

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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IMPERATIVE CARE, INC.,  
Petitioner,

v.

INARI MEDICAL, INC.,  
Patent Owner.

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Case No. IPR2025-01562  
Patent No. 12,109,384

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**DECLARATION OF TROY L. THORNTON  
IN SUPPORT OF PETITION FOR *INTER PARTES* REVIEW OF  
U.S. PATENT NO. 12,109,384**

|                                                                                                             |
|-------------------------------------------------------------------------------------------------------------|
| <p><i>Imperative Care v. Inari Medical</i><br/>US Patent 12,109,384<br/><b>Imperative Care Ex. 1003</b></p> |
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| <b>Exhibit No.</b> | <b>Description</b>                                                                                                                                                                    |
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| 1001               | U.S. Patent No. 12,109,384 (“the ’384 patent”)                                                                                                                                        |
| 1002               | Prosecution History of the ’384 Patent                                                                                                                                                |
| 1003               | Expert Declaration of Troy Thornton                                                                                                                                                   |
| 1004               | Resume of Troy Thornton                                                                                                                                                               |
| 1005               | U.S. Patent Publication US 2003/0225379 A1 to Schaffer et al. (“Schaffer”)                                                                                                            |
| 1006               | U.S. Patent Publication US 2003/0116731 A1 to Hartley (“Hartley”)                                                                                                                     |
| 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. 5,599,305 to Hermann (“Hermann”)                                                                                                                                      |
| 1010               | U.S. Patent Publication US 2011/0144592 A1 to Wong et al. (“Wong”)                                                                                                                    |
| 1011               | RESERVED                                                                                                                                                                              |
| 1012               | RESERVED                                                                                                                                                                              |
| 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               | Google Dictionary Definition of “String”                                                                                                                                              |
| 1015               | Cambridge Dictionary Definition of “String”                                                                                                                                           |

| <b>Exhibit No.</b> | <b>Description</b>                                                                                                                                                                                   |
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| 1016               | Deposition Transcript of PO's Expert Paul Zalesky, Ph.D. dated June 23, 2025                                                                                                                         |
| 1017               | Deposition Transcript of PO's Expert Paul Zalesky, Ph.D. dated August 27, 2025                                                                                                                       |
| 1018               | Deposition Transcript of Troy Thornton dated March 19, 2025                                                                                                                                          |
| 1019               | RESERVED                                                                                                                                                                                             |
| 1020               | Case Management & Scheduling Order (Dkt. #54) in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 24-cv-03117-EKL (N.D. Cal.) (issued December 19, 2024)                                        |
| 1021               | RESERVED                                                                                                                                                                                             |
| 1022               | U.S. Patent No. 11,697,011 ("the '011 patent")                                                                                                                                                       |
| 1023               | U.S. Patent No. 11,697,012 ("the '012 patent")                                                                                                                                                       |
| 1024               | RESERVED                                                                                                                                                                                             |
| 1025               | 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) |
| 1026               | Decision Granting Institution of <i>Inter Partes</i> Review for U.S. Patent No. 11,697,012 (Paper 6) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-00156 (P.T.A.B. Apr. 22, 2025) |
| 1027               | Imperative Care, Inc.'s Notice of Motion and Motion to Stay Pending <i>Inter Partes</i> Review in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 5:24-cv-03117-EKL (N.D. Cal.)                |
| 1028               | Order Regarding Case Schedule and Motion to Stay in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 5:24-cv-03117-EKL (N.D. Cal.)                                                              |

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| Exhibit No. | Description                                                                                                                                                                                           |
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| 1029        | Decision Granting Institution of <i>Inter Partes</i> Review for U.S. Patent No. 11,554,005 (Paper 10) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-00289 (P.T.A.B. June 18, 2025) |
| 1030        | Patent Owner Response for <i>Inter Partes</i> Review for U.S. Patent No. 11,697,011 (Paper 3) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2024-01157 (P.T.A.B. Apr. 18, 2025)         |
| 1031        | Supplemental Declaration of Paul J. Zalesky submitted in IPR2024-01157                                                                                                                                |
| 1032        | Robert C. Allen, <i>The Gore DrySeal Sheath</i> , Supp. Endovascular Today (Feb. 2011) (“Allen”)                                                                                                      |
| 1033        | Cara M. Michelson, et al., <i>Use of a Modified Cardiopulmonary Bypass Circuit for Suction Embolectomy with the Angiovac Device</i> , 49 J. Extra Corpor. Tech., 299-303 (2017) (“Michelson”)         |
| 1034        | Jacques Kpodonu, <i>Manual of Thoracic Endoaortic Surgery</i> (2010) (“Kpodonu”)                                                                                                                      |
| 1035        | 510(k) Summary – K123990, Sentrant Introducer Sheath with Hydrophilic Coating (Apr. 26, 2013) (“Sentrant”)                                                                                            |
| 1036        | Matthew Kruse, <i>Thoracic Endovascular Aortic Repair (TEVAR) Sheaths</i> , CTSNet (Jan. 18, 2011) (“Kruse”)                                                                                          |
| 1037        | Cook Medical, <i>Endovascular Aortic Repair – Abdominal: Zenith Endovascular Grafts</i> (2012) (“Zenith Brochure”)                                                                                    |
| 1038        | U.S. Patent No. 8,137,321 B2 to Argentine (“Argentine”)                                                                                                                                               |
| 1039        | U.S. Patent Pub. No. 2017/0080200 A1 (“Bickhart”)                                                                                                                                                     |
| 1040        | U.S. Patent No. 11,730,942 B2 to Fantuzzi (“Fantuzzi”)                                                                                                                                                |
| 1041        | U.S. Patent No. 8,777,893 B2 to Malewicz (“Malewicz”)                                                                                                                                                 |
| 1042        | U.S. Patent No. 5,125,903 to McLaughlin (“McLaughlin”)                                                                                                                                                |

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| <b>Exhibit<br/>No.</b> | <b>Description</b>                                  |
|------------------------|-----------------------------------------------------|
| 1043                   | U.S. Patent No. 8,808,350 B2 to Schreck (“Schreck”) |

I, Troy L. Thornton, do hereby declare:

## **I. INTRODUCTION**

### **A. Engagement**

1. I have been retained on behalf of Imperative Care, Inc. (“Imperative Care”) to provide my opinions regarding the patentability of Claims 1-4, 6-18, and 20-30 of U.S. Patent No. 12,109,384 (“the ’384 patent”). For the reasons discussed herein, I have concluded that Claims 1-4, 6-18, and 20-30 of the ’384 patent are unpatentable because the prior art references render them obvious.

2. I understand that this Declaration supports Imperative Care’s Petition for the above-captioned *inter partes* review (“IPR”) of the ’384 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 ’384 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 '384 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 '384 patent;
- The level of ordinary skill in the art pertaining to the '384 patent;
- The teachings of the prior art; and
- Whether Claims 1-4, 6-18, and 20-30 of the '384 patent would have been obvious to a person of ordinary skill in the art at the time of the alleged invention, in view of the prior art.

**D. Materials Considered**

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

17. I have also relied on my education, training, and experience, and my knowledge of pertinent literature in the field of the '384 patent.

**II. APPLICABLE LEGAL STANDARDS**

18. I am a biomedical engineer by training and profession. The opinions I am expressing in this Declaration involve the application of my education, training, and technical knowledge and experience to the evaluation of certain prior art with respect to the '384 patent.

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

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

**A. Claim Construction**

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

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

**B. Obviousness**

22. 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.

23. 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.

24. 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.

25. 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.

26. 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.

27. 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.

28. 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 1-4, 6-18, and 20-30 of the '384 patent would have been non-obvious, as further explained in Section §IX (Heading: "Secondary Considerations") below.

**C. Person of Ordinary Skill in the Art**

29. It is my understanding that when interpreting the claims of the '384 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 '384 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.

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

31. 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.

32. Based on my review of the specification and claims of the '384 patent, it is my opinion that a person of ordinary skill in the art would have had an undergraduate degree in mechanical engineering or a related engineering discipline and 2-4 years of catheter design experience and, where necessary, would have consulted with a physician regarding the methods of treatment.

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

**D. The Prior Art Is from the Same Field as the '384 Patent**

34. 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 '384 patent, e.g., 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.

### **III. THE '384 PATENT**

#### **A. Summary of the '384 Patent**

35. The '384 patent is titled “Hemostasis Valves and Methods of Use” and describes a hemostasis (or “garrote”) valve for use during minimally invasive intravascular procedures. Ex. 1001 ('384 patent) at 5:55-6:6. The hemostasis valve is used with a catheter that is inserted into the patient’s vasculature and prevents blood from passing through the valve. In this way, the valve helps provide a seal to minimize blood loss, prevent the introduction of air into the vasculature, and maintain sterility during the procedure. *Id.* at 1:42-45. The '384 patent states that the hemostasis valve “can seal with or without a tool extending through the valve.” *Id.* at 5:56-58.

36. As illustrated in Figure 2 of the '384 patent below, the hemostasis valve described in the '384 patent includes a “housing 128” that defines a “interior channel 130,” and a collapsible “elongate member 132” or “tubular member 132” that extends through the housing 128:

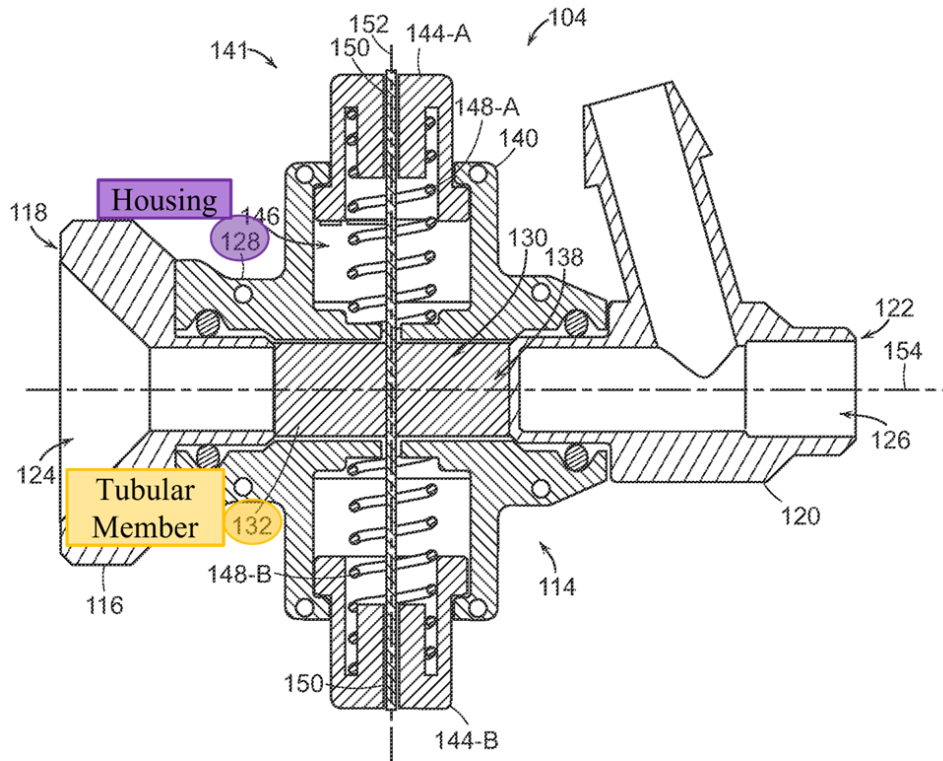


FIG. 2

*Id.* at 6:56-7:31, Fig. 2. The '384 patent explains that the elongate member 132 has a “thin-walled compliant tubular structure,” which helps facilitate “the uniform collapse of the elongate member 132 and the sealing of the elongate member 132.”

*Id.* at 7:17-23.

37. The '384 patent describes that the tubular member is sealed by a “constricting mechanism,” which can “collapse and seal the elongate member 132 via compression and/or constriction, and specifically via constriction with at least one filament 150.” *Id.* at 8:5-8. The '384 patent explains that the filament “can extend at least partially around the elongate member.” *Id.* at 8:5-12. The

constricting mechanism also includes an actuator, which the '384 patent states “can be a manual actuator such as one or several buttons 144”:

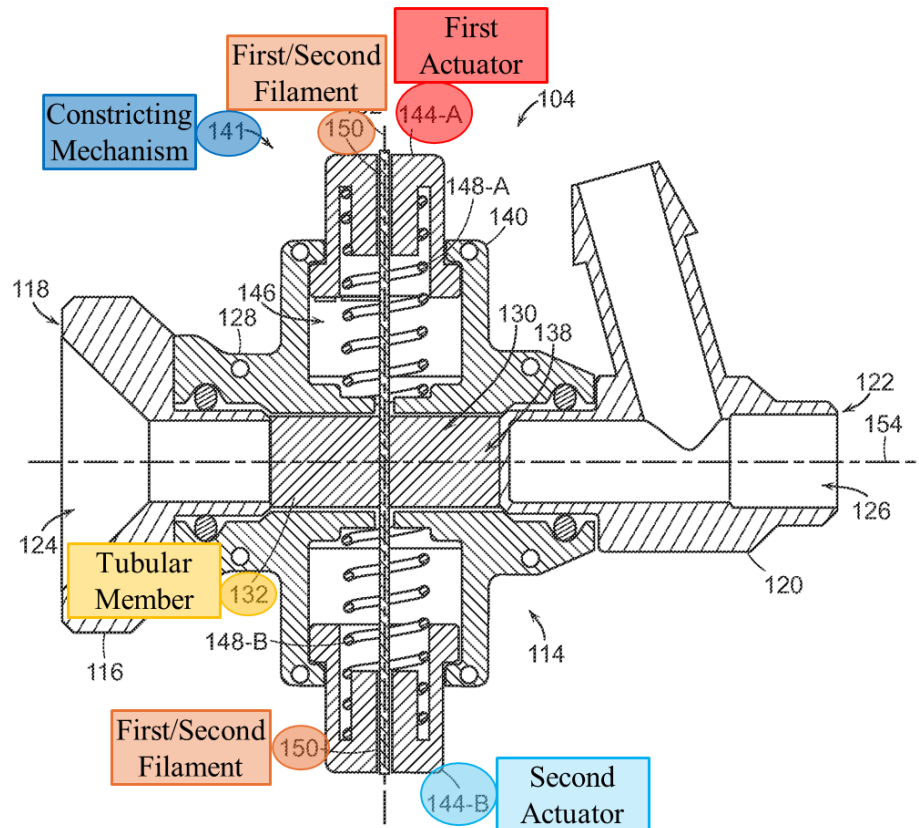


FIG. 2

*Id.* at 8:8-10, Fig. 2. The filament is “coupled to the actuator 142 such that the filament 150 selectively constricts, collapses, and/or seals the elongate member 132 ... based on the movement and/or position of the actuator 142.” *Id.*, at 9:24-28.

38. The '384 patent also explains that the valve can include a “bias feature,” such as a spring, which biases the valve to either the closed (referred to as first) or open (referred to as second) position when no outside forces are being

applied to the actuator button(s). *Id.* at 8:38-56. Figure 4 shows the valve biased toward the first, closed position:

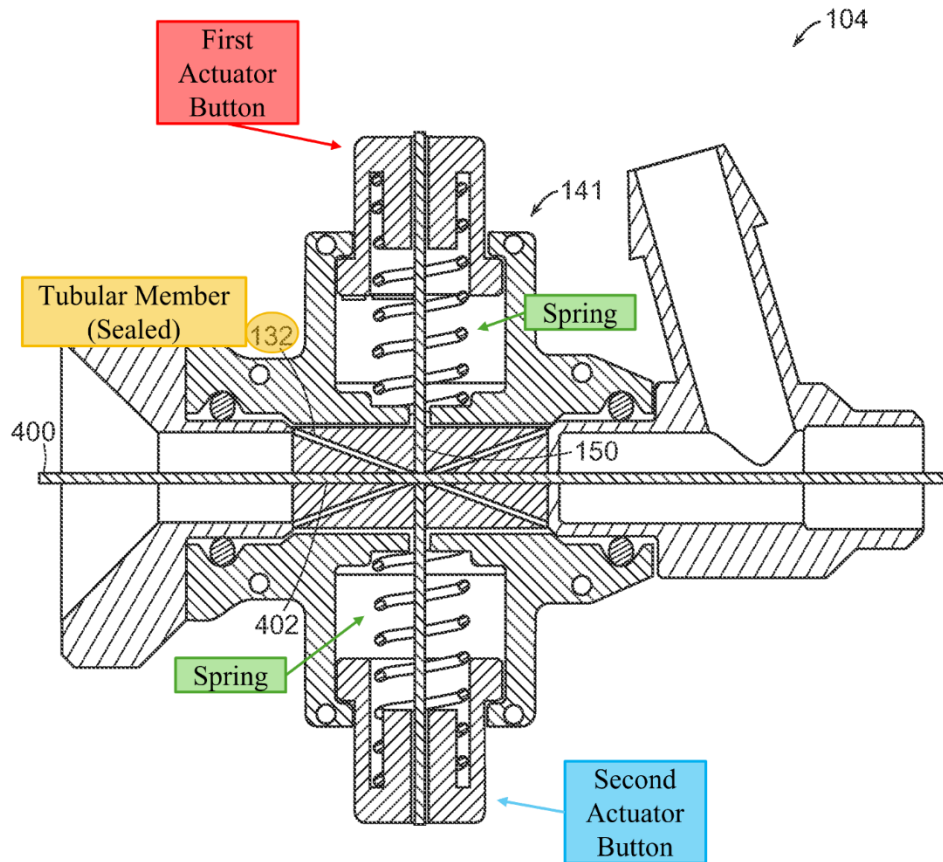


FIG. 4

*Id.* at 8:38-56, Fig. 4. The '384 patent explains that when the actuator buttons are depressed by an outside force, the tension on the filament is loosened “thereby allowing the expansion of the elongate member 132 and the unsealing of the central lumen 138 of the elongate member 132.” *Id.* at 9:54-62. Figure 3 below depicts the valve in the second, opened position when the actuator buttons are depressed:

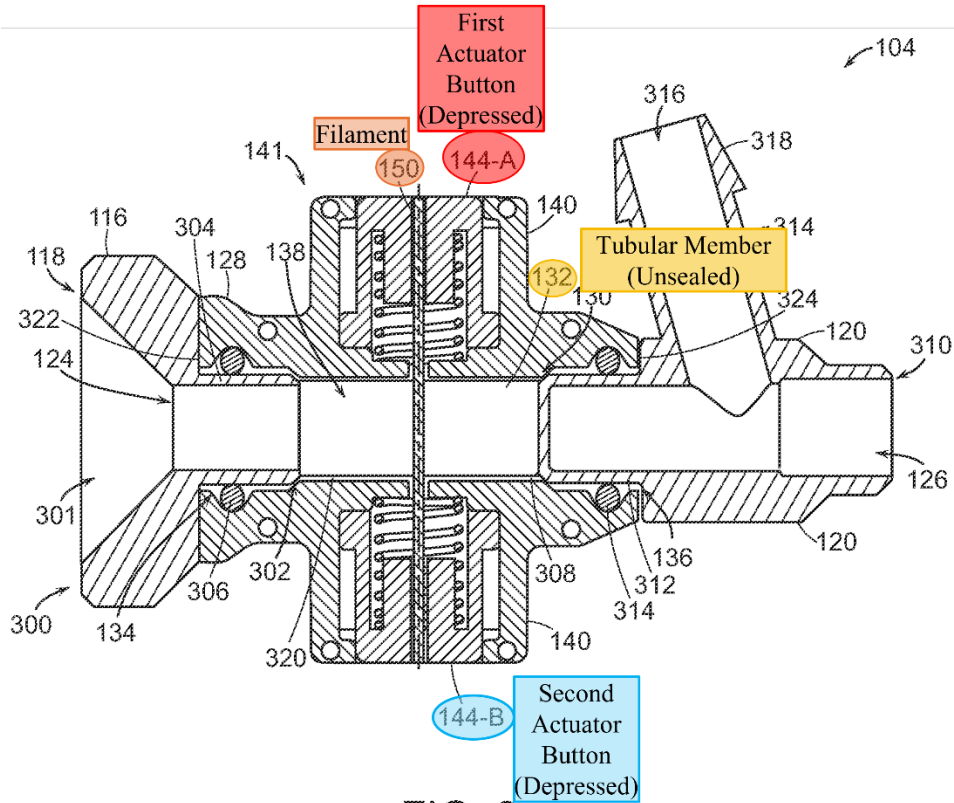


FIG. 3

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

39. The '384 patent explains that its constricting mechanism, including the filament, can constrict the elongate member around a tool that is inserted through the central lumen of the elongate member to “seal the valve 104 around the tool.”

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

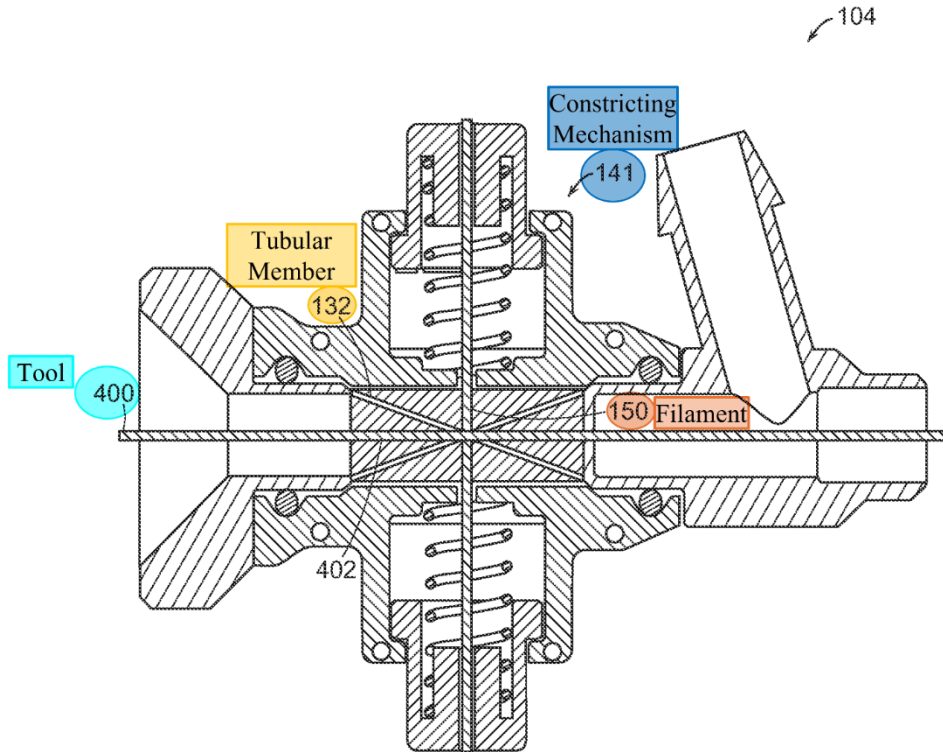


FIG. 4

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

40. The '384 patent discloses that the “filament 150 can be arranged in a variety of configurations” including a single loop 604 that can extend around the elongate member 132 as shown in Figure 6, multiple loops that can extend around the elongate member as shown in Figure 7, or a “U-shaped section between the two ends of the filament 150” (i.e., a bight) that can extend around the elongate member as shown in Figures 8 and 9:

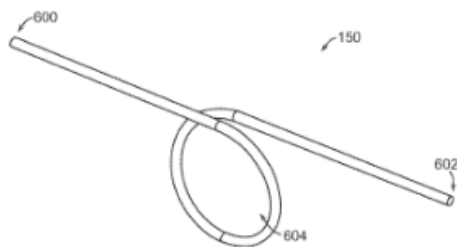


FIG. 6

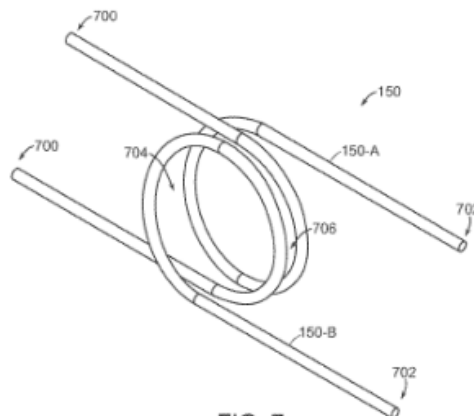


FIG. 7

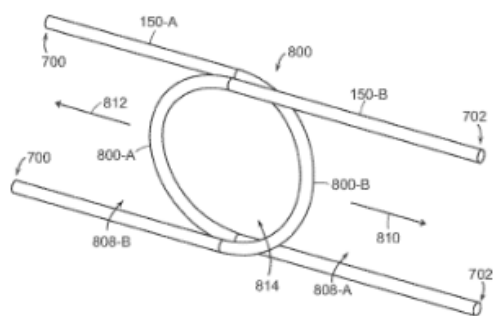


FIG. 8

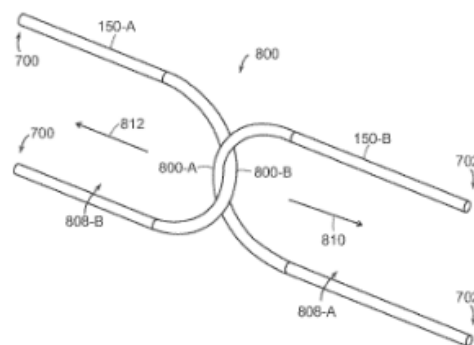
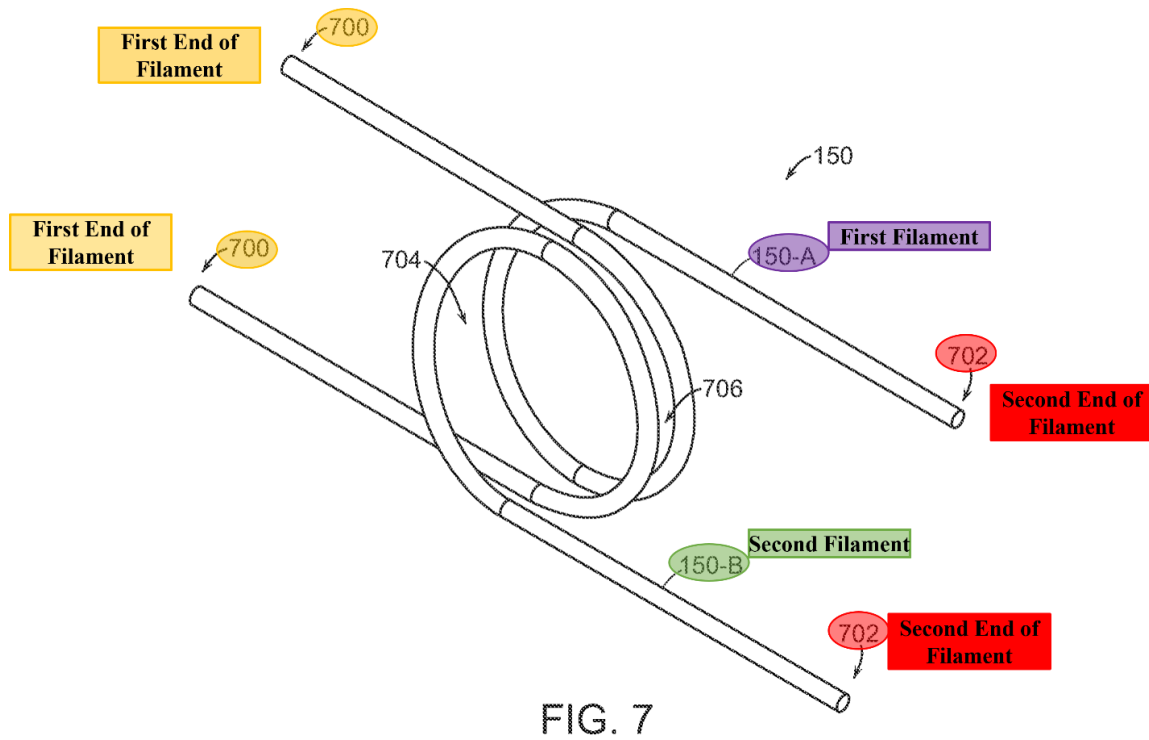


FIG. 9

*Id.*, 13:17-14:34, Figs. 6-9.

41. The '384 patent also discloses that the filament can be formed from a range of materials “including, for example, a polymer, a synthetic, and/or a metal.” *Id.* at 9:13-15. The filament can also “comprise a single strand such as, for example, a monofilament” or it “can comprise a plurality of strands that can be, for example, twisted, woven, grouped, and/or fused to form the filament.” *Id.* at 9:16-20. Accordingly, “the filament 150 can comprise one or several threads, lines, cords, rope, ribbon, flat wire, sheet, or tape.” *Id.* at 9:21-23. Additionally, “in some embodiments, each of the first end 700 and the second end 702 of one or more of the multiple filaments 150 can be coupled to different buttons 144”:



*Id.* at 12:61-67, Fig. 7.

## B. The Challenged Claims

42. The challenged claims include Claims 1-4, 6-18, and 20-30 of the '384 patent. Claims 1, 15, and 23 are independent.

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

1. A valve assembly, comprising:

a tubular member defining a lumen;

a first filament extending in a first loop around the tubular member, wherein the first filament is flexible;

a second filament extending in a second loop around the tubular member, wherein the second filament is flexible;

a pair of actuators movable from a first position to a second position, wherein—

the first filament includes a first portion operably acted upon by a first one of the actuators and a second portion operably acted upon by a second one of the actuators;

the second filament includes a first portion operably acted upon by the first one of the actuators and a second portion operably acted upon by the second one of the actuators;

in the first position, the actuators are positioned to tension the first filament and the second filament thereby decreasing a dimension of the first loop and a dimension of the second loop to constrict the lumen of the tubular member;

in the second position, the actuators are positioned to loosen the first filament and the second filament thereby permitting the tubular member to expand against the first loop and the second loop to increase the dimension of the first loop and the dimension of the second loop to at least partially open the lumen of the tubular member; and

the actuators are biased to the first position.

Ex. 1001 ('384 patent) at Claim 1.

### **C. Prosecution History**

44. I have reviewed the '384 patent's prosecution history. From my review of the References, it appears that Schaffer, Hartley, and Eller were listed on an IDS submitted to the Examiner. Ex. 1002 ('834 Prosecution History Excerpt) at 266, 274. I notice that the Examiner did not cite or apply Schaffer and did not issue any substantive office actions.

45. I see that in a Notice of Allowance issued on July 26, 2024, the Examiner found that the Hartley and Eller prior art references, which I discuss herein, and another reference called Wong were the closest prior art. The Examiner stated the following regarding Hartley:

Harley [sic] discloses a valve assembly comprising: a tubular member 4 defining a lumen; a first filament 20 extending in a first loop around the tubular member, wherein the first filament is flexible; an actuator 12 movable from a first position (Fig. 4) to a second position (Fig. 3); a first filament includes a first portion operably acted upon by a first one actuator 12; wherein the first position, the actuator is positioned to tension the first filament; whereby a dimension of the first loop (in Fig. 4); wherein the second position (the actuator being rotated, see arrows in Fig. 5), the actuator is positioned to loosen the first filament thereby permitting the tubular member to expand against the first loop to increase the dimension of the first loop.

Harley [sic] fails to disclose that the actuator is as [sic] a pair of actuators; a second filament. Therefore, Harley [sic] fails to disclose the limitations as mentioned in the claims 1, 15 & 23 above.

*Id.* at 20. In sum, the Examiner found that Hartley discloses every limitation of Claim 1 of the '384 patent except for "the actuator is as [sic] a pair of actuators; a second filament."

46. The Examiner stated the following regarding Eller:

Eller discloses a valve assembly comprising:

A tubular member being attached to a handle 18; a first filament 22 extending in a first loop around the tubular member, see Figs. 9A-9C, wherein the first filament is flexible; a second filament 24 (or 26) extending in a second loop around the tubular member, wherein the second filament is flexible, an actuator 18 movable first a first position (being rotated, see arrow 159, in Figs. 1, 10C) to a second position (Fig. 9A-9B, 10A-10B); a first filament includes a first portion operably

acted upon by the actuator; a second filament 24/26 includes a first portion operably acted upon the actuator, in the first position the actuator is positioned to tension the first filament and the second filament thereby decreasing a dimension of the first loop and second loop to constrict the lumen of the tubular member, see Figs. 9C & 10C; in the second position, the actuator is positioned to loosen the first filament and the second filament thereby permitting the tubular member to expand against the first loop and the second loop to increase the dimension of the first loop and the dimension of the second loop to at least partially open the lumen of the tubular member, Figs. 9A-9B; 10A-10B.

Eller fails to disclose that the actuator is as [sic] a pair of the actuator. Therefore Eller fails to disclose the claimed limitations as mentioned in the claims 1, 15 & 23 above.

*Id.* at 21. In sum, the Examiner also found that Eller discloses every limitation of Claim 1 of the '384 patent except “the actuator is as [sic] a pair of actuators.” The Examiner similarly found Wong to disclose most of the elements of the '384 patent, including “a pair of actuators.” *Id.*

#### **IV. CLAIM CONSTRUCTION**

47. The challenged claims of the '384 patent require a valve assembly having “a first ***filament***” formed in a “first loop” and “a second ***filament***” formed in a “second loop.” Ex. 1001 (emphasis added). I have offered a construction for “filament” in previous IPRs involving Patent Owner and Petitioner, including IPRs for U.S. Patent Nos. 11,697,011, 11,697,012, 11,844,921, and 11,865,291. I understand that the '384 patent shares a specification with each of these patents. Consistent with my previous analysis, it is my opinion that a person of ordinary skill in the art in September 2017 (the earliest priority date of the '384 patent) would

have understood the term “filament” in the claims of the ’384 patent to mean at least: “one or more threads, lines, cords, ropes, ribbons, flat wires, sheets, or tapes.”

48. 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. I see that independent claim 1 of the ’384 patent explicitly requires the filament to be “flexible.” However, the other two independent claims, claims 15 and 23, do not recite that the filament is “flexible.” Instead, dependent claims 17 and 27 (which depend from claims 15 and 23, respectively) add a limitation requiring a “flexible” filament. Thus, I understand that claims 15 and 23 do not require a “flexible” filament.

49. However, the debate about whether the term “filament” is limited to “flexible” filaments, even in claims that do not explicitly require flexibility, does not impact my views on unpatentability here. The meaning of “filament” does not have any impact on my opinions regarding Schaffer in combination with Hartley or Eller because Patent Owner has not disputed that Hartley or Eller describe “flexible” filaments. As the Board preliminarily found in the Institution Decisions for the ’011, ’012, and ’005 Patents, Hartley includes a “filament,” regardless of whether the claims are limited to “flexible” filaments. The Board specifically found that Patent Owner “does not dispute that Hartley ... disclose[s] a flexible filament (e.g., flexible string or flexible wire).” Ex. 1026 (’012 Institution Decision) at 21,

n.13. The Board also preliminarily found that a person of ordinary skill in the art would have found it obvious to combine Hartley’s filament with Schaffer’s valve. Additionally, Eller expressly states that its wire members can be formed from “flexible materials.” Ex. 1007 (Eller) at 15:41-60. Therefore, Schaffer in combination with Hartley or Eller renders the claimed “filament” limitations obvious regardless of whether the Board construes “filament” to require flexibility.

## **V. SUMMARY OF IPR GROUNDS**

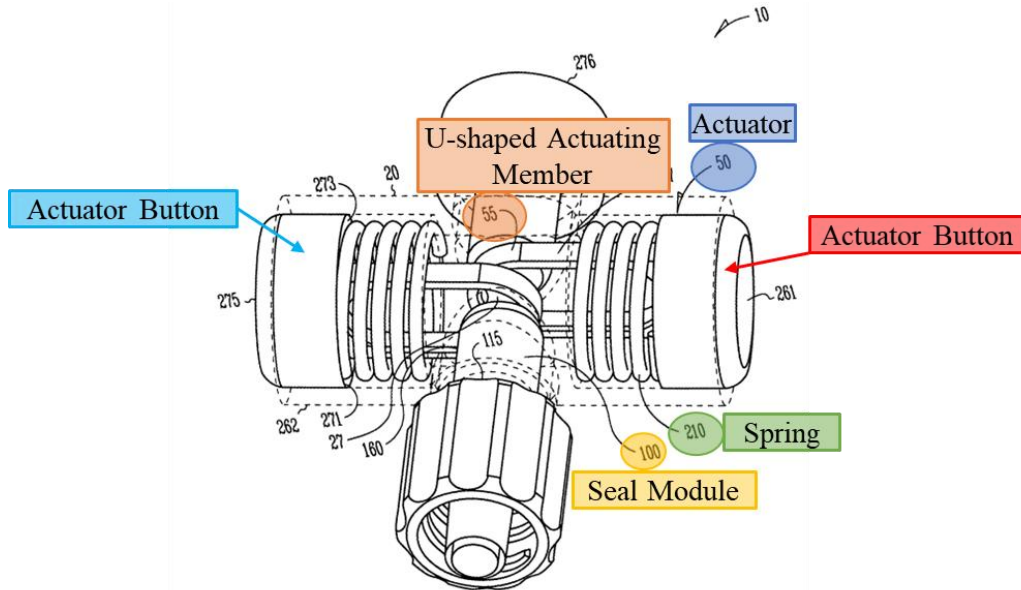
50. I have identified the following grounds of unpatentability in this Declaration:

| <b>Ground</b> | <b>Reference(s)</b>                  | <b>Basis</b> | <b>Challenged Claims</b> |
|---------------|--------------------------------------|--------------|--------------------------|
| 1             | Schaffer + Hartley                   | Obvious      | 1-4, 6-18, 20-30         |
| 2             | Schaffer + Eller                     | Obvious      | 1-4, 6-18, 20-30         |
| 3             | Schaffer + Hartley + Eller           | Obvious      | 1-4, 6-18, 20-30         |
| 4             | Hermann + Schaffer + Hartley         | Obvious      | 11-14, 20-22, 28-30      |
| 5             | Hermann + Schaffer + Eller           | Obvious      | 11-14, 20-22, 28-30      |
| 6             | Hermann + Schaffer + Hartley + Eller | Obvious      | 11-14, 20-22, 28-30      |

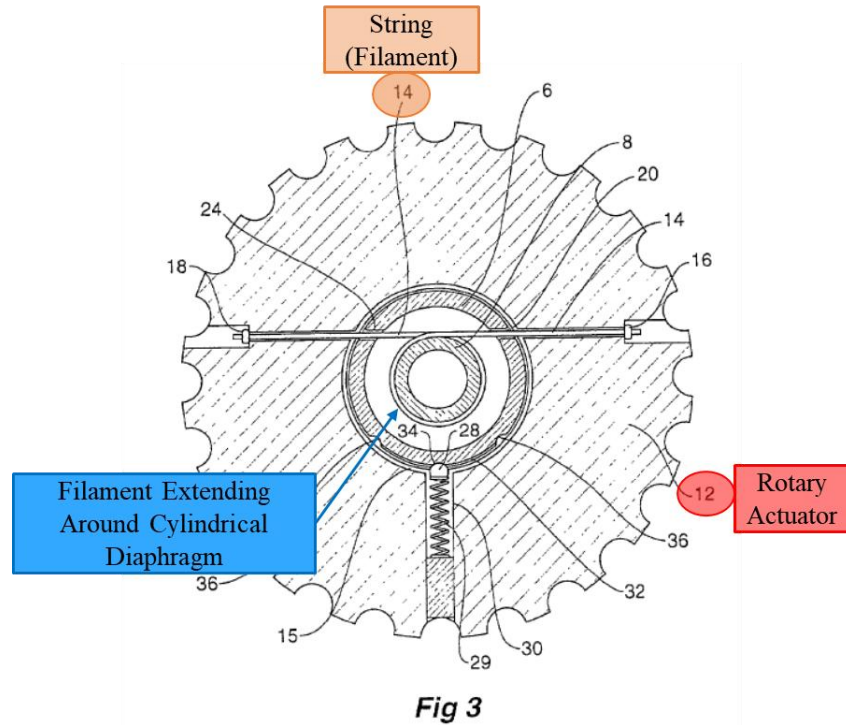
## **VI. GROUNDS 1 AND 2: CLAIMS 1-4, 6-18, AND 20-30 ARE OBVIOUS OVER SCHAFFER COMBINED WITH HARTLEY OR ELLER**

51. 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 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 that constrict the seal module when the actuating buttons are undepressed:







Ex.1006 (Hartley) at [0031], Fig. 3.

53. Eller's "filament" is described as a wire member (or suture or cable) secured to the actuator and valve housing, illustrated in Eller's Figure 2 below:

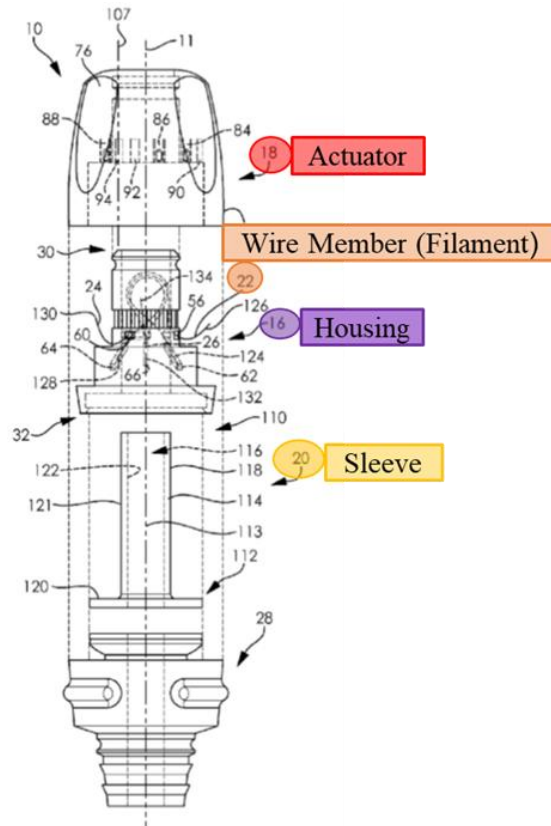


FIG. 2

Ex. 1007 (Eller) at 5:1-5, 16:5-6, Fig. 2.

54. 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 u-shaped actuating members in Schaffer's hemostasis valve. In addition, I believe that a person of ordinary skill in the art would have found it obvious, and been motivated, to use a first filament and a second filament in Schaffer's valve. Accordingly, based on my review of these references, I believe that the combination of Schaffer with Hartley *or* Eller renders Claims 1-4, 6-18, and 20-30 obvious.

**A. Claim 1**

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

**1. “A valve assembly”**

56. The preamble of Claim 1 recites: “a valve assembly.” If the Board finds that the preamble of Claim 1 is limiting, Schaffer, Hartley, and Eller each disclose this limitation.

57. Schaffer discloses 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].

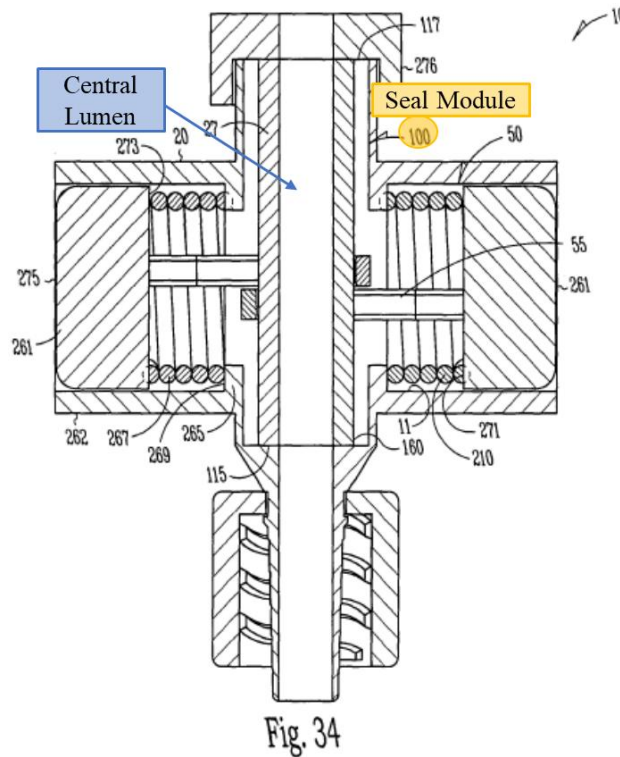
58. Hartley discloses “an access valve” for use in “medical applications ... where it is desired to seal around a catheter or other instrument ... to prevent loss of blood or other fluid.” Ex. 1006 (Hartley) at [0002]-[0004].

59. 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. “a tubular member defining a lumen”**

60. Claim 1 next recites “a tubular member defining a lumen.” Schaffer discloses this limitation.

61. Schaffer discloses that its hemostasis valve includes a “seal module 100” that comprises “a flexible, elongate tubular structure 101.” Ex. 1005 (Schaffer) at [0049], [0051], [0054], [0075]. The elongate tubular structure 101 defines a lumen 193 as seen in Figure 34 of Schaffer:



*Id.* at Fig. 34. Schaffer further discloses that “a range of instruments [can be] used within the seal module,” such as “a catheter, guidewire, needle, or fiber.” *Id.* at [0056]. Accordingly, Schaffer discloses “a tubular member defining a lumen” as recited in Claim 1.

3. **“a first filament extending in a first loop around the tubular member, wherein the first filament is flexible; a second filament**

**extending in a second loop around the tubular member, wherein the second filament is flexible”**

62. Claim 1 next recites “a first filament extending in a first loop around the tubular member, wherein the first filament is flexible; a second filament extending in a second loop around the tubular member, wherein the second filament is flexible.” Schaffer in combination with Hartley *or* Eller renders these limitations obvious.

63. As I discussed above, Schaffer discloses a valve having “two circular actuators 50” on opposite sides of the housing that are “movable from a first position to a second position”:

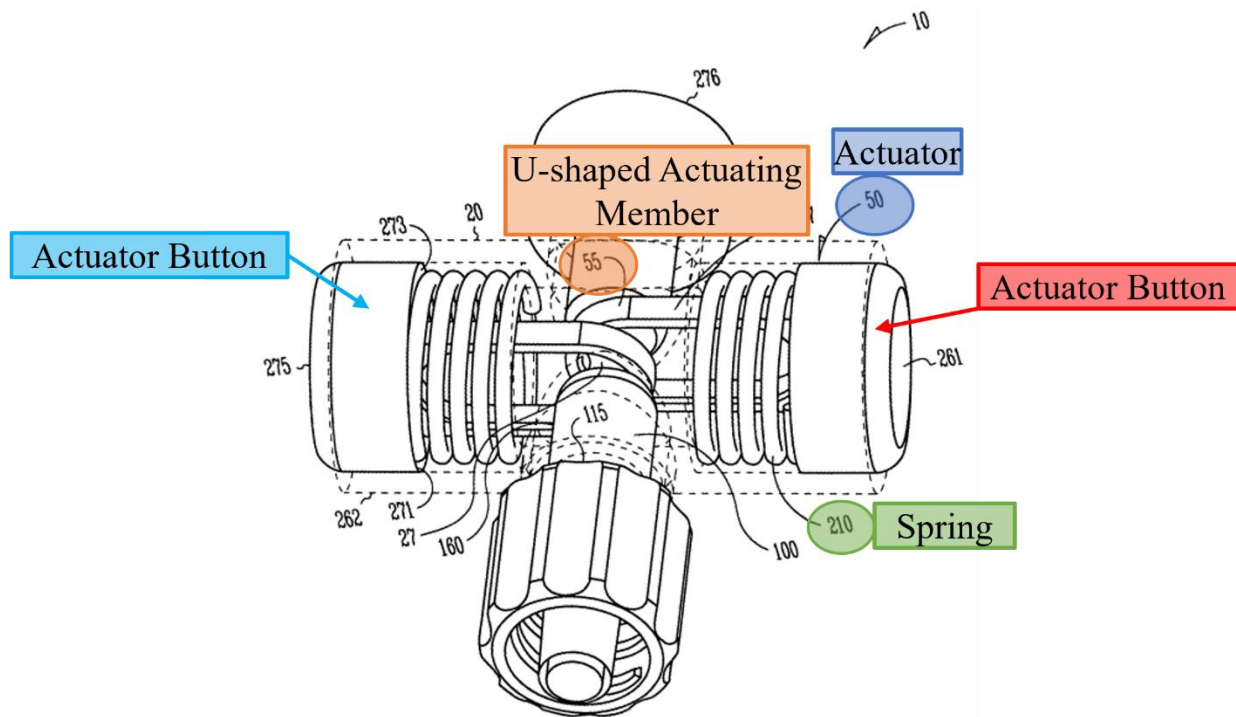
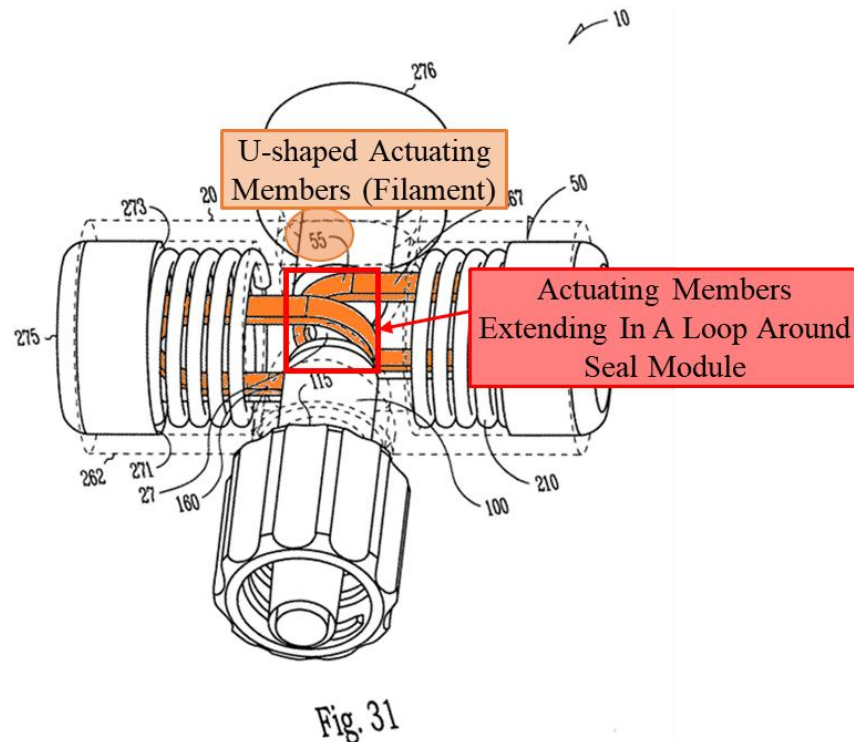


Fig. 31

Ex. 1005 (Schaffer) at [0075]-[0076], Figs. 31-32. Each actuator 50 includes “an

actuator button 261” and a “spring 210.” *Id.* Schaffer’s valve also includes two actuating members, which may be U-shaped, coupled to the actuator buttons and forming a loop around the seal module 100 (tubular member):



*Id.* at [0076], Fig. 31.

64. As shown in Figure 31 of Schaffer above, Schaffer’s configuration of its filament differs slightly from the filament configuration recited in Claim 1, which requires that each of the first and second filaments forms a loop around the tubular member. Schaffer’s two u-shaped filaments collectively form a loop around the tubular member. However, as I explain below, the filament configuration recited in Claim 1 was not novel in 2017. Both Hartley and Eller disclose hemostasis valves with first and second filaments that form a loop around a

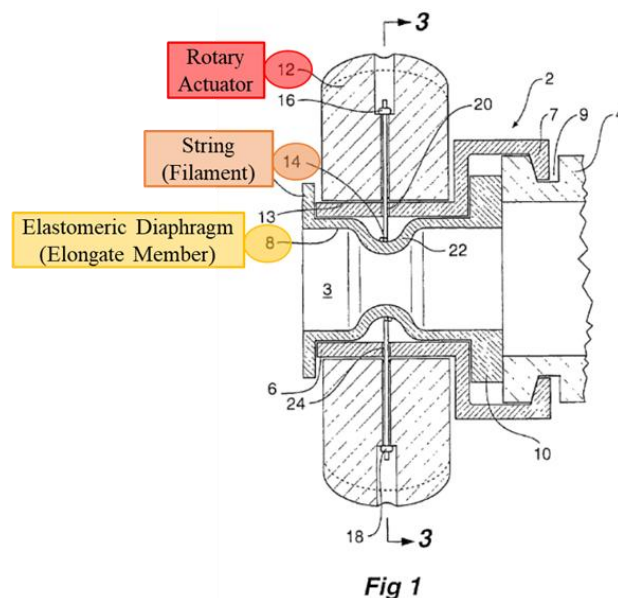
collapsible tubular member, and a person of ordinary skill in the art would have been motivated to substitute Hartley's or Eller's filaments for Schaffer's u-shaped actuating members, and they would have had a reasonable expectation of success in doing so.

**a. Hartley**

65. Schaffer in combination with Hartley renders obvious a “first filament” and a “second filament” as recited in Claim 1 in two ways.

**i. Hartley's String Includes Two Filaments**

66. *First*, Hartley describes a hemostasis valve having a cylindrical housing that holds a “cylindrical elastomeric diaphragm,” and a rotary actuator mounted to the housing:



Ex. 1006 (Hartley) at [0031], Fig. 1. Hartley's valve includes a “string 14 ... mounted into the rotary actuator.” *Id.*

67. A person of ordinary skill in the art would have understood that Hartley's string 14 would be formed from at least two threads twisted together. The common understand of a string is a "material consisting of threads of cotton, hemp, or other material twisted together to form a thin length." Ex. 1014; *see also* Ex. 1015. Therefore, each thread forming Hartley's string is a "filament" as described by the '384 patent because it is at least one or more threads, lines, or cords. Ex. 1001 ('384 patent) at 9:21-23 (stating that the filament "can comprise one or several threads, lines, cords, rope, ribbon, flat wire, sheet, or tape"). I also note that each of the threads making up Hartley's string would be a "filament" under the construction that Patent Owner proposed in the prior IPRs, which is "a thin, flexible length of material formed by one or more strands of material." Accordingly, Hartley's string 14 includes a "first filament" and a "second filament" as recited in Claim 1 of the '384 patent.

68. Claim 6 of the '384 patent confirms my opinion that the threads making up Hartley's string are a "first filament" and "second filament" as recited in Claim 1. Claim 6 depends from Claim 1 and adds the following limitation: "wherein the first filament and the second filament each comprise a plurality of strands woven together." Ex. 1001 ('384 patent) at Claim 6. Thus, in Claim 6, each of the first and second filaments must each be formed from multiple "strands woven together." I understand from counsel that in patent law, an independent claim must

be broader than the dependent claims that depends from it. In other words, I understand that Claim 1 does not require that the first and second filaments are formed from a plurality of woven strands, otherwise Claim 6 would be superfluous. The first and second filaments in Claim 1 therefore encompass the individual threads forming Hartley's string.

69. Hartley discloses that the string "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":

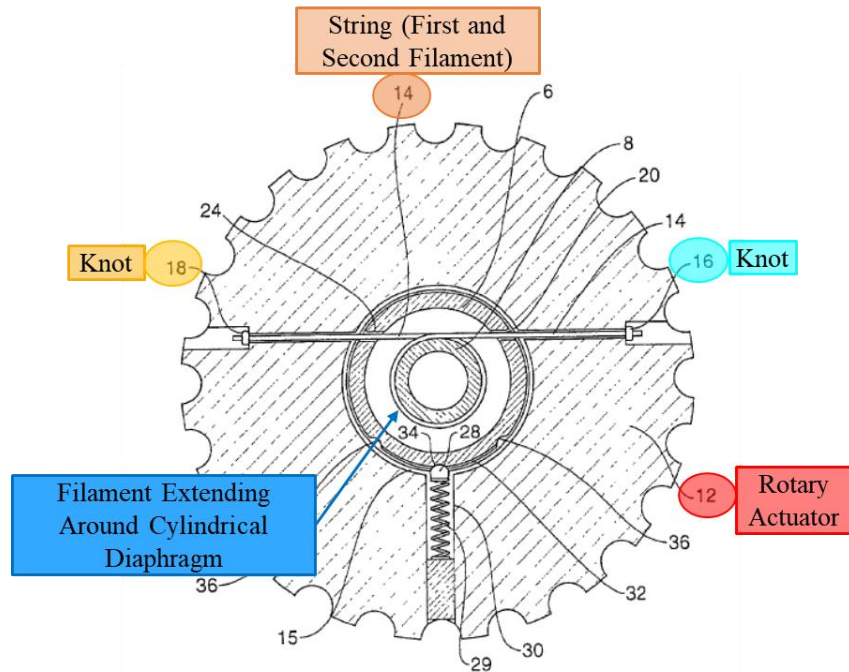


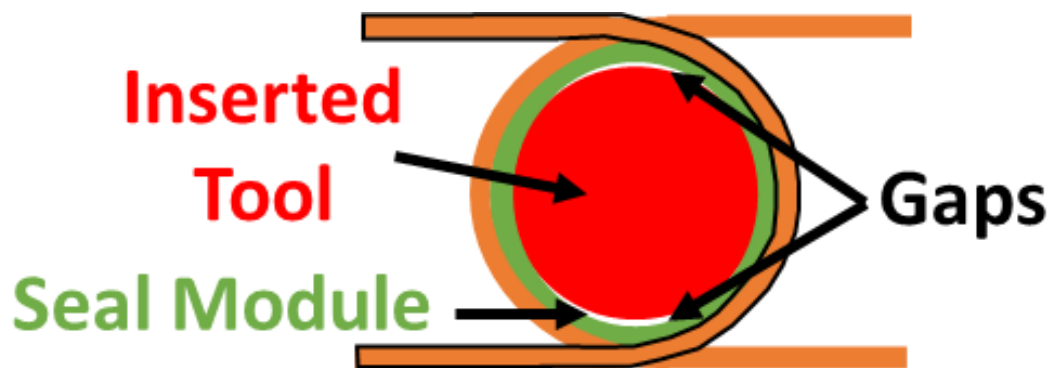
**Fig 3**

*Id.* at [0031], Fig. 3. Hartley’s string, and therefore each of the at least two filaments making up the string, is therefore formed into a loop around the “tubular member.”

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

71. Hartley’s disclosure that its string can “close over a range of diameters of devices passed through the valve or can close completely down to be self-sealing” would have further motivated a person of ordinary skill in the art to substitute Hartley’s string for Shaffer’s actuating members. Ex. 1006 (Hartley) at

[0037]. A person of ordinary skill in the art would have recognized that Hartley's string may seal more effectively across a wider range of tool diameters and shapes than Schaffer's U-shaped actuating members. A person of ordinary skill in the art would have recognized that if the tool inserted through the valve does not match the size or shape of Schaffer's U-shaped actuating members or if the members do not conform sufficiently to the size or shape of the tool inserted, small gaps could form between the tool and the valve's lumen. , as I illustrate below:



Hartley's string would improve on this potential issue because the string more precisely conforms to the tool diameters.

72. A person of ordinary skill in the art had a finite number of materials to select from to constrict a tubular member in a hemostasis valve in September 2017. Hartley and Schaffer disclose two such materials: Hartley's string and Schaffer's actuating members (which can be plastic or metal). Eller discloses another material, a wire member (which can be metals or polymers). A person of ordinary skill in the art would have found it obvious to select from these finite, predictable materials

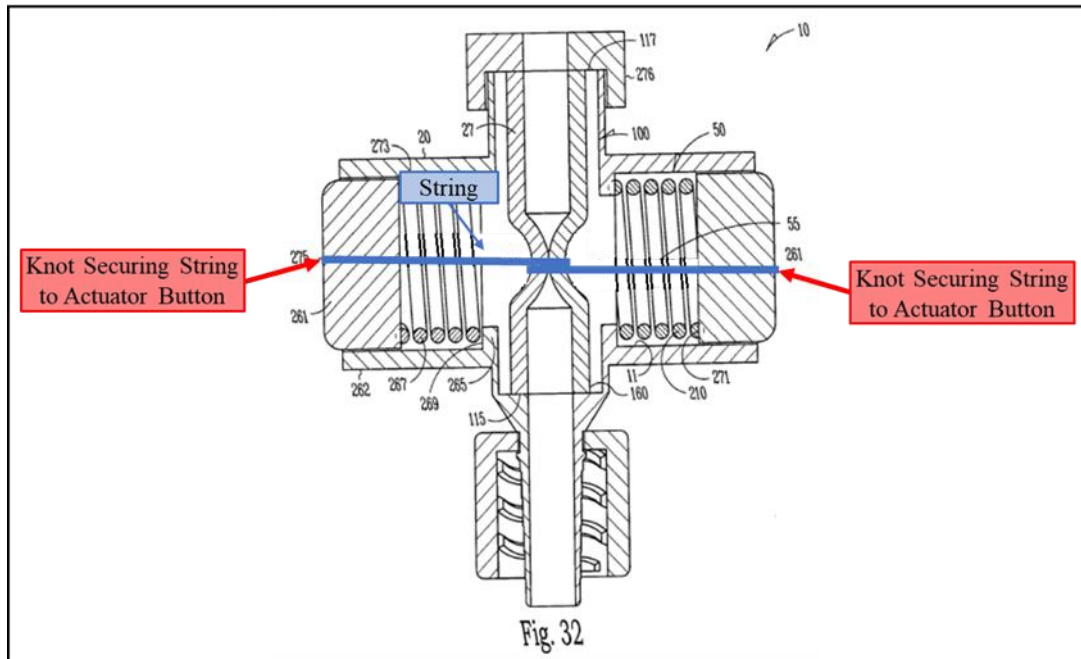
for constricting a valve and, as discussed below, would have had a reasonable expectation of success in implementing them.

73. Likewise, a person of ordinary skill in the art would have had a finite number of filament configurations to select from to constrict a tubular member in a hemostasis valve in September 2017. Hartley discloses a string that runs from one side of the valve to the other and forms a loop around the tubular member, while Schaffer discloses two u-shaped members that collectively form a loop around the tubular member. A person of ordinary skill in the art would have found it obvious to select either of these finite, predictable configurations for constricting a valve and, as discussed below, would have had a reasonable expectation of success in implementing them.

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

### Demonstrative Illustration Schaffer + Hartley's String



75. Also, a person of ordinary skill in the art would have recognized that Hartley's string and Schaffer's actuating members function in similar ways and, therefore, no other modifications to Schaffer's valve would be necessary. Both Hartley and Schaffer collapse a valve lumen by pulling the ends of the actuating members/string in opposite directions. Ex. 1005 (Schaffer) at [0077]; Ex. 1006 (Hartley) at [0031]. Thus, if Hartley's string were incorporated into Schaffer's valve, a person of ordinary skill in the art would have reasonably expected

Schaffer's springs to pull the ends of the string in opposite directions to constrict Schaffer's seal module. *Id.*

76. Likewise, a person of ordinary skill in the art would have also reasonably expected that pressing Schaffer's buttons inwardly (i.e., second position) would release the tension on the string, allowing the lumen to open. *See* Ex. 1005 (Schaffer) at [0077]; Ex. 1006 (Hartley) at [0034]. Schaffer's seal module is formed from a "highly deformable, non-compressible material 166 (e.g., plastic)" and is "configured to maintain an open lumen 193 when no compressive force 67 is applied." Ex. 1005 (Schaffer) at [0054]. Thus, Schaffer's seal module has the resilience to open when the tension on the string is released. Moreover, if the resiliency of Schaffer's lumen required adjustment to function with Hartley's string, a person of ordinary skill in the art would have possessed the skills and knowledge to select an appropriate material with the proper resiliency. Schaffer discloses various materials for the seal module, including "modified vinyl, silicone, polyurethane or a combination thereof." *Id.* at [0081].

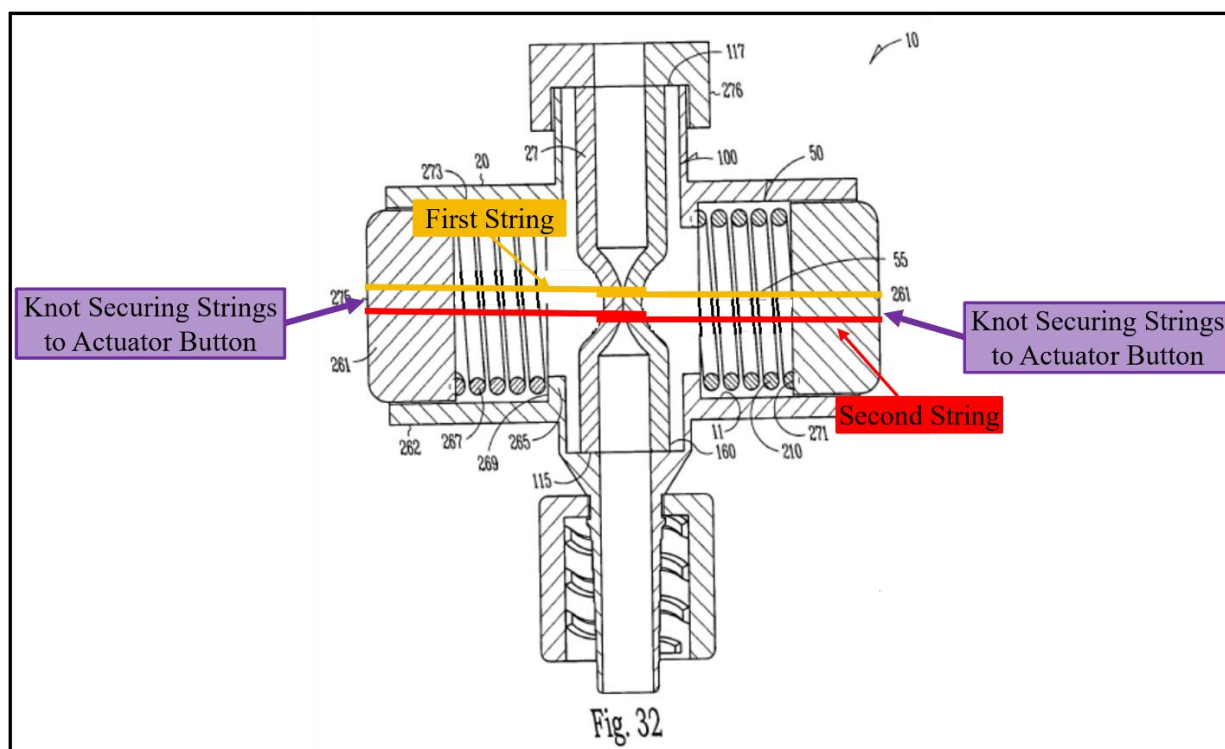
77. Further, Hartley discloses that winding the string around the central lumen forms an effective seal. Ex. 1006 (Hartley) at [0031], [0037]. Thus, when replacing Schaffer's actuating members with Hartley's string, a person of ordinary skill in the art would have been motivated to similarly wind Hartley's string around Schaffer's seal module. A person of ordinary skill in the art would have reasonably

expected success in using this configuration because Hartley teaches the configuration forms an effective seal.

ii. **A POSITA Would have been Motivated to Use Two of Hartley's Strings**

78. ***Second***, if the Board concludes that Hartley's string does not constitute first and second filaments as recited in Claim 1, a person of ordinary skill in the art would have found it obvious to substitute two of Hartley's strings for Schaffer's two actuator members. Such a substitution can be seen in the figure below:

Demonstrative Illustration  
Schaffer + Hartley's String



79. A person of ordinary skill in the art would have been motivated to use two of Hartley's strings when replacing Schaffer's u-shaped actuating members

based on Hartley's teachings and to create a more robust and reliable seal. Hartley discloses that its string "is wound preferably twice around the cylindrical diaphragm." Ex. 1007 (Hartley) at [0031]. A person of ordinary skill in the art exchanging Hartley's string for Schaffer's two u-shaped actuating members would have recognized that another way to create two loops (or windings) around the tubular member would have been to use two strings, each forming a single loop, as opposed to a single string wrapped twice around the tubular member. Hartley does not explain why the string would be "preferably" wound twice around the tubular member. However, a person of ordinary skill in the art would have understood that two loops of string would apply constricting force along a greater length of the tubular member, thereby creating a larger sealing area and a more robust seal.

80. A person of ordinary skill in the art would have been motivated to combine Hartley with Schaffer for the reasons I provided in the previous section. A person of ordinary skill in the art would have been motivated to use two separate strings, each wound or looped around the tubular member once, instead of a single string looped twice around the tubular member for several reasons. First, a person of ordinary skill in the art would have recognized that a single string looped twice around the tubular member would create more friction with the outer surface of the tubular member because more of the string is in contact with the surface of the tubular member. Because of the higher friction of the string against the tubular

member, the springs of Schaffer's valve would need to exert more pulling force to constrict the tubular member, and the tubular member would need greater resiliency to overcome the friction of the string and return to its expanded configuration. A person of ordinary skill would have been motivated to use two separate strings to form two separate loops to reduce the friction, which would reduce the force needed to operate the valve, while still accomplishing the same result (a larger sealing area).

81. Second, a person of ordinary skill in the art would have recognized that using two separate strings, each looped once around the tubular member, would allow the manufacturer to optimally space the strings to achieve the maximum sealing area. With only a single string, the loops formed by the string would tend to lie immediately next to each other on the outer surface of the tubular member, particularly after Schaffer's buttons have been depressed once or twice. However, with two strings, the manufacturer can design a small gap between the strings that remains after use to ensure that the sealing area is wider. A person of ordinary skill in the art would have recognized that a wider sealing area may be advantageous because it would create constrictive pressure over a larger area of the tools inserted through the valve.

82. Third, the second string would provide redundancy to the valve that cannot be accomplished with a single string. The second string would help ensure that the valve seals even if one of the strings were to fail to tighten around the

tubular member. This backup would not exist with a single string looped twice around the tubular member. Thus, the second string would add advantages not available with a single-string arrangement.

83. A person of ordinary skill in the art would have reasonably expected success in substituting Schaffer's two actuating members with two of Hartley's strings because Schaffer already discloses attaching two filament ends to each of its actuator buttons. Ex. 1005, [0075]-[0077], Figs. 30-34. In Schaffer's valve, both ends of each u-shaped actuating member are attached to the same actuator button on either side of the valve. *Id.* Thus, Schaffer already discloses that two filament ends can be secured to each of the buttons. *Id.* When Schaffer's actuating members are replaced with two of Hartley's strings, one end of each of the strings would be attached to each of the actuator buttons, resulting in two filament ends attached to each button. This is the same arrangement used for Schaffer's u-shaped actuating members, and a person of ordinary skill in the art would have therefore reasonably expected success implementing it for Hartley's strings.

84. In addition, as explained above, Hartley teaches using simple knots to attach the string to Hartley's rotary actuator. Ex. 1006, [0031]. A person of ordinary skill in the art would have reasonably expected that similar knots would secure Hartley's strings to Schaffer's actuator buttons. For example, each end of Hartley's strings could be threaded through small holes drilled or otherwise created

in Schaffer's buttons and knotted on the other side. This simple modification would have been within a person of ordinary skill in the art's knowledge. Thus, Schaffer combined with Hartley discloses this limitation.

**b. Eller**

85. Schaffer combined with Eller renders the first/second filament limitations obvious in two ways.

**i. Eller's Wire Member Includes Two Filaments**

86. *First*, Eller discloses a hemostasis valve that includes “a housing 16, an actuator 18, a sleeve 20, a first wire member 22, a second wire member 24, [and] a third wire member 26”:

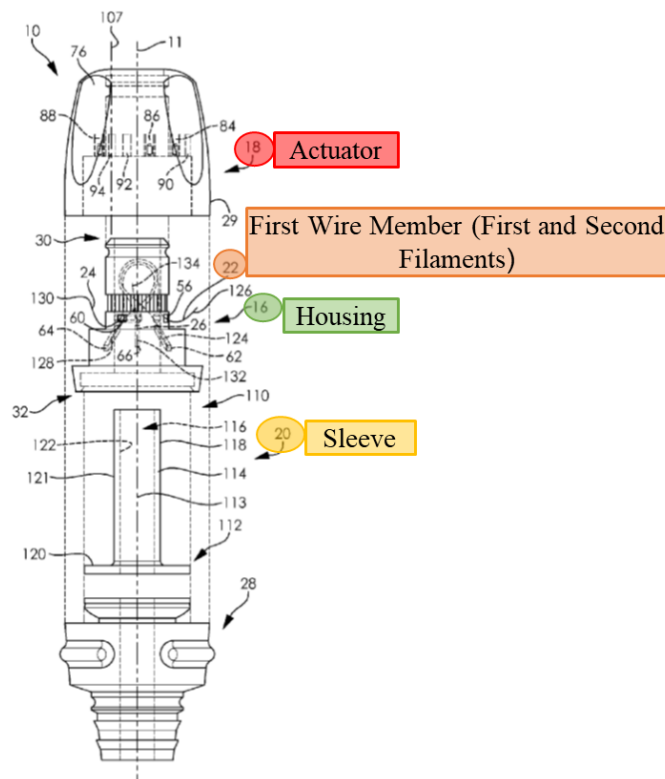


**FIG. 2**

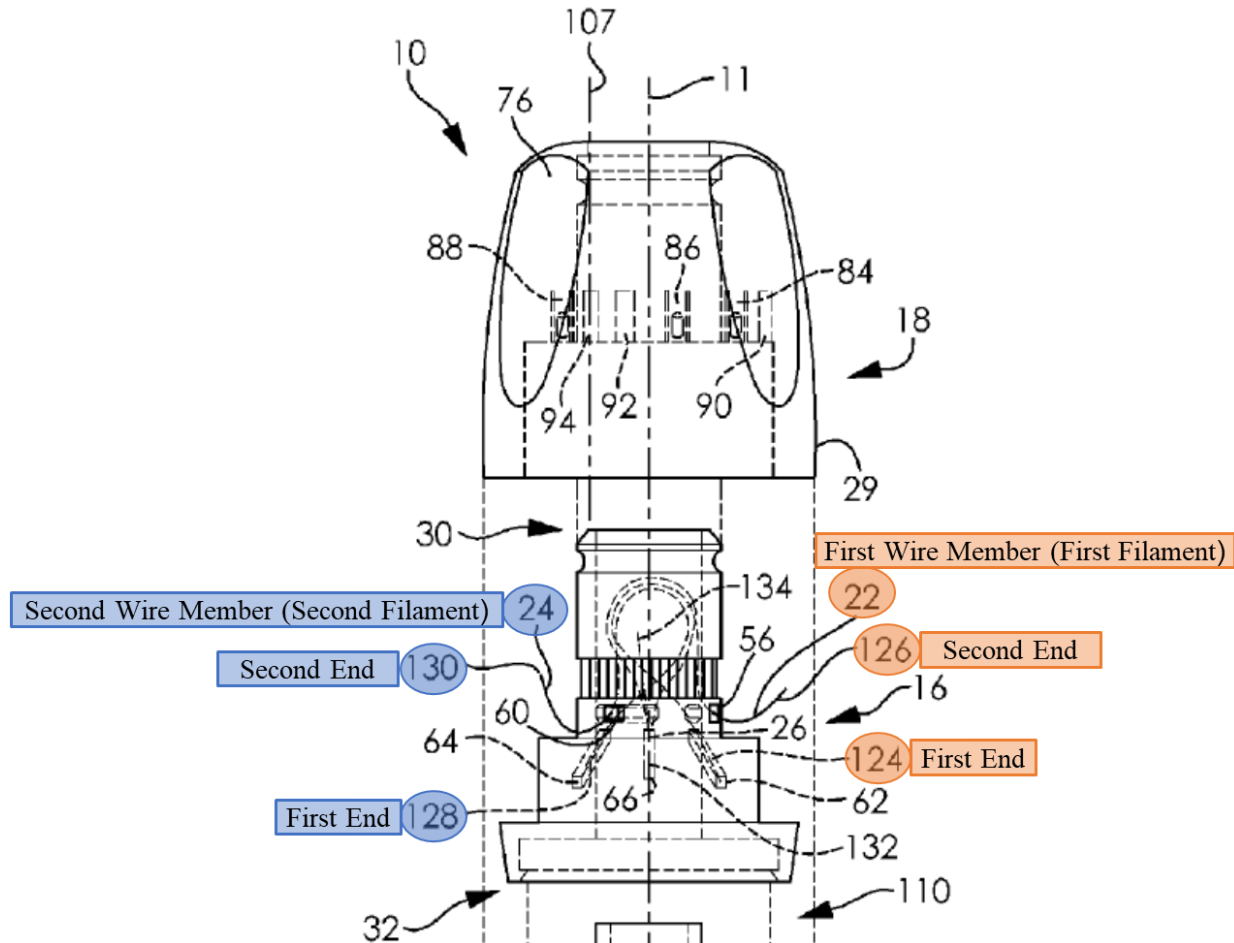
Ex. 1007 (Eller) at 5:1-5, Figs. 2.<sup>2</sup> Eller explains that its wire member “can have any suitable structure and comprise any suitable number of strands and/or fibers that are twisted, or otherwise interconnected to one another” and can comprise, for example, “a suture or a cable.” *Id.* at 15:61-16:6. Eller states that the wire member can be formed from various materials including “metals,” “polymers,” “polyester,” “nylon,” and “flexible materials. *Id.* at 15:41-60. A person of ordinary skill in the art would have therefore understood that each of the twisted “strands and/or fibers” making up Eller’s wire member would be a flexible filament so that Eller’s wire member includes at least a first and second filament as recited in Claim 1 of the ’384 patent. *See* Ex. 1001 (’384 patent) at 9:21-23 (stating that the filament “can comprise one or several threads, lines, cords, rope, ribbon, flat wire, sheet, or tape”).

87. I also note that each of the “strands and/or fibers” making up Eller’s wire member would be a “filament” under the construction that Patent Owner has proposed in prior IPRs, which is “a thin, flexible length of material formed by one or more strands of material.” Eller’s wire member therefore comprises a flexible “first filament” and a flexible “second filament” as recited in Claim 1.

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<sup>2</sup> 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.

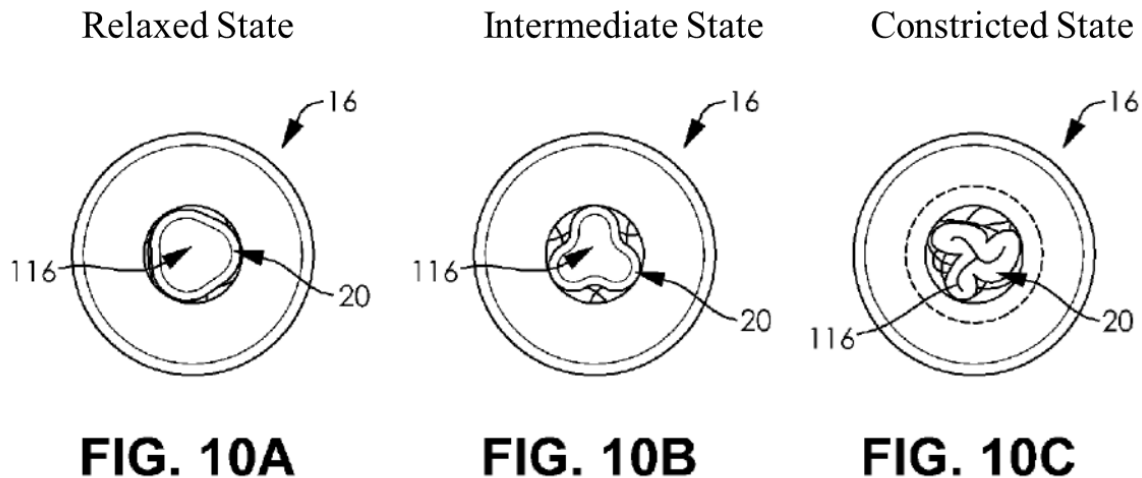
88. In some embodiments, Eller's wire members each have a first end attached to the housing 16 and a second end attached to the actuator 18. Ex. 1007 (Eller) at 12:52-58. Eller discloses that the first wire member extends from its first end attached to the housing 16 and “around a portion of the outer 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:



*Id.* at 24:50-57, Fig. 21. Eller further explains that the “wire member can be positioned such that it extends at least one full revolution around the outer surface

of the sleeve.” *Id.* at 22:22-24. When replacing Schaffer’s actuating members with Eller’s wire member, a person of ordinary skill in the art would have been motivated to loop Eller’s wire member(s) at least one full revolution around Schaffer’s seal module to ensure the wires formed a constrictive seal. A person of ordinary skill in the art would have reasonably expected success in doing so because Eller encourages looping the wires one revolution around the sleeve and discloses that such a configuration forms a seal.

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



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

90. A person of ordinary skill in the art would have found it obvious to substitute Eller’s wire member for Schaffer’s two actuating members by attaching one end of the wire to Schaffer’s first button, looping the wire around the seal module, and attaching the second end of the wire to Schaffer’s second button. This combination of Eller’s wire member and Schaffer’s valve would have merely entailed substituting one known element (Eller’s wire member) for another (Schaffer’s two actuating members) to yield the predictable results of constricting Schaffer’s valve. A person of ordinary skill in the art would have been motivated

to replace Schaffer's actuating members with Eller's wire member for several reasons.

91. 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. *Id.* 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.

92. 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 compliance 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 the tool inserted through the valve does not match the size or shape of Schaffer's U-shaped actuating members or if the members do not conform sufficiently to the size or shape of the tool inserted, 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.

93. 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.

94. 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 materials available to constrict the resilient material in a hemostasis valve in September 2017. Eller and Schaffer disclose two such methods – Eller's wire member and Schaffer's U-shaped actuating members. Hartley discloses another – a string. A person of ordinary skill

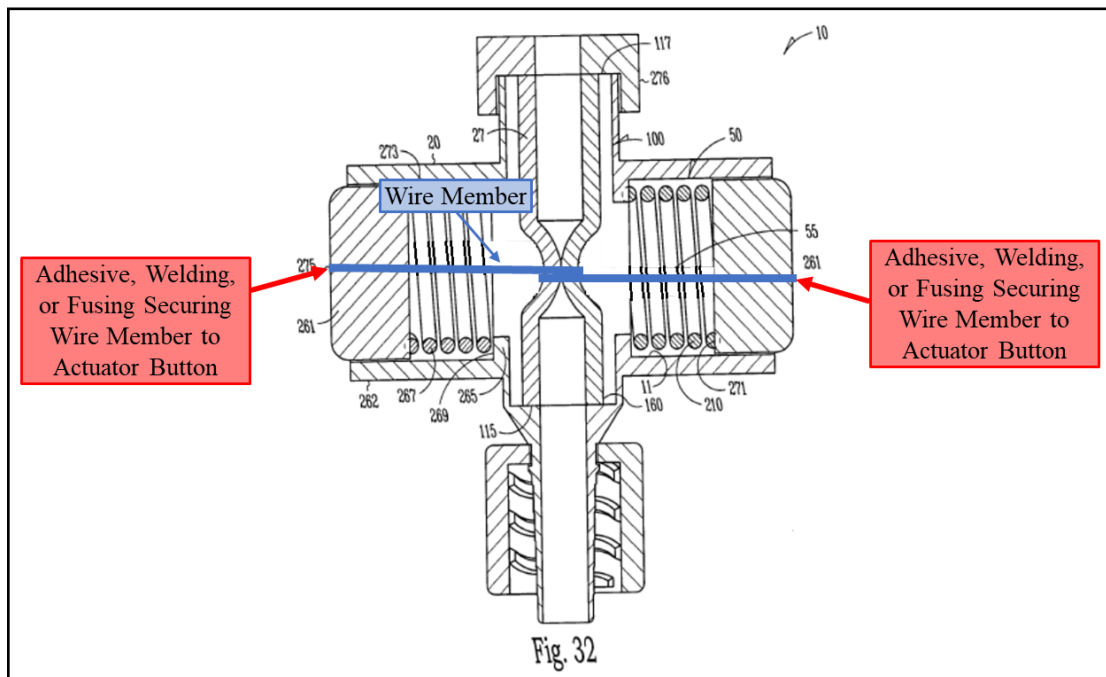
in the art in September 2017 would have found it obvious to select from these finite, predictable options. And as I explain below, they would have had a reasonable expectation of success in implementing them.

95. Likewise, a person of ordinary skill in the art would have had a finite number of filament configurations to select from to constrict a tubular member in a hemostasis valve in September 2017. Eller discloses a wire member(s) that forms a loop around the tubular member, while Schaffer discloses two u-shaped members that collectively form a loop around the tubular member. A person of ordinary skill in the art would have found it obvious to select either of these finite, predictable configurations for constricting a valve and, as discussed below, would have had a reasonable expectation of success in implementing them.

96. 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:

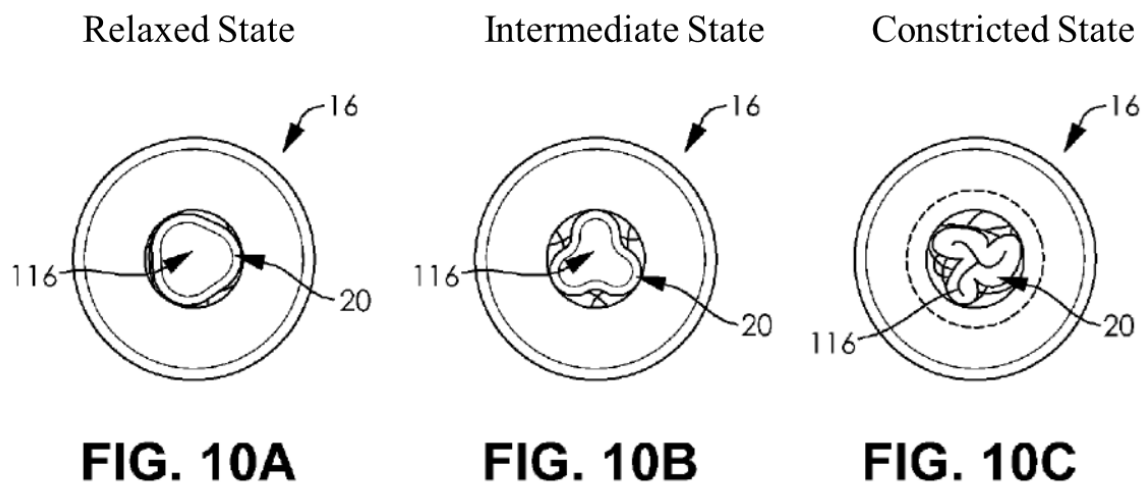
## Demonstrative Illustration Schaffer + Eller's Wire Member



97. 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.

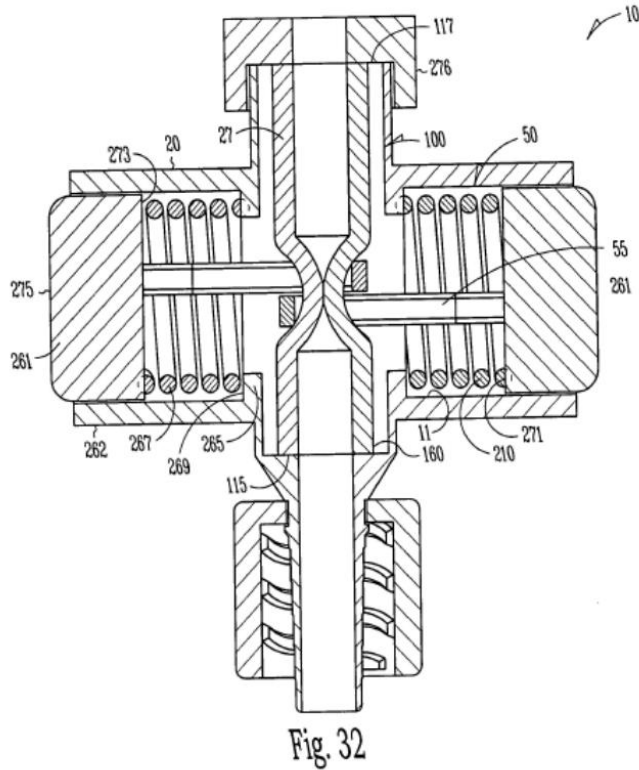
98. Third, a person of ordinary skill in the art would have recognized that Eller's wire member and Schaffer's U-shaped actuating members use similar mechanisms to constrict and seal the central lumen of the valve. Eller's wire member seals the valve when the actuator is placed in the second position, 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

Figure 32:

### Constricted State



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

99. In view of the similarities between Eller and Schaffer's valves, a person of ordinary skill in the art would have expected that Eller's wire member would serve as a reasonable, if not superior, substitute for the U-shaped actuating

members. For example, in a first position Schaffer's undepressed actuator buttons would pull the wire member in opposing directions, placing tension on the wire member. *See* Ex. 1005 (Schaffer) at [0077]; Ex. 1007 (Eller) at 15:21-40, 17:47-18:3. This would cause the string to constrict and collapse the lumen of Schaffer's containment structure and seal module, 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.

100. Also, 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.*

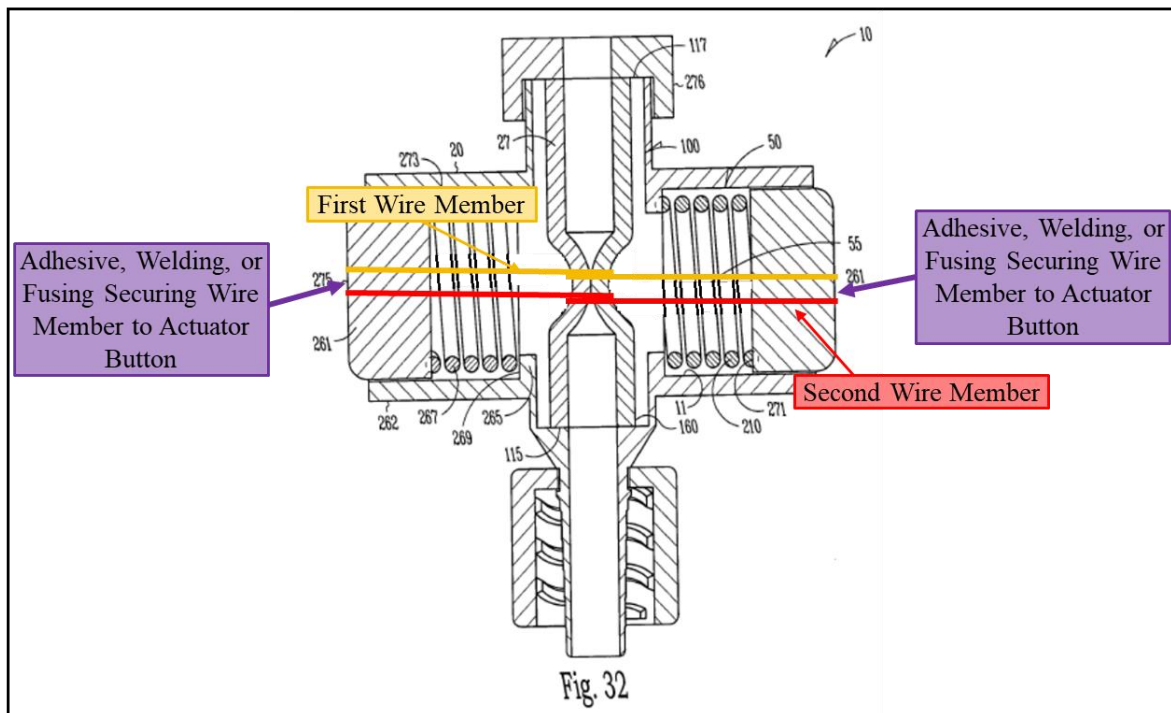
101. Further, as I explained with respect to the Schaffer-Hartley ground, if the resiliency of Schaffer's lumen required adjustment to function with Eller's wire,

a person of ordinary skill in the art would have possessed the skills and knowledge to select an appropriate material with the proper resiliency. (*Supra* §VI.A.3.a.) 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.

ii. **A POSITA Would have been Motivated to Use Two of Eller's Wire Members**

102. *Second*, if the Board concludes that one of Eller's wire members does not constitute a "first filament" and a "second filament" as recited in Claim 1, a person of ordinary skill in the art would have found it obvious to substitute two of Eller's wire members for Schaffer's two actuator members. Specifically, a person of ordinary skill in the art would have found it obvious to substitute Schaffer's two actuating members with two of Eller's wire members by attaching one end of the first and second wire members to Schaffer's first button, looping the wire members around the seal module, and attaching the second end of the first and second wire members to Schaffer's second button:

## Demonstrative Illustration Schaffer + Eller's Wire Member



103. A person of ordinary skill in the art would have been motivated to combine Eller with Schaffer for the reasons I provided in the previous section. Further, Eller's teachings would have motivated a person of ordinary skill in the art would have been motivated to use two of Eller's wire members with Schaffer's valve. Eller states that its valve "can include any suitable number of wire members," including "one, at least one, *two*, a plurality, three, four, five, or any other number considered suitable for a particular embodiment." Ex. 1007 (Eller) at 16:7-19 (emphasis added). Eller also explains that "[s]killed artisans will be able to select a suitable number of wire members to include in a selective fluid barrier valve device according to a particular embodiment based on various considerations,

including the material(s) that forms the sleeve of an embodiment.” *Id.* Eller’s statement is consistent with the skills and knowledge that a person of ordinary skill in the art would have possessed in September 2017. Accordingly, Eller expressly suggests varying the number of wire members (i.e., filaments) in a valve depending on the conditions of its use and confirms a person of ordinary skill in the art would have possessed the skills to make such routine adjustments.

104. In addition, combining two of Eller’s wire members with Schaffer’s valve would have entailed merely substituting one known element (Eller’s two wire members) for another (Schaffer’s two actuating members) to yield the predictable results of constricting and sealing Schaffer’s valve. A person of ordinary skill in the art would have been motivated to use two wire members with Schaffer’s valve to provide a more robust and reliable seal for the same reasons that I explained above with respect to Hartley (e.g., creating a larger sealing area, allow the manufacturer to optimally space the strings, adding redundancy to the system). *Supra* §VI.A.3.a.ii.

105. A person of ordinary skill in the art would have reasonably expected success in substituting two of Eller’s wire members for Schaffer’s actuating members for several reasons. First, as I explained above for Hartley, Schaffer already discloses a method of attaching two ends of a filament with each button. Ex. 1005 (Schaffer) at [0075]-[0077], Figs. 30-34. In Schaffer’s valve, both ends

of each u-shaped actuating member are attached to the same actuator button on either side of the valve. *Id.* Thus, Schaffer already discloses that two filament ends can be secured to each of the buttons. *Id.* When Schaffer's actuating members are replaced with two of Eller's wire members, one end of each of the wires would be attached to each of the actuator buttons, resulting in two filament ends attached to each button. This is the same arrangement used for Schaffer's u-shaped actuating members, and a person of ordinary skill in the art would have therefore reasonably expected success implementing it for Eller's wires.

106. Second, as I explained above, Eller discloses that the "[a]ttachment between a wire member and a housing and/or an actuator can be accomplished using any suitable method or technique" and identifies several means for securing its wire members to an actuator. Ex. 1007 (Eller) at 14:37-49. A person of ordinary skill in the art would have reasonably expected success in securing Eller's wire members to Schaffer's actuator buttons using these simple methods.

c. **Schaffer's Seal Module Would Not Dissuade A Person Of Ordinary Skill From Combining Schaffer With Hartley Or Eller**

107. I am aware that in related proceedings Patent Owner argues a person of ordinary skill in the art would not have been motivated to modify Schaffer's valve with Hartley's string or Eller's wire member because Schaffer would not result in gaps because Schaffer discloses an exemplary embodiment with a

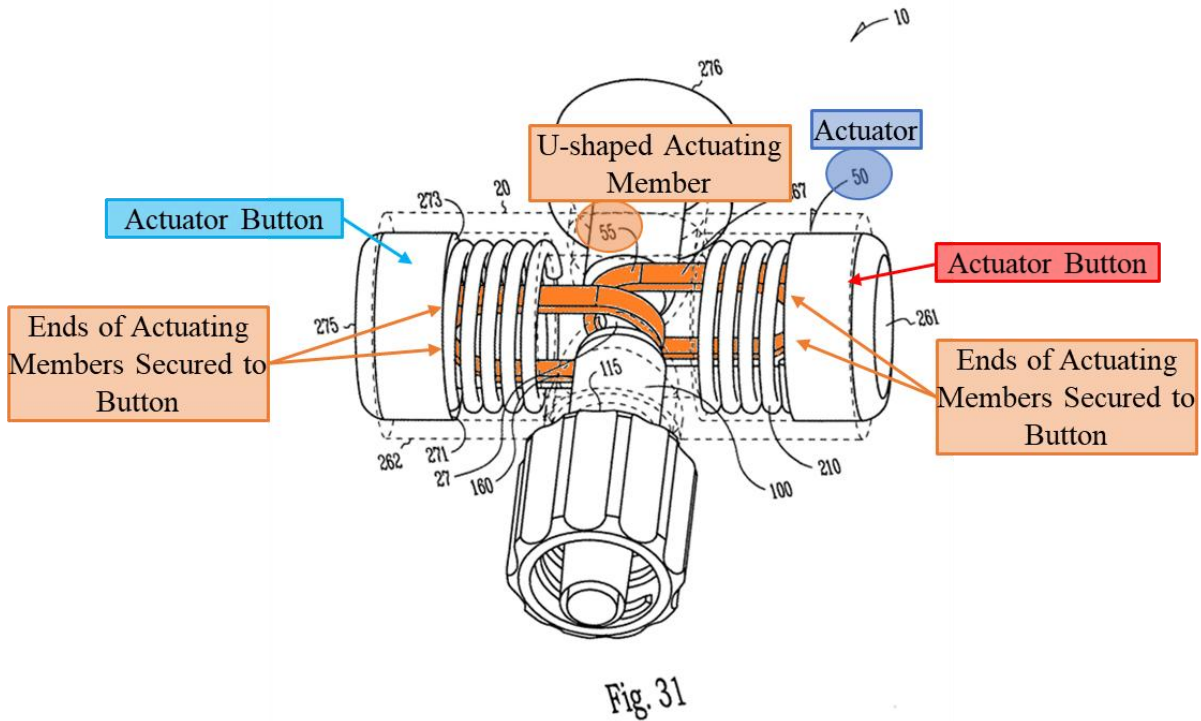
“gelatinous” or “sticky” seal module with “selfclosing” properties. Ex. 1044 (’011 IPR POR) at 46-52. I disagree for several reasons.

108. First, even Schaffer recognizes it may not form a complete seal with the “gelatinous” and “sticky” valves identified by Patent Owner, stating the valves form a “*nearly* fluid/gas tight seal.” Ex. 1005 (Schaffer) at [0059].

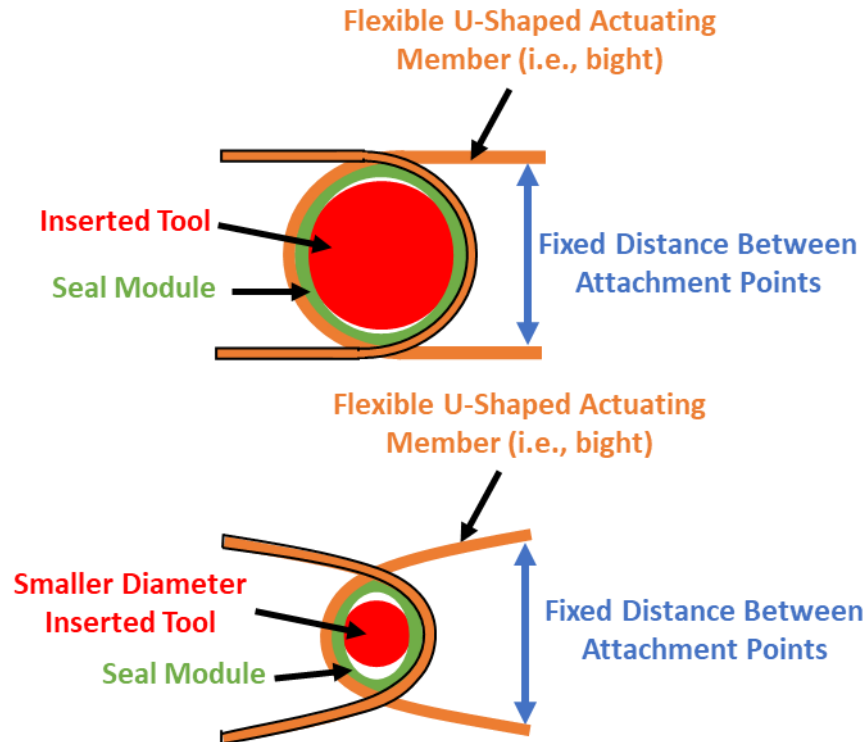
109. Second, Schaffer discloses that the “sticky” or “gelatinous” seal module is an optional feature for some embodiments, but it does not state or suggest that it is required for all embodiments, including the embodiment depicted in Figures 31-34. *See id.* at [0059], [0081]. Moreover, the portion of Schaffer that refers to a “sticky” or “gelatinous” substance refers to embodiments of the valve having three portions where one of the portions can optionally be made from a “sticky” or “gelatinous” substance having a specific “shore hardness.” *Id.* 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 30-34 do not require three portions stating: “The seal module 100 is formed of one or more seal members, as discussed above.” *Id.* at [0075].

110. Third, a person of ordinary skill in the art would have recognized that the “sticky” or “gelatinous” materials would not work well with the seal modules disclosed in Figures 30-34 because those seal modules must “retract to an uncollapsed configuration” when the tension on the module is released by the actuating members. A seal module made of very “sticky” or “gelatinous” materials would not have the requisite resilience to return to its uncollapsed configuration. Thus, even if the seal module had some stickiness, a person of ordinary skill in the art would have understood that the seal module cannot be so sticky as to prevent the seal module from retracting to its unsealed state when the constricting force from the actuating members is removed. *See id.*; *see also id.* at [0054] (“The third central seal member 165 is sized and configured to maintain an open lumen 193 when no compressive force 67 is applied.”).

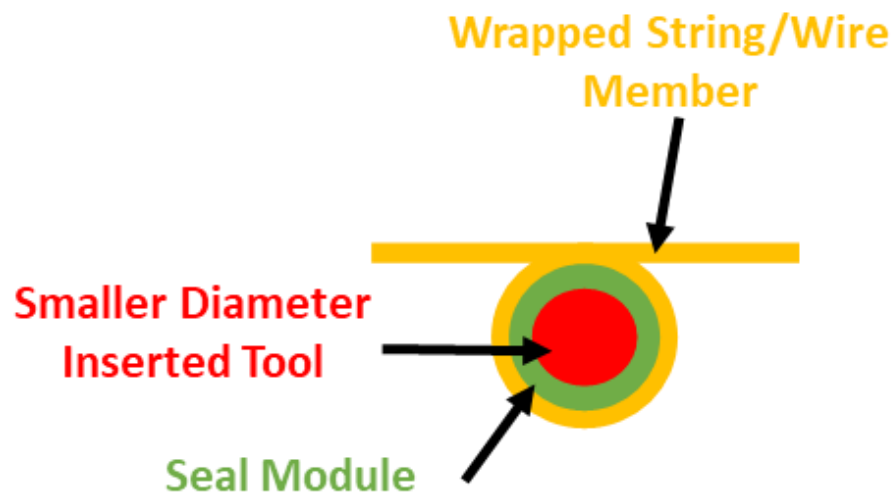
111. A person of ordinary skill in the art would have understood that small gaps may form with Schaffer’s valve, particularly if the tool inserted through the valve does not match the size or shape of Schaffer’s U-shaped actuating members or if the members do not conform sufficiently to the size or shape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



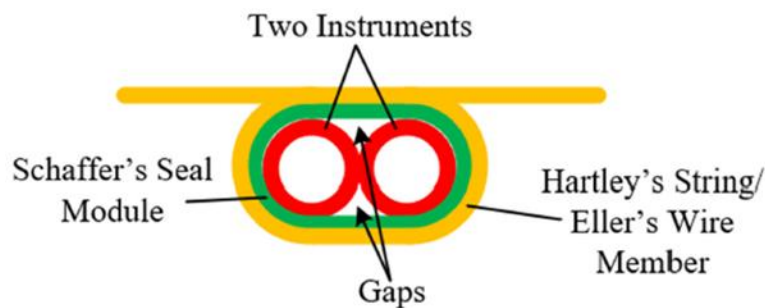
*Id.* at Fig. 31. Because of this arrangement, even when the U-shaped actuating members (or bights) are relatively flexible, the fixed attachment points to the actuator buttons may prevent the U-shaped actuating members from completely conforming to the exterior of a tool with a smaller diameter than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



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



112. I am also aware that in the related IPR proceedings, Patent Owner argues that Schaffer's valve with Hartley's string would seal "less effectively" when two instruments are inserted through the valve. Ex. 1044 ('011 IPR POR) at 52. Patent Owner cites to Schaffer's disclosure of an embodiment with sealing member that is "so compliant that it forms a seal around the instruments 260 even if the instruments 260 are irregularly shaped." Ex. 1005 (Schaffer) at [0068]. This particular disclosure appears in the section of Schaffer referring to Figures 12-15 (not Figure 30-34), which describes a three-piece valve that closes as a result of "pressure from the antegrade flow 272," not an actuator. *Id.* at [0068]-[0069]; *see also id.* at [0063] (referencing Figures 12-15). Clearly, this embodiment operates differently than the embodiment in Figures 30-34. *See id.* at [0069] ("While this arrangement may not be as friction-less as the other embodiments using an actuator 50, it may offer the advantages of 'hands-free' operation."). Patent Owner also provides the following illustration as alleged support for its argument:



Ex. 1044 ('011 IPR POR) at 52. Patent Owner's illustration does not depict the compliant sealing member described in Schaffer's Paragraph [0068]. The sealing

member depicted in Patent Owner's illustration is not "so compliant that it forms a seal around the instruments 260 even if the instruments 260 are irregularly shaped." In addition, Patent Owner does not explain how the illustration would be any different if the string or wire was replaced with two U-shaped actuating members. Because of the non-compliant seal depicted in the illustration, the same gaps would exist with U-shaped actuating members. Accordingly, Patent Owner's illustration is not representative of Schaffer's valve and does not demonstrate that Schaffer's valve would work less effectively with a string.

**d. Substituting Hartley's String(s) Or Eller's Wire Member(s) For Schaffer's Actuating Members Would Not Change Schaffer's Principles Of Operation**

113. I am aware that in the related IPR proceedings, Patent Owner and Dr. Zalesky assert that substituting Schaffer's U-shaped actuating members with Hartley's string or Eller's wire member would "change Schaffer's principles of operation." Patent Owner and Dr. Zalesky provide three rationales for why they believe this to be the case: (1) Hartley's string or Eller's wire member would not "forcibly disengage" from Schaffer's seal module, (2) Hartley's string or Eller's wire member would prevent "easy assembly" of Schaffer's valve, and (3) Hartley's string or Eller's wire member would reduce the durability of Schaffer's valve. *See* Ex. 1044 ('011 IPR POR) at 52-60; Ex. 1045('011 IPR, Zalesky Supp. Decl.) at §§VIII.E-F. I disagree with each of these assertions for the reasons I explain below.

i. **Hartley's String(s) Or Eller's Wire Member(s)**  
**Would Not Prevent "Forcible Disengagement" From**  
**Schaffer's Seal Module**

114. I disagree with Patent Owner's contention that depressing Schaffer's actuator buttons would not allow Hartley's string or Eller's wire member to "forcibly disengage opposing outer walls 27 of the seal module 100 allowing the portion 108 of the containment structure 160 to retract to an uncollapsed configuration." Ex. 1005 (Schaffer) at [0077]. The description in Schaffer that the actuating members "forcibly disengage opposing outer walls of the seal module 100" does not mean that the actuating members do not remain in contact with the seal module. As shown in Figure 34 above, the actuating members are still in contact with the seal module 100 even after being forcibly disengaged. Rather, the term "forcibly disengage" refers to the act of applying force to the buttons to release the tension created by the actuating members on the seal module, which in turn allows the seal module "to retract to an uncollapsed configuration where gases and fluids can pass therethrough." *Id.* at [0077], Fig. 34. Schaffer's buttons move inwardly when force is applied, releasing tension on the actuating members (filaments) and allowing the seal module/tubular member to retract to an uncollapsed configuration, the exact same way that the '384 patent's filament does.

115. Further, when the buttons of Schaffer's valve are undepressed, the actuating members must forcibly engage the valve. Once again, the actuating

members contact the lumen, and the force is applied to the members by the springs.

This reinforces my opinions stated above.

ii. **Hartley's String(s) Or Eller's Wire Member(s)**  
**Would Not Prevent Assembly Of Schaffer's Valve**

116. Patent Owner and Dr. Zalesky have argued that Hartley's string or Eller's wire member would "introduce assembly difficulties" to Schaffer's valve and would prevent assembly of the valve using the exemplary steps provided in paragraph 83 of Schaffer. I disagree.

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

118. Second, Schaffer states that the assembly steps in paragraphs 82-83 are "one option" or "an example." Ex. 1005 (Schaffer) at [0082]-[0083]. Schaffer does not state or suggest that the exemplary processes described in paragraphs 82-83 are the only way to assemble the valve.

119. Third, as I explained during my deposition in the Litigation, Hartley's string and Eller's wire member would not have made Schaffer's valve so much more difficult to manufacture that it would have discouraged a person of ordinary skill in the art from making the combination. A person of ordinary skill in the art would have known of many ways to assemble the valve with the string or wire member. For example, a tapered fixture could be used to introduce the seal module through the looped string/wire member that is already attached to the buttons.

Alternatively, the seal module could be positioned in the valve and the string/wire member could be looped around the module, then the springs and buttons inserted before the string/wire member is attached to the buttons. Schaffer's housing could also be formed from two detachable pieces, which would allow the internal components of the valve to be assembled prior to closing the housing. After the string/wire member and seal module are assembled, the housing could then be secured through well-known means such as adhesives, screws, or clips.

120. Notably, the '384 patent is silent on how its disclosed hemostasis valves can or should be assembled. The '384 patent therefore presumes that it would have been within the capabilities of a person of ordinary skill in the art to determine how to assemble its valves. Thus, the '384 patent is consistent with my opinion that a person of ordinary skill in the art would have known of many ways to assemble a hemostasis valve with a string like the valve that would result from the combination of Schaffer and Hartley or Eller.

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

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

122. I am aware that in related IPRs, Patent Owner has argued that substituting Schaffer's U-shaped actuating members with Hartley's string or Eller's wire member would weaken the durability of Schaffer's valve. I disagree with Patent Owner's arguments regarding durability.

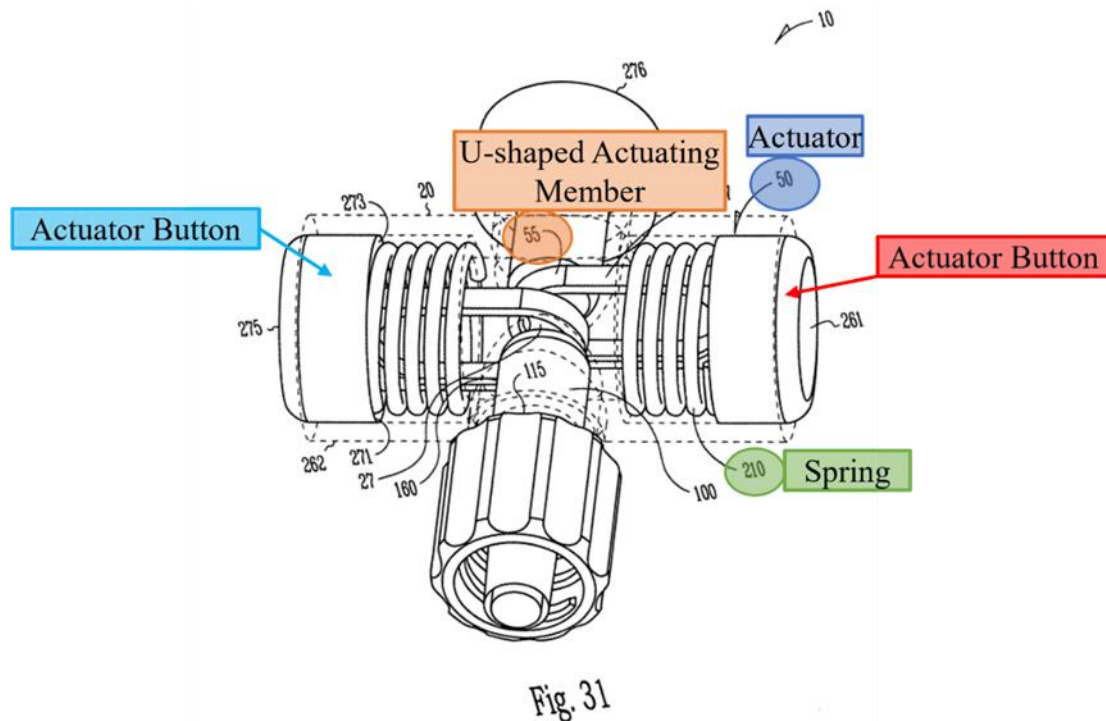
123. Hartley and Eller use the string/wire member for the same purpose they would be used in Schaffer's valve and neither suggests any issues with durability. In addition, a person of ordinary skill in the art in 2017 would have known of many durable materials that could be used to form a string or wire for use in a medical device, such as polypropylene or other suture material. Accordingly, to the extent that a person of ordinary skill in the art was concerned about the durability of the valve, they could have simply used one of the known, durable materials to form the string or wire. Durability concerns would not have dissuaded a person of ordinary skill in the art from substituting Schaffer's U-shaped actuating members with Hartley's string or Eller's wire member.

124. I also note that the same durability concerns that Patent Owner raises for Hartley's string and Eller's wire member would apply equally to the filaments disclosed in the '384 patent. Therefore, I do not believe that durability provides any basis to distinguish the '384 patent from the prior art.

4. **“a pair of actuators movable from a first position to a second position”**

125. Claim 1 next recites “a pair of actuators movable from a first position to a second position.” Schaffer discloses this limitation.

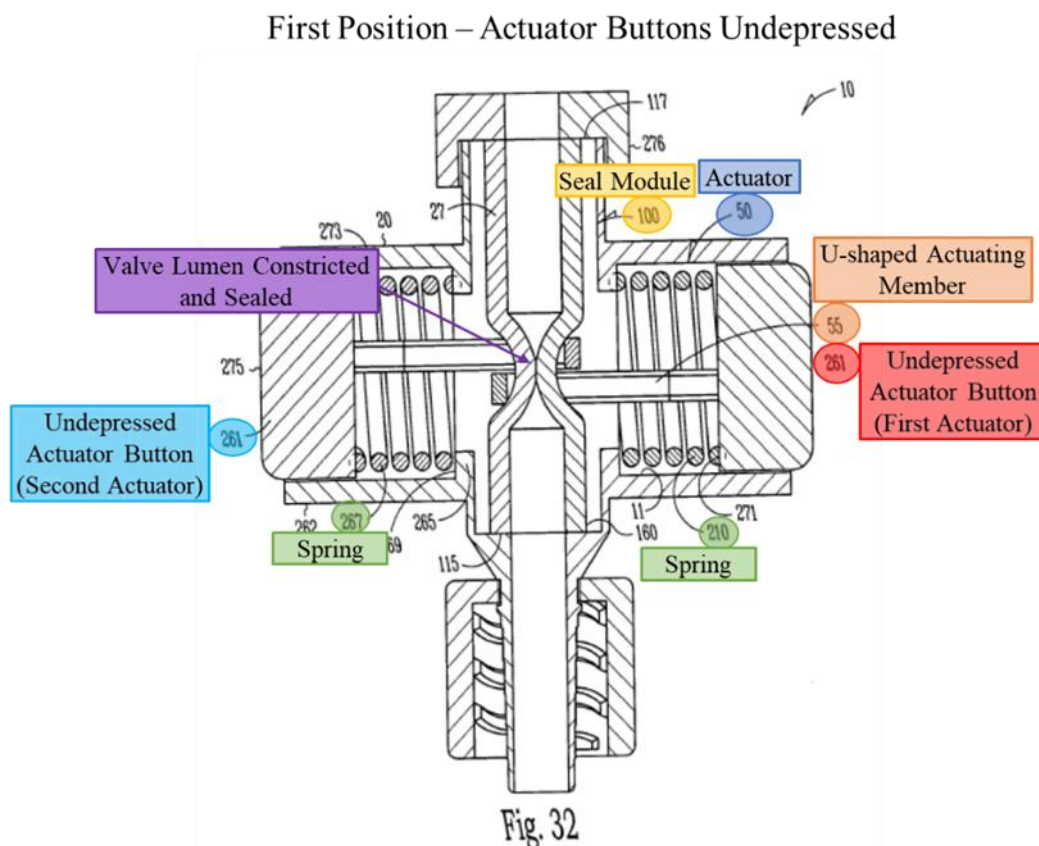
126. Schaffer discloses a hemostasis valve, depicted in Figures 30-34, that includes two spring-loaded actuators 50 that are “movable from a first position to a second position on opposing sides of the housing.” Ex. 1005 (Schaffer) at [0075]-[0076]. The actuators each include an actuator button 261 and a spring 210/267, as illustrated in Figure 32 below:



*Id.* at [0075]-[0076], Fig. 31.

127. Schaffer’s actuators are “movable from a first position to a second position.” Schaffer discloses that in a first position, the U-shaped actuating

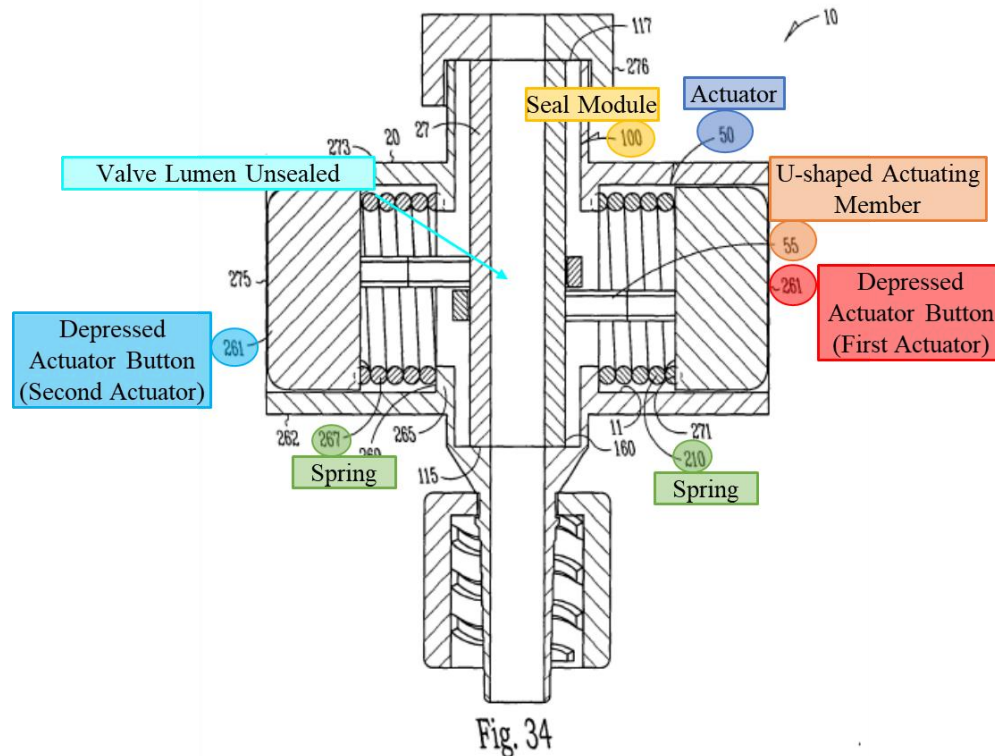
members are “at least partially circumferentially [sic] disposed about the portion 108 of the seal module 100 depressing and at least partially collapsing a portion 108 of the containment structure 160 by a compressive force 67 (e.g. by a spring 210).” Ex. 1005 (Schaffer) at [0077]. This position is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



*Id.* at [0077], Fig. 32. Schaffer then explains that in a second position, the actuator buttons are depressed, which compresses the spring and allows the actuator members to “forcibly disengage opposing outer walls 27 of the seal module 100 allowing the portion 108 of the containment structure 160 to retract to an

uncollapsed configuration where gases and fluids can pass therethrough.” *Id.* The second position is illustrated in Figure 34:

Second Position – Actuator Buttons Depressed



*Id.* at [0077], Fig. 34.

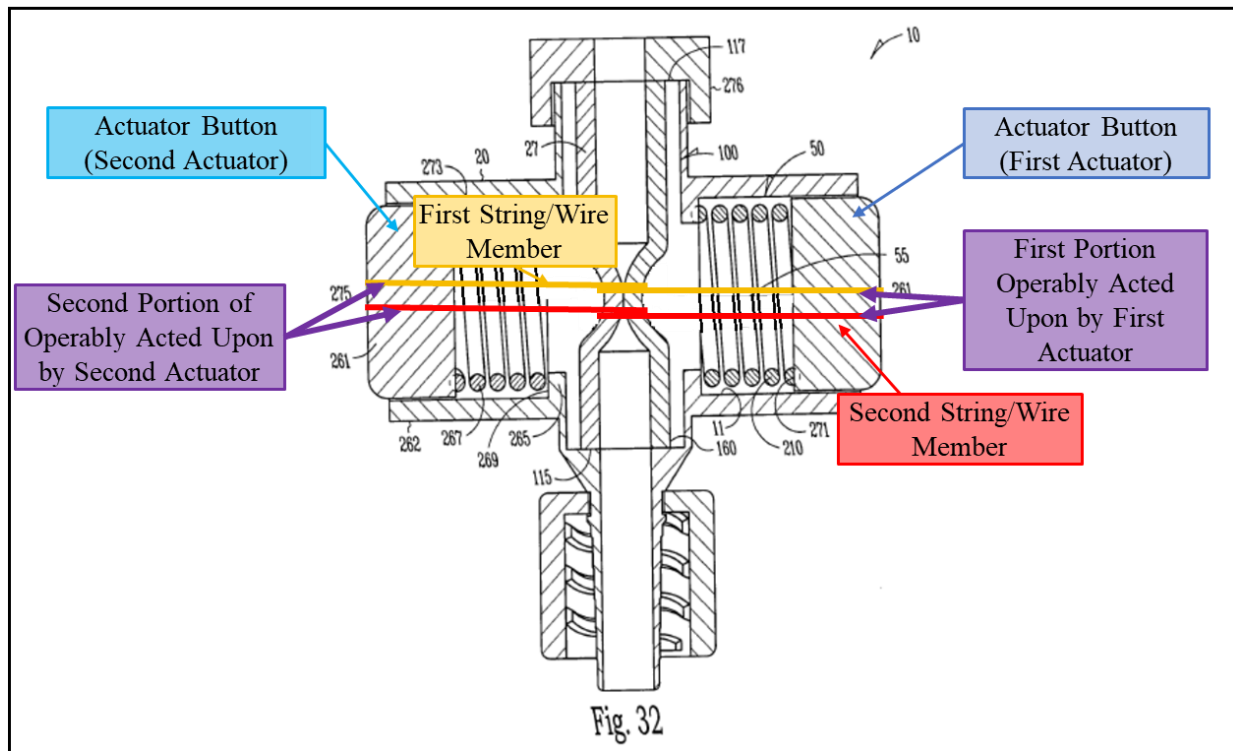
5. **“the first filament includes a first portion operably acted upon by a first one of the actuators and a second portion operably acted upon by a second one of the actuators; the second filament includes a first portion operably acted upon by the first one of the actuators and a second portion operably acted upon by the second one of the actuators”**

128. Claim 1 next recites “the first filament includes a first portion operably acted upon by a first one of the actuators and a second portion operably acted upon by a second one of the actuators; the second filament includes a first portion

operably acted upon by the first one of the actuators and a second portion operably acted upon by the second one of the actuators.” Schaffer renders this limitation obvious in view of Hartley *or* Eller.

129. As I explained previously, a person of ordinary skill in the art would have been motivated to secure the first end of Hartley’s string(s) or Eller’s wire member(s) to a first one of Schaffer’s actuator buttons using the well-known and conventional means described in Hartley and Eller, such as knots, adhesives, welding, or fusing. *Supra* §VI.A.3. As I further explained above, the person of ordinary skill in the art would have also been motivated to secure the second end of Hartley’s string(s) or Eller’s wire member(s) to Schaffer’s second actuator button on the opposite side of the tubular member using similar means. *Id.* The illustration below demonstrates the arrangement of the string(s)/wire member(s) resulting from this simple substitution:

## Demonstrative Illustration Schaffer + Hartley's String Or Eller's Wire Member



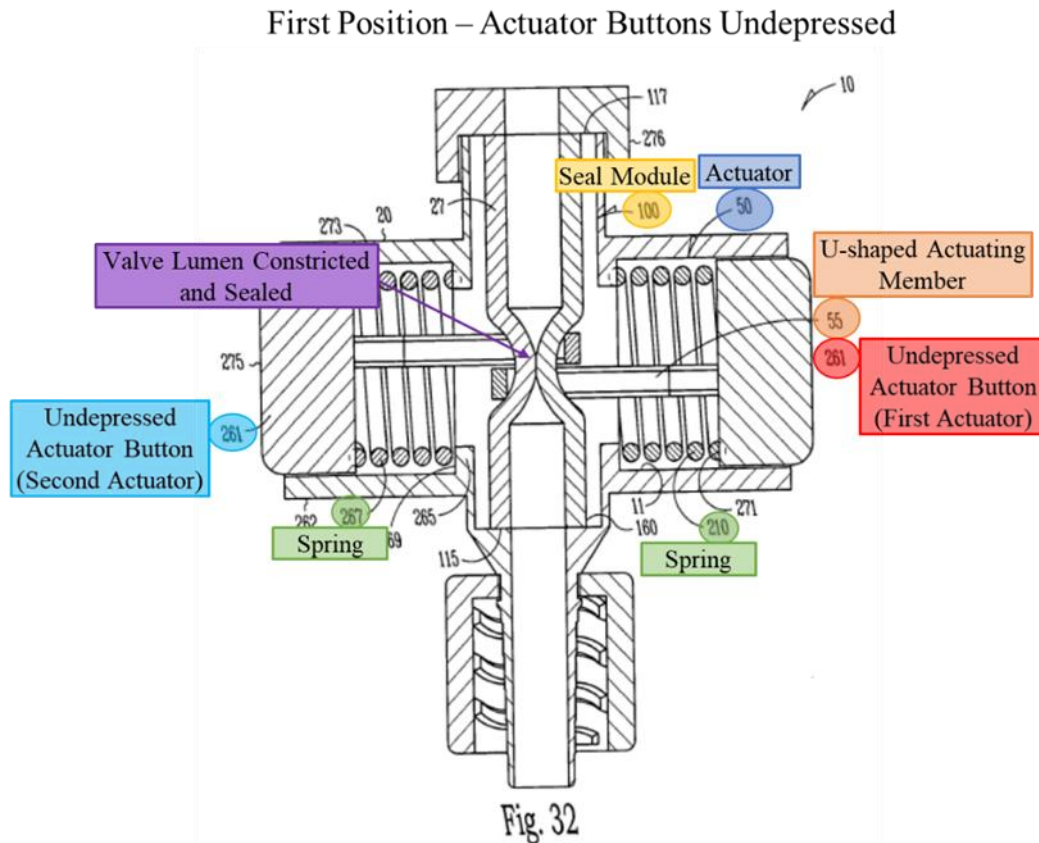
130. As illustrated in the demonstrative above, when Schaffer's u-shaped actuating members are replaced by Hartley's string(s) or Eller's wire member(s), a first portion of the string(s)/wire member(s) would be attached to and "operably acted upon" by the first one of Schaffer's actuator buttons. The actuator button would "operably act upon" the first portion of the string(s)/wire member(s) at least because it would pull the string(s)/wire member(s) to create tension in the first, undepressed position. As also illustrated above, a second portion of the string(s)/wire member(s) would be attached to and "operably acted upon" by the second one of Schaffer's actuator buttons.

6. “in the first position, the actuators are positioned to tension the first filament and the second filament thereby decreasing a dimension of the first loop and a dimension of the second loop to constrict the lumen of the tubular member; in the second position, the actuators are positioned to loosen the first filament and the second filament thereby permitting the tubular member to expand against the first loop and the second loop to increase the dimension of the first loop and the dimension of the second loop to at least partially open the lumen of the tubular member”

131. Claim 1 next recites “in the first position, the actuators are positioned to tension the first filament and the second filament thereby decreasing a dimension of the first loop and a dimension of the second loop to constrict the lumen of the tubular member; in the second position, the actuators are positioned to loosen the first filament and the second filament thereby permitting the tubular member to expand against the first loop and the second loop to increase the dimension of the first loop and the dimension of the second loop to at least partially open the lumen of the tubular member.” Schaffer in combination with Hartley *or* Eller renders these limitations obvious.

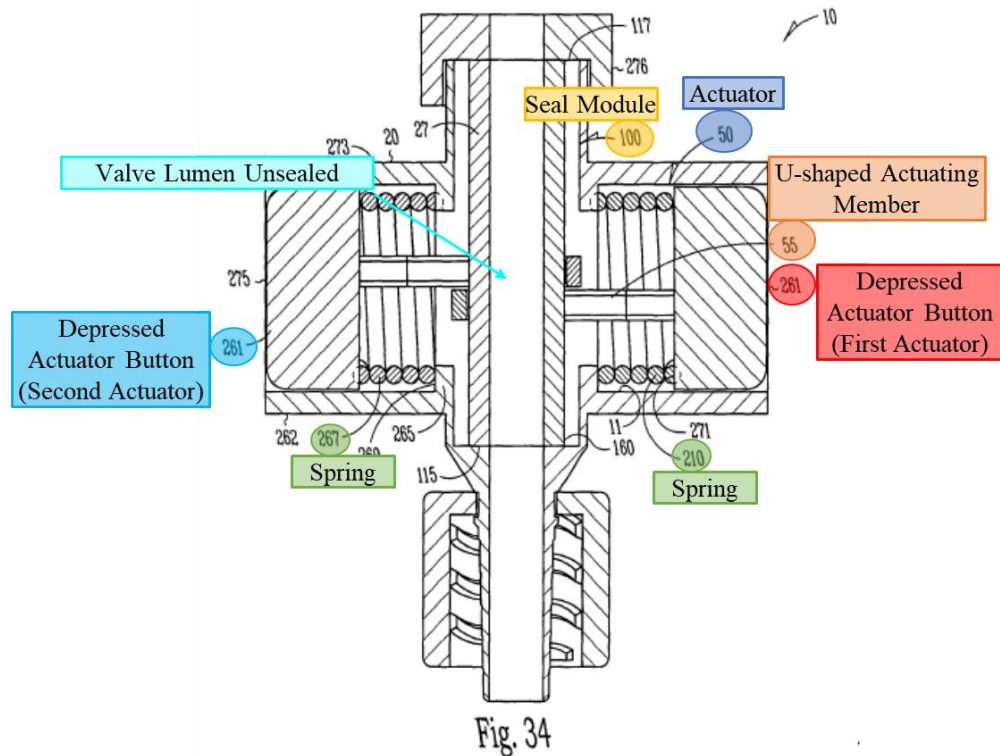
132. As I explained previously, Schaffer discloses that in a first position when the actuator buttons are undepressed, the actuating members are “at least partially circumferentially [sic] disposed about the portion 108 of the seal module 100 depressing and at least partially collapsing a portion 108 of the containment structure 160 by a compressive force 67 (e.g. by a spring 210).” Ex. 1005 (Schaffer)

at [0077]. This position is depicted in Figure 32, which shows that the central lumen constricted and sealed in the first position, when the buttons are undepressed:



*Id.* at [0077], Fig. 32. Schaffer then explains that in a second position, the actuator buttons are depressed, which compresses the spring and allows the actuator members to “forcibly disengage opposing outer walls 27 of the seal module 100 allowing the portion 108 of the containment structure 160 to retract to an uncollapsed configuration where gases and fluids can pass therethrough.” *Id.* The second position is illustrated in Figure 34:

## Second Position – Actuator Buttons Depressed



*Id.* at [0077], Fig. 34.

133. Hartley discloses that “[r]otation of the rotary actuator 12 with respect to the cylindrical housing 6 will cause the string 14 to be pulled in both directions at once and hence the cylindrical diaphragm 8 to be constricted.” Ex. 1006 (Hartley) at [0031], [0034], Fig. 4. Thus, tension placed on Hartley’s string by the actuator reduces the size of the loop to constrict and seal the valve. This is shown in Figures 3 and 4 of Hartley:

Relaxed State

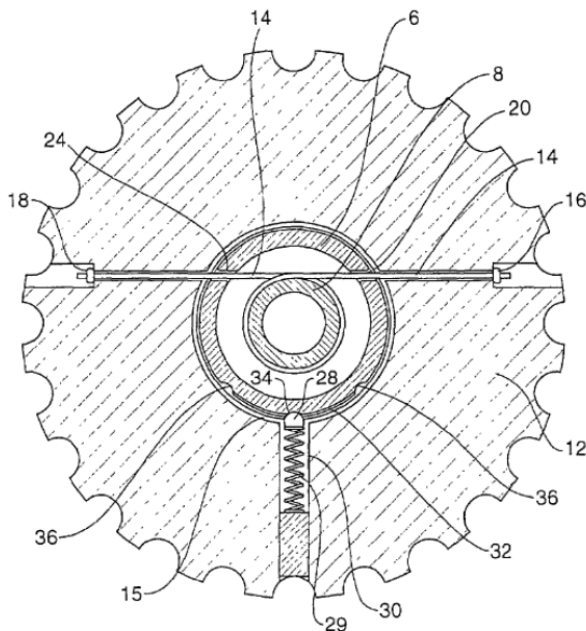


**Fig 3**

Constricted State

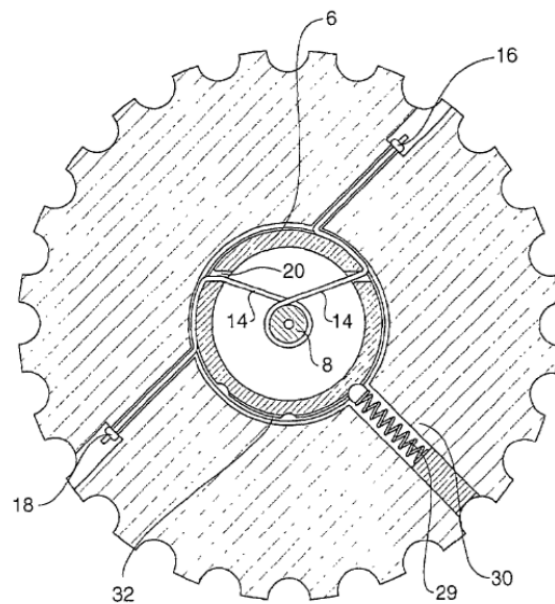
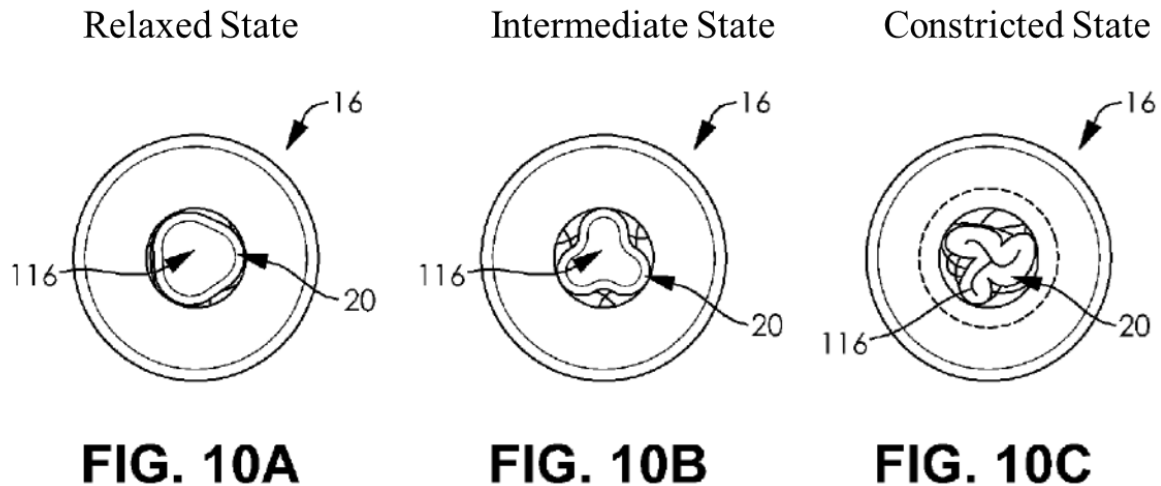


**Fig 4**

*Id.* at Figs. 3-4.

134. Eller similarly discloses that rotation of its actuator places the wire members under tension, which reduces the size of the wire loops and causes the wire members to constrict the sleeve and prevent fluid from passing therethrough. Ex. 1007 (Eller) at 15:21-40, 17:62-67. This is illustrated in Figures 10A-C of Eller:



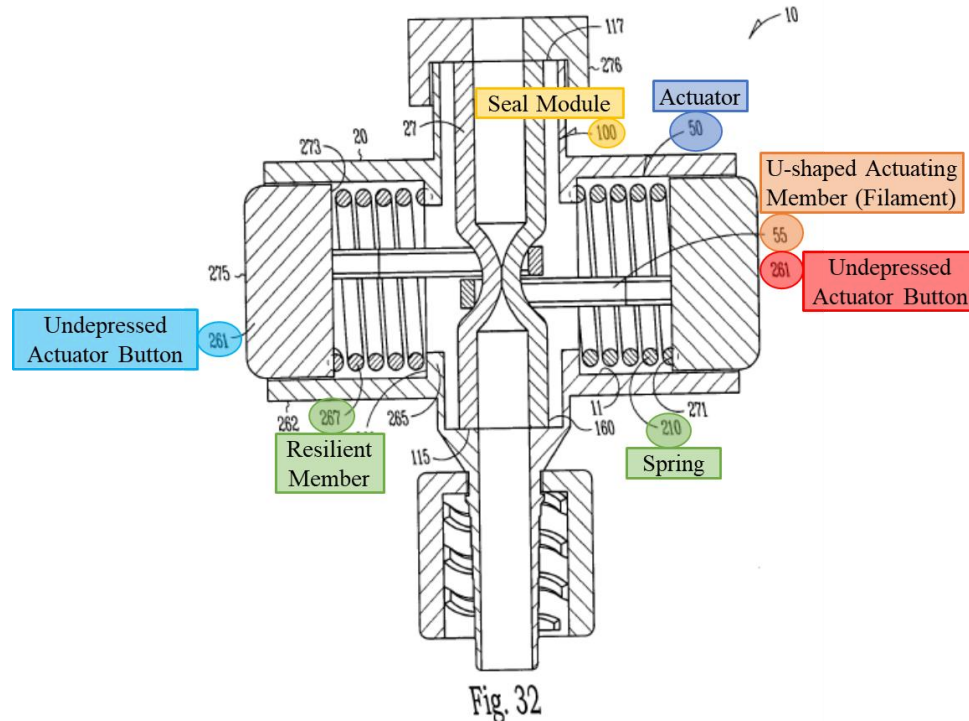
*Id.* at Figs. 10A-C.

135. Given the disclosures in Schaffer, Hartley, and Eller, a person of ordinary skill in the art would have reasonably expected that attaching the ends of Hartley’s string(s) or Eller’s wire member(s) to the Schaffer’s actuator buttons would likewise result in pulling the ends of the string(s)/wire member(s) in both directions, decreasing the dimension of the string/wire loops and causing the lumen to constrict. Then, when the actuators are depressed to the second position, the tension on the string(s)/wire member(s) would loosen, increasing the dimension of the string/wire loops and allowing the tubular member to expand and the lumen to open.

**7. “the actuators are biased to the first position”**

136. Claim 1 finally recites “the actuators are biased to the first position.” Schaffer discloses this limitation.

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



Ex. 1005 (Schaffer) at [0076], Fig. 31. Schaffer's resilient members bias Schaffer's actuator buttons (first and second actuators) toward the first (i.e., closed) position, which in turn causes the actuating members attached to the buttons to collapse the seal module, preventing the flow of fluid through the valve. *Id.* at [0077]. Thus, Schaffer discloses this limitation.

138. Modifying Schaffer by replacing its actuating members with Hartley's string(s) or Eller's wire(s) would not change the mechanism of the biasing system. As discussed above, Schaffer as modified by Hartley's string(s) or Eller's wire member(s) would have the same principle of operation for preventing flow through

the valve. One skilled in the art would not change the general configuration of the biasing system of Schaffer when using Hartley's string(s) or Eller's wire member(s).

**B. Claim 2**

139. Claim 2 recites "the valve assembly of claim 1 wherein the first loop extends completely around the tubular member, and wherein the second loop extends completely around the tubular member." Schaffer combined with Hartley *or* Eller renders claim 2 obvious.

**1. Schaffer + Hartley**

140. Hartley discloses that its string "is wound preferably twice around the cylindrical diaphragm":

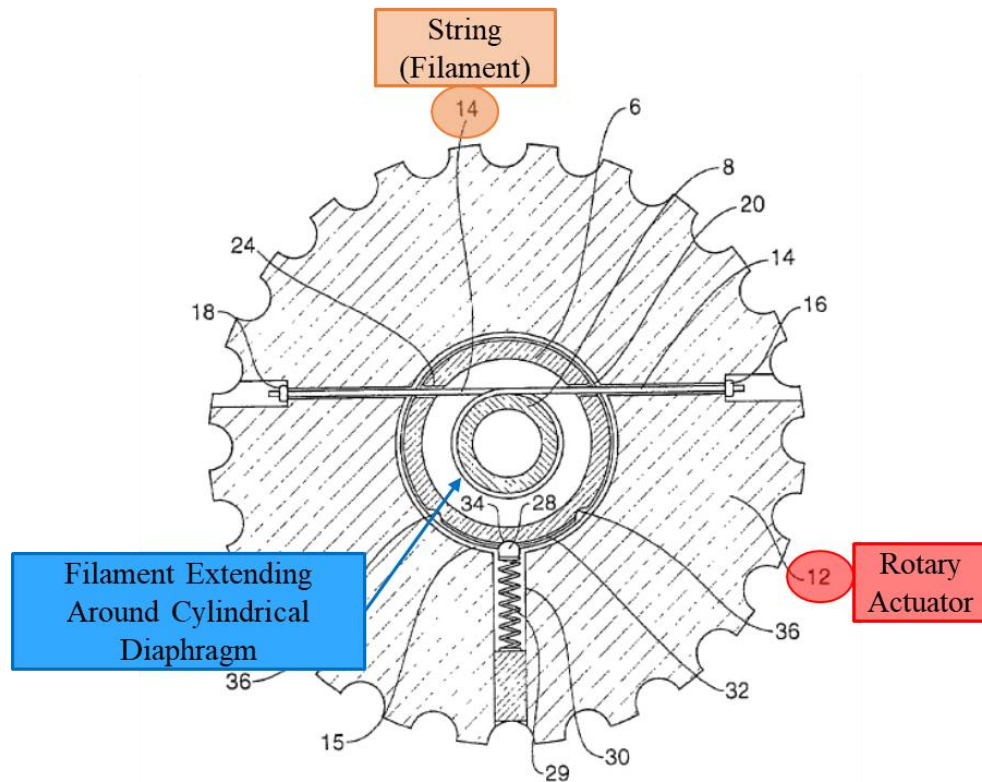


**Fig 3**

Ex. 1006 (Hartley) at [0031], Fig. 3. Hartley's string therefore includes first and second filaments that each "extends in a loop completely around the tubular member," regardless of the first and second filaments are a single string or two strings. *See supra* §VI.A.3.a (my discussion of how Hartley satisfies the filament requirements in two ways).

141. Hartley further discloses that looping the string around the central lumen forms an effective seal. *Id.* at [0031], [0037]. Thus, when replacing Schaffer's actuating members with Hartley's string(s), a person of ordinary skill in the art would be motivated to loop Hartley's string (or two of Hartley's strings) around Schaffer's seal module. As discussed above, a person of ordinary skill in

\_\_\_\_\_

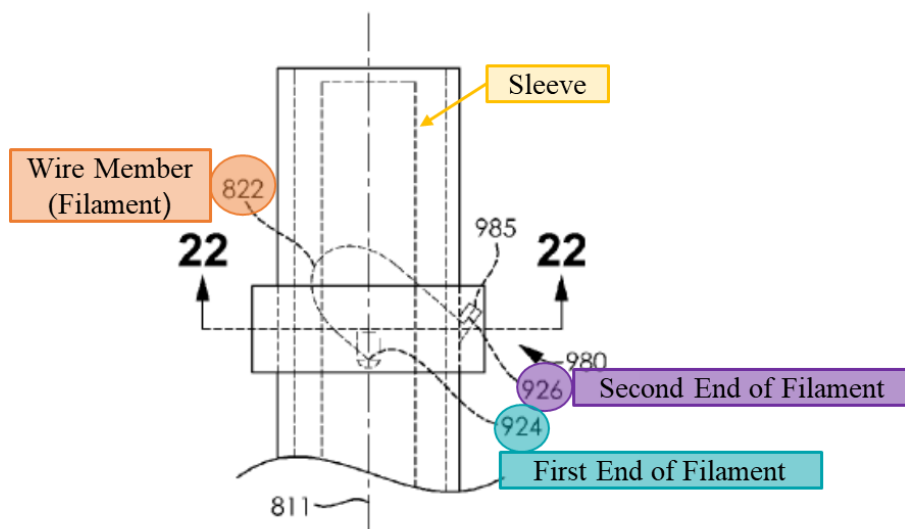


FIG. 21

Ex. 1007 (Eller) at 22:18-24; *see also id.* at 12:52-64, 24:50-57, Fig. 21.) Eller’s wire member therefore includes first and second filaments that each “extends in a loop completely around the tubular member,” regardless of the first and second filaments are a single wire member or two wire members. *See supra* §VI.A.3.b (my discussion of how Eller satisfies the filament requirements in two ways).

143. When replacing Schaffer's actuating members with Eller's wire member(s), a person of ordinary skill in the art would have been motivated to loop Eller's wire (or two of Eller's wires) at least one revolution around Schaffer's seal

module to ensure the wire formed a constrictive seal. As discussed above, a person of ordinary skill in the art would have reasonably expected success because Eller encourages looping the wire one revolution around the sleeve and discloses that such a configuration is effective. *Supra* § VI.A.3.b.

**C. Claim 3**

144. Claim 3 recites “the valve assembly of claim 1 wherein the first portion of the first filament is a first end portion of the first filament, wherein the second portion of the first filament is a second end portion of the first filament, wherein the first portion of the second filament is a first end portion of the second filament, and wherein the second portion of the second filament is a second end portion of the second filament.” For the reasons I discuss in section VI.A.3 above, Schaffer combined with Hartley *or* Eller renders Claim 3 obvious.

**D. Claim 4**

145. Claim 4 recites “the valve assembly of claim 3 wherein the first end portion of first filament is directly attached to the first one of the actuators, wherein the second end portion of the first filament is directly attached to the second one of the actuators, wherein the first end portion of the second filament is directly attached to the first one of the actuators, and wherein the second end portion of the second filament is directly attached to the second one of the actuators.” As I explained above, Schaffer as modified by Hartley or Eller would include a first end

portion of each filament directly attached to a first actuator and a second end portion of each filament directly attached to a second actuator. *Supra* § VI.A.3-5. Thus, Schaffer combined with Hartley or Eller renders claim 4 obvious for the reasons I provide in Claim 1.

**E. Claim 6**

146. Claim 6 recites “the valve assembly of claim 1 wherein the first filament and the second filament each comprise a plurality of strands woven together.” Schaffer combined with Hartley *or* Eller renders Claim 6 obvious.

147. As I explained above for Claim 1, a person of ordinary skill in the art would have understood that Hartley’s string would be formed from a “plurality of strands woven together.” *Supra* § VI.A.3.a; Ex. 1014 (defining “string” as “material consisting of threads of cotton, hemp, or other material twisted together to form a thin length”); Ex. 1015. Thus, substitution of two of Hartley’s strings for Schaffer’s actuating members renders Claim 6 obvious.

148. Likewise, Eller discloses that its wire members can have various compositions (e.g., “braided materials,” “twisted materials”), be formed from various materials (e.g., “metals,” “polymers,” “polyester,” “nylon,” “flexible materials”), and have different shapes (e.g., “round,” “rectangular”). *Supra* §VI.A.3.b; Ex. 1007 (Eller) at 15:41-16:6. A person of ordinary skill in the art would have understood that Eller’s wire members formed of “braided” or “twisted”

materials would “each comprise a plurality of strands woven together.” Thus, substitution of two of Eller’s wire members formed of “braided” or “twisted” materials for Schaffer’s actuating members renders Claim 6 obvious.

**F. Claim 7**

149. Claim 7 recites “the valve assembly of claim 1 wherein the tubular member is elastically deformable.” Schaffer combined with Hartley *or* Eller renders Claim 7 obvious.

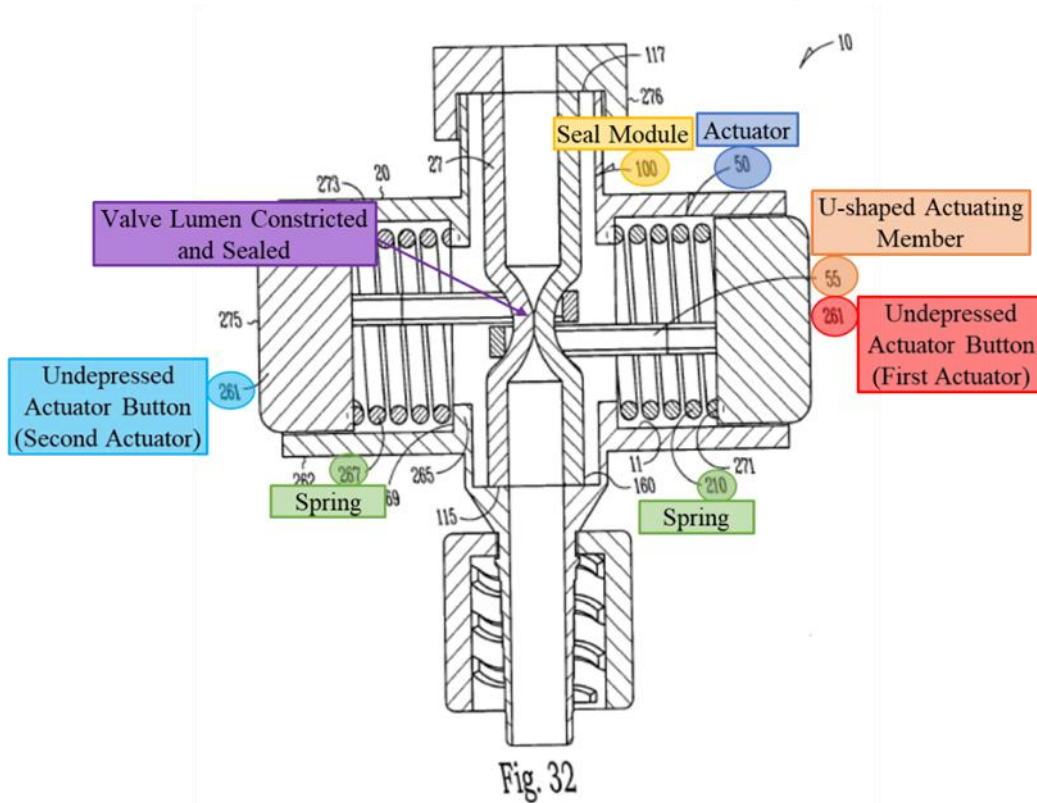
150. As I discussed above, Schaffer discloses an elastically deformable tubular member. Schaffer’s valve assembly includes a “seal module 100” that comprises “a flexible, elongate tubular structure 101.” Ex. 1005 (Schaffer) at [0049], [0051], [0054], [0075].

**G. Claim 8**

151. Claim 8 recites “the valve assembly of claim 1 wherein the tubular member is configured to resiliently expand.” Schaffer combined with Hartley *or* Eller renders Claim 8 obvious.

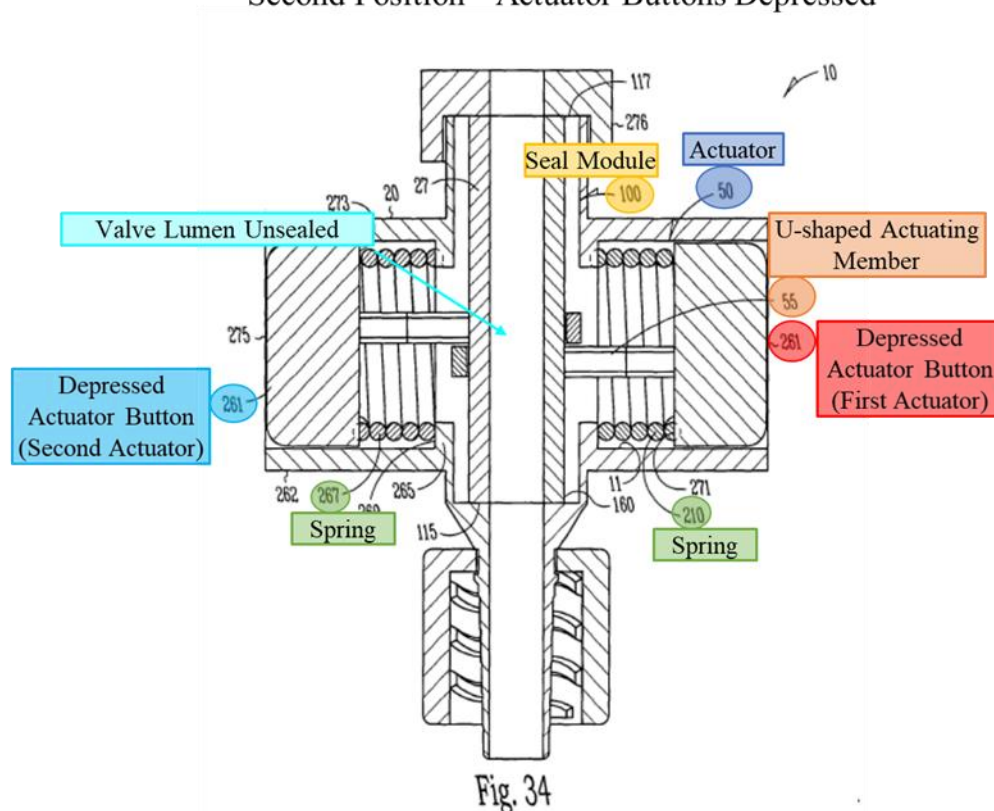
152. Schaffer’s valve lumen is configured to be constricted when the actuator buttons are in the first position (undepressed) and force is applied to the tubular member by Schaffer’s actuating members:

# First Position – Actuator Buttons Undepressed



Ex. 1005 (Schaffer) at [0077], Fig. 32. When the actuator buttons are in the second position (depressed) the actuating members are loosened which “allows each engaged actuating member 55 to forcibly disengage opposing outer walls 27 of the seal module 100 allowing the portion 108 of the containment structure 160 to retract to an uncollapsed configuration where gases and fluids can pass therethrough”:

Second Position – Actuator Buttons Depressed

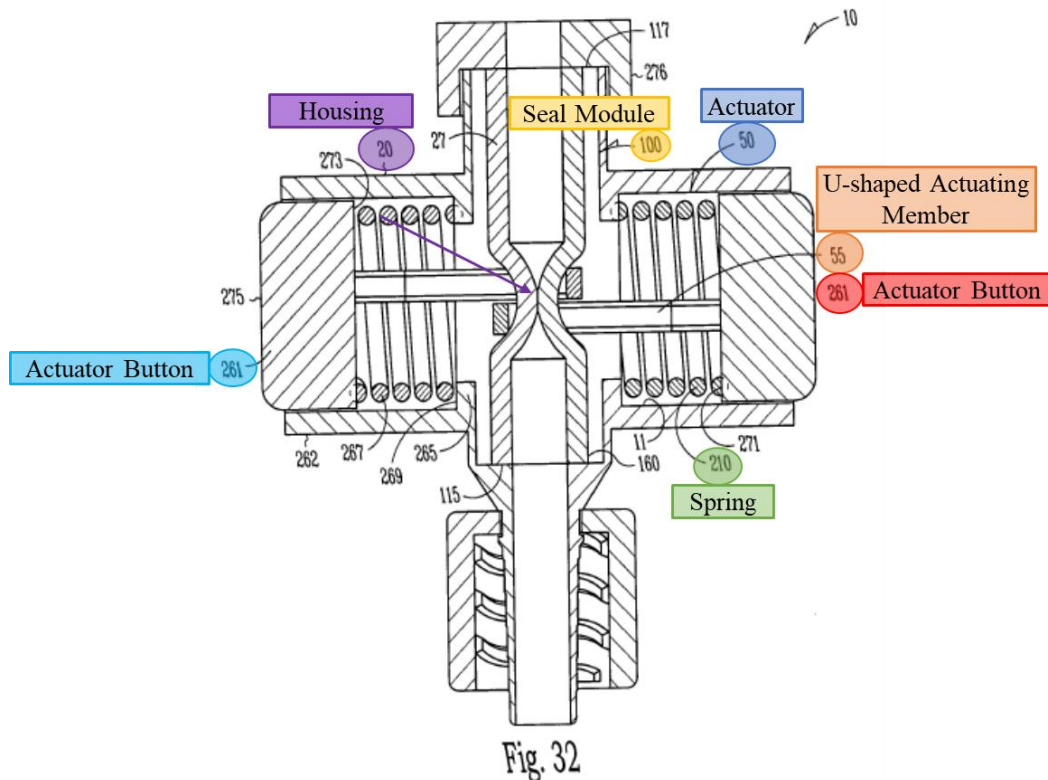


*Id.* at [0077], Fig. 34. Schaffer also discloses that its seal module (i.e., tubular member) “is sized and configured to maintain an open lumen 193 when no compressive force 67 is applied.” *Id.* at [0054]. Thus, Schaffer’s tubular member is “configured to resiliently expand” as required by the ’384 patent.

## H. Claim 9

153. Claim 9 recites “the valve assembly of claim 1 further comprising a rigid housing, wherein the tubular member, the first filament, and the second filament are positioned within the housing, and wherein the actuators are movably coupled to the housing.” Schaffer combined with Hartley or Eller renders Claim 9 obvious.

154. Schaffer's hemostasis valve includes a housing 20:



Ex. 1005 (Schaffer) at [0076], Fig. 32. Schaffer describes that “the housing 20 is sized and configured to hold and control a composite seal module 100, a portion of an actuator 50, and an actuating member 55.” *Id.* at [0046]. Thus, Schaffer’s tubular member is located within the housing, and Hartley’s strings or Eller’s wire members would be similarly located within the housing when replacing Schaffer’s u-shaped actuating members.

155. Schaffer states that “the actuators 50 are configured cylindrically to slide along the cylindrical interior wall 11 of the housing 20 from a first position to

a second position.” *Id.* at [0076]. The actuators are therefore “movably coupled to the housing.”

156. The ‘384 Patent does not explain the level of flexibility or composition necessary for a “rigid” housing. However, Schaffer discloses that the “housing 20, in one option, is made of ABS plastic.” *Id.* at [0081]. Moreover, Schaffer explains that the housing 20 can “provide an opposing support for the resilient member 267 (e.g. spring 210).” *Id.* at [0078]. A person of ordinary skill in the art would have understood that Schaffer’s housing 20 constructed from ABS plastic and providing sufficient support for springs would be “rigid” as recited in Claim 9.

**I. Claim 10**

157. Claim 10 recites “wherein the actuators are depressed toward one another in the second position, and wherein the actuators are moved away from one another in the first position.” Schaffer combined with Hartley or Eller renders Claim 10 obvious for the same reasons I explained previously for Claim 1. *Supra* §VI.A.6.

**J. Claim 11**

158. Claim 11 recites “the valve assembly of claim 1 wherein, in the second position, the tubular member has a diameter of at least 14 French.” Schaffer combined with Hartley or Eller renders Claim 11 obvious.

159. Schaffer's hemostasis valve is designed for use with catheters and includes a seal module 100 defining a central lumen 193. Ex. 1005 (Schaffer) at [0002]. Schaffer further discloses that "a range of instruments [can be] used within the seal module," such as "a catheter, guidewire, needle, or fiber," and that "a guidewire and catheter may be placed into the same lumen 193 for extension into a body passage." *Id.* at [0056], [0074]; *see also id.*, [0047] ("The second end-wall 22 of the housing 20 is sized and configured to receive an inserted instrument, catheter or guide wire through a receiving member 45.").

160. A person of ordinary skill in the art would have understood that the lumen of a hemostasis valve, including Schaffer's valve, must be at least as large as the outer diameter of any catheter or tool that is inserted through the valve. If the lumen was not at least as large as the size of an inserted catheter or tool, a physician would likely be unable to pass the tool through the lumen, or if they could do so, it would likely result in damage to the lumen and/or the tool or unacceptably high friction forces. Because of this, and as I explained in my prior deposition for a related IPR, it was common for people practicing in the field to adjust the size of the hemostasis valves used in the systems they were working on to conform to the diameter of the devices that would be inserted through the valve. Ex. 1018 (Thornton March 2025 Dep.) at 19:1-22:22, 25:21-26:2, 31:4-32:24. As I explained, in my own prior work, "[w]e would choose the hemostasis valve based

on the needs of what had to go through it, what the size was, what the frictional requirements might be.” *Id.* at 22:20-22. As I also explained, the sizing requirements for the hemostasis valve varied based on the use and purpose of the system. “For some hemostasis valves, only a guide wire needed to go through. For some hemostasis valves, a 20 French catheter needed to go through.” *Id.* at 25:24-26:2. In all cases, we would design the valve to ensure that it was large enough to accommodate the devices that were going to be inserted through the valve. *Id.* at 31:4-32:24.

161. Patent Owner’s expert, Dr. Zalesky, appeared to agree that it was common practice for a person of ordinary skill in the art to adjust the size of hemostasis valves to accommodate the size of devices that would be inserted through the valve. Ex. 1016 (Zalesky June 2025 Dep.) at 35:20-36:3, 44:12-21, 45:6-15, 46:8-21, 66:9-19; Ex. 1017 (Zalesky August 2025 Dep.) at 136:13-139:13.

162. Given the person of ordinary skill in the art’s understanding that the lumen of Schaffer’s hemostasis valve must be at least as large as the outer diameter of any tools or catheters inserted through the valve, the person of ordinary skill in the art would find it obvious and been motivated to size Schaffer’s valve to fit the size of catheters or instruments inserted through the tubular member. The person of ordinary skill in the art would have reasonably expected success in doing so due

to the frequency of this practice in the field, which was very common prior to September 2017.

163. A person of ordinary skill in the art would have been aware of many types of catheters and/or tools that were used in endovascular medical procedures that had a diameter of at least 14F and up to 24F. They would have also been aware of many different hemostasis valves with lumens ranging from 14F-24F that were designed to be used with such catheters or tools. For example, introducer sheaths with integrated hemostasis valves having diameters up to 24F were commercially available from several manufacturers before September 2017. The DrySeal Sheath, manufactured by Gore, was an introducer sheath system with an integrated hemostasis valve with sizes ranging up to 26F that were used in aspiration procedures prior to September 2017. Ex. 1032 (Allen); Ex. 1033 (Michaelson) at 301. Gore introducer sheaths with a hemostasis valve formed from a “silicone pinch valve” were also available in sizes ranging from 20-24F. Ex. 1034 (Kpodonu) at 239. Medtronic manufactured an introducer system known as the Sentrant Sheath which was available in sizes ranging from 12-26Fr and included a “rigid seal housing containing a hemostatic valve assembly.” Ex. 1035 (Sentrant) at 2. Cook manufactured introducer systems that included its CheckFlo hemostatic valve with sizes ranging from 10-24Fr. Ex. 1036 (Kruse) at 3. Cook also manufactured an introducer system known as the Z-Trak, which was used for endovascular graft

procedures. Ex. 1037 (Zenith Brochure) at 7-8. The Z-Trak was available in sizes ranging from 14-22Fr and included Cook's Captor Hemostatic Valve. *Id.* at 7-8, 10.

164. Eller also discloses that the lumen of its hemostasis valve is at least 14Fr. Specifically, Eller describes testing the performance of tubular members (i.e., sleeves) in its valve by inserting different tools through the valve. Ex. 1007 (Eller) at 36:25-45. In one test, Eller describes testing a "14 French dilator disposed within sleeve passageway." *Id.* As I explained above, a person of ordinary skill in the art would have recognized that the diameter of the sleeve used in this test must have been at least 14 French to accommodate the dilator.

165. Many additional prior art references also disclosed hemostasis valves designed to accommodate tools with diameters up to 26Fr prior to September 2017. For example, U.S. Patent No. 5,599,305 (Hermann) discloses a catheter introducing system that includes an introducer sheath that "preferably employs a hemostasis valve construction which provides for tight lateral sealing against catheters having a wide range of outside diameters, e.g., from guide wires to catheters as large as 30 French (10 mm; one French (F) equals 0.33 mm), often as large as 26 F, and preferably as large as 22 F." Ex. 1009 (Hermann) at 7:25-39. U.S. Patent No. 8,137,321 (Argentine) discloses an introducer sheath with a hemostasis valve that is designed to accommodate catheter sizes ranging from 11-26Fr inserted into the

valve. Ex. 1038 (Argentine) at Abstract, 10:24-49. U.S. Patent Pub. No. 2017/0080200 (Bickhart) discloses a hemostasis valve “sized to allow passage of a portion of an elongate instrument that includes an outer diameter of greater than or equal to 9 Fr, 12 Fr, and/or 14 Fr without damaging the valve.” Ex. 1039 (Bickhart) at [0024]. Bickhart further discloses an embodiment where “in the resting state, the first cylindrical surface may have a diameter that corresponds to the outer diameter of an elongate member that is between 9Fr and 24Fr.” *Id.* at [0046]. U.S. Patent No. 11,730,942 (Fantuzzi) discloses an introducer system having a hemostasis valve that includes a central opening 314 with a diameter “315 [that] may be 1 cm, 5 mm, 4 mm, 3 mm, 2 mm, 1 mm, less than 1 mm, or any other suitable dimension,” i.e. 30Fr. down to 3Fr. Ex. 1040 (Fantuzzi) at Abstract, 6:17-20. U.S. Patent No. 8,777,893 (Malewicz) discloses a hemostasis valve with a lumen that “is configure to allow hemostasis with devices ranging from under 1 mm to approximately 12 mm in diameter,” i.e. 3Fr. up to 36Fr. Ex. 1041 (Malewicz) at 6:30-40. U.S. Patent No. 5,125,903 (McLaughlin) discloses a hemostasis valve in which an “over-all diameter of the disk-shaped valve gasket member 50 is in the range of 0.312 inches” (i.e., 7.92 mm or 24F). Ex. 1042 (McLaughlin) at 7:6-22. U.S. Patent No. 8,808,350 (Schreck) discloses a modular catheter system that includes a hemostasis valve that “can be configured to provide a seal against devices with a profile ranging from 1 Fr to 20 Fr.” Ex. 1043 (Schreck) at 10:44-65.

166. The wide range of hemostasis valves known in the prior art with lumen diameters of 14-36Fr would have reinforced the person of ordinary skill in the art's motivation and reasonable expectation of success in adjusting the size of Schaffer's lumen to be at least 14Fr and up to 24Fr for procedures that involved catheters requiring such a size. Such an adjustment to Schaffer's valve would have involved merely applying a known technique (valve sizing) to a known device (Schaffer's valve) that was ready for improvement to yield predictable results (the ability to insert a larger tool).

167. Additionally, as the devices and patents that I discussed above show, a hemostasis valve for inserting catheters into a patient could have had only a finite number of sizes ranging from approximately 3Fr to 36Fr. A person of ordinary skill in the art would have found it obvious to choose from this finite number of identified and predictable sizes for the hemostasis valve, which was in fact common practice in the field prior to September 2017. Further, as the devices and patents that I discussed above demonstrate, the known art at the time had demonstrated that hemostasis valves having sizes ranging specifically from 3Fr to 36Fr worked effectively to prevent blood leakage. These successes would have given a person of ordinary skill in the art a reasonable expectation of success in adapting Schaffer's valve to range in size from at least 14Fr to 24Fr.

**K. Claim 12**

168. Claim 12 recites “the valve assembly of claim 1 wherein, in the second position, the tubular member has a diameter of at least 16 French.” Schaffer combined with Hartley *or* Eller renders Claim 12 obvious for the same reasons I explained above for Claim 11. *Supra* §VI.J.

**L. Claim 13**

169. Claim 13 recites “the valve assembly of claim 1 wherein, in the second position, the tubular member has a diameter of at least 20 French.” Schaffer combined with Hartley *or* Eller renders Claim 13 obvious for the same reasons I explained above for Claim 11. *Supra* §VI.J.

**M. Claim 14**

170. Claim 14 recites “the valve assembly of claim 1 wherein, in the second position, the tubular member has a diameter of at least 24 French.” Schaffer combined with Hartley *or* Eller renders Claim 14 obvious for the reasons explained for Claim 11. *Supra* §VI.J.

**N. Claim 15**

171. Claim 15 recites similar limitations to those in claims 1, 2, and 7, and is therefore rendered obvious by Schaffer combined with Hartley *or* Eller for the same reasons I explained above.

1. **“A valve assembly”**

172. The preamble of Claim 15 recites “a valve assembly.” If the preamble is limiting, Schaffer, Hartley, and Eller each disclose a “valve assembly” as I explained above for Claim 1. *Supra* §VI.A.1.

2. **“a tubular member defining a lumen, wherein the tubular member is elastically deformable from a first position in which the lumen is constricted to a second position in which the lumen is at least partially open”**

173. Claim 15 next recites “a tubular member defining a lumen, wherein the tubular member is elastically deformable from a first position in which the lumen is constricted to a second position in which the lumen is at least partially open.” Schaffer discloses this limitation for the reasons I explained above for Claims 1 and 7. *Supra* §§VI.A.2, F.

3. **“a first actuator; a second actuator; a first filament configured in a first loop completely around the tubular member and having a first portion extending from the first loop toward the first actuator and a second portion extending from the first loop toward the second actuator; and a second filament configured in a second loop completely around the tubular member and having a first portion extending from the second loop toward the first actuator and a second portion extending from the second loop toward the second actuator”**

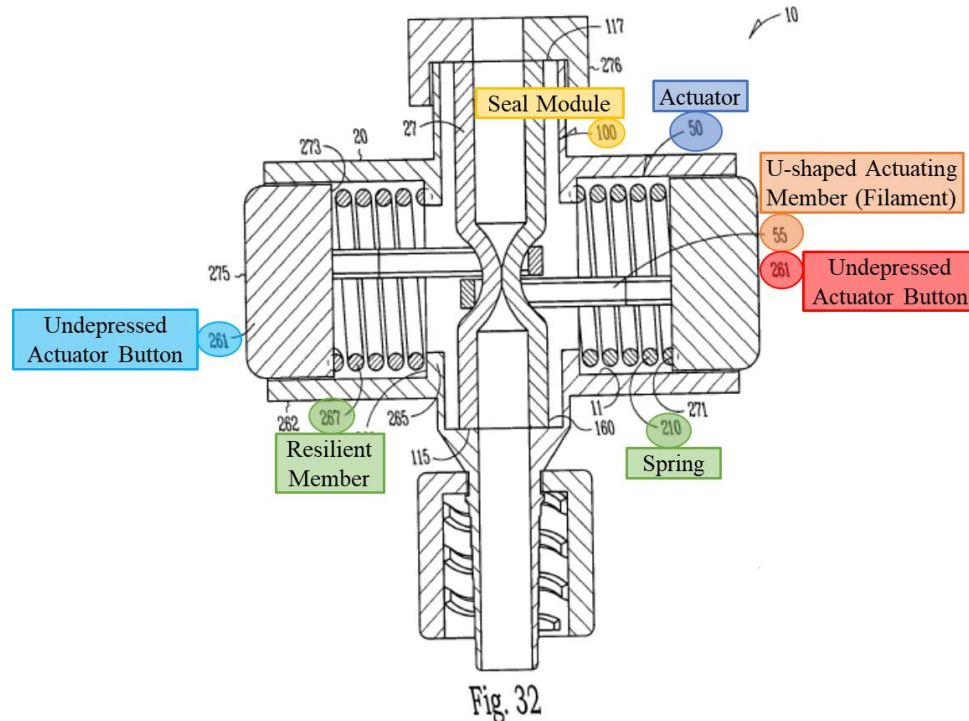
174. Claim 15 next recites “a first actuator; a second actuator; a first filament configured in a first loop completely around the tubular member and having a first portion extending from the first loop toward the first actuator and a second portion extending from the first loop toward the second actuator; and a

second filament configured in a second loop completely around the tubular member and having a first portion extending from the second loop toward the first actuator and a second portion extending from the second loop toward the second actuator.” Schaffer combined with Hartley *or* Eller renders these limitations obvious for the reasons I explained above explained for Claims 1 and 2. *Supra* §§VI.A.3-5, VI.B.

4. **“wherein– the first actuator and the second actuator are biased away from one another to elastically deform the tubular member to the first position by (a) increasing a tension in the first filament to decrease a dimension of the first loop and (b) increasing a tension in the second filament to decrease a dimension of the second loop; and the first actuator and the second actuator are movable toward one another to permit the tubular member to return to the second position by (a) decreasing the tension in the first filament and (b) decreasing the tension in the second filament”**

175. Claim 15 next recites “wherein– the first actuator and the second actuator are biased away from one another to elastically deform the tubular member to the first position by (a) increasing a tension in the first filament to decrease a dimension of the first loop and (b) increasing a tension in the second filament to decrease a dimension of the second loop; and the first actuator and the second actuator are movable toward one another to permit the tubular member to return to the second position by (a) decreasing the tension in the first filament and (b) decreasing the tension in the second filament.” Schaffer combined with Hartley *or* Eller renders these limitations obvious.

176. As I explained above, Schaffer's stasis valve includes "two resilient members 267 (e.g., spring 210) disposed within the actuating member 55":



Ex. 1005 (Schaffer) [0076], Fig. 31. Schaffer's resilient members bias Schaffer's actuator buttons (first and second actuators) away from each other to the first (i.e., closed) position, which causes the actuating members attached to the buttons to collapse the seal module, preventing the flow of fluid through the valve. *Id.* at [0077]. Schaffer also discloses that moving the actuators towards one another depresses the springs and relieves tension on the actuating members, allowing the lumen to retract to an open, unsealed state. *Id.*

177. As I explained above, a person of ordinary skill in the art would have understood that replacing Schaffers actuating members with Hartley's string or

Eller's wire would not change the principle of operation of Schaffer's valve. *Supra* §VI.A.3. Accordingly, a person of ordinary skill in the art would have understood that when Schaffer's U-shaped actuating members are replaced with Hartley's strings or Eller's wire members, the actuating members would increase tension in the first/second strings/wire members to decrease the dimension of the loops and seal the lumen when the actuators are biased away from each other. Then, when the actuators are depressed toward one another, tension would be relieved on the strings/wire members, allowing the lumen to expand.

**O. Claim 16**

178. Claim 16 recites "the valve assembly of claim 15 wherein the first actuator and the second actuator each comprise a button." Schaffer combined with Hartley *or* Eller renders Claim 16 obvious.

179. Each of Schaffer's actuators comprises an actuator button:

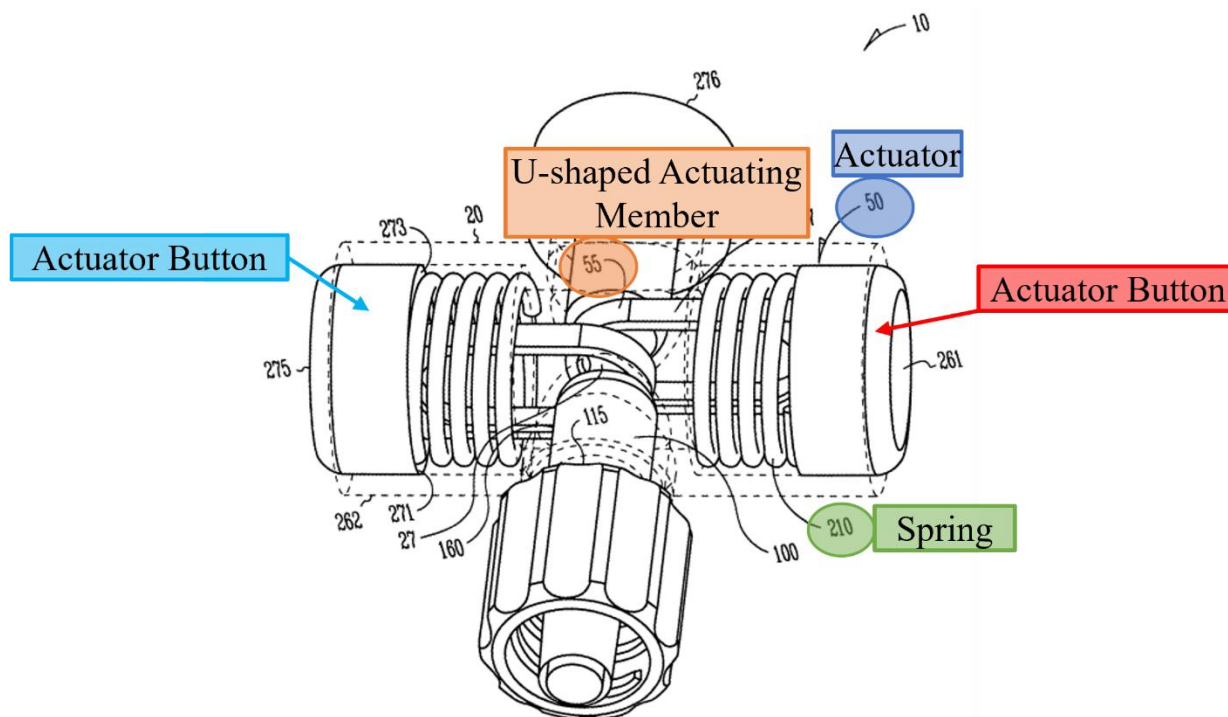


Fig. 31

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

**P. Claim 17**

180. Claim 17 recites “the valve assembly of claim 15 wherein the first filament is flexible, and wherein the second filament is flexible.” Schaffer combined with Hartley *or* Eller renders Claim 17 obvious for the same reasons I explained for Claims 1 and 15. *Supra* §§VI.A.3, N.3.

**Q. Claim 18**

181. Claim 18 recites “the valve assembly of claim 15 wherein the first portion of first filament is directly attached to the first actuator, wherein the second

portion of the first filament is directly attached to the second actuator, wherein the first portion of the second filament is directly attached to the first actuator, and wherein the second portion of the second filament is directly attached to the second actuator.” Schaffer combined with Hartley *or* Eller renders Claim 18 obvious for the same reasons I explained for Claims 4 and 15. *Supra* §§VI.D, N.3.

**R. Claim 20**

182. Claim 20 recites “the valve assembly of claim 15 wherein, in the second position, the tubular member has a diameter of at least 16 French.” Schaffer combined with Hartley *or* Eller renders Claim 20 obvious for the same reasons I explained for Claims 11 and 15. *Supra* §§VI.J, VI.N.

**S. Claim 21**

183. Claim 21 recites “the valve assembly of claim 15 wherein, in the second position, the tubular member has a diameter of at least 20 French.” Schaffer combined with Hartley *or* Eller renders Claim 21 obvious for the reasons explained for Claims 11 and 15. *Supra* §§VI.J, VI.N.

**T. Claim 22**

184. Claim 22 recites “the valve assembly of claim 15 wherein, in the second position, the tubular member has a diameter of at least 24 French.” Schaffer combined with Hartley *or* Eller renders Claim 22 obvious for the reasons explained for Claims 11 and 15. *Supra* §§VI.J, VI.N.

U. **Claim 23**

185. Claim 23 recites the same limitations as Claims 1 and 7 and is therefore rendered obvious by Schaffer combined with Hartley *or* Eller for the same reasons I explained above.

1. **“A valve assembly”**

186. If the preamble is limiting, Schaffer, Hartley, and Eller each disclose a “valve assembly” for the same reasons I explained for claim 1. *Supra* §VI.A.1.

2. **“a tubular member defining a lumen”**

187. Claim 23 next recites “a tubular member defining a lumen.” Schaffer discloses this limitation for the same reasons I explained for claim 1. *Supra* §VI.A.2.

3. **“a first filament extending in a first loop around the tubular member; a second filament extending in a second loop around the tubular member; and a pair of actuators biased to circumferentially constrict the first loop and the second loop to elastically deform the tubular member to a first position in which the lumen is constricted, wherein at least one the actuators is movable to decrease a level of tension in the first filament and a level of tension in the second filament to permit the tubular member to expand against the first loop and the second loop to a second position in which the lumen of the tubular member is at least partially open”**

188. Claim 23 next recites “a first filament extending in a first loop around the tubular member; a second filament extending in a second loop around the tubular member; and a pair of actuators biased to circumferentially constrict the

first loop and the second loop to elastically deform the tubular member to a first position in which the lumen is constricted, wherein at least one the actuators is movable to decrease a level of tension in the first filament and a level of tension in the second filament to permit the tubular member to expand against the first loop and the second loop to a second position in which the lumen of the tubular member is at least partially open.” Schaffer combined with Hartley *or* Eller renders these limitations obvious for the same reasons I explained for Claims 1 and 15. *Supra* §§VI.A.3-6, N.3.

**V. Claim 24**

189. Claim 24 recites “the valve assembly of claim 23 wherein the actuators each comprise a button.” Schaffer combined with Hartley *or* Eller renders Claim 24 obvious for the same reasons I explained above for Claims 1, 15, and 16. *Supra* §§VI.A.4, N.3, O.

**W. Claim 25**

190. Claim 25 recites “the valve assembly of claim 23 wherein the first filament includes a first portion operably coupled to a first one of the actuators and a second portion operably coupled to a second one of the actuators, and wherein the second filament includes a first portion operably coupled to the first one of the actuators and a second portion operably coupled to the second one of the actuators.”

Schaffer combined with Hartley *or* Eller renders Claim 25 obvious for the same reasons I explained for Claims 1 and 23. *Supra* §§VI.A.5, U.3.

**X. Claim 26**

191. Claim 26 recites “the valve assembly of claim 25 wherein the first portion of first filament is directly attached to the first one of the actuators, wherein the second portion of the first filament is directly attached to the second one of the actuators, wherein the first portion of the second filament is directly attached to the first one of the actuators, and wherein the second portion of the second filament is directly attached to the second one of the actuators.” Schaffer combined with Hartley *or* Eller renders Claim 26 obvious for the same reasons I explained for Claims 1 and 23. *Supra* §§VI.A.3-5, U.3.

**Y. Claim 27**

192. Claim 27 recites “the valve assembly of claim 23 wherein the first filament is flexible, and wherein the second filament is flexible.” Schaffer combined with Hartley *or* Eller renders Claim 27 obvious for the same reasons I explained for Claims 1 and 23. *Supra* §§VI.A.3, U.3.

**Z. Claim 28**

193. Claim 28 recites “the valve assembly of claim 23 wherein, in the second position, the tubular member has a diameter of at least 16 French.” Schaffer

combined with Hartley *or* Eller renders Claim 28 obvious for the same reasons I explained for Claims 11 and 23. *Supra* §§VI.J, U.

**AA. Claim 29**

194. Claim 29 recites “the valve assembly of claim 23 wherein, in the second position, the tubular member has a diameter of at least 20 French.” Schaffer combined with Hartley *or* Eller renders Claim 29 obvious for the same reasons I explained for Claims 11 and 23. *Supra* §§VI.J, U.

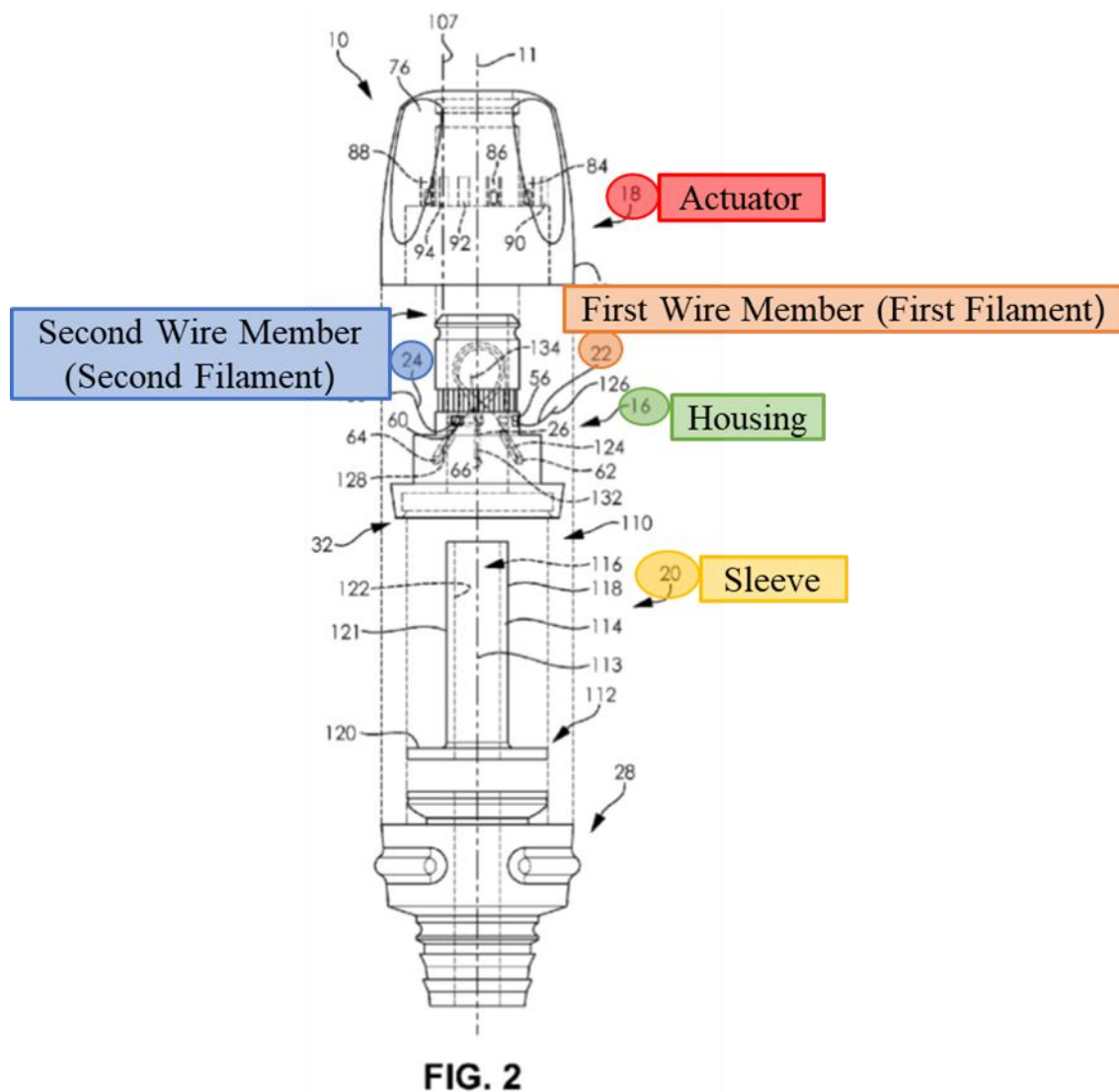
**BB. Claim 30**

195. Claim 30 recites “the valve assembly of claim 23 wherein, in the second position, the tubular member has a diameter of at least 24 French.” Schaffer combined with Hartley *or* Eller renders Claim 30 obvious for the same reasons I explained for Claims 11 and 23. *Supra* §§VI.J, U.

**VII. GROUND 3: CLAIMS 1-4, 6-18, AND 20-30 ARE OBVIOUS OVER SCHAFFER COMBINED WITH HARTLEY AND ELLER**

196. As I explained above for Ground 1, a person of ordinary skill in the art would have been motivated to replace Schaffer’s u-shaped actuating members with two of Hartley’s strings, and they would have had a reasonable expectation of success in doing so in September 2017. *Supra* §VI.A.3.a. In my opinion, Eller would have provided a person of ordinary skill in the art with even further motivation to use two of Hartley’s strings when replacing Schaffer’s u-shaped actuating members.

197. As I explained above, Eller describes hemostasis valves having “a housing 16, an actuator 18, a sleeve 20, a first wire member 22, a second wire member 24, [and] a third wire member 26”:



Ex. 1007 (Eller) at 5:1-5, 16:7-19, Fig. 2. Eller also explains that its valve “can include any suitable number of wire members,” and it expressly recognizes that “[s]killed artisans will be able to select a suitable number of wire members to include in a selective fluid barrier valve device according to a particular

embodiment.” *Id.* at 16:7-19. Further, Eller specifically identifies two wire members as one acceptable configuration. *Id.* at 16:7-19. I agree with Eller’s statement that “[s]killed artisans will be able to select a suitable number of wire members to include in a selective fluid barrier valve device according to a particular embodiment.” *Id.* Such a selection, and particularly the selection of two wire members, would have been well within the ordinary level of skill in the field of hemostasis valves in September 2017.

198. Eller’s disclosure of a hemostasis valve having first and second wire members that constrict the lumen to form a seal would have further motivated a person of ordinary skill in the art to use a similar configuration when replacing Schaffer’s actuating members with Hartley’s strings. Moreover, Eller’s recognition that “[s]killed artisans will be able to select a suitable number of wire members to include in a selective fluid barrier valve device according to a particular embodiment” confirms that a person of ordinary skill in the art would have found it obvious to adjust the number of filaments used to constrict a hemostasis valve according to the needs of a particular valve.

199. A person of ordinary skill in the art would have been motivated to combine the teachings of Schaffer, Hartley, and Eller because all three references relate to the same subject matter—hemostasis valves used to prevent blood leaks

during intravascular procedures. All three references also use similar mechanisms to constrict the lumen of the valve to create a seal. *Supra* §VI.A.3.

200. Accordingly, it is my opinion that the challenged claims would have been obvious to a person of ordinary skill in the art in September 2017 in view of Schaffer combined with Hartley and Eller.

**VIII. GROUNDS 4-6: CLAIMS 11-14, 20-22, AND 28-30 ARE OBVIOUS OVER SCHAFFER AND HERMANN COMBINED WITH HARTLEY AND/OR ELLER**

201. As I mentioned above in Grounds 1-2, challenged claims 11-14, 20-22, and 28-30 each recite that the lumen of the hemostasis valve has a diameter in the second (opened) position that ranges from at least 14 French to at least 24 French. It is my opinion that these claims would have been obvious to a person of ordinary skill in the art in September 2017 in view of Hermann in combination with Schaffer and Hartley and/or Eller.

202. As I explained in Grounds 1-2, Schaffer states that its hemostasis valve is intended “for use with catheters,” but Schaffer does not expressly disclose a specific diameter for the lumen of its valve. Ex. 1005 (Schaffer) at [0005]. However, Schaffer does disclose that “a range of instruments [can be] used within [its] 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]. As I explained previously, a person of

ordinary skill in the art would have known that the diameter of Schaffer's lumen must be at least as large as the outer diameter of any catheters or tools inserted through the lumen. *Supra* §VI.J. As I also explained in Grounds 1-2, there were many hemostasis valves with lumens ranging from 14Fr-24Fr that were known in the art and used in endovascular medical procedures prior to September 2017. *Id.* U.S. Patent No. 5,599,305, Hermann, discloses one such prior art system.

203. Hermann is titled "Large-Diameter Introducer Sheath Having Hemostasis Valve and Removable Steering Mechanism." Ex. 1009 (Hermann). Hermann discloses a catheter introduction system that includes a flexible introducer sheath, an obturator, and a hemostasis valve:

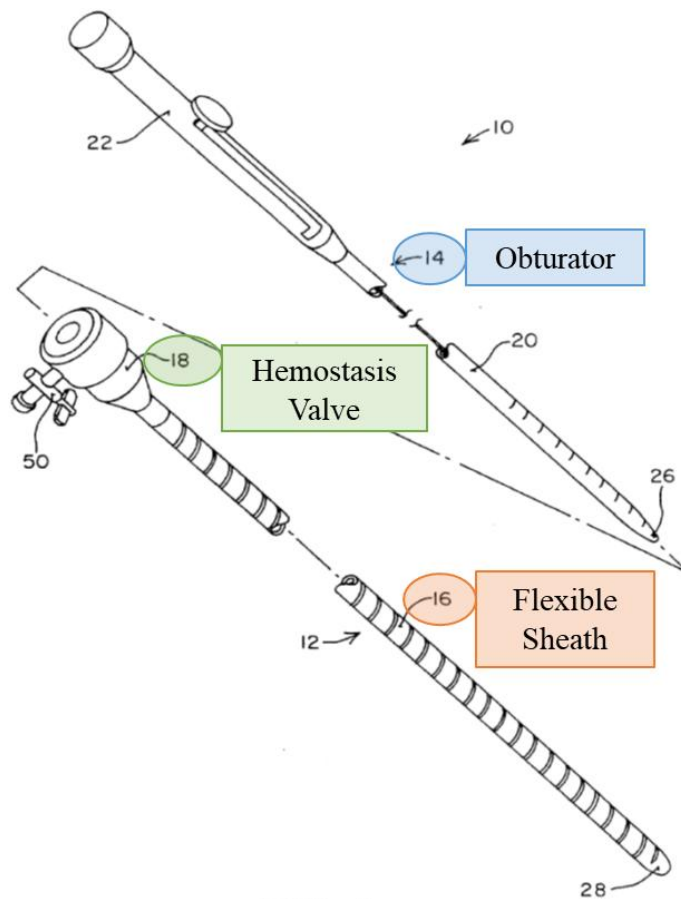


FIG. 1

*Id.* at 9:41-45, Fig. 1. Hermann discloses that its system can be used for a wide variety of “minimally invasive procedures where it is desired to introduce a large diameter sheath into a body cavity or lumen,” such as endovascular graft procedures or laparoscopic procedures. *Id.* at 2:50-3:1.

204. Hermann discloses that its introducer catheter “will include a hemostasis valve secured to the proximal end of the sheath.” *Id.* at 7:25-27. Hermann states that a “wide variety of hemostasis valves would be suitable,” but the catheter “preferably employs a hemostasis valve construction which provides for tight lateral sealing against catheters having a wide range of outside diameters,

e.g., from guide wires to catheters as large as 30 French (10 mm; one French (F) equals 0.33 mm), often as large as 26 F, and preferably as large as 22 F.” *Id.* at 7:27-39.

205. In my opinion, a person of ordinary skill in the art would have been motivated, and found it obvious, to use Schaffer’s valve (as modified in view of Hartley and/or Eller) with Hermann’s catheter introducer system for several reasons.

206. First, 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]. Schaffer further discloses that a range of instruments can be used within the valve, such as “a catheter, guidewire, needle, or fiber.” *Id.* at [0056], [0074]. Thus, Schaffer’s valve would allow for tools to be inserted into Hermann’s introducer catheter while preventing blood from leaking through the system during the procedure.

207. Second, a person of ordinary skill in the art would have recognized that Schaffer’s hemostasis valve could seal more effectively around a wider range of device diameters than Hermann’s valve. The size of the opening in Schaffer’s valve can be adjusted by pressing the buttons so that it more nearly matches the size of the inserted device. This feature allows the valve to accommodate a wider range of

devices and also allows the user to reduce the insertion friction by opening the valve wider. A person of ordinary skill in the art would have therefore been motivated to implement Schaffer's valve in Hermann's system to achieve this benefit.

208. Third, combining Schaffer's valve (as modified in view of Hartley and/or Eller) with the introducer catheter in Hermann would merely entail the substitution of one known element (Schaffer's valve) with another (Hermann's valve) according to known methods (attaching Schaffer's valve to the proximal end of the introducer catheter). 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.

209. Fourth, a person of ordinary skill in the art in September 2017 had a finite number of predictable hemostasis valves to choose from, including Schaffer's valve. A person of ordinary skill in the art would have found it obvious to try any of these hemostasis valves in combination with Hermann's system. Moreover, the known valves, including Schaffer's adjustable-opening hemostasis valve, were simple mechanical structures that operate in a predictable way. Hermann's disclosure underscores this fact by stating that a "wide variety of hemostasis valves would be suitable" for its introducer system. Ex. 1009 (Hermann) at 7:27-32. 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 Hermann's introducer catheter. A person of ordinary skill in the art would have therefore reasonably expected success in combining Schaffer's valve with Hermann's catheter.

210. When using Schaffer's valve with Hermann's system, a person of ordinary skill in the art would have been motivated to size Schaffer's valve to accommodate catheters as large as 30 Fr because Hermann expressly suggests doing so. Ex. 1009 (Hermann) at 7:25-39. A person of ordinary skill in the art would have reasonably expected success in sizing Schaffer's valve for such devices for the same reasons I explained above in Grounds 1-2. *Supra* §VI.J.

211. Accordingly, for these reasons it is my opinion that claims 11-14, 20-22, and 28-30 of the '384 patent would have been obvious to a person of ordinary skill in the art in September 2017 in view of Schaffer and Hermann combined with Hartley and/or Eller.

## **IX. SECONDARY CONSIDERATIONS**

212. I am not aware of any secondary considerations of nonobviousness relating to the claims of the '384 patent.

213. The methods and devices claimed in the '384 patent are not new and were invented long before September 2017. Therefore, I am not aware of any long-felt need in the industry, unexpected results, skepticism of the invention, or teaching away from the invention. I am also not aware of any praise for the alleged

inventions or copying of the alleged inventions by other companies. Many aspiration systems were available on the market by September 2017, and many of those systems were used to perform the conventional method steps with the conventional components recited in the claims of the '384 patent.

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

## **X. CONCLUSION**

215. For the foregoing reasons, it is my opinion that Claims 1-4, 6-18, and 20-30 of the '384 patent are not patentable because they 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.

216. 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.

217. 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 September 16, 2025 in Glen Ellen, CA.

troy thornton

Troy Thornton