tubular structure 101.” Ex. 1005 (Schaffer) at [0049], [0051], [0054], [0075]. The seal module 100 defines a valve lumen 193 extending therethrough:



Id. at [0022, 0075], Figs. 12³, 34. Schaffer's seal module may be “partially collaps[ed] ... by a compressive force” and is completely collapsed in Figure 32 (shown below). *Id.* at [0077].

92. The seal module 100 of Schaffer is carried by housing 20 (support) because, for example, the “seal module 100 [is] enclosed in the housing 20.” *Id.* at [0070]; *see also* [0083] (“the seal module 100 is inserted through the housing 20 and between each actuator”); claim 3 (“wherein the seal module is enclosed in a housing”).



Id. at Fig. 32. Thus, Schaffer's seal module 100 is a “a collapsible tubular sidewall defining a lumen carried by the support.”

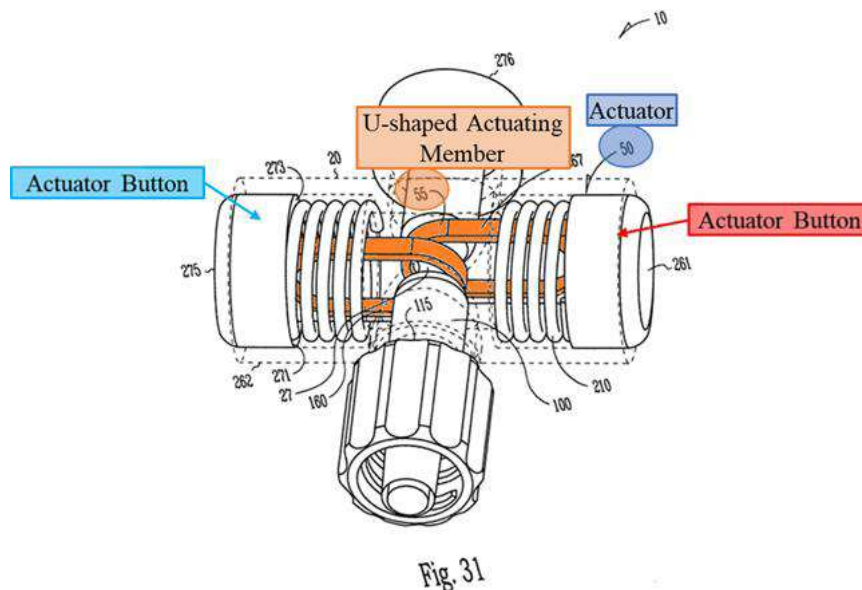
³ While Figure 12 shows a seal module 100 comprised of three seal members 160, 170, and 180, Schaffer discloses that the “seal module 100 is formed of one or more seal members.” *Id.* at [0075], Figs. 32, 34. Thus, the seal module 100 may be formed from a single seal member.

5. Filament

93. Claim 1 recites “a filament formed in a loop around the tubular sidewall, the filament having at least a first end portion extending away from the loop to the first member.” Schaffer discloses this limitation or renders the limitation obvious alone or in combination with Hartley or Eller.

a. Schaffer

94. Schaffer discloses a “filament,” as that term is claimed in the ’291 patent. I addressed the meaning of “filament” in the claim construction section above. *Supra* §IV. Schaffer’s valve includes two actuating members, which may be U-shaped, that are coupled to the actuator buttons and constrict the valve when the buttons are undepressed:



Id. at [0076], Fig. 31. The U-shaped actuating members are formed from metals, such as aluminum, or plastic, which is consistent with the description of the

filaments in the '291 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, or tape, as described in the '291 patent:

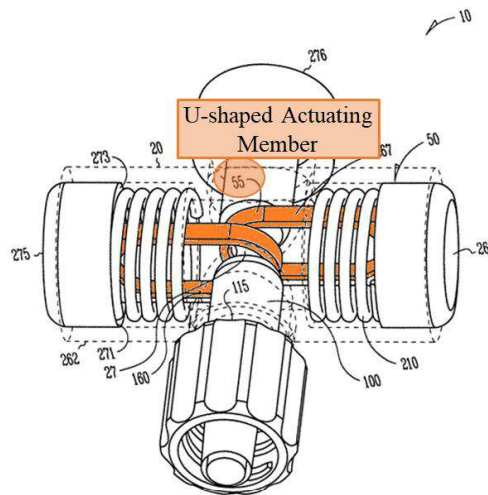


Fig. 31

Id. at Fig. 31; *see also id.* at Figs. 32-34.

95. I notice in related IPRs that Patent Owner characterizes Schaffer's actuating members as "rigid." Ex. 1017 ('011 patent Institution Decision) at 38; Ex. 1032 ('012 patent Institution Decision) at 32. However, Schaffer does not describe the actuating members as "rigid," and does not provide any other information that would suggest to a person of ordinary skill in the art that the actuating members are rigid, such as requirements for minimum or maximum dimensions or specific material properties. Thus, I see nothing in Schaffer that would require the actuating members to be "rigid." To the contrary, a person of

ordinary skill in the art would have understood that Schaffer's U-shaped actuating members would have preferably been formed from a thin, flexible material. Such a material would have permitted the actuating members to conform, as much as possible, to the outer surface of the seal module and tool inserted through the valve. For example, not all tools inserted through the valve would have a circular profile. In those cases, U-shaped actuating members having some flexibility would better seal around the irregular shapes. A thin metallic or plastic flat wire, ribbon, or tape would have provided the flexibility required for the actuating members to best seal around tools of various shapes and sizes.

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

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

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

2017, a person of ordinary skill in the art could have simply purchased pre-made flat wire or plastic tapes or ribbons. Further, the actuating members in Schaffer would work if they were “flexible.” For example, if each U-shaped actuating member were formed of a small diameter wire similar to the material in a paper clip or a smaller diameter, the members would effectively collapse the tube. The members would also be flexible.

97. I note that in previous IPRs, Patent Owner has attempted to suggest that Schaffer’s actuating members behave differently from a filament because the patent says the members “forcibly disengage” the walls of the seal. I disagree. The description in Schaffer that the actuating members “forcibly disengage opposing outer walls of the seal module 100” does not mean that the actuating members do not remain in contact with the seal module. As shown in Figure 34 above, the actuating members are still in contact with the seal module 100 even after being forcibly disengaged. Rather, the term “forcibly disengage” refers to the act of applying force to the buttons to release the tension created by the actuating members on the seal module, which in turn allows the seal module “to retract to an uncollapsed configuration where gases and fluids can pass therethrough.” Ex. 1005 (Schaffer) at [0077], Fig. 34. Schaffer’s actuating members move in opposition directions when force is applied to the buttons, allowing the seal module/tubular

member to retract to an uncollapsed configuration, the exact same way that the '291 patent's filament does.

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

99. Schaffer's actuating members also satisfy the "filaments formed in a loop around the tubular sidewall." Schaffer discloses that the actuating members are "at least partially circumferentially [sic] disposed about the portion 108 of the seal module 100." Ex. 1005 (Schaffer) at [0076]. As shown in Figure 31 below, the actuating members collectively encircle the seal module 100 to form a loop thereabout:

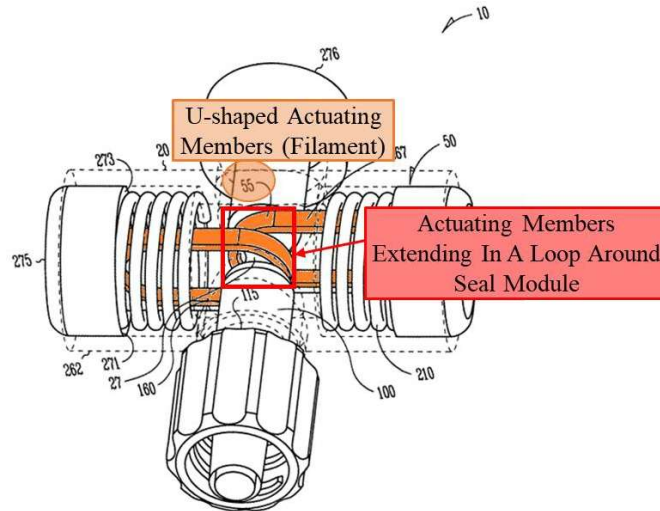
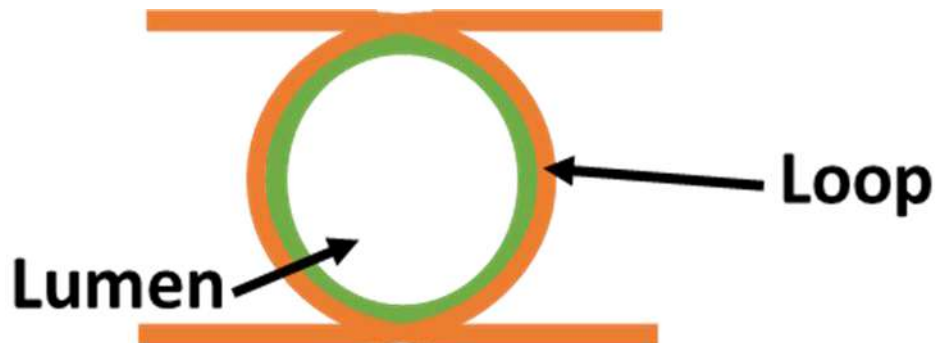


Fig. 31

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



100. This arrangement is similar to the arrangement of the filament depicted in Figures 8 and 9 of the '291 patent (shown below). The '291 patent specifically discloses that two sub-filaments, like Schaffer's two U-shaped actuating members 55, can form "a filament," as required by claim 1. The '291 patent states, "*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”:

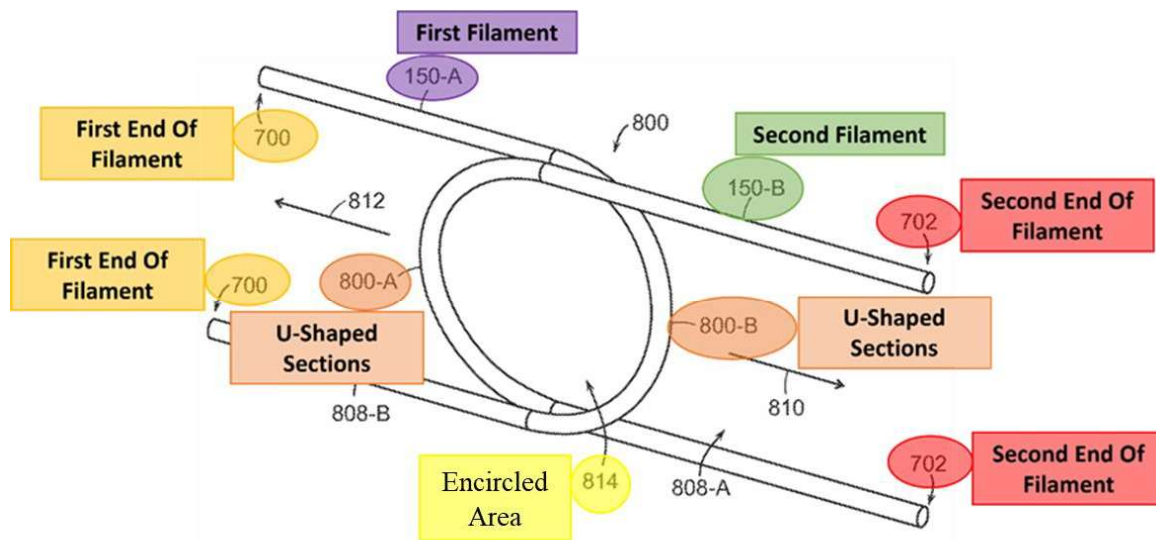


FIG. 8

Ex. 1001 ('291 patent) at Figs. 8-9. The '291 patent also 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. As I explained in the claim construction section for “filament,” the claims establish (particularly claim 4) that the filament can be formed by multiple filaments. Thus, Schaffer’s actuating members form a similar loop around the seal module (elongate member).

101. Schaffer also discloses the “filament having at least a first end portion extending away from the loop to the first member.” Schaffer explains that the actuating members are connected to the actuator buttons. Ex. 1005 (Schaffer) at

[0076]-[0077], Figs. 31-34. As shown in Figure 31, Schaffer's actuating members have a first end portion extending away from the loop towards the actuator button:

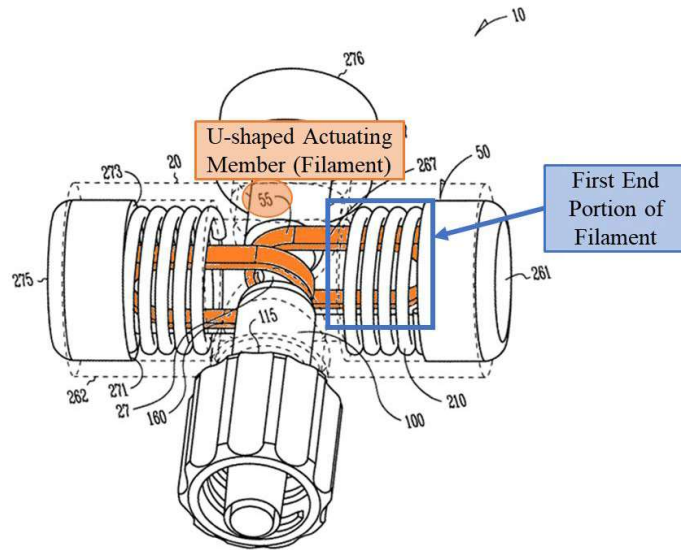
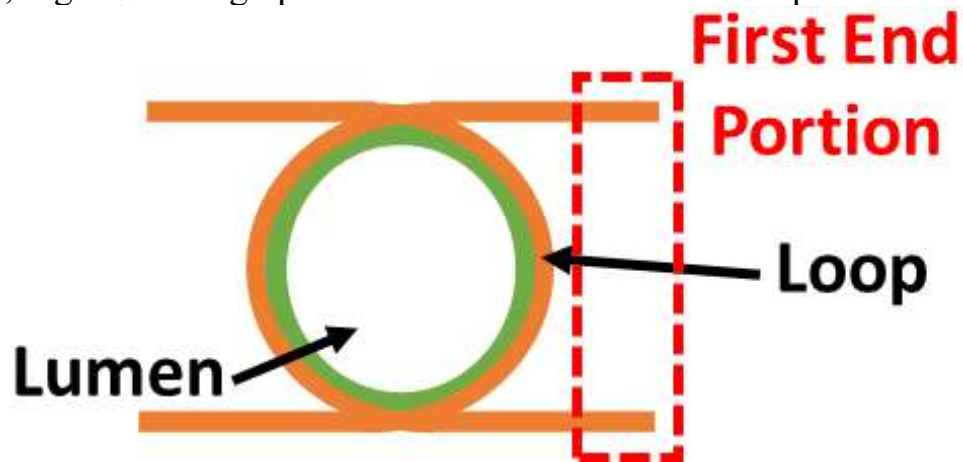


Fig. 31

Ex. 1005, Figs. 31. The graphic below illustrates the first end portion:



102. This arrangement is similar to the configuration in Figures 8 and 9 of the '291 patent. The '291 patent discloses that where “*the filament 150* comprises multiple filaments, each of the multiple filaments can have a *first end 700* and a *second end 702*”:

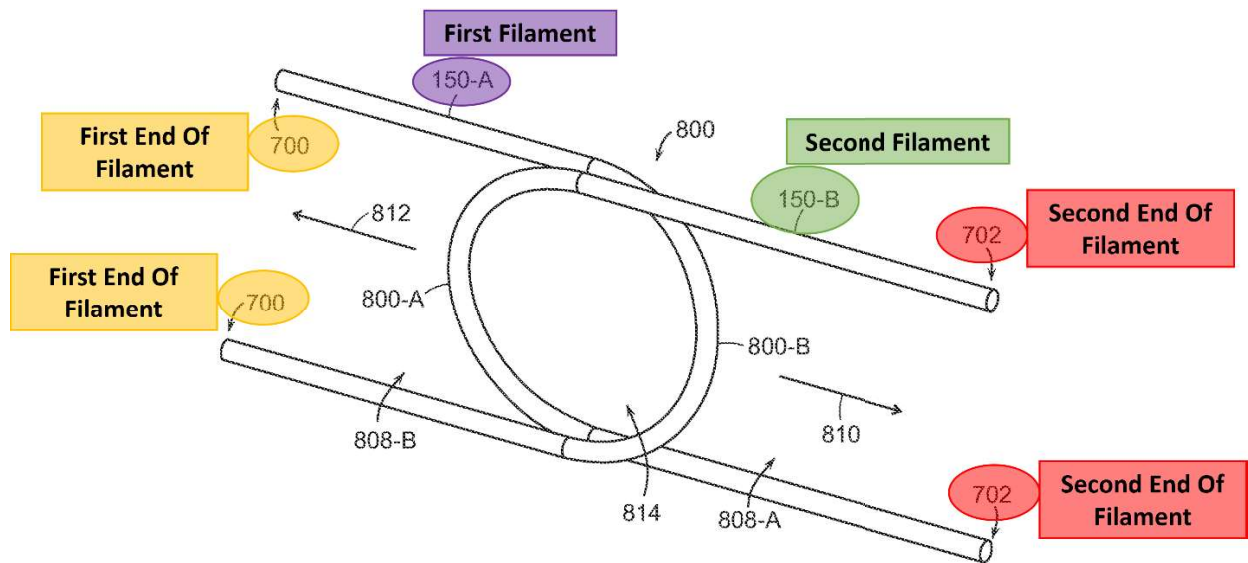


FIG. 8

Ex. 1001 at 12:64-67, Fig. 8. Like the disclosure in the '291 patent, Schaffer's U-shaped actuating members have a first end portion extending away from the loop.

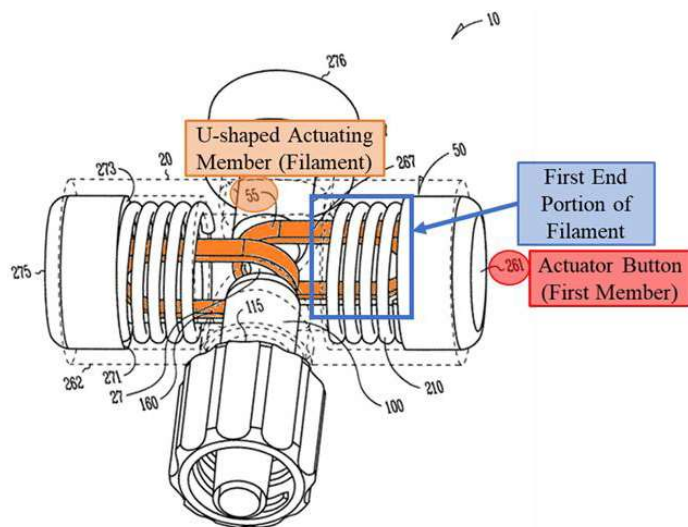


Fig. 31

Thus, Schaffer discloses the “filament” required by claim 1 or renders it obvious.

b. Hartley

103. Hartley also discloses a “filament.” 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,” (tubular sidewall) and a rotary actuator mounted onto the housing:

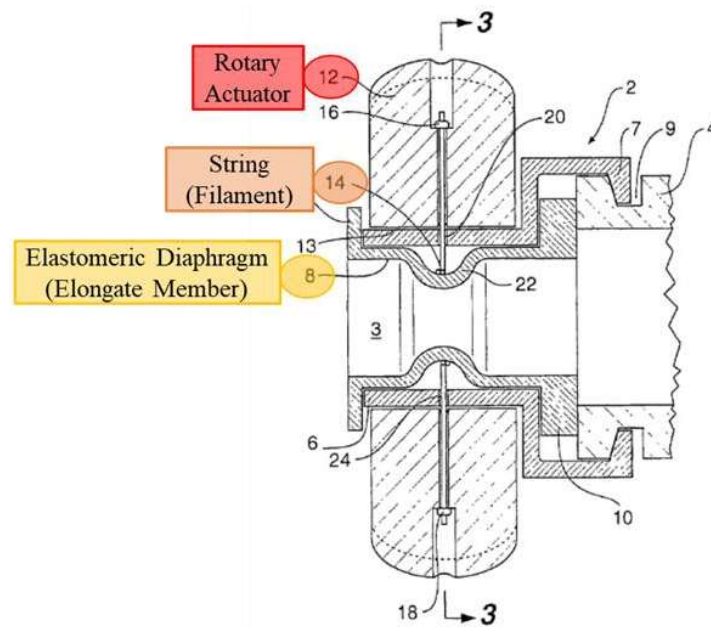


Fig 1

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 claimed in the ’291 patent because a “string” is made of at least one or more threads, lines, or cords.

104. 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”:

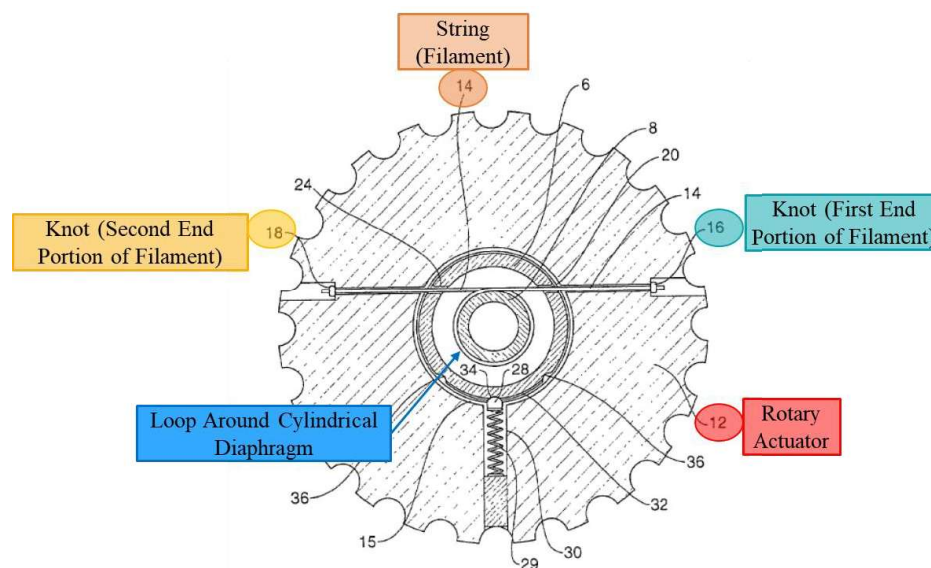


Fig 3

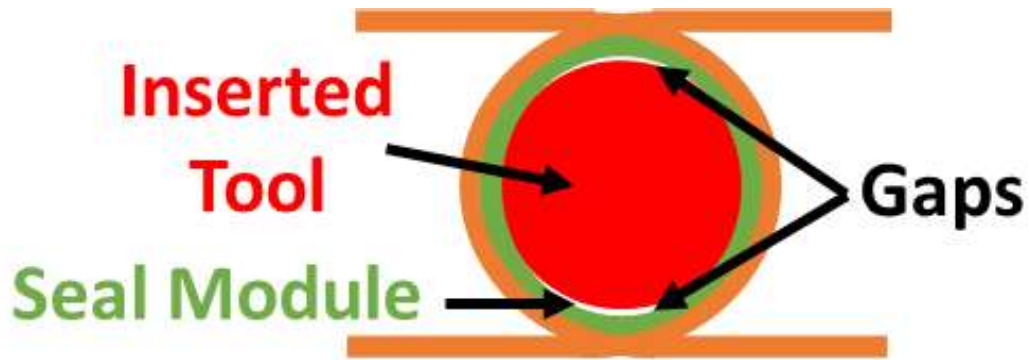
Id. at [0031], Fig. 3. Hartley’s string “is formed in a loop around the tubular sidewall” and has a first end portion extending away from the loop as recited in Claim 1.

105. 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”).

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

sizes and shapes could be required for a medical procedure, so Hartley's ability to seal around a range of diameters/shapes 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.

107. 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, materials, and mechanical properties 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.

108. I note in related proceedings that Patent Owner argues a person of ordinary skill in the art would not have been motivated to modify Schaffer's valve with Hartley's string because Schaffer would not result in gaps. Patent Owner Preliminary Response re: '011 patent filed in *Imperative Care, Inc. v. Inari Medical Inc.*, IPR2024-01157, Paper 5 at 28-29 (P.T.A.B. Oct. 29, 2024); Patent Owner Preliminary Response re: '012 patent filed in *Imperative Care, Inc. v. Inari Medical Inc.*, IPR2025-00156, Paper 5 at 43-44 (P.T.A.B. Feb. 25, 2025). However, even Schaffer recognizes it may not form a complete seal with the "gelatinous" and "sticky" valves identified by Patent Owner, stating the valves form a "**nearly** fluid/gas tight seal." Ex. 1005 (Schaffer) at [0059]. Further, Patent Owner argues that Schaffer's "gelatinous" or "sticky" valve has "selfclosing" properties so it would not form any gaps. Patent Owner Preliminary Response re: '011 patent filed

in *Imperative Care, Inc. v. Inari Medical Inc.*, IPR2024-01157, Paper 5 at 29 (P.T.A.B. Oct. 29, 2024). But the portion of Schaffer that refers to a “sticky” or “gelatinous” substance refers to embodiments of the valve having three portions where one of the portions can optionally be made from a “sticky” or “gelatinous” substance having a specific “shore hardness.” Ex. 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.

109. 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 a folded/collapsed seal module through the looped strings that are already attached to the buttons. Alternatively, the seal module could be positioned in the valve before the strings were 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. I note that the '291 patent does not describe any special manufacturing procedures that would be needed to assemble a valve having a relatively flexible filament. Moreover, I see no basis for Patent Owner's argument that Hartley's strings would "weaken the valve's durability." Hartley uses the strings for the same purpose they would be used in Schaffer's valve and does not identify 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.

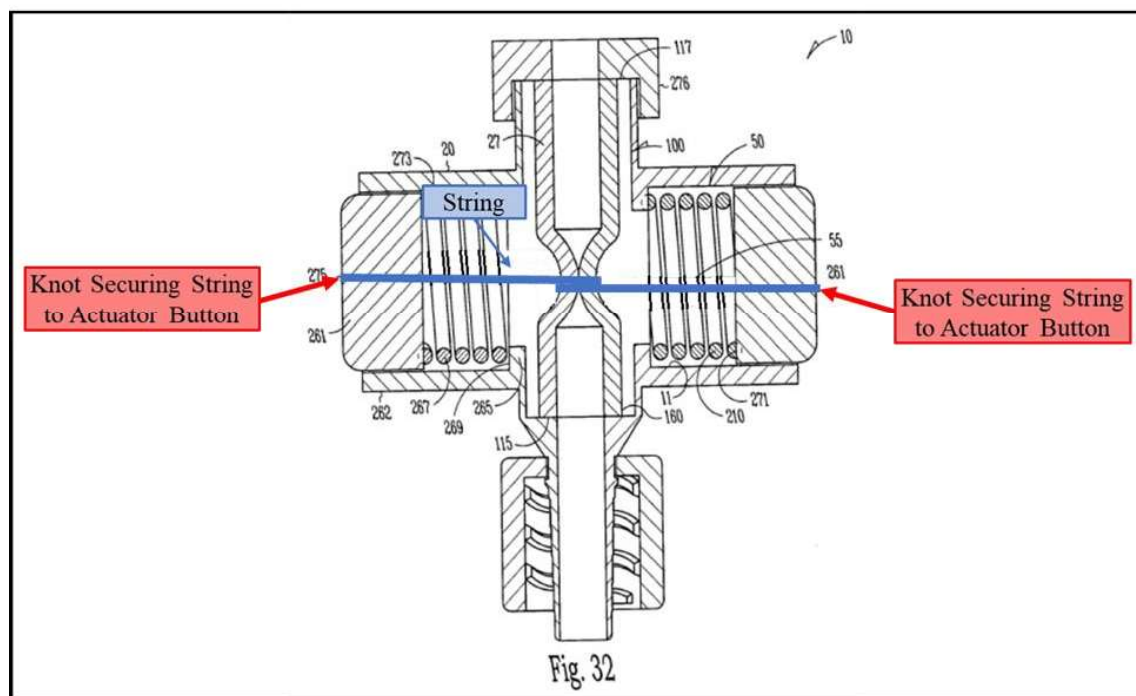
110. Fourth, as Schaffer recognizes, fluid stasis valves generally comprise "a resilient material in compression within a housing or clamping member." Ex. 1005 (Schaffer) at [0003]. There were a finite number of ways to compress the resilient material in a hemostasis valve to create a seal in September 2017. Hartley and Schaffer disclose two such methods – Hartley's single string and Schaffer's two U-shaped actuating members formed from metal 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.

111. 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.

112. 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

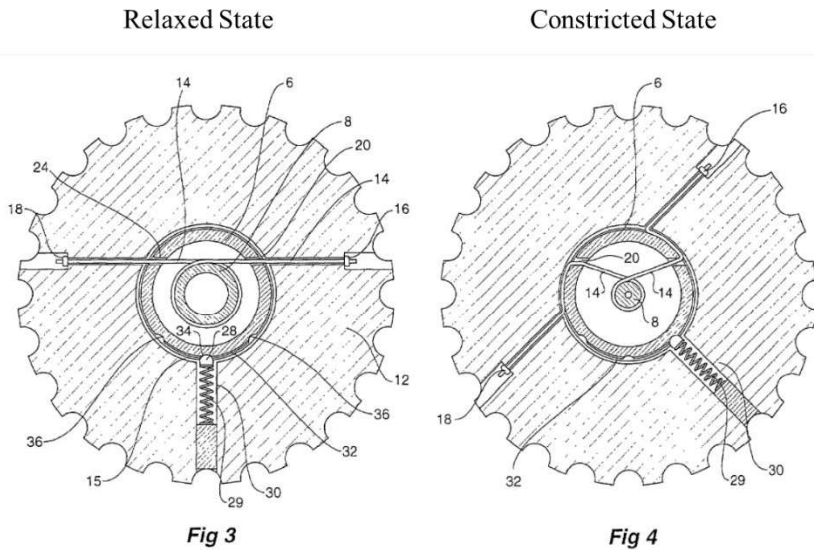
I provide below depicts a basic diagram of how this modification could be achieved. As shown, the first end of the string would be secured to the first actuator button (first actuator member), the string would loop at least once around the lumen of Schaffer's valve, and then the second end of the string would be secured to the second actuator button (second actuator member) on the opposite side of the valve:

Demonstrative Illustration Schaffer + Hartley's String

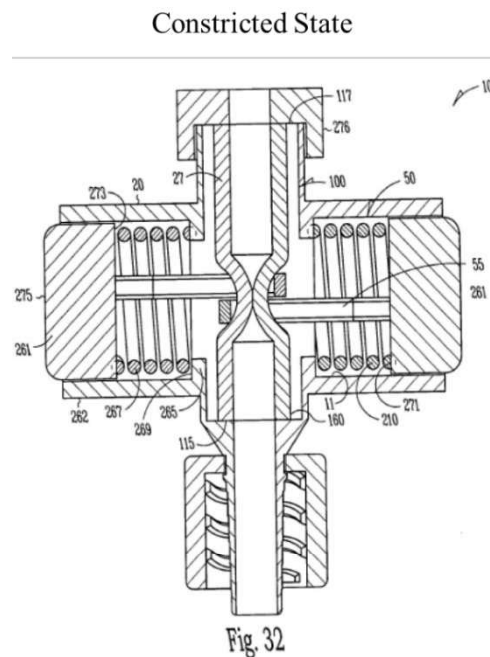


113. Second, a person of ordinary skill in the art would have recognized that Hartley's string and Schaffer's U-shaped actuating members use similar mechanisms to compress and seal the central lumen of the valves, and therefore no additional modifications of Schaffer's valve would be necessary when implementing 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

3 (relaxed) and 4 (constricted):



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



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

114. 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. If Schaffer’s springs did not initially exert sufficient

force to pull the string of Hartley to constrict the valve, 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.

115. 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.*

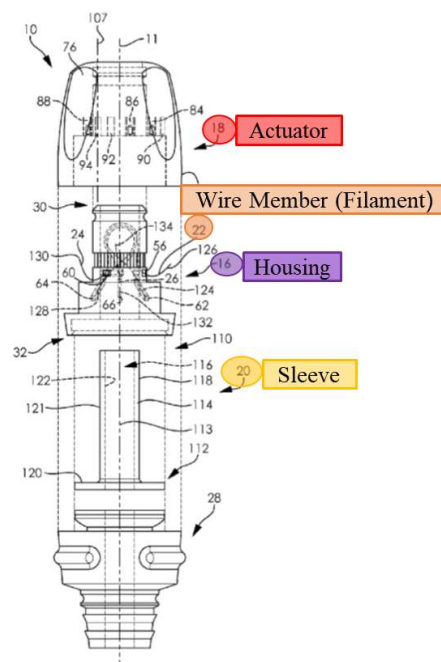
116. Moreover, if the person of ordinary skill found that the resiliency of Schaffer's lumen required adjustment to function with Hartley's string, the person

of skill would have possessed the skills and knowledge to select an appropriate material with the proper resiliency. There were a range of suitable materials disclosed in the prior art for forming the lumen of a hemostasis valve. For example, Schaffer discloses that the materials for the lumen can include “modified vinyl, silicone, polyurethane or a combination thereof,” as well as modifications of those materials with “waxes and/or oils or un-cross-linked modifiers.” Ex. 1005 (Schaffer) [0081]. Hartley discloses that “[p]referably the cylindrical diaphragm is formed from a resilient material so that after constriction and release of the flexible member the valve reopens” and further discloses that “[i]n a preferred form the cylindrical diaphragm of the valve may be constructed from an elastomeric material such as silicone rubber.” Ex. 1006 (Hartley) at [0008], [0016]. Eller discloses a variety of sleeves made from “NuSil MED-4755, NuSil MED-4765, and NuSil MED-4014.” Ex. 1007 (Eller) at 36:27-60. The components referred to as the “seal module” in Schaffer, the “cylindrical diaphragm” in Hartley, and the “sleeve” in Eller all correspond to the portion of the hemostasis valve that forms the central lumen of the valve. *See* Ex. 1005 (Schaffer) at [0049], [0051], [0054], [0075]; Ex. 1006 (Hartley) at [0031]; Ex. 1007 (Eller) at 11:60-64. Thus, the prior art would have provided a person of ordinary skill with a range of suitable options for selecting a suitable lumen material that was both deformable and possessed the resilience to return to its open state when constricting force is removed.

117. Hartley also discloses that looping the string around the central lumen forms an effective seal. Ex. 1006 at [0031], [0037]. Thus, when replacing Schaffer's actuating members with Hartley's string, a person of ordinary skill in the art would have been motivated to similarly loop Hartley's string around Schaffer's seal module. A person of ordinary skill in the art would have reasonably expected success in using this configuration because Hartley teaches the configuration forms an effective seal. For all of the above reasons, Schaffer in combination with Hartley renders claim 1 obvious.

c. **Eller**

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



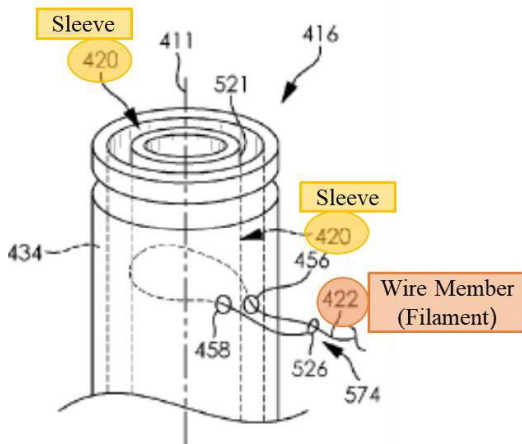


FIG. 16

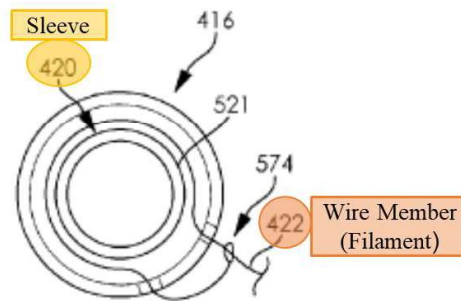


FIG. 17

Ex. 1007 (Eller) at 5:1-5, Figs. 2,⁴ 16-17. Some of Eller's examples, such as Figure 2 above, include three wire members: a first wire member, a second wire member, and a third wire member. *See* Ex. 1007 (Eller) at 5:1-5, Figs. 2, 8-10. However, Eller also discloses that "a selective fluid barrier device can include any suitable number of wire members," including only one wire member. *Id.* at 16:7-19. Eller depicts examples having only one wire member in Figures 15-17 and 20-22. *Id.* at 21:37-22:31, 23:50-25:9, Figs. 15-17, 20-22. Thus, Eller's disclosure of examples having more than one wire member does not affect my opinions on whether the claims of the '291 patent are patentable.

119. 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."

⁴ 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.

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 claimed in the ’291 patent because the wire member is at least one or more threads, lines, cords, rope, ribbon, flat wire, sheet, or tape.

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

121. Eller’s first wire member has a first end 124 (first end portion) 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:

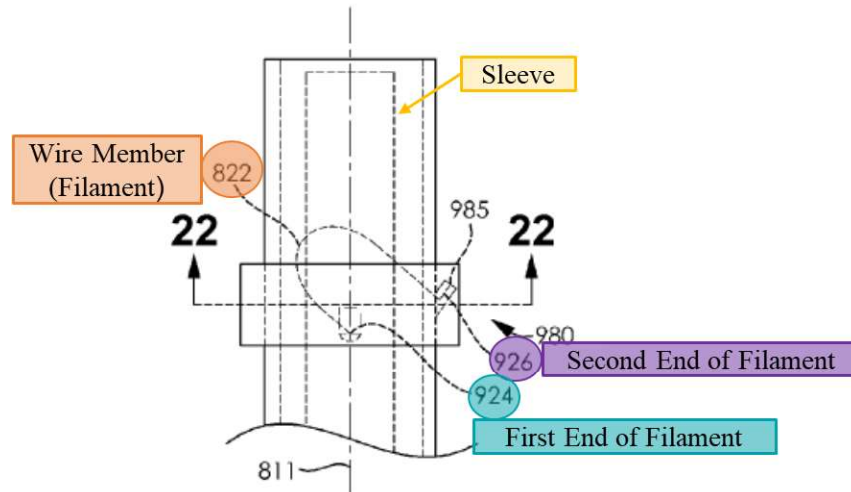
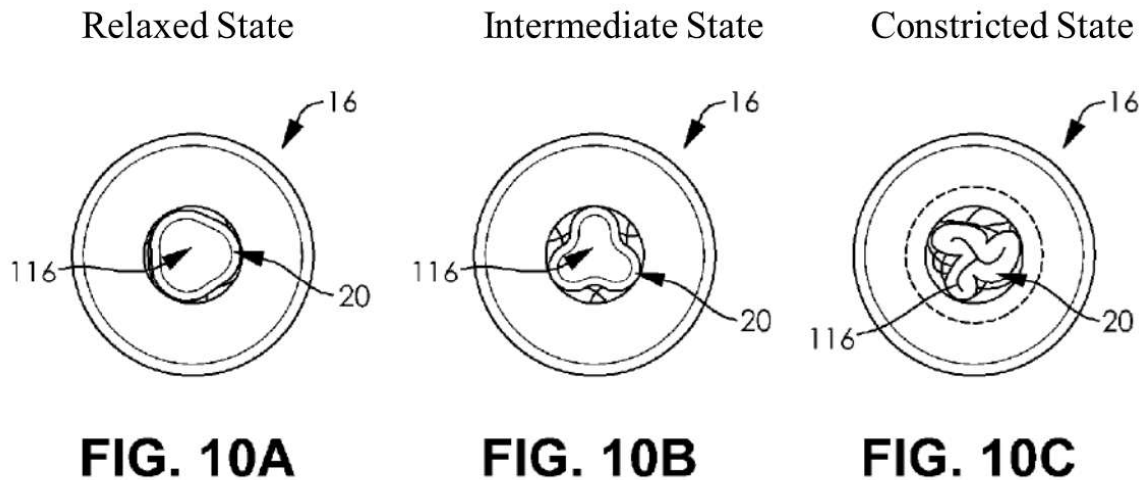


FIG. 21

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

122. Eller's actuator and wire member are “movable between a first configuration and a second configuration.” *Id.* at 15:21-25. Eller explains that in the first configuration, the actuator is rotated so that the wire member is in a relaxed state and fluid is permitted to flow through the sleeve. *Id.* at 15:21-40, 17:38-43. Then, when the actuator is rotated, the valve is moved to the second configuration where the actuator places the wire member in a tensioned state, causing the wire member to constrict the sleeve and prevent fluid from passing therethrough. *Id.* at 15:21-40, 17:62-67. Figures 10A through 10C illustrate the valve transitioning from the first relaxed position (10A) to the second constricted position (10C):



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

123. A person of ordinary skill in the art would have found it obvious, and been motivated, to substitute Eller’s wire member for Schaffer’s U-shaped actuating members 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.

124. 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.

125. 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

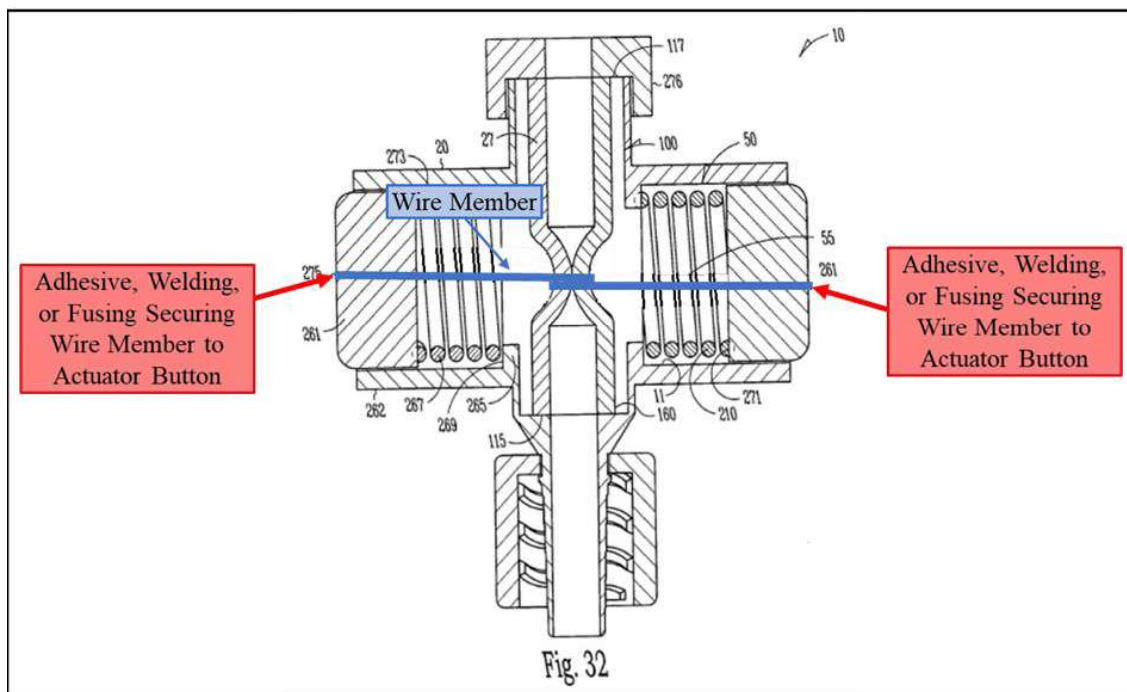
of ordinary skill in the art from combining Eller's wire member with Schaffer's valve. The substitution would have been well within the level of ordinary skill in September 2017.

126. Fourth, as Schaffer recognizes, fluid stasis valves generally comprise "a resilient material in compression within a housing or clamping member." Ex. 1005 (Schaffer) at [0003]. 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.

127. 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, 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 on the opposite side of the valve:

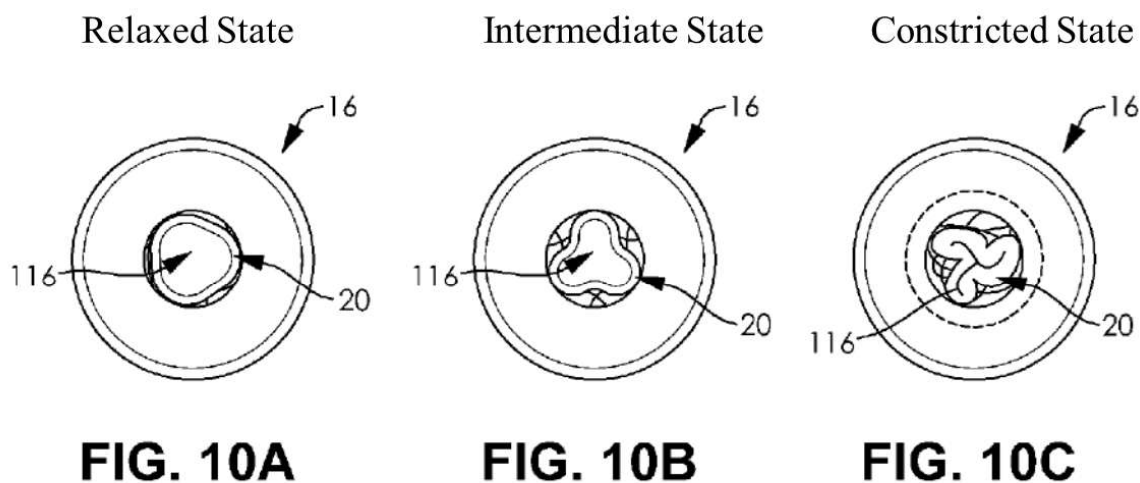
Demonstrative Illustration Schaffer + Eller's Wire Member



128. 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.

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



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

Constricted State

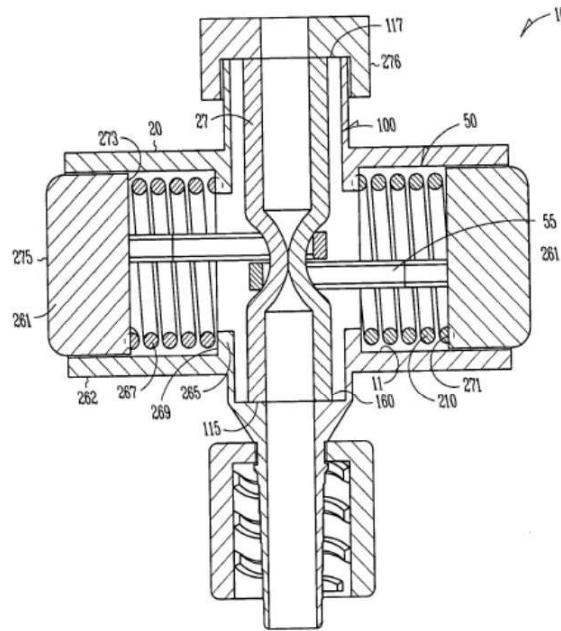


Fig. 32

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.

130. 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 wire member 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 (Schaffer) at [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 spring of Schaffer did not initially exert sufficient force to constrict the valve, 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. *Supra* §VI.A.5.b. Likewise, 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* ¶105.

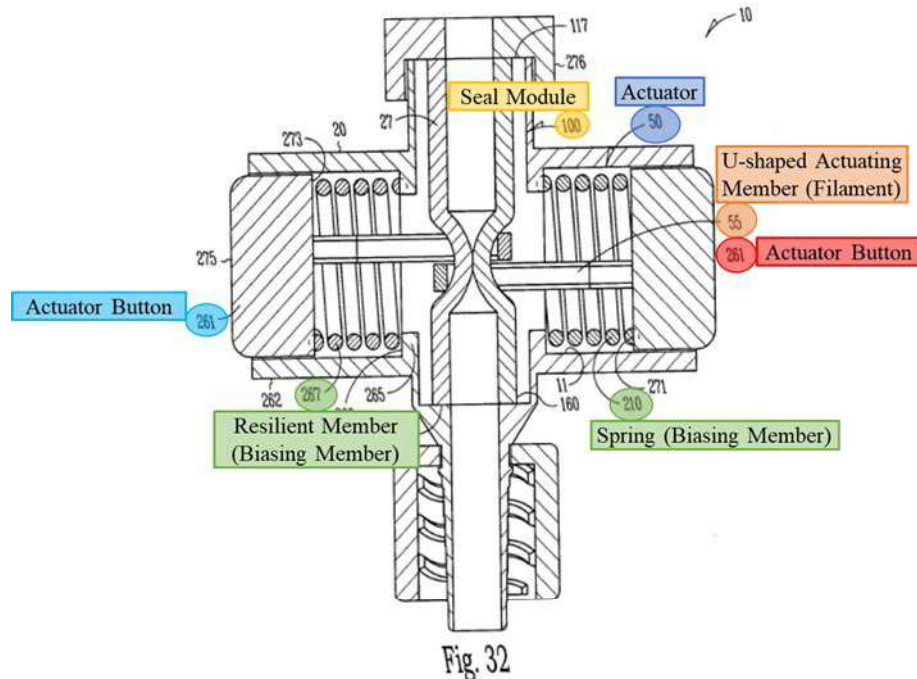
These similarities between Eller's wire member and Schaffer's U-shaped actuating members would have reinforced a person of ordinary skill in the art's reasonable expectation that Eller's wire member could be successfully implemented in Schaffer's valve.

131. Further, a person of ordinary skill in the art would have been motivated to use the looped configuration of Eller's wire member when replacing Schaffer's U-shaped actuating members with Eller's wire member. A person of ordinary skill in the art would have recognized that looping the wire member around the entire circumference of Schaffer's seal module would maximize the constrictive seal of the wire member around Schaffer's seal module and any tools inserted therethrough because it would ensure that the entire outer circumference of tools would be constricted against the seal module, eliminating any gaps that might otherwise exist. For all of the above reasons, Schaffer in combination with Eller renders claim 1 obvious.

6. Spring

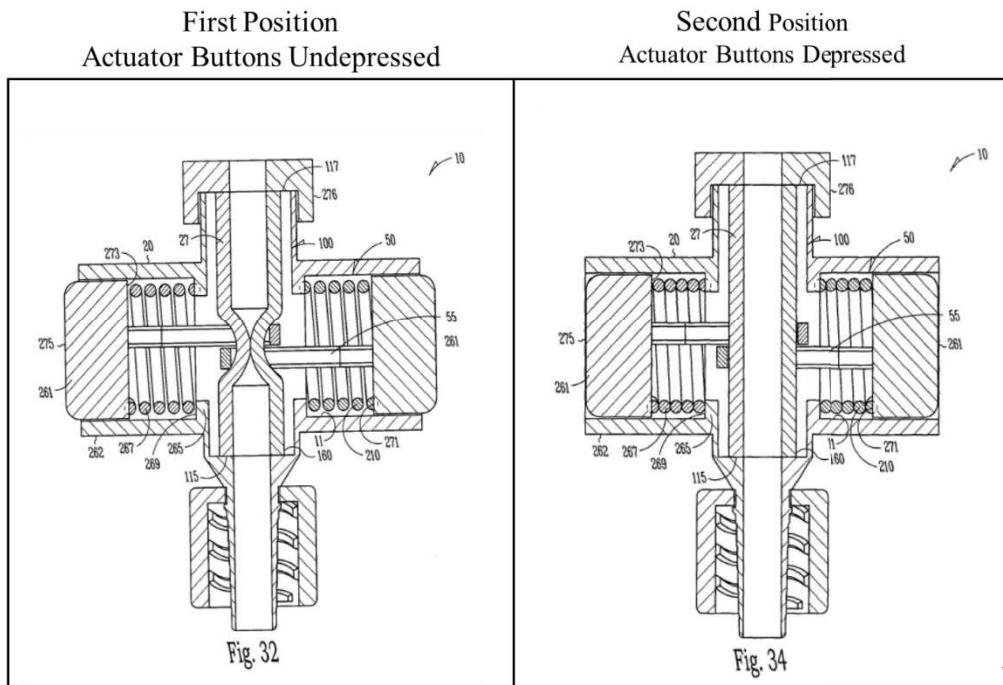
132. Claim 1 finally recites that the hemostasis valve comprises "a spring configured to move the first member in a direction that pulls the first end portion away from the tubular sidewall, reducing a diameter of the lumen in response to reducing a diameter of the loop." Schaffer discloses this limitation.

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

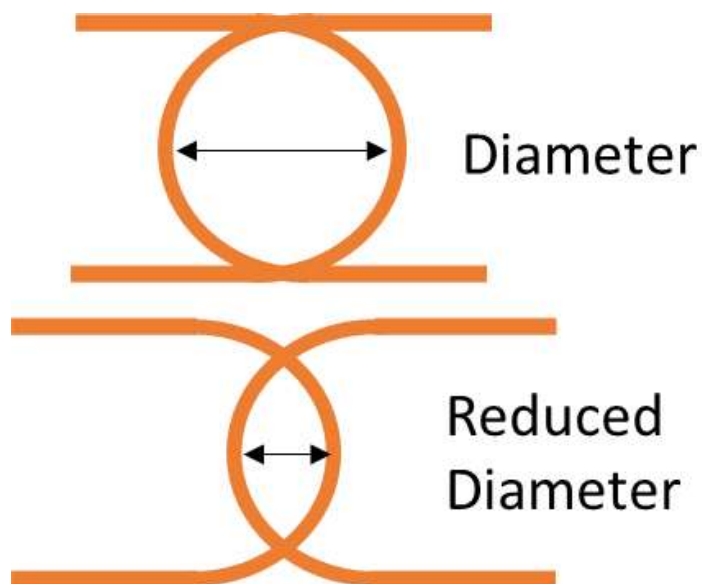


Ex. 1005 (Schaffer) at [0077], Fig. 31.

134. As discussed above, Schaffer's actuator buttons are "movable from a first position to a second position." *Id.* at [0077]. Schaffer's springs are configured to move the actuator buttons toward the first (i.e., sealed) position by imposing a force on the actuator buttons when the buttons are undepressed. *Id.* The force supplied by the springs causes the actuating members coupled to the buttons to collapse and seal the seal module, preventing the flow of fluid through the valve. *Id.* The system remains in this sealed state until the actuator buttons are depressed, which relieves the force applied by the springs:



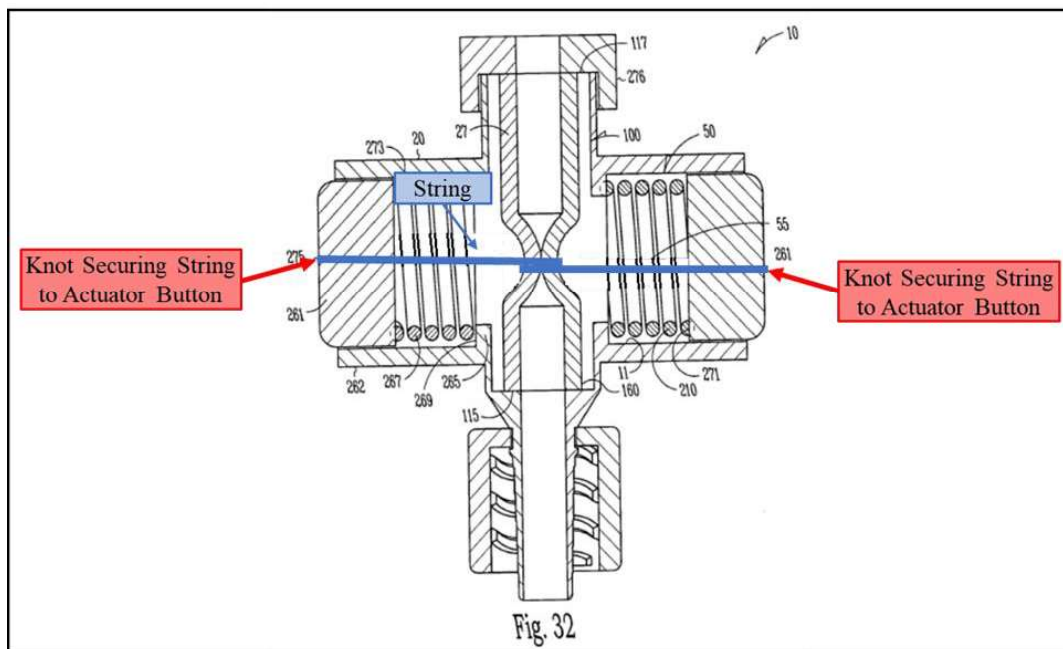
Id. at [0077], Figs. 32, 34. In the first position, the force supplied by the spring causes the first member (actuator button) to move outwardly and pull the first end portion of the actuating member (filament) to reduce the diameter of the seal module lumen and constrict the valve. This reduction in diameter is illustrated in the diagram below:



Thus, Schaffer discloses each limitation of claim 1 and anticipates claim 1.

135. If a person of ordinary skill in the art replaced Schaffer's two actuating members with Hartley's string or Eller's wire member, pulling on the ends of the string/wire would also reduce the diameter of the lumen in response to reducing the diameter of the loop formed by the string/wire. As discussed in the prior sections, Hartley and Eller each disclose looping a filament around a collapsible tubular sidewall and pulling on the ends of the filament to reduce the diameter of the loop to constrict the tubular sidewall. *Supra* §§VI.A.5b-c. If Hartley's string or Eller's wire member were combined with Schaffer's valve, Schaffer's spring would move the buttons outwardly (away from the collapsible tubular sidewall), thereby pulling on the ends of the string/wire member to reduce the diameter of Schaffer's seal module (tubular sidewall) and the diameter of the loop, as demonstrated below:

Demonstrative Illustration Schaffer + Hartley's String



A person of ordinary skill in the art would have been motivated to combine Hartley's string or Eller's wire member with Schaffer's valve, and reasonably expected success in doing so, for the reasons provided previously. *Supra* §§VI.A.5.b-c. Thus, Schaffer combined with Hartley or Eller renders claim 1 obvious.

B. Claim 2

136. Claim 2 recites: "The hemostasis valve of claim 1 further comprising a second member movably coupled to the support." Schaffer anticipates claim 2 or renders claim 2 obvious alone or in view of Hartley *or* Eller.

Fig. 32

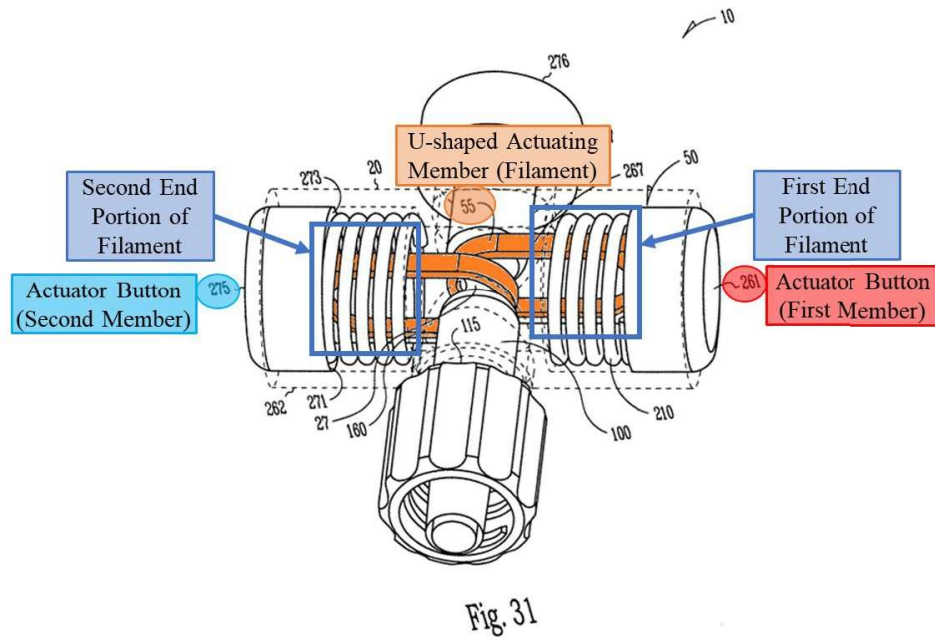


C. Claim 3

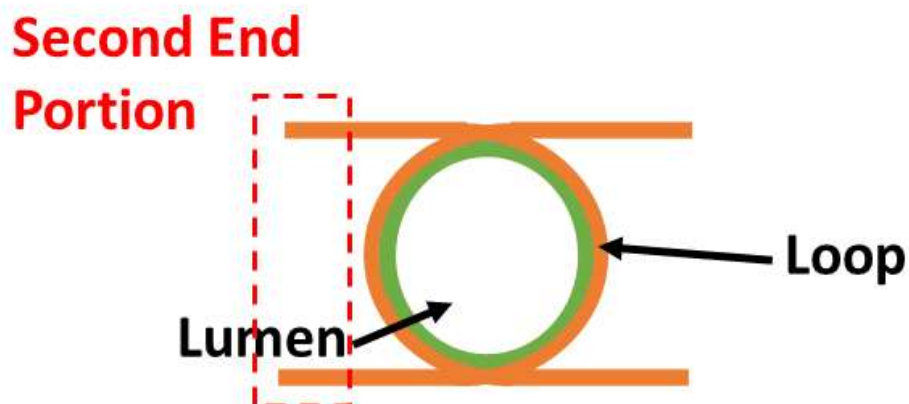
- 85 -

member.” Schaffer anticipates claim 3 or renders claim 3 obvious alone in view of Hartley *or* Eller.

140. Schaffer’s left actuating member has a second end portion extending away from the loop and attaching to a second actuator button (second member) as seen in Figure 31:



141. The second end portion of the actuating member can be seen in the illustration below:



142. Schaffer's second end portion is consistent with the '291 patent for the same reasons I discussed regarding the first end portion above. The '291 patent discloses that where "*the filament 150* comprises multiple filaments, each of the multiple filaments can have a *first end 700* and a *second end 702*":

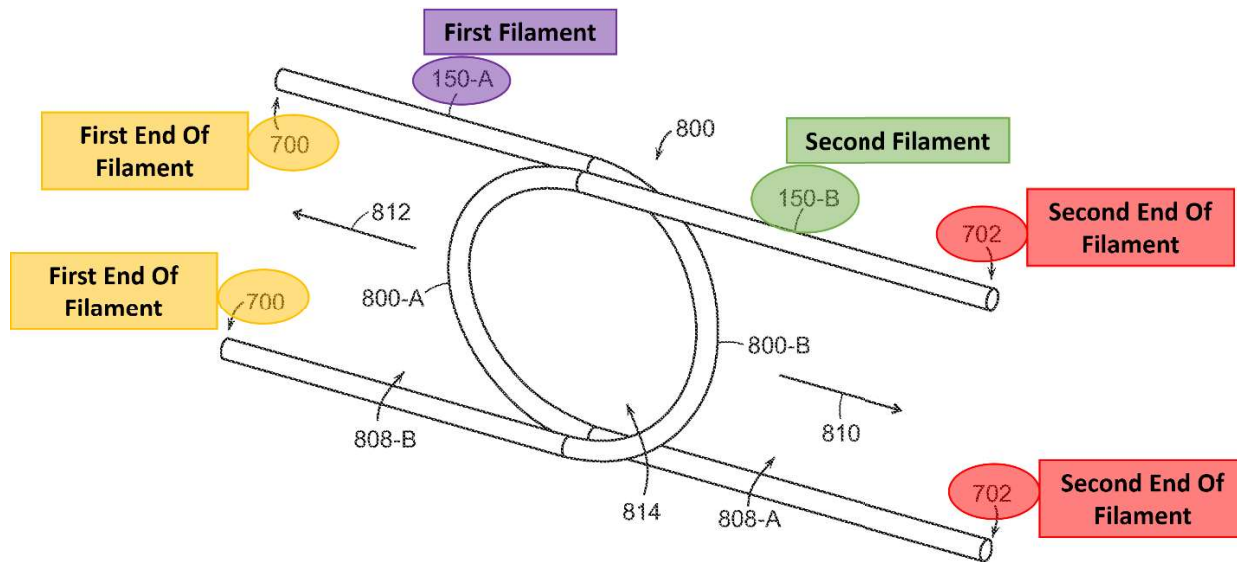


FIG. 8

Ex. 1001 at 12:64-67, Fig. 8. Like the disclosure in the '291 patent, Schaffer's U-shaped actuating members have a second end portion extending away from the loop and attaching to a second actuator button. Thus, Schaffer discloses the limitation required by claim 3, or renders it obvious.

143. The string of Hartley and wire member of Eller also disclose a second end portion extending away from the loop. Hartley's discloses that its string is connected to its rotary actuator via knots 16 at the ends of the filament that "is wound preferably twice around the cylindrical diaphragm 8." Ex. 1006 [0031]. As

seen in Figure 3, the left end of Hartley's string forms a second end portion extending away from the loop around the cylindrical diaphragm:

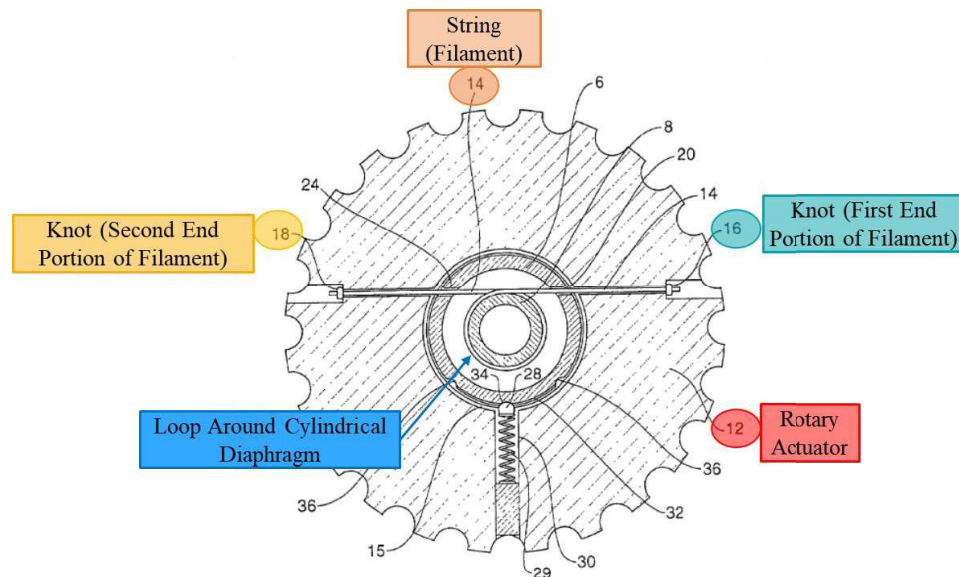


Fig 3

Id. at [0031], Fig. 3.

144. Eller's wire member loops around the valve "sleeve" such that a first end 124 can attach to the housing 16 and a second end 126 can attach to an actuator 18:

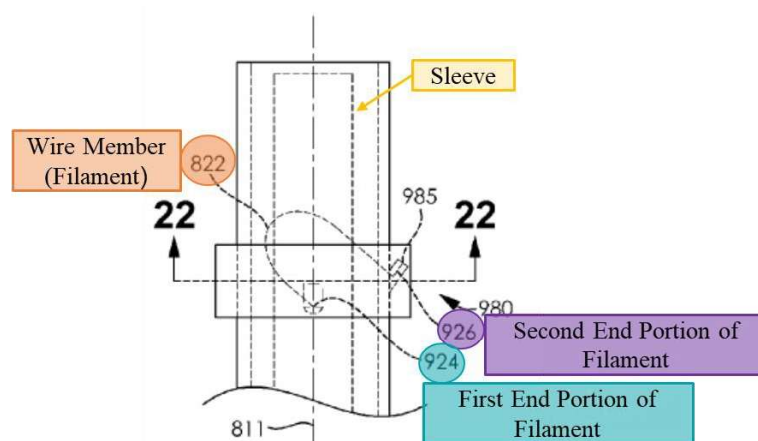


FIG. 21

(Ex. 1007, 12:52-64, 24:50-57, Fig. 21.)

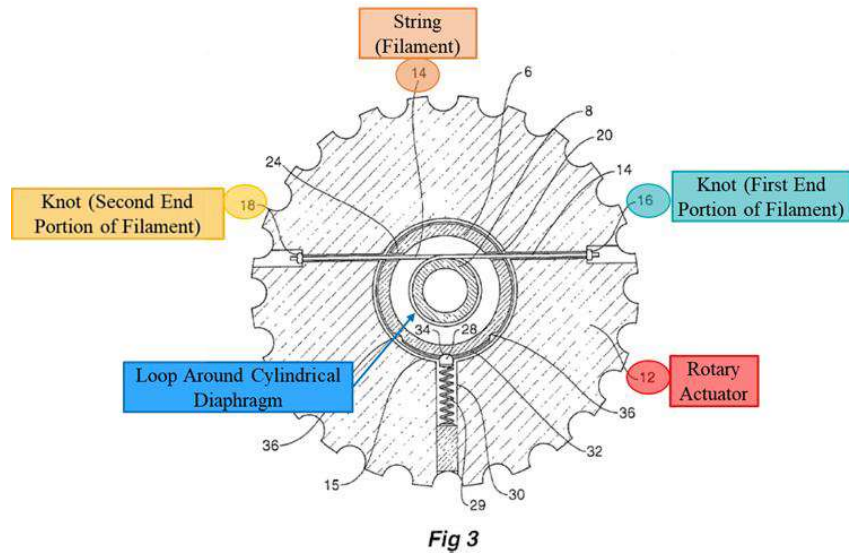
145. A person of ordinary skill in the art would have been motivated to replace the U-shaped actuating members with Hartley's string or Eller's wire members, and reasonably would have expected success in doing so, for the same reasons I discussed above in claim 1. *Supra* §VI.A.5.b-c. The string of Hartley or wire member of Eller would attach to Schaffer's second actuator button (second member) in such a configuration. Thus, Schaffer combined with either Hartley or Eller renders claim 3 obvious.

D. Claim 4

146. Claim 4 recites "the hemostasis valve of claim 3 wherein the first end portion, the loop, and the second end portion are one continuous element." Schaffer in combination with Hartley *or* Eller renders claim 4 obvious.

1. Shaffer-Hartley

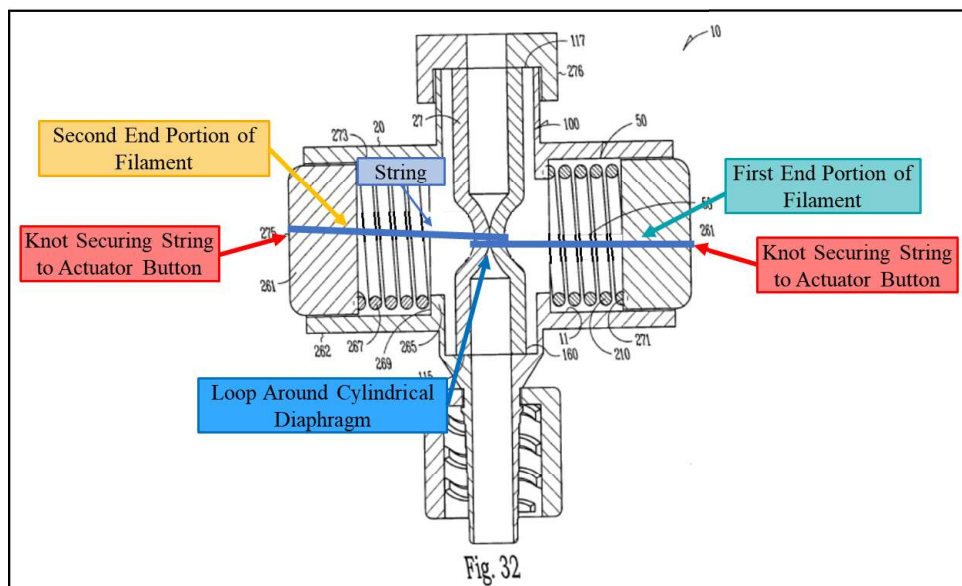
147. Hartley discloses a continuous string (filament) that has a first end portion, a second end portion, and a loop in one continuous element. Hartley's string is attached to a first knot (first end portion), is looped around a cylindrical diaphragm (collapsible tubular member), and attached to a second knot (second end portion):



Ex. 1006 at [0031], Figs. 1, 3.

148. As I discussed above in relation to claim 1, a person of ordinary skill in the art would have been motivated to substitute Hartley's string for Schaffer's U-shaped actuating members, and reasonably would have expected success in doing so. *Supra* §VI.A.5.b. Such a combination is demonstrated below:

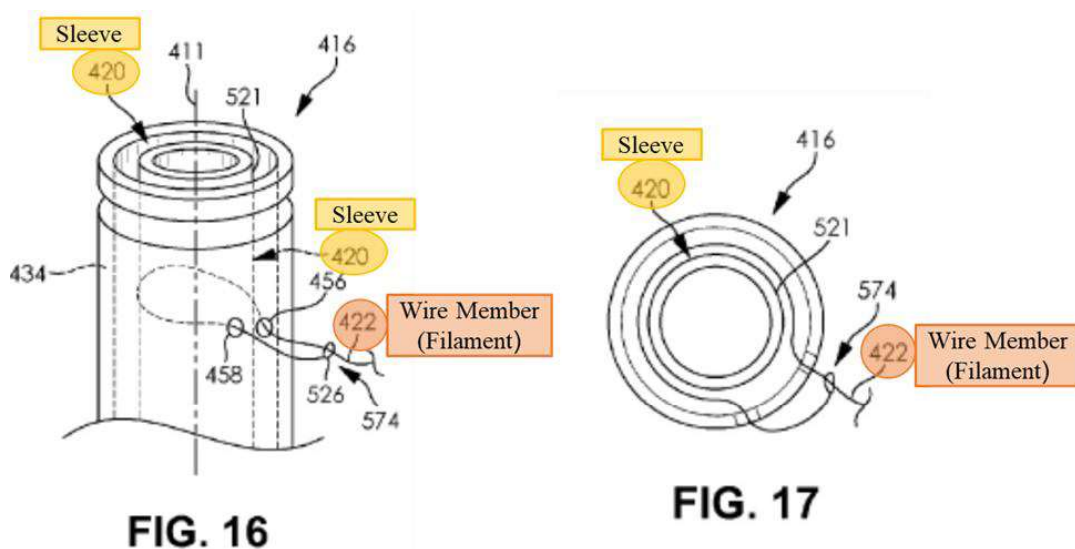
Demonstrative Illustration Schaffer + Hartley's String



In this combination, the string forming a loop, first end portion, and second end portion would be a continuous filament. Thus, Schaffer combined with Hartley renders claim 4 obvious.

2. Schaffer-Eller

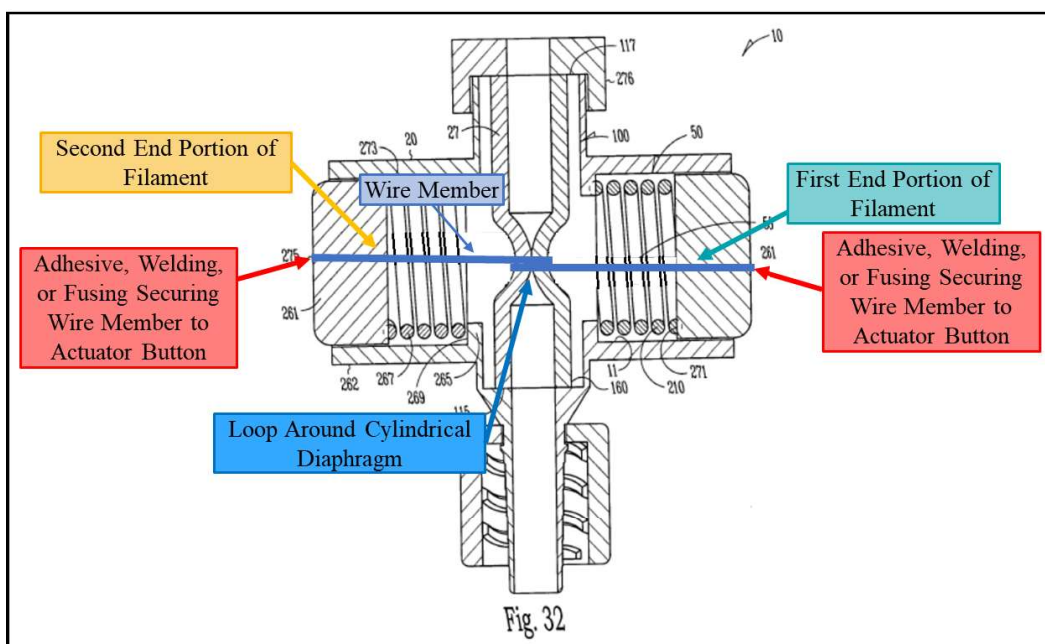
149. Eller discloses a continuous wire member (filament) that forms a loop around the outer surface of a sleeve (collapsible tubular member):



Ex. 1007 at 5:1-5, 16:7-19, 21:37-22:31, 23:50-25:9, Fig. 2, 16-17.

150. As I explained above in relation to claim 1, a person of ordinary skill in the art would have been motivated to substitute Eller's wire member for Schaffer's U-shaped actuating members. *Supra* §VI.A.5.c. Such a combination is demonstrated below:

Demonstrative Illustration Schaffer + Eller's Wire Member



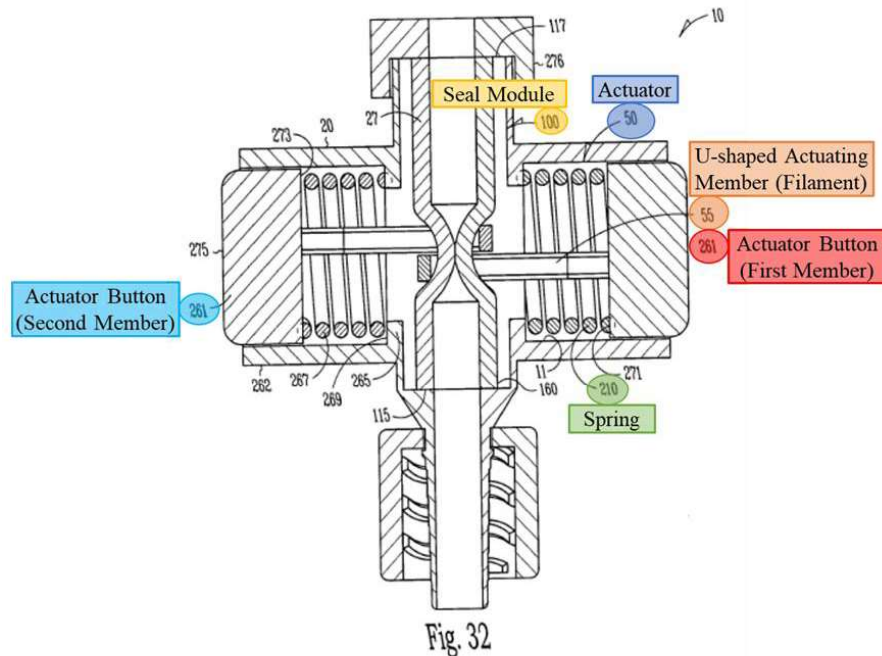
In this combination, the wire member forming a loop, first end portion, and second end portion is a continuous filament. Thus, Schaffer combined with Eller renders claim 4 obvious.

E. Claim 5

151. Claim 5 recites the “hemostasis valve of claim 3, wherein the first member and the second member are biased in a direction that places the first end portion and the second end portion under sufficient tension to reduce the diameter of the lumen and provide a seal around a device extending through the lumen.” Schaffer discloses this limitation.

152. As I explained for claims 1 and 2 above, Schaffer’s valve includes two spring-loaded actuator buttons 261 that are “movable from a first position to a

second position on opposing sides of the housing.” Ex. 1005 at [0075]-[0076], Figs. 31-32; *supra* §§VI.A.3, VI.B. Schaffer further discloses that when the actuator buttons are undepressed (i.e., in the first position), “the actuating members 55 of the actuators 50 are, in one option, disposed and at least partially circumferentially [sic] disposed about the portion 108 of the seal module 100 depressing and at least partially collapsing a portion 108 of the containment structure 160 by a compressive force 67 (e.g. by a spring 210)”:



Ex. 1005 (Schaffer) at [0075]-[0076], Figs. 31-32.

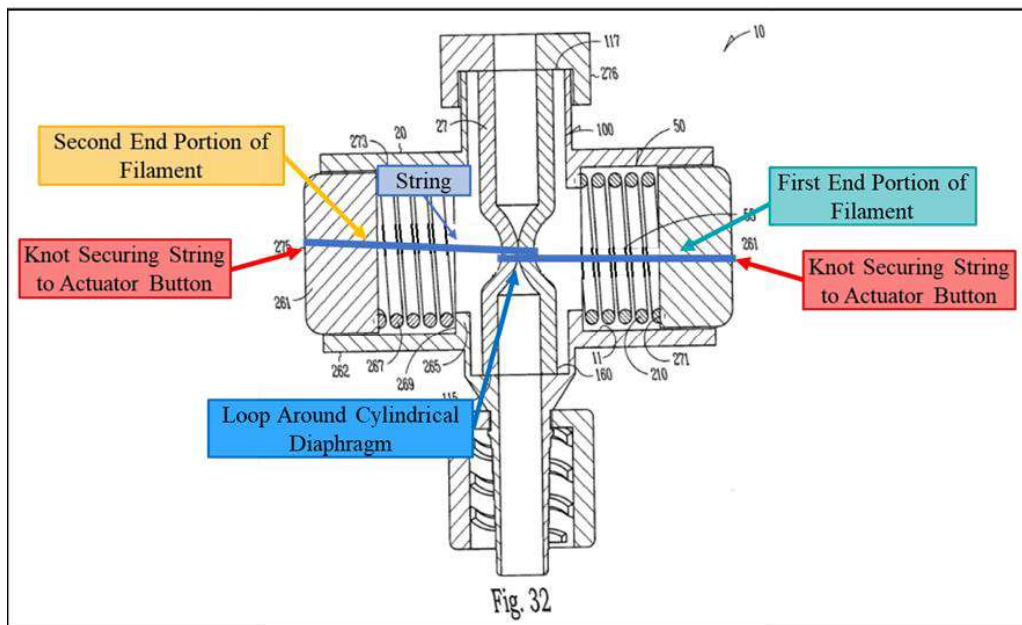
153. Each actuator button 261 is attached to a spring 210. *Id.* The springs 210 bias both the first and second actuator buttons outwardly to the first (closed) position. Ex. 1005 (Schaffer) at [0076]-[0077], Figs. 31-34. When the actuator buttons are in the first position, the first and second end portions are placed under

154. The tension created between the first and second end of the actuating member is sufficient to reduce the diameter of the lumen and provide a seal around a device inserted through the lumen. Schaffer expressly discloses 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.” Ex. 1005 at [0008]. Thus Schaffer’s valve places the actuating members under sufficient tension to provide a seal around a device inserted through the lumen and anticipates claim 5.

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extending through the lumen. As I explained above in claims 1 and 3, it would have been obvious to a person of ordinary skill in the art to substitute Hartley's string or Eller's wire members for the U-shaped actuating members of Schaffer. *Supra* §§VI.A.5.b-c, VI.C. The string of Hartley or wire member of Eller would be attached to one of Schaffer's actuator buttons in such a combination. Schaffer's springs would then bias the actuator buttons in the same manner described above to provide sufficient tension on the filament to seal the valve:

Demonstrative Illustration
Schaffer + Hartley's String



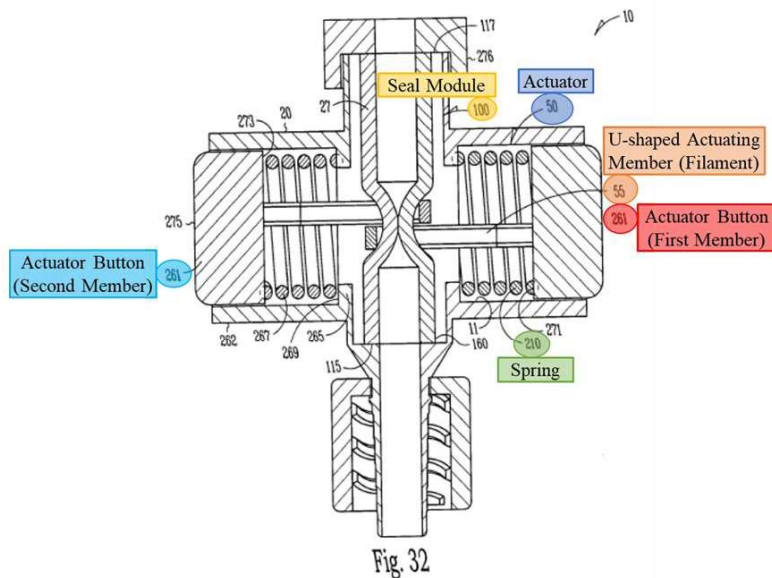
156. If Schaffer's valve did not initially seal when combined with Hartley's string or Eller's wire member, a person of ordinary skill in the art would have possessed the knowledge to modify the configuration to ensure a seal. *Supra* §§VI.A.5.b-c. As I explained in reference to claim 1, as person of ordinary skill in

the art would have known to modify the configuration or material of the spring or collapsible tubular sidewall to ensure a seal. *Id.* Thus, Schaffer in combination with Hartley or Eller renders claim 5 obvious.

F. Claim 6

157. Claim 6 recites: “The hemostasis valve of claim 3 wherein the first member and the second member are biased in a direction that places the first end portion and the second end portion under sufficient tension to close the lumen.” Schaffer anticipates claim 6 or renders it obvious alone or in combination with Hartley and Eller.

158. As I discussed in claims 1 and 5, Schaffer’s actuator buttons (first and second members) are biased to a first position such that the first and second end portions of the filament are under tension to close the loop and in response the diameter of the lumen. Schaffer’s valve “blocks the flow of gas or fluid completely and immediately with or without an instrument in place within the gas/fluid path” as seen in Figure 32:



Ex. 1005 (Schaffer) at [008], Fig. 32. Therefore, Schaffer's first and second members are biased in a direction that places the first end portion and second end portion under sufficient tension to close the lumen.

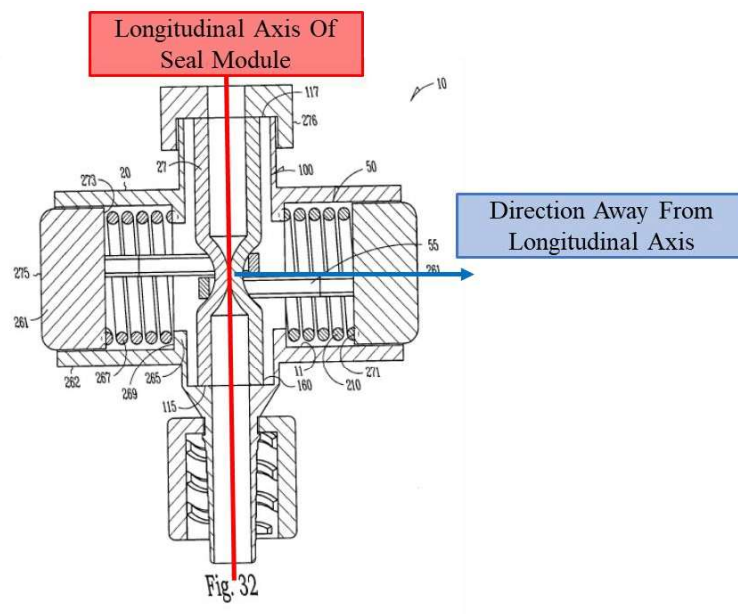
159. As I explained in detail in claims 1 and 5, if Hartley's string or Eller's wire member were substituted for Schaffer's actuating members, the springs and actuator buttons of Schaffer would also keep the first and second end portions of the filament under tension to close the lumen of the seal module. *Supra* §§VI.A.5-6, VI.E. If the spring of Schaffer did not initially exert sufficient force to fully close the lumen, 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. Likewise, if the resiliency of Schaffer's lumen required adjustment to function with Hartley's string or Eller's wire member, a person of ordinary skill in the art would have

possessed the skills and knowledge to select an appropriate material with the proper resiliency. *Id.* Thus, Schaffer in combination with Hartley or Eller renders claim 6 obvious.

G. Claim 7

160. Claim 7 recites: “The hemostasis valve of claim 1 wherein the lumen extends along a longitudinal axis, and wherein the direction is a direction away from the longitudinal axis.” Schaffer anticipates this claim or renders it obvious alone or in combination with Harley or Eller.

161. As I discussed in claims 1 and 5 above, Schaffer’s springs bias the actuator buttons to create tension on the filament and constrict the lumen. As shown in the illustration below, the direction of this biasing force is away from the longitudinal axis of the lumen:



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

H. Claim 8

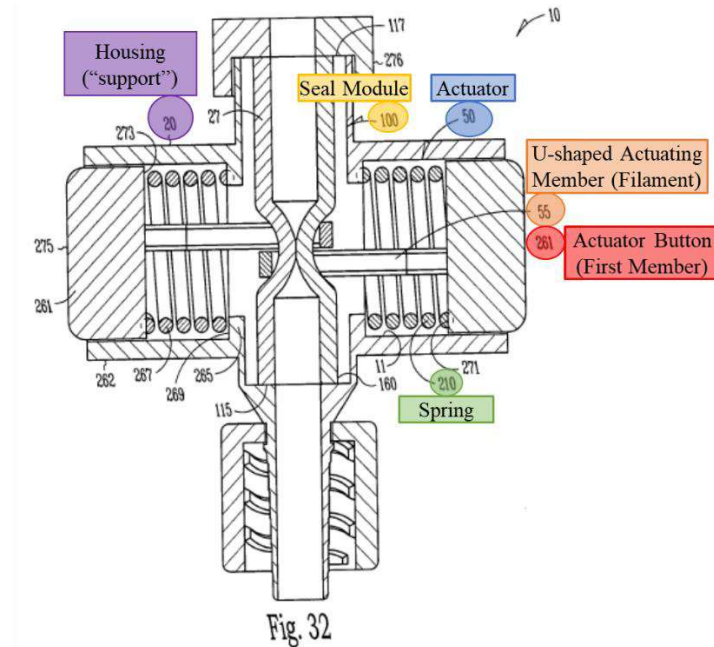
162. Claim 8 recites: “The “hemostasis valve of claim 1 wherein the lumen extends along a first longitudinal axis, and wherein the direction is a direction orthogonal to the longitudinal axis.” Schaffer anticipates this claim or renders it obvious alone or in view of Hartley *or* Eller.

163. As I discussed and illustrated in claim 7 above, Schaffer’s actuator buttons are biased in a direction orthogonal to the longitudinal axis of the seal module lumen. Ex. 1005 (Schaffer) at [0077], Figs. 31-34.

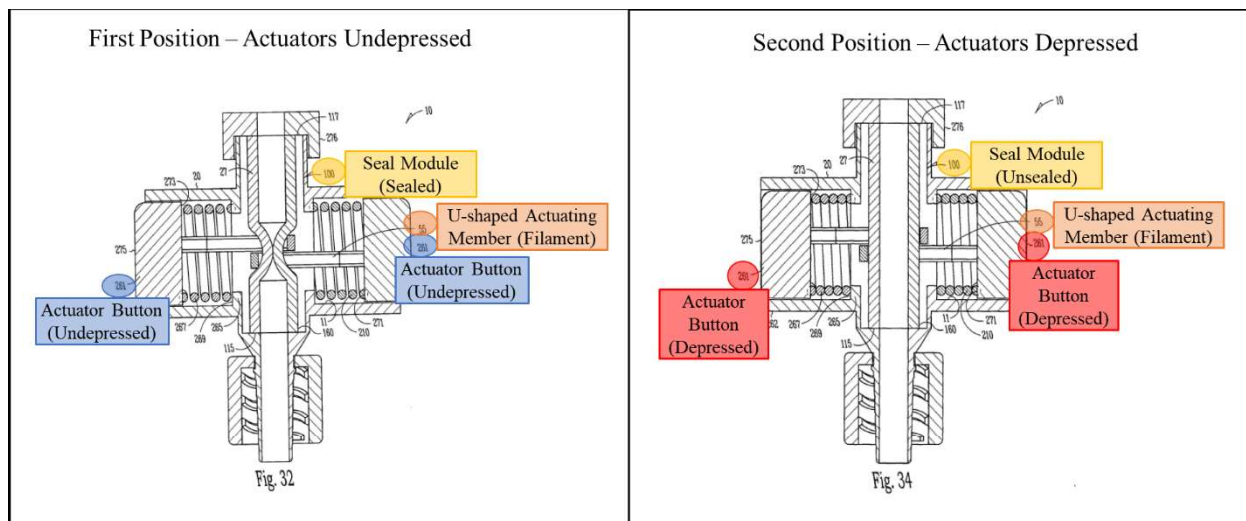
I. Claim 12

164. Claim 12 recites: “The hemostasis valve of claim 1 wherein the direction is a first direction, and wherein the first member is actuatable in a second direction to move the first end portion toward the tubular sidewall to increase the diameter of the lumen in response to increasing the diameter of the loop.” Schaffer anticipates claim 12 or renders it obvious alone or in combination with Hartley *or* Eller.

165. As I discussed above in claim 1, Schaffer includes “two circular actuators 50” that are “movable from a first position to a second position on opposing sides of the housing”:



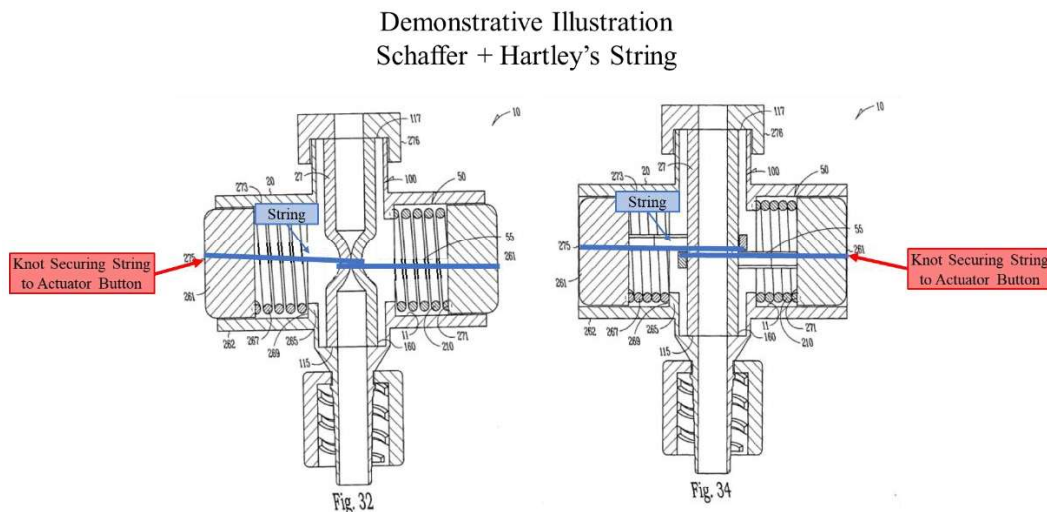
Ex. 1005 (Schaffer) at [0075]-[0076], Fig. 32. The actuator buttons are undepressed in the first position, shown in Figure 32, and are depressed when the valve is in the second position, shown in Figure 34 below:



Id. at [0077], Figs. 32, 34. When Schaffer's actuator buttons are in the undepressed position, the first end portion of the actuating member (filament) is pulled away from the seal module (tubular sidewall), reducing the diameter of the loop and

sealing the lumen. When the buttons are depressed, the first end portion of the actuating member (filament) is moved toward the seal module (tubular sidewall), which increases the diameter of the lumen in response to increasing the diameter of the loop. Thus, it is my opinion that Schaffer anticipates this claim.

166. If Schaffer's actuating members were replaced with Hartley's string or Eller's wire member, the depression of the actuator buttons (shown in Figure 34) would move the first end portion of the string or wire member toward the seal module as illustrated below:



As I have discussed above in claim 1, a person of ordinary skill in the art would have been motivated to combine Hartley's string or Eller's wire member with Schaffer's valve and reasonably would have expected success in doing so. *Supra* §§VI.A.5.b-c. Thus, it is my opinion that Schaffer in combination with Hartley or Eller renders claim 12 obvious.

J. Claim 13

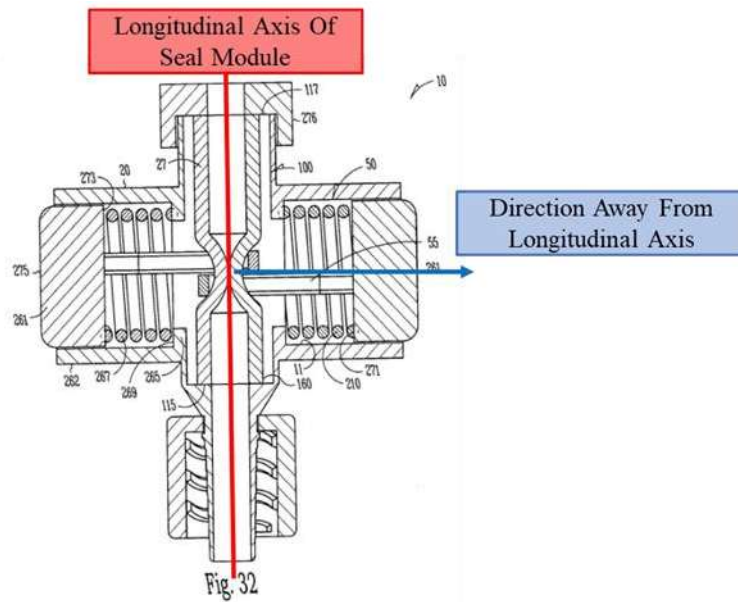
167. Claim 13 recites: “The hemostasis valve of claim 12 wherein the first direction is opposite the second direction.” Schaffer anticipates this claim or renders it obvious alone or in combination with Hartley or Eller.

168. As shown and described above in claim 12, the “first direction” required by the claims is outward from the longitudinal axis of the seal module and the “second direction” required by the claims is inward toward the longitudinal axis of the seal module. *Supra* §VI.I. Thus, the first direction is ***opposite*** the second direction.

K. Claim 14

169. Claim 14 recites: “The hemostasis valve of claim 13 wherein the lumen extends along a longitudinal axis, and wherein the first direction and the second direction are orthogonal to the longitudinal axis.” Schaffer anticipates claim 14 or renders it obvious alone or in combination with Hartley or Eller.

170. As discussed in claims 7, 8, 12, and 13, the first direction and second direction are orthogonal to the longitudinal axis of the lumen in Schaffer’s seal module.



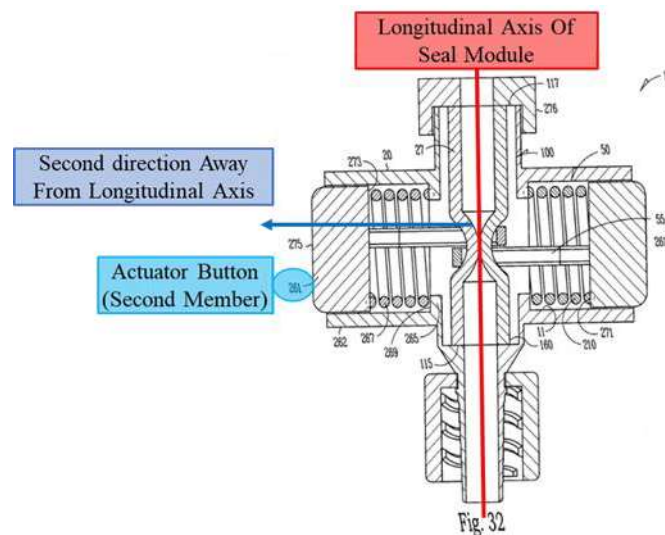
L. Claim 15

171. Claim 15 recites: “The hemostasis valve of claim 1 wherein the actuator further comprises a second member movably coupled to the support, wherein the filament further comprises a second end portion extending away from the loop to the second member, wherein the spring is a first spring, wherein the direction is a first direction, and further comprising a second spring configured to move the second member in a second direction that pulls the second end portion away from the tubular sidewall, reducing the diameter of the lumen in response to reducing the diameter of the loop.” Claim 15 is anticipated by Schaffer or rendered obvious by Schaffer alone or in combination with Hartley or Eller.

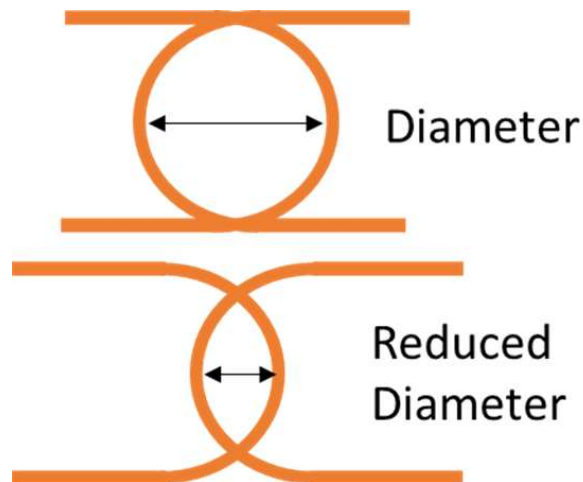
172. As I discussed in claim 2 above, Schaffer discloses an actuator comprising a second member movably coupled to the support. *Supra* §VI.B. As I discussed in claim 3, Schaffer either alone or on combination with Hartley’s string

or Eller's wire member discloses a filament comprising a second end portion extending away from the loop to the second member. *Supra* §VI.C. As discussed in claims 1 and 5, Schaffer discloses a first spring that biases the actuator button to a first direction that pulls the first end portion of the filament away from the tubular sidewall. *Supra* §§VI.A.6, VI.E.

173. Schaffer also discloses a second spring configured to move the second member in a second direction that pulls the second end portion away from the tubular sidewall:



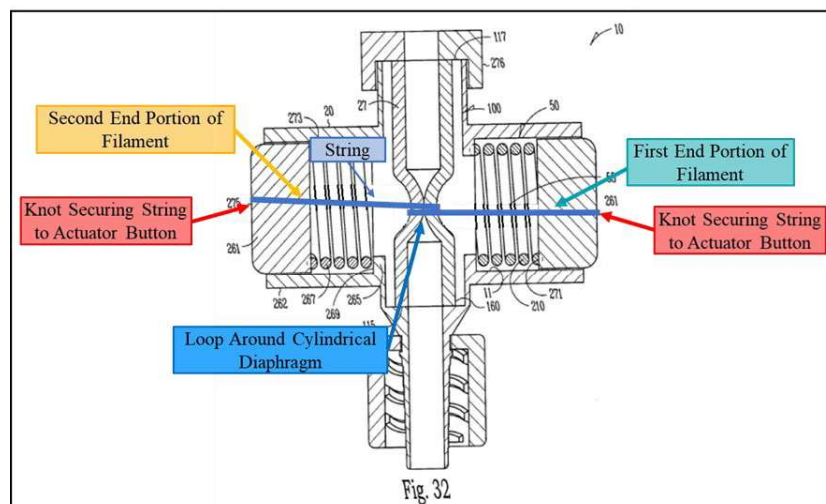
Ex. 1005 at Fig. 31. By pulling the second end portion of the filament away from the tubular sidewall, the actuator reduces the diameter of the lumen in response to reducing the diameter of the loop, as I demonstrated in claim 1:



Ex. 1005 at [0077], Fig. 32.

174. For the reasons I discussed in claim 1, a person of ordinary skill in the art would have found it obvious to combine Schaffer with the string of Hartley or wire member of Eller. *Supra* §§VI.A.5.b-c. As illustrated below, and for the same reasons discussed in claim 1, pulling the second end portion of the Hartley's string or Eller's wire member away from seal module's lumen reduces the diameter of the lumen in response to reducing the diameter of the loop:

Demonstrative Illustration
Schaffer + Hartley's String

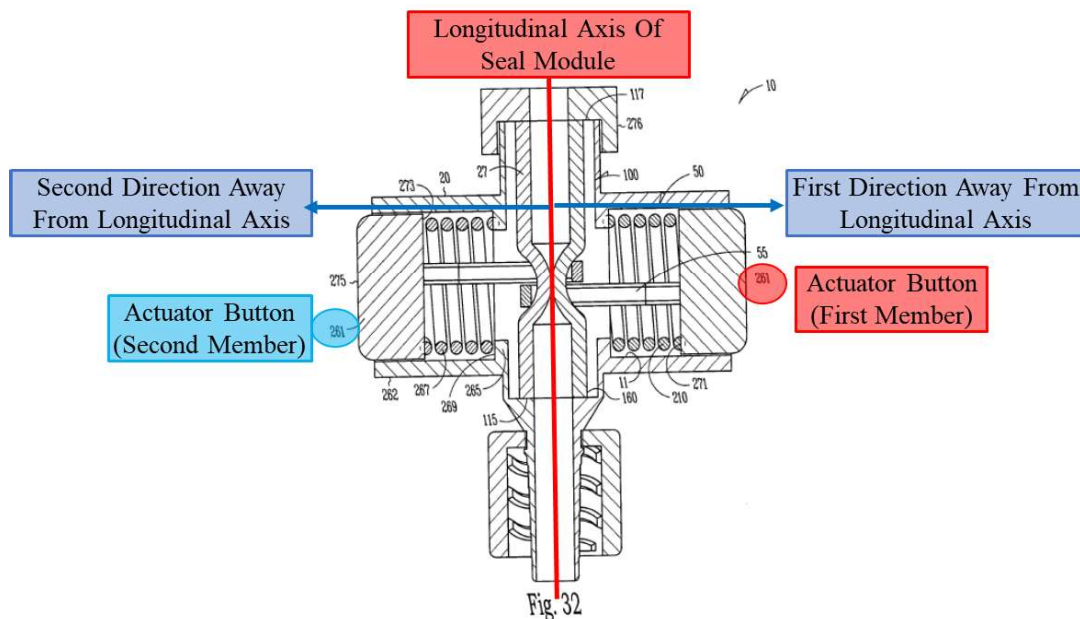


Ex. 1005 at Fig. 32. Thus, it is my opinion that Schaffer anticipates claim 15 or renders it obvious alone or in combination with Hartley or Eller.

M. Claim 16

175. Claim 16 recites: “The hemostasis valve of claim 15 wherein the first direction is opposite to the second direction.” Schaffer anticipates this claim or renders it obvious alone or in combination with Hartley or Eller.

176. As shown below, the first direction and second direction are opposite:

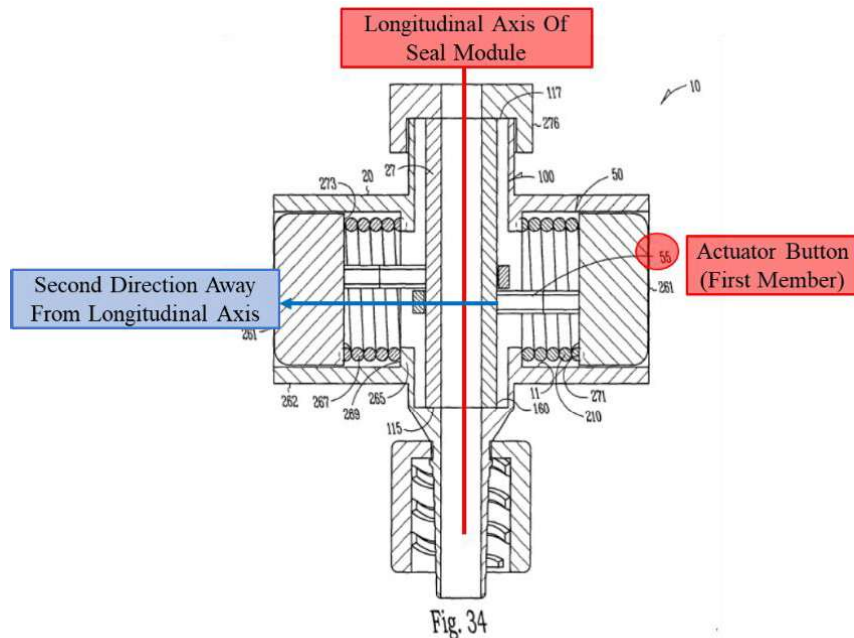


Ex. 1005, Fig. 32. The first direction and second direction would remain opposite if Schaffer’s actuating members were replaced with Hartley’s string or Eller’s wire member. Thus, it is my opinion that Schaffer anticipates claim 16 or renders it obvious alone or in combination with Hartley or Eller.

N. Claim 17

177. Claim 17 recites: “The hemostasis valve of claim 15 wherein the first member is actuatable in the second direction and/or the second member is actuatable in the first direction to move the first end portion toward the tubular sidewall to increase the diameter of the lumen in response to increasing the diameter of the loop.” Schaffer anticipates this claim or renders it obvious alone or in combination with Hartley or Eller.

178. As I explained above in claim 15, the right actuator button (first member) of Schaffer, may move between a first position (undepressed) and a second position (depressed). When the right actuator button (first member) is pushed inward from the first position to the second position (i.e., in the second direction), the first end portion of the filament is moved toward the seal module (tubular sidewall) to increase the diameter of the lumen in response to increasing the diameter of the loop:



Ex. 1005 at [0077], Fig. 34. This mechanism of action would be the same regardless of whether the filament is Schaffer's actuating members, Hartley's string, or Eller's wire member.

O. Claim 19

179. Claim 19 recites the “aspiration catheter system of claim 1 wherein the direction is a first direction, and wherein the first member is actuatable in a second direction to move the first end portion toward the tubular sidewall to increase the diameter of the lumen in response to increasing the diameter of the loop to fluidly couple the lumen of the tubular sidewall to the lumen of the aspiration catheter.”

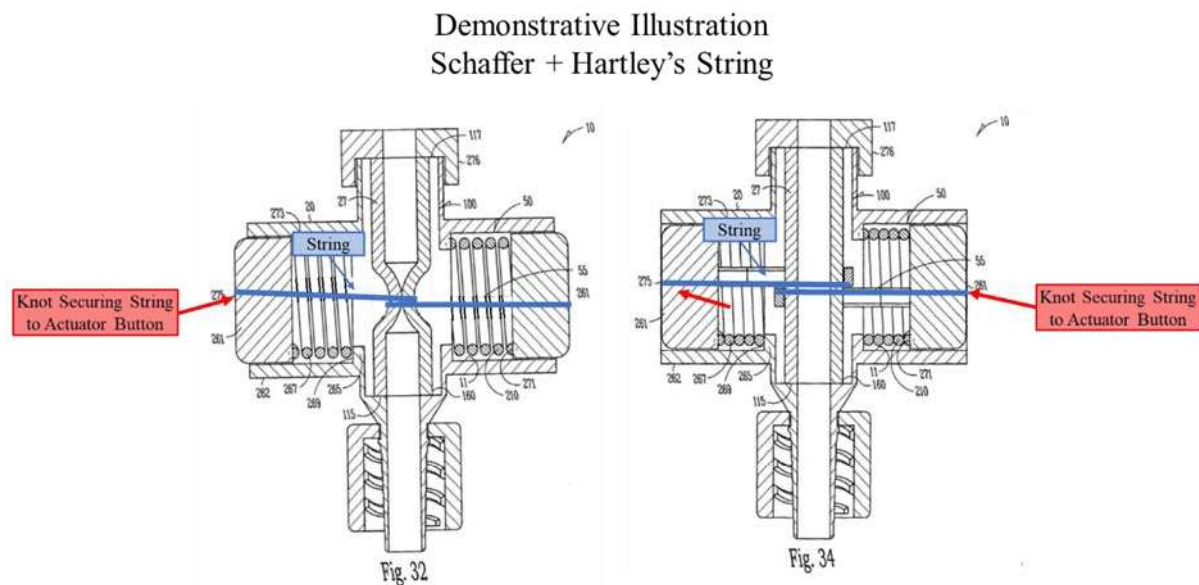
180. I can see that claim 19 includes an error. Claim 19 recites “the aspiration catheter of claim 1.” However, claim 1 does not include an aspiration catheter. Rather, claim 18 does recites an “aspiration catheter.” I cannot determine

whether claim 19 was intended to depend from claim 1, in which case the phrase “aspiration catheter” was inserted in error, or whether claim 19 should depend from claim 18, in which case “of claim 1” was inserted in error. Because I cannot tell the source of the error, I have addressed both variations. If claim 19 depends from claim 1, then Schaffer anticipates claim 19 or renders it obvious alone or in combination with Hartley or Eller. I address the scenario where claim 19 depends from claim 18 in the next section.

181. As I explained above in claim 17, Schaffer’s actuator button is actuatable in second direction, moving the first end portion of the filament closer to the seal module (tubular sidewall) and opening the valve such that “gases and fluids can pass therethrough” to any attached catheter. *Supra* §VI.N, Ex. 1005 at [0077], Fig. 34. Schaffer’s description includes the passage of fluids from an aspiration catheter. Schaffer explains that the described invention expressly “relates to catheters, in particular to a composite fluid-stasis valve for use with catheters” and more specifically discloses connecting a syringe to the valve for creating an aspiration catheter. Ex. 1005 at [0002]-[0003], [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.”). Thus, the lumen of Schaffer’s valve would be coupled to an aspiration catheter when the buttons are depressed and the valve is open.

182. The same would be true if Schaffer was combined with Hartley’s string or Eller’s wire member. Pressing the actuator button of Schaffer inward (in the second direction) would move the first end portion of the filament toward the seal module (tubular sidewall) to increase the diameter of the loop and the lumen. The illustration below shows the valve with an undepressed actuator button and closed lumen on the left. When the actuator button is pushed inward (in the second direction), the diameter of the lumen increases in response to increasing the diameter of the loop:



Ex. 1005, [0077], Figs. 32, 34. The increase in lumen diameter is such that “gases and fluids can pass therethrough” to any attached catheter, as described above.

Thus, it is my opinion that Schaffer combined with Hartley or Eller renders claim 19 obvious.

**VII. GROUND 5-7: CLAIMS 18-19 OBVIOUS OVER GARRISON
COMBINED WITH SCHAFFER AND OPTIONALLY HARTLEY OR
ELLER**

A. Claim 18

183. Claim 18 recites:

18. An aspiration catheter system, comprising:
an aspiration catheter defining a lumen and having a proximal end portion;
and
a hemostasis valve comprising—
a support;
an actuator having at least a first member movably coupled to the support;
a collapsible tubular sidewall defining a lumen carried by the support, wherein the lumen of the tubular sidewall is selectively fluidly couplable to the lumen of the aspiration catheter;
a filament formed in a loop around the tubular sidewall, the filament having at least a first end portion extending away from the loop to the first member; and
a spring configured to move the first member in a direction that pulls the first end portion away from the tubular sidewall, reducing a diameter of the lumen in response to reducing a diameter of the loop to fluidly decouple the lumen of the tubular sidewall from the lumen of the aspiration catheter.

I see that the limitations describing the hemostasis valve in claim 18 are the same as the limitations I addressed in claim 1. It is my opinion that Garrison combined with Schaffer and optionally Hartley or Eller renders claim 18 obvious.

1. Preamble

184. The preamble of claim 18 recites: “An aspiration catheter system.” If the preamble is limiting, it is my opinion that Garrison discloses this limitation.

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

2. Aspiration Catheter

185. Claim 18 next recites: “An aspiration catheter defining a lumen and having a proximal end portion.” It is my opinion that Garrison discloses this limitation. Garrison discloses a “catheter 2030 [that] may be connected to sources of passive or active aspiration via flow lines ... 2045 (Fig. 1) on the devices.”:

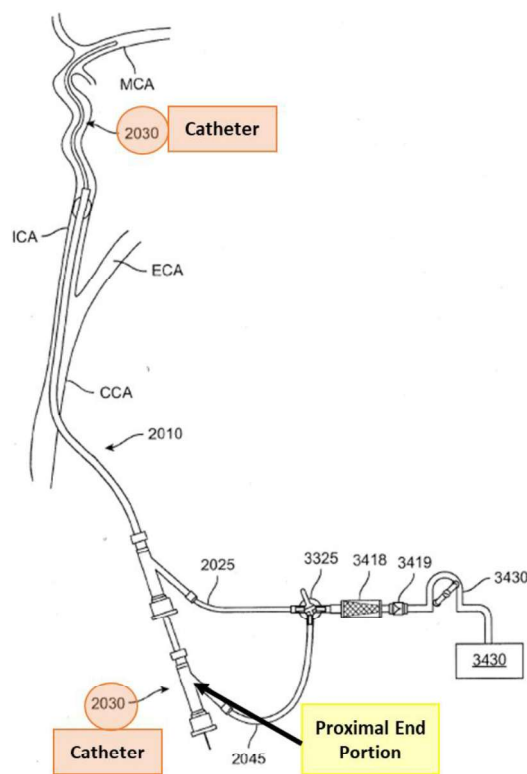
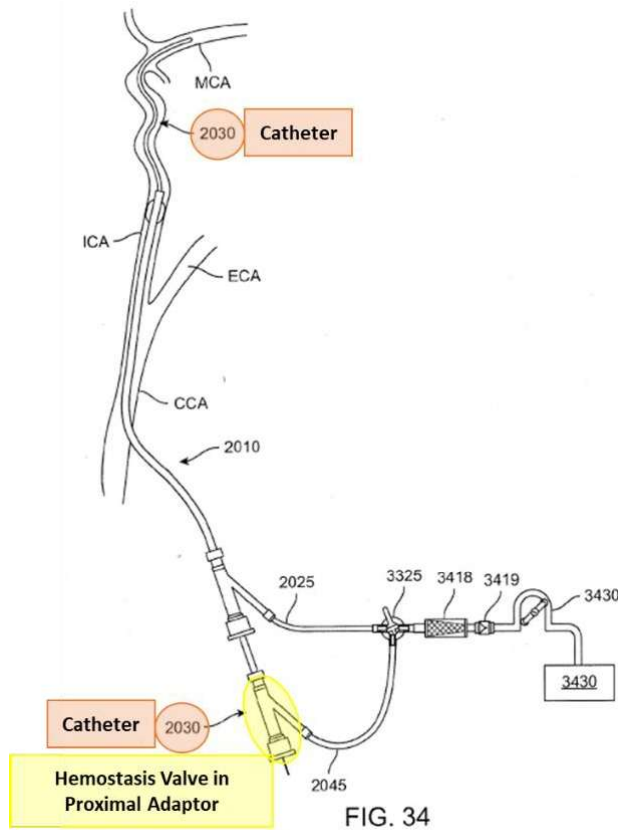


FIG. 34

Ex. 1011 (Garrison) at [0130], Figs. 1-3. Garrison further explains that catheter 2030 includes a lumen 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.” *Id.* at [0054]; *see also id.* (“The catheter 2030 may then be used to apply aspiration to the occlusion.”). As shown above, Garrison’s aspiration catheter has a proximal end portion. Therefore, Garrison discloses “an aspiration catheter defining a lumen and having a proximal end portion.”

3. Hemostasis Valve

186. Claim 18 next recites: “A hemostasis valve.” Garrison discloses a hemostasis valve. Garrison’s catheter 2030 includes a “proximal hub 2065” or “proximal adaptor” containing a hemostasis valve:



Ex. 1011 at [0098], Fig. 34. Garrison explains that the hemostasis valve allows “introduction of devices such as a microcatheter, guide wire, or thrombectomy device while preventing or minimizing blood loss during the procedure.” *Id.* at [0098]. Garrison further explains that “a separate hemostasis valve may be attached to proximal hub 2065” or “the hemostasis valve may be integral to the catheter proximal adaptor.” *Id.*

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

188. Schaffer discloses embodiments of an adjustable-opening “fluid stasis valve” that is intended for use with catheters to prevent the flow of blood through the valve during medical procedures, and Schaffer discloses or renders obvious the hemostasis valve limitations of claim 1 as I explained above. Ex. 1005 (Schaffer) at [0002], [0046], [0055]; *supra* §VI.A. A person of ordinary skill in the art in 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.

189. 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.

190. 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].

191. 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.

192. Fourth, combining Schaffer's valve with Garrison's aspiration catheters (such as catheter 2030) would merely entail the combination of known elements

(Schaffer's valve and Garrison's aspiration catheter) according to known methods (attaching the valve to a proximal hub on the catheter or forming it integrally with the hub). This combination would yield the predictable result of preventing or minimizing blood loss and preventing the introduction of air into the catheter. Combining known elements in such a predictable fashion would have been well within the level of ordinary skill in the art in September 2017.

193. 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.

194. 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.

195. 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.

196. For the reasons I explain in detail in claim 1, Schaffer discloses or renders obvious, both alone and combined with Hartley or Eller, the hemostasis valve recited in claim 18 of the ’291 patent.

a. Support and Actuator

197. As I explained in detail for claim 1, Schaffer discloses “a support” and “an actuator having at least a first member movably coupled to the support.” *Supra* §§VI.A.2-3.

b. Collapsible Tubular Sidewall

198. As I explained in detail for claim 1, Schaffer discloses “a collapsible tubular sidewall defining a lumen carried by the support.” *Supra* §VI.A.4. Garrison in combination with Schaffer further discloses “wherein the lumen of the tubular sidewall is selectively fluidly couplable to the lumen of the aspiration catheter.” Schaffer’s valve includes “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]. As I explained in detail in claims 1 and 5, depressing the actuator buttons of Schaffer (first and second members) allows the lumen to “retract to an uncollapsed configuration where gases and fluids can pass therethrough” to any attached catheter. *Id.* at [0008]. This description would apply to Garrison’s aspiration catheter if it were combined with Schaffer’s valve. Therefore, it is my opinion that Garrison in combination with Schaffer discloses this limitation.

c. Filament

199. As I explained in detail for claim 1, Schaffer, or Schaffer combined with Hartley or Eller, discloses “a filament formed in a loop around the tubular sidewall, the filament having at least a first end portion extending away from the loop to the first member.” *Supra* §VI.A.5.

d. Spring

200. As I explained in detail for claim 1, Schaffer discloses “a spring configured to move the first member in a direction that pulls the first end portion away from the tubular sidewall, reducing a diameter of the lumen in response to reducing a diameter of the loop to fluidly decouple the lumen of the tubular sidewall from the lumen of the aspiration catheter.” *Supra* §VI.A.6. Schaffer’s springs are configured to move the actuator buttons toward a first (i.e., sealed) position by imposing a force on the actuator buttons when the buttons are undepressed. Ex. 1005 at [0077]. The force supplied by the springs causes the actuating members coupled to the buttons to collapse and seal the seal module. *Id.* This prevents the flow of fluid through the valve and connecting member to any attached catheter, including Garrison’s aspiration catheter. For the reasons above, Garrison in combination with Schaffer, whether combined with Hartley or Eller or not, renders claim 18 obvious.

B. Claim 19

201. Claim 19 recites: “The aspiration catheter system of claim 1 wherein the direction is a first direction, and wherein the first member is actuatable in a second direction to move the first end portion toward the tubular sidewall to increase the diameter of the lumen in response to increasing the diameter of the loop to fluidly couple the lumen of the tubular sidewall to the lumen of the aspiration catheter.” As I discussed above, the error in claim 19 makes it such that I cannot determine whether claim 19 depends from claim 1 or claim 18. *Supra* §VI.O. If claim 19 depends from claim 18, then it is my opinion that Garrison in combination with Schaffer and optionally Hartley or Eller renders the claim obvious.

202. As I explained in claims 1, 5, and 18 above, depressing the actuator buttons of Schaffer (first and second members) allows the lumen to “retract to an uncollapsed configuration where gases and fluids can pass therethrough” to any catheter, including the aspiration catheter of Garrison. *Supra* §§VI.A, VI.E, VII.A; Ex. 1005 at [0008]. As I explained in claim 12, depressing Schaffer’s right actuator button (first member) moves the first end portion of the actuating member (filament) toward the seal module (tubular sidewall) to increase the diameter of the lumen in response to an increase of the diameter of the loop to fluidly couple the lumen of the tubular sidewall to the lumen of the aspiration catheter. *Supra* §VI.I. The mechanism would be the same if the actuating member of Schaffer was

replaced with the string of Hartley or wire member of Eller. Therefore, Garrison in combination Schaffer and optionally Hartley or Eller renders claim 19 obvious.

VIII. SECONDARY CONSIDERATIONS

203. I am not aware of any secondary considerations of nonobviousness relating to the claims of the '291 patent. The devices claimed in the '291 patent were 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.

204. I am aware that Patent Owner argued in the related Litigation that the valve described in the '291 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 passive valve required no manipulation by the physician and was always operated with one hand. 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

205. For the foregoing reasons, it is my opinion that Claims 1-8 and 12-19 of the '291 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.

206. 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.

207. 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 May 8, 2025 in San Francisco, CA.

troy thornton

Troy Thornton