

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

IMPERATIVE CARE, INC.,
Petitioner,

v.

INARI MEDICAL, INC.,
Patent Owner.

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

SUPPLEMENTAL DECLARATION OF PAUL J. ZALESKY

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I, **Paul J. Zalesky**, declare as follows:

I. INTRODUCTION

1. I have been retained by counsel for Patent Owner Inari Medical, Inc. (“Patent Owner” or “Inari”) as an independent expert consultant in this proceeding in connection with *inter partes* review (IPR) proceeding IPR 2025-00289 concerning U.S. Patent 11,554,005 (“’005 Patent”; EX1001), pending before the U.S. Patent and Trademark Office, Patent Trial and Appeal Board (“Board”).
2. I understand that Imperative Care, Inc. (“Petitioner” or “Imperative”) has filed a petition of *inter partes* review before the Board asserting:

Ground 1: Claims 1-12, 14, and 15 of the ’005 Patent are unpatentable under 35 U.S.C. § 103 as obvious over U.S. Patent Application Publication No. 2015/0173782 to Garrison et al. (“Garrison”) in combination with U.S. Patent Application Publication No. 2003/0225379 to Schaffer et al. (“Schaffer”);

Ground 2: Claims 1-15 of the ’005 Patent are unpatentable under 35 U.S.C. § 103 as obvious over Garrison in combination with Schaffer and U.S. Patent Publication No. 2003/0116731 to Hartley (“Hartley”);

Ground 3: Claims 1-15 of the ’005 Patent are unpatentable under 35 U.S.C. § 103 as obvious over Garrison in combination with Schaffer and U.S. Patent No. 9,980,813 to Eller (“Eller”); and

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Ground 4: Claims 1-3, 5, 6, and 9-15 of the '005 Patent are unpatentable under 35 U.S.C. § 103 as obvious over Garrison in combination with Hartley and Eller.

I have been asked by counsel for Inari Medical, Inc. (“Inari” or “Patent Owner”) to opine on the patentability of the Claims of the '005 patent and, in particular, the patentability of independent Claims 1 and 10 with respect to grounds 1-4.

3. Along with my years of education, research, and experience, my opinions are based on investigation and study of relevant materials. The materials that I evaluated in support of this Declaration include all exhibits cited in this Declaration and in the Petition.
4. I may rely upon these materials, my knowledge and experience, and/or additional materials to rebut arguments raised by Petitioner. Further, I may also consider additional documents and information in forming any necessary opinions, including documents that may not yet have been provided to me.
5. My analysis of the materials produced in this matter is ongoing, and I will continue to review any new material as it is provided. This Declaration represents only those opinions I have formed to date. I reserve the right to revise, supplement, and/or amend my opinions stated herein based on new information and on my continuing analysis of the materials already provided.

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6. My work in this case is being billed at my normal hourly consulting rate, with reimbursement for actual expenses. My compensation is not related to the outcome of this proceeding. I have no personal interest in the outcome of the case.

II. BACKGROUND AND QUALIFICATIONS

7. My qualifications for forming the opinions set forth in this Declaration are summarized here and explained in more detail in my attached curriculum vitae.
8. I received my Ph.D. in Biomedical Engineering from the University of Michigan. My doctoral research focused on the prediction of optimal surgical timing for the repair of congenital heart defects. I received an undergraduate degree in Aerospace Engineering from the University of Notre Dame. I also received a Master of Science in Aerospace Engineering from the University of Michigan.
9. My industrial career has been focused on the development and commercialization of specialty medical devices for the diagnosis and treatment of heart disease, encompassing more than 30 years of management/engineering positions in both large and small companies. As outlined below, I have been directly involved with the development and clinical use of various

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interventional catheters and devices, all requiring the insertion and use of a hemostatic valve to minimize or prevent back bleeding.

10. Following the initiation of “interventional” cardiology by Dr. Andreas Gruntzig in the late 1970s, when he pioneered coronary balloon angioplasty, the 1980s saw the evolution of less invasive treatments of cardiovascular disease. Today, those treatments are generally referred to as interventional cardiology or radiology. Early on, I became directly involved in the development of devices associated with interventional cardiology and related cardiovascular disciplines. Such devices range from simple, diagnostic catheters to complex electromechanical systems used for cardiovascular disease and associated issues, including thrombosis. In 1986, I led Boston Scientific’s entry into the coronary angioplasty (PTCA) market as the Director of R&D, presenting device efficacy data to the FDA Panel towards a soon-approved Pre-Market Application (PMA). In that role I also supervised the development of guide catheters and guidewires needed as accessories to the diagnosis and treatment of cardiovascular disorders.
11. In 1986, I co-founded InterTherapy with cardiologist Dr. Walt Henry. InterTherapy was focused on the development of intravascular ultrasound for assessment of coronary and peripheral vascular disease that directed subsequent therapy. The disposable component of the product was a 5 French catheter

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with design and materials that enabled its passage through standard guide catheters into the branches of the coronary artery or peripheral arteries. From 1986 through 1990 I managed all company operations, with emphasis on device use in the cardiac catheterization and special procedure labs of center-of-excellence hospitals.

12. I recruited, and worked closely with, Dr. Martin Leon, then a Fellow at the National Institutes of Health, and collaborated with Dr. Leon on the creation of a new, interventional cardiology symposium, Transcatheter Cardiovascular Therapeutics, which subsequently evolved into the largest and most comprehensive symposium in the field of interventional cardiology. I also collaborated closely with cardiologists, vascular and cardiac surgeons, and interventional radiologists from multiple U.S. and European Centers of Excellence, including the Mayo Clinic, Mass General Hospital, UCLA, Rhode Island Hospital, Emory University, Stanford University, Clinico Cardiologica in Milan, Italy, and many others. In this, and subsequent professional positions, I participated in hundreds of patient cases in the cardiac catheterization lab and operating room, donning protective lead aprons and masks while assisting or observing patient cases. The InterTherapy technology effectively enabled the development and evolution of coronary and peripheral vascular stents, as the

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real time, intravascular imaging enabled review and optimization of treatment with specialized catheters or stents.

13. In the early 1990s I served as a VP R&D for a division of Baxter International, where I led the development of and presented the corporation's interventional cardiology and cardiopulmonary bypass product portfolio to cardiologists and surgeons and associated symposia, including the development of critical devices for treatment of cardiovascular disease.
14. In 1995 I co-founded, with cardiologist Dr. J. Richard Spears, TherOx. TherOx was focused on the development of oxygen supersaturated solutions to the coronary artery, following acute myocardial infarction (heart attack). The primary product included a sub-selective catheter that could access distal segments of the coronary branches, for fluid delivery. By sub-selective, I mean a catheter that can be placed into and advanced through a larger catheter, sometimes referred to as a "mother-and-child" catheter configuration.
15. In the 1995-2005 time period, myriad guide catheter configurations were developed and tested by many different companies, including multi-hardness bodies, multi-flexibility properties, various tip geometries and materials, and various lumen geometries. Simultaneously, variations on angioplasty, thrombectomy, atherectomy, and other devices were developed and tested, including catheters with active energy capability for lesion (disease) ablation or

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removal, miniature balloons on wires, and selective pharmacologic infusions.

I was directly involved with physician use and assessment of these and related devices while directing and participating in formal clinical studies in the U.S., Europe, Canada, and Israel.

16. During my time with Volcano Corporation (now Philips) I supervised coronary and peripheral artery catheter development, manufacture, and clinical use.
17. Since 2013, I have focused on consulting and have provided expert advice or opinion on numerous projects, including such areas as algorithms for cardiac arrhythmia diagnosis, implantable cardiac defibrillators, blood oxygen diagnostic devices, and cardiovascular devices and processes associated with vascular disease or obstruction treatment. For 1½ years, I served as interim CEO for Keystone Medical, an Israel-based start-up for the development of cerebral protection devices for use with transcatheter heart valve replacement. Our product development activities included cardiac delivery catheters, guide-wires, and associated catheterization lab procedures for device insertion, deployment, use, and removal.
18. In many of my management positions, I was responsible for development and maintenance of intellectual property, including both direct management of in-house patent counsel and collaboration with outside patent counsel. I am a

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named co-inventor on more than 20 issued U.S. patents, almost all focused on
cardiovascular, coronary artery devices.

19. I have devoted most of my 35-plus years in product development to diagnosis and treatment of cardiovascular disease. Multiple experiences provided me with keen insights into the various aspects of heart disease, the optimized use of least invasive therapies, and the underlying pathophysiology of cardiovascular disease. I observed or participated in several hundred patient cases in the special procedure labs across the U.S. and Europe. I co-pioneered Intravascular Ultrasound, utilized to characterize vascular disease, guide treatment, and confirm therapeutic efficacy via complete stent deployment or other treatment at the lesion site. I co-pioneered the use of Aqueous Oxygen in patients with acute myocardial infarctions (heart attacks), providing resuscitation of ischemic, stunned or damaged cardiac muscle. Both of these technologies are currently part of the interventional cardiologist armamentarium for heart disease diagnosis and treatment.

III. BASES OF MY OPINION

A. Materials Considered

20. The opinions included in this Declaration are based on the documents I reviewed, my professional judgment, and my education and experience.

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21. In forming my opinion expressed in this Declaration, I reviewed all the materials listed in the attachment hereto, and any other material I refer to in this Declaration in support of my opinion.

B. Relevant Legal Principles

22. I am not an attorney, but in preparing and forming my opinions, I have been informed of certain legal principles. I have applied my understanding of those principles and taken them into account when forming the opinions I describe. My understanding of the relevant legal principles is summarized below.
23. I understand that claim terms are generally given their ordinary and customary meaning as understood by a person of ordinary skill in the art at the time of the invention when read in the context of the specification and prosecution history unless a patentee sets out a different definition or clearly disavows claim scope.
24. I further understand that extrinsic evidence such as expert and inventor testimony, dictionaries, and learned treatises can help determine the meaning of claim terms, although that evidence is less significant than the claims, specification, and prosecution history.
25. I have been informed that Imperative bears the burden of proving unpatentability by a preponderance of evidence. I have been told that this means that Imperative must prove that it is more likely than not that the claims of the '005

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patent are obvious over the combination of Garrison and Schaffer, obvious over the combination of Garrison, Schaffer, and Hartley, obvious over the combination of Garrison, Schaffer, and Eller, or obvious over the combination of Garrison, Hartley, and Eller.

26. I understand that my opinions regarding patentability are from the viewpoint of a person having ordinary skill in the field of the technology of the patent as of the time of the invention. For the purposes of this Declaration, I have assumed that date is the earliest priority date of the '005 Patent which is August 13, 2018. Petitioner also applies August 13, 2018, as the priority date for the '005 Patent. Petition, pp. 16-17.
27. I understand that if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains, the claimed invention is obvious.
28. I understand there are four fact-based inquiries involved in determining patent obviousness. These include: (1) the scope and content of the prior art; (2) the differences between the claimed invention and the prior art; (3) the level of ordinary skill in the art; and (4) objective indicia of non-obviousness. I have been informed that examples of objective indicia include unexpected results,

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commercial success of the invention, whether the invention satisfied a long felt need in the industry, failure of others to find a solution to the problem at hand, commercial acquiescence via licensing, professional approval, unexpected results, and copying and praise by infringers.

29. I understand that even if all limitations of a claimed invention are disclosed by the prior art combination, the patent challenger must demonstrate an apparent reason to combine the known elements in the fashion of the patent claim at issue and that a person of ordinary skill in the art would have reasonable expectation of success in pursuing that combination.
30. I understand that a prior art reference teaches away from a modification of a prior art reference when a person of ordinary skill in the art would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path followed by and claimed in the patent.

IV. SUMMARY OF OPINIONS

31. For the reasons I discuss below, I believe that the asserted claims of the '005 Patent are not rendered obvious by any combination of the prior art asserted in the Petition.

V. THE '005 PATENT

A. Overview

32. Thrombi and emboli are blood clots that block (occlude) blood flow through blood vessels. If blood flow is sufficiently blocked, oxygen deprivation of

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tissues results which may cause tissue death. Clot blockages can cause many very serious health conditions if the clot is located in a critical blood vessel. For example, venous thromboembolism (“VTE”) is a disease caused by blood clot formation in the veins of the body, and is, unfortunately, a leading cause of both hospital preventable death and disease worldwide. EX1001, 1:39-61. Pulmonary embolism (“PE”) and deep vein thrombosis (“DVT”) are common types of VTE. *Id.*

33. DVT is a type of blood clot (thrombus) that typically forms in the deep veins of a limb, such as the leg. *Id.* at 1:40-47. DVT or other venous clots can embolize and flow from the vein towards the heart and then lungs. *Id.* at 1:47-50. A PE may result if the embolized clot material lodges in an artery or branch thereof of the lungs. *Id.* at 1:51-61.
34. Treatment of PE and DVT has long been a challenge, with the existing methods of treatment failing to significantly improve patient mortality rates over the last five decades. For example, PE and DVT have traditionally been treated with invasive procedures or drugs, e.g., streptokinase, urokinase, or other drugs in a class of agents called “thrombolytics” (or just “lytics”) that break down and dissolve the clot over hours or days, but do not physically remove the clot material from the body. *Id.* at 2:19-21. However, lytics have many disadvantages. For example, they can take many hours to work, can

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cause hemorrhages and serious risks of death, and cannot be used at all in some patients because of conditions related to increased risk of bleeding. *Id.* at 2:21-25.

35. The '005 Patent is directed to vacuum aspiration systems for rapidly aspirating clot material from a patient's blood vessel that offer significant benefits over such conventional treatments. *Id.* 4:10-12. For example, the '005 Patent describes various vacuum aspiration systems that generate (pre-charge or store) negative (vacuum) pressure in a chamber or canister before applying the vacuum to an aspiration catheter positioned near clot material (e.g., PE or DVT) in a patient's blood vessel to generate suction forces and corresponding fluid flow velocities that are (i) needed to effectively aspirate and remove the clot material from the patient, especially where the clot material is chronic and strongly lodged within the vessel and (ii) that are larger than conventional systems. *Id.* at 4:27-43 & 10:22-26.
36. Figure 1 of the '005 Patent shows a vacuum aspiration system with a flow path extending through a housing, a valve 126 in the flow path (e.g., an on-off control), and a first catheter 102 in fluid communication with a pressure source 140 via a connector 108:

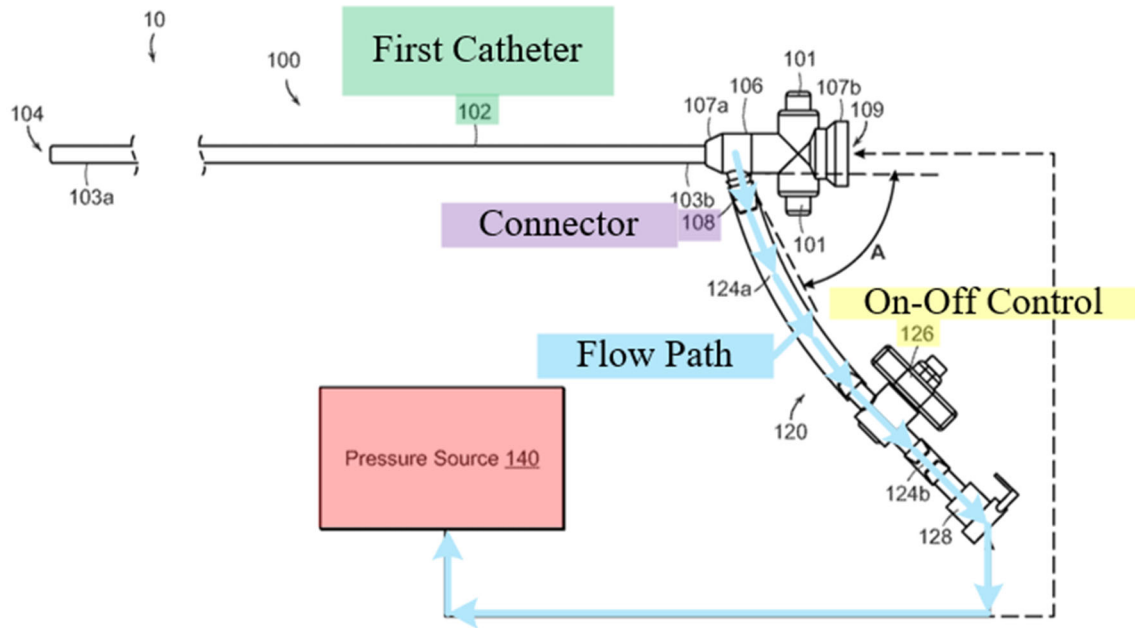
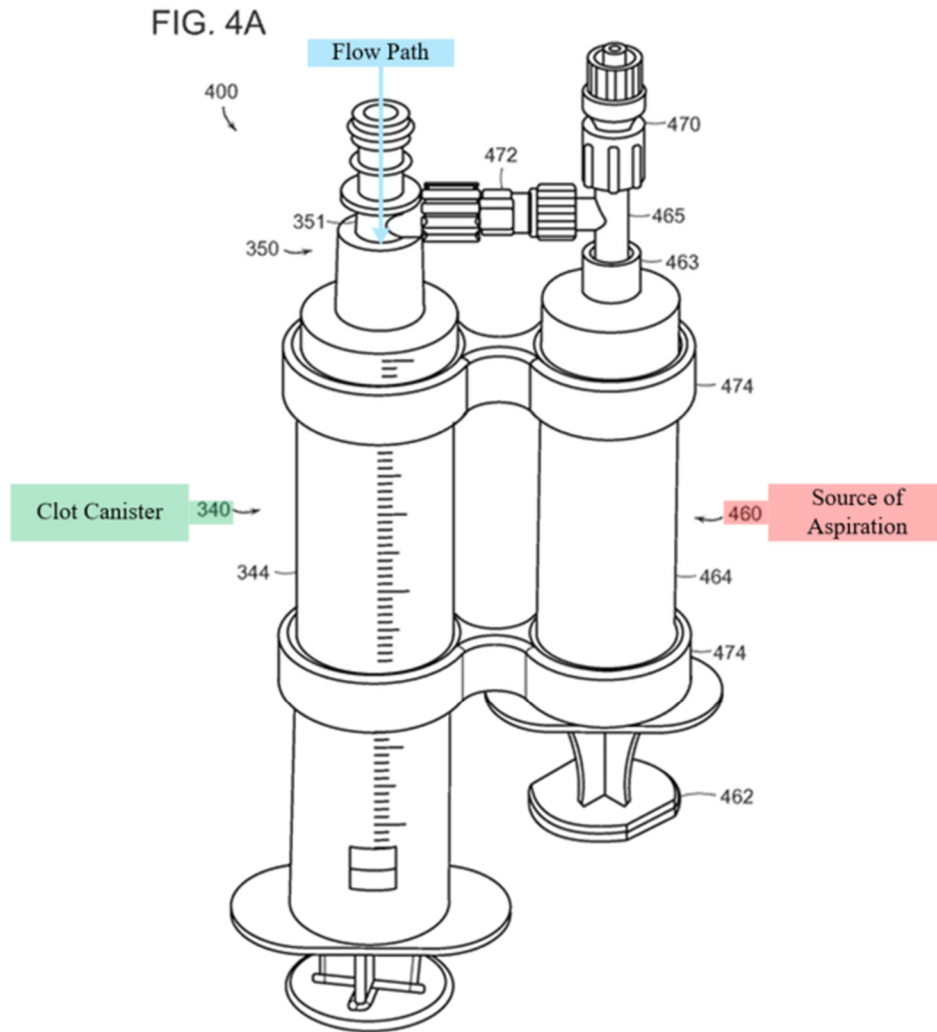


FIG. 1

Id. at 5:18-29, 6:3-11.

37. Figures 4A-4C of the '005 Patent show one example of the pressure source comprising a clot canister 340 that is fluidly coupled to the fluid path and a source of aspiration 460:



Id. at 10:45-48. The source of aspiration 460 is shown as a syringe in Figures 4A-4C, but the '005 Patent discloses that “the secondary syringe 460 can comprise a pump or vacuum source other than a syringe.” *Id.* at 12:45-47. Figure 19 of the '005 Patent shows another example of the pressure source comprising a clot canister 1940 that is fluidly coupled to the fluid path and the source of aspiration 460 shown in Figures 4A-4C:

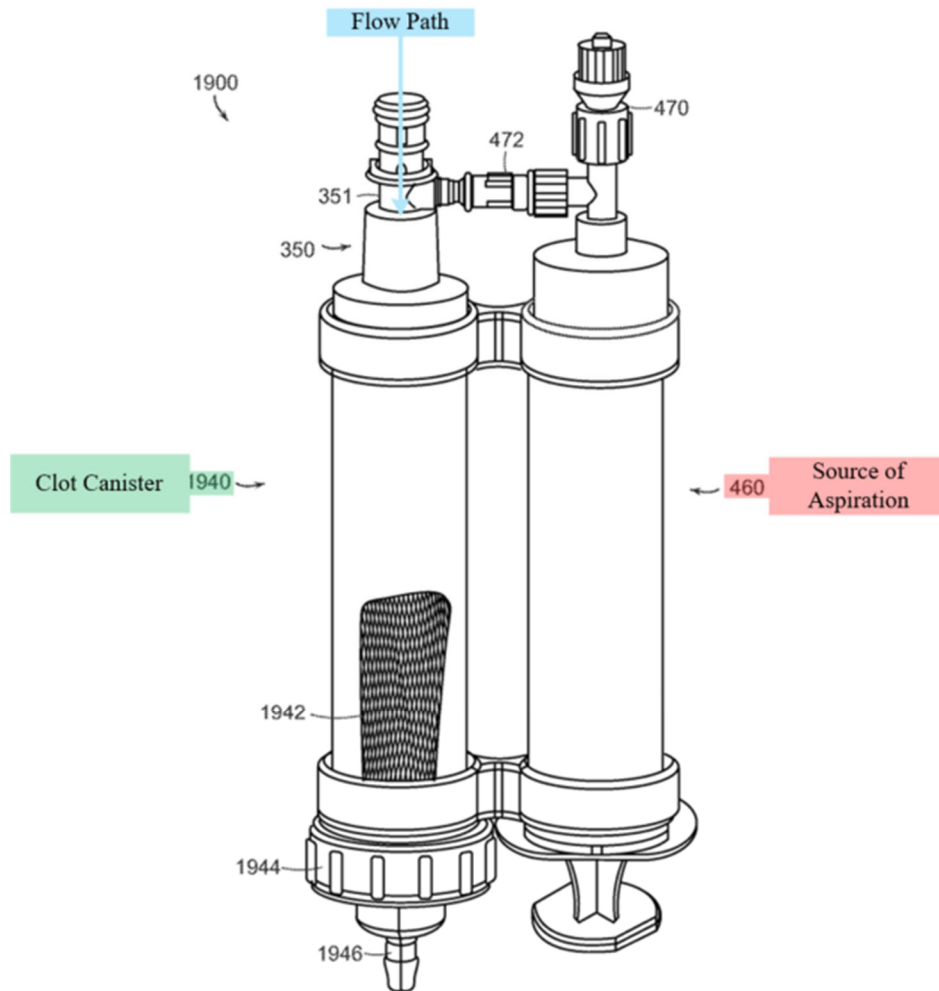


FIG. 19

Id. at 31:9-27.

38. Figure 1 of the '005 Patent shows a hemostasis valve 106 (i.e., a valve that inhibits or prevents blood from flowing through the valve) attached to a proximal end of the first catheter 102:

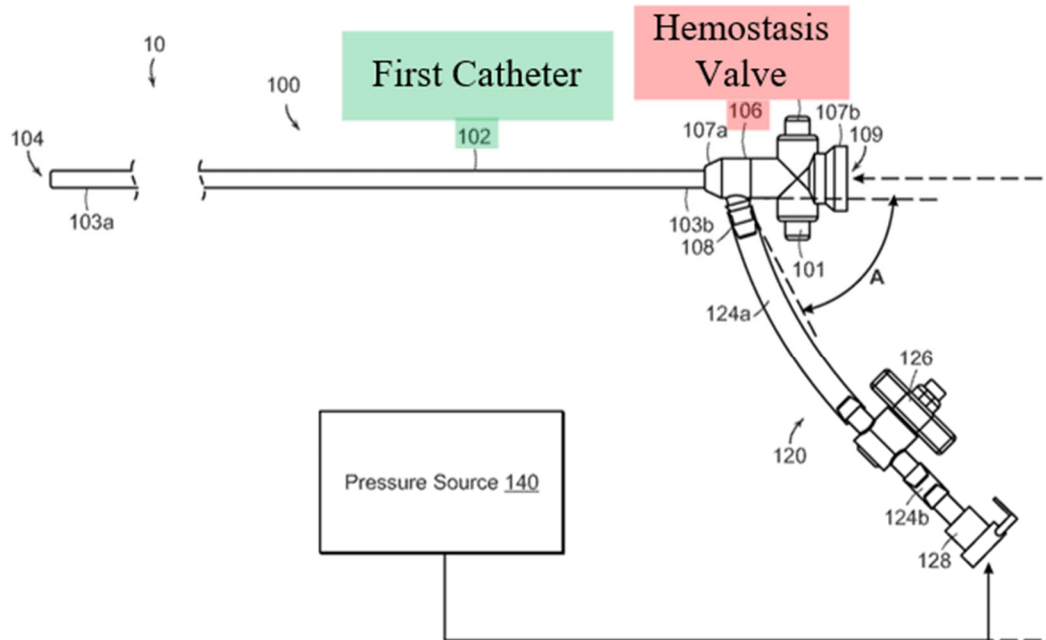


FIG. 1

Id. at 5:27-29. The hemostasis valve 106 includes buttons 101 that can be actuated (e.g., depressed) to open a conduit within the lumen 109. *Id.* at 5:47-49. The hemostasis valve 106 is configured to receive a second catheter therethrough as shown, in for example, Figure 11 of the '005 Patent:

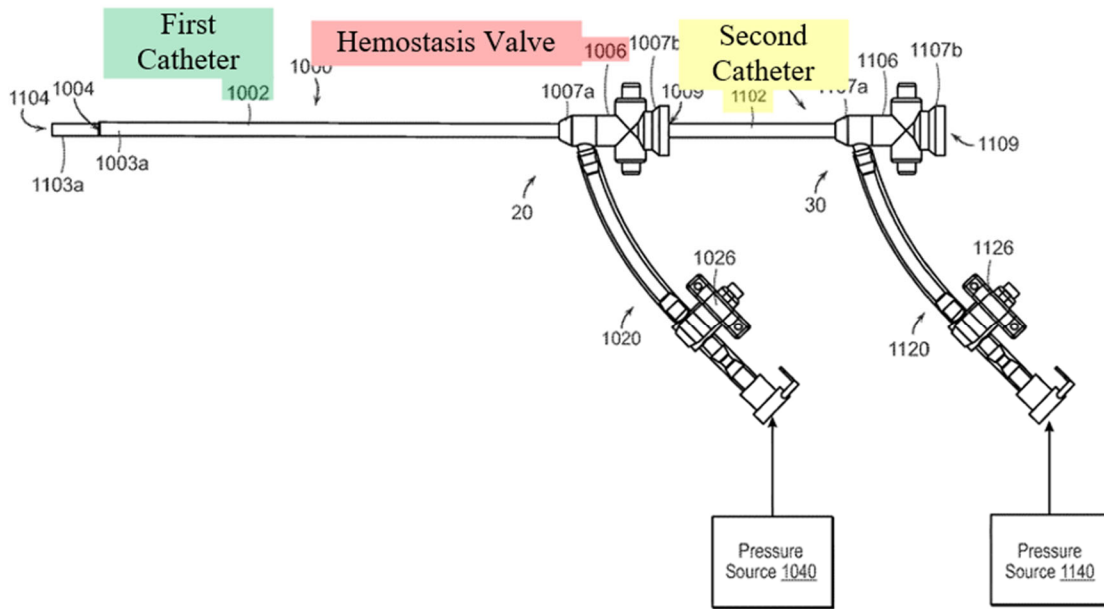


FIG. 11

39. The hemostasis valve 106 “can be a valve of the type disclosed in U.S. patent application Ser. No. 16/117,519, filed Aug. 30, 2018, and titled ‘HEMOSTASIS VALVES AND METHODS OF USE,’ which is incorporated herein by reference in its entirety.” *Id.* at 5: 49-54. Thus, the ’005 Patent incorporates by reference all the subject matter of U.S. patent Application No. 16/117,519 (“the ’519 Application”; EX1017) and explains that the hemostasis valve 106 can be of the type described therein.
40. The ’005 Patent, via its incorporation of the ’519 Application, explains that while “traditional hemostasis valves are greatly beneficial for intravascular access, they have some drawbacks. For example, some valves may not seal

adequately for all interventional applications or tools, and/or the operation of some valves may be complicated for operator use.” EX1017, ¶ [0005]. The ’005 Patent addresses those drawbacks by providing a hemostasis valve that provides for easy one-handed operation and strong sealing around a variety of different sized instruments, both of which are particularly important for hemostasis valves for use with vacuum aspiration systems as claimed in ’005 Patent. These features are important to treating physicians and critical to patient health. For example, without a strong and complete seal, patients will quickly lose blood through the valve endangering the patient, especially during thrombectomy procedures using large-bore catheters and vacuum aspiration.

41. Specifically, the ’005 Patent discloses a “valve that can be used [as] a hemostasis valve.” EX1017, ¶ [0033]. This valve, also referred to in the ’005 Patent as a garrote valve, can seal with or without a tool extending through the valve. *Id.* The ’005 Patent used the term “garrote valve” to evoke the mechanism and action of the valve in which a filament is pulled tightly around a flexible tubular member to seal the flexible tubular member.
42. The design and functionality of this hemostasis valve enables medical professionals to operate the valve with one hand while maintaining a robust seal to prevent blood loss during vacuum aspiration procedures. *Id.*; EX1001, 5:47-

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54. Specifically, the design enables such ease of use while maintaining an effective and strong seal under the high-pressure differential caused by vacuum aspiration during aspiration thrombectomy procedures. *Id.* at ¶¶ [0005], [0033], [0034]. This type of valve, because of its strong seal and ability to minimize patient blood loss, is particularly well-suited for medical procedures involving the use of large-bore catheters, where the risk of blood loss is generally greater and the need for a tight valve is critical.
43. In the claimed vacuum aspiration systems, the garrote valve can be used to seal a lumen of the first catheter and maintain hemostasis (i.e., inhibit or prevent blood flow from the catheter through the valve) when the second catheter extends through the garrote valve and the lumen of the first catheter, and when no instruments extend through the garrote valve. *Id.* at ¶ [0033]. The garrote valve provides for convenient single-handed operation to open and close the garrote valve while also providing robust sealing with or without an instrument inserted therethrough during various catheter operations, such as vacuum aspiration of the first catheter. *Id.*
44. In an embodiment, the '005 Patent discloses a garrote valve 104 that includes a housing 128 (e.g., a support) defining an interior channel 130 and an elongate/tubular member 132 extending through the interior channel 130. *Id.* at ¶ [0039]. The tubular member 132 defines a lumen 138 in communication with

the central lumen 112 of the catheter 102 and configured to receive the second catheter therethrough. *Id.* at ¶ [0040]. The tubular member 132 can comprise a compliant tubular sidewall that facilitates collapse and sealing of the tubular member 132:

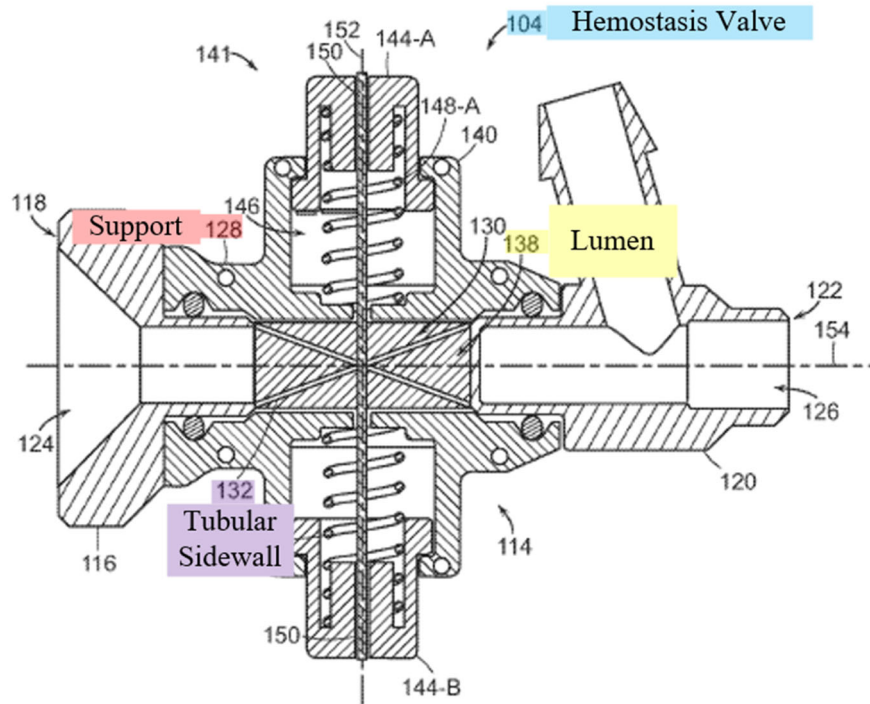


FIG. 2

Id. at ¶¶ [0039], [0041].

45. The garrote valve further includes a constricting mechanism 141 or garrote that can collapse and seal the tubular sidewall 132 via constriction with a filament 150 that can extend at least partially around the tubular member 132. *Id.* at ¶ [0043]. Specifically, the constricting mechanism 141 can comprise an actuator 142 “which can be a manual actuator such as one or several buttons 144” (a first button 144-A and second button 144-B), and the filament 150

can be coupled to the actuator 142 such that the filament 150 selectively constricts, collapses, and/or seals the tubular sidewall 132 (the central lumen 138 of the tubular sidewall 132) based on the movement and/or position of the actuator 142:

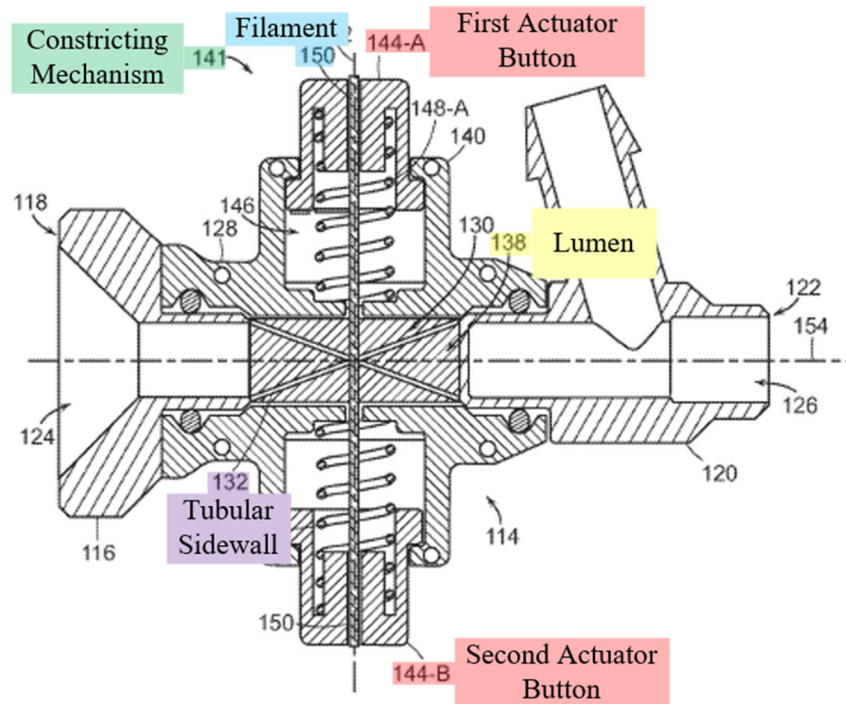


FIG. 2

Id. at ¶¶ [0043], [0044], [0048].

46. The garrote valve also includes a first spring 148-A configured to bias the first button 144-A and a second spring 148-B configured to bias the second button 144-B to bias the actuator 142 toward a first (closed) configuration of the garrote valve shown in Figure 2 wherein the tubular sidewall 132 is “collapsed and/or sealed”:



23

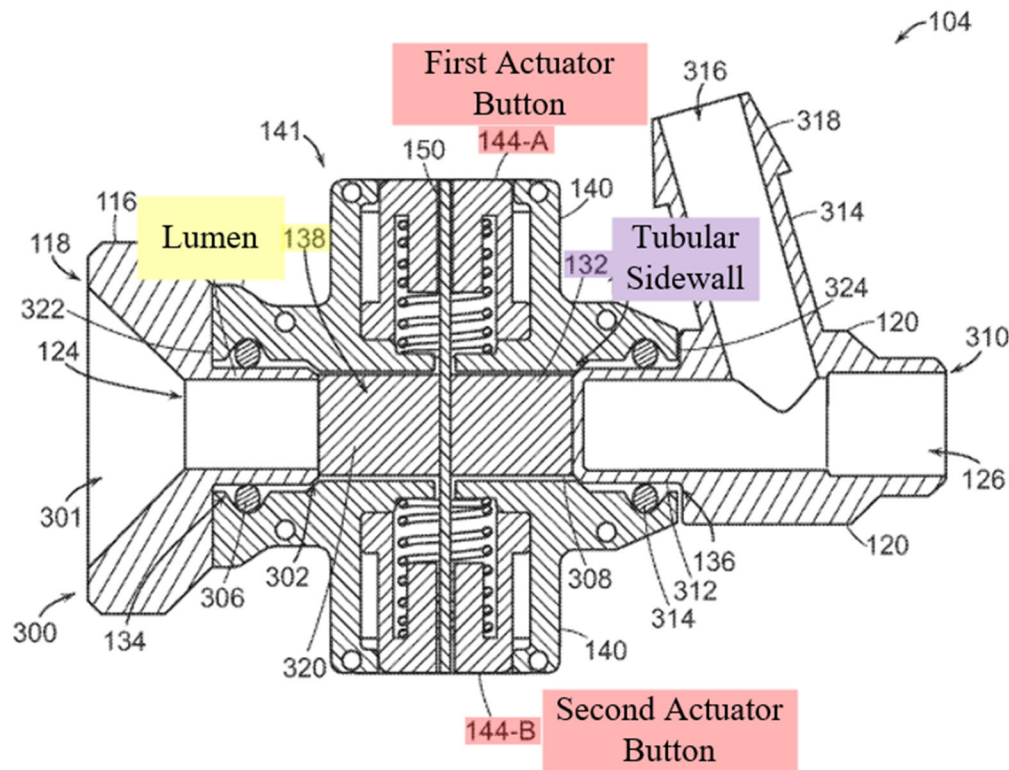


FIG. 3

Id. at ¶¶ [0048], [0050]. For example, the first and second buttons 144-A, 144-B can be depressed against the first and second springs 148-A, 148-B, respectively, in the second configuration. *Id.* In this position, the filament 150 is loosened, thereby allowing the expansion of the tubular sidewall 132 and the unsealing of the central lumen 138 thereof. *Id.* This arrangement of the constricting mechanism 141 can facilitate sealing of the garrote valve around tools or instruments of a wide range of sizes and/or diameters that fit through the elongate member 132. *Id.* at ¶ [0043].

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47. The filament 150 can be made from various materials, including a polymer, a synthetic, a metal, nylon, stainless steel, nitinol, silicone, or the like. *Id.* at ¶ [0047]. The filament 150 can comprise a single strand or a plurality of strands, and therefore can comprise one or several threads, lines, cords, rope, ribbon, flat wire, sheet, or tape. *Id.*
48. The filament 150 “can comprise a single filament 150” as shown in Figure 6 of the ’519 Application. *Id.* at ¶ [0064]. The filament 150 can also “comprise multiple filaments” such as a first filament 150-A and a second filament 150-B as shown in Figures 7-9 of the ’519 Application. *Id.* at ¶ [0065].
49. The filament 150 can have different configurations as shown in Figures 6-9 of the ’519 Application, including loop or bight embodiments. For example, as shown in Figure 6 (a loop embodiment), the filament 150 can be configured to form a single loop 604 having a first end 600 and a second end 602:

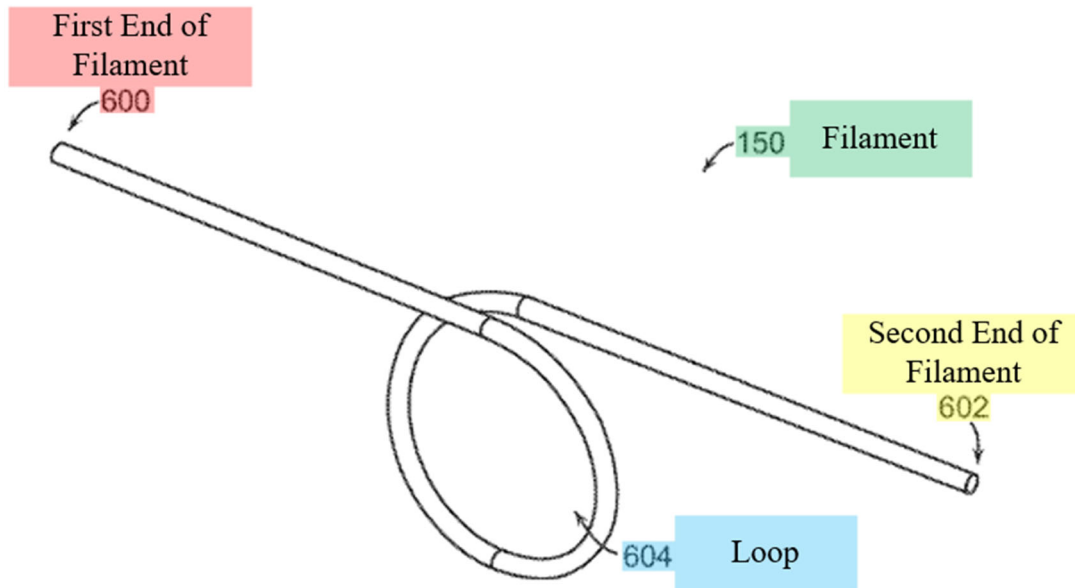
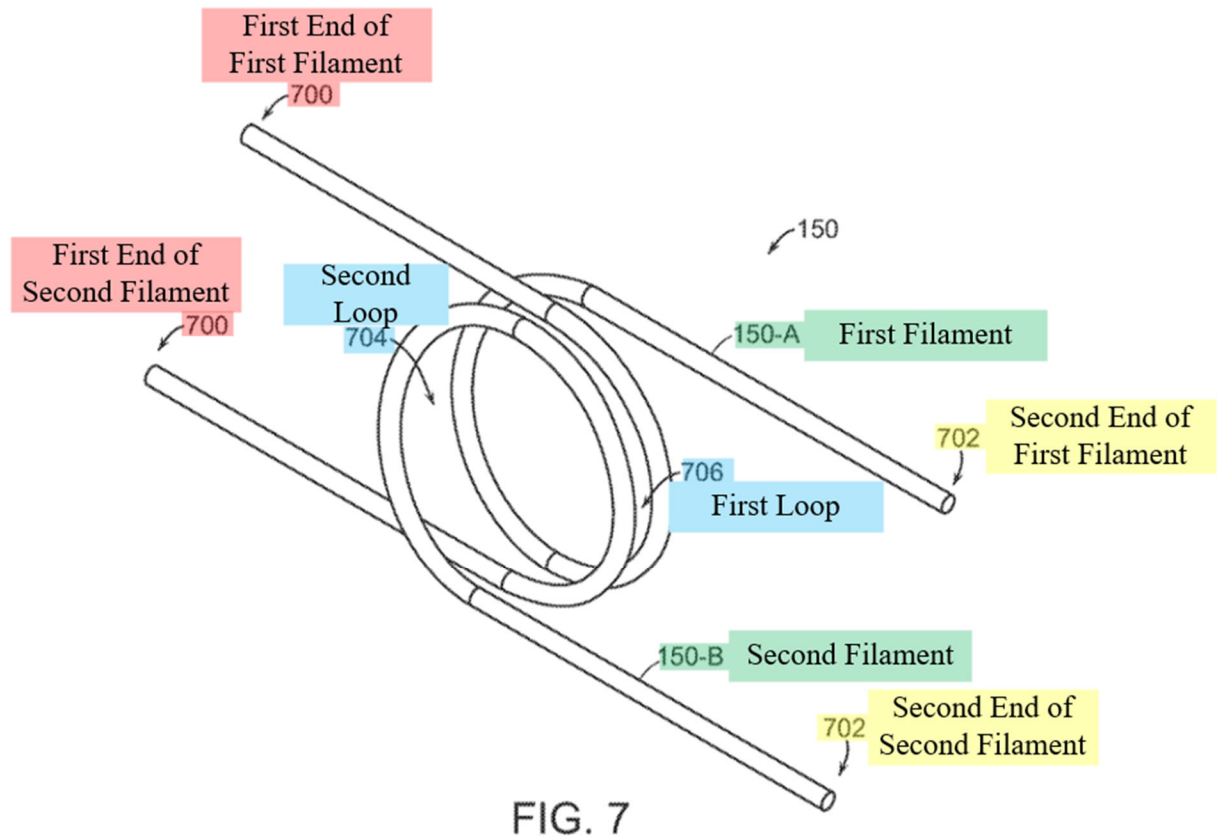


FIG. 6

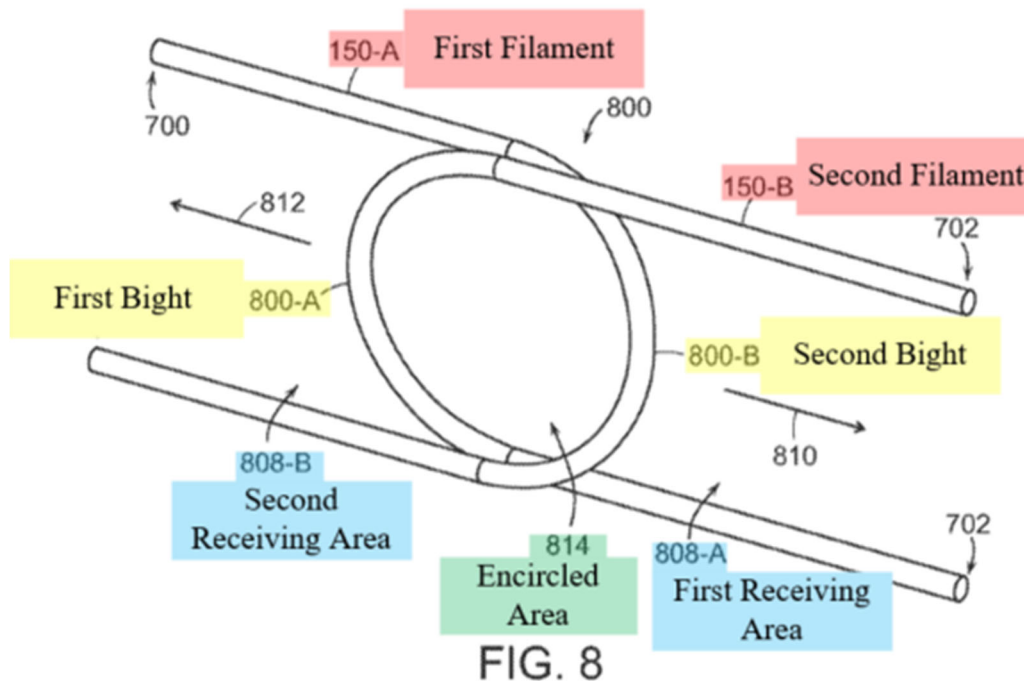
Id. at ¶ [0064]. For example, as shown in Figure 7 (also a loop embodiment), the filament 150 can comprise a first filament 150-A and a second filament 150-B each having a first end 700 and a second end 702, with each of the single filaments forming an individual loop—a first loop 704 and a second loop 706, respectively:



Id. at ¶¶ [0065], [0066].

50. For the filament loop embodiments shown in Figures 6 and 7, the constricting mechanism 141 acts to decrease a diameter or size of the loop 604 (Figure 6) or the first and second loops (Figure 7) when the constricting mechanism 141 is moved from the second (open) configuration to the first (closed configuration) as shown in Figures 2 and 3. *Id.* at ¶ [0066]. To do this, a POSITA would understand that the filament must have sufficient flexibility such that the loop can change size to conform to various shapes and sizes when transitioning between the first and second configurations.

51. As shown in Figures 8 and 9, in bight embodiments of the '519 Application the filament 150 can be formed into a single bight or multiple bights. *Id.* at ¶ [0067]. The '005 Patent specifies that in contrast to a loop, the term “‘bight’” refers to a U-shaped section between the two ends of the filament 150.” *Id.* Figures 8 and 9 show the first and second filaments 150-A and 150-B each forming an individual U-shaped bight—a first bight 800-A and a second bight 800-B, respectively:



Id.

52. As shown above, for the filament bight embodiments shown in Figures 8 and 9, the first and second bights 800-A and 800-B each define a partially enclosed receiving area 808—a first receiving area 800-A and a second receiving area

800-B, respectively, for receiving the elongate member 132. *Id.* at ¶ [0068].

As further shown above, the first and second receiving areas 808-A and 808-B overlap to define a constricting area 814. *Id.* at ¶ [0069]. The movement of the constricting mechanism 141 to the first (closed) configuration moves the bights 800-A, 800-B to decrease the size of the encircled area 814 and constrict, collapse, and/or seal the elongate member 132 extending through the encircled area 814, as shown in Figure 9:

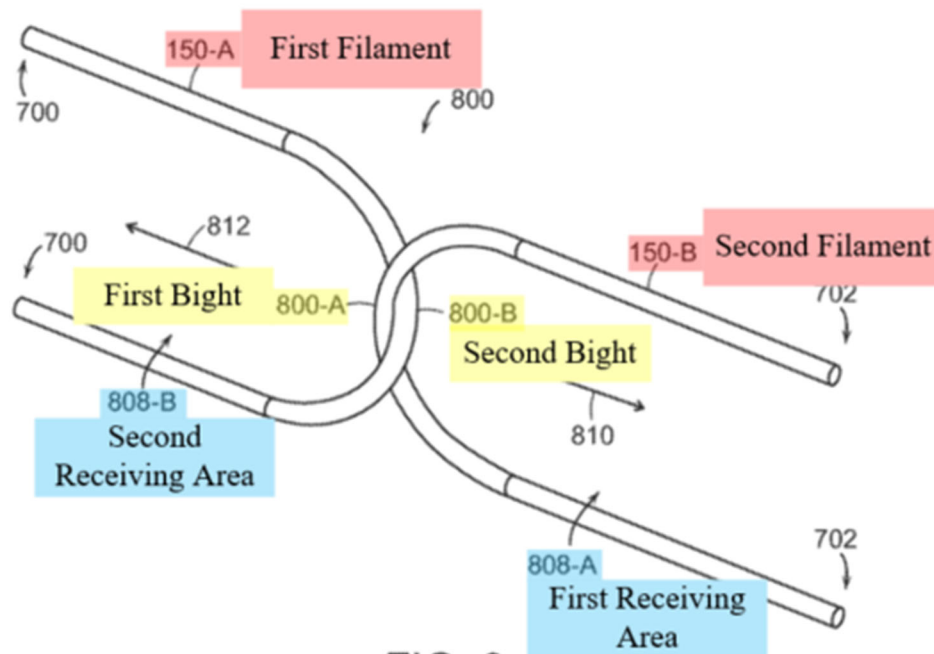


FIG. 9

Id. Movement of the constricting mechanism 141 from the first (closed) configuration to the second (open) configuration loosens (e.g., reduces a tension) in the first and second filaments 150-A, 150-B such that the first and second bights 800-A, 800-B slacken to allow the elongate member 132 to expand and

unseal the lumen 138 of the elongate member 132. *Id.* at ¶ [0050]. The '005 Patent includes both interlocking bights, as shown in Figures 8 and 9, and non-interlocking bights. *Id.* at ¶ [0067].

53. The '005 Patent explains that when the filament 150 comprises multiple filaments as shown in Figures 7-9, each individual filament has a “first end” and a second end” as follows: “[i]n embodiments in which the filament 150 comprises multiple filaments, each of the multiple filaments can have a first end 700 and a second end 702.” *Id.* at ¶ [0065].
54. I note that Figures 8 and 9 include a typographical error that is obvious and readily apparent in view of that clear disclosure in the specification. Specifically, Figures 8 and 9 show an embodiment having two individual filaments 150-A and 150-B. As expressly set forth in the specification, each of those individual filaments 150-A and 150-B has a first end and a second end. A typographical error in Figures 8 and 9 identifies individual filament 150-A as having two first ends 700 and individual filament 150-B as having two second ends 702. But, in accordance with the express disclosure in the specification, a POSITA would understand that each individual filament 150-A and 150-B in Figures 8 and 9 include a first end 700 and a second end 702:

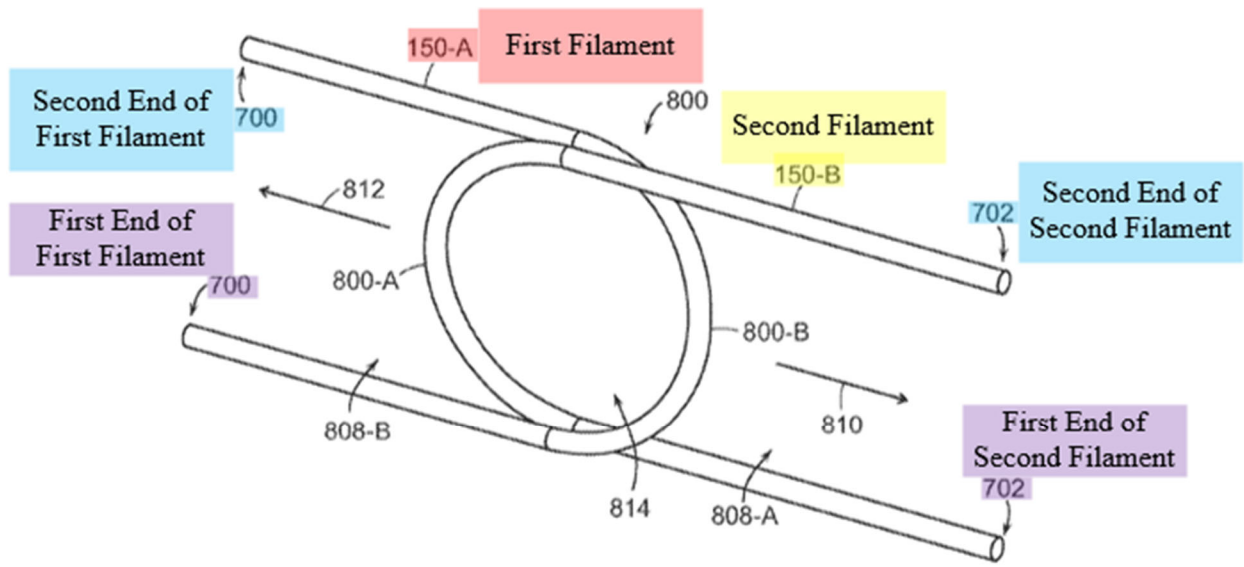


FIG. 8

55. In addition, the '005 patent consistently refers to various continuous (not separate) components as having a “first end” and a “second end.” For example, the catheter 102 has a first end 108 and a second end 110 (*id.* at ¶ [0035]), the tubular member 132 has a first end 134 and a second end 136 (*id.* at ¶ [0040]), and the reinforcement structure 320 has a proximal (e.g., first) end 322 and a distal (e.g., second) end 324 (*id.* at ¶ [0058]).
56. The above understanding is consistent with a common sense understanding of an individual filament which would have a first and second end, not two first ends or two second ends. I have applied that understanding in forming my opinions.
57. As I note above, the easy one-handed operation and strong seal of the garrote valve is particularly useful in vacuum aspiration systems, such as those

disclosed and claimed in the '005 Patent. For example, the garrote valve 104 is particularly useful to provide for convenient single-handed access to the first catheter (e.g., an aspiration catheter) while also providing robust sealing with or without the second catheter inserted therethrough during vacuum aspiration of the aspiration catheter 102 via the side port. EX1017, ¶ [0033]. More particularly, the garrote valve 104 provides robust sealing and easy access to the first catheter when the first catheter is a large-bore catheter wherein blood loss is a significant concern during a thrombectomy procedure.

58. For example, the first catheter can have a size of “20 French or greater.” EX1001, 21:39-40. Sealing a large-bore catheter is particularly challenging because of the large lumen size and the additional polymer material inherent to the larger catheter, requiring additional and focused material collapse/compression. A garrote valve that essentially “cinches” at a particular point is necessarily more effective in this setting than alternative valve configurations imposing diffuse sealing force. Thus, a POSITA would understand, for example, the garrote valve to be particularly useful in thrombectomy procedures using large-bore catheters to apply significant vacuum pressure, such as thrombectomy procedures used to treat pulmonary embolism or deep vein thrombosis.

59. Overall, the garrote valve's design prioritizes user control, allowing for single-handed operation while maintaining the integrity of the catheter system, including in the face of significant pressure differentials applied during aspiration thrombectomy procedures. In particular, the design allows for quicker and more effective sealing of large-bore catheters used for aspiration thrombectomy in large veins and pulmonary arteries, such as for treating deep vein thrombosis or pulmonary embolism. These features are important to treating physicians and critical to patient health. A robust seal and quick, self-closing valve are critical to reduce patient blood loss during procedures, which can be significant through a large catheter. Traditional rotating hemostasis valves take many turns to seal the larger bore catheters used in such procedures. The incorporation of bias features and springs ensures that the actuator can quickly and easily function effectively, providing a reliable and efficient means of achieving hemostasis. Many thrombectomy procedures require one or more changes in aspiration catheter positioning. Fast valve activation or release is critical in such situations to minimize patient blood loss associated with catheter placement changes.

B. Prosecution History of the '005 Patent

60. I have reviewed the prosecution history of the '005 Patent, including the Non-Final Office Action mailed October 5, 2022 (EX1002, pp. 209-216), the

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Response to the Non-Final Office Action filed October 27, 2022 (*id.* at pp. 191-199), and the Notice of Allowance mailed November 14, 2022 (*id.* at pp. 170-175).

61. The Examiner initially rejected original claim 1 under 35 U.S.C. § 102 over U.S. Patent Application Publication 2016/0220741 (EX1019). *Id.* at pp. 211-212. The Examiner objected to original dependent claims 2-10 as depending from a rejected independent claim, but indicated those claims would be allowable if rewritten in independent form. *Id.* at p. 212. The Examiner allowed original claims 11-16. *Id.*
62. In response, the Applicant rewrote original dependent claim 2 in independent form, incorporating the features of original claim 1. *Id.* at pp. 191-199. The Applicant canceled original independent claim 1. *Id.*
63. The Examiner allowed claims 2-16 based on the Applicant's response. *Id.* at pp. 168-175. The Examiner considered the patentability of the claims in view of Garrison, Wong, Kees, and Hartley. *Id.* at pp. 173-174. The Examiner concluded that Wong and Kees both fail to disclose the claimed filament, and that Hartley fails to disclose the claimed "first spring" or "biasing system." *Id.* The Examiner further concluded that a POSITA would recognize that it would be improper to add the filament of Hartley to either device of Wong or Kees "for this would conflict with the operation of the devices." *Id.* at p 174.

64. The '005 Patent issued on January 17, 2023, with original claims 2-16 issuing as renumbered Claims 1-15. *Id.* at p. 37.

C. Cited References

65. Petitioner has cited three different references—Schaffer, Hartley, and Eller—in its Petition challenging the patentability of the claims of the '012 Patent. I describe those references in this section below.

1. Garrison

66. Petitioner does not allege that Garrison discloses the “filament” of Claim 1, and instead alleges that Schaffer, Hartley, or Eller discloses this feature. Petition, pp. 43-60. I agree with Petitioner that Garrison does not disclose the “filament.”

2. Schaffer

67. The sealing mechanism present in the hemostasis valve of the '012 Patent is different from the sealing mechanism employed by Schaffer. As seen in Figure 12 below, Schaffer's mechanism involves several sealing components within a seal module 100, specifically identified as seal members 165, 170, and 180.

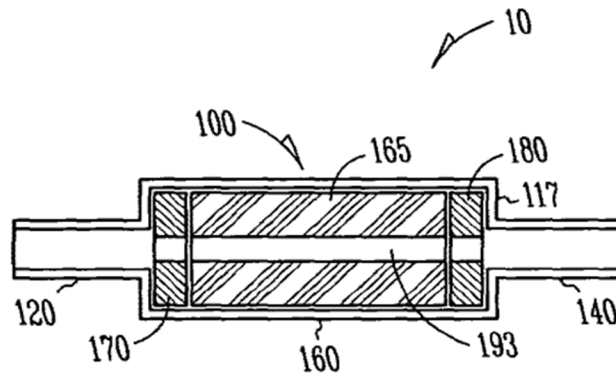


Fig. 12

68. These components are integral to Schaffer's sealing process, with seal member 165 being a consistent element in all of Schaffer's various embodiments. According to Schaffer, "[t]he third central seal member 165 is sized and configured to maintain an open lumen 193 when no compressive force 67 is applied." EX1005, ¶ [0054]. To achieve sealing, actuating members 55 are "forcibly pushed against the central portion of the seal module 100, [and] the compressive force 67 of the actuating member 55 against the outer wall 27 of the containment structure 160 inwardly depresses or collapses the third central seal member 165 of the containment structure 160 as the actuator 50 progresses toward the first side wall 23 of the housing 20." *Id.* at ¶ [0055]. The internal seal member 165 is made from a material 166 that is "highly elastic, deformable, compliant and yet virtually non-compressible." *Id.* at ¶ [0054]. This "highly compliant third central seal member 165 seals around a variety of profile shapes 192 and diameters 194 of the lumen 193 when at least one side of compressive force 67 is exerted upon the central region 195 with

respect to the central portion 110 of the containment structure 160.” *Id.* at ¶ [0060].

69. In essence, Schaffer employs actuating members 55 to apply an external compressive force 67 to a seal module 100, without those actuating members 55 conforming to the outer surface of the seal module during compression. The internal seal member 165 adapts to various shapes and sizes to seal a lumen, as illustrated in Figures 16-19 below.

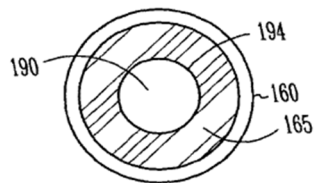


Fig. 16

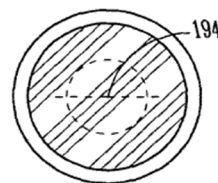


Fig. 17

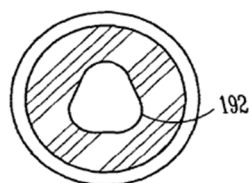


Fig. 18

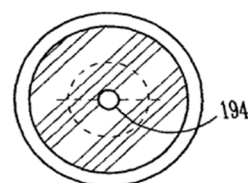


Fig. 19

Schaffer’s internal seal member 165 provides a seal with precise control of compression force for easy manipulation of, and to prevent damage to, delicate tools inserted therethrough:

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Thus, the problems are complex and involve a balance between closing force, opening force, friction, compression and durability. If a valve is inordinately tight, having a closed lumen, it may not allow the insertion of soft, flexible instrumentation such as a “floppy-tip” guidewire, a delicate laser fiber or a soft-tipped catheter. Some catheters, optical fibers and fluid transmission tubes are very delicate and can be damaged by excessive compression or insertion force.

EX1005, ¶[0006].

70. Schaffer additionally explains that a “compressive load” necessary for sealing can be provided by a “movable, sliding or hinged, actuator 50,” which results in a compressive force on the third central seal member 165, ensuring the seal is effectively formed and maintained. *Id.* at ¶ [0060]. However, the embodiments shown in Figures 12-15 disclose configurations that do not include actuating members, as they require “no compressive load for use in sealing the stasis valve 10 closed.” *Id.* at ¶ [0063]. In these embodiments, the sealing member 165 is relied upon to form a seal instead of the compressive load. As illustrated in Schaffer’s Figures 13 and 14, “retrograde flow 270 forces the first seal member 170 toward the third central seal member 165 in the containment structure 160. As the first seal member 170 moves distally, or toward the second seal member 180 under the influence of the pressure from the gas or fluid, the third central seal member 165 is compressed.” *Id.* at ¶ [0065].

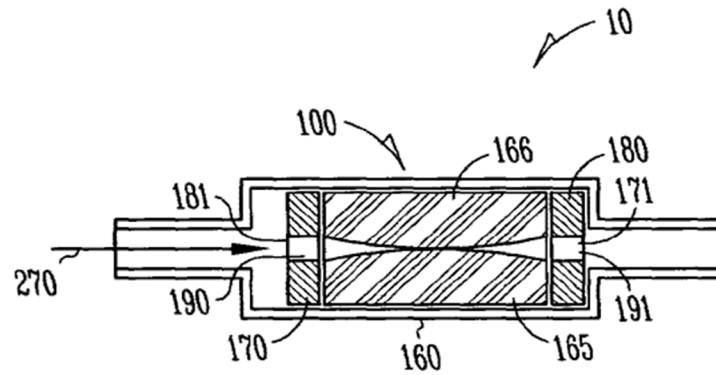


Fig. 13

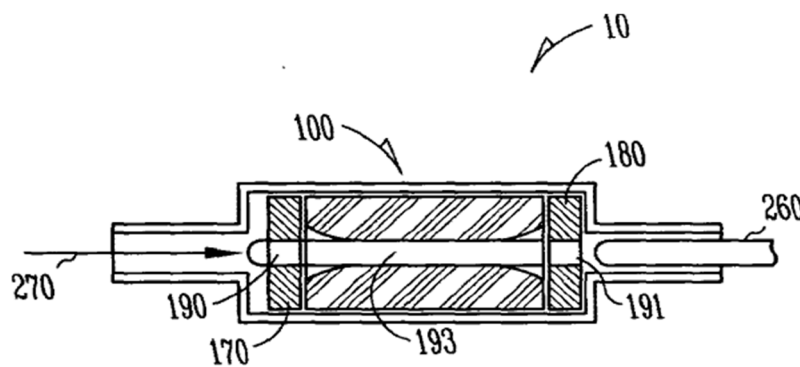


Fig. 14

71. Schaffer discloses that improved durability and control and ease of manufacture are among the several advantages of using a non-conforming actuating members 55 with an internal conforming seal member 165. In fact, each embodiment in Schaffer functions in this way, as illustrated in Figures 4, 6-8, 9-10, 12-15, and 23-29, and includes the seal member 165. Additionally, in relation to Figures 30-34 relied upon by Petitioner, Schaffer discloses that the “seal module 100 is formed of one or more seal members, as discussed above” with reference to Figures 1-29 and that (i) in the first sealed position of the

valve 10 the “lumen 193 of the third seal member 165 is at least partially collapsed by the compressive force 67” and (ii) in the second unsealed position of the valve 10 the “lumen 193 of the third seal member 165 is able to retract in an unsealed configuration.” EX1005, ¶¶ [0075], [0077]. Thus, the embodiment of Figures 30-34 includes the seal member 165.

3. Hartley

72. As shown below, Hartley describes an access valve featuring a string 14 that extends around a cylindrical elastomeric diaphragm 8 and is secured by knots 16 and 18 to a single rotary actuator 12. EX1006, ¶ [0031]. This rotary actuator 12 is a single, integral piece, such that that both knots 16 and 18 are attached to the same actuator. Consequently, the single rotary actuator 12 controls the movement of both ends of the string 14.

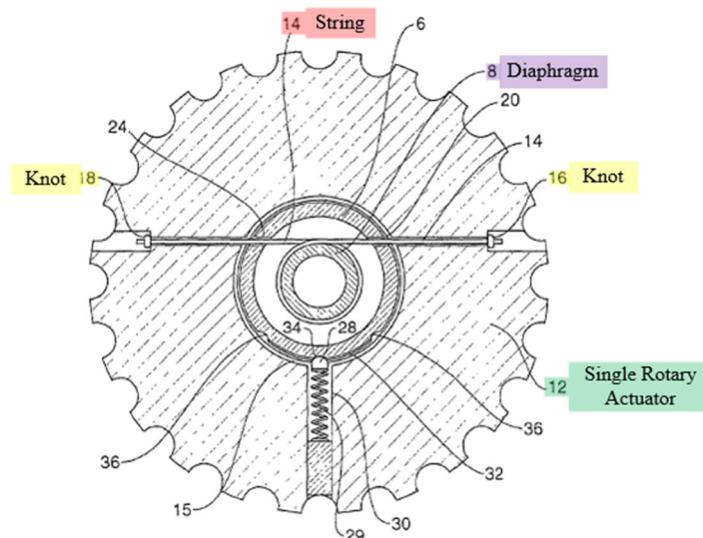


Fig 3

4. Eller

73. As displayed below, Eller describes a selective fluid barrier device 810 that comprises a housing 816, an actuator 818, a sleeve 820, and a wire member 822 with a first end 924 attached to the housing 816 and a second end 926 attached to the actuator 818. EX1007, 23:50-62, 24:50-52. Additionally, Eller describes other embodiments featuring multiple wire members, each with a first end connected to a housing and a second end connected to a single actuator. In all these embodiments, the wire members have one end fixed to the housing and the other end attached to the actuator. The actuator's movement (e.g., rotation or translation) pulls only the second end of the wire member, while the first end remains stationary. Thus, the movement of the single actuator governs the movement of the wire member.

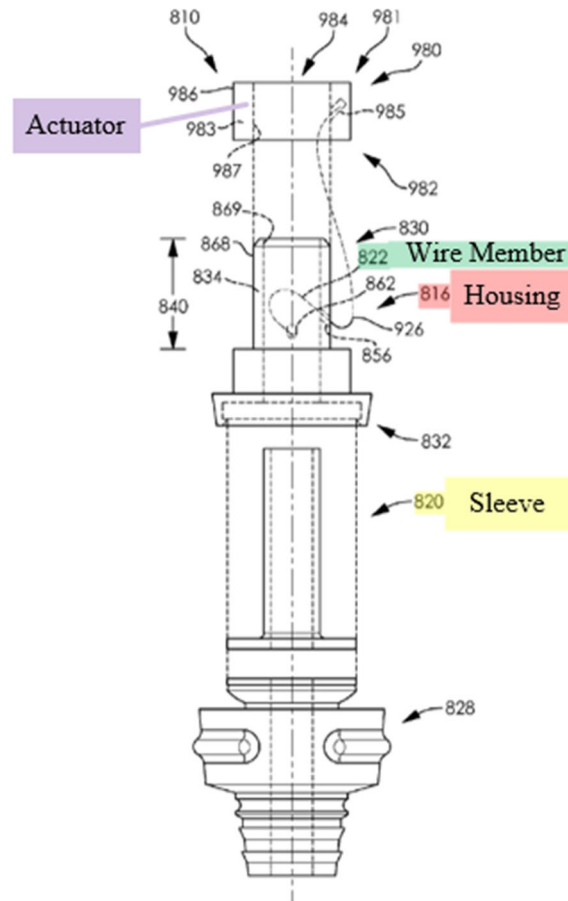


FIG. 20

D. Claim Construction

74. I understand that to properly construe a claim the words of the claim must be considered. I also understand terms are generally given their ordinary and customary meaning as understood by a person of ordinary skill in the art at the time of the invention when read in the context of the specification and prosecution history unless the patentee “deviate[s] from the plain and ordinary meaning of a claim term by disavowing claim scope or acting as his own lexicographer.” *Augme Techs., Inc. v. Yahoo! Inc.*, 755 F.3d 1326, 1333 (Fed.

Cir. 2014). I understand that in order for a patentee to act as its own lexicographer, it “must ‘clearly set forth a definition of the disputed claim term’ other than its plain and ordinary meaning.” *Cont’l Cirs. LLC v. Intel Corp.*, 915 F.3d 788, 796 (Fed. Cir. 2019).

75. Claim 1 recites “a constricting mechanism including a filament.” Claim 10 recites “a filament formed in a loop around the tubular sidewall.” In both claims, the ’005 Patent uses the plain and ordinary meaning for the term “filament”—a “thin, flexible length of material formed by one or more strands of material”—as would be understood by a person of ordinary skill in the art as of August 13, 2018. The claim language itself, the specification, the prosecution history, and other evidence, including dictionaries, support that this is the plain and ordinary meaning of “filament.” References in the patent to example materials that can be used to make the filament does not change that meaning.
76. I understand that Petitioner contends that the proper construction for “filament” is “at least ‘one or more threads, lines, cords, ropes, ribbons, flat wires, sheets, or tapes.’” Petition, p. 17. In other words, Petitioner argues that a filament is any structure that includes “at least one or more” of the recited list of non-limiting structures provided in a list at ¶ [0047] of the ’519 Application (EX1017). I disagree.

77. The language of the claims itself confirms that a filament must be flexible. For example, Claim 1 recites that “the filament circumferentially constricts the lumen to create a seal.” To “circumferentially constrict,” the filament must be flexible and extend circumferentially about the lumen to constrict the lumen. With this design, the filament will adapt to the shape of the lumen as the lumen is constricted and thus “circumferentially constrict” the lumen as recited in Claim 1. If the filament were rigid or inflexible, it could not “circumferentially constrict” the lumen because a rigid material cannot adapt/change its shape to reduce a circumferential contact area between the filament and the lumen. Indeed, a rigid member coupled between two actuator members would not permit the actuator members to move at all—instead rigidly tethering them together. A filament, which is flexible, allows the actuator members to move relative to one another (e.g., between the “first position” and the “second position” of Claim 1) such that filament changes shape dynamically, allowing for better adaptability to the contours of the valve lumen as it is constricted. Thus, a POSITA would understand that the filament that “circumferentially constricts the lumen to create a seal” requires a flexible component consistent with the plain and ordinary meaning of filament.
78. Claim 10 similarly specifies a flexible filament, explicitly reciting that “the first filament [is] formed into a loop around the collapsible tubular sidewall”

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and that a “diameter of the valve lumen decreases in response to reducing a diameter of the loop.” To “reduc[e] a diameter of the loop,” the filament must be “flexible” because if it were rigid or inflexible the loop would retain the same diameter when acted on by the first actuator. That is, a loop in a rigid filament would necessarily be fixed in size. In contrast, because a filament is flexible, the first filament can be pulled by the actuator to reduce a diameter of the loop. This inherent property of flexibility is essential to the loop structure of the claims. Thus, a POSITA would understand that the recitation that the filament “formed into a loop” such that a “diameter of the valve lumen decreases in response to reducing a diameter of the loop,” requires a flexible component consistent with the plain and ordinary meaning of filament.

79. The specification further confirms that a filament must be flexible. Specifically, the '519 Application incorporated by reference in the '005 Patent discloses that when the buttons 144 are depressed in the second position, “the filament 150 is **loosened**, thereby allowing the expansion of the elongate member 132 and the unsealing of the central lumen 138 of the elongate member 132.” EX1017, ¶ [0050] (emphasis added). A POSITA would understand that when the filament is “loosened,” the filament slackens and relaxes as tension is decreased in the filament and the elongate member expands against the filament as it loosens. *See, e.g., Merriam-Webster’s Collegiate Dictionary,*

EX2002, p. 735 (defining “loose” as “not tightly drawn or stretched: **slack**” and “being **flexible** or relaxed”). Thus, the ability of the filament to flex or slack is a necessary property of the claimed filament that allows the filament to “loosen” and thereby allow the elongate member to expand and unseal the valve. Accordingly, the specification confirms that the filament must be flexible to “loosen” to allow for the expansion of the elongate member.

80. Moreover, Figure 6 of the '519 Application shows a single filament 150 configured to form a single loop 604 that extends around the elongate member 132:

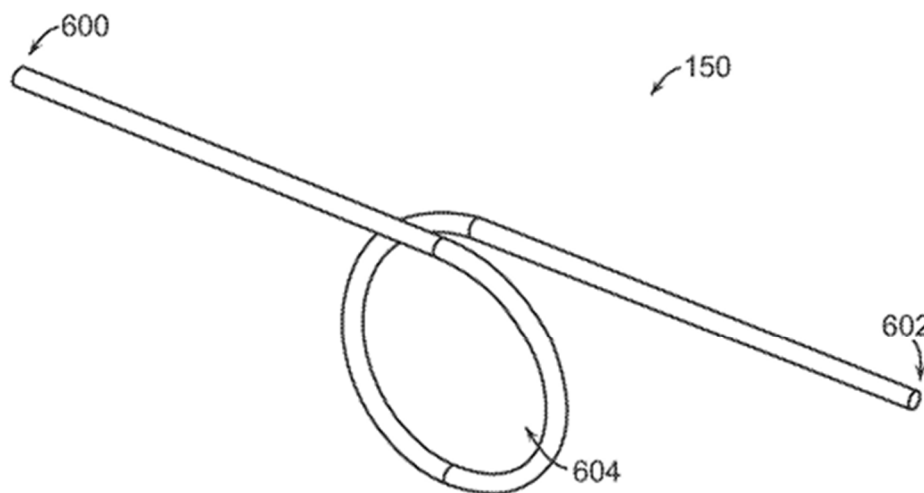


FIG. 6

EX1017, ¶¶ [0064], [0066]. “[E]ach of the first end 600 and the second end 602 can be coupled to different buttons 144” of the actuator. *Id.* at ¶ [0064]. When these buttons are actuated, they exert opposing forces on the respective

filament ends, causing the loop's diameter to decrease and constrict the elongated member. If the filament of Figure 6 were completely inflexible, it could not work as intended. That is, applying a force that seeks to pull the respective ends 600 and 602 of the filament in opposing directions would not "circumferentially constrict" the lumen as recited in Claim 1 or decrease the "diameter of the loop" as recited in Claim 10. Instead, the portion of the filament that "circumferentially constricts" the lumen (Claim 1) and the loop (Claim 12) would stay the same size and an elongate member extending through that loop would not be constricted and sealed. *Id.* at ¶ [0065]. Thus, in the above embodiment the filament must be sufficiently flexible that it can decrease the size/diameter of the loop to constrict and seal the valve, consistent with the plain and ordinary meaning of filament. Likewise, Figure 7 of the '005 Patent illustrates two filaments each formed into a loop that must also be sufficiently flexible to reduce in diameter. *Id.*

81. The bight embodiments shown in Figures 8 and 9 of the '519 Application also do not redefine the term filament to include embodiments that are not flexible. First, the interlocking bight embodiments shown in Figures 8 and 9 must be flexible. If they were not, then the interlocking bights would need to be rotated in opposite directions when moving from the looser configuration shown in Figure 8 to the tighter configuration shown in Figure 9 to accommodate the

inflexible curved region of each bight. But the '519 Application contains no such description. Thus, a POSITA reading the '519 Application would understand that the interlocking bight embodiments are formed of filaments in accordance with the plain and ordinary meaning of this term—that each filament is flexible and can thus accommodate the other filament as the filaments are pulled in opposite directions. Second, a POSITA would understand that when the filaments loosen as described by the '519 Application, slack is induced in each of the bights. This in accordance with the meaning of “bight”: a “**slack** part or loop in a rope.” EX2002, p. 120. That other bight embodiments disclosed in the '519 Application, such as the non-interlocking bight embodiments, could, in theory, work with rigid members would not make a POSITA ignore the above evidence supporting that the term filament is being used in accordance with its normal meaning that requires flexibility.

82. While the '519 Application describes the filament as comprising various potential materials, such as “a polymer, a synthetic, and/or a metal” (EX1017, ¶ [0047]), that the filament can be formed from materials within broad categories like polymers and metals that can, but certainly do not have to, be formed into rigid components (depending on the structure) does not mean that the term “filament” is broadened from its plain meaning to include a rigid component. Flexibility is a function of both a structure’s material and form. For

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instance, metals can be used to create a girder for a building, which is rigid, but metals can also be formed into long, narrow strands to produce a flexible wire or cable. Similarly, polymers—while potentially rigid in certain configurations—can be formed into flexible strands or lines that could serve as a filament. Thus, the material chosen to form the filament does not alter the plain and ordinary meaning of the term “filament” as understood by a POSITA, which is flexible and thin. Petitioner’s misplaced reliance on the composition of the filament ignores the essential principle that the structural characteristics of a component, not merely the materials from which it is made, define its function and properties. Likewise, while Petitioner contends that the proper construction for “filament” is “at least ‘one or more threads, lines, cords, ropes, ribbons, flat wires, sheets, or tapes’” regardless of whether or not those configurations are flexible (Petition, p. 17; EX1003, ¶ 54), a POSITA would understand those forms are commonly considered flexible. Though some of those forms can also be configured to be rigid does not redefine the term filament to include rigid members. Each recited structure is consistent with the plain meaning of a filament, which is flexible.

83. The prosecution history further supports that “filament” means a “thin, flexible length of material formed by one or more strands of material” because the prior art the Examiner asserted to include a filament was a flexible string. For

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example, in the Notice of Allowance dated November 14, 2022, the Examiner states that Hartley discloses “a filament.” EX1002, p. 174. Hartley discloses a string that is flexible given Hartley refers to this item as a “flexible member,” explicitly reciting flexibility as a necessary characteristic. EX1006, ¶ [0034]. Accordingly, the file history demonstrates that the examiner understood that a “filament” is flexible, consistent with the term’s plain and ordinary meaning.

84. In contrast, the Examiner found that Wong “fails to teach a collapsible tubular sidewall defining a lumen carried by the support; a filament formed in a loop around the tubular sidewall, the filament having at least a first end portion extending away from the loop to the first member; and a spring that pulls the first end portion such that a diameter of the lumen decreases in response to reducing a diameter of the loop.” EX1002, p. 174. Likewise, the Examiner found that Kees “fails to teach a filament formed in a loop around the tubular sidewall, the filament having at least a first end portion extending away from the loop to the first member; and the spring configured to move the first member in a direction that pulls the first end portion such that a diameter of the lumen decreases in response to reducing a diameter of the loop.” *Id.* Accordingly, the file history demonstrates that the examiner understood that a “filament” is flexible, consistent with the term’s plain and ordinary meaning.

85. Contemporaneous extrinsic evidence in the form of dictionaries also demonstrate that a “filament” is flexible. For example, the Merriam-Webster’s Collegiate Dictionary defines a filament as “a single thread or a thin **flexible** threadlike object, process, or appendage.” EX2002, p. 467 (emphasis added). Likewise, the New Oxford American Dictionary defines a filament as “a slender threadlike object or fiber.” EX2003, p. 644.
86. Taking into account the claim language itself, the specification, the prosecution history, and other evidence, a POSITA would readily understand the degrees of flexibility required for the claimed filament—the filament must be sufficiently flexible so that it can loosen, reduce in diameter when formed in a loop as shown in Figures 6 and 7 of the ’519 Application, and similarly slacken when formed in a bight as shown in Figures 8 and 9 of the ’519 Application. That is, a POSITA would understand that the filament must be flexible to the degree necessary to slacken/loosen when the actuator is depressed.
87. I understand that Petitioner may assert that claims in US12,109,384 (“the ’384 Patent”) support its claim construction. I have reviewed those claims, and they do not change my opinion herein. Specifically, the ’384 patent and claims recite the term “filament” in accordance with the plain and ordinary meaning set forth here, namely, “thin, flexible length of material formed by one or more strands of material.” Independent claims 1, 15, and 23 each require that the

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filament must meet that construction such that any recitation regarding that the “filament is flexible” in the claims does not change that construction particularly in view of the clear use of the term in the ’005 Patent. Claims 1 and 15 of the ’384 Patent require the filament “[extending/configured] in a [first/second] loop” and then require “decreasing a dimension of the [first/second] loop” or similar, and claim 23 requires “circumferentially restrict.” As such, those claims support that filament is used in accordance with its plain and ordinary meaning and do not contradict the clear meaning of the term in the specification. I reserve the right to address these or any other arguments that the Petitioner may make regarding the ’384 Patent.

E. Person of Ordinary Skill in the Art

88. Petitioner asserts that a “POSITA in August 2018 would have had an undergraduate degree in mechanical engineering or a related engineering discipline and 2-4 years of catheter design experience.” Petition, p. 17. This is insufficient to qualify as a POSITA. Nevertheless, I apply Petitioner’s definition throughout my declaration as, even under this too-low definition of ordinary skill, a POSITA would have understood the Claims of ’005 Patent to be patentable over the prior art references cited in grounds 1–4. I was also at least a person of ordinary skill in the art as of the priority date of the ’005 Patent according to this standard.

VI. GROUND 1—GARRISON IN COMBINATION WITH SCHAFFER DOES NOT RENDER OBVIOUS ANY OF CLAIMS 1-12 OR 14-15

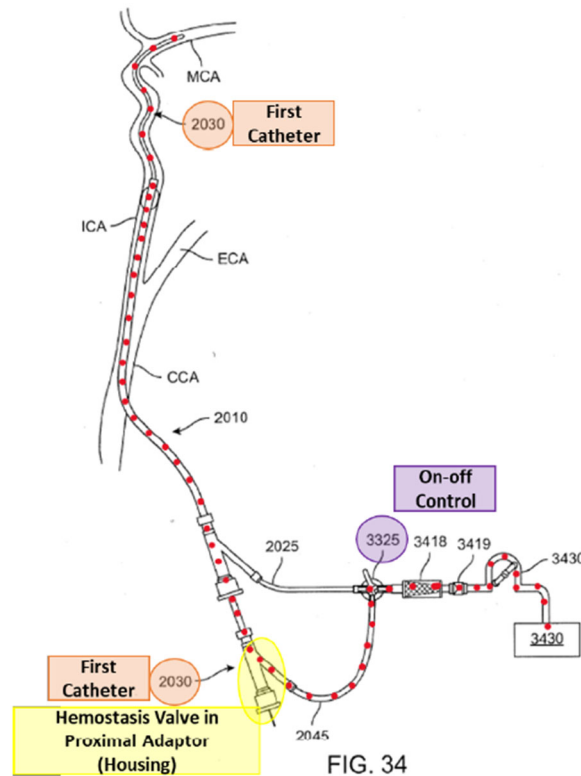
89. Petitioner and its expert, Mr. Thornton, allege that Garrison in combination with Schaffer renders obvious Claims 1-12 and 14-15 of the '005 Patent. I disagree for the reasons I discuss in further detail in this section. A POSITA would understand that the combination of Garrison and Schaffer does not disclose several limitations of Independent Claim 1 and Independent Claim 10, and that a POSITA would not have been motivated or found it obvious to modify Garrison in view of Schaffer to arrive at the features of Claim 1 or Claim 10. Therefore, the combination of Garrison and Schaffer does not render obvious Claim 1 or Claim 10. And, because Claims 2-9, 11-12, and 14-15 depend from one of Claims 1 or 10 and thus include all the features of one of these claims, those claims are also not rendered obvious by the combination of Garrison and Schaffer.

90. As I explained above, I understand that for a patent claim to be rendered obvious, the differences between the claimed invention and the prior art must be such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains, the claimed invention is obvious. Even if all limitations of a claimed invention are disclosed by the prior art combination, Petitioner must demonstrate an apparent reason to

combine the known elements in the fashion of the patent claim at issue and that a person of ordinary skill in the art would have reasonable expectation of success in pursuing that combination. A prior art reference teaches away from a modification of a prior art reference when a person of ordinary skill in the art would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path followed by and claimed in the patent.

A. The Combination of Garrison and Schaffer Does Not Disclose the “Housing” of Claims 1 and 10.

91. Claims 1 and 10 both require a “housing, “a flow path extending through the housing,” and “an on-off control in the flow path.” Petitioner alleges that Garrison’s proximal adaptor discloses the “housing” of Claims 1 and 10, and that Garrison further discloses a flow path that extends through the housing, referencing a red dashed line in Petitioner’s annotated Figure 34:



Petition, pp. 22-25. Petitioner further alleges that Garrison’s valve 3325, which is not positioned in the housing, discloses the claimed “on-off control in the flow path.” *Id.* at 24-25.

92. A POSITA would not have considered Garrison’s valve 3325 to be “in the flow path” “extending through the housing,” as recited in Claims 1 and 10. First, the red dashed line that Petitioner uses to denote the purported flow path extends well beyond either end of the alleged housing and thus tracks more than just “the flow path” “extending through the housing.” A POSITA would understand that the proper illustration of “the flow path” “extending through the housing” would be from one end of the proximal adaptor to the other. Any

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portion that extends beyond that would not be “extending through the housing.” With this context, the valve 3325 is not in the flow path extending through the housing as claimed. Instead, the valve 3325 is at most fluidly coupled to the flow path extending through the housing.

93. The '005 Patent claims and description support that Garrison does not disclose that the valve 3325 is “in the flow path” “extending through the housing.” First, claims 1 and 10 use the term “*in*” to describe the relative position of the on-off control relative to the flow path, but use the term “*fluidly coupled to*” to describe the relative position of the clot cannister to the flow path. A POSITA would understand that these terms (“in” versus “fluidly coupled to”) are not the same, with the former requiring a direct connection and the latter simply requiring a fluid connection, either direct or via intermediate components. The '005 Patent description reflects this difference as well, drawing a distinction between embodiments in which a fluid control device is fluidly coupled to a valve housing (e.g., via tubing), and embodiments in which the fluid control device is part of the valve housing. *E.g.*, compare EX1001, 6:3-11 and Figure 1 with EX1001, 6:45-49. Claims 1 and 10 clearly require the former.

B. The Combination of Garrison and Schaffer Does Not Disclose the “Filament” of Claims 1 and 10.

94. Petitioner does not allege that Garrison discloses the “filament” of Claim 1 or Claim 10, and instead alleges that Schaffer discloses this claim feature. Petition, pp. 36, 43-48. I agree with Petitioner that Garrison does not disclose the “filament,” but disagree with Petitioner that Schaffer does.
95. According to Petitioner, “Schaffer’s actuating members are a ‘filament’ as claimed in the ’005 patent.” Petition, p. 44. That is, Petitioner contends that “Schaffer’s U-shaped actuating members collectively constitute the ‘filament’ claimed in the ’005 patent.” *Id.* at p. 45. I disagree—Schaffer’s actuating members 55 are rigid metal or plastic U-shaped members and not thin and flexible and thus are not individually or collectively one or more “filaments.”
96. As I explain in §V.D. above, the term “filament” means “a thin, flexible length of material formed by one or more strands of material.” A POSITA would understand that Schaffer’s actuating members 55 are rigid and therefore do not disclose “a filament,” as recited in either Claim 1 or Claim 10.

Fig. 32 and Fig. 34 are cross-sectional views of a multi-layered electronic device assembly, likely a semiconductor package or a microelectronic assembly. The assembly consists of several layers and components, including a central core (117), a top layer (111), a bottom layer (115), and various interconnects and solder layers (27, 271, 273, 275, 276, 277, 278, 279, 280, 281, 282, 283, 284, 285, 286, 287, 288, 289, 290, 291, 292, 293, 294, 295, 296, 297, 298, 299, 300, 301, 302, 303, 304, 305, 306, 307, 308, 309, 310, 311, 312, 313, 314, 315, 316, 317, 318, 319, 320, 321, 322, 323, 324, 325, 326, 327, 328, 329, 330, 331, 332, 333, 334, 335, 336, 337, 338, 339, 340, 341, 342, 343, 344, 345, 346, 347, 348, 349, 350, 351, 352, 353, 354, 355, 356, 357, 358, 359, 360, 361, 362, 363, 364, 365, 366, 367, 368, 369, 370, 371, 372, 373, 374, 375, 376, 377, 378, 379, 380, 381, 382, 383, 384, 385, 386, 387, 388, 389, 390, 391, 392, 393, 394, 395, 396, 397, 398, 399, 400, 401, 402, 403, 404, 405, 406, 407, 408, 409, 410, 411, 412, 413, 414, 415, 416, 417, 418, 419, 420, 421, 422, 423, 424, 425, 426, 427, 428, 429, 430, 431, 432, 433, 434, 435, 436, 437, 438, 439, 440, 441, 442, 443, 444, 445, 446, 447, 448, 449, 450, 451, 452, 453, 454, 455, 456, 457, 458, 459, 460, 461, 462, 463, 464, 465, 466, 467, 468, 469, 470, 471, 472, 473, 474, 475, 476, 477, 478, 479, 480, 481, 482, 483, 484, 485, 486, 487, 488, 489, 490, 491, 492, 493, 494, 495, 496, 497, 498, 499, 500, 501, 502, 503, 504, 505, 506, 507, 508, 509, 510, 511, 512, 513, 514, 515, 516, 517, 518, 519, 520, 521, 522, 523, 524, 525, 526, 527, 528, 529, 530, 531, 532, 533, 534, 535, 536, 537, 538, 539, 540, 541, 542, 543, 544, 545, 546, 547, 548, 549, 550, 551, 552, 553, 554, 555, 556, 557, 558, 559, 560, 561, 562, 563, 564, 565, 566, 567, 568, 569, 570, 571, 572, 573, 574, 575, 576, 577, 578, 579, 580, 581, 582, 583, 584, 585, 586, 587, 588, 589, 590, 591, 592, 593, 594, 595, 596, 597, 598, 599, 600, 601, 602, 603, 604, 605, 606, 607, 608, 609, 610, 611, 612, 613, 614, 615, 616, 617, 618, 619, 620, 621, 622, 623, 624, 625, 626, 627, 628, 629, 630, 631, 632, 633, 634, 635, 636, 637, 638, 639, 640, 641, 642, 643, 644, 645, 646, 647, 648, 649, 650, 651, 652, 653, 654, 655, 656, 657, 658, 659, 660, 661, 662, 663, 664, 665, 666, 667, 668, 669, 670, 671, 672, 673, 674, 675, 676, 677, 678, 679, 680, 681, 682, 683, 684, 685, 686, 687, 688, 689, 690, 691, 692, 693, 694, 695, 696, 697, 698, 699, 700, 701, 702, 703, 704, 705, 706, 707, 708, 709, 710, 711, 712, 713, 714, 715, 716, 717, 718, 719, 720, 721, 722, 723, 724, 725, 726, 727, 728, 729, 730, 731, 732, 733, 734, 735, 736, 737, 738, 739, 740, 741, 742, 743, 744, 745, 746, 747, 748, 749, 750, 751, 752, 753, 754, 755, 756, 757, 758, 759, 760, 761, 762, 763, 764, 765, 766, 767, 768, 769, 770, 771, 772, 773, 774, 775, 776, 777, 778, 779, 780, 781, 782, 783, 784, 785, 786, 787, 788, 789, 790, 791, 792, 793, 794, 795, 796, 797, 798, 799, 800, 801, 802, 803, 804, 805, 806, 807, 808, 809, 810, 811, 812, 813, 814, 815, 816, 817, 818, 819, 820, 821, 822, 823, 824, 825, 826, 827, 828, 829, 830, 831, 832, 833, 834, 835, 836, 837, 838, 839, 840, 841, 842, 843, 844, 845, 846, 847, 848, 849, 850, 851, 852, 853, 854, 855, 856, 857, 858, 859, 860, 861, 862, 863, 864, 865, 866, 867, 868, 869, 870, 871, 872, 873, 874, 875, 876, 877, 878, 879, 880, 881, 882, 883, 884, 885, 886, 887, 888, 889, 890, 891, 892, 893, 894, 895, 896, 897, 898, 899, 900, 901, 902, 903, 904, 905, 906, 907, 908, 909, 910, 911, 912, 913, 914, 915, 916, 917, 918, 919, 920, 921, 922, 923, 924, 925, 926, 927, 928, 929, 930, 931, 932, 933, 934, 935, 936, 937, 938, 939, 940, 941, 942, 943, 944, 945, 946, 947, 948, 949, 950, 951, 952, 953, 954, 955, 956, 957, 958, 959, 960, 961, 962, 963, 964, 965, 966, 967, 968, 969, 970, 971, 972, 973, 974, 975, 976, 977, 978, 979, 980, 981, 982, 983, 984, 985, 986, 987, 988, 989, 990, 991, 992, 993, 994, 995, 996, 997, 998, 999, 1000). The assembly is shown in a cross-sectional view, with various layers and components labeled with reference numerals. The central core (117) is surrounded by a top layer (111) and a bottom layer (115). The assembly is further divided into four quadrants by a central vertical and horizontal axis. Each quadrant contains a series of layers and components, including a top layer (111), a middle layer (115), and a bottom layer (115). The assembly is shown in a cross-sectional view, with various layers and components labeled with reference numerals. The central core (117) is surrounded by a top layer (111) and a bottom layer (115). The assembly is further divided into four quadrants by a central vertical and horizontal axis. Each quadrant contains a series of layers and components, including a top layer (111), a middle layer (115), and a bottom layer (115).

¹ I refer to the versions of Schaffer's drawings relied on by Petitioner that were submitted during prosecution on June 18, 2003 (EX1008) that Petitioner has asserted are clearer than the drawings in the published application.

movement 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.” *Id.* (emphasis added). That is, when the actuator buttons 261 are depressed, the actuating members 55 are forced to disengage from the seal module 100 with one of the actuating members 55 moving away from and out of contact with one of the outer walls 27 of the seal module 100 and the other one of the actuating members 55 moving away from and out of contact with the other opposing one of the outer walls 27 of the seal module 100. A POSITA would understand that for each of the actuating members 55 to “forcibly disengage” opposing outer walls 27 of the seal module 100, the actuating members 55 must be rigid. For example, if the actuating members 55 were flexible, depressing the actuator buttons 261 to move the actuating members 55 would simply reduce a tension in the actuating members 55 such that they would deform/loosen without forcibly disengaging the seal module 100. That is, the flexible actuating members 55 would remain in contact with and never disengage the seal module 100, contrary to Schaffer’s teachings.

99. Moreover, as I explain in greater detail in §VII.A. below, Schaffer discloses that the seal module 100 is formed of a material 166 that “is extremely soft

and compliant and intrinsically ‘sticky.’” EX1005, ¶ [0059]. A POSITA would understand that the forcible disengagement provided by the rigid actuating members 55 is desirable or necessary to allow the seal module 100 to expand when the actuator buttons 261 are depressed. For example, flexible actuating members 55 would not disengage the soft and sticky seal module 100 at all when the actuator buttons 261 are depressed such that the seal module 100 may stick to and retain the actuating members 55 in the closed position—rendering Schaffer’s valve inoperable by inhibiting or even preventing movement of the seal module 100 to the open position. Petitioner’s expert even admits that the actuating members 55 sticking to the seal module 100 could be a problem that makes it difficult for the seal module 100 to return to the uncollapsed open position. EX1003, ¶ 124.

100. Second, in both the first and second positions shown in Figures 32 and 34, the actuating members 55 have an identical U-shape indicating that the depression of the actuating members 55 via the actuator buttons 261 and corresponding expansion of the seal module 100 does not affect any shape of the actuating members 55 as it would likely if the actuating members 55 were flexible rather than rigid. For example, if the actuating members 55 were flexible, and Schaffer’s stasis valve 10 was tilted when the actuator buttons 261 were actuated (e.g., without the actuator buttons 261 positioned to be depressed

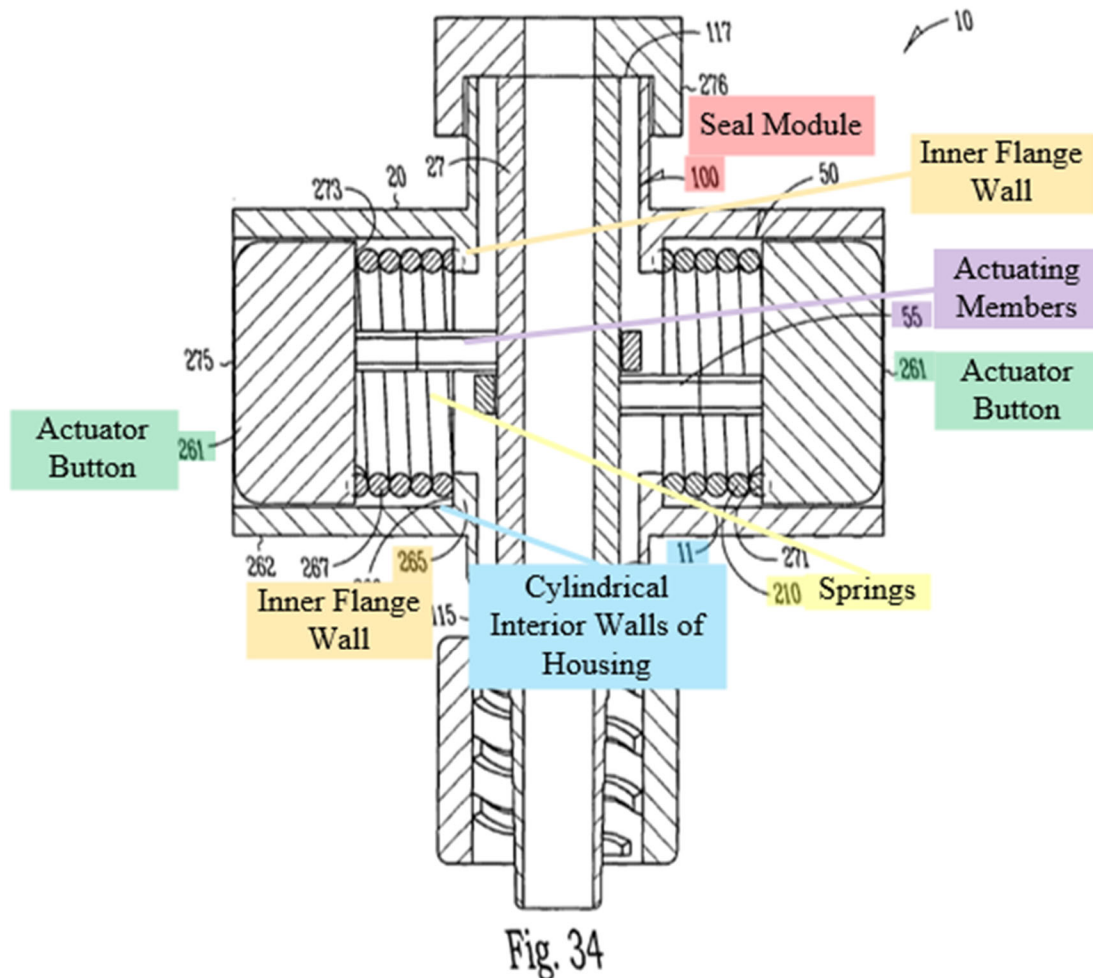
perpendicular to gravity), a POSITA would understand that the actuating members 55 could slide along the seal module 100 and be positioned at a non-orthogonal angle to the actuator buttons 55. In contrast, Figures 31-34 of Schaffer show that the actuating members 55 retain their shape and orientation in the first and second positions.

101. Third, Schaffer teaches and Petitioner highlights that “Schaffer’s actuating members [are] formed from aluminum or plastic.” Petition, p. 44; EX1005, ¶¶ [0081]-[0082]. Further, Schaffer provides that the actuating members 55 are “machined from aluminum” or “machined from plastic.” EX1005, ¶ [0082]. A POSITA would understand that these members are rigid and that machining is a manufacturing process in which the desired part (e.g., the U-shaped actuating members 55) is created using the controlled removal of a bulk material (e.g., plastic or metal), typically a rigid material. A POSITA would further understand that flexible parts, such as a thin and flexible filament, are difficult to machine conventionally, as flexible materials will deform when force is applied during the machining process—inhibiting or even preventing accurate manufacturing of the part.
102. Fourth, Schaffer discloses how its stasis valve is assembled, which necessitates rigid members that provide a space through which the seal module can be inserted:

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[T]he stasis valve 10 is assembled by inserting the actuator button 261 and resilient member 267 (e.g., spring 210) into one side of the housing 20. The actuator button 261 and resilient member 267 (e.g., spring 210) are inserted into an opposing side of the housing 20. Each actuator button 261 is completely compressed and held while the seal module 100 is inserted through the housing 20 and between each actuator 50. Each actuator button is released and the cap 276 secured to the housing 20, for example, with an adhesive. Further, the connecting member 35 is snapped onto the housing.

EX1005, ¶ [0083]. That is, a POSITA would understand that each of the actuator buttons 261 and the springs 210 are inserted into the cylindrical opening defined by a corresponding one of the cylindrical interior walls 11 of the housing 20 until the springs 210 abut the inner flange wall 265, then the actuator buttons 261 are depressed to form an opening through the U-shaped actuating members 55, and finally the seal module 100 is inserted through the opening:



103. A POSITA would understand that if the actuating members 55 were flexible rather than rigid, it would be much more difficult to assemble Schaffer's valve in the simple manner taught by Schaffer because the flexible actuating members would not provide a space through which the seal module 100 can be inserted. In particular, such flexible actuating members would be not tensioned (e.g., loose) when the actuator buttons 261 are compressed before the seal module 100 is inserted into Schaffer's valve such that they would not provide a uniform opening like the rigid actuating members 55 to permit

positioning of the seal module 100 therethrough. Accordingly, a POSITA would understand that Schaffer's actuating members 55 are rigid because, if they were not, it would render the actuating members 55 unsuitable for their intended purpose of simple manufacturability via insertion of the seal module 100 when the actuator buttons 261 are depressed. Further, the relaxed geometry of the proposed flexible actuating members 55 would be unpredictable and uncontrolled because of their flexibility—they would not hold their shape and could, for example, move or deflect along the seal module 100 in the relaxed open configuration.

104. In sum, a POSITA would understand based on Schaffer's description and illustration of the operation of the actuating members 55, its description of the materials and methods of forming the actuating members 55, as well as its description of how its stasis valve is assembled, that the actuating members 55 are rigid rather than flexible. As such, Schaffer's actuating members 55, either alone or in combination, are not a "filament" as recited in Claim 1 or Claim 10 of the '005 patent because they are not flexible. Therefore, Schaffer does not disclose this feature of Claim 1 or Claim 10.
105. As conceded by Petitioner, Garrison also does not disclose the claimed "filament." Therefore, the combination of Garrison and Schaffer does not disclose

the claimed “filament,” and thus the combination of Garrison and Schaffer does not render obvious Claim 1 or Claim 10.

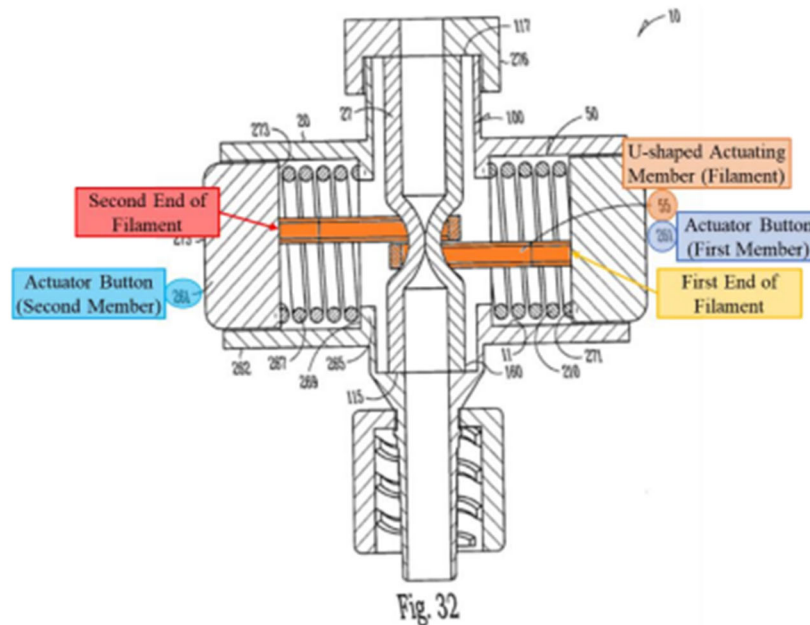
C. The Combination of Garrison and Schaffer Does Not Disclose the Properties of the Filament Recited in Claim 1 and Claim 10.

106. Petitioner also does not allege that Garrison discloses the properties of the “filament” of Claim 1 or Claim 10, and instead alleges that Schaffer discloses these claim features. Petition, pp. 36, 43-48. I agree with Petitioner that Garrison does not disclose these features, but disagree with Petitioner that Schaffer does.

1. Claim 1—Schaffer does not disclose a “filament” that “circumferentially constricts the lumen to create a seal.”

107. Even assuming Petitioner’s construction of “filament,” Garrison and Schaffer do not render obvious Claim 1 because Schaffer’s filament does not “circumferentially constrict[] the lumen to create a seal.” I understand that Petitioner argues that Schaffer’s valve circumferentially constricts the lumen when the actuator buttons move from the first position to the second position. Petition, p.41; EX1003, ¶ 111. In support of this, Petitioner cites a portion of Schaffer explaining that the actuating members are “at least partially circumferentially disposed about the portion 108 of the seal module 100...” Petition, p.42, citing EX1005, ¶ 77. But neither this portion nor any other portion of Schaffer discloses a filament that circumferentially constricts a lumen.

108. Schaffer discloses side-by-side (i.e., parallel) U-shaped members that do not interlock or overlap, as shown in Petitioner's own annotated Figure 32 from Schaffer:



Petition, p.48. Because Schaffer's two U-shaped members (1) extend only partially around the lumen, and (2) do not overlap, they cannot individually or even collectively form a circumference around the lumen. That is, nowhere along the length of Schaffer's lumen does a material fully encircle the lumen. And because Schaffer's U-shaped members do not individually or collectively form a "circumference," a POSITA would understand that Schaffer's U-shaped members cannot individually or collectively "circumferentially constrict" Schaffer's lumen. Instead, a POSITA would understand that Schaffer's

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U-shaped member exert a compressive force in two opposite directions, which does not result in the lumen being constricted around its circumference.

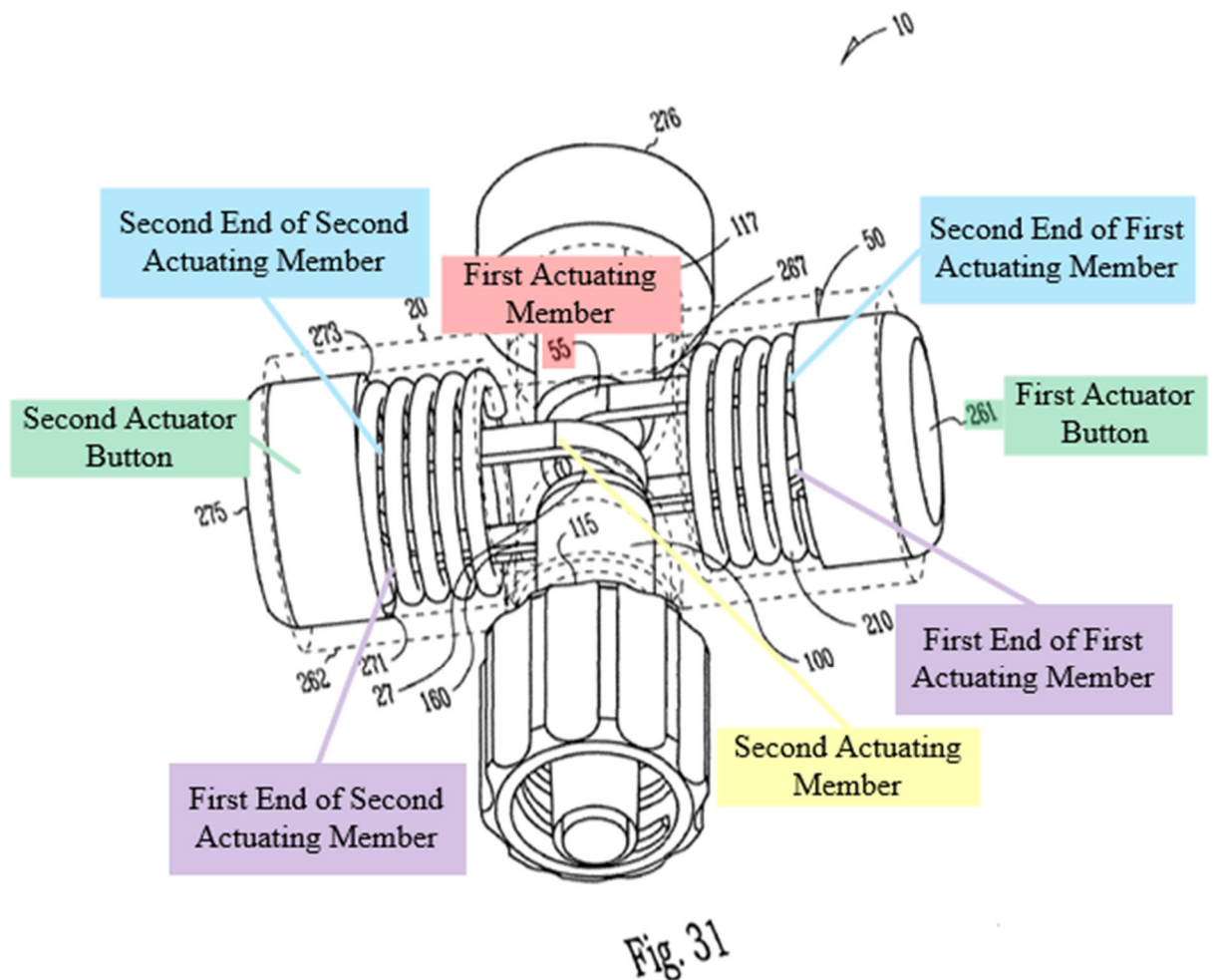
109. In sum, a POSITA would understand based on the specification and plain language of the '005 Patent that Claim 1 requires a filament to “circumferentially constrict[.]” Schaffer’s actuating members 55, alone or together, do not “circumferentially constrict[.]” and therefore, Schaffer does not disclose this feature of Claim 1. Schaffer’s actuating members create a “pinching” closure, not a circumferential constriction.
110. As conceded by Petitioner, Garrison also does not disclose this feature of Claim 1. Therefore, the combination of Garrison and Schaffer does not render obvious Claim 1.

2. Claim 1—Schaffer does not disclose the “filament” having two ends extending in different directions and coupled to different members of an actuator.

111. Even assuming Petitioner’s construction of “filament,” Garrison and Schaffer do not render obvious Claim 1 because Schaffer does not disclose the “filament comprising...a second portion having a first end extending from the first portion in one direction and a second end extending from the first portion in another direction” or an “actuator comprises a first member coupled to the first end of the filament and a second member coupled to the second end of the filament.” Petitioner does not allege that either of Schaffer’s actuating

members 55 has the claimed “first end portion” and “second end portion” but instead alleges that “Schaffer’s U-shaped actuating members collectively constitute the ‘filament’ claimed in the ’005 patent.” Petition, p. 45.

112. Indeed, Schaffer’s two actuating members 55 each have a first end and a second end that extend in the same direction and are both coupled to the same actuator button 261:



EX1005, ¶[0076]. That is, each end of the actuating members 55 identified by Petitioner extends in a same direction such that the actuating members 55

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do not include “a first end extending from the first portion in one direction and a second end extending from the first portion in another direction,” as recited in Claim 1. Likewise, Schaffer does not disclose “the actuator comprises a first member coupled to the first end of the filament and a second member coupled to the second end of the filament,” as recited in Claim 1. Instead, Schaffer discloses that both of the ends of each of the actuating members 55 are coupled to the same actuator button 261 (both ends coupled to the same first button/“first member” for the first U-shaped actuating member and the same second button/“second member” for the second U-shaped actuating member).

113. I disagree that “[t]hat Schaffer uses two separate actuating members is of no moment here,” as Petitioner and Mr. Thornton contend. Petition, p. 45. For example, as I explain in §V.A. above, a POSITA would understand Claim 1’s recitation of “the filament comprising ... a first end extending from the first portion in one direction and a second end extending from the first portion in another direction” to mean a single filament has the first end and the second end. That is, the claim language requires a singular element, “the filament,” that has the recited properties. In particular, as I explain in §V.A. above, the ’005 Patent recites that when the filament 150 comprises multiple individual filaments, each individual filament has a “first end” and a “second end” as

follows: “[i]n embodiments in which the filament 150 comprises multiple filaments, **each of the multiple filaments can have a first end 700 and a second end 702.**” EX1017, ¶ [0065] (emphasis added).

114. Petitioner’s reliance on an obvious typographical error in the ’519 Application to argue otherwise is contradicted by both the plain language of the claim and the express disclosure in the specification as I explain above in §V.A. In particular, a POSITA would understand that in Figure 8 each of the first and second filaments 150-A and 150-B have two ends—a first end (the first end 700) and a second end (the second end 702)—rather than two “first ends 700” or two “second ends 702” as relied on by Petitioner.
115. Accordingly, a POSITA would understand that Claim 1 requires a single filament having the “first end extending ... in one direction” and coupled to the first member and the “second end extending ... in another direction” and coupled to the second member. Schaffer’s U-shaped actuating members 55 each have first and second ends extending in the **same direction** and coupled to the **same** actuator button 261. Therefore, Schaffer does not disclose this feature of Claim 1.
116. As conceded by Petitioner, Garrison also does not disclose this feature of Claim 1. Therefore, the combination of Garrison and Schaffer does not render obvious Claim 1.

3. Claim 10—Schaffer does not disclose the “filament formed in a loop around the tubular sidewall.”

117. Even assuming Petitioner’s construction of “filament,” Garrison and Schaffer do not render obvious Claim 10 because Schaffer does not disclose a “filament formed in a loop around the tubular sidewall.” Petitioner does not allege that either of the actuating members 55 is “formed in a loop” but instead alleges that “Schaffer’s U-shaped actuating members collectively constitute the ‘filament’ claimed in the ’005 patent” and that “the actuating members collectively loop around the seal module 100.” Petition, pp. 45, 62-63, 82. Indeed, neither of Schaffer’s actuating members 55 are “formed in a loop” about the seal module 100 because they are rigid and U-shaped. EX1005, ¶ [0076].
118. Again, I disagree that “[t]hat Schaffer uses two separate actuating members is of no moment here,” as Petitioner and Mr. Thornton contend. Petition, p. 45. For example, as I explain in §V.A. above, the ’005 Patent discloses multiple different filament arrangements in Figures 6–9, and expressly distinguishes the bight embodiments from the loop embodiments. The term “loop” is only used to describe the embodiments shown in Figures 6 and 7—which respectively illustrate (i) an arrangement with one filament formed in a loop and (ii) an arrangement with two filaments in which each of the first filament and a second filament each form an individual loop:

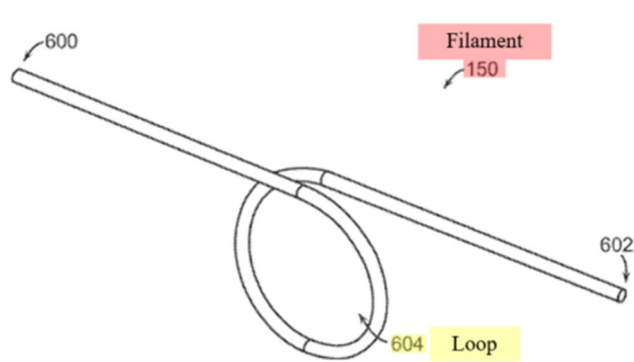


FIG. 6

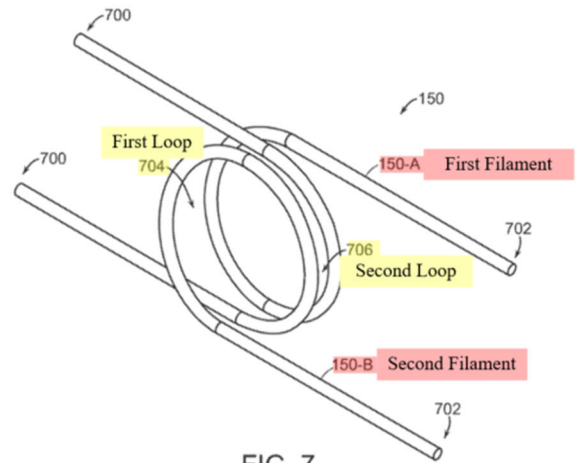


FIG. 7

EX1017, ¶¶ [0064]-[0065].

119. In contrast, Figures 8 and 9 of the '005 Patent illustrate a two-filament arrangement on which a first filament and a second filament each form an individual U-shaped bight:

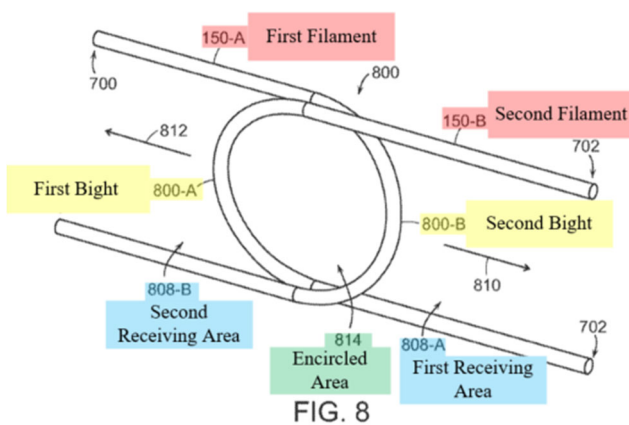


FIG. 8

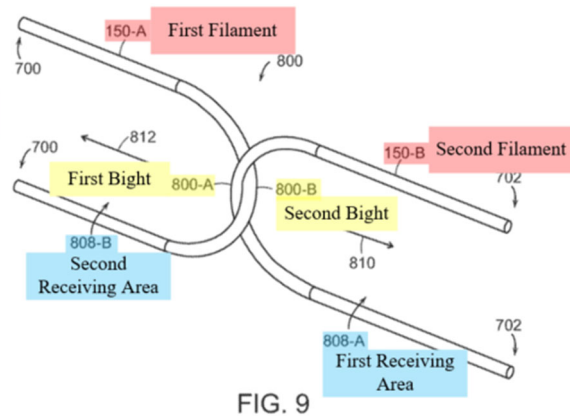
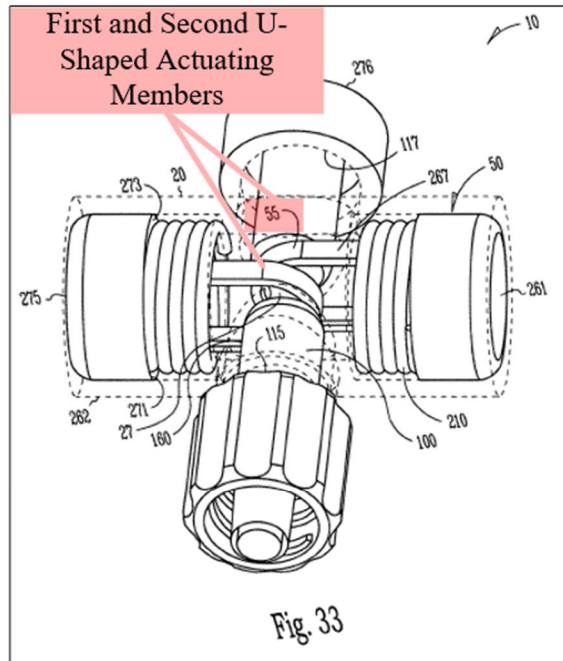


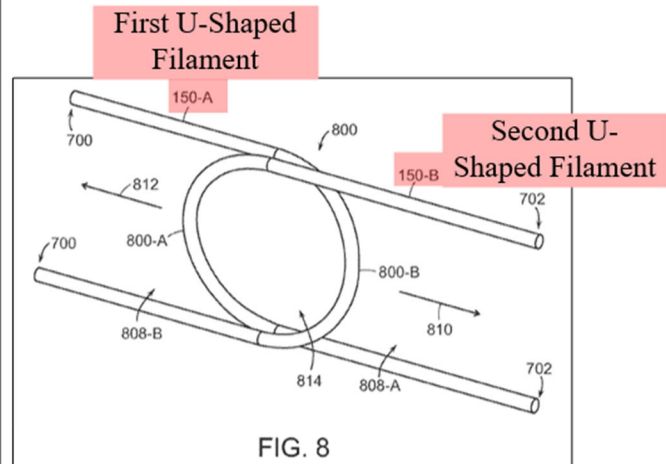
FIG. 9

In this arrangement of the filaments, the '005 Patent discloses that the filaments each define a partially enclosed receiving area 808-A, 808-B, and together the first and second receiving areas 808-A and 808-B overlap to define an encircled area 814. *Id.* at ¶¶ [0067]-[0068].

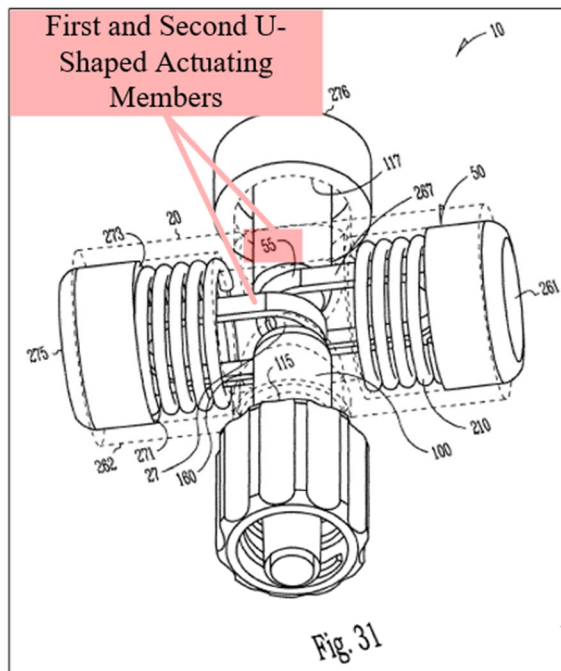
120. Accordingly, a POSITA would understand that, when the '005 Patent uses the term “loop,” the term refers to one or more filaments that are each individually formed in a loop, and not multiple U-shaped filaments that overlap as shown in Figures 8 and 9. Multiple filaments each arranged in a U-shaped bight could collectively define an “encircled area” as shown in Figures 8 and 9—but not a “loop.” Accordingly, a POSITA would understand that Claim 10 requires at least one individual filament that is itself “formed in a loop” and excludes multiple filaments—including U-shaped filaments—that collectively, but not individually, define an encircled or other area of overlap.
121. Accordingly, Petitioner’s reliance on Figure 8 of the '519 Application to allege that the “filament” of Claim 10 could comprise multiple filaments and thus that Schaffer’s U-shaped actuating members 55 could together comprise the “filament” is incorrect. Petition, pp. 45, 62-63, 82. The arrangement of Schaffer’s U-shaped actuating members 55 is similar to the embodiment shown in Figures 8 and 9 of the '005 Patent as illustrated in the comparison below:



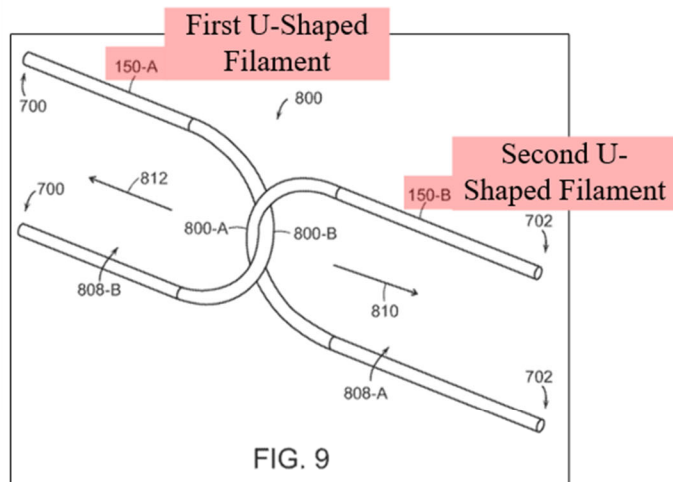
Schaffer's Valve 10 Opened



'519 Application Figure 8



Schaffer's Valve 10 Closed



'519 Application Figure 9

122. But, as I explain above, the '005 Patent does not disclose that the arrangement of multiple filaments in Figures 8 and 9 forms a "loop"—instead the bights

800-A, 800-B overlap to define an encircled area 814. The term “loop” is used only with reference to Figures 6 and 7 of the '012 Patent which each show one or multiple filaments each individually forming a loop. That is, a POSITA would understand that the bight embodiment of Figures 8 and 9 to be a distinct alternative to the loop embodiments of Figures 6 and 7.

123. In sum, a POSITA would understand based on the specification and plain language of the '005 Patent that Claim 10 requires a single filament “formed in a loop.” Both of Schaffer’s actuating members 55 are U-shaped and are therefore not “formed in a loop.” Accordingly, Schaffer does not disclose this feature of Claim 10.
124. As conceded by Petitioner, Garrison also does not disclose this feature of Claim 10. Therefore, the combination of Garrison and Schaffer does not render obvious Claim 10

4. Claim 10—Schaffer does not disclose the “diameter of the lumen decreases in response to reducing a diameter of the loop.”

125. Even assuming Petitioner’s construction of “filament,” Garrison and Schaffer do not render obvious Claim 10 for the additional reason that Schaffer does not disclose “a diameter of the lumen decreases in response to reducing a diameter of the loop.” As I explain above in §VI.C.3., neither of Schaffer’s two U-shaped actuating members 55 are “formed in a loop,” and the two actuating

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members 55 cannot together be construed as the “filament” of Claim 10. Accordingly, because Schaffer does not disclose a “filament formed in a loop,” Schaffer cannot disclose a “reducing a diameter of the loop.” Moreover, the shape and dimension of Schaffer’s actuating members 55 cannot reduce or otherwise change during operation of Schaffer’s valve 10 because the actuating members are rigid, as I explain above in §VI.B.

126. As conceded by Petitioner, Garrison also does not disclose this feature of Claim 10. Therefore, the combination of Garrison and Schaffer does not render obvious Claim 10.

D. A POSITA Would Not Have Found It Obvious to Have Modified Schaffer to Include the Filament as Claimed.

127. Petitioner alleges that “[e]ven if the Board concludes that Schaffer’s U-shaped actuating members do not ‘circumferentially constrict[] the lumen [of Schaffer’s valve] to create a seal’ as claimed in the ’005 Patent, a POSITA would have found it obvious to modify the U-shaped actuating members to closely conform to the seal module to circumferentially constrict the lumen.” Petition, pp. 48-49. I disagree.
128. As I explain in §§VI.B-C. above, Garrison and Schaffer do not disclose a single flexible filament having a “first end extending ... in one direction” and coupled to a first member and “second end extending ... in another direction” and coupled to a second member, as recited in Claim 1. Likewise, Garrison

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and Schaffer do not disclose a single flexible filament “formed into a loop” or “reducing a diameter” of that loop, as recited in Claim 10. Petitioner does not assert that it would have been obvious for a POSITA to have modified Schaffer such that one of the U-shaped actuating members 55 had (i) a first end extending in one direction and coupled to one of the actuator buttons 261 and (ii) a second end extending in another direction and coupled to the other one of the actuator buttons 261. Likewise, Petitioner does not assert that it would have been obvious for a POSITA to have modified Schaffer such that one of the U-shaped actuating members 55 is formed into a loop. Accordingly, because Garrison and Schaffer do not disclose the features of Claim 1 and Claim 10 listed above, and Petitioner does not contend that Garrison or Schaffer render such features obvious, Garrison and Schaffer do not render obvious Claim 1 or Claim 10.

129. Nor would it have been obvious to a POSITA to have modified Garrison and Schaffer to arrive at the foregoing features of Claim 1 and Claim 10. In particular, as I explain in detail in §VII. below, a POSITA would understand that Schaffer’s valve seals completely with or without instruments inserted therethrough and that any modification to make the U-shaped members flexible, coupled to separate one of the actuator buttons, and/or formed in a loop

would render Schaffer inoperable for its intended purposes of easy manufacturability, durability, and assembly.

VII. GROUNDS 2 AND 3—THE COMBINATION OF GARRISON, SCHAFFER, AND HARTLEY OR ELLER DOES NOT RENDER OBVIOUS ANY OF CLAIMS 1-15

130. Petitioner and its expert, Mr. Thornton, allege that Garrison in combination with Schaffer and Hartley or Eller renders obvious Claims 1-15 of the '005 patent. I disagree for the reasons I discuss in further detail in this section. A POSITA would not have been motivated to or found it obvious to have modified Garrison and Schaffer in view of Hartley or Eller to arrive at the features of Independent Claim 1 or Independent Claim 10. Therefore, the combinations of Garrison, Schaffer, and Hartley or Eller do not render obvious Claim 1 or Claim 10. And, because Claims 2-9 and 11-15 depend from one of Claims 1 or 10 and thus include all the features of one of these claims, those claims are also not rendered obvious by the combination of Garrison and Schaffer.

131. As I explained above, I understand that for a patent claim to be rendered obvious, the differences between the claimed invention and the prior art must be such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains, the claimed invention

is obvious. Even if all limitations of a claimed invention are disclosed by the prior art combination, Petitioner must demonstrate an apparent reason to combine the known elements in the fashion of the patent claim at issue and that a person of ordinary skill in the art would have reasonable expectation of success in pursuing that combination. A prior art reference teaches away from a modification of a prior art reference when a person of ordinary skill in the art would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path followed by and claimed in the patent.

132. Petitioner argues that “POSITAs would have found it obvious to substitute Hartley’s string [or Eller’s wire member] for Schaffer’s actuating members.” Petition, pp. 49-60.

133. I disagree that it would have been obvious to have, or that a POSITA would have, substituted Hartley’s string or Eller’s wire member for Schaffer’s U-shaped actuating members 55 for at least the reasons set forth below.

A. Petitioner’s Stated Motivations to Modify Schaffer in View of Hartley or Eller Are Based on an Incorrect Understanding of the Sealing Mechanism of Schaffer Which Is Designed to Eliminate Gaps With or Without Instruments Inserted Through the Valve.

134. A POSITA would not have been motivated to modify Schaffer to substitute Hartley’s string or Eller’s Wire for Schaffer’s U-shaped actuating members as in Petitioner’s proposed combination because Schaffer expressly discloses

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and illustrates the ability of its valve to seal completely across a wide range of instruments. Specifically, I disagree with Petitioner's stated motivation to modify Schaffer in view of Hartley ("POSITAs 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") or Eller ("POSITAs would have recognized that Eller's wire may seal more effectively across more device diameters than Schaffer's actuating members"). Petition pp. 51, 57, 82.

135. I also disagree with Petitioners assertion that "Schaffer's actuating members may form small gaps between the valve's seal module and the tool's outer surface" as purportedly shown by Mr. Thornton's simple graphic. *Id.* at 51. Petitioner's assertions that Hartley's string or Eller's wire member "would not suffer from [the potential formation of small gaps] because the string more precisely conforms to the tool diameters" is based on an incorrect understanding of Schaffer, and more specifically, Schaffer's sealing member 165. *Id.*; EX1003, ¶ 138. A POSITA would understand that small gaps would not form in Schaffer's valve.
136. In short, Schaffer contradicts Petitioner's purported motivations to have substituted Hartley's string or Eller's wire member for Schaffer's U-shaped actuating members. Schaffer recites that "**existing devices** do not perform a

complete seal against leakage **in the presence of a wide range of instruments** or in the presence of multiple instruments.” EX1005, ¶ [0006] (emphasis added). Schaffer continues that its valve addresses this issue of prior valves, specifically via “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.**” *Id.* at ¶ [0008] (emphasis added). Based at least on this disclosure of Schaffer, a POSITA would understand that Schaffer’s valve is explicitly designed to—and does—seal effectively and completely (i.e., without gaps) in the presence of a wide range of different instruments, or without any instruments inserted therethrough.

137. Schaffer expressly discloses and illustrates the ability of its valve to seal completely across a wide range of instruments using a third central seal member 165 that is included in every embodiment of Schaffer—including the embodiment of Figures 30-34—as I explain above in §V.C.2. For example, Schaffer discloses with respect to Figures 30-34 that the “seal module 100 is formed of one or more seal members, as discussed above” with reference to Figures 1-29 and that (i) in the first sealed position of the valve 10 the “lumen 193 of the third seal member 165 is at least partially collapsed by the compressive force 67” and (ii) in the second unsealed position of the valve 10 the “lumen 193 of the third seal member 165 is able to retract in an unsealed

configuration.” EX1005, ¶¶ [0075], [0077]. Therefore, Schaffer is clear that the embodiment of Figures 30-34 includes the seal member 165.

138. Schaffer discloses how the third central seal member 165 completely seals, without gaps, around a variety of instruments with reference to Figures 16-19: “the highly compliant third central seal member 165 seals **around a variety of profile shapes 192 and diameters 194 of the lumen 193** when at least one side of compressive force 67 is exerted upon the central region 195 with respect to the central portion 110 of the containment structure 160”:

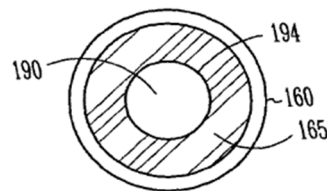


Fig. 16

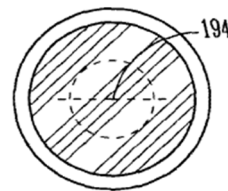


Fig. 17

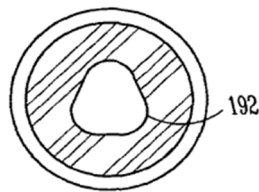


Fig. 18

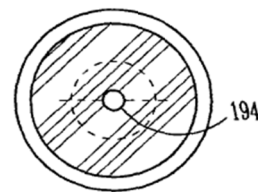


Fig. 19

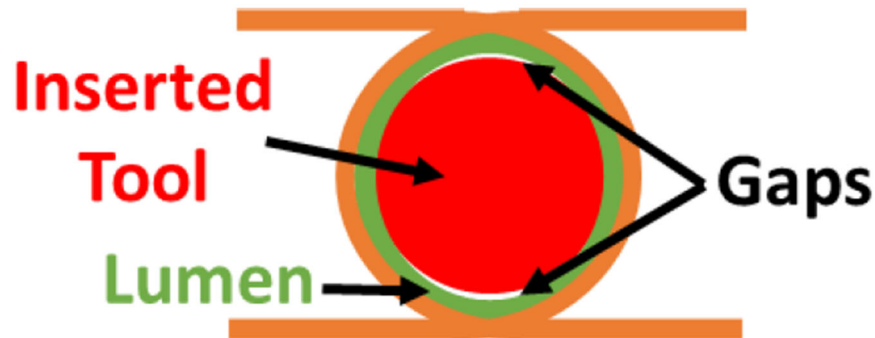
Id. at ¶ [0060] (emphasis added). The “material 166 of the third central seal member 165 is so compliant that it forms a seal around [multiple instruments

260 [inserted therethrough] even if the instruments 260 are irregularly shaped.” *Id.* at ¶ [0068]. The same materials are used for the third seal member in the embodiment shown in Figures 30-34. *Compare* EX1005, ¶[0059] with ¶[0081]

139. A POSITA would understand based on the foregoing disclosure of Schaffer that the third central seal member 165—including in the embodiment of Figures 30-34 along with every other embodiment of Schaffer—completely seals without gaps “around a variety of profile shapes 192 and diameters 194 of the lumen 193” of the third seal member 165 due to, for example, the highly compliant nature of the seal member 165. *Id.* at ¶ [0060]. For example, a POSITA would understand Figure 16 of Schaffer to show the seal member 165 sealing without gaps around a large circular lumen 193, Figure 17 to show the seal member 165 in a sealed state with the lumen 193 completely closed (e.g., without an instrument inserted through the lumen 194), Figure 18 to show the seal member 165 sealing around an irregularly shaped lumen 193, and Figure 19 to show the seal member 165 sealing around a small circular lumen 193.
140. I understand that in an IPR in related U.S. Patent No. 11,697,011, Petitioner’s expert Mr. Thornton stated at deposition that there would be no need to modify Schaffer’s U-shaped actuating members if Schaffer forms a complete seal around various instruments. EX2029, 116:18-117:2. (“If it worked perfectly

for all the range of tools, then there probably wouldn't be a need to make adjustments and move to a string-type member.") I agree. And, as I explained above, Schaffer's valve does just that—seal around all the range of tools.

141. Accordingly, a POSITA would not have been motivated to modify Schaffer or to have substituted Hartley's string or Eller's wire member for Schaffer's U-shaped actuating members to form a better seal and avoid the potential formation of gaps because Schaffer expressly discloses and illustrates that its valve performs both of these functions. Mr. Thornton's figure showing purported gaps is based on an incorrect understanding of Schaffer, and more specifically, the function of the seal member 165.



Petition, p. 51. As described above, Schaffer expressly discloses that the seal module 100 including the seal member 165 completely seals around a variety of profile shapes and diameters of the lumen, around small instruments, around large instruments, in the absence of instruments, and even around irregularly shaped instruments:

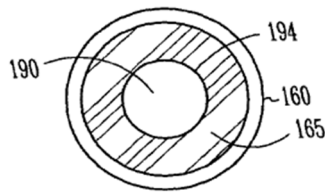


Fig. 16

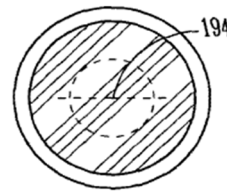


Fig. 17

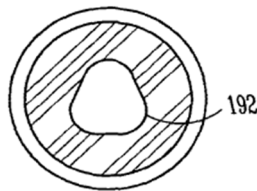


Fig. 18

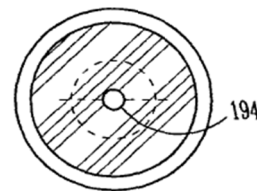


Fig. 19

It does so via compression of the highly-compliant seal member 165 with the rigid actuating members 55.

142. The Petition largely ignores Schaffer's disclosure that its valve would completely seal, specifically how its rigid actuating members 55 operate in conjunction with the seal member 165 to form a complete seal around instruments of different shapes. Petitioner does argue that Patent Owner's similar arguments in the related IPR regarding U.S. Patent No. 11,697,011 that "Schaffer's valve would not create gaps" is not supported by "the portions of Schaffer cited by" Patent Owner. Petition, pp. 51-52. However, as I explain above and in §V.C.2, Schaffer discloses that the seal member 165 is included in

every embodiment, including the embodiment of Figures 30-34. *See*, e.g., EX1005, ¶¶ [0075], [0077] (Schaffer provides with respect to Figures 30-34 that the “seal module 100 is formed of one or more seal members, as discussed above” and that (i) in the first sealed position of the valve 10 the “lumen 193 of the third seal member 165 is at least partially collapsed by the compressive force 67” and (ii) in the second unsealed position of the valve 10 the “lumen 193 of the third seal member 165 is able to retract in an unsealed configuration.”). Likewise, Schaffer discloses that in **every embodiment** the seal member 165 is highly compliant to effect a seal around tools of different shapes. *See*, e.g., *id.* at ¶ [0057] (“[t]low friction nature of the first and second seal members 170, 180 is in contrast to the highly deformable and compliant nature of the third central seal member 165”), ¶ [0160] (“the highly compliant third central seal member 165 seals around a variety of profile shapes 192 and diameters 194 of the lumen 193 when at least one side of compressive force 67 is exerted upon the central region 195”), ¶ [0068] (“[t]he material 166 of the third central seal member 165 is so compliant that it forms a seal around the instruments 260 even if the instruments 260 are irregularly shaped”).

143. I understand that in the Institution Decision, the Board stated that Schaffer’s disclosure of the “use of certain materials for portions of a seal module that provide ‘a nearly fluid/gas tight seal’ and ‘exhibit[] a ‘selfclosing’ nature,’ ...

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concern only *some embodiments*, using *optional* features” and that the “valve of Schaffer’s Figures 30–34 does not require a seal module that includes the above-described optional third seal member with an extremely compliant, soft, gelatinous, self-closing material.” Institution Decision, pp. 38-39. Petitioner’s expert, Mr. Thornton, similarly contends that “[n]othing in Schaffer suggests that the third valve portion must be made with a ‘sticky’ or ‘gelatinous’ substance” because paragraph [0059] of Schaffer discloses “many other materials that would not be ‘sticky’ or ‘gelatinous’ that could make up that same portion of the valve.” EX1003, ¶ 124. Regardless of whether the sticky, gelatinous, and self-closing material is optional, and as I explain above, Schaffer’s Figures 30-34 **do require** the third seal member 165 that is highly compliant to effect sealing under compression. That is, even if Schaffer discloses embodiments of the third seal member 165 that are not “sticky” or “self-closing,” the seal member 165 nevertheless effects a complete seal without gaps due to its highly-compliant nature. In other words, every embodiment disclosed by Schaffer can effect a complete seal by virtue of the third seal member 165, regardless of whether the third seal member 165 is “sticky” or “gelatinous.”

144. In order for Schaffer’s valve to form the gaps as alleged by the Petitioner and its expert, a POSITA would have to first **modify** Schaffer’s valve to **remove**

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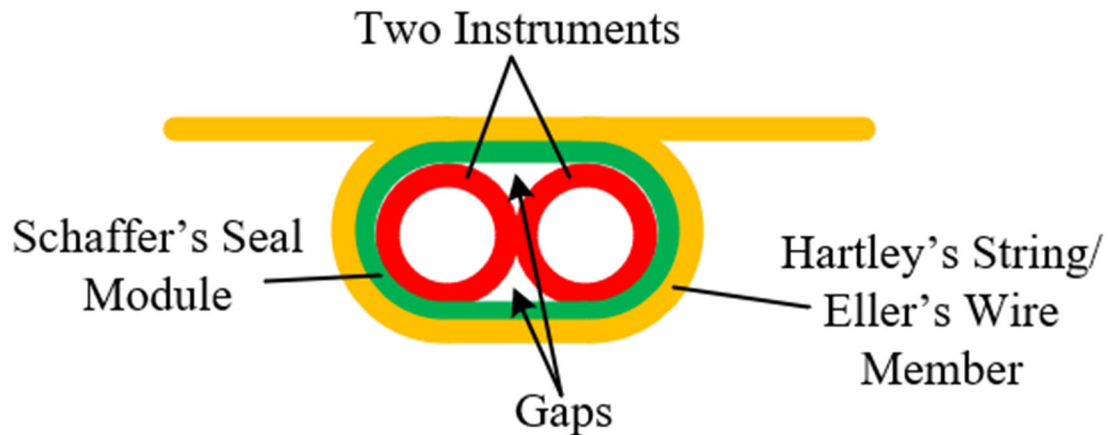
the third seal member 165, because as I explained above the presence of the third seal member 165 effects a complete seal. But a POSITA would not have any reason to remove the third seal member 165 because its presence achieves Schaffer's goals of creating a "stasis valve that blocks the flow of gas or fluid completely and immediately with or without an instrument in place" and forming a "complete seal against leakage in the presence of a wide range of instruments or in the presence of multiple instruments." EX1005, ¶¶[0006], [0008].

145. Further, even assuming that (a) Schaffer discloses using materials that are not sticky or self-closing, and (b) the absence of a such a sticky or self-closing material would create gaps (which I disagree agree with for the reasons explained above), neither Petitioner nor its expert Mr. Thornton explain why a POSITA would have substituted Hartley's string or Eller's wire member for Schaffer's U-shaped members rather than simply use the specific sticky and self-closing material taught by Schaffer. As I explain below in §VII.C., unlike using the specific material taught by Schaffer or adjusting other simple properties of Schaffer's valve (e.g., spring strength), using Hartley's string or Eller's wire member with Schaffer's valve would not be a simple substitution. Further, as I explain below in §§VII.D-E., such a modification would greatly hinder the durability and ease of manufacturing of Schaffer's valve and likely

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render Schaffer's valve inoperable. Thus, in this scenario, a POSITA would have been motivated to use the sticky and self-closing material taught by Schaffer—which Schaffer expressly discloses can provide a complete seal around a wide variety of instruments—rather than completely redesign Schaffer's valve in view of Hartley or Eller.

146. Moreover, Petitioner's proposed combination could actually seal less effectively (and would not seal any more effectively than Petitioner's allegedly defective Schaffer valve without the seal member 165) around multiple instruments inserted through Schaffer's valve and/or when an instrument is irregularly shaped—scenarios for which Schaffer's valve is specifically designed to form a seal as I explain above. For example, if two circular instruments were inserted side-by-side through Schaffer's seal module, Hartley's string or Eller's wire member in Petitioner's combination (which removes the sealing properties of Schaffer's seal member 165 in order to manufacture a motivation to substitute Hartley or Eller) would be unable to seal the space (e.g., gaps/divots) between the instruments in Petitioner's combination as I demonstrate below:



Thus, a POSITA would not have had a reasonable expectation of success at achieving Schaffer's goal—"a durable stasis valve that blocks the flow of gas or fluid completely and immediately with or without an instrument in place," including **"in the presence of a wide range of instruments or in the presence of multiple instruments"**—by modifying Schaffer's valve to include Hartley's string or Eller's wire member. EX1005, ¶¶ [0006] and [0008] (emphasis added). In contrast, Schaffer's sealing member 165 is designed to seal when multiple instruments are inserted through the valve, and thus a POSITA would have reasonably expected Schaffer's disclosed designs to achieve this goal. EX1005, ¶ [0068]. A POSITA would have simply utilized Schaffer's design including the seal member 165 to prevent gaps.

147. For the foregoing reasons, Petitioner's assertion that a POSITA would have been motivated to substitute Hartley's string or Eller's wire member for Schaffer's U-shaped actuating members to seal more effectively and avoid the

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formation of small gaps is contradicted by Schaffer. Schaffer discloses a valve that addresses the then-existing need for complete sealing around a variety of instruments and specifically describes how the valve is configured to achieve such complete sealing by compression of the highly-compliant seal member 165 included in every embodiment of Schaffer. There was no need to change the sealing mechanism in Schaffer based on Schaffer's disclosure. Schaffer's structure is not deficient and would not leave gaps in the seal.

148. Mr. Thornton provides additional reasons why it would have been obvious to a POSITA to have substituted Harley's string or Eller's wire member for Schaffer's U-shaped actuating members in paragraph 124 of his declaration. EX1003, ¶ 124. I disagree with those reasons.
149. First, Mr. Thornton alleges that "Hartley's flexible string may better conform to varying diameters or shapes of tools inserted into the valve than Schaffer's U-shaped actuating members." *Id.* But, again, Schaffer's highly-compliant seal member 165 is specifically designed to conform to varying diameters and shapes of tools as shown in Figures 16-19. A POSITA would understand that there is simply not a need for the actuating members 55 to conform to a tool—and would not have so modified the actuating members—because the seal member 165 effectively conforms to the shapes of various tools to seal.

150. Second, Mr. Thornton attempts to support his argument that it would have been obvious to substitute Hartley's string or Eller's wire member for Schaffer's U-shaped actuating members to "seal more effectively" by stating that "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'" in paragraph [0059] of Schaffer. *Id.* (emphasis in original). However, Mr. Thornton's analysis of Schaffer's disclosure omits the remainder of the citation which concludes that the "material 166 exhibits a 'selfclosing' nature in that it sticks occlusively to itself forming a nearly fluid/gas tight seal **under very light compression.**" EX1005, ¶ [0059] (emphasis added). A POSITA would understand that the material 166 of the seal module 100 can form a nearly fluid/gas tight seal under very light compression, but would also understand that the compressive force 67 provided by the rigid actuating members 55 and springs 210 of Schaffer's valve 10 shown in Figures 31–34 would provide sufficient compression to the seal module 100, effecting a complete fluid/gas tight seal. *Id.* at ¶ [0077]. Indeed, as I explained in detail above, Schaffer expressly discloses that the purpose of the valve 10 is to "block[] the flow of gas or fluid **completely** and immediately with or without an instrument in place within the gas/fluid path." *Id.* at ¶ [0008].

151. Third, Mr. Thornton alleges that “Schaffer makes clear that the valves in Figures 31-34 do not require the third portion stating: ‘The seal module 100 is formed of one or more seal members, as discussed above’” in paragraph [0075] of Schaffer. EX1003, ¶ 124. As I explain above in §V.C.2., every embodiment of Schaffer does require the third seal member 165. Indeed, Mr. Thornton’s conclusion ignores that Schaffer expressly discusses the third central seal member 165 in combination with Figures 31-34 at, for example, paragraph [0081]. EX1005, ¶ [0081]. Accordingly, a POSITA would understand that seal module 100 in Figures 31-34 of Schaffer includes the third seal member 165 as I describe in detail above.
152. Fourth, Mr. Thornton alleges that “a person of ordinary skill in the art would have recognized that the ‘sticky’ or ‘gelatinous’ materials would not work well with the seal modules disclosed in Figures 31-34 because those seal modules must ‘retract to an uncollapsed configuration’ when the tension on the module is released by the actuating members ... [a] seal module made of the ‘sticky’ or ‘gelatinous’ materials would not easily return to its uncollapsed configuration.” EX1003, ¶ 124. To the contrary, a POSITA would understand Schaffer’s U-shaped actuating members 55 to be rigid such that they “**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.” EX1005, ¶ [0077] (emphasis added). That is, the seal module 100 can open with any of the disclosed materials because the actuating member 55 disengage the seal module 100 to remove all compressive force.

B. Petitioner and Its Expert Assert that Schaffer’s Valve Forms a Complete Seal and Prevents Leaks, Even When Instruments are Inserted Therethrough.

153. As I explain in detail above in §VII.A., Schaffer discloses that its valve seals completely with or without instruments inserted therethrough such that no gaps would form, and details the specific mechanisms and properties of its seal module that enable such complete sealing. Petitioner and its expert, Mr. Thornton, nevertheless assert that a POSITA would have been motivated to substitute Schaffer’s U-shaped actuating members with Hartley’s string or Eller’s wire member to “seal more effectively” and avoid the formation of small gaps.” Petition, pp. 51 and 57. Not only is this incorrect as I explain above, Petitioner and its expert concede at other times that Schaffer’s valve forms a complete seal—even when instruments are inserted therethrough—contradicting Petitioner’s stated reason to modify Schaffer.
154. For example, when describing why a POSITA would use Schaffer’s valve in Garrison’s system, Mr. Thornton states:

Second, Schaffer discloses that its hemostasis valve is intended “for use with catheters” and provides “a durable stasis valve that

blocks the flow of gas or fluid completely and immediately **with or without an instrument in place** within the gas/fluid path.” Ex. 1005 (Schaffer) at [0002], [0008]. Accordingly, **a person of ordinary skill in the art would have understood that Schaffer’s valve would perform the stated function of the “hemostasis valve”** in Garrison’s system—to “allow for the introduction of devices therein while **preventing** or minimizing blood loss via the internal lumen during the procedure.” Ex. 1011 (Garrison) at [0062].

EX1003, ¶ 96 (emphasis added). Mr. Thornton continues that:

A person of ordinary skill in the art would have reasonably expected that Schaffer’s valve would allow the tools in Garrison’s system, such as the catheter 2030 or a smaller catheter through catheter 2030, to pass through the valve into the patient’s vasculature **while also preventing blood from leaking around those tools.**”

Id. at ¶ [0101] (emphasis added). Accordingly, Mr. Thornton acknowledges, at least when it suits him, that Schaffer discloses that its valve completely seals with or without an instrument in place, and then goes on to state that a POSITA would have expected that Schaffer’s valve could be used to prevent leaks around an instrument (a catheter smaller than the catheter 2030) inserted through the valve. This is completely contrary to Mr. Thornton’s and Petitioner’s stated motivations for substituting Schaffer’s U-shaped actuating

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- members with Hartley's string or Eller's wire member to "seal more effectively" and avoid the formation of small gaps. If a POSITA would have expected that Schaffer's valve would prevent leaks around a catheter inserted through the valve, a POSITA would **not** have understood that Schaffer's valve sealed ineffectively or that small gaps (i.e., leak paths) would form (Petitioner's stated motivation to combine Hartley or Eller with Schaffer). That is, Petitioner's stated motivations including the formation of "gaps" and ineffective sealing are contradicted by Mr. Thornton's statements that Schaffer's valve **prevents** leaks (i.e., gaps) when a catheter is inserted through the valve.
155. Likewise, Petitioner states "the purpose of Schaffer's valve is to prevent leaks when a catheter is inserted into a patient" (Petition, p. 75) and that Schaffer "discloses that its valve prevents leakage across 'a range of instruments,' such as 'a catheter, guidewire, needle, or fiber'" (Petition, p. 72; *see also* EX1003, ¶¶ 166 & 178). Again, a POSITA would have understood Schaffer's valve to prevent leaks around an instrument inserted through the valve, so a POSITA would not have understood that small gaps (i.e., leak paths) would form (Petitioner's stated motivation to combine Hartley or Eller with Schaffer).
156. Similarly, when describing why a POSITA would use Schaffer's valve in Garrison's system, Petitioner states:

Schaffer discloses that its hemostasis valve is "for use with catheters" and "**blocks the flow of gas or fluid completely** and

immediately with or without an instrument in place within the gas/fluid path.” (Ex. 1005, [002], [0008], [0047], [0049].) Schaffer further discloses that a range of instruments can be used within the valve such as “a catheter, guidewire, needle, or fiber,” (*Id.*, [0056], [0074].) Thus, Schaffer’s valve performs the stated function of Garrison’s “hemostasis valve”—to **“allow introduction of devices...while preventing or minimizing blood loss during the procedure.** For this added reason, a POSITA would have been motivated to combine, and reasonably expected success in combining, Schaffer’s valve with Garrison.”

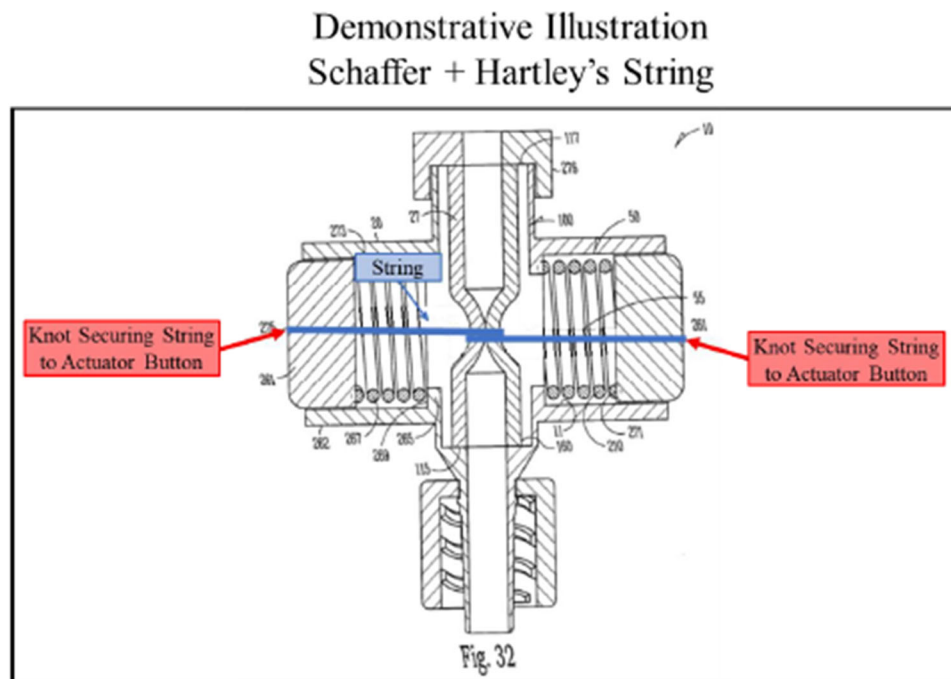
Petition, p. 36 (emphasis added). Accordingly, Petitioner acknowledges that Schaffer discloses that its valve completely seals with or without an instrument in place to prevent blood loss. This is completely contrary to Petitioner’s stated motivations for substituting Schaffer’s U-shaped actuating members with Hartley’s string or Eller’s wire member to “seal more effectively” and avoid the formation of small gaps.” That is, Petitioner’s stated motivations are contradicted by its own and Mr. Thornton’s statements that Schaffer’s valve blocks the flow of gas or fluid completely and forms a seal about a catheter inserted through the valve.

C. Petitioner’s Proposed Substitution of Hartley’s String or Eller’s Wire Member for Schaffer’s U-Shaped Actuating Members is Not a Simple Substitution of One Known Element for Another.

157. A POSITA would not have found it obvious to have substituted Hartley’s string or Eller’s wire member for Schaffer’s U-shaped actuating members because neither Schaffer, Hartley, nor Eller disclose a “filament” connected at opposite ends to two actuators as proposed in Petitioner’s combination. That

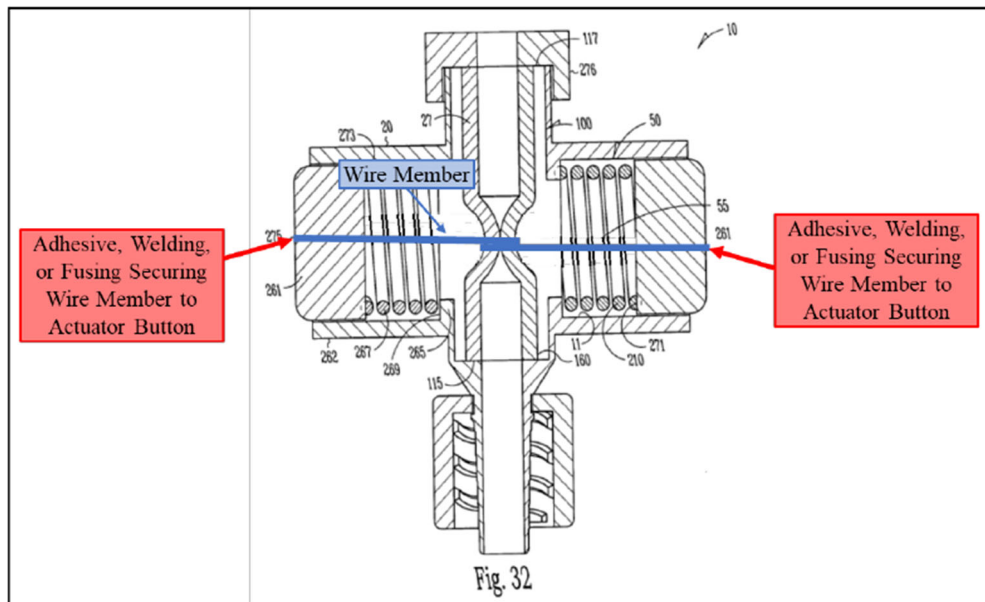
is, Petitioner's proposed combinations do not involve the substitution of a known element for another but, instead, a new construction that differs from the arrangements taught by Schaffer, Hartley, and Eller.

158. Petitioner contends that in its proposed combination the first end of Hartley's string would be secured to Schaffer's first actuator button, Hartley's string would wrap around Schaffer's seal module, and the second end of Hartley's string would be secured to Schaffer's second actuator button. Petition, pp. 52-56. Petitioner provides the following demonstrative illustration to illustrate the proposed substitution:



Id. at p. 53. Petitioner's proposed combination of Schaffer and Eller identically positions Eller's wire member to be attached at opposite ends to both actuator buttons of Schaffer and to loop around Schaffer's seal module:

Demonstrative Illustration
Schaffer + Eller's Wire Member



Id. at p. 58.

159. Accordingly, Petitioner's proposed substitution requires eliminating the two U-shaped actuating members of Schaffer and replacing them with a single actuating member (Hartley's string or Eller's wire member) and attaching opposite ends of Hartley's string or Eller's wire member to the two different actuator buttons 261 of Schaffer. But neither Schaffer, Hartley, nor Eller disclose such an arrangement.
160. For example, in Schaffer each of the actuating members 55 is attached to only one of the actuator buttons 261 such that movement of a single one of the actuator buttons 261 controls movement of a single one of the actuating members 55:

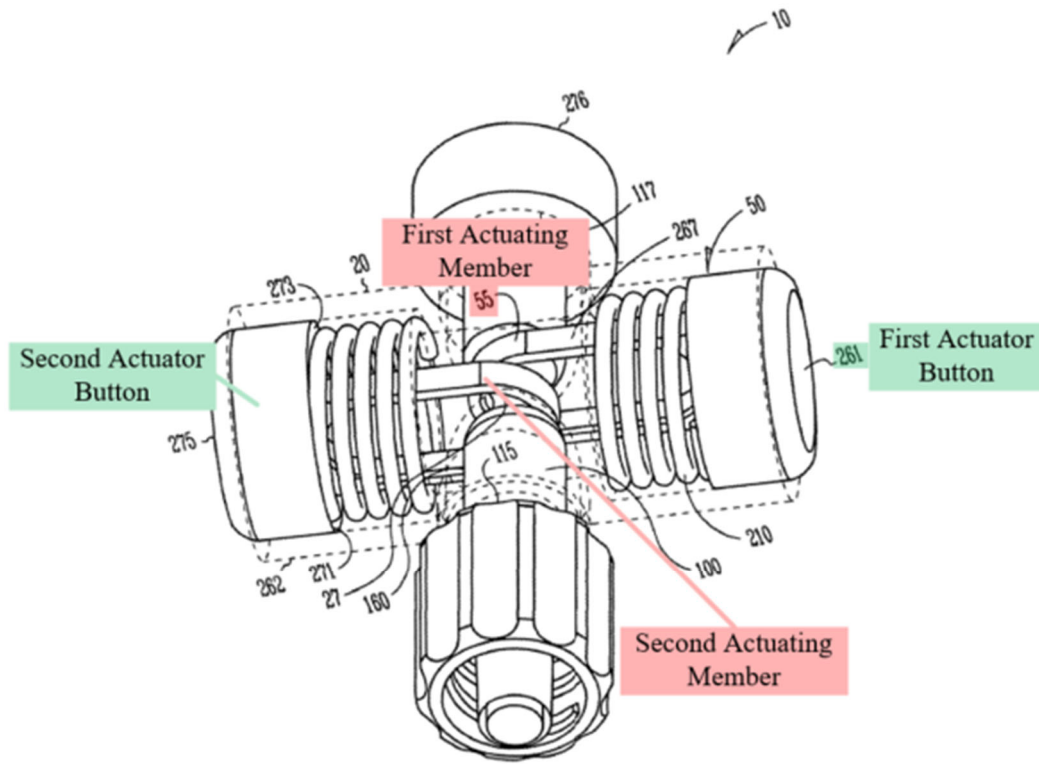


Fig. 31

If Schaffer's valve would not function if a single one of its actuating members were coupled to both actuator buttons 261, because the rigidity of Schaffer's actuating members would prevent movement of the actuator buttons 261, and thus prevent loosening or tightening of the valve.

161. Hartley discloses an access valve having a string 14 extending around a cylindrical elastomeric diaphragm 8 and attached by knots 16 and 18 at each end to a **single** rotary actuator 12 that controls movement of both ends of the string 14:

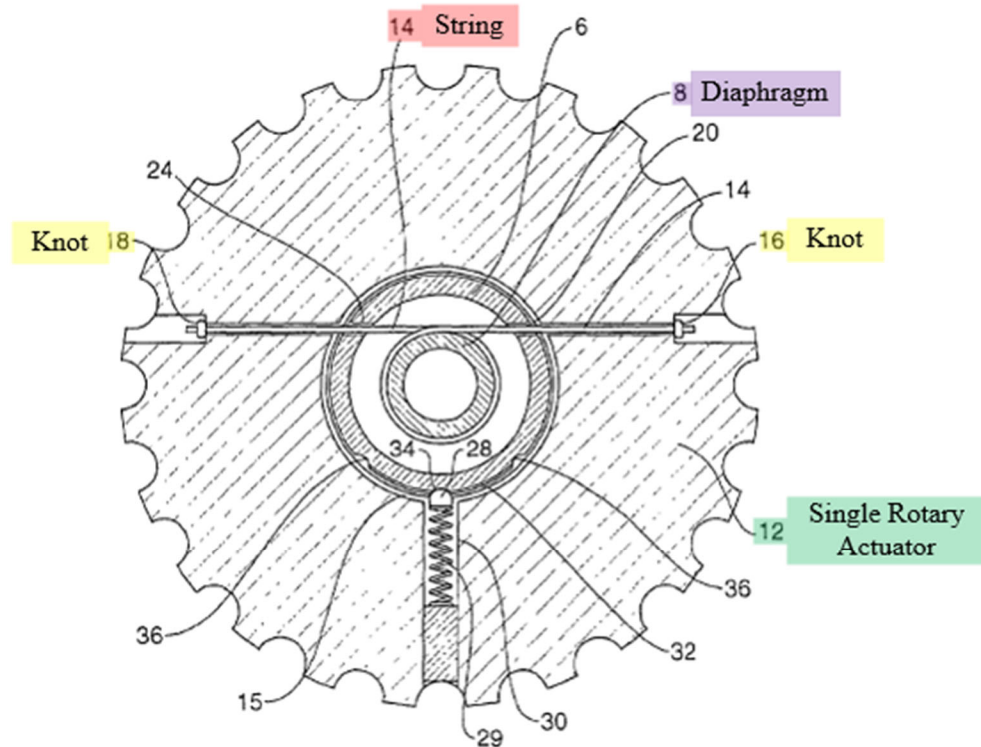


Fig 3

EX1006, ¶ [0031]. Rotation of the rotary actuator 12 pulls each end of the string 14 precisely the same amount. That is, movement of the string 14 is precisely controlled by the rotary actuator 12 such that the string 14 moves a predictable amount with movement of the actuator 12—neither end of the string 14 can move without the exact same and equal movement of the other end of the string 14.

162. Figures 1-10C of Eller illustrate a “selective fluid barrier valve device 10 that has ... 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:”

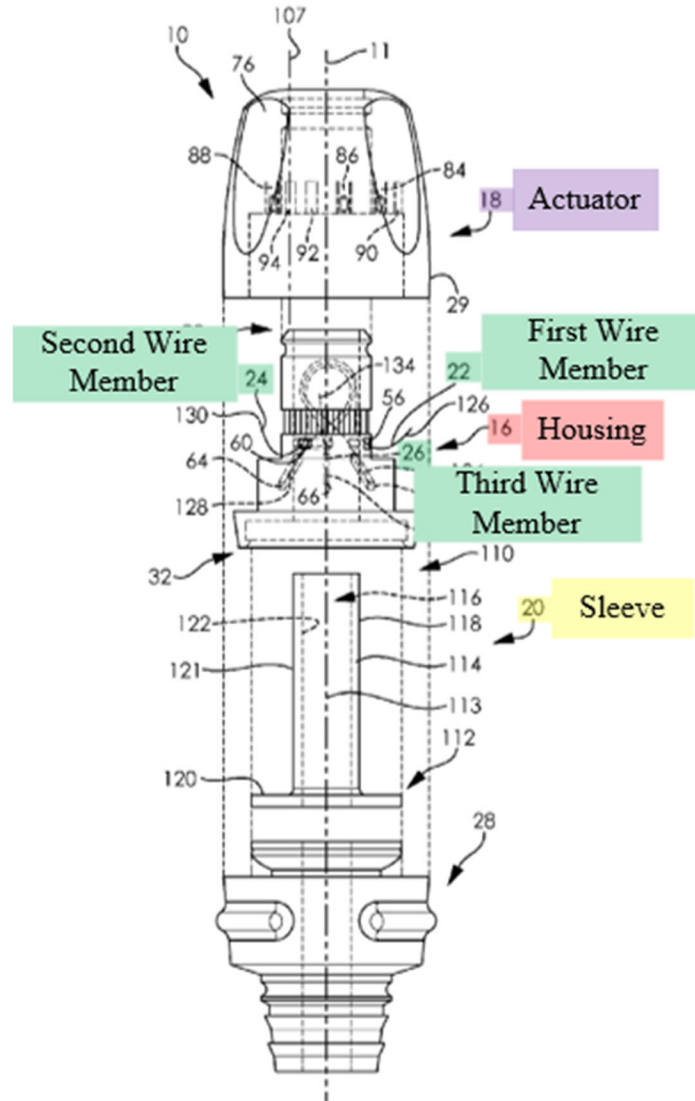


FIG. 2

EX1007, 5:2-6. As conceded by Petitioner, the “wire member has a first end 124 attached to the housing 16 and a second end 126 attached to the actuator 18.” Petition, p. 48; EX1007:12:52-58. The second wire member 24 and the third wire member 26 likewise have a first end attaching to the housing 16 and a second end attached to the actuator 18. EX1007, 12:21-14:27. Rotation of the actuator 18 acts to pull the second end of each the first, second, and third

wire members 22, 24, and 26 to tension the wire members to compress the sleeve 20. *Id.* at 15:21-40 & 17:38-18:8.

163. Similarly, Figures 20-22 of Eller illustrate a selective fluid barrier device 810 including a housing 816, an actuator 818, a sleeve 820, and a single first wire member 822 having “a first end 924 attached to the housing 816 ... and a second end 926 attached to the actuator 818”:

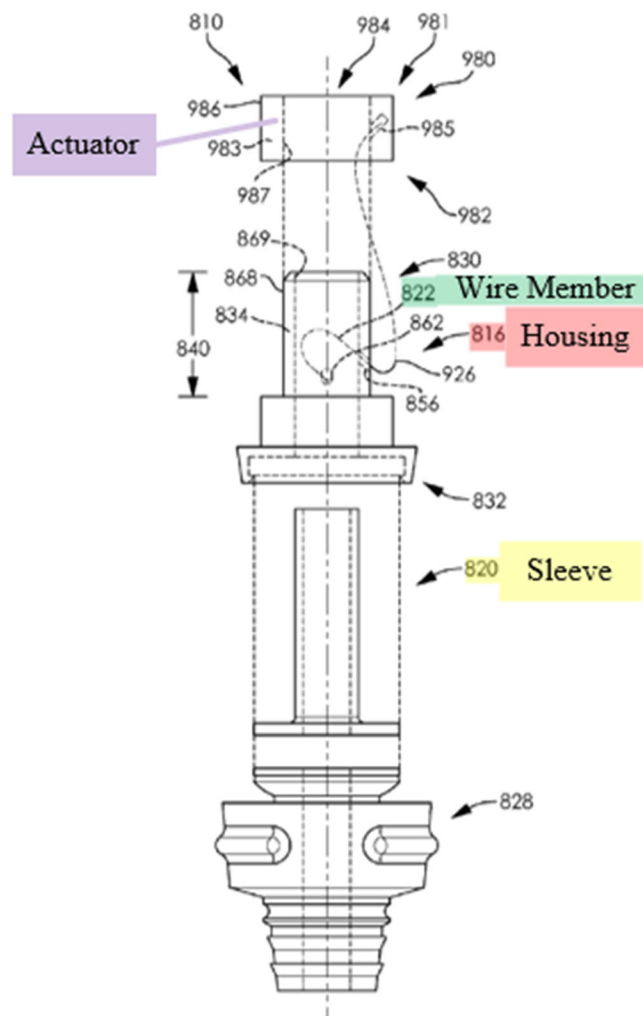


FIG. 20

Id. at 23:50-62 & 24:50-52. Movement of the actuator 818 pulls the second end 926 of the wire member 822 to tension the wire member 822 and compress the sleeve 820. *Id.* at 24:58-25:2.

164. Figures 15-17 illustrate a selective fluid barrier device 410 including a housing 416, an actuator 418, a sleeve 420, and a single first wire member 422 having “a first end 524 attached to the actuator 418 within the first cavity 490 and a second end 526 attached to the first wire member 422”:

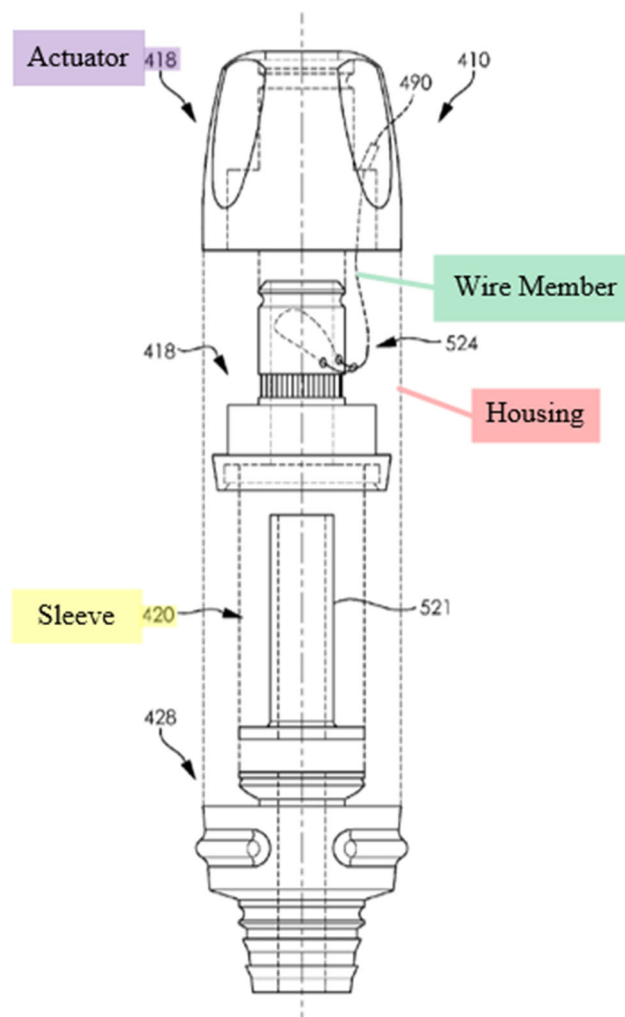


FIG. 15

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Id. at 21:37-67. Rotation of the actuator 418 pulls the second end 526 of the wire member 422 to tension the wire member 422 and compress the sleeve 420. *Id.* at 22:25-31.

165. Thus, in each of Eller's various selective fluid barrier devices, the various wire members have a first end coupled to either a housing of the selective fluid barrier device or to the wire member and a second end coupled to an actuator of the selective fluid barrier device. Movement (e.g., rotation) of the actuator pulls only the second end of the wire member while the first end remains stationary to tension the wire member. That is, movement of the single actuator controls movement of the wire member such that the wire member moves predictably and a precise amount upon movement of the actuator.
166. While Petitioner proposes a purported simple substitution of Hartley's string or Eller's wire member for Schaffer's U-shaped actuating members, Petitioner's proposed combination not only substitutes a flexible string or wire member for Schaffer's rigid U-shaped members, but also redesigns Schaffer to eliminate one rigid U-shaped member completely and instead attach a single flexible string/wire member to two actuator buttons, an arrangement not found in Schaffer, Hartley, or Eller. Moreover, in Petitioner's proposed combinations of Schaffer and Hartley or Eller, Hartley's string and Eller's wire

member would be controlled by Schaffer's two actuator buttons 261—rather than by a single actuator as taught by Hartley or Eller.

167. Accordingly, it is incorrect that 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” or that the “combination of Eller's wire member and Schaffer's valve would have merely entailed merely substituting one known element (Eller's wire member) for another (Schaffer's actuating members) to yield the predictable results of constricting Schaffer's valve.” Petition pp. 50-51, 57. Instead, Petitioner's proposed combination requires significant additional modification and departs from the intended purpose and express disclosure of each of Schaffer, Hartley, and Eller in which a **single** U-shaped actuating member 55, string 14, or wire member, respectively, are controlled by a **single** actuator. A POSITA would understand that controlling a string, wire member, or actuating member with two independently movable actuators would increase the complexity and variability of the valve and make the valve more difficult to manufacture. Accordingly, neither Schaffer, Hartley, nor Eller disclose any element (U-shaped actuator, string, or wire member) coupled to separate, individually controlled actuator buttons as in Petitioner's proposed combination. If anything, Petitioner's

proposed combinations appear to be based on hindsight in view of the '012 Patent.

168. I understand that the Board contends that “Schaffer’s two actuating members apply a constricting force to the valve’s seal module when pulled by opposing spring-actuated buttons,” and that “replacing those members with a single string (or wire) would provide substantially the same function.” Institution Decision, p. 37. However, even if it were true that Petitioner’s proposed combination would provide “substantially the same function” as Schaffer’s valve seal module, this alone does not mean that it would have been simple to redesign Schaffer’s valve to accommodate Hartley’s string or Eller’s wire member. This is because there are many design considerations that a POSITA would need to contemplate if they had been motivated to redesign Schaffer’s valve seal module. As I explain *infra* in §VII.D-E, several of these design considerations—including the durability of the valve and the ease of manufacturing the valve—mean that it would **not** have been simple to have redesigned Schaffer’s valve to accommodate Hartley’s string or Eller’s wire member. This is not to say that no modification could be made to Schaffer. For example, as I explain *infra* in §VII.F., there are **simple** modifications that a POSITA could make to Schaffer that could resolve Petitioner’s alleged shortcomings of Schaffer—but these simple modifications do not include

incorporating Hartley's string or Eller's wire member into Schaffer's valve seal module.

D. Modifying or Substituting Hartley's String or Eller's Wire Member for Schaffer's U-Shaped Actuating Members Would Render Schaffer's Valve Inoperable for Its Intended Purposes of Durability and Easy Manufacturing.

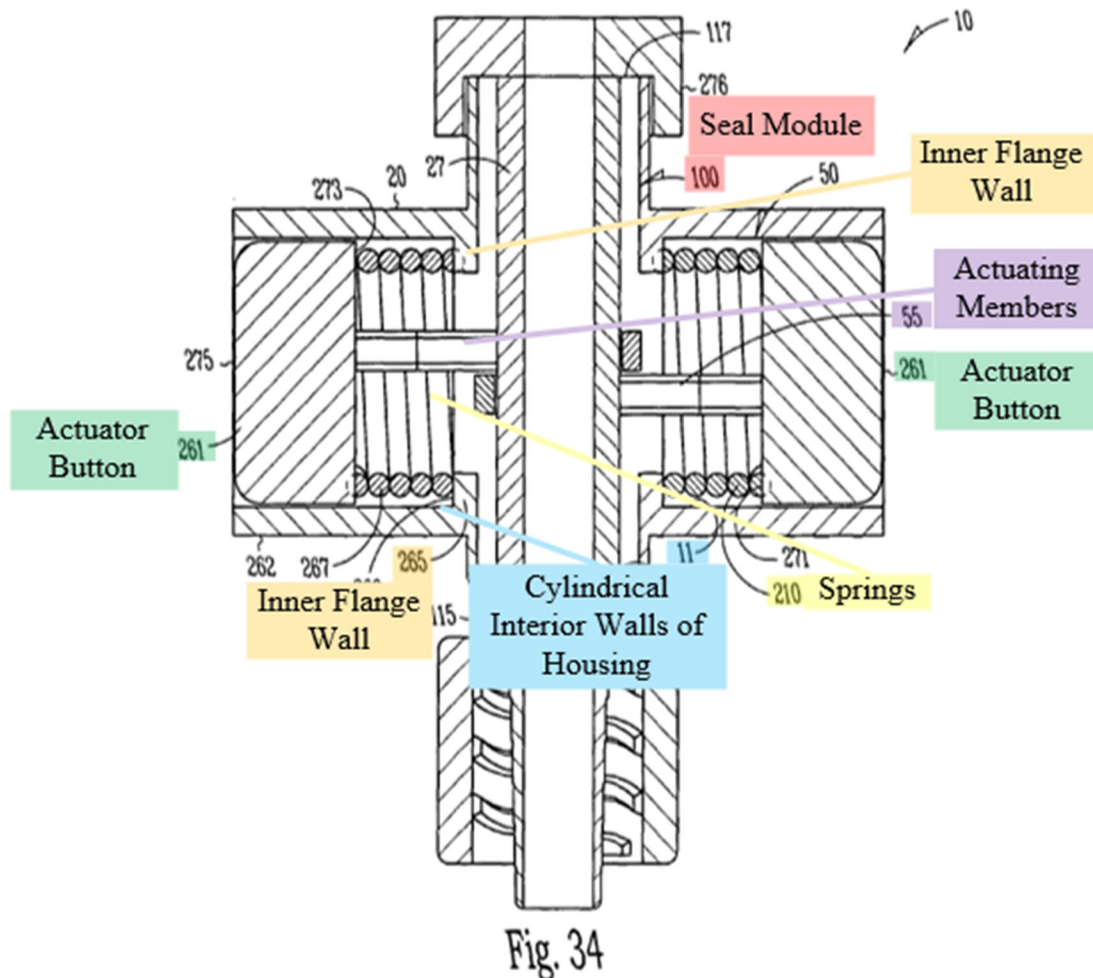
169. It also would not have been obvious to a POSITA to substitute Hartley's string or Eller's wire member for Schaffer's U-shaped actuating members because doing so would make Schaffer's valve less durable and more difficult to manufacture. In particular, Schaffer's U-shaped actuating members 55 are purposefully designed to be rigid and attached to only a single actuator to simplify manufacturing and make the valve durable.
170. Regarding manufacturability, Petitioner contends that in its proposed combination the first end of Hartley's string or Eller's wire member would be secured to Schaffer's first actuator button, the string would wrap at least once around Schaffer's seal module, and the second end of the string or wire member would be secured to Schaffer's second actuator button. Petition, pp. 53 and 58 (Petitioner's Demonstrative Illustrations showing the proposed combination of Schaffer and Hartley and Schaffer and Eller, respectively). As Petitioner explains with respect to Hartley, "each end of Hartleys [*sic*] string could be threaded through small holes in Schaffer's buttons and knotted on

the other side.” *Id.* at 52. This purported arrangement is speculative and would remove the advantages Schaffer identifies its structure as providing.

171. Schaffer specifically describes how its stasis valve is assembled:

[T]he stasis valve 10 is assembled by inserting the actuator button 261 and resilient member 267 (e.g., spring 210) into one side of the housing 20. The actuator button 261 and resilient member 267 (e.g., spring 210) are inserted into an opposing side of the housing 20. Each actuator button 261 is completely compressed and held while the seal module 100 is inserted through the housing 20 and between each actuator 50. Each actuator button is released and the cap 276 secured to the housing 20, for example, with an adhesive. Further, the connecting member 35 is snapped onto the housing.

EX1005, ¶ [0083]. That is, a POSITA would understand that each of the actuator buttons 261 and the springs 210 are inserted into the cylindrical opening defined by a corresponding one of the cylindrical interior walls 11 of the housing 20 until the springs 210 abut the inner flange wall 265, then the actuator buttons 261 are depressed to form an opening through the U-shaped actuating members 55, and finally the seal module 100 is inserted through the opening:



Thereafter, the actuator buttons 261 and the actuating members 55 are retained within the cylindrical openings—even when the actuator buttons 261 are not depressed—by the resistive force of the seal module 100 against the U-shaped actuating members 55.

172. A POSITA would understand that Petitioner's proposed substitution of Hartley's string or Eller's wire member for Schaffer's actuating members 55 would make it more difficult to assemble Schaffer's valve in the simple manner taught by Schaffer using rigid actuating members 55. In particular, in

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Petitioner's proposed combination of Schaffer and Hartley, the first end of Hartley's string is secured via a knot to one of Schaffer's actuator buttons 261 and the second end of Hartley's string is secured via a knot to the other one of Schaffer's actuator buttons 261. Petition, pp. 52-53. Similarly, in Petitioner's proposed combination of Schaffer and Eller, the first end of Eller's wire member is secured via "simple methods" such as adhesive, welding, or fusing to one of Schaffer's actuator buttons, and the second end of Eller's wire member is secured via a similar method to the other one of Schaffer's actuator buttons 261. Petition, p. 58. A POSITA would understand that to achieve this arrangement Hartley's string or Eller's wire member would either need to be (1) secured to the actuator buttons 261 before the actuator buttons 261 are inserted into the cylindrical openings in the housing 20 or (2) secured to the actuator buttons 261 after the actuator buttons 261 are inserted into the cylindrical openings.

173. However, the first method of assembly in which Hartley's string or Eller's wire member is secured to the actuator buttons 261 before their assembly into the valve would not be possible because the tethered actuator buttons 261 could not be inserted through the respective cylindrical openings on either side of the housing 20 while also positioning Hartley's string or Eller's wire member as alleged by Petitioner. Put differently, the inner flange wall 265

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prevents either of Schaffer's actuator buttons 261 from passing entirely through the housing 20 as would be required to position Hartley's string or Eller's wire member around Schaffer's seal module 100 in Petitioner's combination.

174. Likewise, a POSITA would understand the second method of assembly in which Hartley's string or Eller's wire member is secured to the actuator buttons 261 after their assembly into the valve to be unduly difficult, because the housing 20 and the actuator buttons 261 would block access to the interior of the housing 20 and inhibit or even prevent the positioning of Hartley's string or Eller's wire member in Petitioner's combinations. That is, with the actuator buttons 261 inserted into the cylindrical openings in the housing 20, the interior of the housing 20 would be inaccessible for manipulating Hartley's string or Eller's wire member into position around the seal module 100.
175. Even if the first or second method of assembly was somehow workable, Schaffer teaches that the "[e]ach actuator button 261 is completely compressed and held while the seal module 100 is inserted through the housing 20 and between each actuator 50." EX1005, ¶ [0083]. Hartley's flexible string and Eller's flexible wire member would be not tensioned (e.g., loose) when the actuator buttons 261 are compressed in Petitioner's proposed combinations such that it would not provide a uniform opening like Schaffer's rigid

actuating members 55 to permit positioning of the seal module 100 therethrough.

176. Petitioner's expert asserts that "a tapered fixture could be used to introduce the seal module through the looped strings that are already attached to the buttons" or "[a]lternatively, the seal module could be positioned in the valve and the strings could be looped around the module and connected to the buttons." EX1003, ¶ 125. The inherent floppiness/flexibility of the string would render its relaxed geometry uncontrollable, resulting in non-orthogonal positioning around the seal module. And, even if these methods were possible, Schaffer does not disclose such methods further confirming that the U-shaped members are rigid. However, if a looped string were attached to the actuator buttons before the seal module was inserted, nothing would retain the loop in the string. Instead, because the string is flexible, the string would simply slacken in an uncontrolled manner and there would be no "loop" to target with the tapered fixture. And even if there was some way to ensure the loop was maintained, the loop would not have a predefined position that could be targeted by the tapered fixture. Rather, the looped string would move in an uncontrolled manner that would make it exceedingly difficult to reliably insert a tapered fixture therethrough.

177. In sum, a POSITA would recognize the advantage of Schaffer's design when it comes to ease of assembly. Namely, each of the actuator buttons 261 is attached to a single one of the actuating members 55 to allow these individual components to be inserted into the cylindrical openings on either side of the housing 20. Tethering the actuator buttons 261 together with Hartley's string or Eller's wire member would unduly complicate this simple assembly process.
178. Accordingly, for the foregoing reasons, a POSITA would understand that Petitioner's proposed substitution of Hartley's string or Eller's wire member for Schaffer's actuating members 55 would make it much more difficult or even impossible to assemble Schaffer's valve in the simple manner taught by Schaffer.
179. Moreover, as I explain in §VI.B. above, a POSITA would understand that flexible parts—such as Hartley's string or Eller's wire member—would be difficult or impossible to machine conventionally, as flexible materials will deform when force is applied during the machining process. This would inhibit or even prevent accurate manufacturing of Hartley's string or Eller's wire member using machining as taught by Schaffer. Accordingly, a POSITA would understand that replacing Schaffer's actuating members with Hartley's

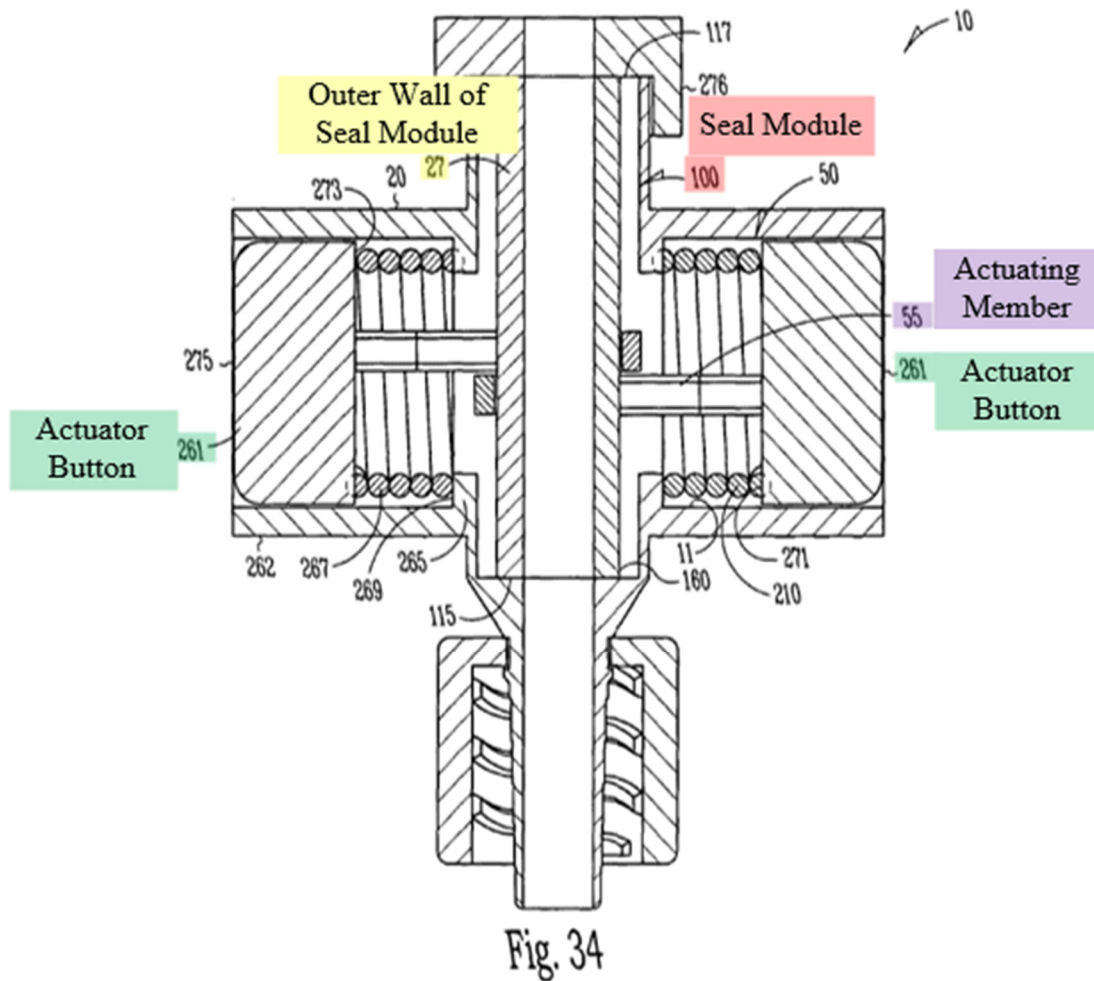
string or Eller's wire member would make Schaffer unsuitable for its intended purpose of simple manufacturability via machining.

180. Regarding durability, Schaffer explains that its invention addresses the then-existing need for “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.” EX1005, ¶ [0008] (emphasis added). Accordingly, a POSITA would understand durability, such as the ability to resist damage during operation, is a key feature of Schaffer's device. As I explain in §VI.B. above, Schaffer's actuating members 55 are rigid and “machined from aluminum” or “machined from plastic.” *Id.* at ¶ [0082]. A POSITA would understand that replacing Schaffer's actuating members 55 with Hartley's string 14 or Eller's wire member would make Schaffer's valve less durable—in direct contrast to Schaffer's intended purpose of having a durable valve. In particular, a POSITA would understand Hartley's thin and flexible string and Eller's thin and flexible wire member to be much more susceptible to damage, positioning errors, and the like during valve operation.

E. Modifying or Substituting Hartley's String or Eller's Wire Member for Schaffer's U-Shaped Actuating Members Would Change the Principle of Operation of Schaffer's Valve in Which the U-

**Shaped Actuating Members Forcibly Disengage the Seal Module
and Likely Render Schaffer's Valve Inoperable.**

181. It also would not have been obvious to a POSITA to substitute Hartley's string or Eller's wire member for Schaffer's U-shaped actuating members because doing so would change the stated principle of operation of Schaffer's valve in which the U-shaped actuating members 55 forcibly disengage the seal module 100. In the second (open) position of Schaffer's valve, "each actuator button 261 is depressed" and "such movement 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":



EX1005, ¶ [0077] (emphasis added). Petitioner explains that in their proffered combination Hartley’s string or Eller’s wire member would loop around the Schaffer’s seal module. Petition, pp. 53-54 and 58. As explained by Petitioner with regard to Hartley, the seal module 100 would expand against Hartley’s string to open when tension is released on the string: “pressing Schaffer’s buttons inwardly (i.e., second position) would release the tension on the string, allowing the lumen to open.” *Id.* at p. 54. Petitioner provides a similar explanation for Eller: “When Schafer’s actuator buttons are pressed inwardly,

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the tension on the wire member would be relaxed, causing the wire member to loosen” permitting Schaffer’s seal module “to return to its open configuration.” *Id.* at pp. 59-60. Thus, Hartley’s string or Eller’s wire member would never disengage—let alone forcibly disengage—Schaffer’s seal module 100. That is, Hartley’s string or Eller’s wire member would remain in contact with and never disengage the seal module 100. Accordingly, a POSITA would understand that substituting Hartley’s string or Eller’s wire member for Schaffer’s U-shaped actuating members 55 would cause the actuating member (i.e., Hartley’s string or Eller’s wire member) not to disengage or forcibly disengage Schaffer’s seal module, changing the principle of operation of Schaffer’s device.

182. Further, a POSITA would recognize that the ability for Schaffer’s U-shaped actuating members to forcibly (i.e., actively) disengage from the seal module is a key aspect of Schaffer’s design because it is part of Schaffer’s solution for “balanc[ing] between closing force, opening force, friction, compression and durability.” EX1005, ¶[0007]. Specifically, Schaffer’s design with forcible disengage promotes strong closing forces while maintaining the ability to easily open the valve and insert “flexible instrumentation” through the valve. *Id.*

183. Even further, A POSITA would recognize that one of Schaffer's goals is to provide a valve that effectively seals but provides a balance of "closing force, opening force, friction, compression and durability" to ensure that different types of instruments, including delicate or floppy-tipped instruments, could be used with the valve. EX1005, ¶[0007]. Schaffer's valve is designed to accomplish this by sealing under light compression. *Id.* at ¶[0059]. A POSITA would not modify Schaffer's valve in a manner that could impair this important balancing act that Schaffer's valve achieves. This is especially true because, as I explained above in §VII.A, the proposed modification would not improve the seal "in the presence of a wide range of instruments or in the presence of multiple instruments." EX1005, ¶[0006].

F. Even Assuming Petitioner's Stated Motivations to Form a Better Seal and Avoid the Formation of Gaps, Petitioner Does Not Explain Why a POSITA Would Have been Motivated to Substitute Hartley's String or Eller's Wire Member for Schaffer's U-Shaped Members as Opposed to Any of the Alternatives It Provides.

184. Even assuming that a POSITA would understand Schaffer's valve to form gaps (they would not), a POSITA would not have been motivated to substitute Hartley's string or Eller's wire member for Schaffer's U-shaped actuating members to have both its ends attached to different actuator buttons (which neither Schaffer, Hartley, nor Eller disclose as I explain in §VII.C. above) as suggested by Petitioner. Rather, a POSITA would make the relatively simple

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modifications to Schaffer's valve that Petitioner suggests. For example, when describing how Schaffer allegedly discloses the features of dependent Claim 5, Petitioner recites that a POSITA would have been motivated to adjust Schaffer's valve in several simple manners to improve/maintain its seal with a reasonable expectation of success. For example, Petitioner states:

[I]f Schaffer's valve did not maintain its seal when a pressure differential exists, POSITAs would have been motivated to make adjustments to the valve to maintain the seal, **including adjusting Schaffer's spring strength to apply additional force, adjusting the resilience and compressibility of the seal module that forms the valve's lumen** POSITAs would have been motivated to adjust Schaffer's hemostasis valve to prevent blood leaks because that is the valve's purpose. (Ex. 1003, ¶¶ 166-167.) POSITAs would have reasonably expected success in making such adjustments. (*Id.*)

Petition, p. 69 (emphasis added).

185. I agree that a POSITA would understand that some simple adjustments to Schaffer that would not change its principles of operation could rectify any alleged deficiencies, but that is another reason why a POSITA would not make the wholesale substitutions and modifications proposed by Petitioner that would contradict Schaffer's principle of operation. For example, the spring strength could be adjusted while maintaining the same manufacturing method disclosed by Schaffer, forcible disengagement of the U-shaped members from the seal module, and durability of the valve. Likewise, even if the "sticky," "self-closing," and "gelatinous" properties of the seal member 165 described

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in paragraph [0059] of Schaffer were considered optional, a POSITA would understand exactly how to make the seal member 165 have those properties to address any sealing issues by, for example, forming the seal member 165 of “commonly available [materials such] as ‘C-Flex’ or ‘Kraton’ in the range of 5 to 15 (shore A),” thereby maintain Schaffer’s principles of operation. EX1005, ¶ [0059]. Accordingly, even assuming that Schaffer’s valve would not form a complete seal around an instrument—it would—Petitioner asserts that a POSITA would have understood that the seal could have been improved by simply adjusting Schaffer’s spring strength or adjusting the properties of the seal module. A POSITA would understand those modifications to be simpler and more likely to work than completely omitting Schaffer’s U-shaped members and substituting in Hartley’s string or Eller’s wire member as proposed by Petitioner (including attaching the string or wire member to two separate actuators which neither Schaffer, Hartley, nor Eller disclose). Petitioner provides no explanation for why a POSITA would have substituted Hartley’s string or Eller’s wire member for Schaffer’s U-shaped members rather than make any of the simple modifications they assert would work to complete the seal and prevent blood leaks through the valve.

186. And, a POSITA would not have modified Schaffer in view of Hartley or Eller instead of, if somehow needed (they are not), making the simple changes

identified above. As I explain in §§VII.D-E. above, substituting Hartley's string or Eller's wire member for Schaffer's U-shaped members would likely render Schaffer's valve inoperable for its intended purpose of durability, easy manufacturing, and forcible disengagement. The simple modifications that Petitioner asserts a POSITA would understand would work to complete Schaffer's seal would not require a complete redesign of Schaffer's valve in a manner that significantly reduces durability and ease of manufacturing and eliminates forcible disengagement of the actuating members from the seal module.

G. A POSITA Would Not Have Found It Obvious to Have Substituted Schaffer's Alleged Ineffective Valve—Which is Integral to Petitioner's Proposed Motivation to Modify Schaffer in view of Hartley or Eller—for Garrison's Hemostasis Valve, and then Have Further Modified Schaffer's Valve Rather than Use the Hemostasis Valves Taught by Garrison

187. As I explain above, Petitioner's stated motivations to modify Schaffer in view of Hartley and Eller is based on a POSITA's alleged understanding that Schaffer's valve forms gaps and thus does not seal effectively. Petition pp. 51, 57. If this were true—it is not—a POSITA would not have been motivated to substitute Schaffer's valve for Garrison's hemostasis valve and then further modify Schaffer's valve (in a manner that destroys the intended purpose and function of Schaffer's valve) in view of Hartley or Eller rather than utilize the conventional hemostasis valves that Garrison discloses "allow introduction of

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devices such as a microcatheter, guide wire, or thrombectomy device while preventing or minimizing blood loss during the procedure.” EX1011, ¶ [0098].

188. Petitioner relies on Garrison’s catheter 2030 shown in Figure 34 for disclosing a “first catheter,” as recited in Claim 1 and Claim 10. Petition, pp. 26-27. The catheter 2030 can include a hemostasis valve “such as a Tuohy-Borst or rotating hemostasis valve (RHV)” or “a passive seal hemostasis valve” to “allow introduction of devices such as a microcatheter, guide wire, or thrombectomy device while preventing or minimizing blood loss during the procedure.” EX1011, ¶ [0098].
189. A POSITA would understand the rotatable or passive hemostasis valves disclosed by Garrison to be easy to use, readily available from many manufacturers, and—based on the disclosure of Garrison—sufficient to allow for the introduction of devices during Garrison’s procedure while “preventing or minimizing blood loss.” Additionally, Garrison’s trans-carotid (neck) approach, with very small catheters or devices, leaves very limited space for the operator to use a hemostasis valve, consistent with the use of axially-oriented Tuohy-Borst valves. Assuming that Petitioner is correct that a POSITA would understand Schaffer’s valve not to seal effectively (a POSITA would understand Schaffer’s valve to seal completely as I explain above), a POSITA

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would not have been motivated to substitute Garrison's conventional hemostasis valve for Schaffer's ineffective valve, and then completely redesign Schaffer's valve to substitute Hartley's string or Eller's wire member to fix the ineffective valve. To save time, complexity, and cost, a POSITA would simply have used Garrison's rotatable or passive hemostasis valves that Garrison discloses are effective to prevent or minimize blood loss.

H. Altogether a POSITA Would Not Have Been Motivated to Substitute Hartley's String or Eller's Wire Member for Schaffer's U-Shaped Members

190. Referring to my explanations in §§VII.A-G. above, in sum a POSITA would not have been motivated to substitute Hartley's string or Eller's wire member for Schaffer's U-shaped actuating members, and then substitute Schaffer's valve for Garrison's conventional hemostasis valves. For example, under a proper reading of Garrison, Schaffer, Hartley, and Eller:

- (1) Garrison's readily-available and easy-to-use rotatable or passive hemostasis valves sufficiently "allow introduction of devices such as a microcatheter, guide wire, or thrombectomy device while preventing or minimizing blood loss during the procedure" such that a POSITA would not have been motivated to substitute Schaffer's allegedly ineffective valve for Garrison's hemostasis

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valve and then further modify Schaffer's valve in view of Hartley or Eller (§VII.H.);

- (2) Schaffer's seal module 100 "blocks the flow of gas or fluid completely" with or without instruments placed therein (§§VII.A-B.);
- (3) Schaffer discloses a highly-compliant seal member 165 in every embodiment that forms a complete seal around a variety of profile shapes and diameters of the lumen, around small instruments, around large instruments, in the absence of instruments, and even around irregularly shaped instruments (§VII.A.);
- (4) Petitioner and its expert assert that a POSITA could simply adjust Schaffer's spring strength and/or adjust the properties of the seal module to address any sealing issues, if any, in Schaffer (§VII.F.);
- (5) Petitioner's proposed substitutions are not a simple substitution of a known element because neither Schaffer, Hartley, nor Eller disclose a "filament" connected at opposite ends to and controlled by two actuators as proposed in Petitioner's combination (§VII.C.);

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- (6) Substituting Hartley's string or Eller's wire member for Schaffer's U-shaped actuating members would fundamentally change Schaffer's principles of operation (§VII.D-E.); and
- (7) Hartley's string and Eller's wire member would not provide a better seal than Schaffer's rigid U-shaped actuating members and seal module (§§VII.A-B.).

191. A POSITA would thus not have modified or substituted Hartley's string or Eller's wire member and further modified the structure to connect the string or wire member to two separate actuators, as Petitioner contends. Petitioner's combination is a valve that operates in complete contrast to Schaffer's stated purposes—one in which (1) the actuating members (i.e., Hartley's string or Eller's wire member) are controlled by multiple rather than one of the actuator buttons 261, (2) the seal module 100 does not form a complete seal despite every embodiment of Schaffer disclosing a seal member 165 that is highly-compliant to form a seal around different tools, and (3) the string or wire member does not forcibly disengage the seal module 100. The proposed combination is such a stark departure from the principles of operation of Schaffer's valve that a POSITA would not have been motivated to arrive at Petitioner's purported combination.

VIII. GROUND 4—GARRISON IN COMBINATION WITH HARTLEY AND ELLER DOES NOT RENDER OBVIOUS ANY OF CLAIMS 1-3, 5-6, OR 9-15

192. Petitioner and its expert, Mr. Thornton, allege that Garrison in combination with Hartley and Eller renders obvious Claims 1-3, 5-6, and 9-15 of the '005 patent. I disagree for the reasons I discuss in further detail in this section. A POSITA would understand that the combination of Garrison, Hartley, and Eller does not disclose several limitations of Independent Claim 1, and that a POSITA would not have been motivated or found it obvious to modify Hartley in view of Eller to arrive at the features of Independent Claim 1 or Independent Claim 10. And, because Claims 2-3, 5-6, 9, and 11-15 depend from one of Claims 1 or 10 and thus include all the features of one of these claims, those claims are also not rendered obvious by the combination of Garrison, Hartley, and Eller.
193. As I explained above, I understand that for a patent claim to be rendered obvious, the differences between the claimed invention and the prior art must be such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains, the claimed invention is obvious. Even if all limitations of a claimed invention are disclosed by the prior art combination, Petitioner must demonstrate an apparent reason to

combine the known elements in the fashion of the patent claim at issue and that a person of ordinary skill in the art would have reasonable expectation of success in pursuing that combination. A prior art reference teaches away from a modification of a prior art reference when a person of ordinary skill in the art would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path followed by and claimed in the patent.

A. Neither Garrison, Hartley, nor Eller Discloses a Filament Having a First End Coupled to a First Member and a Second End Extending in a Different Direction Coupled to a Second Member, as Required by Claim 1

194. Claim 1 recites that “the actuator comprises a first member coupled to the first end of the filament and a second member coupled to the second end of the filament.” Neither Garrison, Hartley, nor Eller disclose this feature of Claim 1.
195. Petitioner does not allege that Garrison discloses this feature. Instead, Petitioner alleges that Hartley discloses this feature. Petition, pp. 91-92. Hartley discloses that each end of its string 14 is connected to the single rotatory actuator 12. EX1006, [0031]. A POSITA would understand the rotary actuator 12 to be a single integral piece such that the knots 16 and 18 are not attached to a respective “first member” and “second member,” as recited in Claim 1. Petitioner simply asserts that the “actuator portions secured to the first and

second ends of the string 14 are the first and second members claimed in the '005 patent”:

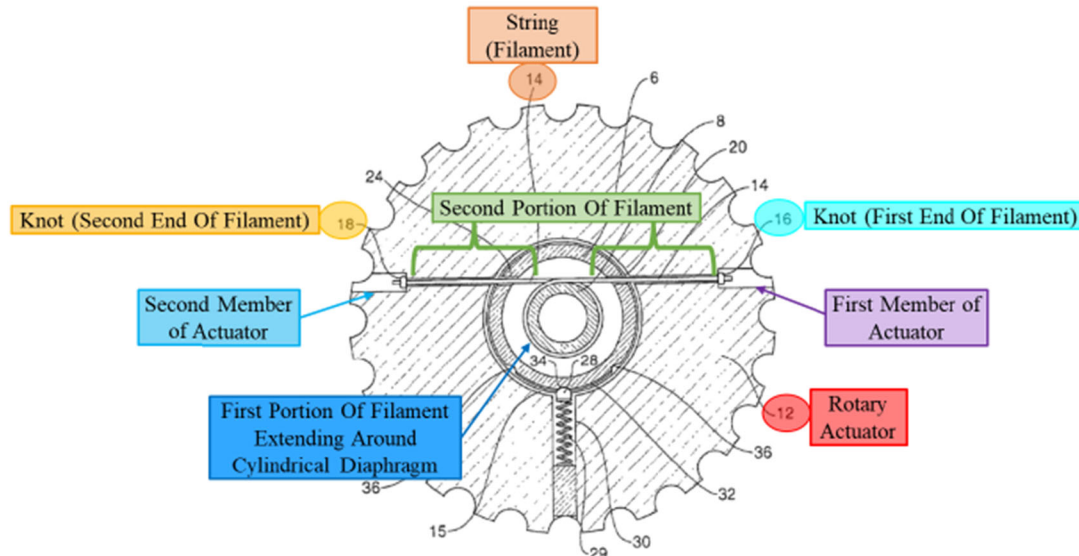


Fig 3

Petition, pp. 91, 93. A POSITA would understand that the different “portions” of Hartley’s actuator do not comprise first and second members in the manner recited in Claim 1.²

² I note that in a related proceeding (*Imperative Care, Inc. v. Inari Medical Inc.*, IPR2024-01157), the Board disagreed with similar arguments raised by Petitioner, stating “We agree with Patent Owner that Petitioner has not established that the modification of Hartley in view of Eller includes an actuator with a ‘first member’ and a ‘second member’ as claimed...[t]he alleged ‘first member’ and ‘second member’ cited by Petitioner (Pet. 73) are simply portions of a single, unitary rotary

196. Eller does not remedy this deficiency of Garrison and Hartley. Eller discloses various selective fluid barrier devices that include one or more wire members each having one end coupled to an actuator and the other end coupled to itself or a housing—not to the same or different actuator:

actuator in Hartley.” Paper 7, p. 42. Petitioner’s arguments here fail for the same reasons.

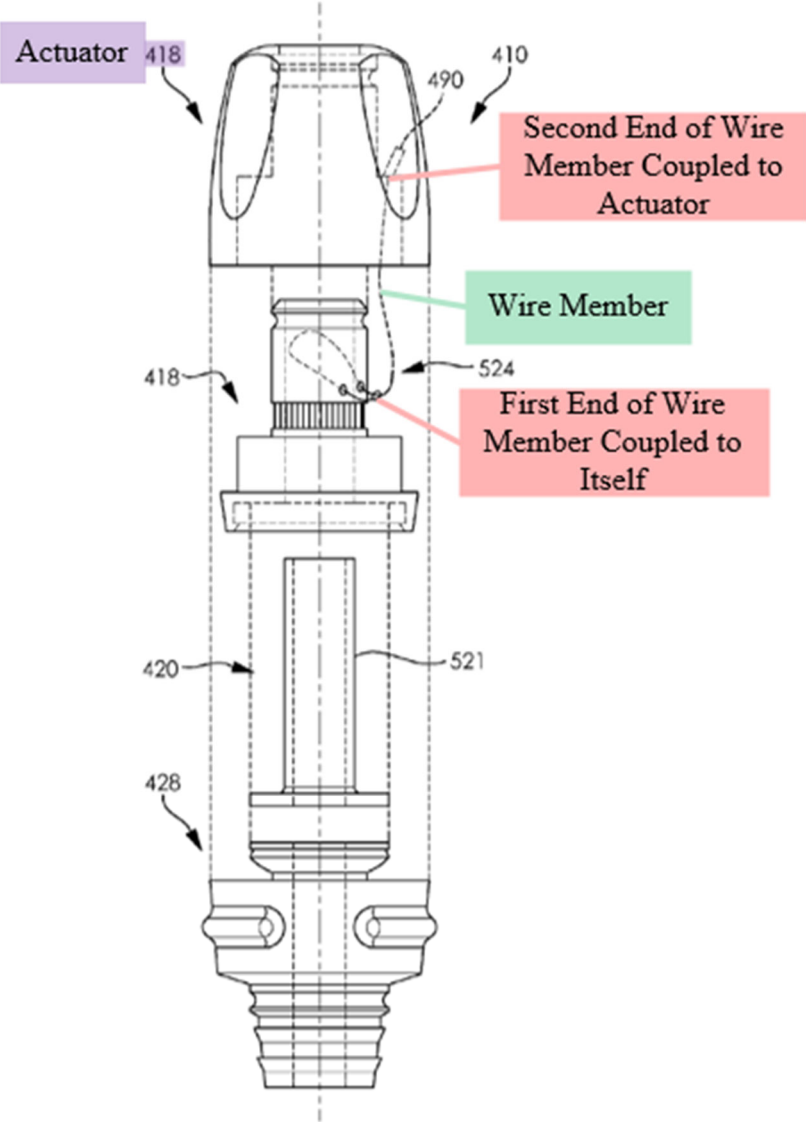
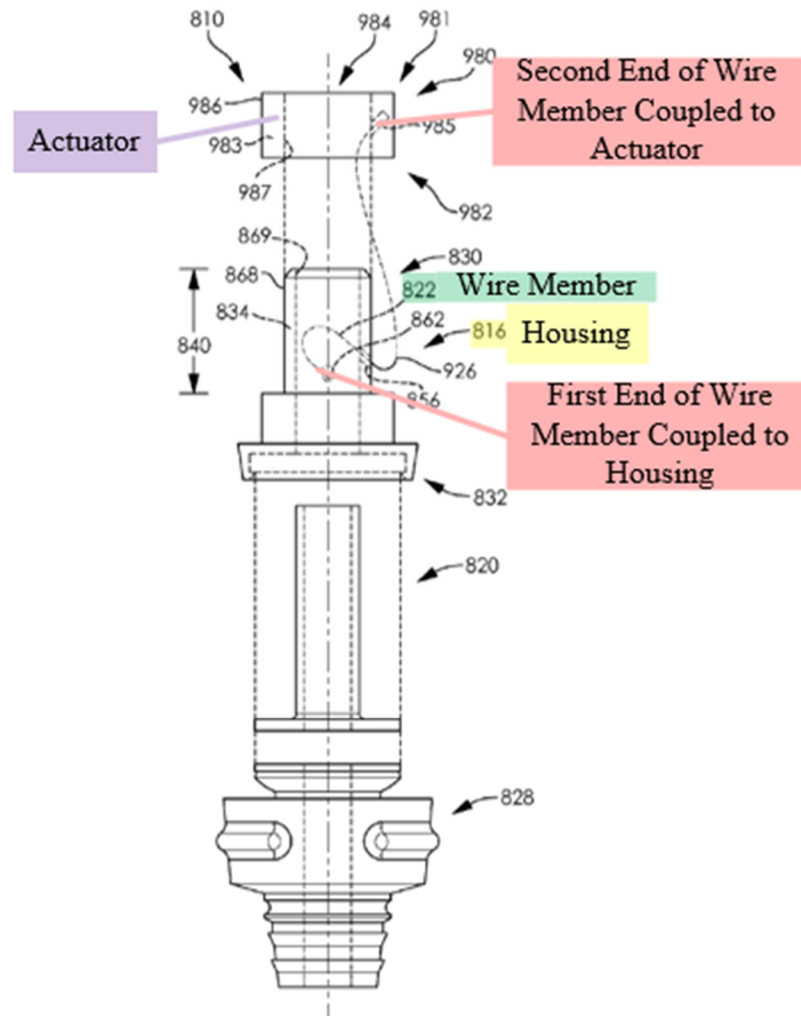


FIG. 15



See, e.g., EX1007:12:52-58, 23:50-62, 24:50-52, & 21:37-67.

197. Accordingly, the combination of Garrison, Hartley, and Eller does not disclose an actuator comprising a “first member coupled to the first end of the filament and a second member coupled to the second end of the filament,” as claimed. The Petition does not allege that a POSITA would have modified Hartley or Eller as claimed. Claim 1 and its dependents are not rendered obvious by the combination of Garrison, Hartley, and Eller for that reason alone.

B. Modifying Hartley to Include Eller's Torsion Spring Would Render Hartley's Valve Inoperable for Its Intended Purpose

198. Petitioner asserts that it would have been obvious to a POSITA to have included Eller's torsion spring in Hartley's device to bias Hartley's device to a sealed position. Petition, pp. 95-97, 106. I disagree because doing so would destroy the functionality and advantages of Hartley's ball and detent arrangement.
199. Hartley's valve includes a "detent arrangement having a ball 28 loaded by a spring 29 in an aperture 30 in the rotary actuator runs in a groove 32 in the cylindrical housing 6 ... [t]he groove 32 has a central recess 34 and end recesses 36":

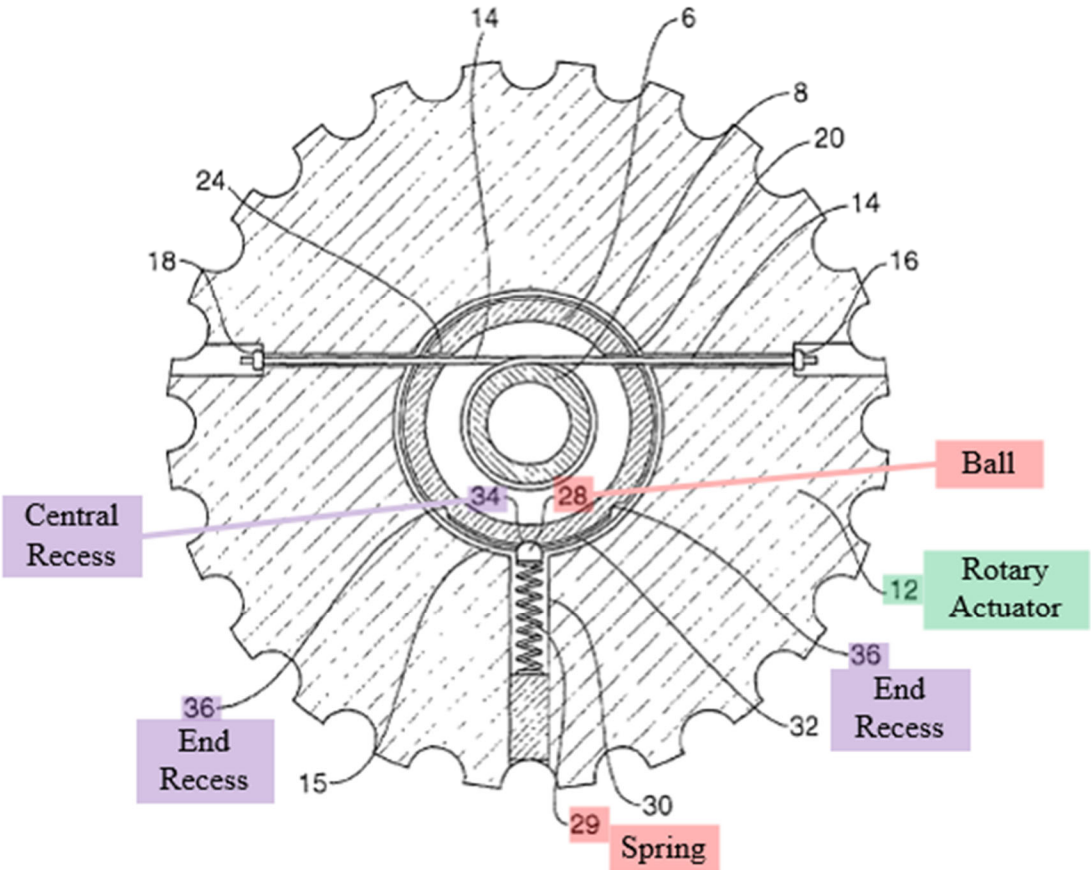
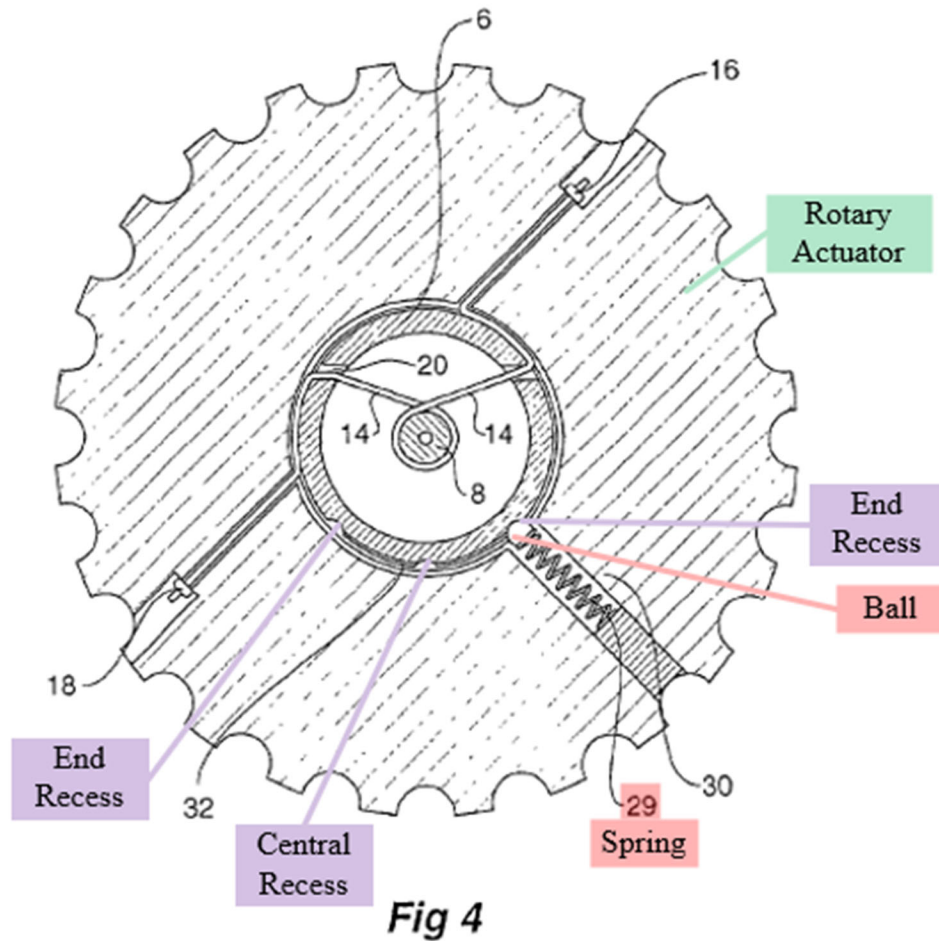


Fig 3



EX1006, ¶ [0033]. The ball and detent arrangement “provide[s] tactile feel [of] the action of the valve” and “assist[s] with retaining the rotary actuator on the cylindrical housing.” *Id.* at ¶¶ [0018], [0033]. “There may also be further recesses or detents between the central recess and the end recesses. *Id.* at ¶ [0033]. In the open position shown in Figure 3 of Hartley, the ball 28 is in the central recess 34 of the groove 32 and, in the sealed position shown in Figure 4 of Hartley, the ball 28 is in one of the end recesses 36 of the groove 32. “Rotation of the rotary actuator back to the central position where the

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detent ball 28 is received in depression 34 will cause the sutures to loosen again so that the resilient cylindrical diaphragm will retain its original shape as shown in FIGS. 1 and 3.” *Id.* at ¶ [0034].

200. Accordingly, a POSITA would understand that Hartley’s ball and detent arrangement provides a tactile feel of the valve state (open, closed) during use and also acts to selectively lock the position of the rotary actuator relative to the cylindrical housing 6 to maintain the valve state—i.e., the amount of constriction of the cylindrical diaphragm 8. That is, Hartley’s ball and detent arrangement allows its valve to be retained at different open and/or closed states with the detent ball 28 in one of the different recesses—the central recess 34, the first one of the end recesses 36, the second one of the end recesses 36, or “further recesses” contemplated by Hartley.
201. Including Eller’s torsion spring in Hartley’s valve as proposed by Petitioner would cause Hartley’s valve to automatically move to the sealed position shown in Figure 4 absent user actuation of the rotary actuator. Accordingly, Hartley’s valve would be unable to be retained in the open position shown in Figure 3 in which “the detent ball 28 is received in depression 34” (or a partially open position with the detent ball 28 positioned in one of the end recesses 36) without the user maintaining their fingers on Hartley’s rotary actuator to provide a force that counteracts the force of Eller’s torsion spring. *Id.*

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That is, in Petitioner’s combination, Hartley’s ball and detent arrangement would be unable to “assist with retaining the rotary actuator on the cylindrical housing” because the spring force of Eller’s torsion spring would simply override the retaining force provided by the spring 29 of the ball and detent arrangement. *Id.* at ¶ [0018]. Therefore, a POSITA would not have been motivated to incorporate Eller’s torsion spring into Hartley’s valve because it would render Hartley’s ball and detent arrangement completely inoperable for its intended purpose of retaining the rotary actuator in position and thereby maintaining the valve in a selected valve state (open, closed, partially open). Moreover, as I explain in §VIII.C. below, Hartley’s functionality of maintaining the valve in an open state provides several advantages over Eller’s system in which the valve is biased closed by a torsion spring.

C. Petitioner’s Stated Motivations to Modify Hartley to Include Eller’s Torsion Spring Would Not Have Been Compelling to a POSITA Considering the Countervailing Advantages of Hartley’s Device

202. Petitioner provides several reasons why a POSITA would have allegedly been motivated to include Eller’s biasing system (torsion spring) in Hartley’s valve: (1) “the biasing system would ensure that Hartley’s valve seals quickly and minimizes blood loss when a catheter is removed through the valve,” (2) “the biasing system would ensure that the physician could not inadvertently leave the valve open after removing a device,” and (3) “the biasing system can

simplify Hartley's valve" by, for example, "eliminat[ing] the need for the operator to manually seal the valve prior to or during the procedure." Petition, p. 95.

203. However, Petitioner fails to consider the advantages of Hartley's valve that would be destroyed by Petitioner's proposed combination. For example, as I describe in §VIII.B. above, incorporating Eller's torsion spring into Hartley's valve would render Hartley's ball and detent arrangement inoperable for its intended purpose of retaining the rotary actuator in position and thereby maintaining the valve in a selected valve state (open, closed). A POSITA would understand that this functionality of the ball and detent arrangement to maintain the valve in an open state would be advantageous during insertion of instruments through Hartley's valve.
204. Specifically, a POSITA would understand that in Petitioner's proposed combination, Eller's torsion spring would exert a significant compression force against an instrument inserted through Hartley's valve—especially for large instruments that greatly compress the torsion spring—as the torsion spring would always act to provide a biasing force to completely constrict and seal Hartley's cylindrical diaphragm 8. This force of the torsion spring would significantly inhibit movement (advancement, retraction) of the instrument through Hartley's valve. In contrast, Hartley's ball and detent arrangement

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allows Hartley's valve to be selectively maintained in an open or partially open state in which there is no or minimal compressive force on the cylindrical diaphragm 8 such that instruments could be easily manipulated through Hartley's valve.

205. A POSITA would understand that this ability to have a loosened valve that exerts little or no compression force against an inserted instrument is desirable in some situations. As one example, Schaffer recognizes that "[i]f a valve is inordinately tight, having a closed lumen, it may not allow the insertion of soft, flexible instrumentation such as a 'floppy-tip' guidewire, a delicate laser fiber or a soft-tipped catheter" and that "[s]ome catheters, optical fibers and fluid transmission tubes are very delicate and can be damaged by excessive compression or insertion force." EX1005, ¶ [0007]. Therefore, a POSITA would recognize that Hartley's ball and detent arrangement allows Hartley's valve to be selectively maintained in a position that does not exert excessive compressive force against an inserted instrument that could damage the instrument and that would act to inhibit manipulation of the instrument.
206. Moreover, a POSITA would recognize that Hartley's valve is designed to and/or could be easily designed to provide the advantage of maintaining the valve in a position that exerts no or little compressive force against instrument while also minimizing blood loss during a medical procedure. For example,

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while Hartley illustrates three recesses (detents) 32 and 34, Hartley provides that “[t]here may also be further recesses or detents between the central recess and the end recesses.” EX1006, [0033]. A POSITA would understand that with three or more than three detents, Hartley’s valve could be selectively locked in a position in which a diameter of the valve lumen closely matches the diameter of an instrument inserted therethrough. In this arrangement, the valve would provide no or relatively little resistance to the manipulation of instruments through the valve while also minimizing blood loss because the valve lumen generally matches the diameter of the instrument.

207. To relieve the compressive force against an instrument in Petitioner’s proposed combination, a user would need to move Hartley’s rotary actuator against the force of Eller’s torsion spring and maintain the rotary actuator in this position to counteract the force of Eller’s torsion spring. This would require the user to constantly engage (e.g., with one or both of the user’s hands) the rotary actuator during manipulation of instruments through the valve. Accordingly, Petitioner’s proposed combination would significantly complicate Hartley’s valve and the steps required to insert instruments therethrough. Accordingly, it would not have been obvious to a POSITA to have modified Hartley to include Eller’s torsion spring. As set forth above, doing so would destroy the functionality of Hartley’s ball and detent system, provide a

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constant compressive force against an instrument inserted through Hartley's valve that would act to greatly hinder manipulation of the instrument through the valve and potentially damage the instrument, and significantly complicate Hartley's valve and the steps required to insert instruments therethrough. Put differently, the advantages set forth by Petitioner of its proposed combination of Hartley and Eller would not have motivated a POSITA to have made the combination in view of the countervailing disadvantages that the combination would introduce and that are counter to the express structure and operation of Hartley's valve.

D. A POSITA Would Not Have Found It Obvious to Have Modified Garrison to Include Hartley's Valve Then Further Modify Hartley's Valve in View of Eller.

208. As explained above, a POSITA would understand the rotatable/passive hemostasis valves disclosed by Garrison to be easy to use, relatively small and therefore advantageous in tight spaces, such as the neck, readily available from many manufacturers, and—based on the disclosure of Garrison—sufficient to allow for the introduction of devices while “preventing or minimizing blood loss.” EX1011, ¶[0098]. A POSITA would understand Garrison's rotatable valves to operate similarly to Hartley's valve in that they can be selectively rotated to maintain various size openings of the valve. For example, Tuohy-Borst rotatable hemostasis valves include a cap that can be rotated to

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tighten or loosen a seal positioned therein and thereby adjust a diameter of a lumen defined by the seal. Likewise, a POSITA would understand Garrison's passive valves to operate similarly to Eller's valve in that they return to a sealed position absent insertion of an instrument therethrough. For example, cross-slit passive hemostasis valves have flaps configured to seal against one another when an instrument is not positioned within the valve and to move away from one another and seal against the instrument when the instrument is inserted through the slit(s).

209. If a POSITA would understand biasing to a sealed position to be the most important consideration for Garrison's valve—they would not have as I explain in §VIII.C. above—Petitioner provides no explanation for why a POSITA would not simply use Garrison's passive valve that provides the same functionality as Petitioner's proposed combination of Hartley and Eller. Indeed, a POSITA would have simply used Garrison's passive hemostasis valve instead of substituting Hartley for Garrison's valve and then further modifying Hartley in view of Eller to provide the self-closing aspect in a manner that destroys the functionality of Hartley.

IX. SECONDARY CONSIDERATIONS

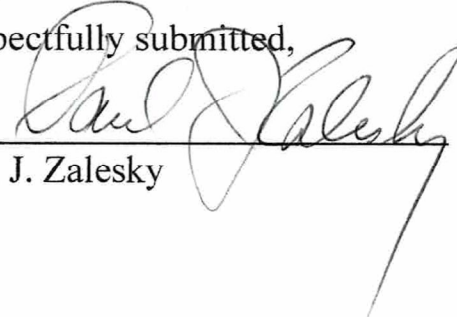
210. I have not rendered any opinions on secondary considerations of non-obviousness at this time, but reserve the right to analyze evidence of secondary considerations at a later stage, if asked to do so.

X. CONCLUSION

211. For all the above reasons, it is my opinion that the Claims of the '005 Patent are not unpatentable based on the prior art grounds asserted by Petitioner and Mr. Thornton.

I, Paul J. Zalesky, declare that all statements made herein of my knowledge are true, and that all statements made on information and belief are believed to be true, and that these 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.

Dated: September 9, 2025

Respectfully submitted,
By: 
Paul J. Zalesky