

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. IPR2024-01157
U.S. Patent No. 11,697,011

SUPPLEMENTAL DECLARATION OF PAUL J. ZALESKY

TABLE OF CONTENTS

I.	INTRODUCTION	1
II.	BACKGROUND AND QUALIFICATIONS	3
III.	BASES OF MY OPINION	8
A.	Materials Considered	8
B.	Relevant Legal Principles	9
IV.	SUMMARY OF OPINIONS	12
V.	THE '011 PATENT	12
A.	Overview	12
B.	Claim 1	27
C.	Prosecution History of Claim 1	30
D.	Cited References	31
1.	Schaffer	31
2.	Hartley	35
3.	Eller	36
E.	Person of Ordinary Skill in the Art	37
F.	Claim Construction	38
VI.	GROUND 1: SCHAFFER DOES NOT ANTICIPATE CLAIMS 1-9	46
A.	Schaffer Does Not Disclose a Filament that “Circumferentially Constricts”	47
B.	Schaffer Does Not Disclose the “Filament” of Claim 1	48
C.	Schaffer Does Not Disclose the “Filament” Having Two Ends Extending in Different Directions and Coupled to Different Members of an Actuator	56

VII.	GROUND 2: SCHAFFER DOES NOT RENDER CLAIMS 1-9 OBVIOUS.....	59
VIII.	GROUNDS 3 AND 4: THE COMBINATION OF SCHAFFER AND HARTLEY OR ELLER DOES NOT RENDER CLAIMS 1-9 OBVIOUS.....	61
A.	Neither Schaffer, Hartley, or Eller Disclose a Single Flexible Filament Having a First End Coupled to a First Member of an Actuator and a Second End Coupled to a Second Member of an Actuator, as Recited in Claim 1	63
1.	Schaffer	63
2.	Hartley.....	64
3.	Eller	65
B.	Petitioner’s Proposed Modification or Substitution of Hartley’s String or Eller’s Wire Member for Schaffer’s U-Shaped Actuating Members is Not a Simple Substitution of One Known Element for Another.....	70
C.	Petitioner’s Stated Motivations to Modify Schaffer in View of Hartley or Eller Are Based on an Incorrect Understanding of the Sealing Mechanism of Schaffer Which Is Designed to Eliminate Gaps With or Without Instruments Inserted Through the Valve.....	74
D.	Petitioner and Its Expert Assert that Schaffer’s Valve Forms a Complete Seal and Prevents Leaks, Even When Instruments are Inserted Therethrough.	90
E.	Modifying or Substituting Hartley’s String or Eller’s Wire Member for Schaffer’s U-Shaped Actuating Members Would Render Schaffer’s Valve Inoperable for Its Intended Purposes of Durability and Easy Manufacturing.....	94
F.	Modifying or Substituting Hartley’s String or Eller’s Wire Member for Schaffer’s U-Shaped Actuating Members Would Change the Principle of Operation of Schaffer’s Valve in Which the U-Shaped Actuating Members Forcibly Disengage	

Supplemental Declaration of Paul J. Zalesky

the Seal Module and Likely Render Schaffer's Valve Inoperable.....	100
G. Even Assuming Petitioner's Stated Motivations to Form a Better Seal and Avoid the Formation of Gaps, Petitioner Does Not Explain Why a POSITA Would Have been Motivated to Substitute Hartley's String or Eller's Wire Member for Schaffer's U-Shaped Members as Opposed to Any of the Alternatives It Provides.....	103
H. Altogether a POSITA Would Not Have Been Motivated to Substitute Hartley's String or Eller's Wire Member for Schaffer's U-Shaped Members	106
IX. GROUND 5: THE COMBINATION OF HARTLEY AND ELLER DOES NOT RENDER CLAIMS 1-3, 5, 6, AND 9 OBVIOUS	108
A. Neither Hartley nor Eller Discloses a Filament Having a First End Coupled to a First Member and a Second End Extending in a Different Direction Coupled to a Second Member	110
B. Modifying Hartley to Include Eller's Torsion Spring Would Render Hartley's Valve Inoperable for Its Intended Purpose	112
C. Petitioner's Stated Motivations to Modify Hartley to Include Eller's Torsion Spring Would Not Have Been Compelling to a POSITA Considering the Countervailing Advantages of Hartley's Device.....	116
X. DEPENDENT CLAIM 3 IS NOT ANTICIPATED BY SCHAFFER OR OBVIOUS IN VIEW OF SCHAFFER, HARTLEY, OR ELLER.....	121
XI. SECONDARY CONSIDERATIONS	121
XII. CONCLUSION.....	121

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 2024-01157 concerning U.S. Patent 11,697,011 (“’011 Patent”; EX1001), pending before the U.S. Patent and Trademark Office, Patent Trial and Appeal Board (“Board”).
2. I understand that Imperative Care, Inc. (“Petitioner” or “Imperative”) has filed a petition of *inter partes* review before the Board asserting:

Ground 1: Claims 1-9 of the ’011 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: Claims 1-9 of the ’011 Patent are unpatentable under 35 U.S.C. § 103 as obvious over Schaffer alone;

Ground 3: Claims 1-9 of the ’011 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: Claims 1-9 of the ’011 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”); and

Supplemental Declaration of Paul J. Zalesky

Ground 5: Claims 1-3, 5, 6, and 9 of the '011 Patent are unpatentable under 35 U.S.C. § 103 as obvious over Hartley in combination with Eller.

I have been asked by counsel for Inari Medical, Inc. (“Inari” or “Patent Owner”) to opine on the patentability of the claims of the '011 Patent and, in particular, the patentability of Claim 1 with respect to grounds 1-5.

3. I have previously submitted a declaration in this proceeding. I hereby incorporate by reference my first declaration dated October 29, 2024 (EX2001), as if fully set forth herein.
4. 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 listed in the attachment I have provided to my Declaration, and any other material I refer to in this Declaration in support of my opinions.
5. 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.
6. 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

Supplemental Declaration of Paul J. Zalesky

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.

7. 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

8. My qualifications for forming the opinions set forth in this Declaration are summarized here and explained in more detail in my attached curriculum vitae.
9. 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.
10. 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

Supplemental Declaration of Paul J. Zalesky

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 bleed.

11. 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.
12. In 1986, I co-founded InterTherapy with cardiologist Dr. Walt Henry. InterTherapy was focused on the development of intravascular ultrasound for

Supplemental Declaration of Paul J. Zalesky

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.

13. 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

Supplemental Declaration of Paul J. Zalesky

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.

14. 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.
15. 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.
16. 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,

Supplemental Declaration of Paul J. Zalesky

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.

17. During my time with Volcano Corporation (now Philips) I supervised coronary and peripheral artery catheter development, manufacture, and clinical use.
18. 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.
19. In many of my management positions, I was responsible for development and maintenance of intellectual property, including both direct management of in-

Supplemental Declaration of Paul J. Zalesky

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.

20. 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

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

22. 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

23. 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.
24. 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.
25. 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.
26. 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 Claim 1 of the '011 Patent

Supplemental Declaration of Paul J. Zalesky

is anticipated by Schaffer, obvious over Schaffer alone, obvious over the combination of Schaffer and Hartley or Eller, or obvious over the combination of Hartley and Eller.

27. 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 the earliest priority date of the '011 Patent is September 6, 2017. Petitioner also applies September 6, 2017, as the priority date for the '011 Patent. Petition, p. 13.
28. 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.
29. 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.

Supplemental Declaration of Paul J. Zalesky

30. 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.
31. 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.
32. 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

33. For the reasons I discuss below, I believe that the asserted claims of the '011 Patent are not anticipated by Schaffer or rendered obvious by any combination of the prior art asserted in the Petition.

V. THE '011 PATENT

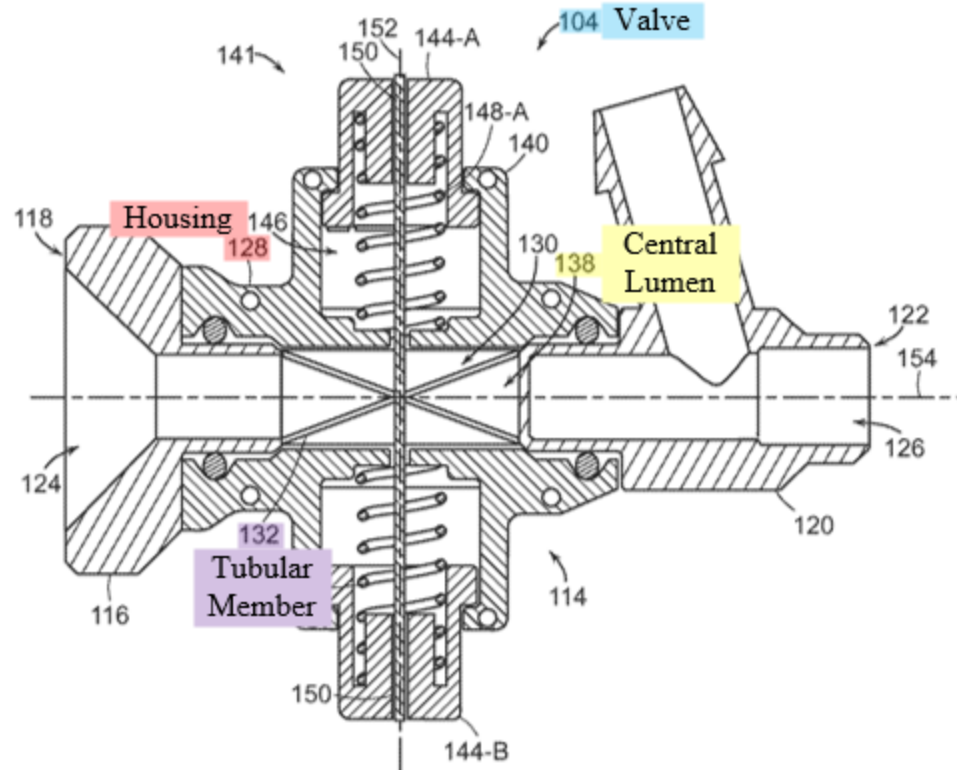
A. Overview

34. The '011 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, 1:48-52. The '011 Patent addresses those drawbacks by providing a hemostasis valve (i.e., a valve that inhibits or prevents blood from flowing through 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 '011 patent. *Id.* at 16:20-44 (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.

35. Specifically, the '011 Patent discloses that “[t]he present disclosure relates to a valve that can be used [as] a hemostasis valve.” EX1001, 5:51-52. This valve, also referred to in the '011 Patent as a garrote valve, can seal with or without a tool extending through the valve. *Id.* at 5:52-53. I understand that the '011 Patent used the term “garrote valve” to evoke the mechanism and action of the valve in which one or more filaments are pulled tightly around a flexible tubular member to seal the flexible tubular member.
36. 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 5:51-65. 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 1:61-2:10, 4:1-10, 5:5-19, 5:51-6:2, 16:20-44. 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 in large veins and pulmonary arteries, such as for treating deep vein thrombosis or pulmonary embolism, where the risk of blood loss is generally greater and the need for a tight valve is critical.

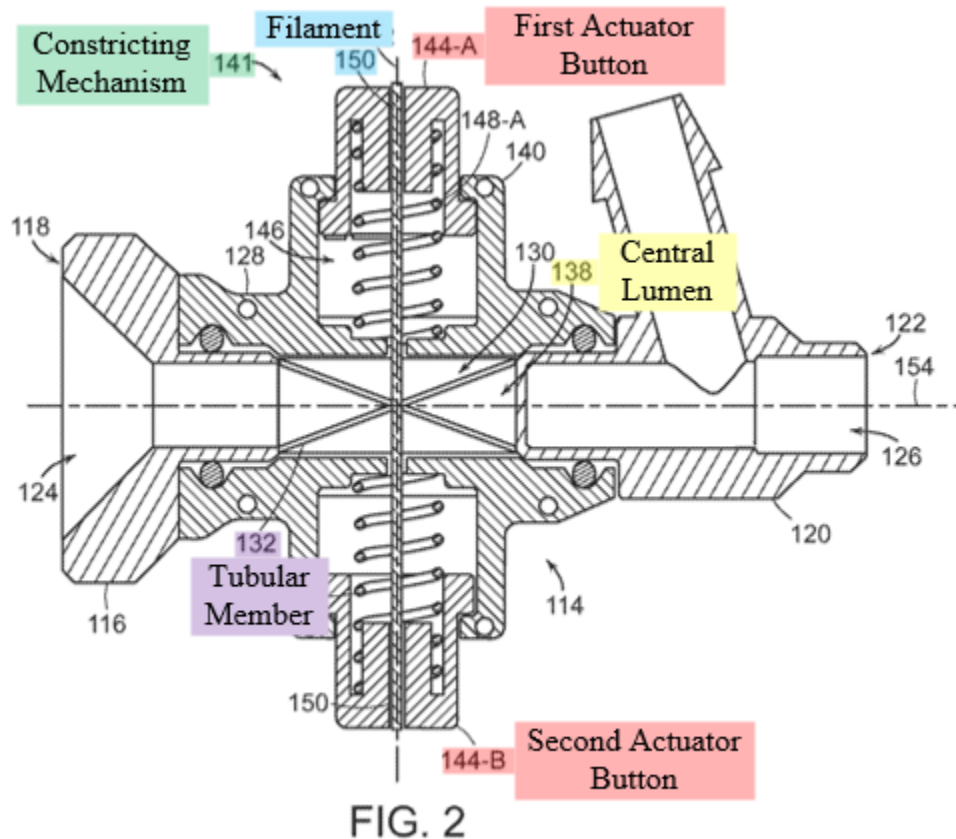
37. When utilizing the garrote valve in a thrombectomy procedure, for example, the garrote valve can be coupled to a proximal end of a catheter and used to seal a lumen of the catheter and maintain hemostasis (i.e., inhibit or prevent blood flow from the catheter through the valve) when an instrument (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 5:51-57 & 6:21-30. 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 5:54-6:2.
38. In an embodiment, the '011 Patent discloses a garrote valve that includes a housing 128 defining an interior channel 130 and an elongate/tubular member 132 extending through the interior channel 130. *Id.* at 7:6-10. The tubular member 132 defines a central lumen 138, and can comprise a compliant tubular structure that facilitates collapse and sealing of the tubular member 132:



Id. at 7:10-19.

39. The garrote valve further includes a constricting mechanism 141 or garrote that can collapse and seal the tubular member 132 via constriction with at least one filament 150 that can extend at least partially around the tubular member 132. *Id.* at 8:1-8. 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 member 132 (the

central lumen 138 of the tubular member 132) based on the movement and/or position of the actuator 142:



Id. at 8:4-8 & 9:21-25.

40. The garrote valve also includes a bias feature 146 configured to bias the actuator 142 toward a first (closed) configuration of the garrote valve shown in Figure 2 wherein the tubular member 132 is “collapsed and/or sealed,” such as 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:

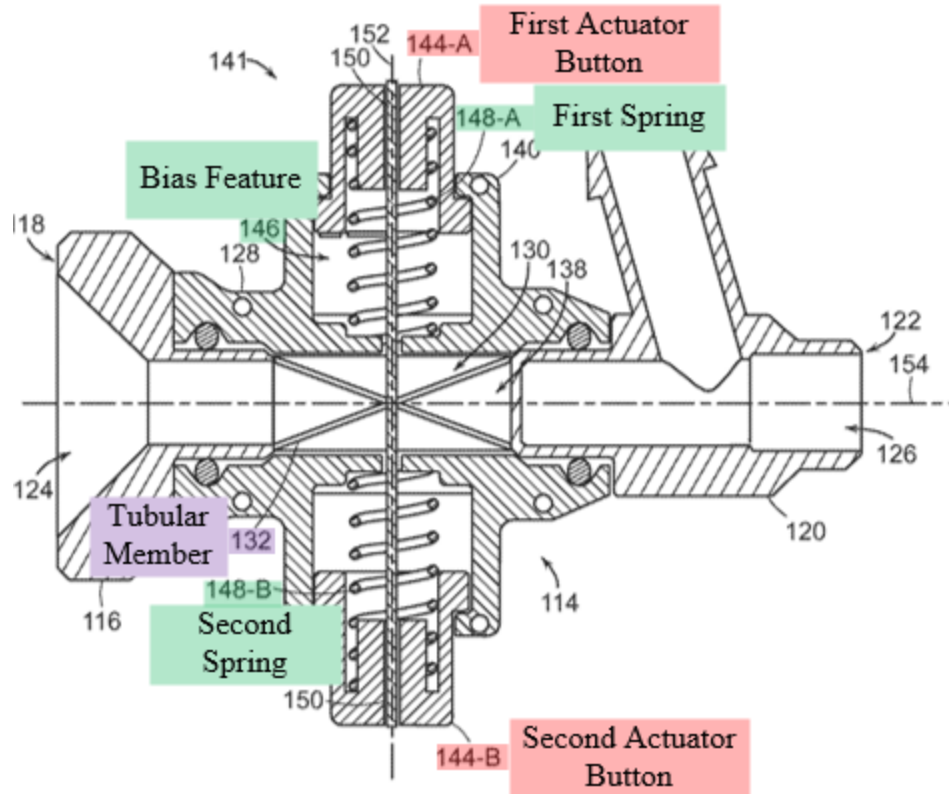


FIG. 2

Id. at 8:35-50. 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 member 132 is expanded and the central lumen 138 of the tubular member 132 is unsealed:

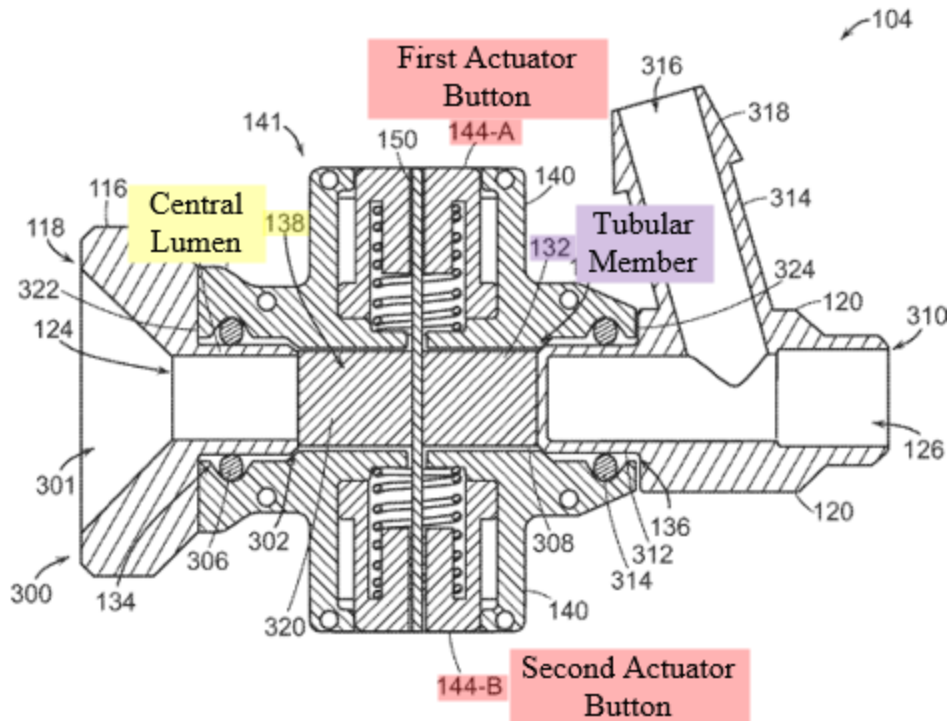


FIG. 3

Id. at 9:51-59. For example, the first and second buttons 144-A, 144-B can be depressed against the first and second biasing members 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 member 132 and the unsealing of the central lumen 138 thereof. *Id.* at 9:55-59. 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 8:8-12.

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

9:10-13. 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 9:13-20.

42. The filament 150 can have different configurations as shown in Figures 6-9. For example, the filament 150 “can comprise a single filament 150 having a first end 600 and a second 602” as shown in Figure 6.

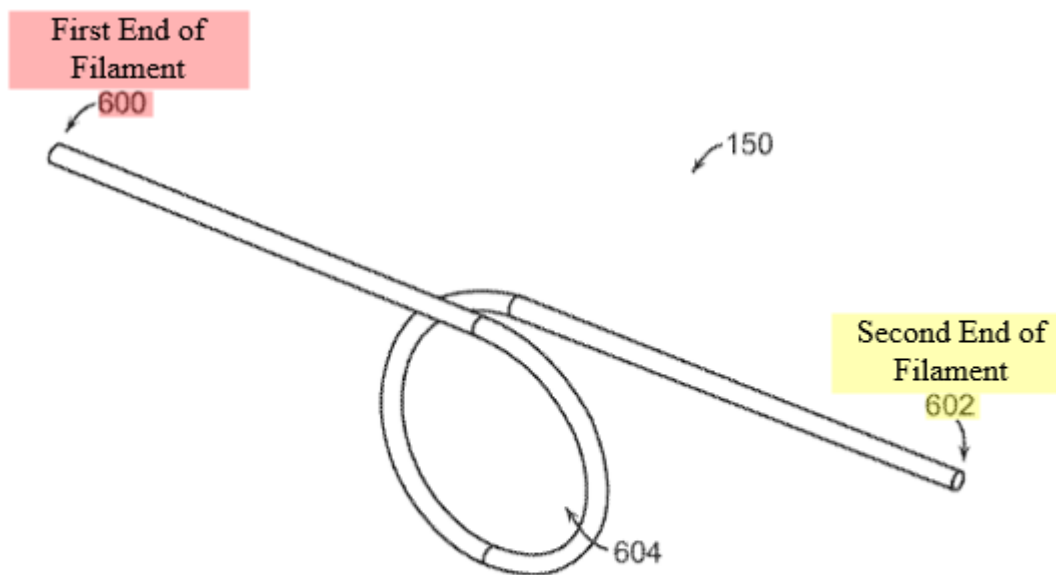


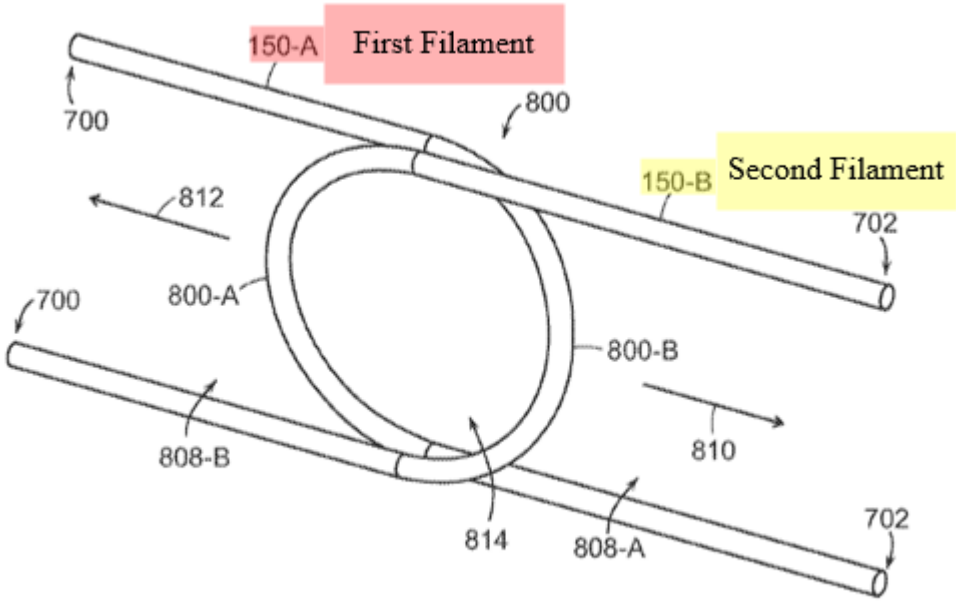
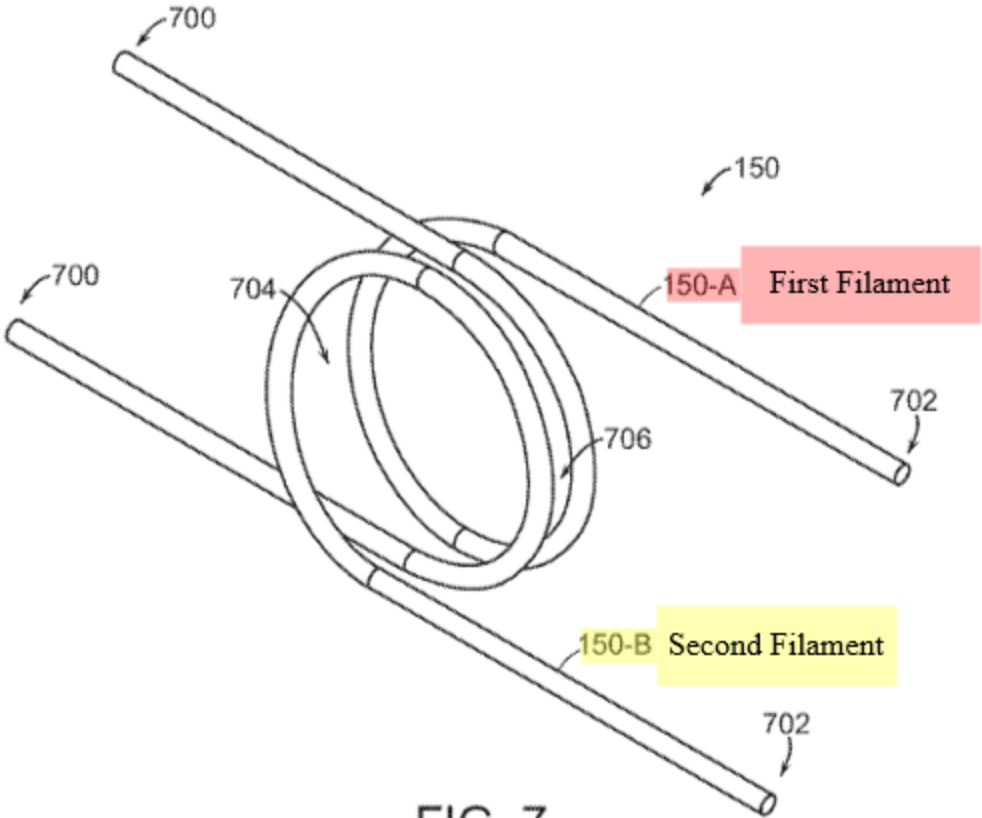
FIG. 6

Id. at 12:56-60. The filament 150, and specifically the first and second ends 600, 602 can be coupled to the actuator 142 to move the filament 150 from the first configuration in which the garrote valve is sealed to the second configuration in which the garrote valve is open. *Id.* at 12:60-64. Both of the first end 600 and the second end 602 can be coupled to a single button 144, or

each of the first end 600 and the second end 602 can be coupled to different buttons 144. *Id.* at 12:64-13:1. The filament 150 forms a loop 604 such that the filament 150 can exert a strong closure and sealing force because it extends around a circumference of the tubular member 132 and circumferentially constricts the tubular member 132 when tensioned—reducing the size of the loop 604 to thereby constrict the tubular member 132 within the loop 604. *Id.* at 4:58-62, 13:29-41.

43. 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 13:6-9. “In embodiments in which the filament 150 comprises multiple filaments, each of the multiple filaments can have a first end 700 and a second end 702.” *Id.* at 13:9-12. The first and second ends 700, 702 can be coupled to the actuator 142 to move the filaments 150-A, 150-B from the first configuration to the second configuration. *Id.* 13:13-17. Both of the first end 700 and the second end 702 of one or more of the multiple filaments 150 can be coupled to a single button 144, or each of the first end 700 and the second end 702 of one or more of the multiple filaments 150 can be coupled to different buttons 144. *Id.* at 13:17-23.
44. Referencing Figures 7 through 9, the specification recites the filament 150 can comprise multiple individual filaments as follows: “[i]n some embodiments,

the filament 150 can comprise multiple filaments, and specifically, as shown in FIGS. 7 through 9, the filament 150 can comprise a first filament 150-A and a second filament 150-B.” *Id.* at 13:6-9.



45. The specification then explains that when the filament 150 comprises multiple filaments as shown in Figures 7-9, each individual filament has a “first end” and a “second end” as follows: “[i]n embodiments in which the filament 150 comprises multiple filaments, each of the multiple filaments can have a first end 700 and a second end 702.” *Id.* at 13:9-12.
46. I note that Figures 8 and 9 include a typographical error that is obvious and readily apparent in view of that clear disclosure in the specification. Specifically, Figures 8 and 9 show an embodiment having two individual filaments 150-A and 150-B. As expressly set forth in the specification, each of those individual filaments 150-A and 150-B has a first end and a second end. A typographical error in Figures 8 and 9 identifies individual filament 150-A as having two first ends 700 and individual filament 150-B as having two second ends 702. But, in accordance with the express disclosure in the specification, a POSITA would understand that each individual filament 150-A and 150-B in Figures 8 and 9 include a first end 700 and a second end 702:

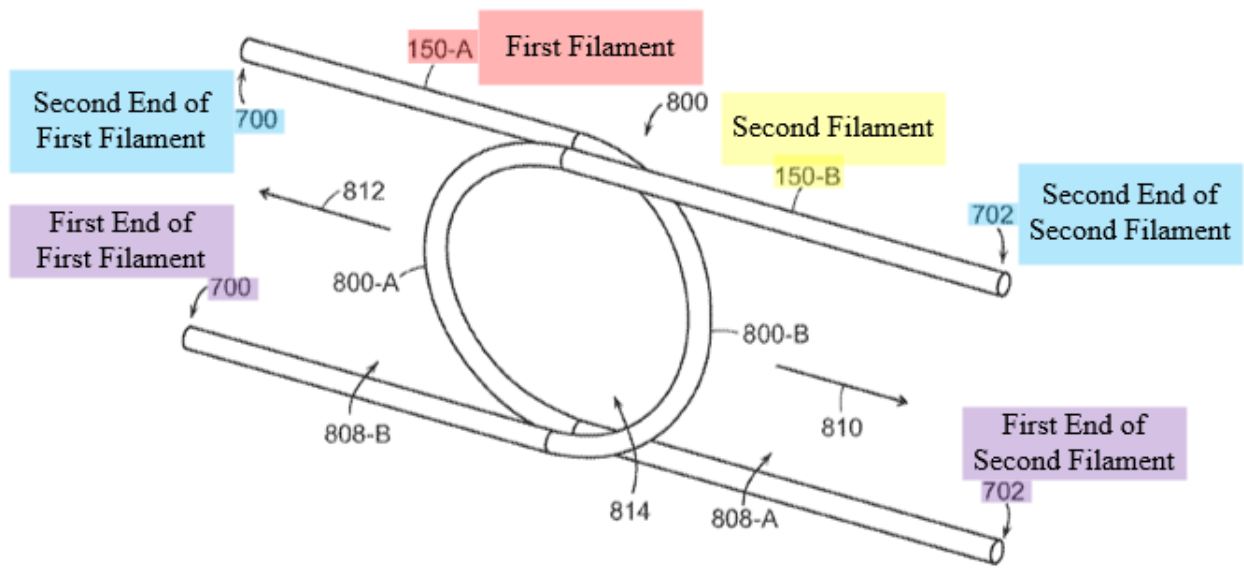


FIG. 8

47. In addition, the '011 Patent consistently refers to various continuous (not separate) components as having a “first end” and a “second end.” For example, the catheter 102 has a first end 108 and a second end 110 (*id.* at 6:25-30), the tubular member 132 has a first end 134 and a second end 136 (*id.* at 7:28-32), and the reinforcement structure 320 has a proximal (e.g., first) end 322 and a distal (e.g., second) end 324 (*id.* at 11:9-10).
48. The above understanding is consistent with a common sense understanding of an individual filament which would have a first and second end, not two first ends or two second ends. I have applied that understanding in forming my opinions.
49. As I note above, the easy one-handed operation and strong seal of the garrote valve is particularly useful in thrombectomy procedures. Figure 11 of the

'011 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 and that is used to treat and/or extract a thrombus 1106 from the blood vessel 1104:

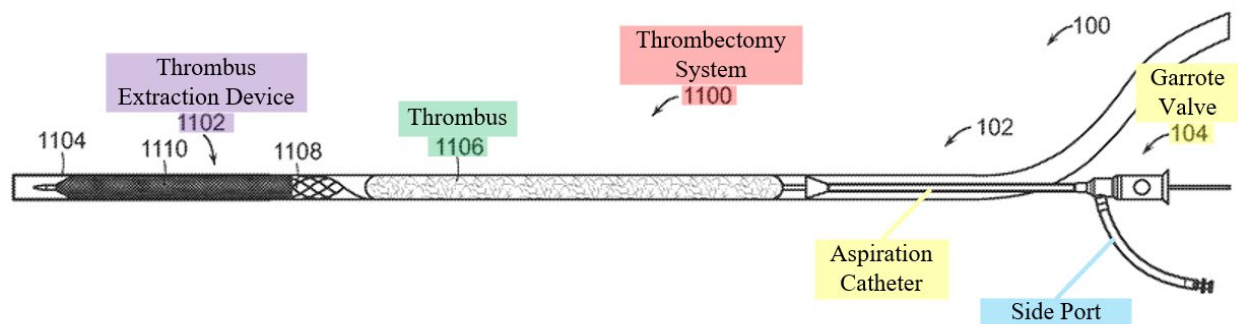


FIG. 11

EX1001, 16:20-44. 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 10:42-52. 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 5:54-6:2. 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 such that blood loss is a significant concern during a thrombectomy procedure.

50. For example, the aspiration catheter 102 can have an outer diameter of at “at least 18 French, at least 20 French, at least 22 French.” *Id.* at 6:36-42. 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.
51. 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

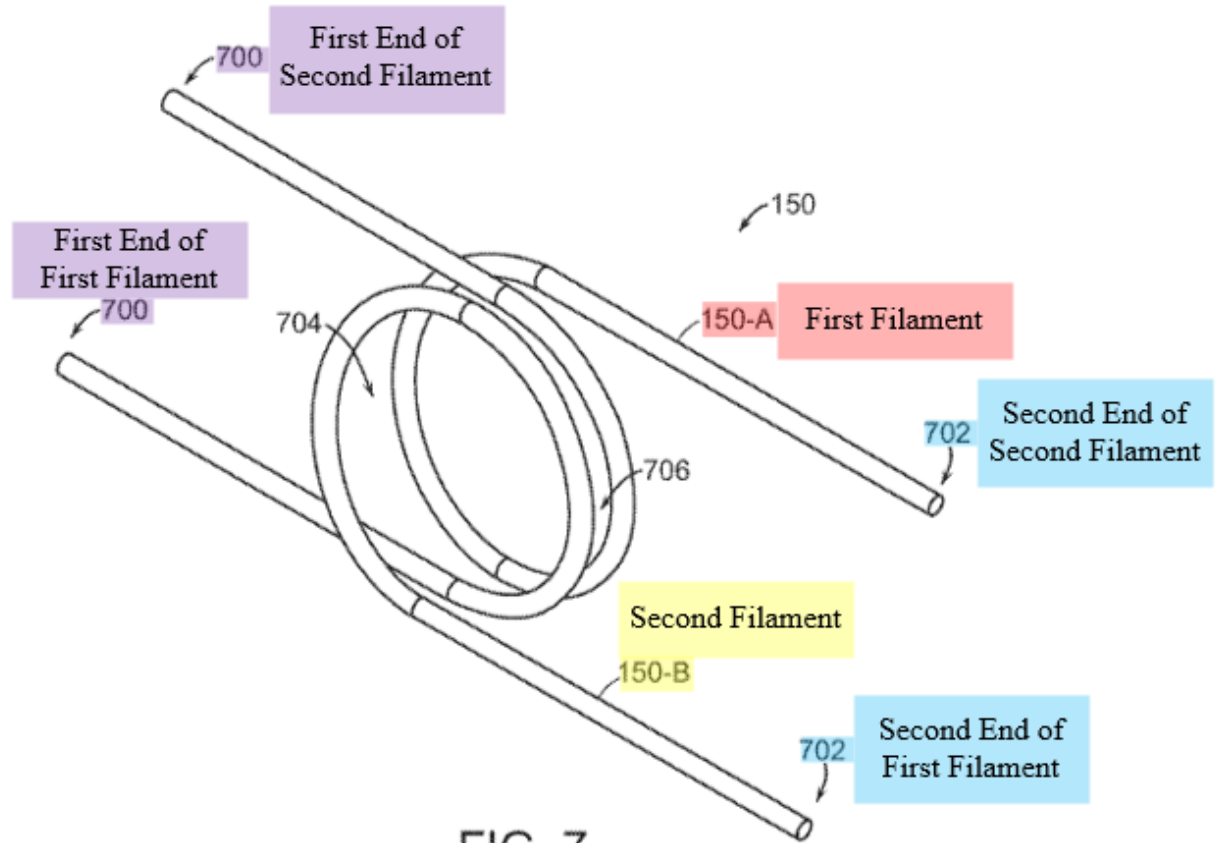
physicians and critical to patient health. A robust seal and quick, self-closing valve are critical to reduce patient blood loss which can be significant through a large catheter. Traditional rotating hemostasis valves take many turns to seal the larger bore catheters used in such procedures. The incorporation 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. Claim 1

52. Claim 1 recites “a constricting mechanism including at least one filament.” The filament comprises a “first portion extending around at least a portion of the tubular member” and a “second portion having a first end extending from the first portion in one direction and a second end extending from the first portion in another direction.” Accordingly, Claim 1 first recites “at least one filament” then refers to the filament as having various features including “a second portion having a first end extending from the first portion in one direction and a second end extending from the first portion in another direction.”
53. I understand that the claim language requires a singular element, “the filament,” that has the recited property “a first end extending from the first portion in one direction and a second end extending from the first portion in another direction.” So, while the specification expressly recites that a “filament”

can comprise multiple individual filaments, Claim 1 requires that each individual filament includes “a first end extending from the first portion in one direction and a second end extending from the first portion in another direction.”

54. In addition, that understanding is expressly set forth in the specification. As I explain in §V.A. above, the specification recites that when the filament 150 comprises multiple individual filaments, each individual filament has a “first end” and a “second end” as follows: “[i]n embodiments in which the filament 150 comprises multiple filaments, each of the multiple filaments can have a first end 700 and a second end 702.” EX1001, 13:9-12. That configuration is depicted in Figure 7, which shows that each individual filament includes a first and second end.



55. I understand that Mr. Thornton relies on an obvious typographical error in Figures 8 and 9 to conclude that an individual filament can include two first ends or two second ends. But, based on the plain language of Claim 1 and the express disclosure in the specification, I disagree. While the “at least one filament” of Claim 1 does not exclude multiple individual filaments, Claim 1 requires an individual filament (a single continuous) that has “a first end extending from the first portion in one direction and a second end extending from the first portion in another direction.”

C. Prosecution History of Claim 1

56. I have reviewed the prosecution history of the '011 Patent, including the Office Action mailed August 19, 2022 (EX1002, pp. 149-155), the Applicant-Initiated Interview Summary dated November 4, 2022 (*Id.* at pp. 144-147), the Amendments and Response to the Office Action mailed August 19, 2022 (*Id.* at pp. 120-129 & 139), and the Notice of Allowance mailed December 14, 2022 (*Id.* at pp. 53-61).
57. I understand that the Examiner initially rejected the claims for allegedly lacking support but that, after conferring with the Applicant during the October 31, 2022, Examiner Interview, agreed to withdraw the rejection. EX1002, pp. 144-147.
58. I also understand that the Examiner considered the patentability of the claims in view of Hartley and Wong and concluded that Hartley fails to disclose a “biasing system” and that Wong fails to disclose a “filament.” *Id.* at p. 60.
59. I also understand that the Examiner stated in the Notice of Allowance that Hartley discloses “the actuator 12 comprises a first member 12 coupled to the first end of the filament and a second member coupled to the second end of the filament.” *Id.* I do not agree that Hartley discloses a “first member” and a “second member” as recited in Claim 1. Rather, as I explain below, Hartley

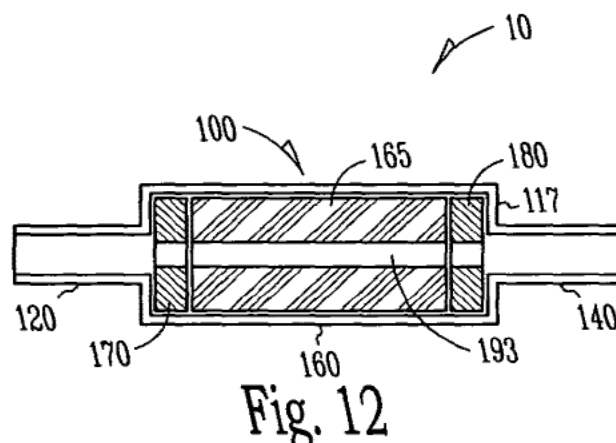
discloses a single rotary actuator 12 and thus does not disclose an actuator having a first member and a second member as claimed.

D. Cited References

60. I understand that the Petitioner has cited three different references—Schaffer, Hartley, and Eller—in its Petition challenging the patentability of the claims of the '011 Patent.

1. Schaffer

61. The sealing mechanism present in the hemostasis valve of the '011 Patent is different from the sealing mechanism employed by Schaffer. As seen in Figure 12 below, Schaffer's mechanism involves several sealing components within a seal module 100, specifically identified as seal members 165, 170, and 180, and 180.



62. These components are integral to Schaffer's sealing process, with seal member 165 being a consistent element in all embodiments. According to Schaffer, "[t]he third central seal member 165 is sized and configured to maintain an

open lumen 193 when no compressive force 67 is applied.” EX1005, ¶ [0054].

To achieve sealing, actuating members 55 are “forcibly pushed against the central portion of the seal module 100, [and] the compressive force 67 of the actuating member 55 against the outer wall 27 of the containment structure 160 inwardly depresses or collapses the third central seal member 165 of the containment structure 160 as the actuator 50 progresses toward the first side wall 23 of the housing 20.” *Id.* at ¶ [0055]. The internal seal member 165 is made from a material 166 that is “highly elastic, deformable, compliant and yet virtually non-compressible.” *Id.* at ¶ [0054]. This “highly compliant third central seal member 165 seals around a variety of profile shapes 192 and diameters 194 of the lumen 193 when at least one side of compressive force 67 is exerted upon the central region 195 with respect to the central portion 110 of the containment structure 160.” *Id.* at ¶ [0060].

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

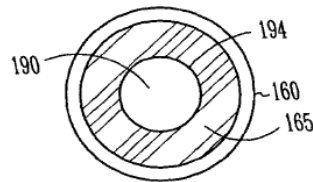


Fig. 16

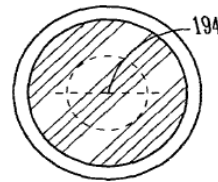


Fig. 17

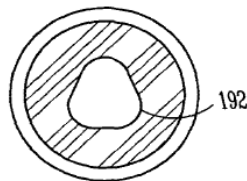


Fig. 18

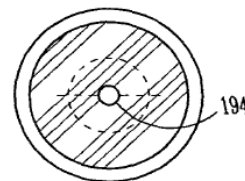
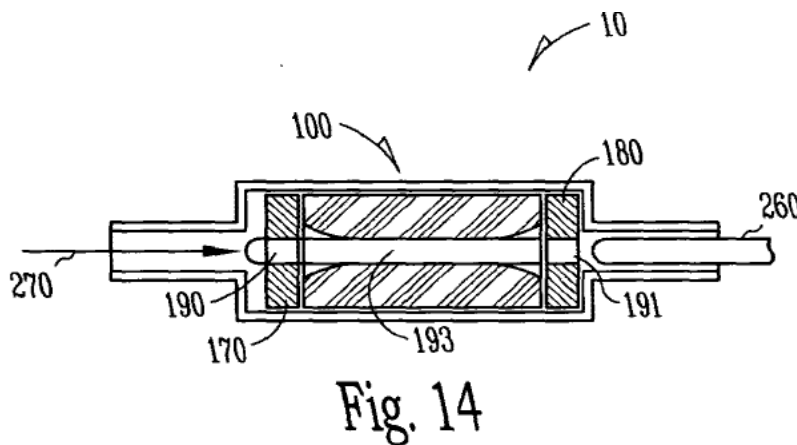
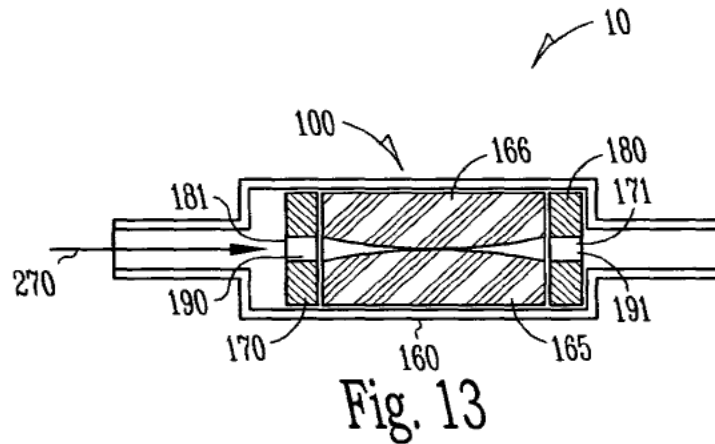


Fig. 19

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

containment structure 160. As the first seal member 170 moves distally, or toward the second seal member 180 under the influence of the pressure from the gas or fluid, the third central seal member 165 is compressed.” *Id.* at ¶ [0065].

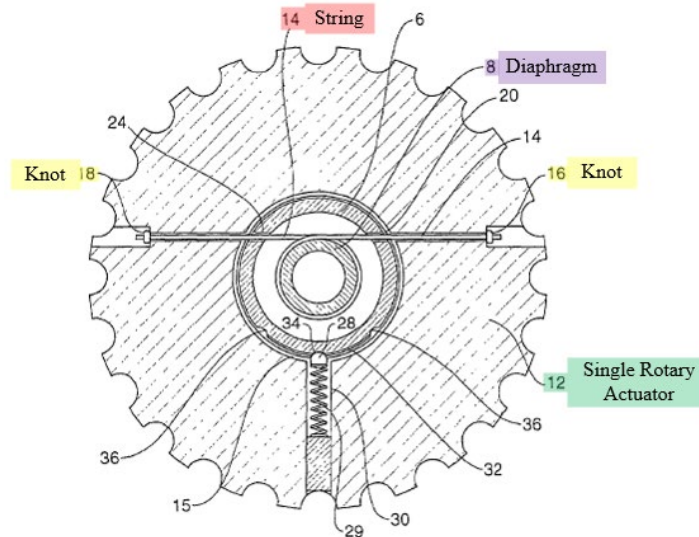


65. Schaffer discloses that improved durability and control and ease of manufacture are among the several advantages of using a non-conforming actuating members 55 with an internal sealing member 165. In fact, each embodiment in Schaffer functions in this way, as illustrated in Figures 4, 6-8, 9-10, 12-15,

and 23-29. Additionally, in relation to Figures 30-34 relied upon by Petitioner, Schaffer references seal member 165 and states that “[t]he seal module 100 is formed of one or more seal members, as discussed above. In another option, the seal module 100 and/or any of its respective seal members can be formed of one or more materials, including their relative properties, as discussed above” *Id.* at ¶¶ [0075], [0077].

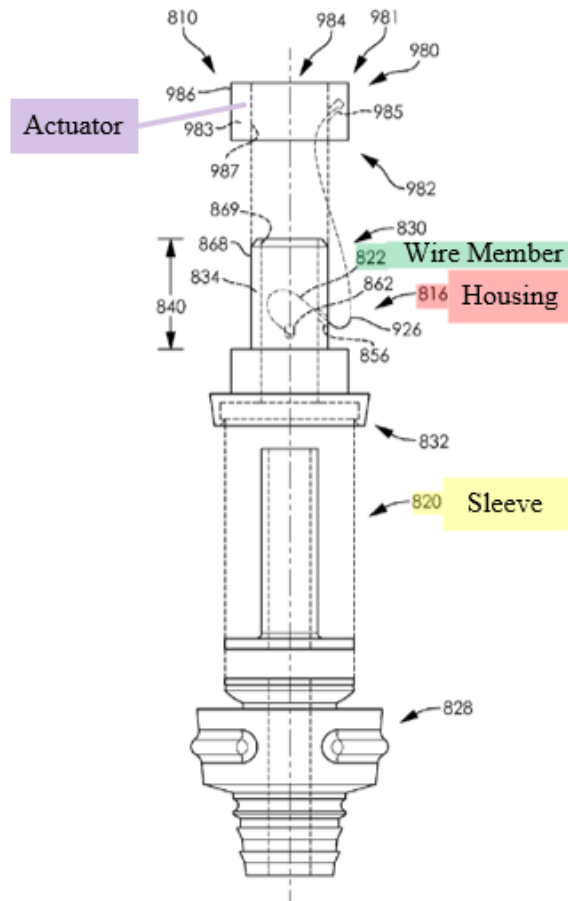
2. Hartley

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

**Fig 3**

3. Eller

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



E. Person of Ordinary Skill in the Art

68. A POSITA in September 2017 would have had an undergraduate degree in mechanical engineering or a related engineering discipline and 2 to 4 years of product design or engineering experience designing medical devices in the field of the '011 Patent. A person with less education but more relevant practical experience, or more relevant education but less practical experience, may also meet this standard.

69. I understand that Petitioner asserts that a “POSITA in September 2017 would have had an undergraduate degree in mechanical engineering or a related engineering discipline and 2-4 years of product design or engineering experience.” Petition, p. 13. I disagree. Although the Petitioner’s suggested definition of a POSITA includes a comparable level of education to mine, it does not include any experience in designing medical devices, particularly in the context of the ’011 Patent. I understand that Petitioner’s expert asserted that a POSITA would not need any experience in designing hemostasis valves or any medical devices. EX2007, 180:5-25. Again, I disagree. Having experience in the relevant field is important for designing hemostasis valves. The initial step in designing or selecting a hemostasis valve involves understanding the specific requirements of the medical procedure for which the valve will be utilized. *Id.* at 24:5-21.
70. Nevertheless, a POSITA would have understood the claims of the ’011 Patent to be patentable over the prior art references cited in grounds 1–5 under either definition.

F. Claim Construction

71. 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

Supplemental Declaration of Paul J. Zalesky

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).

72. Claim 1 recites “a constricting mechanism including at least one filament.” Here, the ’011 Patent uses the plain and ordinary meaning for the term “filament”—a “thin, flexible length of material formed by one or more strands of material”—as would be understood by a person of ordinary skill in the art as of September 6, 2017. The claim language itself, the specification, the prosecution history, and the extrinsic 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.
73. 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. 14. In other words, Petitioner argues that a filament is any structure

Supplemental Declaration of Paul J. Zalesky

that includes “at least one or more” of the recited list of non-limiting structures provided in a list at column 9, lines 18-20 of the specification of the ’011 Patent. I disagree.

74. The language of the claim itself confirms that a filament must be flexible. For example, Claim 1 recites that “the filament circumferentially constricts the lumen to create a seal.” To “circumferentially constrict,” the filament must be flexible and extend circumferentially about the lumen to constrict the lumen. With this design, the filament will adapt to the shape of the lumen as the lumen is constricted and thus “circumferentially constrict” the lumen as recited in Claim 1.
75. If the filament were rigid or inflexible, it could not “circumferentially constrict” the lumen because a rigid material cannot adapt/change its shape to reduce a circumferential contact area between the filament and the lumen. Indeed, a rigid member coupled between two actuator members would not permit the actuator members to move at all—instead rigidly tethering them together. A filament, which is flexible, allows the actuator members to move relative to one another (e.g., between the “first position” and the “second position” of Claim 1) such that filament changes shape dynamically, allowing for better adaptability to the contours of the valve lumen as it is constricted.

76. Thus, a POSITA would understand that the filament that “circumferentially constricts the lumen to create a seal” requires a flexible component consistent with the plain and ordinary meaning of filament.
77. The '011 specification further confirms that a filament must be flexible. The specification discloses that when the buttons 144 are depressed in the second position, “the filament 150 is **loosened**, thereby allowing the expansion of the elongate member 132 and the unsealing of the central lumen 138 of the elongate member 132.” EX1001, 9:56-59 (emphasis added). A POSITA would understand that when the filament is “loosened,” the filament slackens and relaxes as tension is decreased in the filament and the elongate member expands against the filament as it loosens. *See, e.g., Merriam Webster’s Collegiate Dictionary*, EX2009, p. 735 (defining “loose” as “not tightly drawn or stretched: **slack**” and “being **flexible** or relaxed”) (emphasis added). Thus, the ability of the filament to flex or slack is a necessary property of the claimed filament that allows the filament to “loosen” and thereby allow the elongate member to expand and unseal the valve. Accordingly, the specification confirms that the filament must be flexible to “loosen” to allow for the expansion of the elongate member.
78. Moreover, Figure 6 of the '011 Patent shows a single filament 150 configured to form a single loop 604 that extends around the elongate member 132:

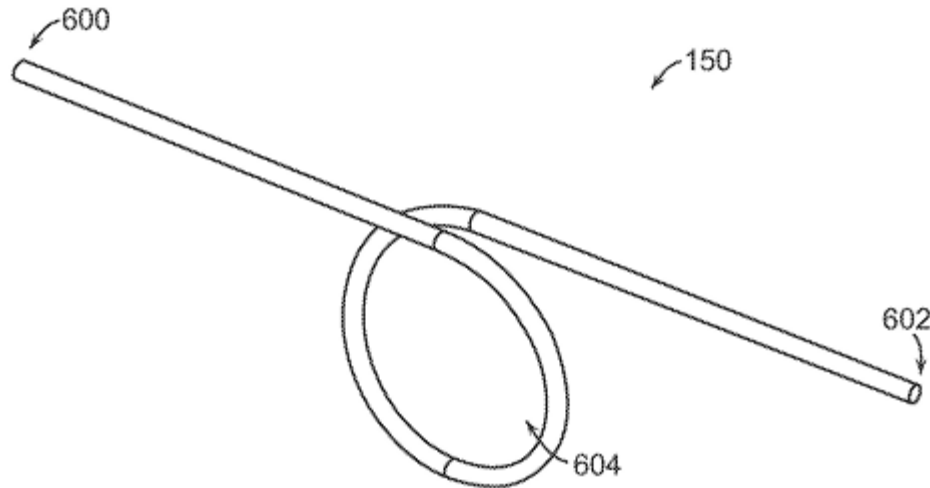


FIG. 6

79. EX1001, 12:56-13:5. “[E]ach of the first end 600 and the second end 602 can be coupled to different buttons 144” of the actuator. *Id.* When these buttons are actuated, they exert opposing forces on the respective filament ends, causing the loop’s diameter to decrease and constrict the elongated member. If the filament of Figure 6 were completely inflexible, it could not work as intended. That is, applying a force that seeks to pull the respective ends 600 and 602 of the filament in opposing directions would not “circumferentially constrict” the lumen as recited in Claim 1. Instead, the portion of the filament around the lumen would stay the same size and an elongate member extending through that loop would not be constricted and sealed. *Id.* at 12:17-24. 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 '011 Patent illustrates two filaments each formed into a loop that must also be sufficiently flexible to reduce in diameter. *Id* at 13:29-41.

80. Regarding the bight embodiments shown in Figures 8 and 9 of the '011 Patent, a POSITA would understand that when the filaments loosen slack is induced in each of the bights. Specifically, this in accordance with the meaning of “bight”: a “**slack** part or loop in a rope.” EX2009, p. 120 (emphasis added).
81. While the specification describes the filament as comprising various potential materials, such as “a polymer, a synthetic, and/or a metal” (EX1001, at 9:10-13), 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 material and form. For instance, metals, such as steel can be used to create a steel girder for a building which is rigid, but steel 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,

Supplemental Declaration of Paul J. Zalesky

which is flexible and thin. Petitioner's misplaced reliance on the composition of the filament ignores the essential principle that the structural characteristics of a component, not merely the materials from which it is made, define its function and properties. Likewise, while Petitioner contends that the proper construction for "filament" is "at least 'one or more threads, lines, cords, ropes, ribbons, flat wires, sheets, or tapes'" regardless of whether or not those configurations are flexible (Petition, pp. 42-43; EX1003, ¶ 90), a POSITA would understand those forms are commonly considered flexible. Though some of those forms can also be configured to be rigid does not redefine the term filament to include rigid members. Each recited structure is consistent with the plain meaning of a filament, which is flexible.

82. 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 December 14, 2022, the Examiner states that Hartley discloses "at least one filament" at item 14. EX1002, p. 60. 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.

83. 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.
84. Taking into account the claim language itself, the specification, the prosecution history, and other evidence, a POSITA would readily understand the degrees of flexibility required for the claimed filament—the filament must be sufficiently flexible so that it can loosen, reduce in diameter when formed in a loop as shown in Figures 6 and 7 of the ’011 Patent, and similarly slacken when formed in a bight as shown in Figures 8 and 9 of the ’011 Patent. That is, a POSITA would understand that the filament must be flexible to the degree necessary to slacken/loosen when the actuator is depressed.
85. I understand that Petitioner may assert that claims in US12,109,384 (“the ’384 Patent”) support its claim construction. I have reviewed those claims, and they do not change my opinion herein. Specifically, the ’384 patent and claims recite the term “filament” in accordance with the plain and ordinary meaning

Supplemental Declaration of Paul J. Zalesky

set forth here, namely, “thin, flexible length of material formed by one or more strands of material.” Independent claims 1, 15, and 23 each require that the filament must meet that construction such that any recitation regarding that the “filament is flexible” in the claims does not change that construction particularly in view of the clear use of the term in the ’011 Patent. Claims 1 and 15 of the ’384 Patent require the filament “[extending/configured] in a [first/second] loop” and then require “decreasing a dimension of the [first/second] loop” or similar, and claim 23 requires “circumferentially restrict.” As such, those claims support that filament is used in accordance with its plain and ordinary meaning and do not contradict the clear meaning of the term in the specification. I reserve the right to address these or any other arguments that the Petitioner may make regarding the ’384 Patent.

VI. GROUND 1: SCHAFFER DOES NOT ANTICIPATE CLAIMS 1-9

86. I understand that Petitioner and its expert, Mr. Thornton, allege that Schaffer discloses each and every feature of Claims 1-9 of the ’011 Patent and therefore anticipates these claims. I disagree for the reasons I discuss in further detail in this section. A POSITA would understand that Schaffer does not disclose each limitation of Claim 1 and therefore does not anticipate Claim 1. And, because Claims 2-9 depend from Claim 1 and thus include all the limitations from Claim 1, those claims are also not anticipated by Schaffer.

87. As I explained above, 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 can anticipate a claimed invention if the prior art reference disclosed each of the claimed limitations of the invention either expressly or inherently.

A. Schaffer Does Not Disclose a Filament that “Circumferentially Constricts”

88. Even assuming Petitioner’s construction of “filament,” Schaffer does not anticipate Claim 1 because Schaffer does not disclose that “the filament circumferentially constricts the lumen to create a seal.” Regarding “circumferentially constricts” Petitioner alleges that “Schaffer discloses these limitations [of Claim 1] or renders them obvious in view of Hartley or Eller,” without explanation. Petition, p. 22. But, neither of Schaffer’s actuating members 55 “circumferentially constricts.” Instead, the actuating members exert a compressive force in two opposite directions, which does not result in the lumen being constricted around its circumference. Schaffer further does not disclose a filament that “circumferentially constricts” because the U-shaped actuating members in Schaffer are configured in parallel (e.g., side-by-side). This parallel configuration means that the actuating members are positioned next to each other and do not cross any part of the same portion of the lumen. Consequently, they do not circumferentially constrict any point of the lumen.

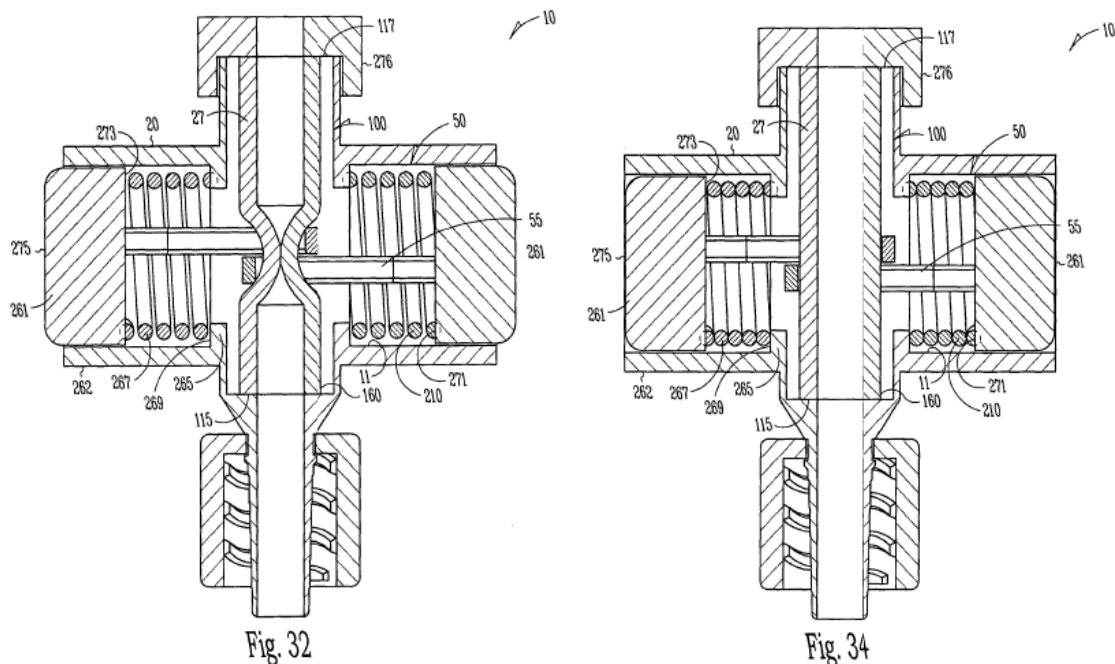
89. The Petition further asserts that even if Schaffer's U-shaped actuating members do not "circumferentially constrict[] the lumen [of Schaffer's valve] to create a seal" as recited in the '011 Patent, it would have been obvious for a POSITA to modify these U-shaped members to achieve such constriction. Petition, p. 32 (citing EX1003, ¶75). The Petition also references the "circumferentially constricts" limitation in relation to Claim 9, where it suggests that replacing Schaffer's U-shaped actuating members with Hartley's string or Eller's wire member would achieve the required circumferential constriction.
90. In sum, a POSITA would understand based on the specification and plain language of the '011 Patent that Claim 1 requires a filament to "circumferentially constrict[]." Schaffer's actuating members 55, alone or together, do not "circumferentially constrict[]," and therefore, Schaffer does not disclose this feature of Claim 1.

B. Schaffer Does Not Disclose the "Filament" of Claim 1

91. According to Petitioner, "Schaffer's U-shaped actuating members are a 'filament' as claimed in the '011 patent." Petition, p. 27. That is, Petitioner contends that "Schaffer's U-shaped actuating members collectively constitute the 'at least one filament' disclosed and claimed in the '011 patent." *Id.* at p. 28. I disagree—Schaffer's actuating members 55 are rigid metal or plastic U-

shaped members and not thin and flexible and thus are not individually or collectively a “filament.”

92. As I explain in §V.F. 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 “at least one filament,” as recited in Claim 1.
93. 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 (Ex. 1008) showing features that are not seen in the published application’s figures.

94. 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/loosen without forcibly disengaging the seal module 100. That is, the flexible actuating members 55 would remain in contact with and never disengage the seal module 100, contrary to Schaffer's teachings.

95. Moreover, as I explain in greater detail in §VIII.C. below, Schaffer discloses that the seal module 100 is formed of a material 166 that "is extremely soft and compliant and intrinsically 'sticky.'" EX1005, ¶ [0059]. A POSITA would understand that the forcible disengagement provided by the rigid actuating members 55 is desirable or necessary to allow the seal module 100 to expand when the actuator buttons 261 are depressed. For example, flexible actuating members 55 would not disengage the soft and sticky seal module 100 at all when the actuator buttons 261 are depressed such that the seal module 100 may stick to and retain the actuating members 55 in the closed position—rendering Schaffer's valve inoperable by inhibiting or even preventing movement of the seal module 100 to the open position.
96. 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

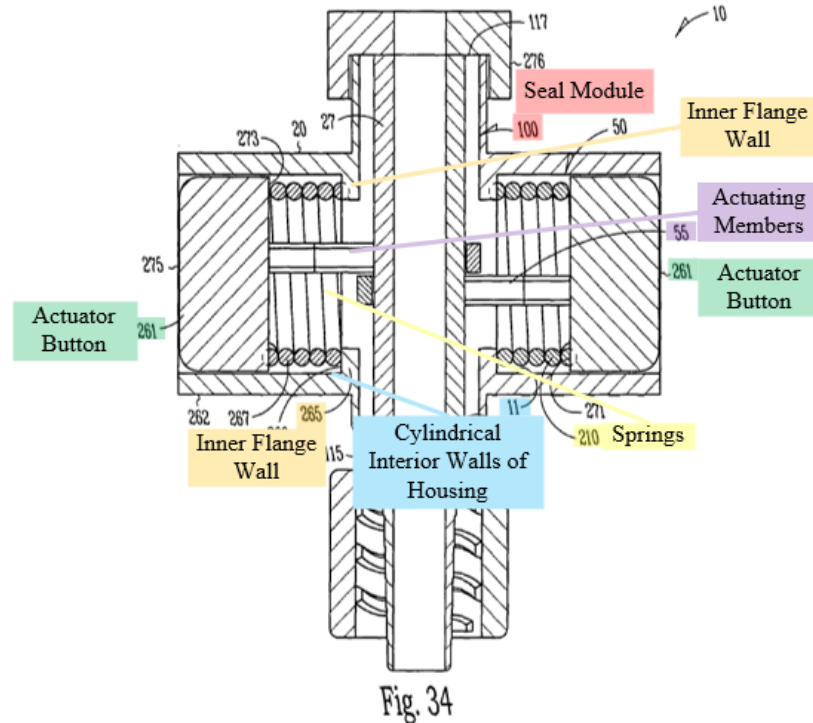
than rigid. For example, if the actuating members 55 were flexible, and Schaffer's stasis valve 10 was tilted when the actuator buttons 261 were actuated (e.g., without the actuator buttons 261 positioned to be depressed perpendicular to gravity), a POSITA would understand that the actuating members 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.

97. Third, Schaffer teaches and Petitioner highlights that “Schaffer’s actuating members are formed from aluminum or plastic.” Petition, p. 27; 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 materials 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.

98. 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:



99. 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.

100. Finally, even if the term "filament" is construed as "threads, lines, cords, ropes, ribbons, flat wires, sheets, or tapes" as suggested by the Petitioner, Schaffer does not disclose a filament. A POSITA would recognize that the U-shaped actuating members of Schaffer are not and cannot be any of those things. For instance, Schaffer's U-shaped actuating members are described as being "machined," which is a process typically used to shape rigid materials, and it is not practically possible to create a flat wire through machining. Flat wires are generally produced through processes such as rolling or drawing, which are fundamentally different from machining.
101. Given that the actuating members in Schaffer are machined, they cannot be "threads, lines, cords, ropes, ribbons, flat wires, sheets, or tapes." Therefore, the method of creating the actuating members as disclosed in Schaffer cannot result in members that fit the Petitioner's definition of a "filament."

Accordingly, Schaffer does not disclose a "filament" even under the Petitioner's construction of the word "filament."

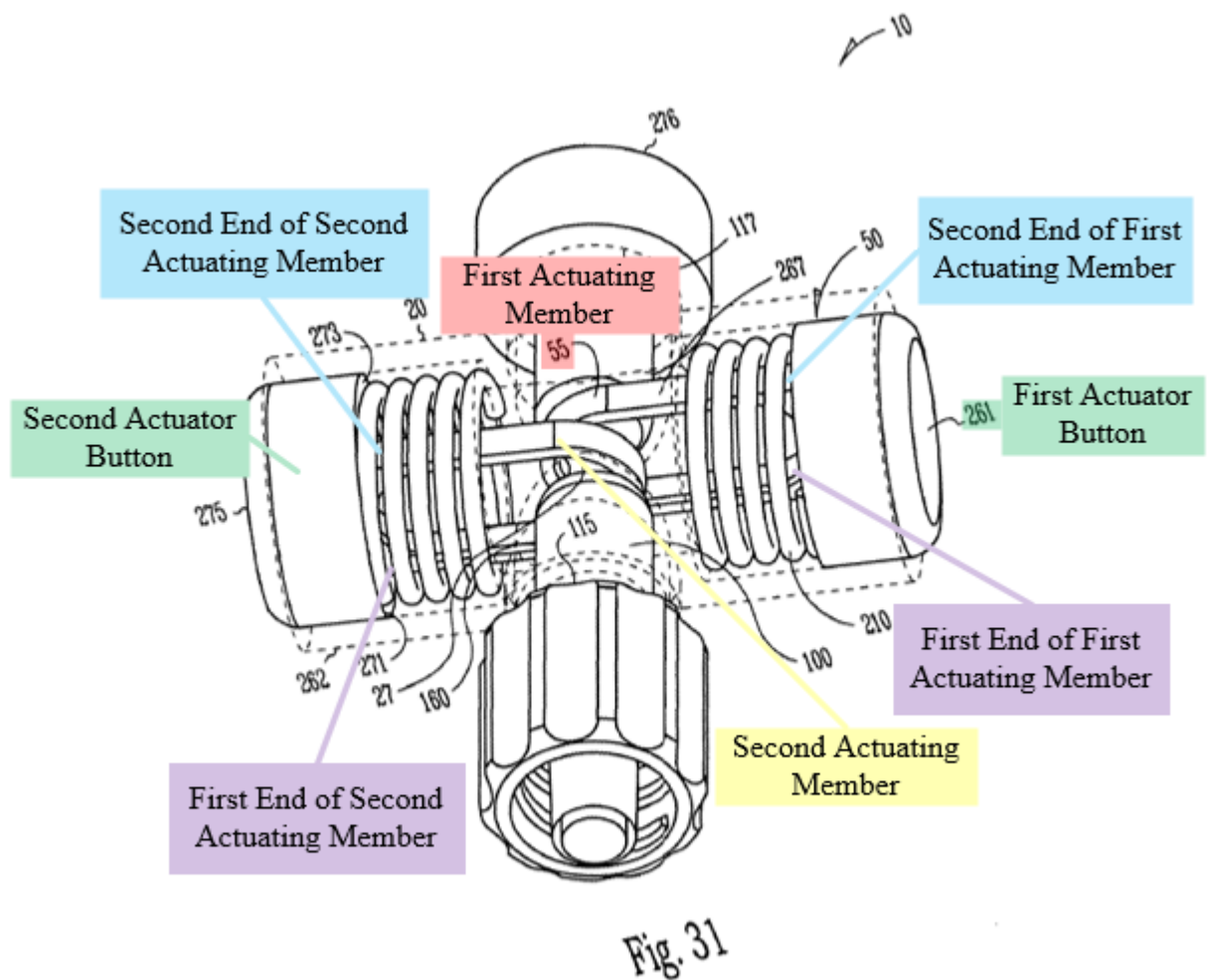
102. In sum, a POSITA would understand based on Schaffer's description and illustration of the operation of the actuating members 55, its description of the materials and methods of forming the actuating members 55, as well as its description of how its stasis valve is assembled, that the actuating members 55 are rigid rather than flexible. As such, Schaffer's actuating members 55, either alone or in combination, are not a "filament" as claimed in the '011 Patent because they are not flexible. Therefore, Schaffer does not disclose this feature of Claim 1 and thus does not anticipate Claim 1.

C. Schaffer Does Not Disclose the "Filament" Having Two Ends Extending in Different Directions and Coupled to Different Members of an Actuator.

103. Even assuming Petitioner's construction of "filament," Schaffer does not anticipate Claim 1 because Schaffer does not disclose the "filament comprising...a second portion having a first end extending from the first portion in one direction and a second end extending from the first portion in another direction" or an "actuator comprises a first member coupled to the first end of the filament and a second member coupled to the second end of the filament." Petitioner does not allege that either of Schaffer's actuating members 55 has the claimed "first end portion" and "second end portion" but instead alleges

that “Schaffer’s U-shaped actuating members collectively constitute the ‘at least one filament’ disclosed and claimed in the ’001 patent.” Petition, p. 28.

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



EX1005, ¶ [0076]. That is, each end of the actuating members 55 identified by Petitioner extends in a same direction such that the actuating members 55 do not include “a first end extending from the first portion in one direction

Supplemental Declaration of Paul J. Zalesky

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

105. I disagree that “[t]hat Schaffer uses two separate actuating members is of no moment here,” as Petitioner and Mr. Thornton contend. Petition, p. 28. For example, as I explain in §§V.A-B. above, a POSITA would understand Claim 1’s recitation of “the filament comprising ... a first end extending from the first portion in one direction and a second end extending from the first portion in another direction” to mean a single filament has the first end and the second end. That is, the claim language requires a singular element, “the filament,” that has the recited properties. In particular, as I explain in §§V.A-B. above, the ’011 Patent recites that when the filament 150 comprises multiple individual filaments, each individual filament has a “first end” and a “second end” as follows: “[i]n embodiments in which the filament 150 comprises multiple

filaments, **each of the multiple filaments can have a first end 700 and a second end 702.**” EX1001, 13:9-12 (emphasis added).

106. Petitioner’s reliance on an obvious typographical error in the ’011 Patent to argue otherwise is contradicted by both the plain language of the claim and the express disclosure in the specification as I explain above in §§V.A-B. In particular, a POSITA would understand that in Figure 8 each of the first and second filaments 150-A and 150-B have two ends—a first end (the first end 700) and a second end (the second end 702)—rather than two “first ends 700” or two “second ends 702” as relied on by Petitioner.
107. Accordingly, a POSITA would understand that Claim 1 requires a single filament having the “first end extending ... in one direction” and coupled to the first member and the “second end extending ... in another direction” and coupled to the second member. Schaffer’s U-shaped actuating members 55 each have first and second ends extending in the **same direction** and coupled to the **same** actuator button 261. Therefore, Schaffer does not disclose this feature of Claim 1 and thus does not anticipate Claim 1.

VII. GROUND 2: SCHAFFER DOES NOT RENDER CLAIMS 1-9 OBVIOUS

108. I understand that Petitioner and its expert, Mr. Thornton, allege that Schaffer, if it does not anticipate, renders obvious Claims 1-9 of the ’011 Patent. I disagree for the reasons I discuss in further detail in this section. A POSITA

Supplemental Declaration of Paul J. Zalesky

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. And, because Claims 2-9 depend from Claim 1 and thus include all the features from Claim 1, those claims are also not rendered obvious by Schaffer.

109. 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.
110. Petitioner alleges that “[e]ven if the Board were to conclude that Schaffer’s U-shaped actuating members do not ‘circumferentially constrict[] the lumen

[of Schaffer's valve] to create a seal' as claimed in the '001 patent, a POSITA would have found it obvious to modify the U-shaped actuating members to closely conform to the seal module to circumferentially constrict the lumen." Petition, p. 32. I disagree.

111. As I explain in §§VI.A-B. above, Schaffer does not disclose either filament or "the filament circumferentially constricts the lumen to create a seal" as recited in claim 1.
112. It would not have been obvious to a POSITA to have modified Schaffer to arrive at the foregoing features of Claim 1. In particular, as I explain in detail in §VIII. below, a POSITA would understand that Schaffer's valve seals completely with or without instruments inserted therethrough such that there is no motivation to modify Schaffer to make the U-shaped members flexible or circumferentially constrict and such modifications would change Schaffer's principle of operation and render Schaffer inoperable for its intended purposes of easy manufacturability, durability, and assembly.

VIII. GROUNDS 3 AND 4: THE COMBINATION OF SCHAFFER AND HARTLEY OR ELLER DOES NOT RENDER CLAIMS 1-9 OBVIOUS

113. Petitioner and its expert, Mr. Thornton, allege that the Schaffer in combination with Hartley or Eller renders obvious Claims 1-9 of the '011 Patent. I disagree for the reasons I discuss in further detail in this section. A POSITA would not

Supplemental Declaration of Paul J. Zalesky

have been motivated to or found it obvious to modify Schaffer in view of Hartley or Eller to arrive at the features of Claim 1. Therefore, the combination of Schaffer and Hartley or Eller does not render obvious Claim 1. And, because Claims 2-9 depend from Claim 1 and thus include all the features from Claim 1, those claims are also not rendered obvious by the combination of Schaffer and Hartley or Eller.

114. 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.

115. Petitioner argues that “POSITAs would have found it obvious to substitute Hartley’s string for Schaffer’s U-shaped actuating members,” and that a “POSITA would have found it obvious to substitute Eller’s wire member for Schaffer’s U-shaped actuating members.” Petition, pp. 35, 44.
116. I disagree that it would have been obvious to or that a POSITA would have substituted Hartley’s string or Eller’s wire for Schaffer’s U-shaped actuating members for at least the reasons set forth below.

A. Neither Schaffer, Hartley, or Eller Disclose a Single Flexible Filament Having a First End Coupled to a First Member of an Actuator and a Second End Coupled to a Second Member of an Actuator, as Recited in Claim 1

1. Schaffer

117. As I explain in §VI.C. above, Schaffer does not disclose a single flexible filament having the “first end extending ... in one direction” and coupled to the first member and the “second end extending ... in another direction” and coupled to the second member, as recited in Claim 1. Rather, each of Schaffer’s U-shaped actuating members are rigid and have first and second ends extending in the **same direction** and coupled to the **same** actuator button 261:

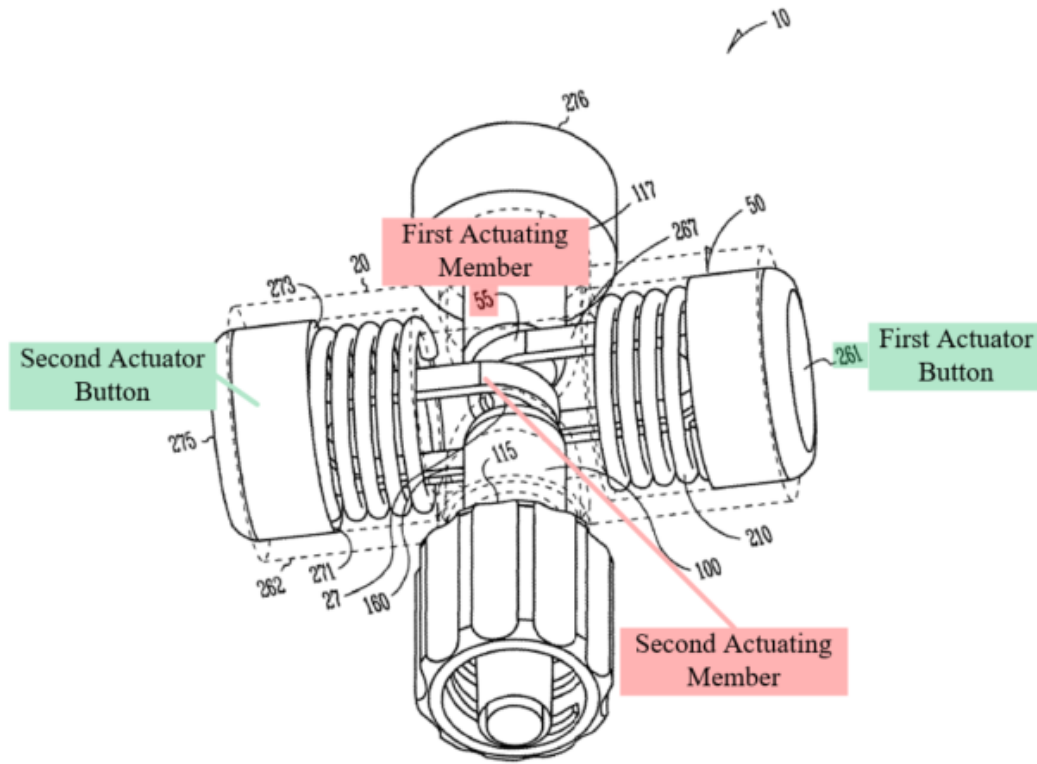


Fig. 31

118. 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.

2. Hartley

119. Hartley does not disclose such an arrangement either. Rather, Hartley discloses a string affixed to a single rotary actuator member. Specifically, 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:

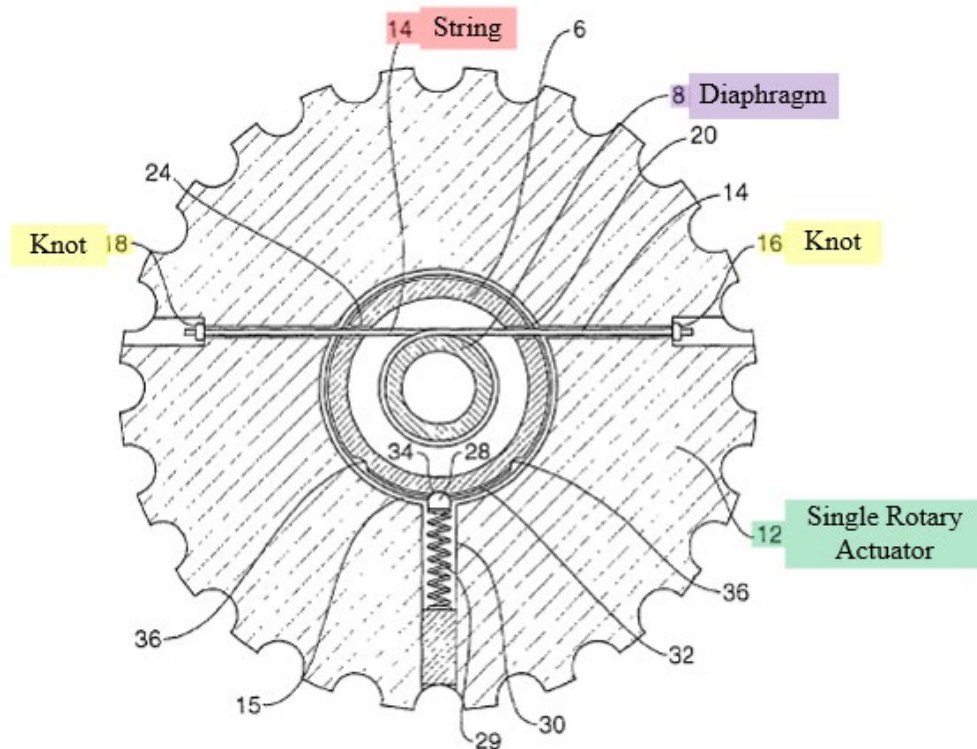


Fig 3

120. EX1006, ¶ [0031]. A POSITA would understand the rotary actuator 12 to be a single integral piece such that the knots 16 and 18 are not attached to a respective “first member” and “second member,” as recited in Claim 1. Movement of the single rotary actuator 12 controls movement of both ends of the string 14.

3. Eller

121. Eller does not disclose such an arrangement either. Rather, Eller discloses various selective fluid barrier devices that include one or more wire members

each having one end coupled to an actuator and the other end coupled to itself or a housing.

122. For example, 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:”

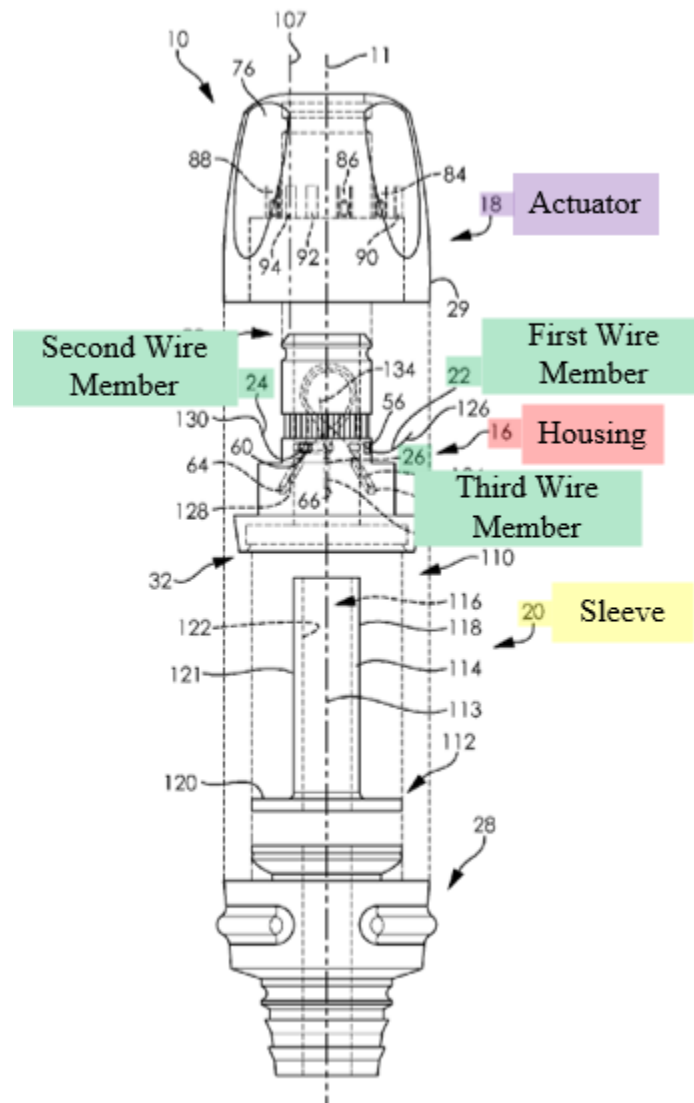
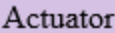


FIG. 2

Supplemental Declaration of Paul J. Zalesky

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. 43; 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. 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”:



822 Wire Member

Housing

Sleeve

828

- 68

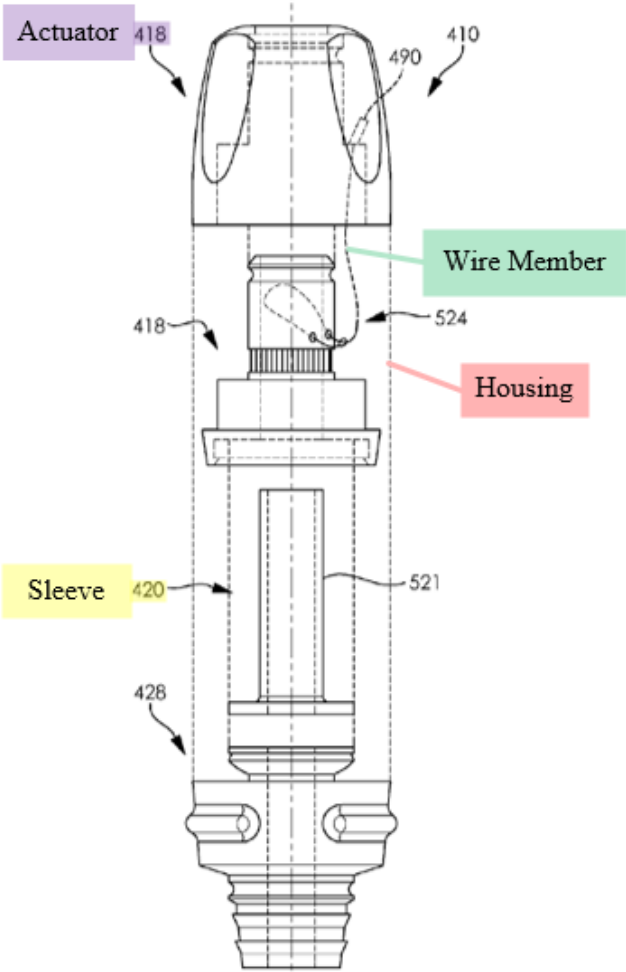


FIG. 15

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.

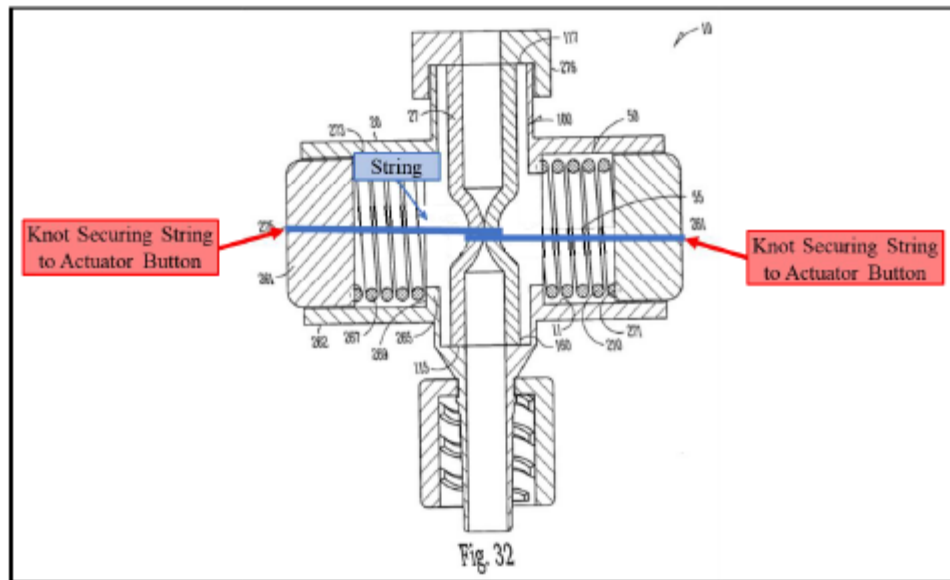
124. Thus, in each of Eller's various selective fluid barrier devices, the various wire members have a first end coupled to either a housing of the selective fluid barrier device or to the wire member and a second end coupled to an actuator of the selective fluid barrier device. Movement (e.g., rotation) of the actuator

pulls only the second end of the wire member while the first end remains stationary to tension the wire member. That is, movement of the single actuator controls movement of the wire member. Thus, A POSITA would understand that Eller does not disclose that the wire member includes a “first end extending ... in one direction” and coupled to a first member and the “second end extending ... in another direction” and coupled to a second member, as recited in Claim 1.

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

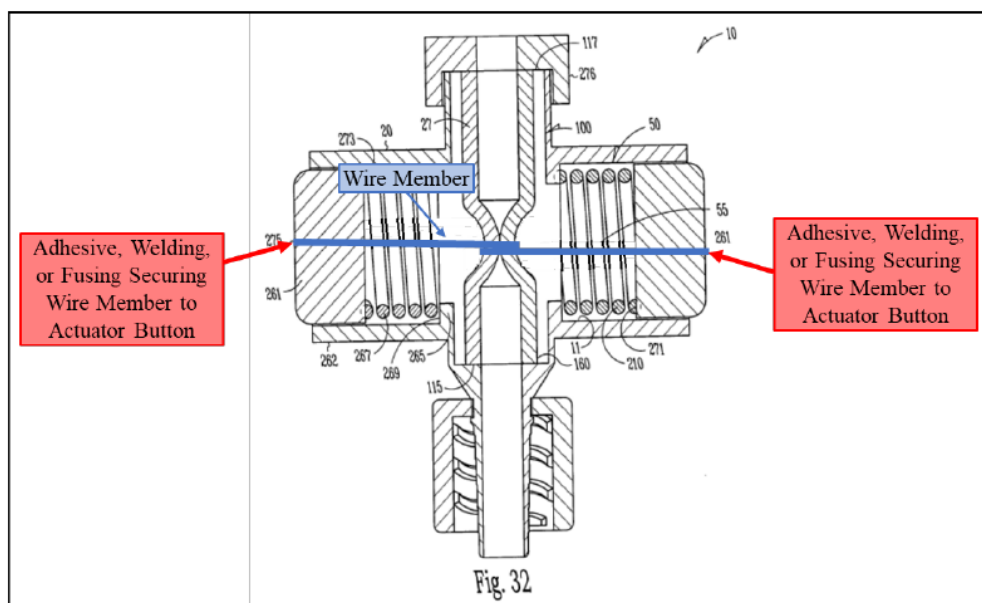
125. A POSITA would not have found it obvious to have modify Schaffer or substitute Hartley’s string or Eller’s wire member for Schaffer’s U-shaped actuating members because, as I explain in §VIII.A. above, neither Schaffer, Hartley, nor Eller disclose a “filament” connected at opposite ends to two actuators as proposed in Petitioner’s combination. Petitioner contends that in its proposed combination the first end of Hartley’s string would be secured to Schaffer’s first actuator button, Hartley’s string would loop around Schaffer’s seal module, and the second end of Hartley’s string would be secured to Schaffer’s second actuator button. Petition, pp. 36-40. Petitioner provides the following demonstrative illustration to illustrate the proposed substitution:

Demonstrative Illustration
Schaffer + Hartley's String



Id. at p. 38. Petitioner's proposed combination of Schaffer and Eller identically positions Eller's wire member to be attached at opposite ends to both actuator buttons of Schaffer and to loop around Schaffer's seal module:

Demonstrative Illustration
Schaffer + Eller's Wire Member



Id. at 46-48.

126. Accordingly, Petitioner's proposed substitution requires eliminating the two U-shaped actuating members of Schaffer and replacing them with a single actuating member (Hartley's string or Eller's wire member) and attaching opposite ends of Hartley's string or Eller's wire member to the two different actuator buttons 261 of Schaffer. But neither Schaffer, Hartley, nor Eller disclose such an arrangement. For example, as I explain above in §VIII.A.: (i) Schaffer discloses two actuating members 55 each having their respective ends coupled to separate ones of 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; (ii) Hartley discloses a single string 14 having both ends coupled to the single rotary actuator 12 such that movement of the single rotary actuator 12 controls movement of both ends of the string 14; and (iii) Eller discloses a wire member having a first end attached to the actuator and a second end to the housing or to the wire member itself such that movement (e.g., rotation) of the actuator pulls only the first end of the wire member while the second end remains stationary.
127. While Petitioner proposes a purported simple substitution of Hartley's string or Eller's wire member for Schaffer's U-shaped actuating members, Petitioner's proposed combination not only substitutes a flexible string or wire

Supplemental Declaration of Paul J. Zalesky

member for Schaffer's rigid U-shaped members, but also redesigns Schaffer to eliminate one rigid U-shaped member completely and instead attach a single flexible string/wire member to two actuator buttons, an arrangement not found in Schaffer, Hartley, or Eller. Moreover, in Petitioner's proposed combinations of Schaffer and Hartley or Eller, Hartley's string 14 and Eller's wire member would be controlled by Schaffer's two actuator buttons 261—rather than by a single actuator as taught by Hartley or Eller.

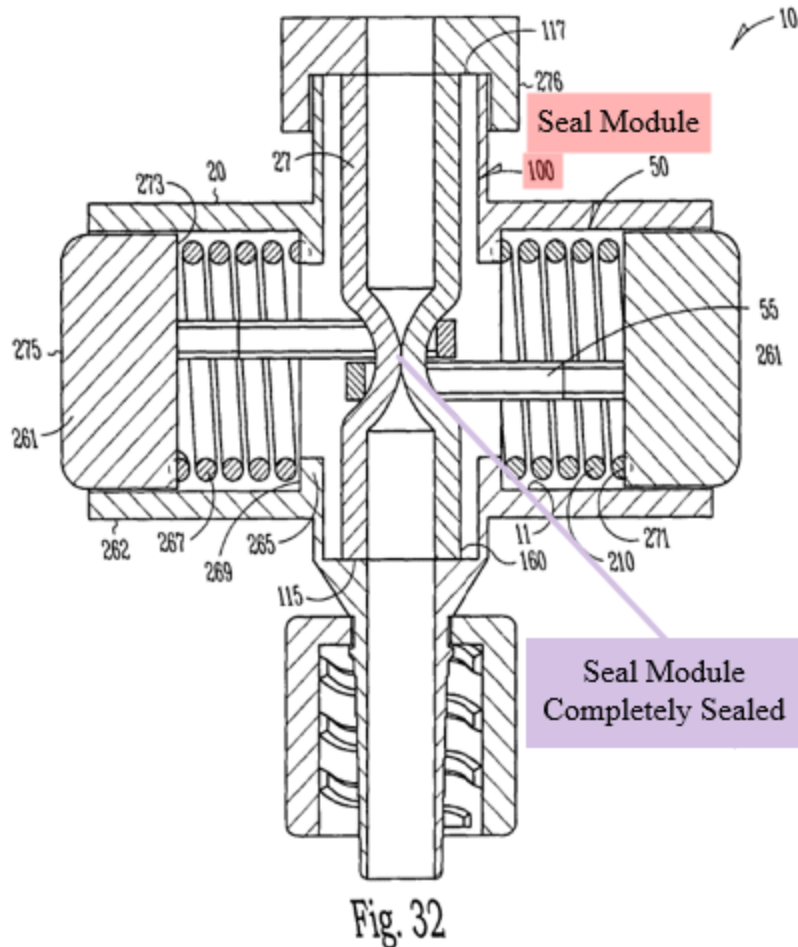
128. Accordingly, it is incorrect that the “combination of Hartley's string and Schaffer's valve would merely entail substituting of one known element (Hartley's string) for another (Schaffer's U-shaped actuating members) to yield [a] predictable result” or that the “combination of Eller's wire member and Schaffer's valve would merely entail substitution of one known element (Eller's wire member) for another (Schaffer's U-shaped actuating members) to yield [a] predictable result.” Petition pp. 35, 44. Instead, Petitioner's proposed combination requires significant additional modification and departs from the intended purpose and express disclosure of each of Schaffer, Hartley, and Eller in which a single U-shaped actuating member 55, string 14, or wire member, respectively, are controlled by a single actuator. A POSITA would understand that controlling a string, wire member, or actuating member with two independently movable actuators would increase the complexity and

variability of the valve and make the valve more difficult to manufacture. Accordingly, neither Schaffer, Hartley, nor Eller disclose any element (U-shaped actuator, string, or wire member) coupled to separate, individually controlled actuator buttons as in Petitioner's proposed combination. If anything, Petitioner's proposed combinations appear to be based on hindsight in view of the '011 Patent.

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

129. A POSITA would not have been motivated to modify Schaffer or substitute Hartley's string or Eller's Wire for Schaffer's U-shaped actuating members as in Petitioner's proposed combination because Schaffer expressly discloses and illustrates the ability of its valve to seal completely across a wide range of instruments. Specifically, I disagree with Petitioner's stated motivation to modify Schaffer in view of Hartley ("POSITAs would have recognized that Hartley's string may seal more effectively across a wider range of diameters for the inserted devices (e.g., other catheters or tools) than Schaffer's U-shaped actuating members") or Eller ("POSITAs would have recognized that Eller's wire may seal more effectively across a wider range of diameters than Schaffer's U-shaped actuating members"). Petition pp. 35, 44.

130. I also disagree with Petitioners assertion that “Schaffer’s U-shaped actuating members may form small gaps between the valve’s lumen and the outer surface of the device” as purportedly shown by Mr. Thornton’s simple graphic. *Id.* at 36. Petitioner’s assertions that Hartley’s string or Eller’s wire member “would not suffer from [the potential formation of small gaps] because the string 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.*; EX1003, ¶ 38. A POSITA would understand that small gaps would not form in Schaffer’s valve.
131. 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:



132. 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].

133. 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.*
134. 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).

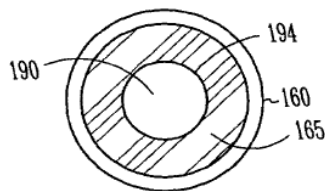


Fig. 16

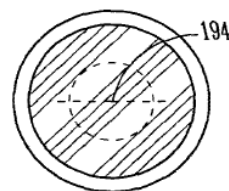


Fig. 17

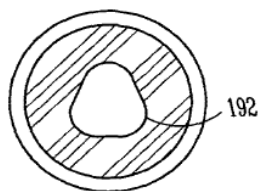


Fig. 18

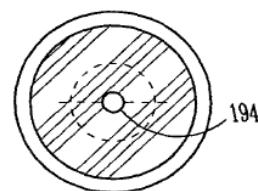
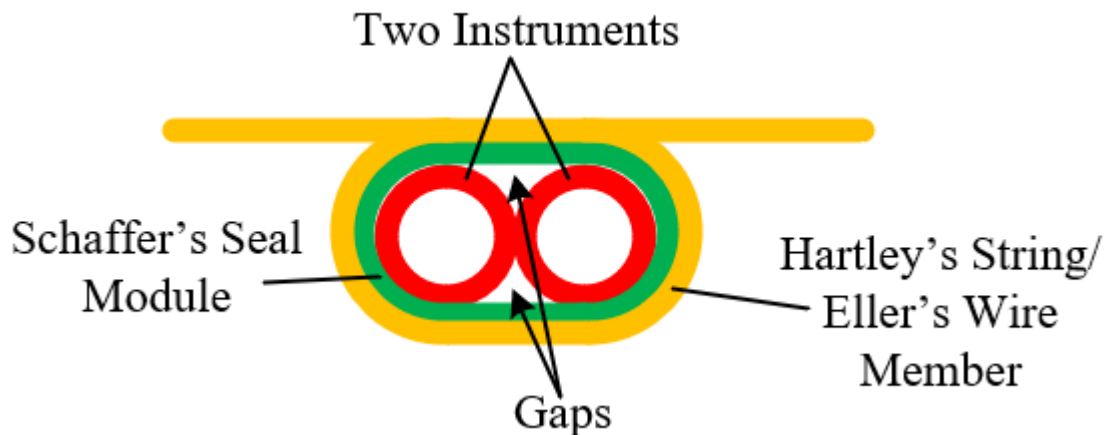


Fig. 19

135. 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].

136. 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]. For example, 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. And, Petitioner’s proposed combination could actually seal less effectively around multiple instruments inserted through Schaffer’s valve and/or when an instrument is irregularly shaped—scenarios for which Schaffer’s valve is specifically designed to form a seal as I explain above. For example, if two circular instruments were inserted side-by-side through Schaffer’s seal module, Hartley’s string or Eller’s wire member in Petitioner’s combination (which

removes the special sealing properties of Schaffer's seal module in order to manufacture a motivation to substitute Hartley or Eller) would be unable to seal the space (e.g., gaps/divots) between the instruments in Petitioner's combination as I demonstrate below:

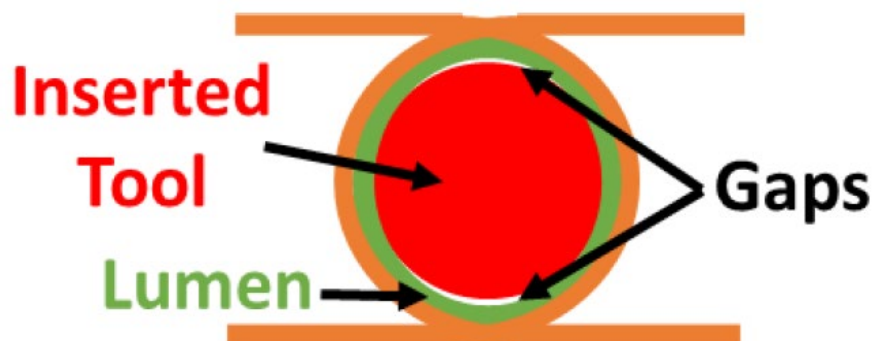


Schaffer's internal sealing member is designed to seal when multiple instruments are inserted through the valve. EX1005, ¶ [0068].

137. 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. Accordingly, a POSITA would not have been motivated to modify Schaffer or to have substituted Hartley's string or Eller's wire member for Schaffer's U-shaped actuating members to form a better seal and avoid the potential formation of

gaps because Schaffer expressly discloses and illustrates that its valve performs both of these functions.

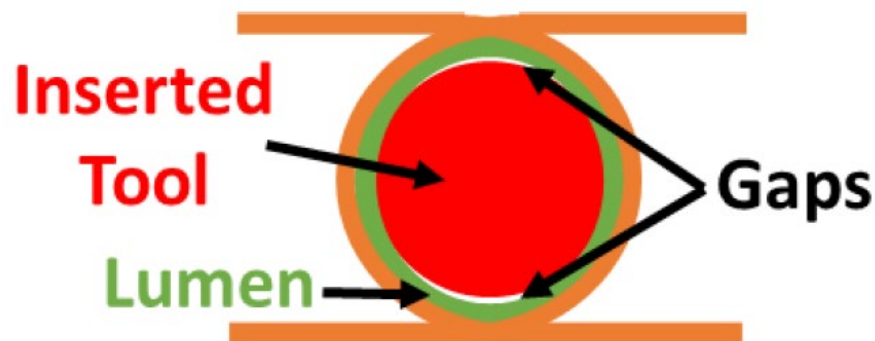
138. First, with regard to forming a better seal, Petitioner alleges that a POSITA would have been motivated to modify Schaffer to include Hartley's string 14 or Eller's wire member to "seal more effectively" across a wider range of tool diameters and shapes than Schaffer's U-shaped actuating members. Petition, pp. 36 and 44. 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 or Eller's wire member to form a better seal around instruments.
139. 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 outer surface of the device," providing a simple two-dimensional graphic of the purported "small gaps":



Id. at 36 (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.

140. In fact, Schaffer contradicts Petitioner’s purported motivations to have substituted Hartley’s string or Eller’s wire member for Schaffer’s U-shaped actuating members. Schaffer recites that “existing devices do not perform a **complete seal** against leakage **in the presence of a wide range of instruments** or in the presence of multiple instruments.” EX1005, [0006] (emphasis added). Schaffer continues that its 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 therethrough using the seal member 165. Petitioner’s stated motivations to modify Schaffer to substitute Hartley’s string or Eller’s wire member for Schaffer’s U-shaped actuating members to seal more effectively and avoid the alleged formation of small gaps are based on an incorrect understanding of Schaffer.

141. 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 or Eller's wire member to seal more effectively and avoid the formation of small gaps is contradicted by Schaffer. Schaffer discloses a valve that addresses the then-existing need for complete sealing around a variety of instruments and specifically describes how the valve is configured to achieve such complete sealing by compression of the seal module 100 including the highly elastic, deformable, and compliant and self-closing third seal member 165.
142. 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. 36. 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:

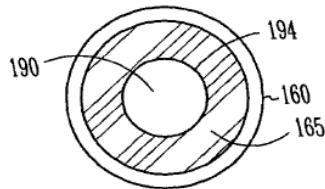


Fig. 16

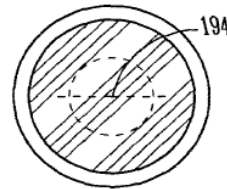


Fig. 17

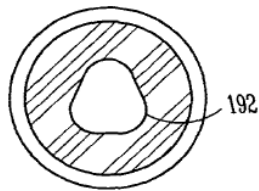


Fig. 18

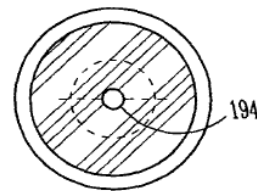


Fig. 19

143. Accordingly, a POSITA would not have been motivated to modify Schaffer or to have substituted Hartley's string or Eller's wire member for Schaffer's U-shaped actuating members 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. Schaffer's structure is not deficient and would not leave gaps in the seal.

144. Additionally, in a related proceeding (*Imperative Care, Inc. v. Inari Medical Inc.*, IPR2025-00289, (P.T.A.B. December 13, 2024) (hereinafter "289 IPR")) Petitioner alleges that "the portions of Schaffer cited by PO do not support its argument. (Ex. 1003, ¶ 124.)." 289 IPR, Petition, p. 52. I disagree. The portions of Schaffer I reference above would not have motivated a POSITA to have substituted Harley's string or Eller's wire member for Schaffer's U-shaped actuating members.
145. First, in the 289 IPR Mr. Thornton attempts to support his argument that it would have been obvious to substitute Hartley's string or Eller's wire member for Schaffer's U-shaped actuating members to "seal more effectively" by stating that "even Schaffer recognizes it may not form a complete seal with the 'gelatinous' and 'sticky' valves identified by Patent Owner, stating the valves form a 'nearly fluid/gas tight seal'" in paragraph [0059] of Schaffer. 289 IPR, EX1003, ¶ 124 (emphasis in original). However, Mr. Thornton's analysis of Schaffer's disclosure omits the remainder of the citation which concludes that the "material 166 exhibits a 'selfclosing' nature in that it sticks occlusively to itself forming a nearly fluid/gas tight seal under very light compression." EX1005, ¶ [0059] (emphasis added). A POSITA would understand that the

Supplemental Declaration of Paul J. Zalesky

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 sufficient compression to the seal module 100, effecting a complete fluid/gas tight seal. *Id.* at ¶ [0077]. Indeed, as I explained in detail above, Schaffer expressly discloses that the purpose of the valve 10 is to “block[] the flow of gas or fluid **completely** and immediately with or without an instrument in place within the gas/fluid path.” *Id.* at ¶ [0008].

146. Second, in the 289 IPR, 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.” 289 IPR, EX1003, ¶124. I disagree. Schaffer describes the characteristics of the material 166 used to form the third central seal member 165—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 can be modified to be “sticky” and “selfclosing” by compounding them with waxes, oils, and/or un-cross-linked modifiers.

147. 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 or Eller’s wire member for Schaffer’s U-shaped members rather than simply use the specific sticky and self-closing material taught by Schaffer. As I explain above in §VIII.B., such a modification would not be a simple substitution. Further, as I explain below in §§VIII.E-F., such a modification would greatly hinder the durability and ease of manufacturing of Schaffer’s valve and likely render Schaffer’s valve inoperable. A POSITA would have been motivated to use the sticky and self-closing material taught by Schaffer—which Schaffer expressly discloses can provide a complete seal around a wide variety of instruments—rather than completely redesign Schaffer’s valve in view of Hartley or Eller.

148. Third, again in the 289 IPR, 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. 289 IPR, EX1003, ¶ 124. However, Mr. Thornton ignores that Schaffer expressly discloses with reference to Figures 31-34 that:

149. [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.

150. 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.

151. Fourth, in the 289 IPR, 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

Supplemental Declaration of Paul J. Zalesky

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.” 289 IPR, EX1003, ¶ 124. To the contrary, a POSITA would understand Schaffer’s U-shaped actuating members 55 to be rigid given 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).

152. 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 any potential issues identified by Mr. Thornton.
153. In fact, the potential problem identified by Mr. Thornton may arise if Hartley’s string 14 or Eller’s wire member were substituted for the U-shaped actuating members 55 as alleged by Petitioner. Petitioner explains that “POSITAs would have been motivated to ... loop Hartley’s string around Schaffer’s seal module.” 289 IPR, Petition, p. 54. 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, allowing the lumen to open." *Id.* 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. Use of Eller's wire member with Schaffer's seal module 100 would suffer from the same issue.

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

154. As I explain in detail above in §VIII.C., 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 modify Schaffer or substitute Schaffer's U-shaped actuating members with Hartley's string or Eller's wire member to "seal more effectively" and avoid the formation of small gaps." Petition, pp. 35 and 44. Not only is this

incorrect as I explain above, Petitioner and its expert concede at other times that Schaffer's valve forms a complete seal—even when instruments are inserted therethrough—contradicting Petitioner's stated reason to modify Schaffer.

155. For example, Petitioner's expert stated at deposition that there would be no need to modify Schaffer's U-shaped actuating members if Schaffer forms a complete seal around various instruments. EX2007, 116:18-117:2. ("If it worked perfectly for all the range of tools, then there probably wouldn't be a need to make adjustments and move to a string-type member.")
156. Also, in the related 289 IPR, when describing why a POSITA would use Schaffer's valve in another reference's system, Mr. Thornton states:

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

289 IPR, Petition, p. 36 (emphasis added); *see also* 289 IPR, EX1003, ¶96.

Mr. Thornton continues that:

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

289 IPR, EX1003 at ¶ 225 (emphasis added). Accordingly, Mr. Thornton acknowledges, at least when it suits him, that Schaffer discloses that its valve completely seals with or without an instrument in place, and then goes on to state that a POSITA would have expected that Schaffer's valve could be used to prevent leaks around an instrument (a catheter smaller than the catheter 2030) inserted through the valve. This is completely contrary to Mr. Thornton's and Petitioner's stated motivations for substituting Schaffer's U-shaped actuating members with Hartley's string or Eller's wire member to "seal more effectively" and avoid the formation of small gaps. If a POSITA would have expected that Schaffer's valve would prevent leaks around a catheter inserted through the valve, a POSITA would **not** have understood that Schaffer's valve sealed ineffectively or that small gaps (i.e., leak paths) would form (Petitioner's stated motivation to combine Hartley or Eller with

Schaffer). That is, Petitioner's stated motivations including the formation of "gaps" and ineffective sealing are contradicted by Mr. Thornton's statements that Schaffer's valve **prevents** leaks (i.e., gaps) when a catheter is inserted through the valve.

157. Likewise, Petitioner states "the purpose of Schaffer's hemostasis valve is to prevent leakage when a catheter or medical device is inserted into a patient" (Petition, p. 59) and that Schaffer "discloses that its valve prevents leakage across 'a range of instruments,' such as 'a catheter, guidewire, needle, or fiber'" Petition, p. 63. Again, a POSITA would have understood Schaffer's valve to prevent leaks around an instrument inserted through the valve, so a POSITA would not have understood that small gaps (i.e., leak paths) would form (Petitioner's stated motivation to combine Hartley or Eller with Schaffer).
158. Accordingly, Petitioner acknowledges that Schaffer discloses that its valve completely seals with or without an instrument in place to prevent blood loss. This is contrary to Petitioner's stated motivations for substituting Schaffer's U-shaped actuating members with Hartley's string or Eller's wire member to "seal more effectively" and avoid the formation of small gaps." That is, Petitioner's stated motivations are contradicted by its own and Mr. Thornton's

statements that Schaffer's valve blocks the flow of gas or fluid completely and forms a seal about a catheter inserted through the valve.

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

159. It would not have been obvious to a POSITA to Modify Schaffer or to substitute Hartley's string or Eller's Wire Member for Schaffer's U-shaped actuating members because doing so would make Schaffer's valve less durable and more difficult to manufacture. In particular, Schaffer's U-shaped actuating members 55 are purposefully designed to be rigid and attached to only a single actuator to simplify manufacturing and make the valve durable.
160. 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, pp. 38 and 46 (Ppetitioner's Demonstrative Illustrations showing the proposed combination of Schaffer and Hartley and Schaffer and Eller, respectively). As Petitioner explains with respect to Hartley, "each end of the string could be threaded through the hole on the opposite buttons and knotted on the other side." *Id.* at 37. This purported arrangement is speculative and would remove the advantages Schaffer identifies its structure as providing.

161. 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.

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

Supplemental Declaration of Paul J. Zalesky

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. 37-38. Similarly, in Petitioner's proposed combination of Schaffer and Eller, the first end of Eller's wire member is secured via "simple methods" such as adhesive, welding, or fusing to one of Schaffer's actuator buttons, and the second end of Eller's wire member is secured via a similar method to the other one of Schaffer's actuator buttons 261. Petition, pp. 45-46. A POSITA would understand that to achieve this arrangement Hartley's string or Eller's wire member would either need to be (1) secured to the actuator buttons 261 before the actuator buttons 261 are inserted into the cylindrical openings in the housing 20 or (2) secured to the actuator buttons 261 after the actuator buttons 261 are inserted into the cylindrical openings.

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

Supplemental Declaration of Paul J. Zalesky

through the housing 20 as would be required to position Hartley's string or Eller's wire member around Schaffer's seal module 100 in Petitioner's combination.

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

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

166. 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 or Eller's wire member would unduly complicate this simple assembly process.
167. Accordingly, for the foregoing reasons, a POSITA would understand that Petitioner's proposed substitution of Hartley's string 14 or Eller's wire member for Schaffer's actuating members 55 would make it much more difficult or even impossible to assemble Schaffer's valve in the simple manner taught by Schaffer.
168. Moreover, as I explain in §VI.B. above, a POSITA would understand that flexible parts—such as Hartley's string or Eller's wire member—would be difficult or impossible to machine conventionally, as flexible materials will deform when force is applied during the machining process. This would inhibit or even prevent accurate manufacturing of Hartley's string or Eller's wire member using machining as taught by Schaffer. Accordingly, a POSITA

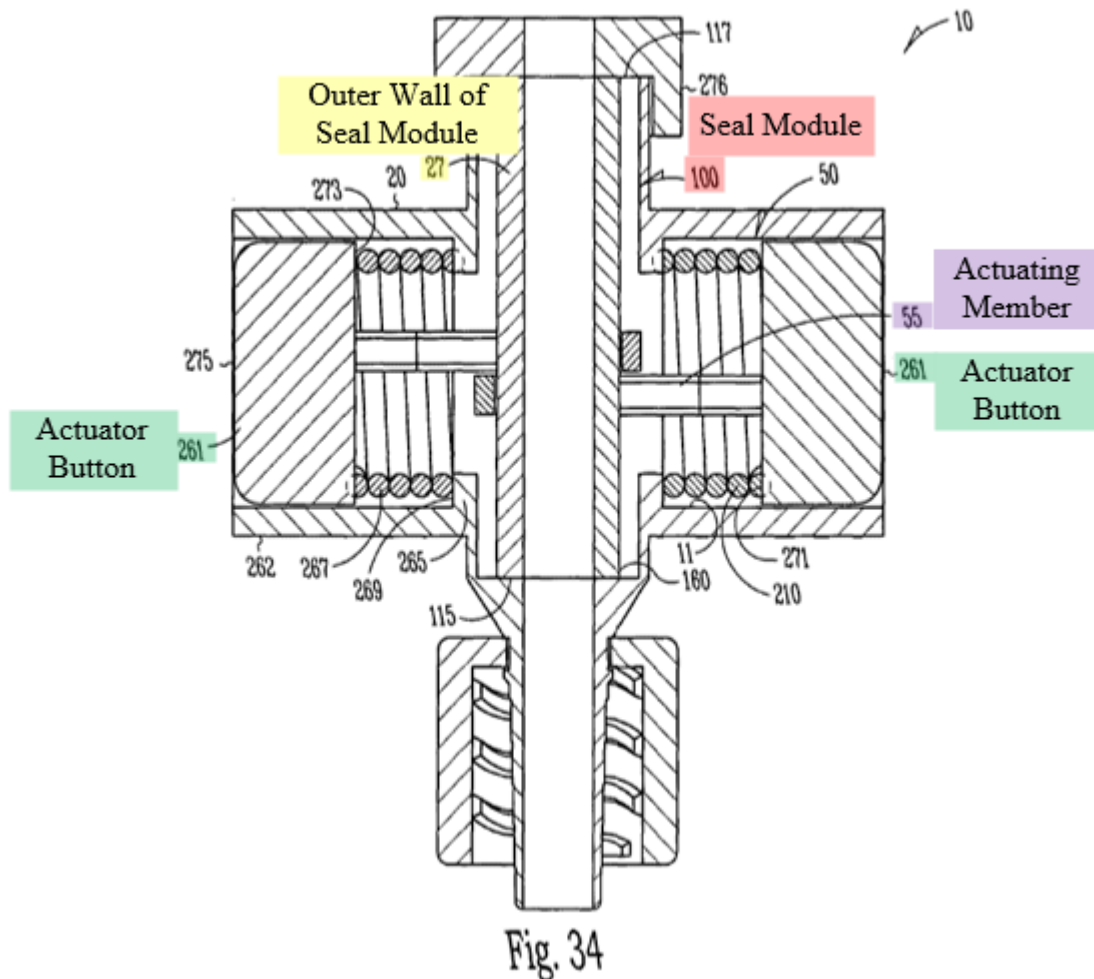
would understand that replacing Schaffer's actuating members with Hartley's string or Eller's wire member would make Schaffer unsuitable for its intended purpose of simple manufacturability via machining.

169. Regarding durability, Schaffer explains that its invention addresses the then-existing need for “a **durable stasis valve** that blocks the flow of gas or fluid completely and immediately with or without an instrument in place within the gas/fluid path.” EX1005, ¶ [0008] (emphasis added). Accordingly, a POSITA would understand durability, such as the ability to resist damage during operation, is a key feature of Schaffer's device. As I explain in §VI.B. above, Schaffer's actuating members 55 are rigid and “machined from aluminum” or “machined from plastic.” *Id.* at [0082]. A POSITA would understand that replacing Schaffer's actuating members 55 with Hartley's string 14 or Eller's wire member would make Schaffer's valve less durable—in direct contrast to Schaffer's intended purpose of having a durable valve. In particular, a POSITA would understand Hartley's thin and flexible string and Eller's thin and flexible wire member to be much more susceptible to damage, positioning errors, and the like during valve operation.

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

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

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



EX1005, ¶ [0077] (emphasis added). Petitioner explains that in their proffered combination Hartley's string or Eller's wire member would loop around Schaffer's seal module. Petition, pp. 37-38 and 45-46. As explained by Petitioner with regard to Hartley, the seal module 100 would expand against Hartley's string to open when tension is released on the string: "pressing Schaffer's buttons inwardly (i.e., second position) would release the tension on the string, causing the string to loosen around the central lumen and allowing the lumen to at least partially open." *Id.* at p. 39. Petitioner provides a similar

Supplemental Declaration of Paul J. Zalesky

explanation for Eller: “When Schafer’s actuator buttons are pressed inwardly, the tension on the wire member would be relaxed, causing the wire member to loosen” permitting Schaffer’s seal module “to return to its open configuration.” *Id.* at p. 48. Thus, Hartley’s string or Eller’s wire member would never disengage—let alone forcibly disengage—Schaffer’s seal module 100. That is, Hartley’s string or Eller’s wire member would remain in contact with and never disengage the seal module 100. Accordingly, a POSITA would understand that substituting Hartley’s string or Eller’s wire member for Schaffer’s U-shaped actuating members 55 would cause the actuating member (i.e., Hartley’s string or Eller’s wire member) not to disengage or forcibly disengage Schaffer’s seal module, changing the principle of operation of Schaffer’s device.

172. As I explain in §VIII.C. above, this problem would be exacerbated by the sticky nature of Schaffer’s seal module. For example, Hartley’s string or 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 Hartley’s string or 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.

G. Even Assuming Petitioner’s Stated Motivations to Form a Better Seal and Avoid the Formation of Gaps, Petitioner Does Not

Explain Why a POSITA Would Have been Motivated to Substitute Hartley's String or Eller's Wire Member for Schaffer's U-Shaped Members as Opposed to Any of the Alternatives It Provides.

173. Even assuming that a POSITA would understand Schaffer's valve to form gaps (they would not), a POSITA would not have been motivated to substitute Hartley's string or Eller's wire member for Schaffer's U-shaped actuating members to have both its ends attached to different actuator buttons (which neither Schaffer, Hartley, nor Eller disclose as I explain in §VIII.A. above) as suggested by Petitioner. Rather, a POSITA would make the relatively simple modifications to Schaffer's valve that Petitioner suggests. For example, when describing how Schaffer allegedly discloses the features of dependent Claim 5, Petitioner recites that a POSITA would have been motivated to adjust Schaffer's valve in several simple manners to improve/maintain its seal with a reasonable expectation of success. For example, Petitioner states:

[T]o the extend Schaffer's valve did not maintain its seal when a pressure differential exists, a POSITA would have found it obvious to make one or more of several adjustments, **including adjusting Schaffer's spring strength to apply additional force to seal the valve, adjusting the resilience and compressibility of the seal module that forms the valve's lumen** POSITAs 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 (Ex. 1003, ¶¶ 122.)

Petition, pp. 58-59 (emphasis added).

174. 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 could be made, 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 that the seal could have been improved by simply adjusting Schaffer's spring strength or adjusting the properties of the seal module. A POSITA would understand those modifications to be simpler and more likely to work than completely omitting Schaffer's U-shaped members and substituting in Hartley's string or Eller's wire member as proposed by Petitioner (including attaching the string or wire member to two separate actuators which neither Schaffer, Hartley, nor Eller disclose). Petitioner provides no explanation for why a POSITA would have substituted Hartley's string or Eller's wire member for Schaffer's U-shaped members rather than make any of the simple modifications they assert would work to complete the seal and prevent blood leaks through the valve.
175. And, a POSITA would not have modified Schaffer in view of Hartley or Eller instead of, if somehow needed (they are not), making the simple changes

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

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

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

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

Supplemental Declaration of Paul J. Zalesky

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 (§VIII.C.);

- (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 (§VIII.G.);
- (4) Neither Schaffer, Hartley, nor Eller disclose a "first filament" connected at opposite ends to two actuators as proposed in Petitioner's combination (§§VIII.A.1-3.);
- (5) Substituting Hartley's string or Eller's wire member for Schaffer's U-shaped actuating members would fundamentally change Schaffer's principles of operation (§VIII.F.); and
- (6) Hartley's string and Eller's wire member would not provide a better seal than Schaffer's rigid U-shaped actuating members and seal module (§§VIII.C-D.).

177. A POSITA would thus not have modified or substituted Hartley's string or Eller's wire member and further modified the structure to connect the string or wire member to two separate actuators, as Petitioner contends. Moreover, to have any expectation of success in Petitioner's proposed combination of Schaffer and Hartley or 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 the string or wire member 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 or Eller's wire member) 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 or 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 a POSITA would not have been motivated to arrive at Petitioner's purported combination.

IX. GROUND 5: THE COMBINATION OF HARTLEY AND ELLER

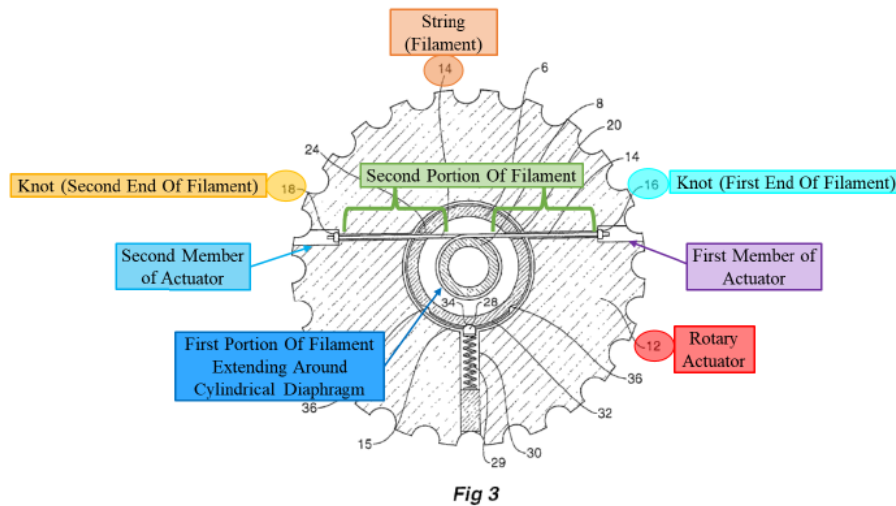
DOES NOT RENDER CLAIMS 1-3, 5, 6, AND 9 OBVIOUS

178. I understand that Petitioner and its expert, Mr. Thornton, allege that Schaffer in combination with Eller renders obvious claims 1-3, 5, 6, and 9 of the '011 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 Hartley in view of Eller to arrive at the features of Claim 1. Therefore, the combination of Schaffer and Eller does not render obvious Claim 1. And, because claims 2, 3, 5, 6, and 9 depend from Claim 1 and thus include all the features from Claim 1, those claims are also not rendered obvious by the combination of Hartley and Eller.
179. As I explained above, for a patent claim to be rendered obvious, the differences between the claimed invention and the prior art must be such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains, the claimed invention is obvious. Even if all limitations of a claimed invention are disclosed by the prior art combination, Petitioner must demonstrate an apparent reason to combine the known elements in the fashion of the patent claim at issue and that a person of ordinary skill in the art would have reasonable expectation of success in pursuing that combination. A prior art reference teaches away from a

modification of a prior art reference when a person of ordinary skill in the art would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path followed by and claimed in the patent.

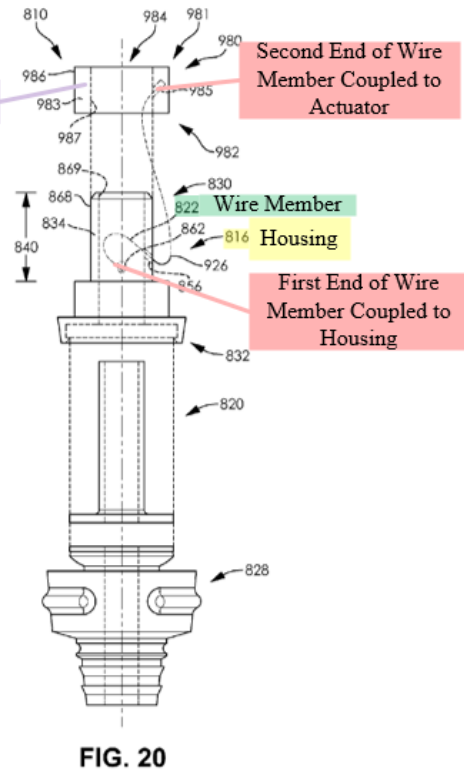
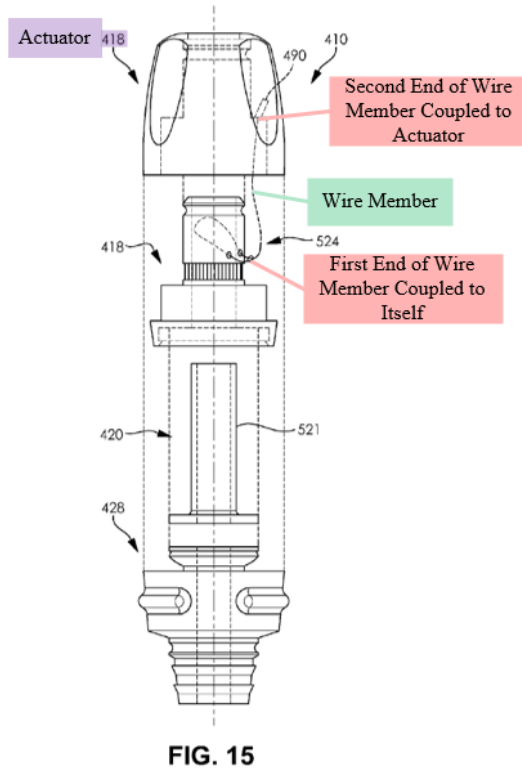
A. Neither Hartley nor Eller Discloses a Filament Having a First End Coupled to a First Member and a Second End Extending in a Different Direction Coupled to a Second Member

180. Claim 1 recites that “the actuator comprises a first member coupled to the first end of the filament and a second member coupled to the second end of the filament.” Neither Hartley nor Eller disclose that feature of Claim 1.
181. Instead, Hartley discloses that each end of its string 14 is connected to the single rotatory actuator 12. EX1006, [0031]. A POSITA would understand the rotary actuator 12 to be a single integral piece such that the knots 16 and 18 are not attached to a respective “first member” and “second member,” as recited in Claim 1. Petitioner simply asserts that the “portions of the rotary actuator secured to the first and second ends of the string 14 are the first and second members of the actuator as claimed in the ’011 patent”:



Petition, pp. 73, 75. A POSITA would understand that the different “portions” of the rotary actuator do not comprise first and second members in the manner recited in Claim 1.

182. Similarly, Eller discloses various selective fluid barrier devices that include one or more wire members each having one end coupled to an actuator and the other end coupled to itself or a housing—not to the same or different actuator:



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

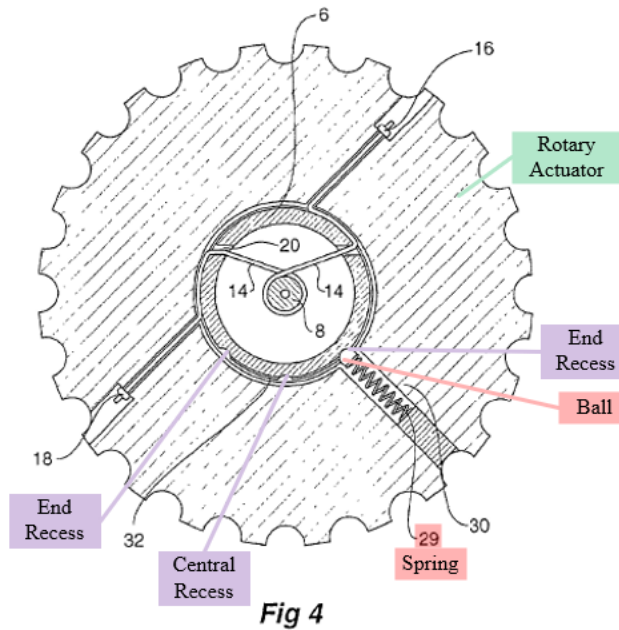
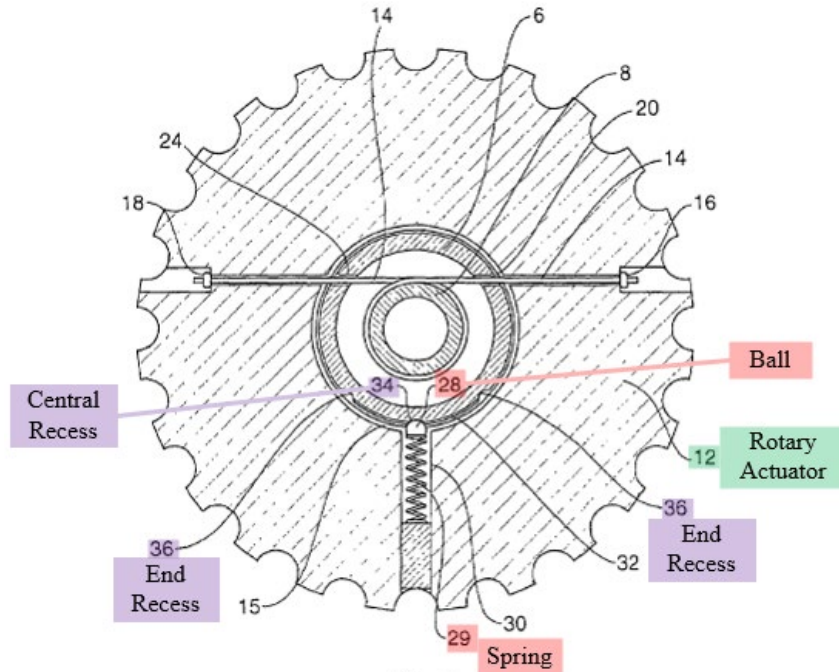
183. Accordingly, the combination of Hartley and Eller does not disclose an actuator comprising a “first member coupled to the first end of the filament and a second member coupled to the second end of the filament,” as claimed. The petition does not allege that a POSITA would have modified Hartley or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

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

184. Petitioner asserts that it would have been obvious to a POSITA to have included Eller’s torsion spring in Hartley’s device to bias Hartley’s device to a

sealed position. Petition, pp. 78-79. I disagree because doing so would destroy the functionality and advantages of Hartley's ball and detent arrangement.

185. Hartley's valve includes a "detent arrangement having a ball 28 loaded by a spring 29 in an aperture 30 in the rotary actuator runs in a groove 32 in the cylindrical housing 6 ... [t]he groove 32 has a central recess 34 and end recesses 36":



EX1006, [0033]. The ball and detent arrangement “provide[s] tactile feel [of] the action of the valve” and “assist[s] with retaining the rotary actuator on the cylindrical housing.” *Id.* at [0018] & [0033]. “There may also be further

recesses or detents between the central recess and the end recesses. *Id.* at [0033]. In the open position shown in Figure 3 of Hartley, the ball 28 is in the central recess 34 of the groove 32 and, in the sealed position shown in Figure 4 of Hartley, the ball 28 is in one of the end recesses 36 of the groove 32. “Rotation of the rotary actuator back to the central position where the detent ball 28 is received in depression 34 will cause the sutures to loosen again so that the resilient cylindrical diaphragm will retain its original shape as shown in FIGS. 1 and 3.” *Id.* at [0034].

186. Accordingly, a POSITA would understand that Hartley’s ball and detent arrangement provides a tactile feel of the valve state (open, closed) during use and also acts to selectively lock the position of the rotary actuator relative to the cylindrical housing 6 to maintain the valve state—i.e., the amount of constriction of the cylindrical diaphragm 8. That is, Hartley’s ball and detent arrangement allows its valve to be retained at different open and/or closed states with the detent ball 28 in one of the different recesses—the central recess 34, the first one of the end recesses 36, the second one of the end recesses 36, or “further recesses” contemplated by Hartley.
187. Including Eller’s torsion spring in Hartley’s valve as proposed by Petitioner would cause Hartley’s valve to automatically move to the sealed position shown in Figure 4 absent user actuation of the rotary actuator. Accordingly,

Hartley's valve would be unable to be retained in the open position shown in Figure 3 in which "the detent ball 28 is received in depression 34" (or a partially open position with the detent ball 28 positioned in one of the end recesses 36) without the user maintaining their fingers on Hartley's rotary actuator to provide a force that counteracts the force of Eller's torsion spring. *Id.* That is, in Petitioner's combination, Hartley's ball and detent arrangement would be unable to "assist with retaining the rotary actuator on the cylindrical housing" because the spring force of Eller's torsion spring would simply override the retaining force provided by the spring 29 of the ball and detent arrangement. *Id.* at [0018]. Therefore, a POSITA would not have been motivated to incorporate Eller's torsion spring into Hartley's valve because it would render Hartley's ball and detent arrangement completely inoperable for its intended purpose of retaining the rotary actuator in position and thereby maintaining the valve in a selected valve state (open, closed, partially open). Moreover, as I explain in §IX.C. below, Hartley's functionality of maintaining the valve in an open state provides several advantages over Eller's system in which the valve is biased closed by a torsion spring.

C. Petitioner's Stated Motivations to Modify Hartley to Include Eller's Torsion Spring Would Not Have Been Compelling to a

POSITA Considering the Countervailing Advantages of Hartley's Device

188. Petitioner provides several reasons why a POSITA would have allegedly been motivated to include Eller's biasing system (torsion spring) in Hartley's valve: (1) "the biasing system would ensure that Hartley's valve is quickly sealed when a catheter or other device is removed through the valve, which would minimize blood loss during a medical procedure," (2) "the biasing system would ensure that the physician could not inadvertently leave the valve open after removing a device, which could lead to harmful blood loss," and (3) "the biasing system simplifies Hartley's valve and the steps required to seal the valve to prevent blood loss" by, for example, "eliminat[ing] the need for the operator to manually seal the valve prior to or during the procedure." Petition, p. 78.
189. However, Petitioner fails to consider the advantages of Hartley's valve that would be destroyed by Petitioner's proposed combination. For example, as I describe in §IX.B. above, incorporating Eller's torsion spring into Hartley's valve would render Hartley's ball and detent arrangement inoperable for its intended purpose of retaining the rotary actuator in position and thereby maintaining the valve in a selected valve state (open, closed). A POSITA would understand that this functionality of the ball and detent arrangement to

Supplemental Declaration of Paul J. Zalesky

maintain the valve in an open state would be advantageous during insertion of instruments through Hartley's valve.

190. Specifically, a POSITA would understand that in Petitioner's proposed combination, Eller's torsion spring would exert a significant compression force against an instrument inserted through Hartley's valve—especially for large instruments that greatly compress the torsion spring—as the torsion spring would always act to provide a biasing force to completely constrict and seal Hartley's cylindrical diaphragm 8. This force of the torsion spring would significantly inhibit movement (advancement, retraction) of the instrument through Hartley's valve. In contrast, Hartley's ball and detent arrangement allows Hartley's valve to be selectively maintained in an open or partially open state in which there is no or minimal compressive force on the cylindrical diaphragm 8 such that instruments could be easily manipulated through Hartley's valve.
191. A POSITA would understand that this ability to have a loosened valve that exerts little or no compression force against an inserted instrument is desirable in some situations. As one example, Schaffer recognizes that “[i]f a valve is inordinately tight, having a closed lumen, it may not allow the insertion of soft, flexible instrumentation such as a ‘floppy-tip’ guidewire, a delicate laser fiber or a soft-tipped catheter” and that “[s]ome catheters, optical fibers and

fluid transmission tubes are very delicate and can be damaged by excessive compression or insertion force.” EX1005, ¶ [0007]. Therefore, a POSITA would recognize that Hartley’s ball and detent arrangement allows Hartley’s valve to be selectively maintained in a position that does not exert excessive compressive force against an inserted instrument that could damage the instrument and that would act to inhibit manipulation of the instrument.

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

193. To relieve the compressive force against an instrument in Petitioner's proposed combination, a user would need to move Hartley's rotary actuator against the force of Eller's torsion spring and maintain the rotary actuator in this position to counteract the force of Eller's torsion spring. This would require the user to constantly engage (e.g., with one or both of the user's hands) the rotary actuator during manipulation of instruments through the valve. Accordingly, Petitioner's proposed combination would significantly complicate Hartley's valve and the steps required to insert instruments therethrough.
194. Accordingly, it would not have been obvious to a POSITA to have modified Hartley to include Eller's torsion spring. As set forth above, doing so would destroy the functionality of Hartley's ball and detent system, provide a constant compressive force against an instrument inserted through Hartley's valve that would act to greatly hinder manipulation of the instrument through the valve and potentially damage the instrument, and significantly complicate Hartley's valve and the steps required to insert instruments therethrough. Put differently, the advantages set forth by Petitioner of its proposed combination of Hartley and Eller would not have motivated a POSITA to have made the combination in view of the countervailing disadvantages that the combination would introduce and that are counter to the express structure and operation of Hartley's valve.

X. DEPENDENT CLAIM 3 IS NOT ANTICIPATED BY SCHAFFER OR OBVIOUS IN VIEW OF SCHAFFER, HARTLEY, OR ELLER

195. Claim 3 depends from Claim 1 and thus includes all the features from Claim

1. Therefore, Claim 3 is also not anticipated by Schaffer or rendered obvious by Schaffer alone or the combination of Schaffer and Hartley or Eller.

196. Additionally, Claim 3 is neither anticipated nor rendered obvious by Schaffer because Schaffer does not disclose "wherein the first portion of the filament

extends in a loop completely around the tubular member," as recited in Claim

3. As I explained in §VI.A., even if taken together the U-shaped actuating members in Schaffer are configured in parallel, meaning the actuating members are positioned next to each other rather than in a loop. Therefore, Claim 3 is patentable over Schaffer for this additional reason.

XI. SECONDARY CONSIDERATIONS

197. 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.

XII. CONCLUSION

For all the above reasons, I find that Petitioner has not met its burden of demonstrating the unpatentability of any challenged claim. Accordingly, I understand that Patent Owner requests the Board confirm the patentability of Claims 1-9.

IPR2024-01157

Supplemental Declaration of Paul J. Zalesky

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.

Respectfully submitted,

Dated: April 18, 2025

By:

Paul J. Zalesky

ATTACHMENT 1

Paul J Zalesky, PhD
124 Gilbert Stuart Dr
East Greenwich, RI 02818

mobile: 714-585-2423
e-mail : pauljzalesky@gmail.com

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. 11,697,011 (“the ’011 Patent”)
EX1002	’011 Patent Prosecution History Excerpt
EX1003	Expert Declaration of Troy Thornton
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 dated June 18, 2003
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”)
Paper 1	Petition for <i>Inter Partes</i> Review
EX2002	Merriam-Webster’s Collegiate Dictionary (11th ed. 2014)
EX2003	New Oxford American Dictionary (3rd ed. 2010)
EX2004	U.S. Patent Application Publication No. 2018/0193043
EX2005	Deposition Transcript of Troy Thornton (September 30, 2024)
EX2006	U.S. Patent No. 7,682,380 to Thornton (“Thornton”)
EX2007	Deposition Transcript of Troy Thornton (March 19, 2025)
EX2009	Merriam-Webster’s Collegiate Dictionary (11 th ed. 2014)