

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. IPR2025-00156
U.S. Patent No. 11,697,012

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 2025-00156 concerning U.S. Patent 11,697,012 (“’012 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: the Claims (1-9) of the ’012 Patent are unpatentable under 35 U.S.C. § 102 as anticipated by U.S. Patent Application Publication No. 2003/0225379 to Schaffer et al. (“Schaffer”);

Ground 2: the Claims of the ’012 Patent are unpatentable under 35 U.S.C. § 103 as obvious over Schaffer alone;

Ground 3: the Claims of the ’012 Patent are unpatentable under 35 U.S.C. § 103 as obvious over Schaffer in combination with U.S. Patent Application Publication No. 2003/0116731 to Hartley (“Hartley”);

Ground 4: the Claims of the ’012 Patent are unpatentable under 35 U.S.C. § 103 as obvious over Schaffer in combination with U.S. Patent No. 9,980,813 to Eller (“Eller”);

Ground 5: the Claims of the '012 Patent are unpatentable under 35

U.S.C. § 103 as obvious over Schaffer in combination with Garrison;

Ground 6: the Claims of the '012 Patent are unpatentable under 35

U.S.C. § 103 as obvious over Schaffer in combination with Hartley and

Garrison; and

Ground 7: the Claims of the '012 Patent are unpatentable under 35

U.S.C. § 103 as obvious over Schaffer in combination with Eller and

Garrison.

I have been asked by counsel for Inari Medical, Inc. (“Inari” or “Patent Owner”) to opine on the patentability of the claims of the '012 patent and, in particular, the patentability of independent Claim 1 with respect to grounds 1-7.

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.
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 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 1970’s, when he pioneered coronary balloon angioplasty, the 1980’s 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 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 real time, intravascular imaging enabled review and optimization of treatment with specialized catheters or stents.

13. In the early 1990's 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 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 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.
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 more likely than not that the claims of the '012 patent are anticipated by Schaffer, obvious over Schaffer alone, obvious over the combination of Schaffer and Hartley, obvious over the combination of Schaffer and Eller, obvious over the combination of Schaffer and Garrison, obvious over the combination of Schaffer, Hartley, and Garrison, or obvious over the combination of Schaffer, Eller, and Garrison.
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 '012 Patent which is September 6, 2017. Petitioner also applies September 6, 2017, as the priority date for the '012 Patent. Petition, p. 15.
27. I understand that for a patent claim to be anticipated, each claim limitation must be present in a single piece of prior art. It is my understanding from counsel that a prior art reference anticipates a claimed invention if the prior

art reference disclosed each of the claimed limitations of the invention either expressly or inherently.

28. 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.
29. 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, 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.
30. 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.

31. 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

32. For the reasons I discuss below, I believe that the asserted claims of the '012 Patent are not anticipated by or rendered obvious by Schaffer, or rendered obvious by any combination of the prior art asserted in the Petition.

V. THE '012 PATENT

A. Overview

33. The '012 Patent 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.” EX1001, 1:51-55. The '012 Patent addresses those drawbacks by providing a hemostasis valve (i.e., a valve that inhibits or prevents blood from flowing through the 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 thrombectomy

systems, an embodiment of the '012 patent. *Id.* at 16:7-31 (incorporating by reference, e.g., U.S. Patent Application 15/498,320, which published as US2018/0193043 (EX2004)). 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.

34. Specifically, the '012 Patent discloses that “[t]he present disclosure relates to a valve that can be used [as] a hemostasis valve.” EX1001, 5:55-56. This valve, also referred to in the '012 Patent as a garrote valve, can seal with or without a tool extending through the valve. *Id.* at 5:56-58. I understand that the '012 Patent used the term “garrote valve” to evoke the mechanism and action of the valve in which a filament is looped around a flexible tubular member and pulled tightly to shrink the loop to thereby collapse and seal the flexible tubular member.
35. 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 procedures. *Id.* at 5:55-67. 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 2:11-13, 5:9-23, 6:2-6. 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.

36. When utilizing the garrote valve in a thrombectomy procedure, for example, the garrote valve can be coupled to a proximal end of a catheter and used to seal a lumen of the catheter and maintain hemostasis (i.e., inhibit or prevent blood flow from the catheter through the valve) when an instrument (e.g., catheter, wire, embolectomy system) extends through the garrote valve and the lumen of the catheter, and when no instruments extend through the garrote valve. *Id.* at 5:55-67. 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 catheter. *Id.* at 5:64-6:6.
37. In an embodiment, the '012 Patent discloses a garrote valve 104 on a proximal end 108 of a catheter 102. *Id.* at 6:28-35. The catheter 102 can comprise an elongate flexible shaft 106 that defines a central lumen 112 and a distal end 110 of the catheter 102:

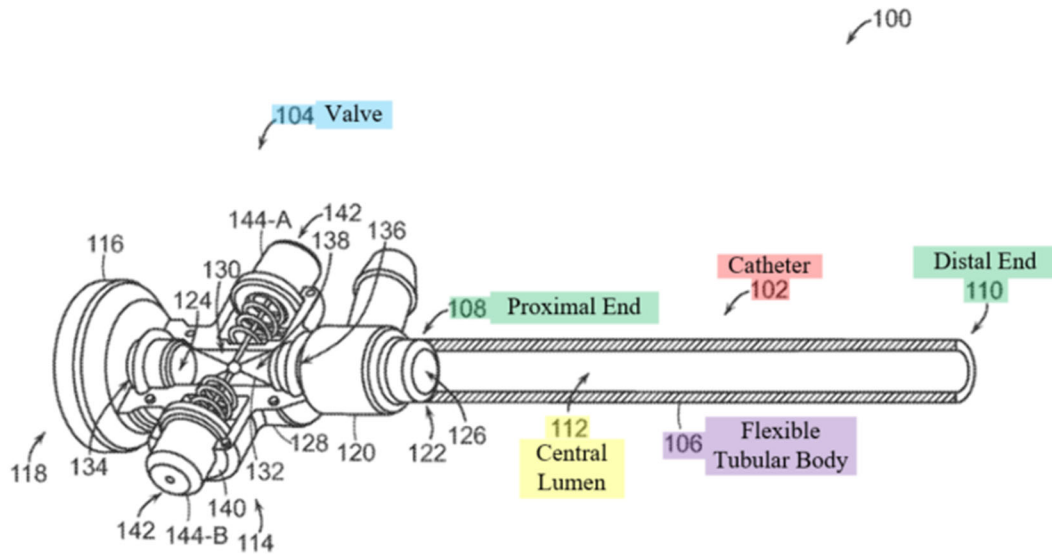


FIG. 1

Id. at 6:30-41.

38. The garrote valve 104 includes a housing defining an interior channel 130 and an elongate/tubular member 132 extending through the interior channel 130.

Id. at 7:11-15. The tubular member 132 defines a valve lumen 138 in communication with the central lumen 112 of the catheter 102. *Id.* at 7:36-45.

The tubular member 132 can comprise a compliant tubular sidewall that facilitates collapse and sealing of the tubular member 132:

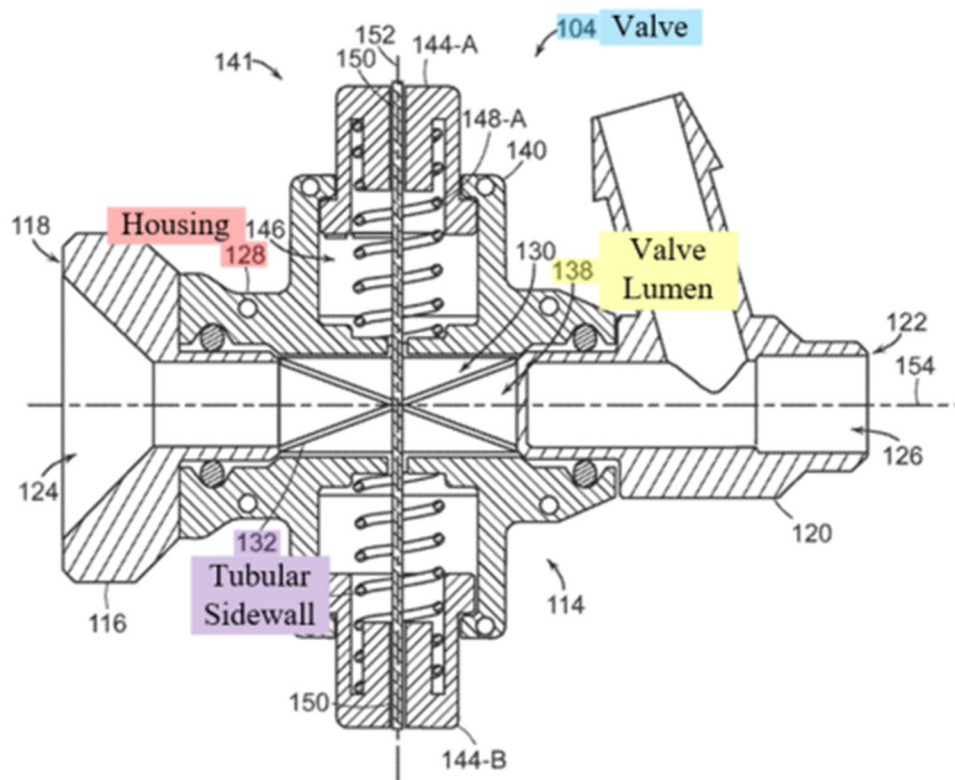
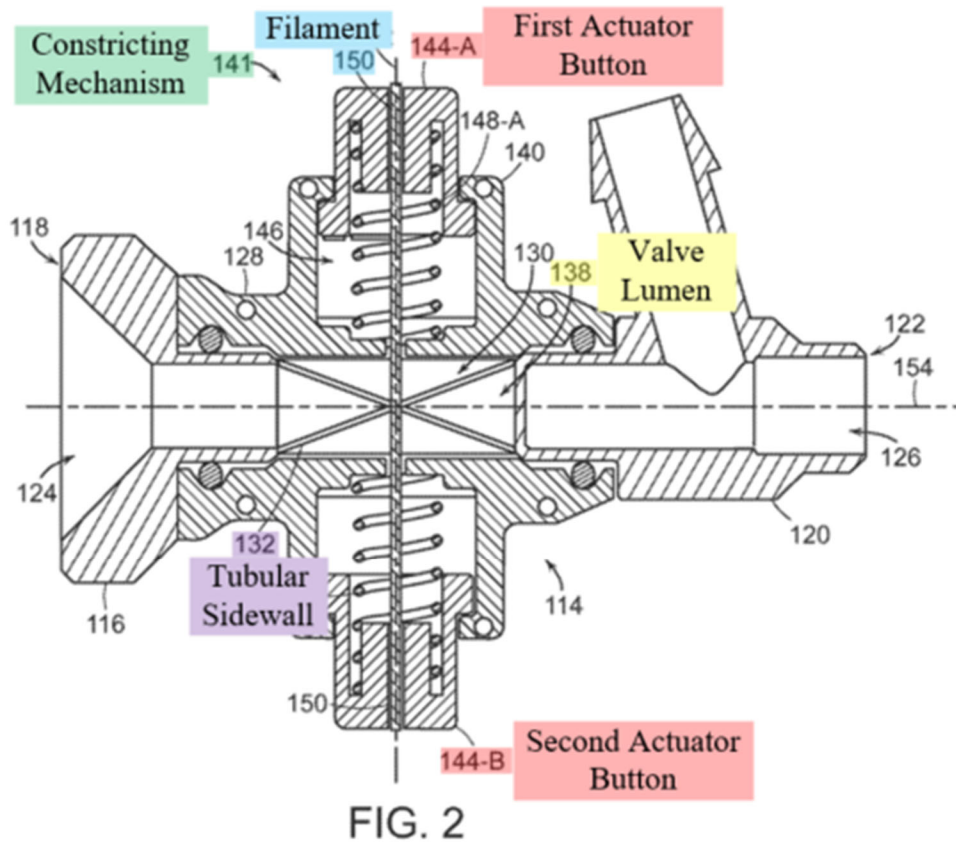


FIG. 2

Id. at 7:17-23 & 7:46-57.

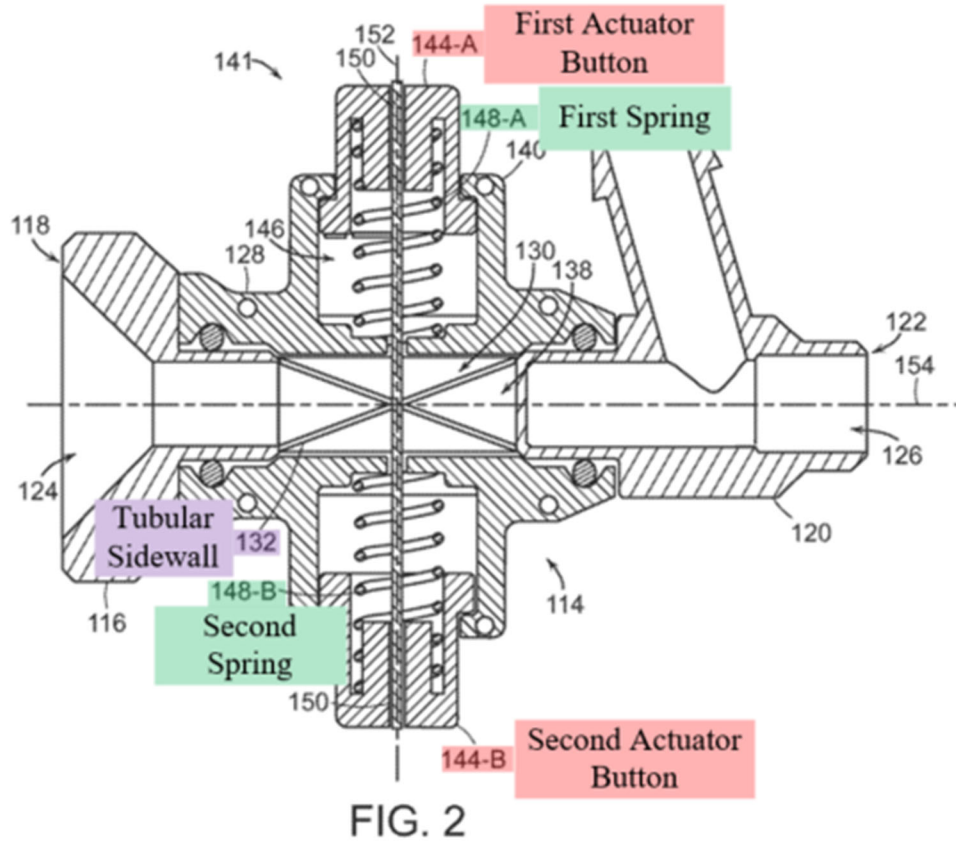
39. The garrote valve further includes a constricting mechanism 141 or garrote that can collapse and seal the tubular sidewall 132 via constriction with at least one filament 150 that can extend at least partially around the tubular member 132. *Id.* at 8:5-12. Specifically, the constricting mechanism 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 at least one 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:



Id. at 8:8-12 & 9:28-31.

40. 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”:



Id. at 8:46-56. The actuator 142 can be actuated to move the garrote valve to a second (open) configuration of the garrote valve shown in Figure 3 wherein the tubular sidewall 132 is expanded and the central lumen 138 of the tubular sidewall 132 is unsealed:

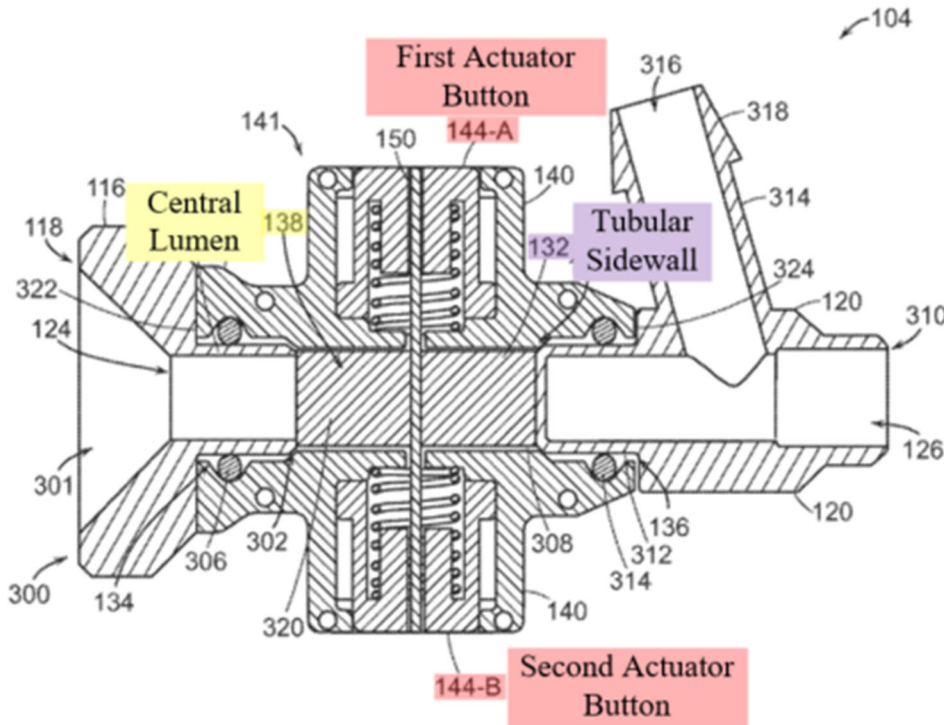


FIG. 3

Id. at 9:54-62. 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 8:12-16.

41. 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

- 9:13-16. 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.* at 9:16-23.
42. The filament 150 “can comprise a single filament 150” as shown in Figure 6. *Id.* at 12:46-48. 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. *Id.* at 12:61-64.
43. The filament 150 can have different configurations as shown in Figures 6-9 of the '012 Patent. For example, as shown in Figure 6, the filament 150 can be configured to form a single loop 604 that extends around the elongate member 132:

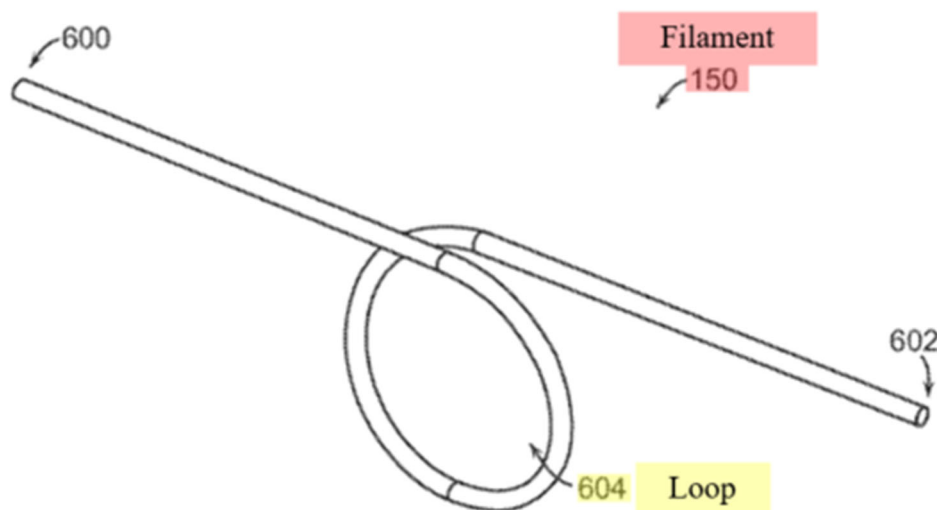
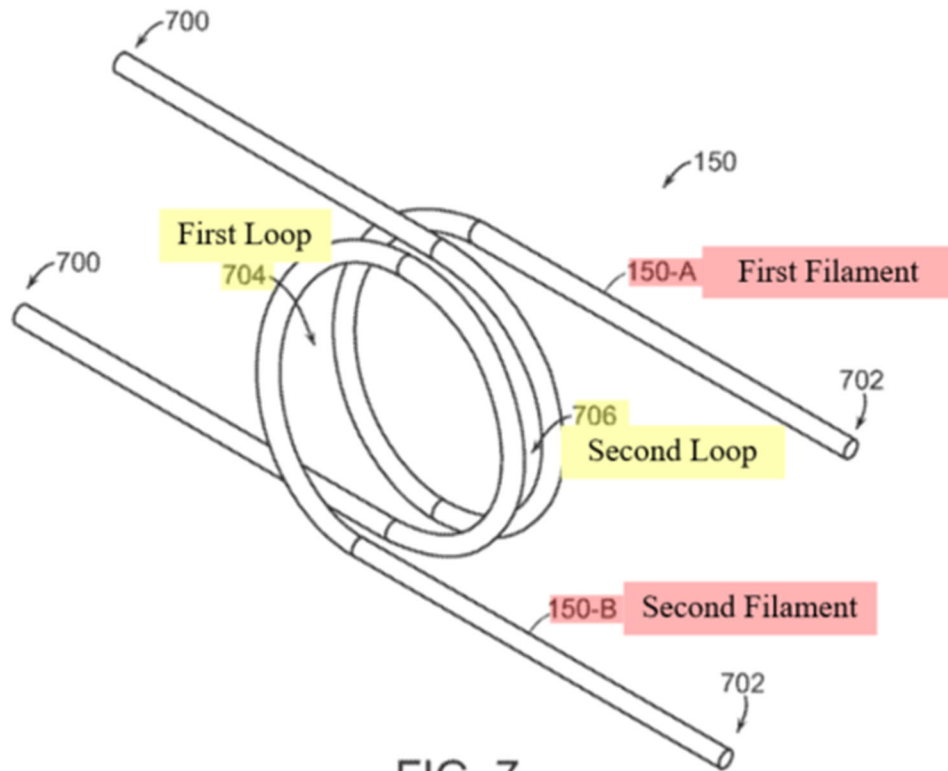


FIG. 6

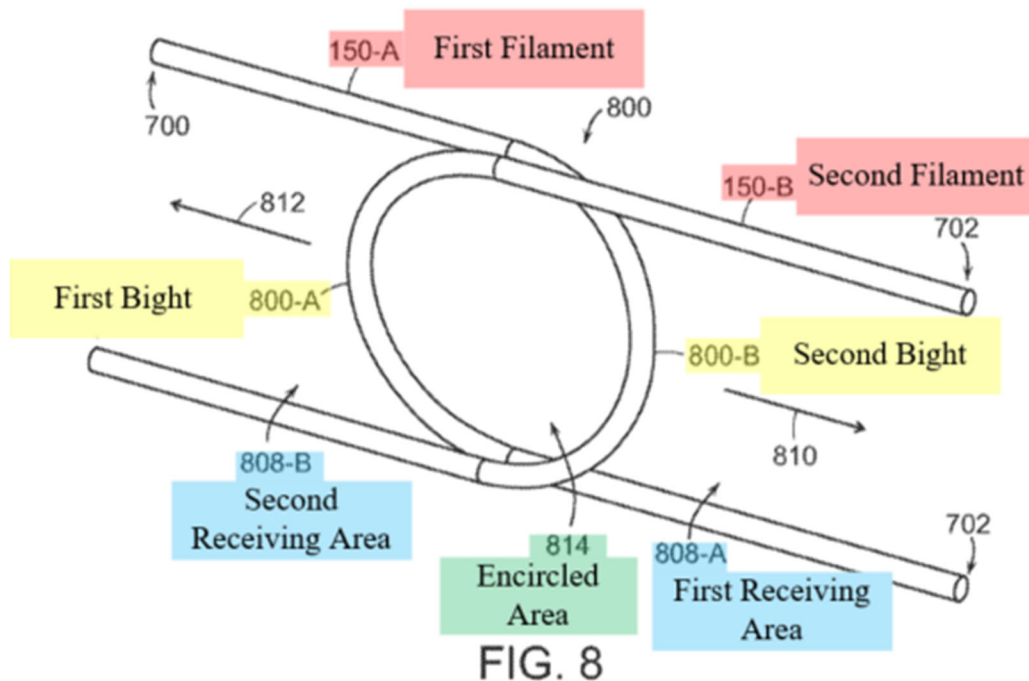
Id. at 13:17-21. For example, as shown in Figure 7, the filament 150 can comprise a first filament 150-A and a second filament 150-B each of the single filaments forming an individual loop—a first loop 704 and a second loop 706, respectively:



Id. at 13:21-25.

44. 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 13:26–29.

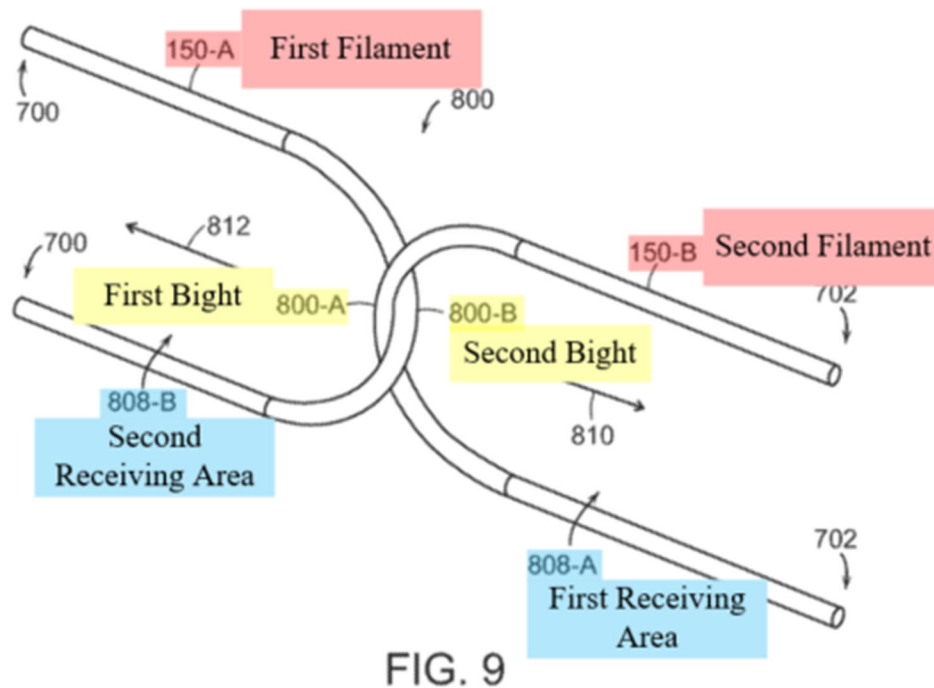
45. As shown in Figures 8 and 9, in other non-loop embodiments of the '012 Patent the filament 150 can be formed into a single bight or multiple bights. *Id.* at 13:30-32. The '012 Patent specifies that in contrast to a loop, the term “‘bight’ refers to a U-shaped section between the two ends of the filament 150.” *Id.* at 13:32-33. 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. at 34-36.

46. 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 47-51. As further shown above, the first and second receiving areas 808-A and 808-B overlap to define a constricting area 814. *Id.* at 13:57-61. 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:



Id. 13:62-14:5.

47. As I note above, the easy one-handed operation and strong seal of the garrote valve is particularly useful in vacuum thrombectomy procedures. Figure 11 of the '012 patent discloses one example of a thrombectomy system 1100

including a thrombus extraction device 1102 inserted through the garrote valve 104 and a coupled aspiration catheter 102 that is used to treat and/or extract a thrombus 1106 from the blood vessel 1104:

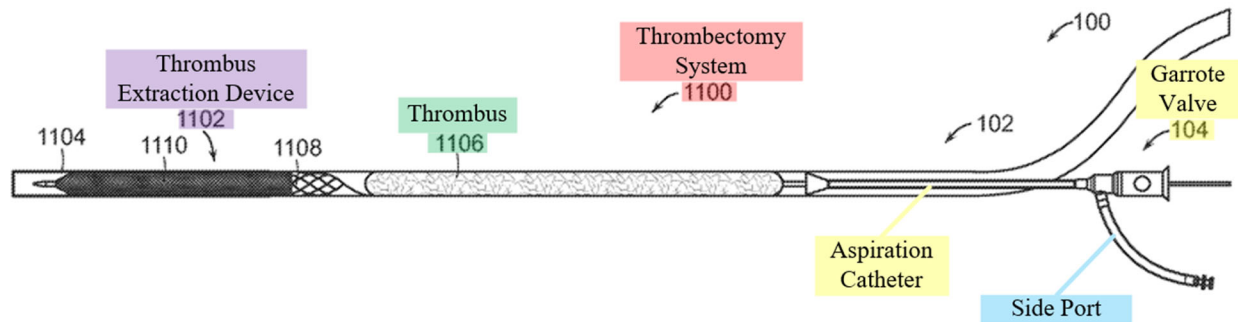


FIG. 11

Id., 16:7-12. The aspiration catheter 102 is fluidly coupled to a side port that is used to apply a vacuum to the aspiration catheter 102 to aspirate clot material therethrough. *Id.* at 10:37-45. The garrote valve 104 is particularly useful in such thrombectomy procedures to provide for convenient single-handed access to the lumen of the aspiration catheter 102 while also providing robust sealing with or without the thrombus extraction device 1102 inserted therethrough during vacuum aspiration of the aspiration catheter 102 via the side port. *Id.* at 5:55-6:6. More particularly, the garrote valve 104 provides robust sealing and easy access to the aspiration catheter 102 when the aspiration catheter 102 is a large-bore catheter wherein blood loss is a significant concern during a thrombectomy procedure.

48. For example, the aspiration catheter 102 can have an outer diameter of “at least 18 French, at least 20 French, at least 22 French.” *Id.* at 6:41-45. 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.
49. 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.

B. Prosecution History of Claim 1

50. I have reviewed the prosecution history of the '012 patent, including the Restriction Requirement mailed September 20, 2022 (EX1002, pp. 178-183), the Response to Restriction Requirement filed October 28, 2022 (*Id.* at pp. 171-176), the Examiner-Initiated Interview Summary mailed November 23, 2022 (*Id.* at p. 88), the Notice of Allowance mailed November 23, 2022 (*Id.* at pp. 79-87), and the Notice of Allowance mailed April 27, 2023 (*Id.* at pp. 27-31).
51. The Examiner initially found the application to be directed to patentably distinct species and required an election between Species I (Figs. 1-5) or Species II (Fig. 12). *Id.* at p. 180. I further understand that, if Species I were elected, the Examiner required an additional election between distinct sub-species of filament: Species IA (Figs. 1-5), Species IB (Fig. 6), Species IC (Fig. 7), Species ID (Fig. 8), or Species IE (Fig. 9). *Id.*
52. The Applicant elected Species I (Figs. 1-5) and Species IB (Fig. 6.) in response. *Id.* at p. 175. I note that the elected Species IB is directed to the

filament loop embodiment rather than the bight embodiments (Figures 8 and 9) as I explain in §V.A. above. I note also that Figure 7 includes Figure 6—just with an additional filament loop—and that Figures 8 and 9 are in fact the same embodiment.

53. The Examiner conferred with the Applicant of the '012 Patent via telephone to resolve an issue with antecedent basis in Claim 1 via an Examiner's Amendment, before allowing the application. *Id.* at p. 88.
54. The Examiner considered the patentability of the claims in view of Hartley, Wong, and Myers and concluded that Hartley fails to disclose a “first spring,” that Wong fails to disclose a “constricting mechanism having a first filament formed in a loop,” and that Myers fails to disclose a “first filament.” *Id.* at pp. 85-87.

C. Construction of Claim 1

55. 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).

1. “Filament”

56. Claim 1 recites “a constricting mechanism having ... a first filament formed into a loop around the collapsible tubular sidewall.” Here, the ’012 patent uses and applies 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 September 6, 2017. 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.
57. 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. 16. 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 column 9, lines 21-23 of the specification of the ’012 patent. I disagree.

58. The claim language itself confirms that a filament must be flexible. Claim 1 recites that “the first filament [is] formed into a loop around the collapsible tubular sidewall” 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.
59. The specification further confirms that a filament must be flexible. Specifically, Figure 6 of the '012 Patent—which was elected by the Applicant of the '012 Patent in Response to a Restriction Requirement during prosecution of the '012 Patent (EX1002, pp. 171-176)—shows a single filament 150 configured to form a single loop 604 that extends around the elongate member 132:

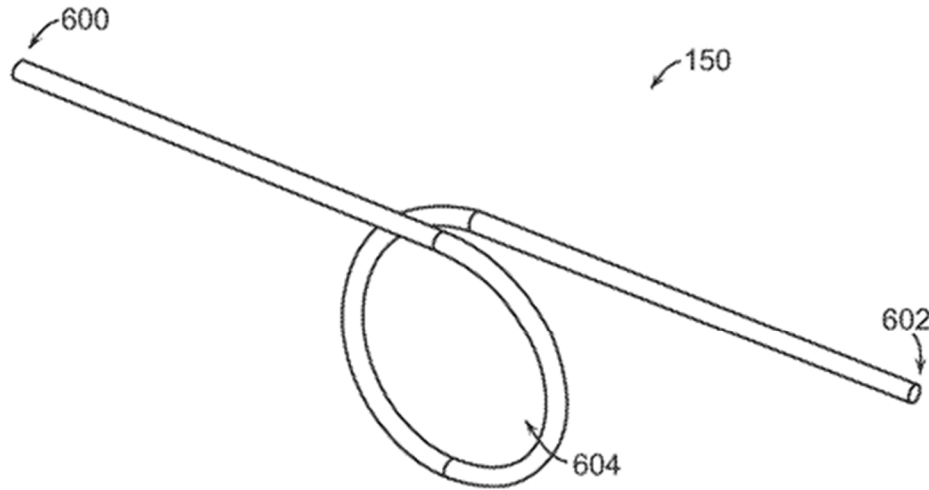


FIG. 6

EX1001, 13:17-21. “[E]ach of the first end 600 and the second end 602 can be coupled to different buttons 144” of the actuator. *Id.* at 12:54-56. 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 decrease the “diameter of the loop” as recited in Claim 1—the loop would stay the same size and an elongate member extending through that loop would not be constricted and sealed. *Id.* at 13:26–29. 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 '012 Patent illustrates two filaments each formed into a loop that must also be sufficiently flexible to reduce in diameter. *Id.* at 13:22-29.

60. While the specification describes the filament as comprising various potential materials, such as “a polymer, a synthetic, and/or a metal” (EX1001, 9:13-15), 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 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.

61. 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 example, in the Notice of Allowance dated November 23, 2022, the Examiner states that Hartley discloses “at least one filament” at item 14. EX1002, p. 85. Item 14 is 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.
62. 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.

2. “Aspiration” in the Preamble

63. Because it is not relevant to my analysis of grounds 1-7 at this preliminary stage, I do not analyze the construction of “aspiration” in the preamble of

Claim 1. Nevertheless, I may, if asked, further review and assess the proper construction of this term.

VI. INDEPENDENT CLAIM 1—SCHAFFER ALONE DOES NOT ANTICIPATE INDEPENDENT CLAIM 1 NOR DOES SCHAFFER ALONE OR IN COMBINATION WITH HARTLEY, ELLER, AND/OR GARRISON RENDER OBVIOUS THIS CLAIM

A. Ground 1: Schaffer Does Not Anticipate Independent Claim 1.

64. Petitioner and its expert, Mr. Thornton, allege that Schaffer discloses each and every feature of Claim 1 of the '012 patent and therefore anticipates this claim.

I disagree for the reasons I discuss in further detail in this section. A POSITA would understand that Schaffer does not disclose several limitations of Claim 1 and therefore does not anticipate Claim 1.

65. As I explained above, for a patent claim to be anticipated, each claim limitation must be present in a single piece of prior art. It is my understanding from counsel that a prior art reference can anticipate a claimed invention if the prior art reference disclosed each of the claimed limitations of the invention either expressly or inherently.

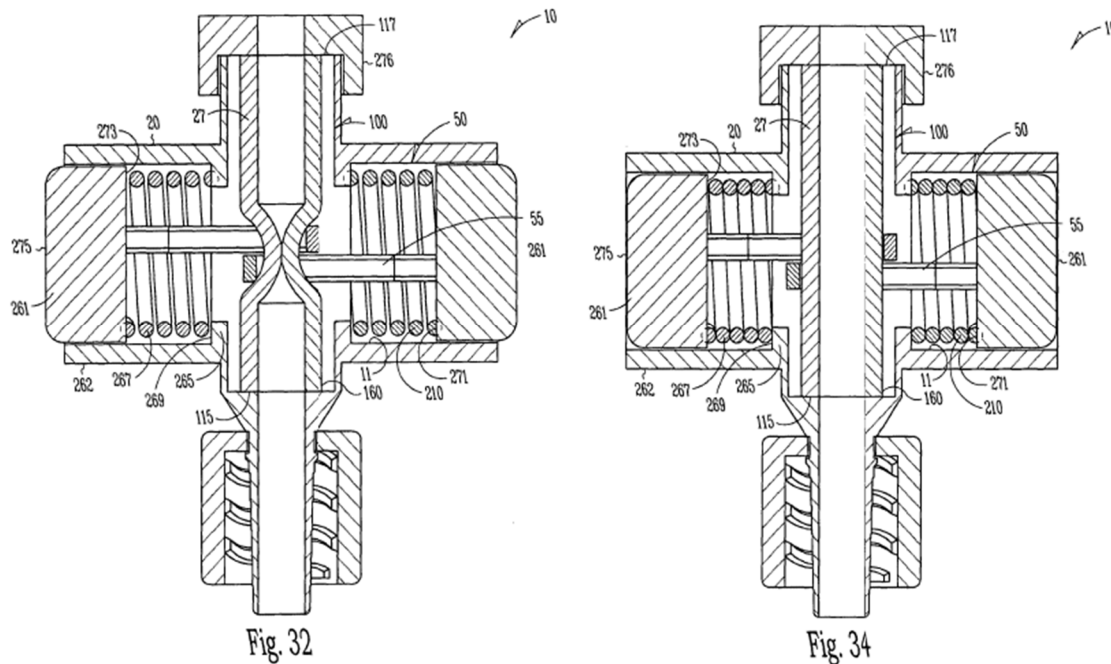
1. Schaffer does not disclose the “first filament” of Claim 1.

66. According to Petitioner, “Schaffer’s U-shaped actuating members are a ‘filament’.” Petition, p. 36. That is, Petitioner contends that “Schaffer’s U-shaped actuating members collectively constitute the ‘first filament’ claimed in the

'012 patent.” *Id.* at p. 37. I disagree—Schaffer’s actuating members 55 are rigid metal or plastic U-shaped structures and not thin and flexible filaments.

67. As I explain in §V.C.1. 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 “first filament,” as recited in Claim 1.

68. First, Schaffer illustrates its stasis valve 10 in a first (sealed) position and a second (open) position in Figures 32 and 34¹, respectively:



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.

Schaffer describes that “[i]n the first position the actuating members 55 of the actuators 50 are, in one option, disposed and at least partially circumferentially disposed about the portion 108 of the seal module 100 depressing and at least partially collapsing a portion 108 of the containment structure 160 by a compressive force 67 (e.g. by a spring 210).” EX1005, ¶ [0077]. “In the second position ... each actuator button 261 is depressed” and “[s]uch 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 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.

69. Moreover, as I explain in greater detail below in §VI.C.2., 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, ¶ 100.)
70. 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.

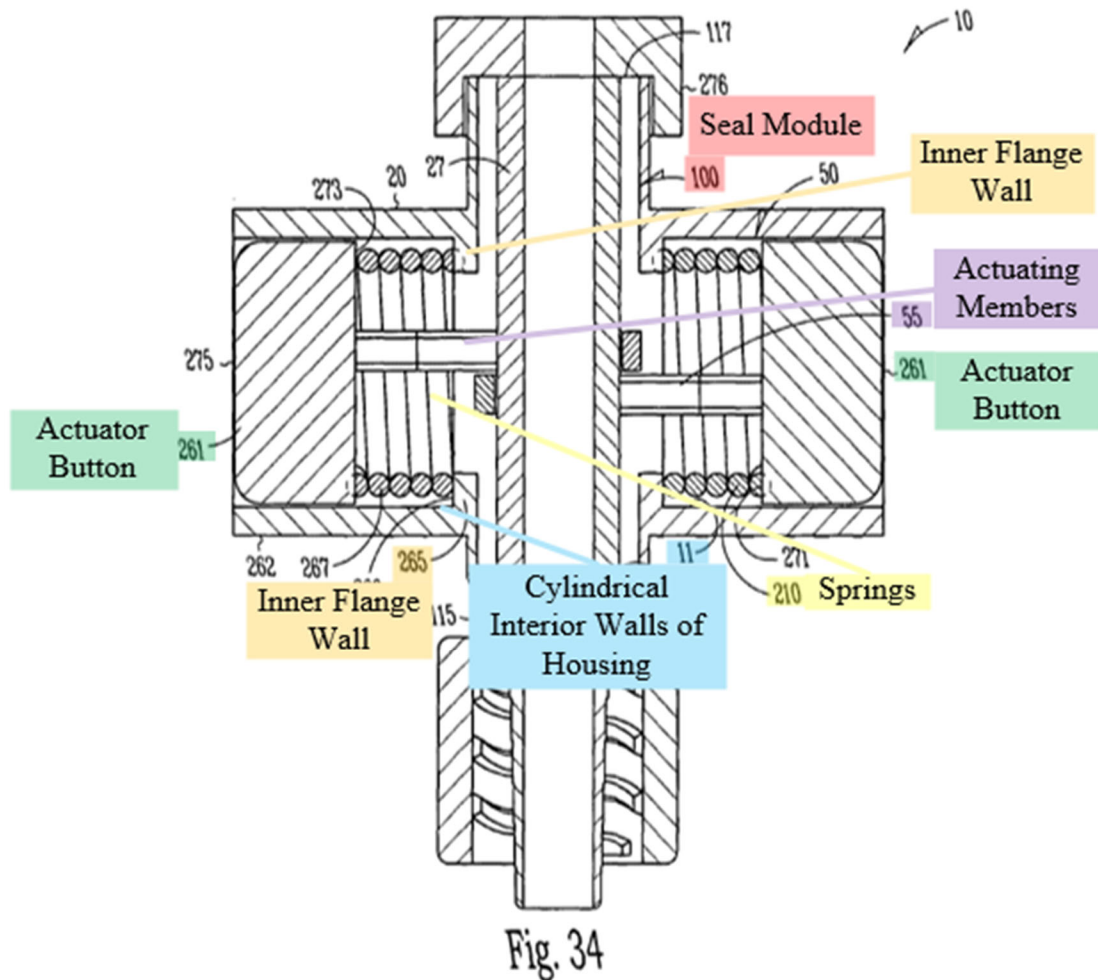
71. Third, Schaffer teaches and Petitioner highlights that "Schaffer's actuating members [are] formed from metal or plastic." Petition, p. 43; EX1005, ¶¶ [0081]-[0082]. Further, Shaffer provides that the actuating members 55 are "machined from aluminum" or "machined from plastic." EX1005, ¶ [0082]. A 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.

72. 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:

[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:



73. 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.

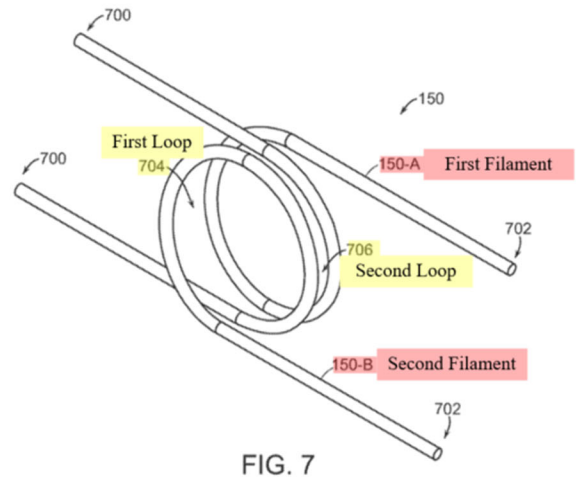
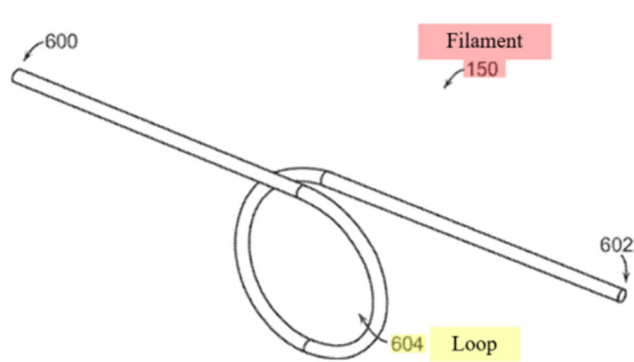
74. In sum, a POSITA would understand based on Schaffer's description and illustration of the operation of the actuating members 55, its description of the materials and methods of forming the actuating members 55, as well as its description of how its stasis valve is assembled, that the actuating members 55 are rigid rather than flexible. As such, Schaffer's actuating members 55, either alone or in combination, are not a "first filament" as claimed in the '012 patent because they are not flexible. Therefore, Schaffer does not disclose this feature of Claim 1 and thus does not anticipate Claim 1.

2. Schaffer does not disclose the "first filament formed into a loop around the collapsible tubular sidewall" of Claim 1.

75. Even assuming Petitioner's construction of "filament," Schaffer does not anticipate Claim 1 because Schaffer does not disclose a "first filament formed

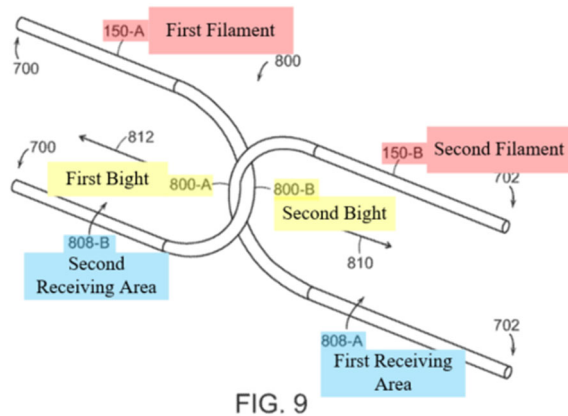
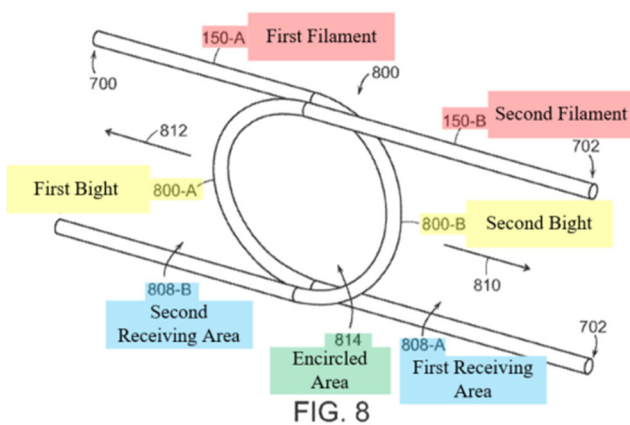
into a loop around the collapsible tubular sidewall.” Petitioner does not allege that either of the actuating members 55 is “formed into a loop” but instead alleges that “Schaffer’s U-shaped actuating members collectively constitute the ‘first filament’ claimed in the ’012 patent” and that “the actuating members collectively loop around the seal module 100.” Petition, pp. 37-38. Indeed, neither of Schaffer’s actuating members 55 are “formed into a loop” about the seal module 100 because they are rigid and U-shaped. EX1005, ¶ [0076].

76. I disagree that Schaffer’s “depict[ion of] two actuating members is of no moment,” as Petitioner and Mr. Thornton contend. Petition, p. 37. A POSITA would understand that Claim 1 of ’012 Patent requires a single filament “formed into a loop” based on the specification and prosecution history of the ’012 Patent. For example, as I explain in §V.A. above, the ’012 Patent discloses multiple different filament arrangements in Figures 6–9. 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:



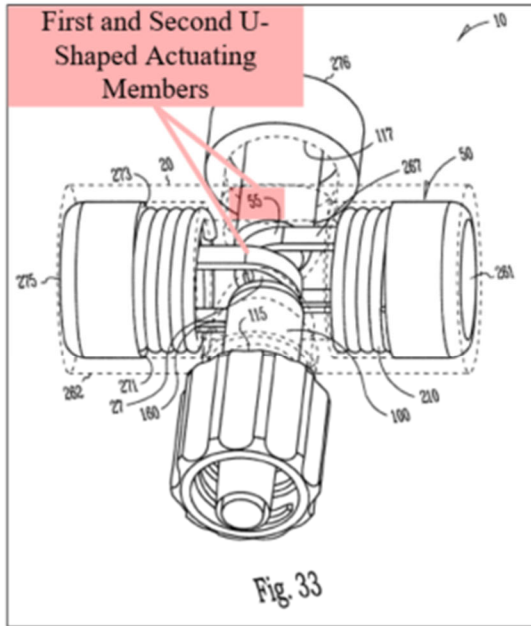
EX1001, 13:18-25.

77. In contrast, Figures 8 and 9 of the '012 Patent illustrate a two-filament arrangement on which a first filament and a second filament each form an individual U-shaped bight:

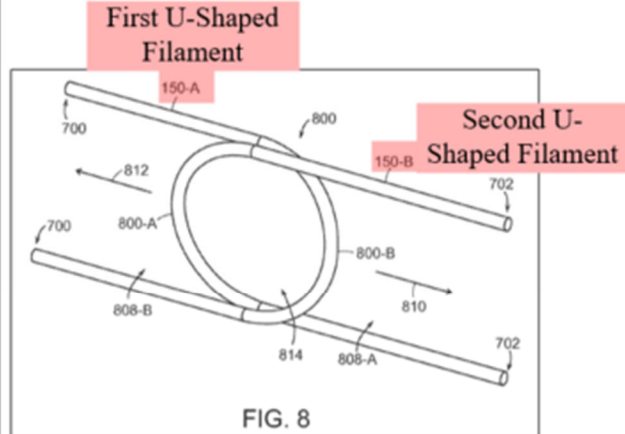


In this arrangement of the filaments, the '012 Patent discloses that the filaments each define a partially enclosed receiving area 808-A, 808-B, and together the first and second receiving areas 808-A and 808-B overlap to define an encircled area 814. *Id.* at 13:47-61.

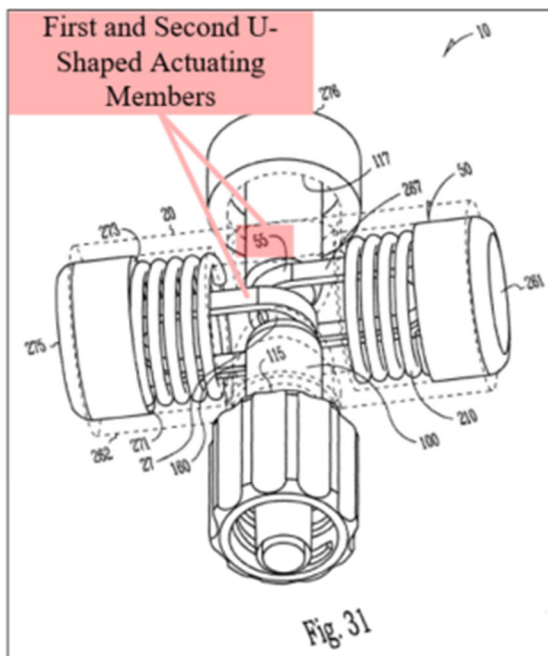
78. Accordingly, a POSITA would understand that, when the '012 Patent uses the term “loop,” the term refers to a single filament formed in a loop, and not multiple U-shaped filaments that overlap as shown in Figures 8 and 9. Multiple filaments each arranged in a U-shaped bight could collectively define an “encircled area” as shown in Figures 8 and 9—but not a “loop.”
79. The prosecution history of the '012 Patent supports this understanding. In particular, as I describe above in §V.B. above, the Applicant elected the filament loop embodiments—rather than the filament bight embodiment of Figures 8 and 9—in response to the Restriction Requirement. EX1002, pp. 171-176. Accordingly, a POSITA would understand that Claim 1 requires at least one individual filament that is itself “formed into a loop” and excludes multiple filaments—including U-shaped filaments—that collectively, but not individually, define an encircled or other area of overlap.
80. Accordingly, Petitioner’s reliance on Figure 8 of the '012 Patent to allege that the “first filament” of Claim 1 could comprise multiple filaments and thus that Schaffer’s U-shaped actuating members 55 could together comprise the “first filament” is incorrect. Petition, p. 37. The arrangement of Schaffer’s U-shaped actuating members 55 is similar to the embodiment shown in Figures 8 and 9 of the '012 Patent as illustrated in the comparison below:



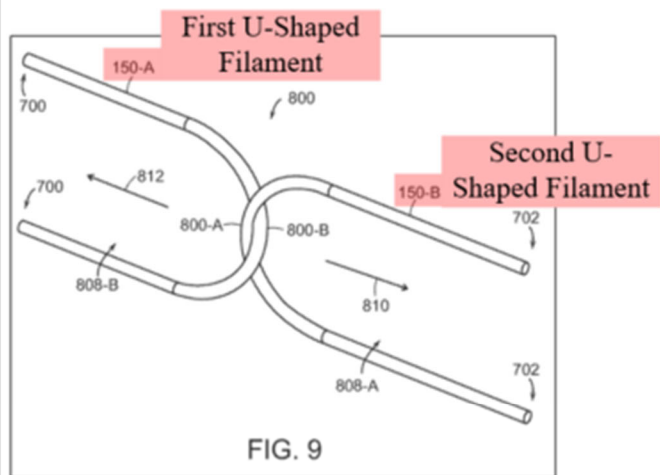
Schaffer's Valve 10 Opened



'012 Patent Figure 8



Schaffer's Valve 10 Closed



'012 Patent Figure 9

81. But, as I explain above, the '012 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.

82. In sum, a POSITA would understand based on the specification and prosecution history of the '012 Patent that Claim 1 requires a single filament “formed into a loop.” Both of Schaffer’s actuating members 55 are U-shaped and are therefore not “formed into a loop.” Accordingly, Schaffer does not disclose this feature of Claim 1 and thus does not anticipate Claim 1.

3. Schaffer does not disclose the “diameter of the valve lumen decreases in response to reducing a diameter of the loop” of Claim 1.

83. Even assuming Petitioner’s construction of “filament,” Schaffer does not anticipate Claim 1 for the additional reason that Schaffer does not disclose “a diameter of the valve lumen decreases in response to reducing a diameter of the loop.” As I explain above in §VI.A.3., neither of Schaffer’s two U-shaped actuating members 55 “form a loop,” and the two actuating members 55 cannot together be construed as the “first filament” of Claim 1. Accordingly, because Schaffer does not disclose a “first filament formed into 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.A.1.

B. Ground 2: Schaffer Does Not Render Obvious Independent Claim 1.

84. Petitioner and its expert, Mr. Thornton, allege that Schaffer, if it does not anticipate, renders obvious Claim 1 of the '012 Patent. I disagree for the reasons I discuss in further detail in this section. A POSITA would understand that it would not have been obvious to modify Schaffer to arrive at the features of Claim 1. Therefore, Schaffer does not render obvious Claim 1.
85. 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.

86. As I explain in §VI.A. above, Schaffer does not disclose (1) a “first filament” that is flexible, (2) a “first filament formed in a loop,” or (3) a “diameter of the valve lumen decreases in response to reducing a diameter of the loop.” I understand that Petitioner does not assert that it would have been obvious for a POSITA to have modified Schaffer to arrive at any of the foregoing features of Claim 1. Instead, Petitioner alleges that it would have been obvious to have modified Schaffer to arrive at other features of Claim 1, such as the “aspiration catheter” recited in the preamble and a “hemostasis valve on the proximal end of the catheter.” Petition, pp. 24-27 & 29-32. Accordingly, because Schaffer does not disclose the features (1)–(3) of Claim 1 listed above, and Petitioner does not contend that Schaffer alone renders such features obvious, Schaffer does not render obvious Claim 1.
87. Nor would it have been obvious to have modified Schaffer to arrive at the foregoing features of Claim 1. In particular, as I explain below in §§VI.C. & VI.D., 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 would render Schaffer inoperable for its intended purposes of easy manufacturability, durability, and assembly.

C. Ground 3: The Combination of Schaffer and Hartley Does Not Render Claim 1 Obvious

88. Petitioner and its expert, Mr. Thornton, allege that Schaffer in combination with Hartley renders obvious Claim 1 of the '012 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 modify Schaffer in view of Hartley to arrive at the features of Claim 1. Therefore, the combination of Schaffer and Hartley does not render obvious Claim 1.
89. 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

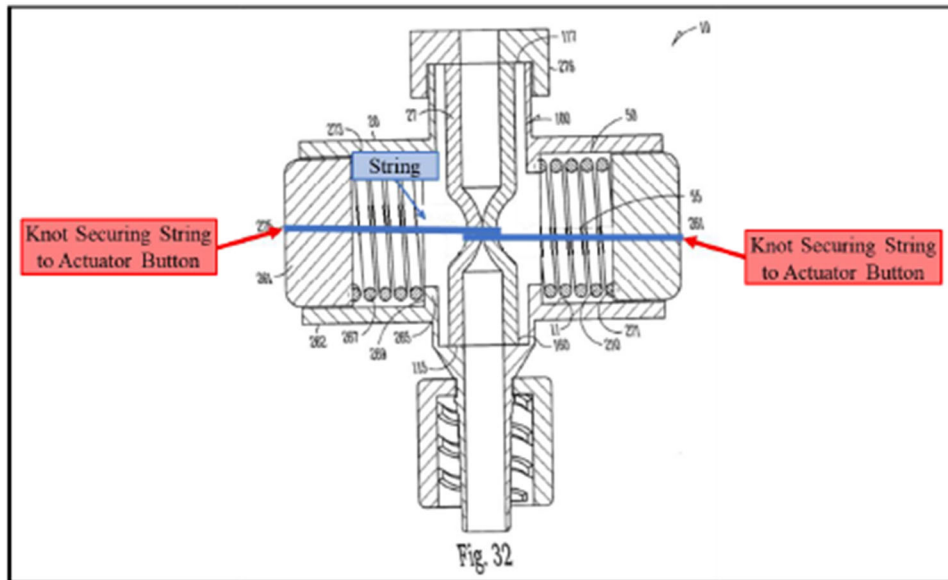
would be led in a direction divergent from the path followed by and claimed in the patent.

90. Petitioner argues that “POSITAs would have found it obvious to substitute Hartley’s string for Schaffer’s actuating members.” Petition, pp. 42-46.
91. I disagree that it would have been obvious to have, or that a POSITA would have, substituted Hartley’s string 14 for Schaffer’s U-shaped actuating members 55 for at least the reasons set forth below.

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

92. A POSITA would not have found it obvious to have substituted Hartley’s string for Schaffer’s U-shaped actuating members because neither Hartley nor Schaffer disclose a “first filament” connected at opposite ends to two actuators as proposed in Petitioner’s combination. Petitioner contends that in its proposed combination the references would be modified so that “the first end of the string would be secured to the first actuator button, the string would loop at least once around Schaffer’s seal module, and the second end of the string would be secured to the second actuator button.” Petition, p. 44. Petitioner provides the following demonstrative illustration to illustrate the proposed substitution:

Demonstrative Illustration
Schaffer + Hartley's String



Id.

93. 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) and attaching opposite ends of Hartley's string to two different actuator buttons 261 of Schaffer. But neither Schaffer nor Hartley disclose such an arrangement. For example, Schaffer discloses two actuating members 55 each having their respective ends coupled to separate ones of actuator buttons 261:

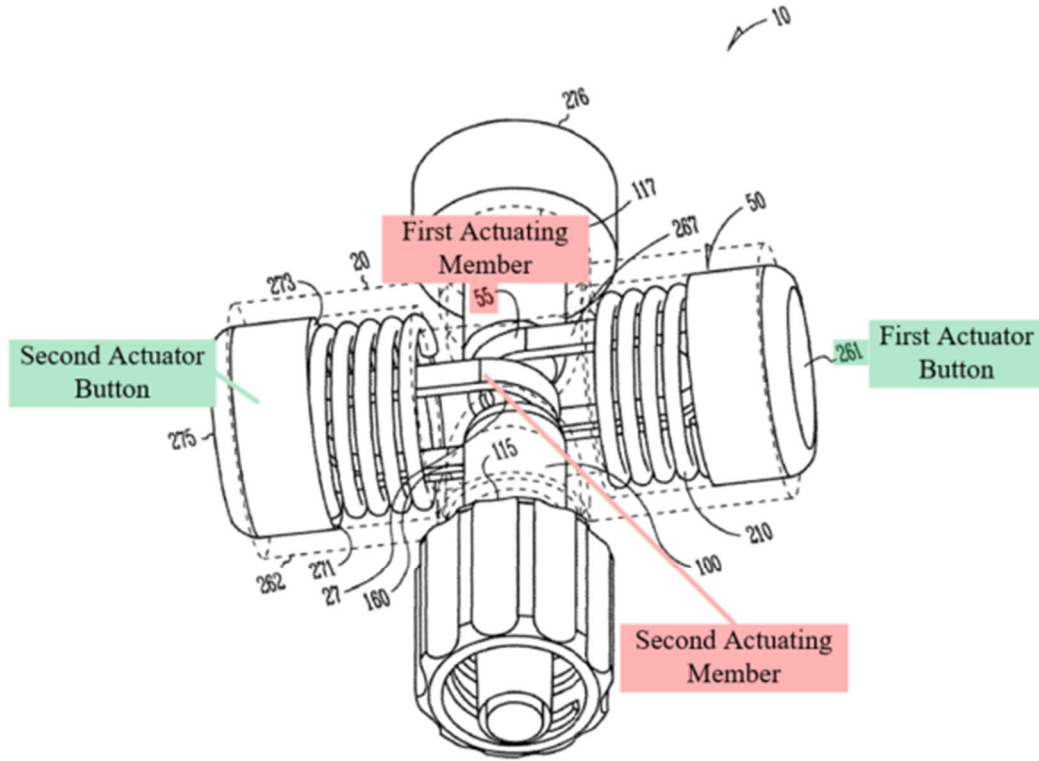


Fig. 31

Accordingly, 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. While Petitioner proposes a purported simple substitution of Hartley's string for Schaffer's U-shaped actuating members, Petitioner's proposed combination not only substitutes a flexible string 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 to two actuator buttons, an arrangement not found in Schaffer or Hartley.

94. Likewise, as can be seen in Figure 3, 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:

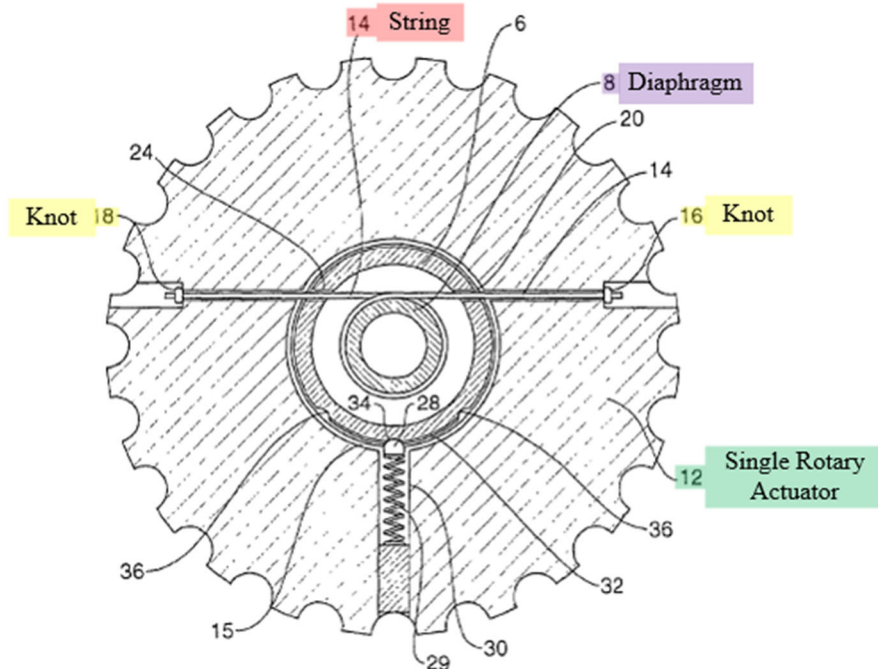


Fig 3

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 separate actuator buttons as shown in Petitioner's purported combination. Movement of the single rotary actuator 12 controls movement of the string 14. In contrast, in Petitioner's proposed combination the string 14 would be controlled by Schaffer's two actuator buttons 261 rather than by a single actuator as taught by Hartley.

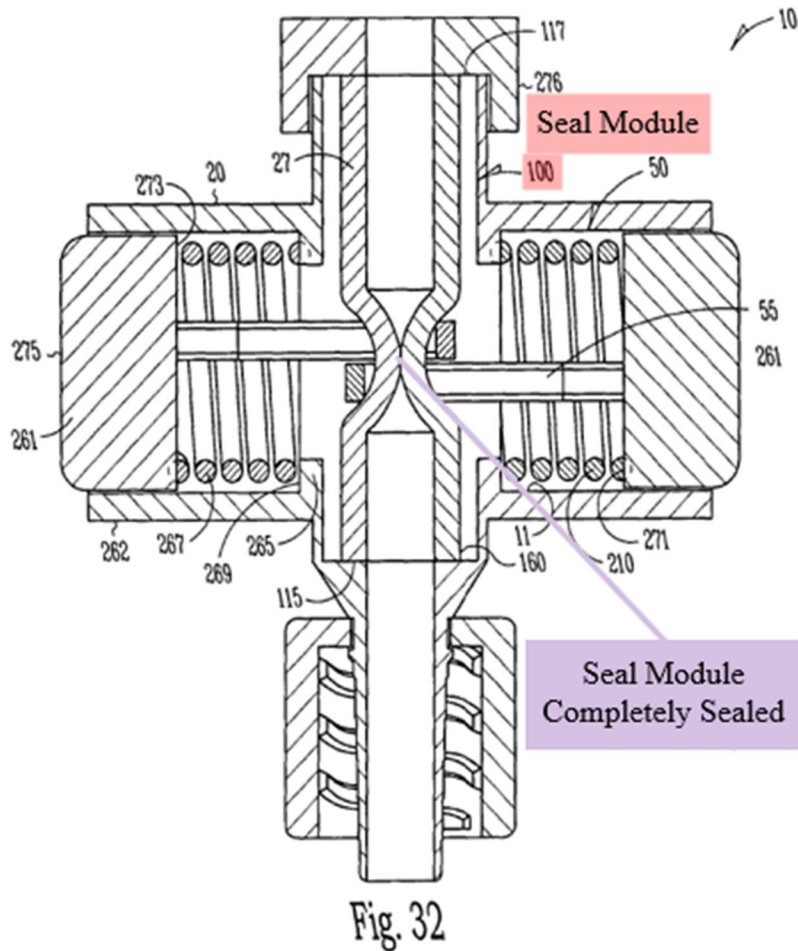
95. Accordingly, it is incorrect that the “combination of Hartley’s string and Schaffer’s valve would have merely entailed substitution of one known element (Hartley’s string) for another (Schaffer’s actuating members) to yield [a] predictable result.” Petition p. 42. Instead, Petitioner’s proposed combination requires significant additional modification and departs from the intended purpose and express disclosure of both Schaffer and Hartley in which a single U-shaped actuating member 55 or string 14, respectively, are controlled by a single actuator. A POSITA would understand that controlling a string 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 nor Hartley disclose any element (U-shaped actuator or string) coupled to separate, individually controlled actuator buttons as in Petitioner’s proposed combination.

2. Petitioner’s Stated Motivations to Modify Schaffer in View of Hartley 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.

96. A POSITA would not have been motivated to substitute Hartley’s string for Schaffer’s U-shaped actuating members as in Petitioner’s proposed combination because neither Schaffer nor Hartley disclose a string or actuating member attached to two actuator buttons as I explain above. A POSITA also would

not have modified Schaffer in view of Hartley to import Hartley's string in place of Schaffer's U-shaped members to improve sealing of Schaffer's valve because Schaffer expressly discloses 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 that "POSITAs would have recognized that Hartley's string may seal more effectively across a wider range of diameters and shapes for the inserted devices than Schaffer's U-shaped actuating members" and "[d]epending on the diameter of the inserted device, Schaffer's U-shaped actuating members may form small gaps between the valve's lumen and the tool's outer surface" as purportedly shown by Mr. Thornton's simple graphic. Petition, pp. 42-43. Petitioner's assertion that "Hartley's string would not suffer from [the potential formation of small gaps] because the string encircles the central lumen and precisely conforms to the diameter of the inserted devices" is based on an incorrect understanding of Schaffer, and more specifically, Schaffer's sealing member 165. *Id.* at p. 43.

97. Schaffer expressly discloses and illustrates the ability of its valve to seal completely across a wide range of instruments. For example, Figure 32 of Schaffer illustrates the completely sealed first position of the seal module 100:



Schaffer's device works to seal the seal module 100 as "[i]n the first position the actuating members 55 of the actuators 50 are ... disposed and at least partially circumferentially [sic] disposed about the portion 108 of the seal module 100 depressing and at least partially collapsing a portion 108 of the containment structure 160 by a compressive force 67 (e.g. by a spring 210)." EX1005, ¶ [0077]. The seal module 100 "is formed of one or more seal members, as discussed above" with reference to the various embodiments shown in Figures 1-29 of Schaffer. *Id.* at ¶ [0075]. The seal module 100 in Figures

30-34 of Schaffer includes at least the third central seal member 165, as Schaffer explains that in the sealed first position the “lumen 193 of the third seal member 165 is at least partially collapsed by the compressive force 67” and that “the third central seal member 165 includes material 166 that is highly elastic, deformable, compliant and yet virtually non-compressible.” *Id.* at ¶¶ [0077] & [0081].

98. Schaffer discloses the special characteristics of the material 166 of the third central seal member 165 that eliminate gaps and allow for complete sealing of the third central seal member 165 around a wide variety of instruments. *Id.* at ¶ [0059]. The material 166 “is extremely soft and compliant and intrinsically ‘sticky.’” *Id.* This “allows the third central seal member 165 to be easily compressed upon itself or upon an inserted instrument.” *Id.* The “nature of the material 166 of the third central seal member 165 can be compared to a gelatinous substance.” *Id.* 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.” *Id.*
99. Schaffer then discloses how the third central seal member 165 completely seals, without gaps, around a variety of instruments with reference to Figures 16-19:

[T]he 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. The compressive load may be supplied by a movable, sliding or hinged, actuator 50 that maintains a compressive load upon the third central seal member 165 under the influence of a spring 210 or other resilient material. The spring 210 provides a compressive load between the actuating member 55 of the actuator 50 and the stationary member 65 positioned in the interior wall 11 of the housing 20.

Id. at ¶ [0060] (emphasis added).

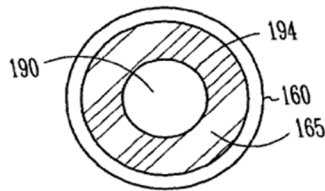


Fig. 16

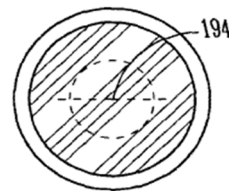


Fig. 17

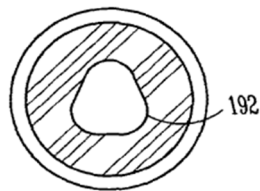


Fig. 18

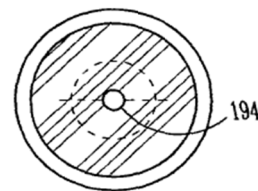


Fig. 19

100. 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].

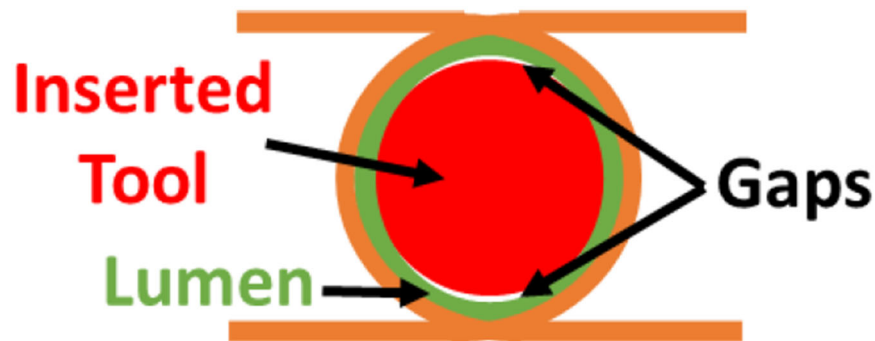
101. A POSITA would understand based on the foregoing disclosure of Schaffer that the seal module 100 completely seals without gaps “around a variety of profile shapes 192 and diameters 194 of the lumen 193” of the third seal member 165 due to, for example, the construction of the third seal member 165. *Id.* at ¶ [0060]. In particular, the gelatinous, sticky, and extremely soft and compliant third seal member 165 can self-close under compression by sticking occlusively to itself to form “a nearly fluid/gas tight seal under very light compression” by the U-shaped actuating members 55. *Id.* at ¶ [0059]. For example, a POSITA would understand Figure 16 of Schaffer to show the seal module 100 sealing around a large circular lumen 194, Figure 17 to show the seal module 100 in a sealed state with the lumen 194 completely closed (e.g., without an instrument inserted through the lumen 194), Figure 18 to show the seal module 100 sealing around an irregularly shaped lumen, and Figure 19 to show the seal module 100 sealing around a small circular lumen 194.
102. 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 without the need for circumferential constriction such as

with a filament garrote.² Accordingly, a POSITA would not have been motivated to have substituted Hartley’s string for Schaffer’s U-shaped actuating members to “form a better seal” and “avoid the potential gaps” because Schaffer expressly discloses and illustrates that its valve performs both of these functions.

103. First, with regard to forming a better seal, Petitioner alleges that a POSITA would have been motivated to modify Schaffer to include Hartley’s string 14 to “seal more effectively across a wider range of diameters and shapes for the inserted devices than Schaffer’s U-shaped actuating members.” Petition, p. 42. As explained above, Schaffer’s seal member 165 comprises a material that can conform to various shapes to form a seal. A POSITA would not have been motivated to modify Schaffer to include Hartley’s string 14 to form a better seal around instruments.

² I note that the Petition attempts to rebuts related arguments made in a related proceeding (*Imperative Care, Inc. v. Inari Medical Inc.*, IPR2024-01157, Paper 5 at 28-29 (P.T.A.B. Oct. 29, 2024)) reciting that “the portions of Schaffer cited by PO do not support its argument. (Ex. 1003, ¶100.)” I address Mr. Thornton’s comments in further detail below.

104. Second, with regard to preventing gaps, Petitioner relies on the opinions of Mr. Thornton and alleges that “[d]epending on the diameter of the inserted device, Schaffer’s U-shaped actuating members **may** form small gaps between the valve’s lumen and the tool’s outer surface,” providing a simple two-dimensional graphic of the purported “small gaps”:

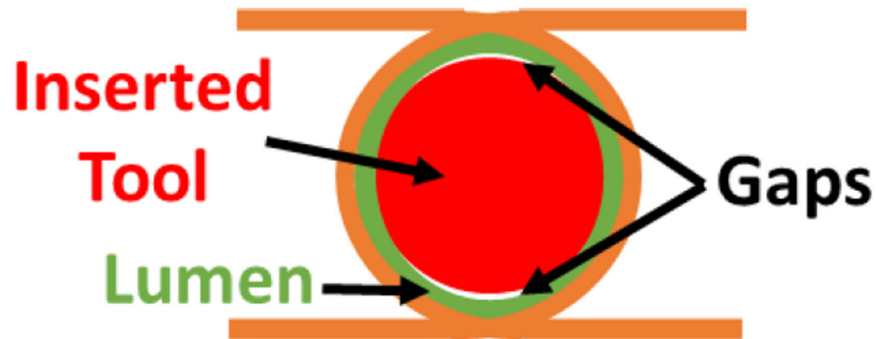


- Id.* at pp. 42-43 (emphasis added). However, Mr. Thornton’s figure is based on an incorrect understanding of Schaffer, and more specifically, the function of the seal member 165. Additionally, by saying that such gaps “*may*” form, Petitioner tacitly acknowledges that the alleged lack of sealing is speculative and would not be inherent to Schaffer’s structure.
105. In fact, Schaffer contradicts Petitioner’s purported motivations to have substituted Hartley’s string 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 disclosure addresses the then-existing need to improve sealing and provide 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.**” *Id.* at ¶ [0008] (emphasis added). Accordingly, a POSITA would understand that Schaffer’s valve is explicitly designed to seal effectively and completely (i.e., without gaps) in the presence of a wide range of different instruments, or without any instruments inserted thereto using the seal member 165. Petitioner’s stated motivations to modify Schaffer to substitute Hartley’s string for Schaffer’s U-shaped actuating members to “seal more effectively” and avoid the alleged “form[ation] of small gaps” are based on an incorrect understanding of Schaffer.

106. For the foregoing reasons, Petitioner’s assertion that a POSITA would have been motivated to substitute Schaffer’s U-shaped actuating members for Hartley’s string to “seal more effectively” and avoid the “form[ation] 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 seal module 100 including the highly elastic, deformable, and compliant and self-closing third seal member 165.

107. Accordingly, Petitioner's reliance on Mr. Thornton's graphic of the alleged "small gaps" is incorrect. The end-on view shows an "inserted tool" (red) and a "lumen" (green) and purported gaps therebetween:



Petition, p. 43. However, as described above, Schaffer expressly discloses that the seal module 100 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:

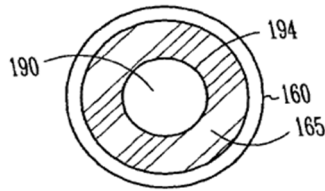


Fig. 16

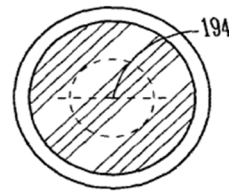


Fig. 17

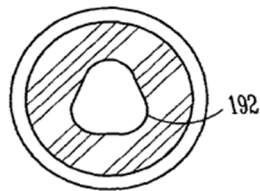


Fig. 18

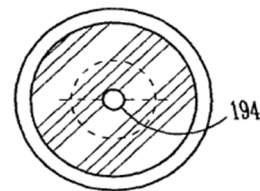


Fig. 19

108. Accordingly, a POSITA would not have been motivated to have substituted Hartley's string for Schaffer's U-shaped actuating members in view of Schaffer's express teachings that the seal module 100 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. EX1005, ¶ [0060]. There was no need to change the sealing mechanism in Schaffer based on Schaffer's disclosure. Mr. Thornton is wrong that Schaffer's structure is deficient and would leave gaps in the seal.

109. As I noted above, the Petition references related arguments made in related proceedings (*Imperative Care, Inc. v. Inari Medical Inc.*, IPR2024-01157, Paper 5 at 28-29 (P.T.A.B. Oct. 29, 2024)) reciting that “the portions of Schaffer cited by PO do not support its argument. (Ex. 1003, ¶ 100.)” I disagree. The portions of Schaffer I reference above would not have motivated a POSITA to have substituted Hartley’s string for Schaffer’s U-shaped actuating members.
110. First, Mr. Thornton attempts to support his argument that it would have been obvious to substitute Hartley’s string 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. EX1003, ¶ 100. 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 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 much more compression than a “very light compression” to the seal module 100, effecting a complete fluid/gas tight seal. *Id.* at ¶ [0076]. 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].

111. Second, Mr. Thornton alleges 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, ¶ 100. I disagree. Schaffer describes the characteristics of the material 166 used to form the third central seal member 165 without alternative—the material “is extremely soft and compliant and intrinsically ‘sticky’” and “exhibits a “selfclosing” nature in that it sticks occlusively to itself forming a nearly fluid/gas tight seal under very light compression.” EX1005, ¶ [0059]. When describing the specific makeup of the material 166, Schaffer discloses that it can include “modified vinyl, silicone, polyurethane or a combination thereof,” and that the “basic materials are, in one option, modified by compounding them with waxes and/or oils or un-cross-linked

modifiers.” *Id.* A POSITA would understand that while the basic materials (e.g., vinyl, silicone, polyurethane) may not themselves be sticky, Schaffer discloses that those basic materials are modified to be “sticky” and “selfclosing” by compounding them with waxes, oils, and/or un-cross-linked modifiers.

112. Further, even assuming that Schaffer discloses using materials that are not sticky or self-closing, Mr. Thornton does not explain why a POSITA would have substituted Hartley’s string 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 §§VI.C.4., such a modification would greatly hinder the durability and ease of manufacturing of Schaffer’s valve, likely render Schaffer’s valve inoperable, and would not be a simple substitution. 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.
113. 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, ¶ 100. However, Mr. Thornton's conclusion ignores that Schaffer expressly discloses with reference to Figures 31-34 that:

[T]he third central seal member 165 includes material 166 that is highly elastic, deformable, compliant and yet virtually non-compressible. Materials 166 include modified vinyl, silicone, polyurethane or a combination thereof. The basic materials are, in one option, modified by compounding them with waxes and/or oils or un-cross-linked modifiers. Such materials are commonly available as "C-Flex" or "Kraton" in the range of 5 to 15 (shore A), as examples. The shore hardness of the material 166 is, in another option, in the range of between 15-20 shore on the "00" scale.

EX1005, ¶ [0081]. That is, Schaffer specifically discloses that the seal module of Figures 31-34 includes the third central seal member 165 that is formed of the same materials 166 Schaffer describes in detail in paragraph [0059] regarding their sticky and self-closing properties. Accordingly, a POSITA would understand that seal module 100 in Figures 31-34 of Schaffer includes the sticky, self-closing properties I describe in detail above.

114. Fourth and finally, 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, ¶ 100. To the contrary, a POSITA would

understand Schaffer's U-shaped actuating members 55 to be rigid for precisely the reason identified by Mr. Thornton above. As I explain in §VI.A.1. above, Schaffer discloses that, "as each actuator button 261 is depressed" to open the valve 10, the actuating members 55 "**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).

115. As highlighted by Mr. Thornton, the sticky nature of the seal module of Figures 31-34 might inhibit retraction of the seal module. However, a POSITA would understand that the rigid nature of the actuating members allows for the forcible disengagement of the actuating members 55 from the seal module—preventing the exact issue identified by Mr. Thornton.
116. In fact, the problem identified by Mr. Thornton may arise if Hartley's string 14 were substituted for the U-shaped actuating members 55 as alleged by Petitioner. Petitioner explains that in their proposed combination "the string would loop at least once around Schaffer's seal module." Petition, p. 44. Petitioner further explains that 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, causing the string to loosen around the seal module and allowing the

lumen to at least partially open.” *Id.* at p. 46. In this arrangement, Hartley’s string would never disengage—let alone forcibly disengage—Schaffer’s seal module 100. Thus, as conceded by Mr. Thornton, the seal module may stick to and retain Hartley’s string in the closed position—rendering Schaffer’s valve inoperable by inhibiting or even preventing movement of the seal module 100 to the uncollapsed open position.

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

117. As I explain in detail above in §VI.C.2., 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 to “seal more effectively” and avoid the “form[ation] of small gaps.” Petition, pp. 42-43. Not only is this incorrect as I explain above, Petitioner and its expert allege that Schaffer’s valve forms a complete seal—even when instruments are inserted therethrough. I have detailed those statements in lists in paragraphs 121 and 122 below, and reference a few of those statements more specifically in paragraphs 118–121 below.

118. For example, when describing how Schaffer discloses the preamble of Claim

1, Mr. Thornton states:

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

EX1003, ¶ 70. 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 (aspiration catheter) inserted through the valve. This is completely contrary to Mr. Thornton's and Petitioner's stated motivations for substituting Schaffer's U-shaped actuating members with Hartley's string to "seal more effectively" and avoid the "form[ation] of small gaps." If a POSITA would have expected that Schaffer's valve would prevent leaks around an instrument inserted through the valve, a POSITA would not have understood that small gaps (i.e., leak paths) would form (Petitioner's stated motivation to combine

Hartley with Schaffer). That is, Petitioner's stated motivations including the formation of "gaps" are contradicted by Mr. Thornton's statements that Schaffer's valve prevents leaks (i.e., gaps) when an instrument is inserted through the valve.

119. Likewise, Petitioner states "the purpose of Schaffer's hemostasis valve is to prevent leaks when a catheter is inserted into a patient" (Petition, p. 80) and that Schaffer "discloses that its valve prevents leakage across 'a range of instruments,' such as 'a catheter, guidewire, needle, or fiber'" (Petition, p. 76 & 80; *see also* EX1003, ¶¶ 149 & 161). 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 with Schaffer).
120. Similarly, when describing how Schaffer discloses the "seal about the elongate, flexible tubular" recited in Claim 2, Petitioner states:

Schaffer discloses that its valve "**blocks the flow of gas or fluid completely and** immediately with or without an instrument in place within the gas/fluid path." (Ex. 1005, [0008].) Schaffer also discloses that "a range of instruments [can be] used within the seal module," such as "a catheter, guidewire, needle, or fiber," and that "a guidewire and catheter may be placed into the same lumen 193 for extension into a body passage." (*Id.*, [0056], [0074].) Accordingly, **when Schaffer's valve is in the first, sealed position, the U-shaped actuating members "constrict[] the valve lumen to create a seal about the elongate, flexible**

tubular body” of a catheter inserted through the valve. (Ex. 1003, ¶ 134.)

Petition, p. 64 (my emphasis added). Accordingly, Petitioner acknowledges that Schaffer discloses that its valve completely seals with or without an instrument in place, and then goes on to state that U-shaped actuated members would create a seal about a catheter inserted through the valve. This is completely contrary to Petitioner’s stated motivations for substituting Schaffer’s U-shaped actuating members with Hartley’s string to “seal more effectively” and avoid the “form[ation] 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.

121. Below I provide a list of Petitioner’s statements indicating the ability of Schaffer’s valve to completely seal with or without instruments inserted therethrough (my emphasis added):

- “Schaffer discloses a hemostasis valve for use with catheters ‘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, [0002], [0008].)” (Petition, p. 22.)
- “As shown in Figure 32, **the valve lumen is completely sealed** in the first position. (*Id.*; see also *id.*, [0008] (disclosing Schaffer’s valve

‘blocks the flow of gas or fluid completely and immediately with or without an instrument in place within the gas/fluid path’).” (Petition, p. 56.)

- “As shown in Figure 32, **the valve lumen is completely sealed** in the first position. (*Id.*; *see also id.*, [0008] (disclosing Schaffer’s valve **‘blocks the flow of gas or fluid completely and immediately with or without an instrument in place** within the gas/fluid path’)).” (Petition, p. 63.)
- “Schaffer discloses that its valve **‘blocks the flow of gas or fluid completely and immediately with or without an instrument in place** within the gas/fluid path.’ (Ex. 1005, [0008].) Schaffer also discloses that ‘a range of instruments [can be] used within the seal module,’ such as ‘a catheter, guidewire, needle, or fiber,’ and that ‘a guidewire and catheter may be placed into the same lumen 193 for extension into a body passage.’ (*Id.*, [0056], [0074].) Accordingly, when Schaffer’s valve is in the first, sealed position, the U-shaped actuating members **‘constrict[] the valve lumen to create a seal about the elongate, flexible tubular body’ of a catheter inserted through the valve.** (Ex. 1003, ¶ 134.)” (Petition, p. 64.)

- Schaffer’s hemostasis valve “**blocks the flow of gas or fluid completely** and immediately **with or without an instrument in place** within the gas/fluid path.” (Ex. 1005, [0008].) “**Schaffer’s valve is sealed** when the first and second actuators (i.e., buttons) are in the first position (i.e., undepressed).” (Petition, p. 69.)
- “Schaffer further discloses that **its valve prevents leakage across ‘a range of instruments,’** such as ‘a catheter, guidewire, needle, or fiber.’ (Ex. 1005, [0056].)” (Petition, p. 76.)
- “POSITAs would have been motivated to do so because **the purpose of Schaffer’s hemostasis valve is to prevent leaks when a catheter is inserted into a patient,** including aspiration catheters.” (Petition, p. 80.)
- “Schaffer discloses that its hemostasis valve is ‘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, [0002], [0008].)” (Petition, p. 91.)

122. Likewise, below I provide a list of Mr. Thornton’s statements indicating the ability of Schaffer’s valve to completely seal with or without instruments inserted therethrough (my emphasis added):

123. “Schaffer discloses a hemostasis valve ‘that **blocks the flow of gas or fluid completely** and immediately **with or without an instrument in place** within the gas/fluid path.’ Ex. 1005 (Schaffer) at [0002], [0008].” (EX1003, ¶ 57.)

- “Further, Schaffer’s hemostasis valve is a part of a system that is inserted into the patient’s vasculature, and the hemostasis valve helps prevent blood and air leaks in the device by ‘**block[ing] the flow of gas or fluid completely** and immediately **with or without an instrument in place** within the gas/fluid path.’ Ex. 1005 (Schaffer) at [0002], [0008]; see also Ex. 1009 (Schaffer ’616) at Abstract, 1:1-9 (disclosing catheter systems for insertion into a blood vessel). Schaffer also discloses that its hemostasis valve can prevent leaks even when ‘a range of instruments,’ such as ‘a catheter, guidewire, needle, or fiber,’ are inserted through the valve. Ex. 1005 at [0056]. Thus, **a person of ordinary skill in the art would have reasonably expected that Schaffer’s hemostasis valve could be used to prevent leaks around an aspiration catheter inserted through the valve.**” (EX1003, ¶ 70.)
- “This position is depicted in Figure 32, which shows that the central lumen is **completely constricted and sealed** in the first position.” (EX1003, ¶ 89.)

- “*See, e.g.*, Ex. 1005 (Schaffer) at [0008] (recognizing that ‘what is needed is a durable stasis valve that **blocks the flow of gas or fluid completely** and immediately **with or without an instrument in place** within the gas/fluid path’).” (EX1003, ¶ 98.)
- “As illustrated in Figure 32 above, the lumen of **Schaffer’s valve is completely constricted and sealed** when the actuator buttons are in the first position. *Id.* This is consistent with Schaffer’s disclosure that the valve ‘**blocks the flow of gas or fluid completely** and immediately **with or without an instrument in place** within the gas/fluid path.’ *Id.* at [0008].” (EX1003, ¶ 124.)
- “As illustrated in Figure 32 above, the lumen of **Schaffer’s valve is completely constricted and sealed** when the actuator buttons are in the first position. *Id.* This is consistent with Schaffer’s disclosure that the valve ‘**blocks the flow of gas or fluid completely** and immediately **with or without an instrument in place** within the gas/fluid path.’ *Id.* at [0008].” (EX1003, ¶ 133.)
- “Schaffer discloses that its hemostasis valve ‘**blocks the flow of gas or fluid completely** and immediately with or without an instrument in place within the gas/fluid path.’ *Id.* at [0008]. Schaffer also discloses that ‘a range of instruments [can be] used within the seal module,’ such

as ‘a catheter, guidewire, needle, or fiber,’ and that ‘a guidewire and catheter may be placed into the same lumen 193 for extension into a body passage.’ *Id.* at [0056], [0074]. Therefore, **when Schaffer’s valve is in the first, sealed position, the U-shaped actuating members would ‘constrict[] the valve lumen to create a seal about the elongate, flexible tubular body’ of a catheter inserted through the valve.”** (EX1003, ¶ 135.)

- “Schaffer’s hemostasis valve is intended for use with catheters inserted into a patient’s blood vessels and **‘blocks the flow of gas or fluid completely and immediately with or without an instrument in place within the gas/fluid path’** during those procedures. Ex. 1005 (Schaffer) [0008].” (EX1003, ¶ 146.)
- “Schaffer’s disclosure that its valve is intended to **‘block[] the flow of gas or fluid completely and immediately’** during intravascular procedures confirms that understanding, as do Schaffer’s descriptions on the sealed state of the valve when the actuator buttons are in the first (undepressed) position. *Id.* at [0008], [0077].” (EX1003, ¶ 148.)
- “A person of ordinary skill in the art would have been motivated to do so because **the purpose of Schaffer’s hemostasis valve is to prevent**

leakage when a catheter or medical device is inserted into a patient.” (EX1003, ¶ 149.)

- “Schaffer also discloses that **its valve prevents leakage across ‘a range of instruments,’** such as ‘a catheter, guidewire, needle, or fiber.’ Ex. 1005 (Schaffer) at [0056].” (Petition, ¶ 161.)
- “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].” (EX1003, ¶ 191.)

4. Substituting Hartley’s String for Schaffer’s U-Shaped Actuating Members Would Render Schaffer’s Valve Inoperable for Its Intended Purposes of Durability and Easy Manufacturing.

124. It would not have been obvious to a POSITA to substitute Hartley’s string 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.

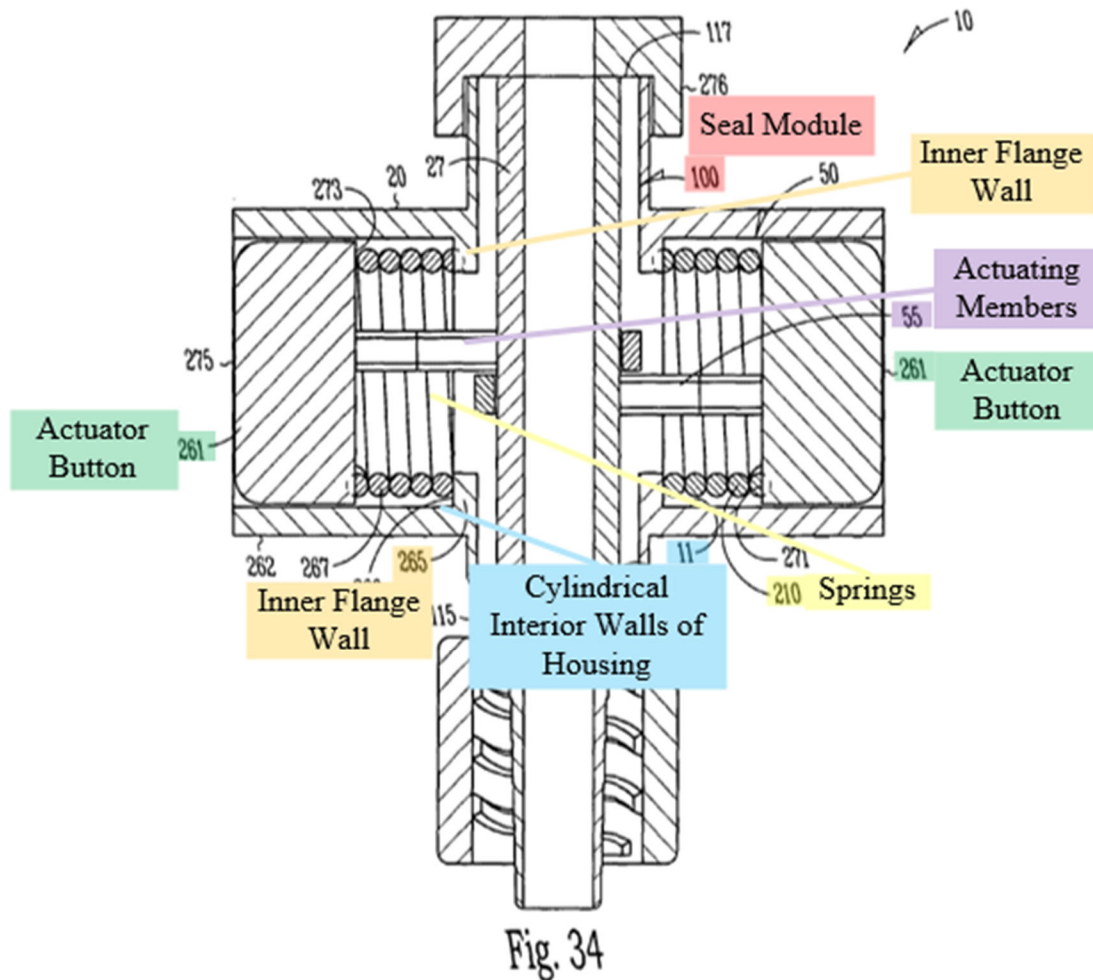
125. Regarding manufacturability, Petitioner contends that in its proposed combination “the first end of the string would be secured to the first actuator button,

the string would loop at least once around Schaffer's seal module, and the second end of the string would be secured to the second actuator button." *Petition*, p. 44. For example, "small holes could be made in each of Schaffer's actuator buttons, and each end of the string could be threaded through the hole and knotted on the other side." *Id.* This is speculative and would remove the advantages Schaffer identifies its structure as providing.

126. 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.

127. A POSITA would understand that Petitioner's proposed substitution of Hartley's string 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 Petitioner's proposed

combination 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. 43-44. A POSITA would understand that to achieve this arrangement Hartley's string 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.

128. However, the first method of assembly in which Hartley's string 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 as alleged by Petitioner. Put differently, the inner flange wall 265 prevents either of Schaffer's actuator buttons 261 from passing entirely through the housing 20 as would be required to position Hartley's string around Schaffer's seal module 100 in Petitioner's combination.

129. Likewise, a POSITA would understand the second method of assembly in which Hartley's string is secured to the actuator buttons 261 after their assembly into the valve to be unduly difficult, because the housing 20 and the

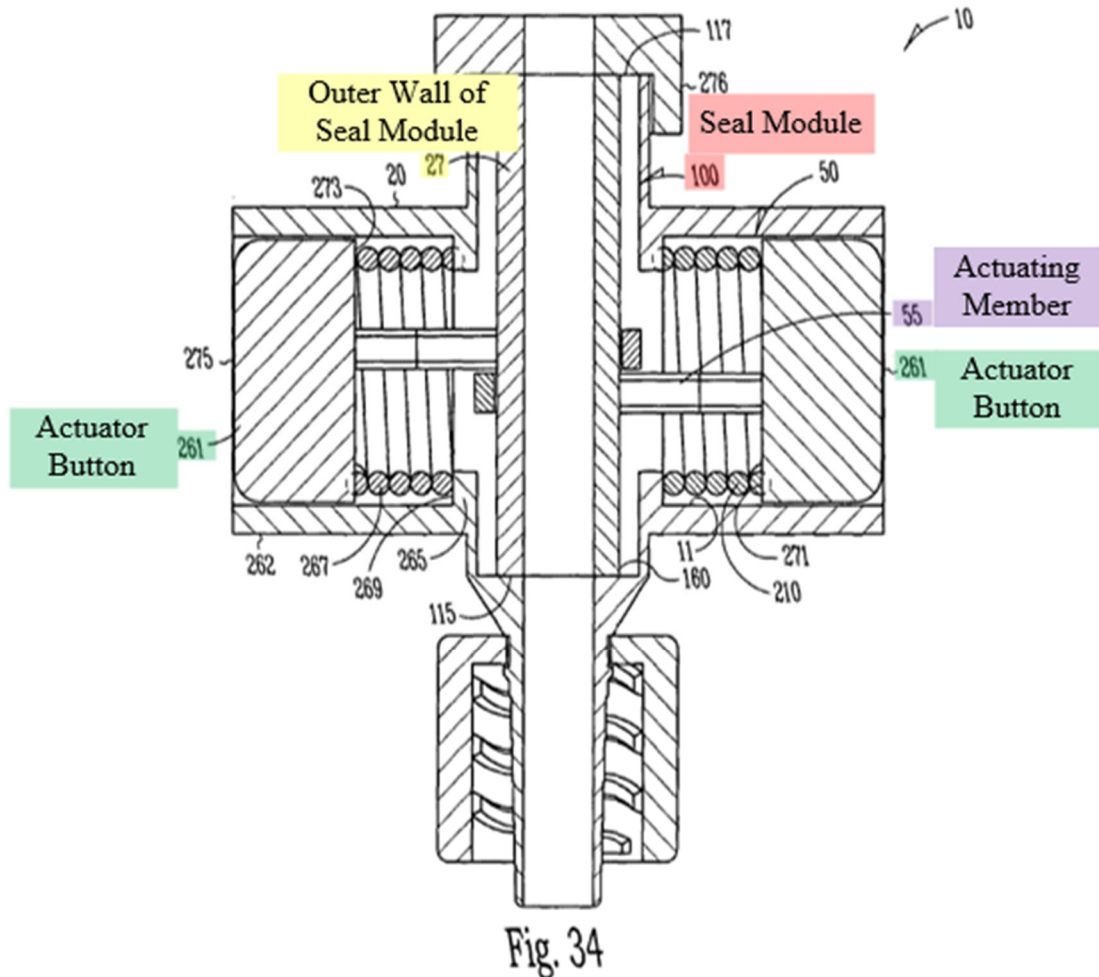
- actuator buttons 261 would block access to the interior of the housing 20 and inhibit or even prevent the positioning of Hartley's string in Petitioner's combination. That is, with the actuator buttons 261 inserted into the cylindrical openings in the housing 20, the interior of the housing 20 would be inaccessible for manipulating Hartley's string into position around the seal module 100.
130. 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]. The thin, flexible string of Hartley would be not tensioned (e.g., loose) when the actuator buttons 261 are compressed in Petitioner's proposed combination 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.
131. 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 14 would unduly complicate this simple assembly process.

132. Accordingly, for the foregoing reasons, a POSITA would understand that Petitioner's proposed substitution of Hartley's string 14 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.
133. Moreover, as I explain in §§VI.A.1. above, a POSITA would understand that flexible parts—such as Hartley's string—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 using machining as taught by Schaffer. Accordingly, a POSITA would understand that replacing Schaffer's actuating members with Hartley's string would make Schaffer unsuitable for its intended purpose of simple manufacturability via machining.
134. 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.A. 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 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 to be much more susceptible to damage, positioning errors, and the like during valve operation.

5. Substituting Hartley's String 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.

135. It also would not have been obvious to a POSITA to substitute Hartley's string 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.
136. 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 “the string would loop at least once around the Schaffer’s seal module.” Petition, p. 44. As explained by Petitioner, 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, causing the string to loosen around the seal module and allowing the lumen to at least partially open.” *Id.* at p. 46. Thus, Hartley’s string would never disengage—let alone forcibly disengage—

Schaffer's seal module 100. That is, Hartley's string would remain in contact with and never disengage the seal module 100. Accordingly, a POSITA would understand that substituting Hartley's string for Schaffer's U-shaped actuating members 55 would cause the actuating member (i.e., Hartley's string) not to disengage or forcibly disengage Schaffer's seal module, changing the principle of operation of Schaffer's device.

137. As I explain in §VI.C.2. above and as conceded by Mr. Thornton (EX1003, ¶ 100), this problem would be exacerbated by the sticky nature of Schaffer's seal module. For example, Hartley's string 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 Hartley's string in the closed position—rendering Schaffer's valve inoperable by inhibiting or even preventing movement of the seal module 100 to the open position.

6. 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 for Schaffer's U-Shaped Members as Opposed to Any of the Alternatives It Provides.

138. 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 for Schaffer's U-shaped actuating members to have both its ends attached to different actuator buttons (which neither Schaffer nor Hartley

disclose as I explain in §VI.C.1 above) rather than make relatively simple modifications to Schaffer's valve that Petitioner suggests. For example, when describing how Schaffer allegedly anticipates 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 found it obvious 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, ¶ 149.)

POSITAs would have reasonably expected success in **adjusting the spring strength** to exert more tension on the filament by, for example, changing the spring material or adjusting the springs coils. (*Id.*) Springs are simple, predictable mechanical devices that would have been well understood by POSITAs. (*Id.*) Additionally, POSITAs would have reasonably expected success in **selecting an alternative material for the seal module** given the long list of suitable materials. (*Supra* §VI.A.5.b.ii.)

Petition. pp. 71-72 (emphasis added).

139. I agree that a POSITA would understand that some simple adjustments to Schaffer that would not change its principles of operation and 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. 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, and 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 as proposed by Petitioner (including attaching the string to two separate actuators which neither Schaffer nor Hartley disclose). Petitioner provides no explanation for why a POSITA would have substituted Hartley's string 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.

140. And, a POSITA would not have modified Schaffer in view of Hartley instead of, if somehow needed (they are not), making the simple changes identified above. As I explain in §§VI.C.4.–VI.C.5. above, substituting Hartley's string 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.

7. Altogether a POSITA Would Not Have Been Motivated to Substitute Hartley's String for Schaffer's U-Shaped Members

141. Referring to my explanations in §§VI.C.1-5 above, in sum a POSITA would not have been motivated to substitute Hartley's string for Schaffer's U-shaped actuating members. For example, under a proper reading of Schaffer and Hartley:

- (1) Schaffer's seal module 100 "blocks the flow of gas or fluid completely" with or without instruments placed therein (§§VI.C.2.-VI.C.3.);
- (2) Schaffer discloses a "sticky," "gelatinous," and "selfclosing" material for the seal module to form 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 (§VI.C.2.);
- (3) 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 (§VI.C.5.);

- (4) Neither Schaffer nor Hartley disclose a “first filament” connected at opposite ends to two actuators as proposed in Petitioner’s combination (§VI.C.1.);
- (5) Substituting Hartley’s string 14 for Schaffer’s U-shaped actuating members would fundamentally change Schaffer’s principles of operation (§VI.C.4.); and
- (6) Hartley’s string 14 would not provide a better seal than Schaffer’s rigid U-shaped actuating members and seal module (§§VI.C.2.-VI.C.3.).

142. A POSITA would thus not have substituted Hartley’s string and further modified the structure to connect the string to two separate actuators, as Petitioner contends. Moreover, to have any expectation of success in Petitioner’s proposed combination of Schaffer and Eller, a POSITA would have realized that the sticky nature of the seal module disclosed in detail by Schaffer might inhibit opening of the seal module (as asserted by Mr. Thornton) as the string 14 would not disengage—let alone forcibly disengage—the seal module, allowing the sticky seal module to remain in a closed position. 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 14) are controlled by multiple rather than one of the actuator buttons 261, (2) the seal module is not "sticky" or "selfclosing" to provide a complete seal, and (3) the string 14 does not forcibly disengage the seal module 100 (requiring the seal module to not be sticky). 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.

D. Ground 4: The Combination of Schaffer and Eller Does Not Render Claim 1 Obvious

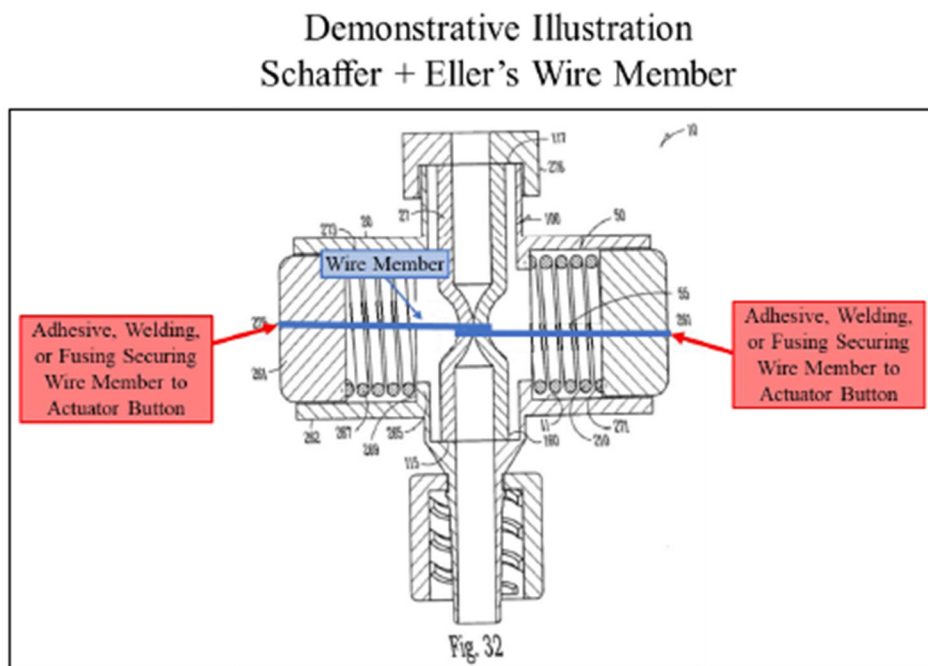
143. I understand that Petitioner and its expert, Mr. Thornton, allege that the Schaffer in combination with Eller renders obvious Claim 1 of the '012 patent. I disagree for the reasons I discuss in further detail in this section. A POSITA would not have been motivated to or found it obvious to modify Schaffer in view of Eller to arrive at the features of Claim 1, for many of the reasons I describe above in §§VI.C. Therefore, the combination of Schaffer and Hartley does not render obvious claim 1.
144. 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. 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.

145. Petitioner argues that “POSITA would have found it obvious to substitute Eller’s wire member for Schaffer’s actuating members” as an alternative to substituting Hartley’s string. Petition, pp. 50-54.
146. I disagree that it would have been obvious to or that a POSITA would have substituted Eller’s wire member for Schaffer’s U-shaped actuating members
55 for at least the reasons set forth below, largely the same reasons discussed above regarding Hartley.

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

147. A POSITA would not have found it obvious to have substituted Eller’s wire member for Schaffer’s U-shaped actuating members because neither Schaffer nor Eller disclose a “first filament” connected at opposite ends to two actuators as proposed in Petitioner’s combination. Petitioner contends that in its proposed combination “the first end of the wire member would be adhered or welded to the first actuator button, looped at least once around Schaffer’s seal module, and the second end of the wire member would be adhered or welded to the second actuator button.” Petition, p. 51. Petitioner provides the following demonstrative illustration to illustrate the proposed combination:



Id. at p. 52

148. Accordingly, Petitioner's proposed substitution and modification requires eliminating the two U-shaped actuating members of Schaffer and replacing them with a single actuating member (Eller's wire member) and further changing the structure by attaching opposite ends of Eller's wire member to different ones of the actuator buttons 261 of Schaffer. But neither Schaffer nor Hartley disclose such an arrangement. For example, as I explain in §VI.C.1., Schaffer discloses two actuating members 55 each having their respective ends coupled to separate ones of actuator buttons 261. Accordingly, each of the actuating members 55 is attached to a separate 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. While Petitioner proposes a purported simple substitution of Eller's wire member for Schaffer's U-shaped actuating members, Petitioner's proposed combination not only substitutes a flexible 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 wire member to two different actuators, an arrangement not found in Schaffer or Eller.
149. 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:"

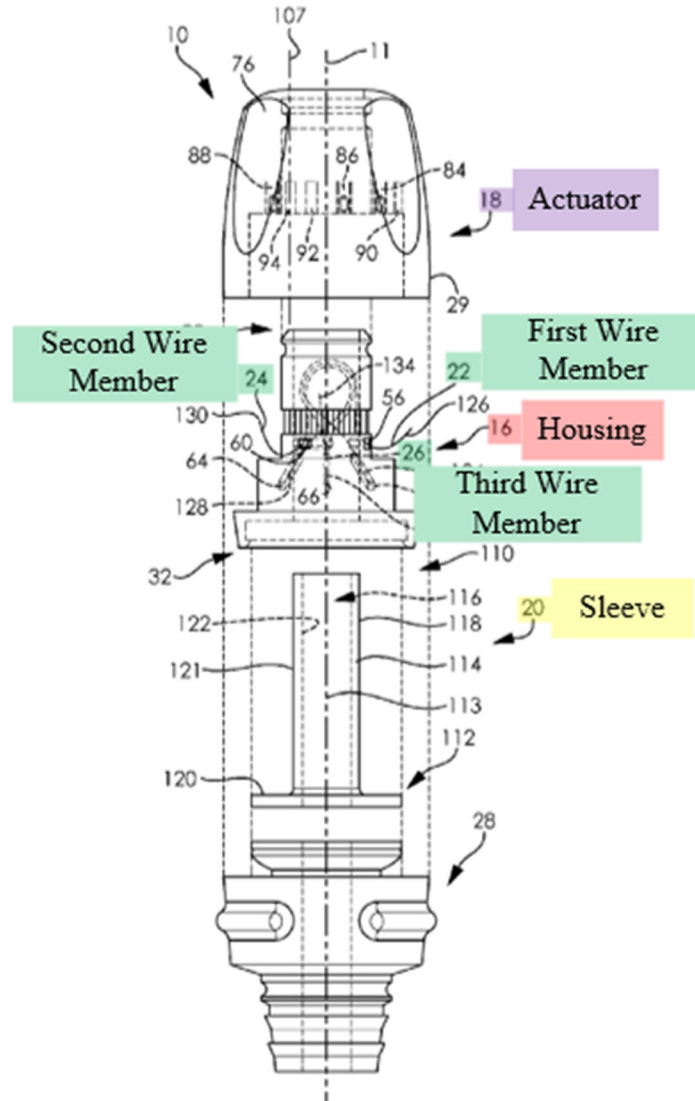
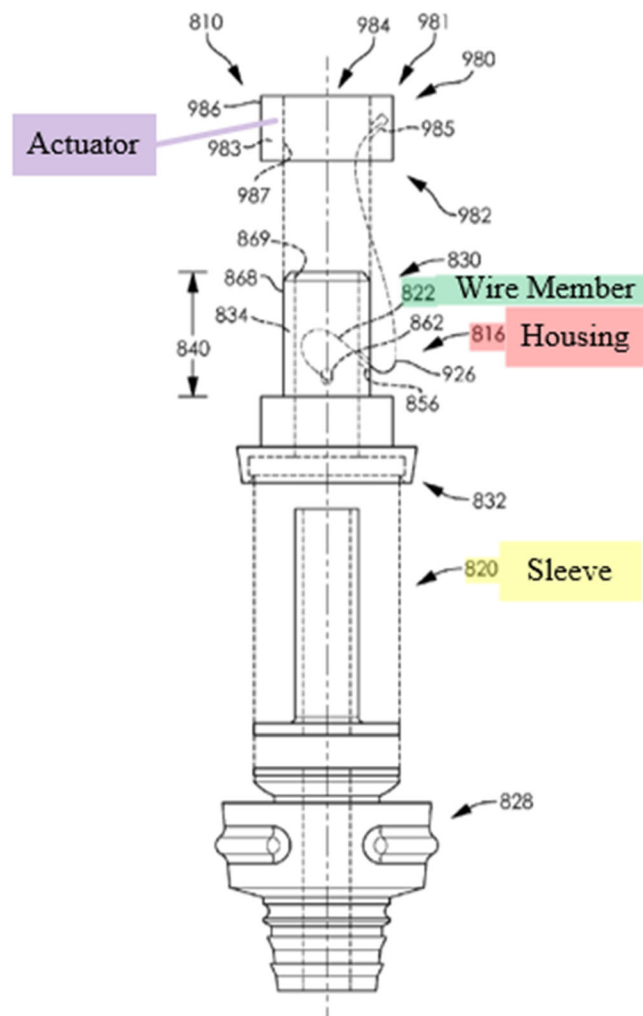


FIG. 2

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.

150. 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”:



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.

151. 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 and a second end 526 attached to the first wire member 422”:

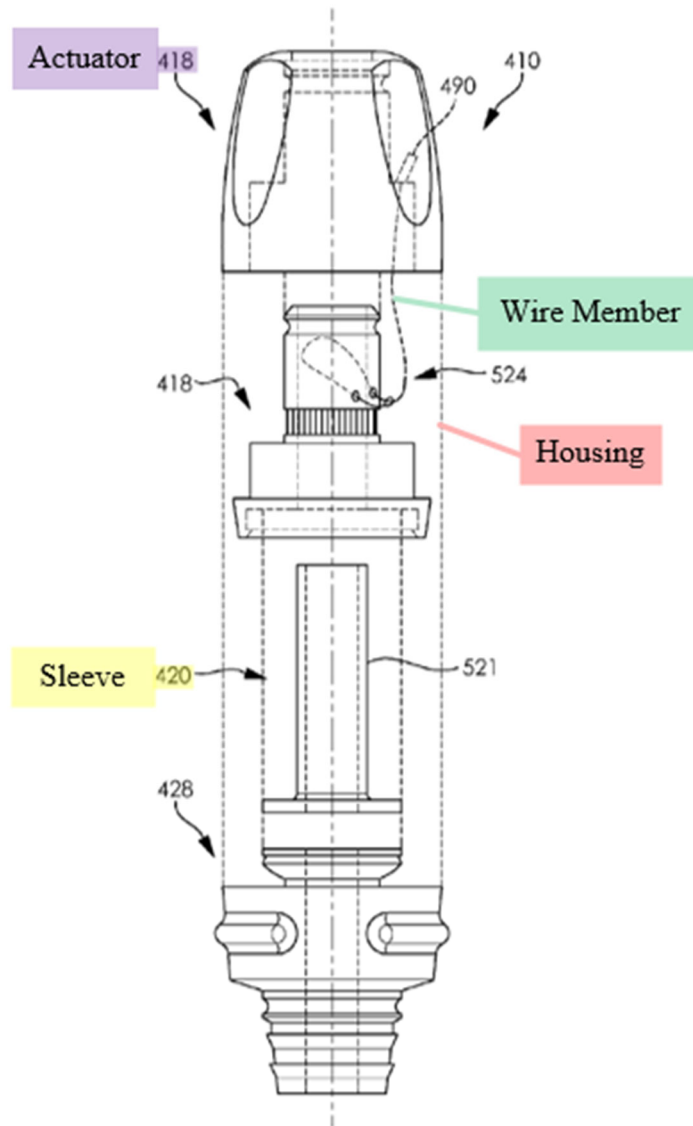


FIG. 15

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.

152. 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. A POSITA would understand that the wire member is attached to a single actuator rather than separate actuator buttons as shown in Petitioner's purported combination. Movement of the single actuator controls movement of the wire member. In contrast, in Petitioner's proposed combination the wire member would be controlled by Schaffer's two U-shaped actuating members 55 rather than by a single actuator as taught by Eller.

153. Accordingly, it is incorrect that the "combination of Eller's wire member and Schaffer's valve would have merely entailed substitution of one known element (Eller's wire member) for another (Schaffer's actuating members) to yield [a] predictable result." Petition, p. 50. Instead, Petitioner's proposed combination departs from the intended purpose and express disclosure of both Schaffer and Eller in which a single U-shaped actuating member 55 or wire member, respectively, are controlled by a single actuator. A POSITA would understand that controlling a 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. That is, neither

Schaffer nor Eller disclose any element (U-shaped actuator or wire member) coupled to separate, individually-controlled actuator buttons as in Petitioner's proposed combination. If anything, Petitioner's proposed combination appears to be based on hindsight in view of the '012 Patent.

2. Petitioner's Stated Motivations to Modify Schaffer in View of Hartley 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.

154. Petitioner's stated motivations to modify Schaffer to include Eller's wire member substantially mirror and refer back to Petitioner's stated motivations for combining Schaffer and Hartley. Petition, p. 50.
155. As I explain in detail §VI.C.2. above, a POSITA would not have modified Schaffer in view of Eller to improve sealing of Schaffer's valve because Schaffer expressly discloses and illustrates the ability of its valve to eliminate gaps and seal completely across a wide range of instruments. Specifically, Petitioner's assertion that a POSITA would have been motivated to modify the U-shaped actuating members of Schaffer to "seal more effectively across more device diameters than Schaffer's U-shaped actuating members" is incorrect based upon the express disclosure of Schaffer. Petition, p. 50. Schaffer describes 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 seal module 100 including the highly elastic, deformable, and compliant and self-closing third seal member 165. Likewise, contrary to Mr. Thornton's provided graphic and statement that "small gaps could form between the tool and the valve's lumen," a POSITA would understand based on Schaffer's disclosure that such small gaps would not form. EX1003, ¶ 115.

156. Accordingly, a POSITA would not have been motivated to have substituted Eller's wire member for Schaffer's U-shaped actuating members in view of Schaffer's express teachings that the seal module 100 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. EX1005, ¶ [0060]. There was no need to change the sealing mechanism in Schaffer based on Schaffer's disclosure. Mr. Thornton is wrong that it would leave gaps.

3. Petitioner and Its Expert Asserts that Schaffer's Valve Forms a Complete Seal and Prevents Leaks, Even When Instruments are Inserted Therethrough.

157. As I explain in §VI.C.3. above, Petitioner and its expert assert that Schaffer's valve forms a complete seal—even when instruments are inserted therethrough. For example, if a POSITA would have expected that Schaffer's valve would prevent leaks around an instrument inserted through the valve as

asserted by Petitioner and its expert (Petition, pp. 76 & 80; EX1003, ¶¶ 70, 149, & 161), a POSITA would not have understood that small gaps (i.e., leak paths) would form (Petitioner's stated motivation to combine Schaffer with Hartley).

4. Substituting Eller's Wire Member for Schaffer's U-Shaped Actuating Members Would Render Schaffer's Valve Inoperable for Its Intended Purpose of Durability and Easy Manufacturing.

158. It would not have been obvious to a POSITA to substitute 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.
159. Regarding manufacturability, Petitioner contends that in its proposed combination "the first end of the wire member would be adhered or welded to the first actuator button, looped at least once around Schaffer's seal module, and the second end of the wire member would be adhered or welded to the second actuator button." Petition, p. 51. This is speculative and would remove the advantages Schaffer identifies its structure as providing. For the same reasons I describe in §VI.C.4. above regarding the proposed substitution of Hartley's string for Schaffer's U-shaped actuating members, a POSITA would

understand that Petitioner's proposed substitution of Eller's wire member for Schaffer's actuating members 55 would make it much more difficult to assemble Schaffer's valve in the simple manner taught by Schaffer and to manufacture Schaffer's valve components using a machining process.

160. Similarly, for the same reasons I describe in §VI.C.4. above regarding the proposed substitution of Hartley's string for Schaffer's U-shaped actuating members, a POSITA would understand that replacing Schaffer's actuating members with 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 Eller's thin and flexible wire member to be much more susceptible to damage, positioning errors, and the like during valve operation.

5. Substituting 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.

161. It also would not have been obvious to a POSITA to substitute 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. For example, for the same reasons I explain above in §VI.C.5. above regarding

the proposed substitution of Hartley's string for Schaffer's U-shaped actuating members, a POSITA would understand that Eller's wire member substituted into Schaffer's valve would never disengage—let alone forcibly disengage—Schaffer's seal module 100. That is, Eller's wire member would remain in contact with and never disengage the seal module 100. Accordingly, a POSITA would understand that substituting Eller's wire member for Schaffer's U-shaped actuating members 55 would cause the actuating member (i.e., Eller's wire member) not to disengage or forcibly disengage Schaffer's seal module, changing the principle of operation of Schaffer's device.

162. And, likewise, as conceded by Mr. Thornton (EX1003, ¶ 100), this problem would be exacerbated by the sticky nature of Schaffer's seal module. For example, Eller's wire member 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 Eller's wire member in the closed position—rendering Schaffer's valve inoperable by inhibiting or even preventing movement of the seal module 100 to the open position.

6. Even Assuming Petitioner's Stated Motivations to Form a Better Seal and Avoid the Formation of Gaps, a POSITA Would Not Have been Motivated to Substitute Eller's String for Schaffer's U-Shaped Members.

163. As I explain above in §VI.C.6., when describing how Schaffer allegedly anticipates 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, such as by adjusting Schaffer's spring strength and/or adjusting the properties of the seal module. Petition pp. 71-72. For the same reasons I provided in §VI.C.6., a POSITA would understand each of these modifications to be simpler than completely omitting Schaffer's U-shaped members and substituting in Eller's wire member as proposed by Petitioner (including attaching the wire member to two separate actuators which neither Schaffer nor Eller disclose). A POSITA would not have substituted Eller's wire member for Schaffer's U-shaped members rather than make any of the simple modifications to complete the seal and prevent blood leaks through the valve if necessary.

164. As I explain in §§VI.D.4-VI.D.5. above, substituting Eller's wire member for Schaffer's U-shaped members would render Schaffer's valve inoperable for its intended purposes of durability, easy manufacturing, and forcible disengagement. The simple modifications that Petitioner recites 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.

7. Altogether a POSITA Would not Have been Motivated to Substitute Eller's Wire Member for Schaffer's U-Shaped Members

165. For the same reasons I describe in §VI.C.4. above, a POSITA would not have been motivated to substitute Eller's wire member for Schaffer's U-shaped actuating members. For example, under a proper reading of Schaffer and Eller:

- (1) Schaffer's seal module 100 "blocks the flow of gas or fluid completely" with or without instruments placed therein (§§VI.D.2.-VI.D.3.);
- (2) Schaffer discloses a "sticky," "gelatinous," and "selfclosing" material for the seal module to form 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 (§VI.D.2);
- (3) 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 (§VI.D.5.);

- (4) Neither Schaffer nor Eller disclose a “first filament” connected at opposite ends to two actuators as proposed in Petitioner’s combination (§VI.D.1.);
- (5) Substituting Eller’s wire member for Schaffer’s U-shaped members 55 would fundamentally change Schaffer’s principles of operation (§VI.D.4.); and
- (6) Eller’s wire member would not provide a better seal than Schaffer’s rigid U-shaped members and seal module (§§VI.D.2.-VI.D.3.).

166. A POSITA would thus not have substituted Eller’s wire member and further modified the structure to connect the wire member to two separate actuators, as Petitioner contends. Moreover, to have any expectation of success in Petitioner’s proposed combination of Schaffer and Eller, a POSITA would have realized that the sticky nature of the seal module disclosed in detail by Schaffer might inhibit opening of the seal module (as asserted by Mr. Thornton) as the string 14 would not disengage—let alone forcibly disengage—the seal module, allowing the sticky seal module to remain in a closed position. Petitioner’s proposed combination is a valve that operates in complete contrast to Schaffer’s stated purposes—one in which (1) the actuating members (i.e.,

Eller's wire member) is controlled by multiple rather than one of the actuator buttons 261, (2) the seal module is not "sticky" or "selfclosing" to provide a complete seal, and (3) the wire member does not forcibly disengage the seal module 100 (requiring the seal module to not be sticky). The proposed combination is such a stark departure from the principles of operation of Schaffer's valve that one of ordinary skill in the art would not have been motivated to arrive at Petitioner's purported combination.

E. Grounds 5–7: The Combinations of Schaffer, Hartley, and Eller With Garrison Do Not Render Claim 1 Obvious

167. Petitioner and its expert, Mr. Thornton, allege that Garrison in combination with Schaffer, Schaffer and Hartley, or Schaffer and Eller as discussed with respect to grounds 1-4 renders obvious Claim 1 of the '012 patent. Petitioner relies on Garrison for allegedly disclosing the term "aspiration" in the preamble of Claim 1, the "tubular body" of Claim 1, and the "hemostasis valve of" of Claim 1, but does not rely on Garrison for disclosing the "constricting mechanism" of Claim 1 that I discuss in detail with regard to grounds 1–4 above. Petition, pp. 83-94.
168. Because of the deficiencies of Schaffer, Hartley, and Eller I explain above with reference to grounds 1-4, I do not analyze the details of Garrison. Nevertheless, I reserve my right to further review and assess any independent reasons of patentability for the claims in view of Garrison.

VII. SECONDARY CONSIDERATIONS

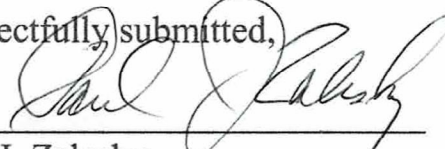
169. I have not rendered any opinions on secondary considerations of non-obviousness at this time, but reserve the right to analyze evidence of secondary considerations at a later stage, if asked to do so.

VIII. CONCLUSION

170. For all the above reasons, it is my opinion that the claims of the '012 Patent are not invalid based on the prior art grounds asserted by Petitioner and Mr. Thorton.

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: February 25, 2025

Respectfully submitted,
By: 
Paul J. Zalesky

ATTACHMENT 1

Paul J Zalesky, PhD
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Summary of Experience: All aspects of medical specialty Product Development and commercialization, emphasizing technological bases and IP management

June 2012 to Present: *Consultant to multiple medical technology companies and legal practices*; Contract CEO for Envisage Medical to develop the Product Development program and raise capital with Research Triangle Institute for a real-time image guidance of structural and rhythm heart procedures; acting VP Bus Dev for Israeli percutaneous mitral valve, management of development with clinical/regulatory strategy; Board member and Key Consultant for China-based BioVention, a drug-eluting stent company; acting CEO for Device Sanitation start-up emphasizing design, development, and commercialization; *Expert Consultant or Witness* to attorney clients and private companies, emphasizing underlying medical technology (cardiovascular emphasis), clinical/regulatory strategies & plans, associated patent validity or infringement, patient injury and associated company liability; medical device product development and commercialization – all aspects.

Mar 2011 to June 2012: Interim *CEO, Keystone Heart, Inc.*: Product Design & Development, pre-clinical, and clinical study, regulatory submission planning and execution for cerebral protection during heart valve repair, in collaboration with international CV Surgeons and Cardiologists. Direct management of Clinical Research Org and Regulatory personnel towards CE Mark and FDA submissions as part of managing all operations.

Feb 2009 to Mar 2011: *Consultant, SVMI, Inc., Accumed, Inc, other start-ups and Investment Institutions*: Product Development plans, Business Development, Financing, FDA and other regulatory body strategy planning, and Intellectual Property Planning and protection. Perform technical due diligence on novel medical technologies towards financial institution investing.

June 2007 to Feb 2009: *Vice President, R&D, Volcano Corporation (now Philips)*
Manage all aspects of Product Development, New Technology, and Intellectual Property for this public company with revenues exceeding \$ 200 MM in Interventional Cardiology; produce numerous pre-market document packages for FDA review and dialog

Sept 2004 to Present: Consultant, Board Member, Consulting Expert:
Round Table Group Scholar program; *Consulting Expert Witness; Medical Specialty Consultant*: advise legal counsel, representing BSC, on multiple patent-related and technical and practical aspects.

The Battelle Institute: advise on key organization changes and recommended practices.

IVIT, Inc.: acting CEO for a Vascular Access company developing technology for chronic hemodialysis patients, emphasizing design for least invasive vascular procedures and fast regulatory approval path

CryoCath, Inc.: mentor VP R&D and technical staff for an electrophysiology / cardiology company seeking fast time-to-market for devices for least invasive treatment of cardiac arrhythmias, with emphasis on atrial fibrillation (subsequently acquired by Medtronic).

Biovention, Inc.: direct, via Board position, strategy, product development and clinical/regulatory path for this novel, heparin-additive, drug-eluting coronary stent company; negotiate M&A with multi-national companies.

Multiple Companies, Investors and Legal Counsel: analyze and advise, in consulting capacity, on multiple Product Development programs for wireless cardiovascular implants, in vitro diagnostics, aorta implants for aneurysm treatment, non-vascular applications of intravascular imaging, and gastroenterological least invasive therapies; enable specialized contract developers / manufacturers to drive selected aspects of product development for expediency; collaborate with key consultants and employees on clinical & regulatory strategies and plans; provide expert consulting for broad-based health care institutions and retained legal counsel. Provide to legal counsel expert opinions / reports on medical device patent cases involving validity and/or infringement; appear for court testimony and depositions associated with numerous patent cases.

Sept 2003 to April 2005: *President & CEO, LumeRx, Inc.*: managed all aspects of this development stage company focused on light-based therapy in Gastroenterology, with emphasis on design and development of therapeutic product; raised \$ 7 MM private equity financing; recruited and managed key technical staff, consultants and contract organizations for Clinical/Regulatory/Quality and Marketing.

August 2003 to December 2006: *Consultant CTO, TherOx, Inc.*: consulting continuity with emphasis on new product development, business development, new financing support, and clinical/regulatory strategies for this multiple opportunity company; continued Board of Directors activities; manage focused development programs for interventional cardiology, cardiovascular surgery, cancer therapy, wound and skin care, and GI therapies.

May 2001 to August 2003: *Chief Technical Officer, TherOx, Inc.*: identified and managed multiple cardiovascular business opportunities, as well as core product development and manufacturing, with associated novel designs and development paths, emphasizing CV Surgery and intra-PTCA alternatives for hyperbaric Oxygenation solution technology, specialty wound care therapy, and selected oncology therapies using vascular administration; managed all aspects of Intellectual Property.

June 1994 to May 2001: *President and Co-founder, TherOx, Inc.*: managed all Product Development and operating aspects of this start-up, integrating a hardware/software bedside system with disposable catheters, focusing on 1) Acute MI, 2) skin & wound care, 3) cancer therapy; raised more than \$ 52 MM in private capital with KPCB as lead investor; recruited initial 45 employees in all operating functions, achieved multiple FDA and CE Mark approvals, established clean room manufacturing of disposables and electromechanical control + delivery systems, directed extensive, multi-phase clinical studies in US and Europe, established and maintained opinion-leading SAB, and recruited key international technology consultants for breakthrough developments; directed development and management of all intellectual property (primarily patents).

May 1991 to June 1994: *VP R&D, Baxter Bentley*: managed all product development, advanced manufacturing, clinical, and related technical support aspects for this cardiopulmonary bypass company with \$ 150 MM annual revenue; served as group R&D and strategic planning representative for all Cardiovascular Group divisions with \$ 900 MM annual revenue base to enable key growth and diversification strategies, with emphasis on interventional cardiology; coordinated use of selected Baxter corporate capabilities to achieve operating efficiencies; interacted with FDA on critical programs.

May 1986 to March 1990: *President & Co-founder, InterTherapy, Inc.*: managed all aspects of this start-up focused on the design and development of intracoronary ultrasound for interventional cardiology; raised more than \$ 11 MM venture capital; organized SAB and Clinical Investigator array with opinion-leading Interventional Cardiologists in the US and Europe; accomplished rapid FDA approval for marketing, ISO certification, and aggressive early marketing with pilot in-house manufacturing capability; managed Intellectual Property development.
(was merged with CVIS, then acquired by BSC).

Previous experience included Executive R&D management positions with Johnson & Johnson, Edwards Labs, and Meadox Medicals, and a Special Expert position for the National Institutes of Health. Additionally, served 3 years of active duty as a Captain in the USAF, performing cardiopulmonary research with human subjects for development of life support systems for high performance aircraft.

Education

PhD, Univ. of Michigan, Biomedical Engineering - NIH pre-doctoral fellow
M.S., Univ. of Michigan, Aerospace Engineering – NSF fellow
B.S., Univ. of Notre Dame, Aerospace Engineering – USAF Scholarship

Publications and Patents

Lead or co-author of approximately 20 articles in medical and research journals, encompassing cardiovascular technology and devices, bench and animal model tests on new technologies for heart-related diagnosis and therapy, and clinical (patient) studies on new devices and procedures.

Representative Publications:

“Intravascular Ultrasonic imaging”, Texas Heart Institute Journal, 1990

“Intravascular Ultrasound imaging of Human Coronary Arteries In Vivo: Analysis of Tissue Characterization with Comparison to In Vitro Histological Specimens”, Circulation, 1991

“A New Bioabsorbable Intravascular Stent: In Vitro Assessment of Hemodynamic and Morphometric Characteristics”, J of Interv Cardiol, 1992

“Topical Oxygen Emulsion – A Novel Wound Therapy”, Arch Dermatol, 2007

“The effect of a topical Oxygen emulsion on granulation tissue formation in second degree burn wound healing”, Ostomy Wound Management, 2004

Co-inventor on more than 16 US and International patents, encompassing intravascular ultrasound, coronary and cerebrovascular catheters and guidewires, electromechanical imaging and control systems, next generation cardiopulmonary bypass systems, Oxygen supersaturated solutions’ preparation and vascular delivery, and photodynamic therapy devices and systems.

Representative Patents:

US 4,841,977 - 1989 – “Ultra-thin acoustic transducer and balloon catheter using same in imaging array subassembly:

US 5,115,814 – 1992 – “Intravascular ultrasonic imaging probe and method of using same”

US 5,976,119 – 1999 – “High pressure perfusion device”

US 6,123,698 – 2000 – “Angioscopy apparatus and methods”

US 6,235,007 – 2001 – “Atraumatic fluid delivery device”

US 6,248,087 – 2001 – “Apparatus for generalized extracorporeal support”

US 6,454,997 – 2002 – “Apparatus for the preparation and delivery of gas-enriched fluids”

US 6,558,501 B2 – 2003 – “Method for forming atraumatic fluid delivery device”

US 6,596,235 B2 – 2003 – “Method for blood oxygenator”

US 6,613,280 – 2005 – “Disposable cartridge for producing gas-enriched fluids”

US 6,974,435 – 2005 – “Method for enriching a bodily fluid with gas”

US 6,676,800 B1 – 2004 – “Method of for preparation and delivery of gas-enriched fluids”

US 6,607,698 B1 – 2003 – “Method for generalized extracorporeal support”

US 7,468,191 B2 – 2008 – “Method of preparing gas delivering perfluorocarbon emulsions with non-fluorinated surfactants”

US 7,357,937 B2 – 2008 – “Perfluorocarbon emulsion with non-fluorinated surfactants”

US 7,820,102 – 2010 – “Disposable cartridge for producing gas-enriched fluids”

US 4,899,756 – 1990 – “Ultrasonic imaging probe with zero dead space”

US 7,135,034 – 2006 – “Flexible array”

US 7,261,730 – 2007 – “Phototherapy device and system”

US 7,449,026 – 2008 – Intra-cavity catheters and methods of use”

Personal

Married with four children

Other

During the past 5 years (2015 – 2020), testified in depositions and court settings regarding specialized medical technologies and various aspects of their commercialization. Examples:

- Multiple appearances in front of arbitration judges regarding a tissue harvesting product, its development and commercialization
- Deposition regarding an algorithm for detecting heart rhythm disturbances
- Deposition regarding a cardiac pacemaker and reported patient injuries and deaths
- Court testimony to FTC officials regarding product attributes and performance claims

In addition, I have produced and delivered several formal reports to legal counsel and affected 3rd parties (insurance arbiters, for example) regarding serious patient injury resulting from the professional use of medical devices.

ATTACHMENT 2

MATERIALS CONSIDERED

EXHIBIT/PAPER No.	DESCRIPTION
EX1001	U.S. Patent No. 11,697,012 (“the ’012 Patent”)
EX1002	’012 Patent Prosecution History Excerpts
EX1003	Thornton Expert Decl. ISO IPR Petition ’012 Patent
EX1004	Resume of Troy Thornton
EX1005	U.S. Patent Publication US 2003/0225379 A1 to Schaffer et al. (“Schaffer”)
EX1006	U.S. Patent Publication US 2003/0116731 A1 to Hartley (“Hartley”)
EX1007	U.S. Patent No. 9,980,813 B1 to Eller (“Eller”)
EX1008	Drawings Submitted During Prosecution of U.S. Patent Application No. 10/371,190
EX1009	U.S. Patent No. 5,429,616 to Schaffer (“Schaffer ’616”)
EX1010	U.S. Patent Publication US 2011/0144592 A1 to Wong et al. (“Wong”)
EX1011	U.S. Patent Publication US 2015/0173782 A1 to Garrison et al. (“Garrison”)
EX1012	U.S. Patent No. 9,216,277 B2 to Myers (“Myers”)
EX1013	Dorland’s Illustrated Medical Dictionary, 32nd ed. (2012) - Definition of “Catheter”
EX1014	U.S. Patent No. 4,723,550 to Bales et al.
EX1015	U.S. Patent No. 5,895,376 to Schwartz et al.
EX1016	U.S. Patent No. 12,109,384 B2 to Merritt et al.
Paper 1	Petition for <i>Inter Partes</i> Review
EX2002	Merriam-Webster’s Collegiate Dictionary
EX2003	New Oxford American Dictionary

EXHIBIT/PAPER No.	DESCRIPTION
EX2004	U.S. Patent Application Publication No. 2018/0193043