

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

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.	Prosecution History of Claim 1	27
C.	Claim 1	28
D.	Construction of Claim 1	31
VI.	GROUND 1: SCHAFFER DOES NOT ANTICIPATE CLAIMS 1-9.....	35
A.	Schaffer Does Not Disclose the “At Least One Filament” of Claim 1	35
B.	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” Of Claim 1	42
VII.	GROUND 2: SCHAFFER DOES NOT RENDER CLAIMS 1-9 OBVIOUS.....	45
A.	Petitioner’s Stated Motivations to Modify Schaffer 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	49

B.	Modifying Schaffer to Replace Its Rigid U-Shaped Actuating Members with a Filament Would Change Schaffer's Principle of Operation and Reduce Durability and Easy Manufacturing.....	58
C.	Modifying Schaffer to Make the U-Shaped Actuating Members Flexible 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.....	61
VIII.	GROUND 3: THE COMBINATION OF SCHAFFER AND HARTLEY DOES NOT RENDER CLAIMS 1-9 OBVIOUS	63
A.	Neither Schaffer nor Hartley Disclose a Single Continuous Flexible Filament Having a First End Coupled to a First Member and a Second End Coupled to a Second Member.....	65
B.	Petitioner's Stated Motivations to Modify Schaffer in View of Hartley Are Based on an Incorrect Understanding of the Sealing Mechanism of Schaffer Which Is Designed to Eliminate Gaps With or Without Instruments Inserted Through the Valve	67
C.	Substituting Hartley's String for Schaffer's U-Shaped Actuating Members Would Render Schaffer's Valve Inoperable for Its Intended Purpose of Durability and Easy Manufacturing	69
D.	Substituting Hartley's String for Schaffer's U-Shaped Actuating Members Would Change the Principle of Operation of Schaffer's Valve in Which the U-Shaped Actuating Members Forcibly Disengage the Seal Module and Likely Render Schaffer's Valve Inoperable.....	75
IX.	GROUND 4: THE COMBINATION OF SCHAFFER AND ELLER DOES NOT RENDER CLAIMS 1-9 OBVIOUS	77
A.	Neither Schaffer nor Eller Discloses a Single Continuous Flexible Filament or a Filament Having a First End Coupled to a First Member and a Second End Coupled to a Second Member.....	78
B.	Petitioner's Stated Motivations to Modify Schaffer in View of 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	85
C.	Substituting Eller's Wire Member for Schaffer's U-Shaped Actuating Members Would Render Schaffer's Valve Inoperable for Its Intended Purpose of Durability and Easy Manufacturing	87
D.	Substituting Eller's Wire Member for Schaffer's U-Shaped Actuating Members Would Change the Principle of Operation of Schaffer's Valve in Which the U-Shaped Actuating Members Forcibly Disengage the Seal Module and Likely Render Schaffer's Valve Inoperable.....	88
X.	GROUND 5: THE COMBINATION OF HARTLEY AND ELLER DOES NOT RENDER CLAIMS 1-3, 5, 6, AND 9 OBVIOUS	89
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	91
B.	Modifying Hartley to Include Eller's Torsion Spring Would Render Hartley's Valve Inoperable for Its Intended Purpose	95
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.....	99
XI.	SECONDARY CONSIDERATIONS	103
XII.	CONCLUSION.....	103

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: the 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: the claims of the ’011 patent are unpatentable under 35 U.S.C. § 103 as obvious over Schaffer alone;

Ground 3: the claims 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: the claims 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

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

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

II. BACKGROUND AND QUALIFICATIONS

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

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

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

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

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

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

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

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

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

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

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

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

III. BASES OF MY OPINION

A. Materials Considered

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

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

B. Relevant Legal Principles

22. I am not an attorney, but in preparing and forming my opinions, I have been informed of certain legal principles. I have applied my understanding of those principles and taken them into account when forming the opinions I describe. My understanding of the relevant legal principles is summarized below.
23. I understand that claim terms are generally given their ordinary and customary meaning as understood by a person of ordinary skill in the art at the time of the invention when read in the context of the specification and prosecution history unless a patentee sets out a different definition or clearly disavows claim scope.
24. I further understand that extrinsic evidence such as expert and inventor testimony, dictionaries, and learned treatises can help determine the meaning of claim terms, although that evidence is less significant than the claims, specification, and prosecution history.
25. I have been informed that Imperative bears the burden of proving unpatentability by a preponderance of evidence. I have been told that this means that Imperative must prove that more likely than not that claim 1 of the '011 patent

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.

26. I understand that my opinions regarding patentability are from the viewpoint of a person having ordinary skill in the field of the technology of the patent as of the time of the invention. For the purposes of this Declaration, I have assumed that date is the earliest priority date of the '011 patent which is September 6, 2017. Petitioner also applies September 6, 2017, as the priority date for the '011 patent. Petition, p. 13.
27. I understand that for a patent claim to be anticipated, each claim limitation must be present in a single piece of prior art. It is my understanding from counsel that a prior art reference anticipates a claimed invention if the prior art reference disclosed each of the claimed limitations of the invention either expressly or inherently.
28. I understand that if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains, the claimed invention is obvious.

29. I understand there are four fact-based inquiries involved in determining patent obviousness. These include: (1) the scope and content of the prior art; (2) the differences between the claimed invention and the prior art; (3) the level of ordinary skill in the art; and (4) objective indicia of non-obviousness. I have been informed that examples of objective indicia include unexpected results, commercial success of the invention, whether the invention satisfied a long felt need in the industry, failure of others to find a solution to the problem at hand, commercial acquiescence via licensing, professional approval, unexpected results, and copying and praise by infringers.
30. I understand that even if all limitations of a claimed invention are disclosed by the prior art combination, the patent challenger must demonstrate an apparent reason to combine the known elements in the fashion of the patent claim at issue and that a person of ordinary skill in the art would have reasonable expectation of success in pursuing that combination.
31. I understand that a prior art reference teaches away from a modification of a prior art reference when a person of ordinary skill in the art would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path followed by and claimed in the patent.

IV. SUMMARY OF OPINIONS

32. For the reasons I discuss below, I believe that the asserted claims of the '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

33. 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.

34. 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.
35. The design and functionality of this hemostasis valve enables medical professionals to operate the valve with one hand while maintaining a robust seal to prevent blood loss during procedures. *Id.* at 5:51-65. 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, 5:50-6:2, 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, where the risk of blood loss is generally greater and the need for a tight valve is critical.

36. When utilizing the garrote valve in a thrombectomy procedure, for example, the garrote valve can be coupled to a proximal end of a catheter and used to seal a lumen of the catheter and maintain hemostasis (i.e., inhibit or prevent blood flow from the catheter through the valve) when an instrument (e.g., catheter, wire, embolectomy system) extends through the garrote valve and the lumen of the catheter, and when no instruments extend through the garrote valve. *Id.* at 5:51-57 & 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.
37. 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:

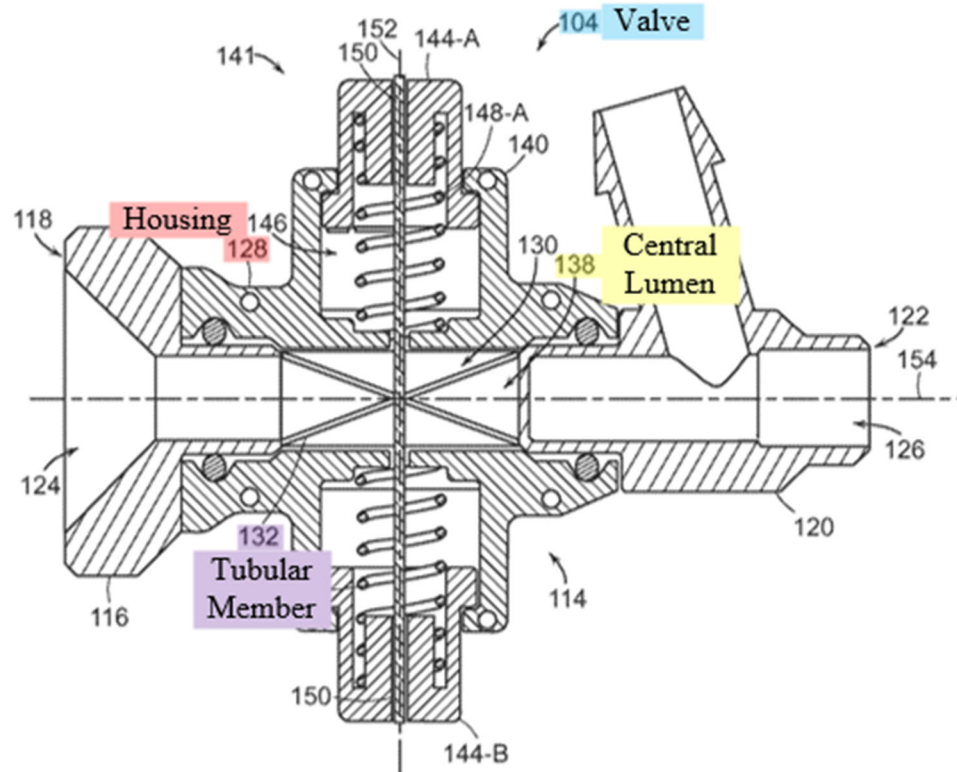
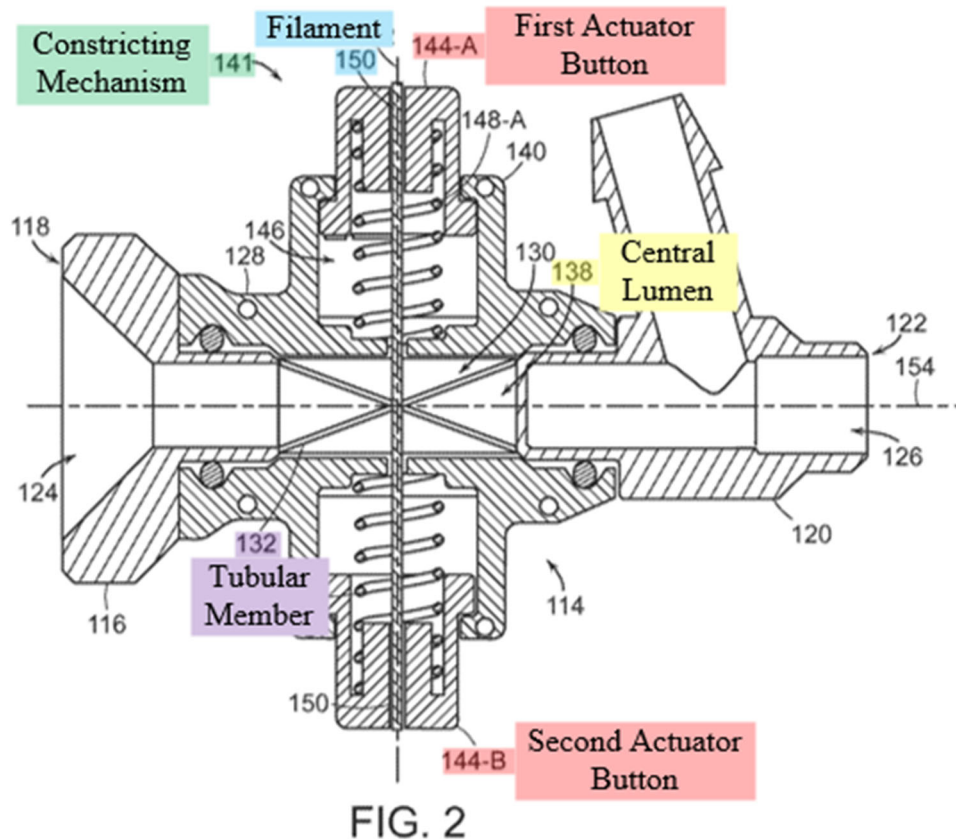


FIG. 2

Id. at 7:10-19.

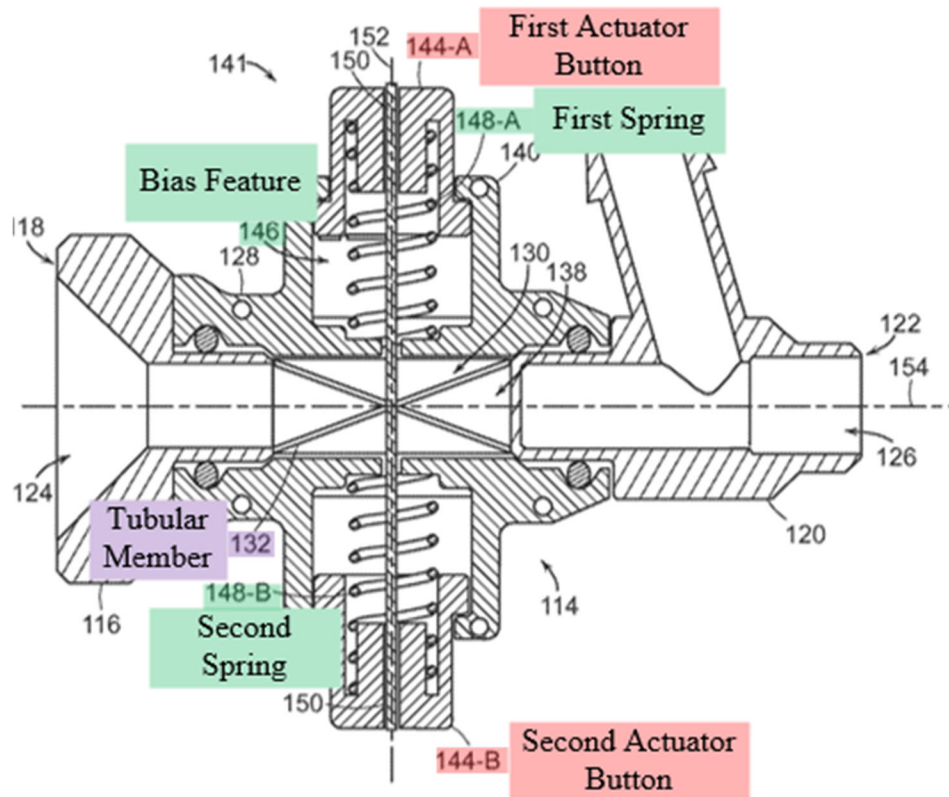
38. The garrote valve further includes a constricting mechanism 141 or garrote that can collapse and seal the tubular member 132 via constriction with at least one filament 150 that can extend at least partially around the tubular member 132. *Id.* at 8:1-8. Specifically, the constricting mechanism 141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

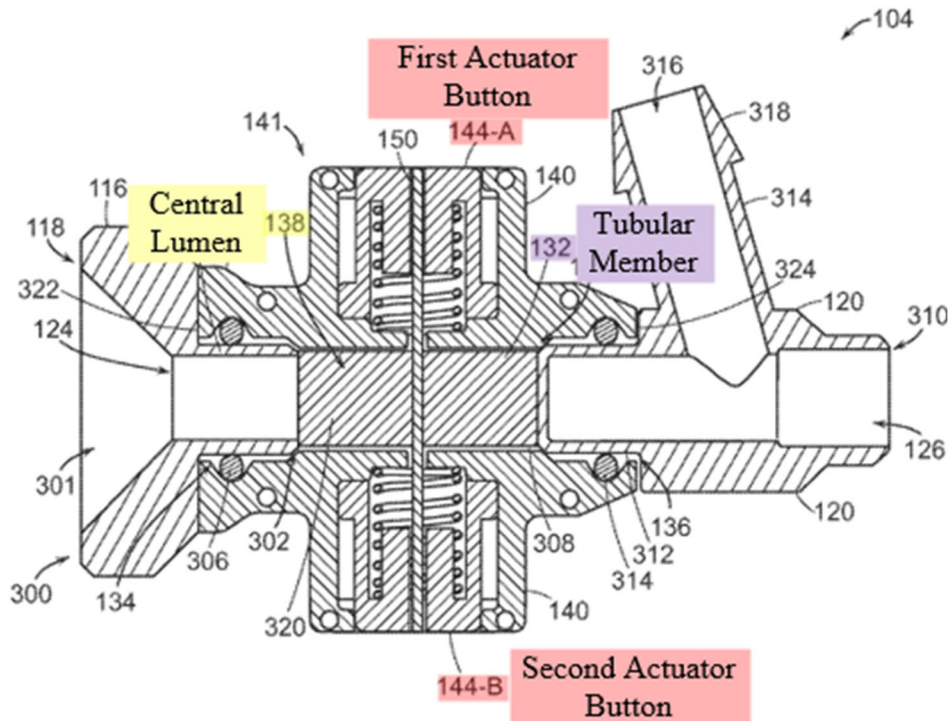


Id. at 8:4-8 & 9:21-25.

39. 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:



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:



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.

40. The filament 150 can be made from 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.

41. 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.

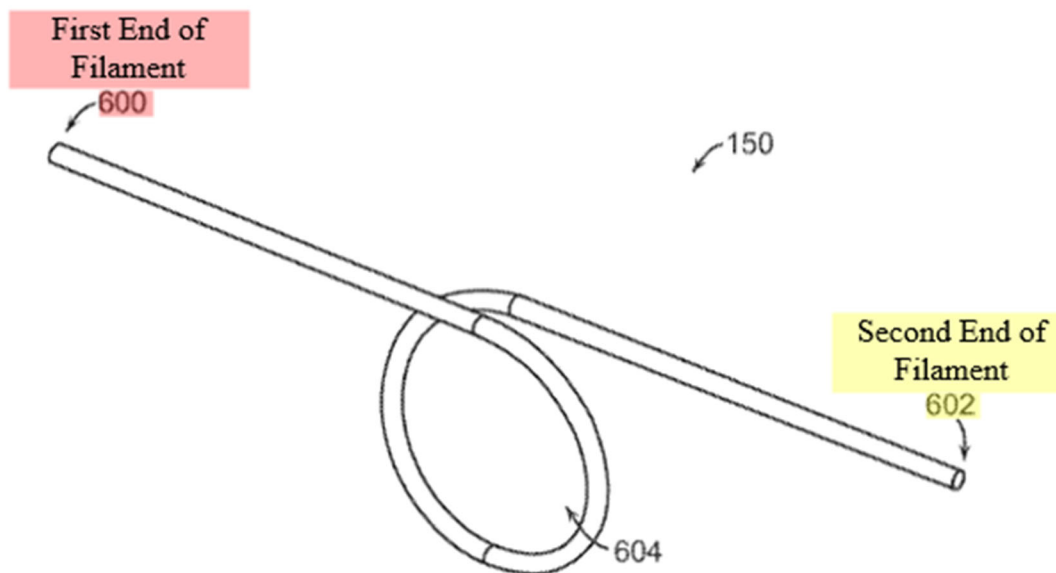


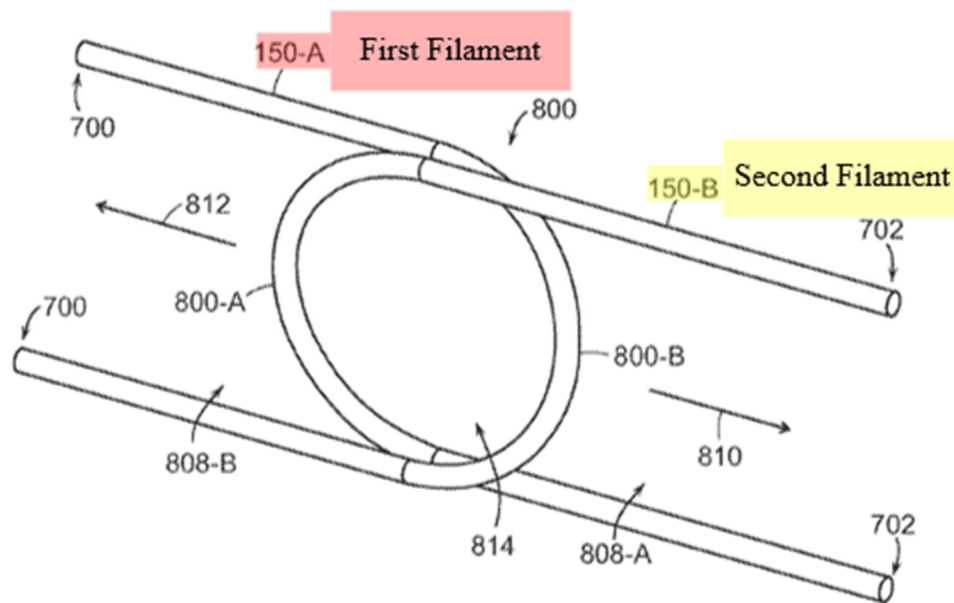
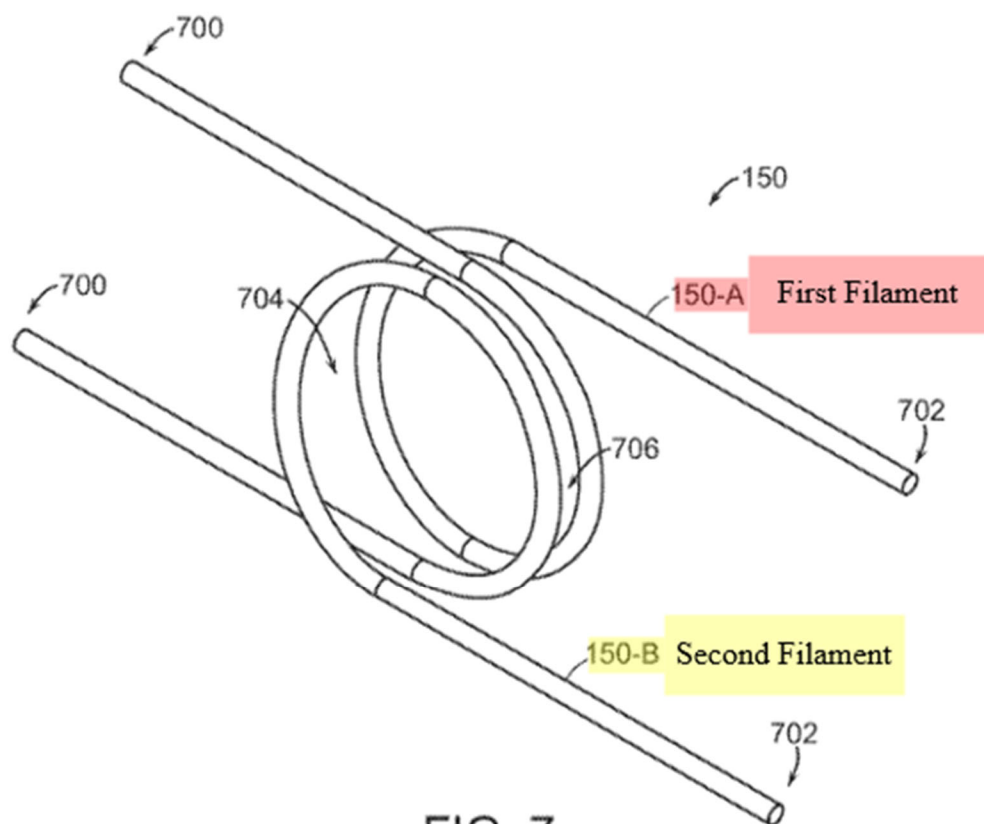
FIG. 6

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.

42. 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.
43. 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.



44. 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.
45. 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:

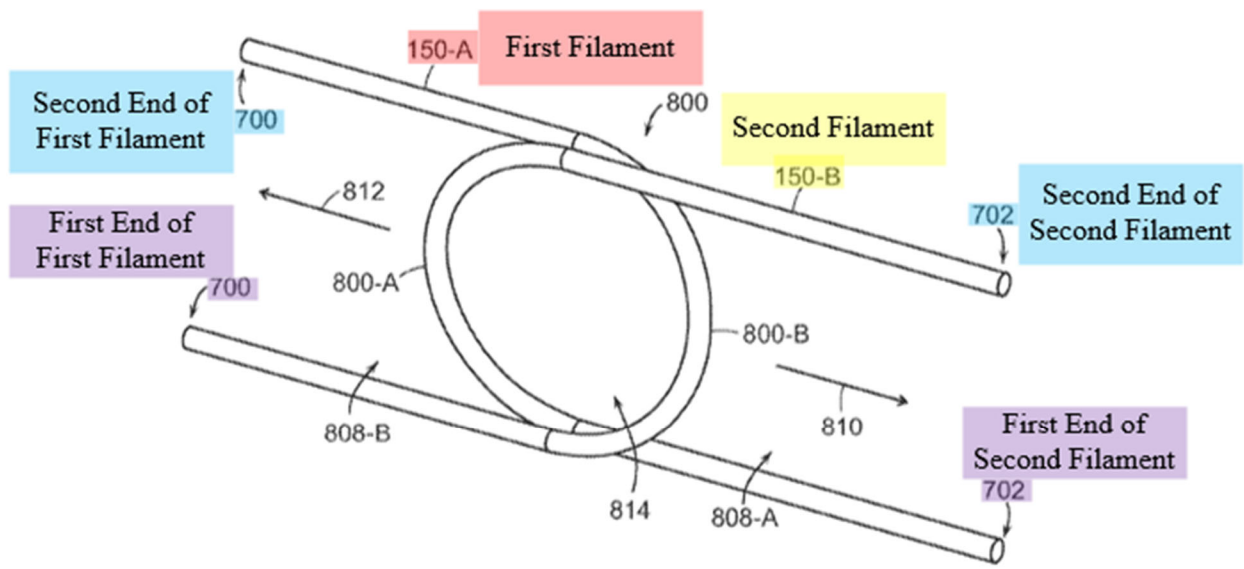


FIG. 8

46. 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).
47. 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.
48. 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:

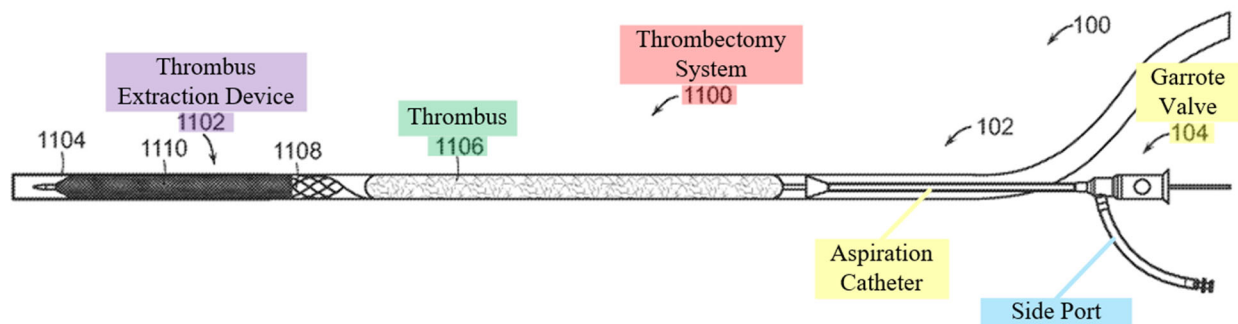


FIG. 11

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 10:43-52. 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.

49. 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.
50. 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. Prosecution History of Claim 1

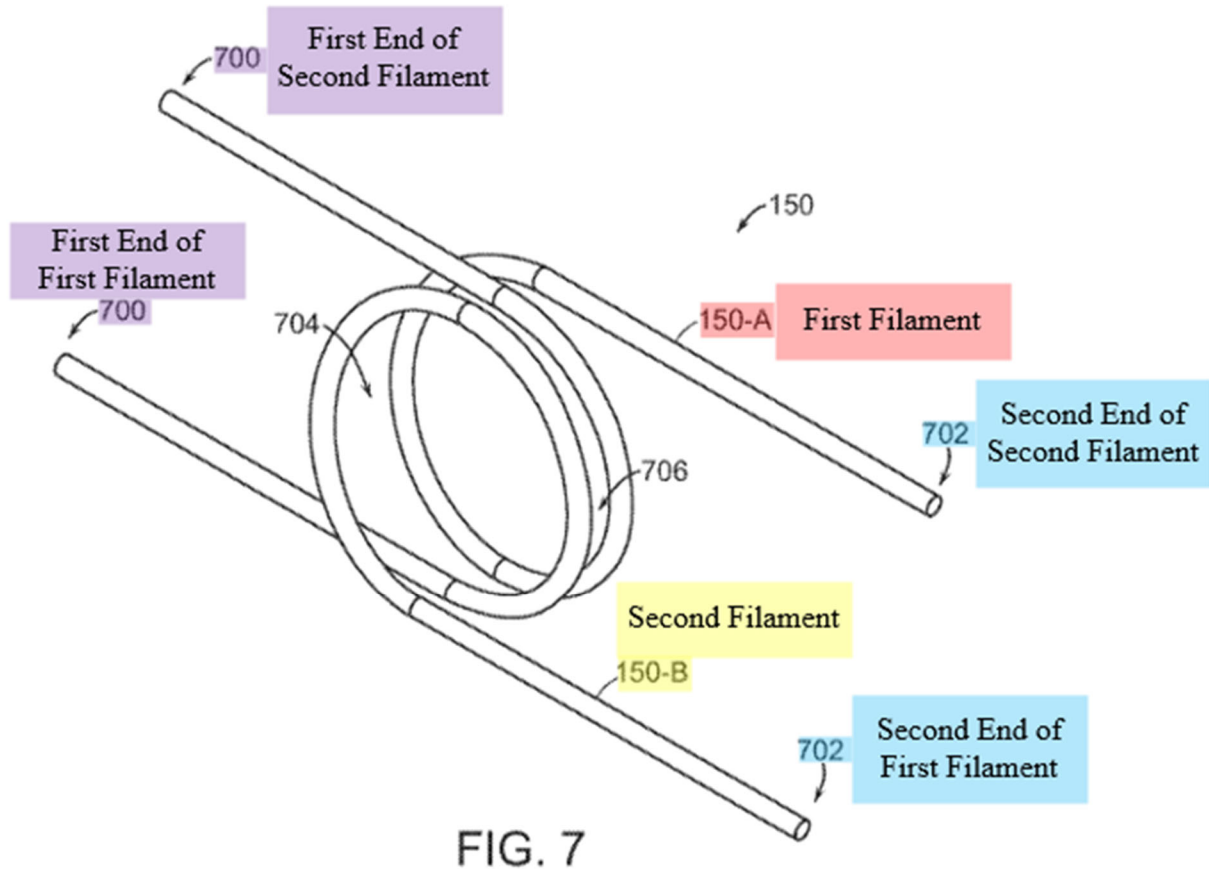
51. I have reviewed the prosecution history of the '011 patent, including the Office Action mailed August 19, 2022 (EX1002, pp. 149-156), the Applicant-Initiated Interview Summary dated November 4, 2022 (*Id.* at pp. 144-147), the Amendments and Response to the Office Action mailed December 30, 2020 (*Id.* at pp. 120-129 & 139), and the Notice of Allowance mailed December 14, 2022 (*Id.* at pp. 53-61).
52. 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.

53. 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 pp. 60.
54. 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.

C. Claim 1

55. 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.”

56. 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.”
57. 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.



58. 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.”

D. Construction of Claim 1

59. I understand that to properly construe a claim the words of the claim must be considered. I also understand terms are generally given their ordinary and customary meaning as understood by a person of ordinary skill in the art at the time of the invention when read in the context of the specification and prosecution history unless the patentee “deviate[s] from the plain and ordinary meaning of a claim term by disavowing claim scope or acting as his own lexicographer.” *Augme Techs., Inc. v. Yahoo! Inc.*, 755 F.3d 1326, 1333 (Fed. Cir. 2014). I understand that in order for a patentee to act as its own lexicographer, it “must ‘clearly set forth a definition of the disputed claim term’ other than its plain and ordinary meaning.” *Cont'l Cirs. LLC v. Intel Corp.*, 915 F.3d 788, 796 (Fed. Cir. 2019).
60. 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, in view of claim language itself, the specification, the prosecution history, and the extrinsic evidence. Reference to the material used to make the filament does not change that meaning.

61. I understand that Petitioner contends that the proper construction for “filament” is “at least ‘one or more threads, lines, cords, ropes, ribbons, flat wires, sheets, or tapes.’” Petition, pg. 14. In other words, Petitioner argues that a filament is any structure that includes “at least one or more” of the recited list of non-limiting structures provided in a list at column 9, lines 18-20 of the specification of the '011 patent. I disagree.
62. The claim language itself confirms that a filament must be flexible. Claim 1 recites that “the filament circumferentially constricts the lumen to create a seal.” To “circumferentially constrict,” the filament must extend circumferentially about the lumen and constrict the lumen around that circumference. Because a filament is flexible, it will adapt to the shape of the lumen as the lumen is constricted and thus “circumferentially constrict” the lumen as recited in claim 1.
63. In contrast, if the filament were rigid, 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. That is, a rigid member would maintain the same contact area with the lumen at all times as it is pulled against the tube. A filament, which is flexible, can change shape dynamically, allowing for better adaptability to the surface contours of the object as it is constricted. Thus, a POSITA would understand that the

recitation that the filament “circumferentially constricts the lumen to create a seal,” requires a flexible component consistent with the plain and ordinary meaning of filament.

64. The '011 specification further confirms that the term filament means “a thin, flexible length of material formed by one or more strands of material.” The specification states that “the at least one filament forms a loop around the elongated member, and moving the tensioning mechanism from the second configuration to the first configuration **reduces the size of the loop** to thereby constrict the tubular member within the loop.” EX1001, 4:58-62 (emphasis added). The filament must be flexible in order to “reduce[] the size of the loop” when tension is applied to constrict the central lumen. A loop in a rigid filament would necessarily be fixed in size.
65. While the specification describes the filament as comprising “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 do not necessarily 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, which is flexible and thin. Petitioner’s 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.

66. 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. 4. 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.
67. 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. 6 (emphasis added).

Likewise, the New Oxford American Dictionary defines a filament as “a slender threadlike object or fiber.” EX2003, p. 6.

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

68. I understand that Petitioner and its expert, Mr. Thornton, allege that the 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.

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

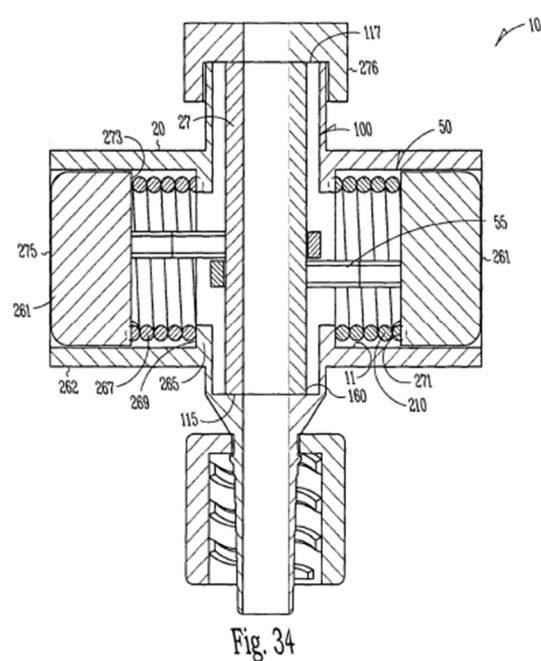
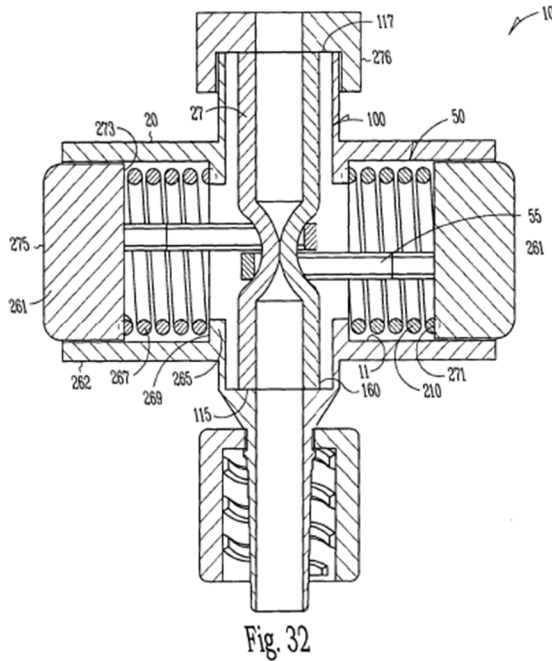
A. Schaffer Does Not Disclose the “At Least One Filament” of Claim 1

70. 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.

71. As I explain in §V.C. 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.
72. 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) that are clearer than the drawings in the published application.



Schaffer describes that “[i]n the first position the actuating members 55 of the actuators 50 are, in one option, disposed and at least partially circumferentially disposed about the portion 108 of the seal module 100 depressing and at least partially collapsing a portion 108 of the containment structure 160 by a compressive force 67 (e.g. by a spring 210).” EX1005, [0077]. “In the second position ... each actuator button 261 is depressed” and “such movement allows each engaged actuating member 55 to **forcibly disengage** opposing outer walls 27 of the seal module 100 allowing the portion 108 of the containment structure 160 to retract to an uncollapsed configuration where gases and fluids can pass therethrough.” *Id.* (emphasis added). That is, when the actuator buttons 261 are depressed, the actuating members 55 are forced to disengage from the seal module 100 with one of the actuating members 55

moving away from and out of contact with one of the outer walls 27 of the seal module 100 and the other one of the actuating members 55 moving away from and out of contact with the other opposing one of the outer walls 27 of the seal module 100. A POSITA would understand that for each of the actuating members 55 to “forcibly disengage” opposing outer walls 27 of the seal module 100, the actuating members 55 must be rigid. For example, if the actuating members 55 were flexible, depressing the actuator buttons 261 to move the actuating members 55 would simply reduce a tension in the actuating members 55 such that they would deform without forcibly disengaging the seal module 100. That is, the flexible actuating members 55 would remain in contact with and never disengage the seal module 100.

73. Moreover, as I explain in greater detail below in §VII.A., 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.

74. 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 30-34 of Schaffer clearly show that the actuating members 55 retain their shape and orientation in the first and second positions.
75. Third, Schaffer teaches and Petitioner highlights that "Schaffer's actuating members are formed from plastic or metal." 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.

76. 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:

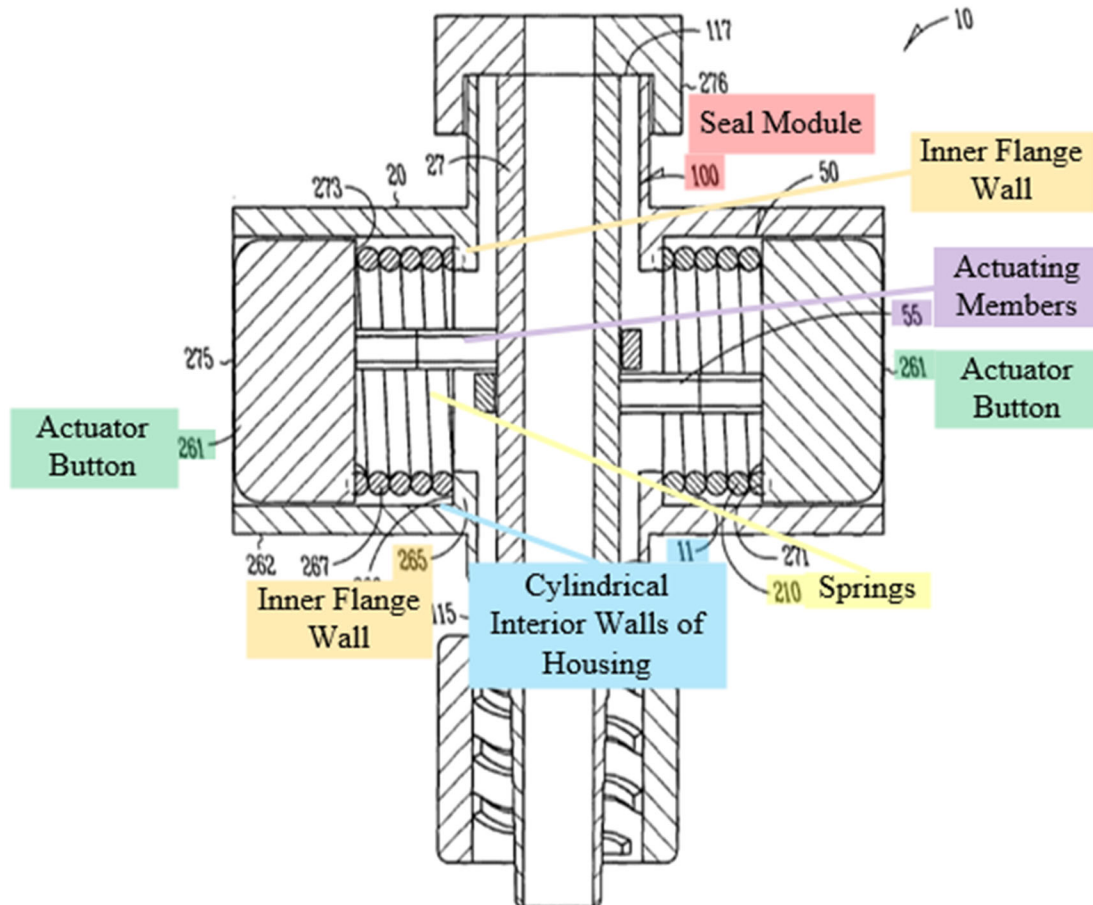


Fig. 34

77. 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

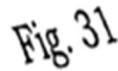
seal module 100 is inserted into Schaffer's valve such that they would not provide a uniform opening like the rigid actuating members 55 to permit positioning of the seal module 100 therethrough. Accordingly, a POSITA would understand that Schaffer's actuating members 55 are rigid because, if they were 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.

78. 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.

B. 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” Of Claim 1

79. I disagree that Schaffer’s U-shaped actuating members collectively constitute a filament having a “first end extending ... in one direction” and coupled to a first member and a “second end extending ... in another direction” and coupled to a second member as recited in claim 1. For example, as I explain in §V.C.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 continuous filament has the first end and the second end. In contrast, 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:



80. Similarly, 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 member 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).

81. 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.C.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.
82. Accordingly, a POSITA would understand that claim 1 requires a single continuous 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

83. I understand that Petitioner and its expert, Mr. Thornton, allege that the 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 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.

84. 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.

85. As I explain in §VI. above, Schaffer does not disclose either an individual flexible filament having the “first end extending ... in one direction” and the “second end extending ... in another direction” or that that filament is also coupled to a first member and coupled to a second member, as recited in claim 1. Petitioner does not assert that it would have been obvious for a POSITA to have modified Schaffer such that one of the U-shaped actuating members 55 had (i) a first end extending in one direction and coupled to one of the actuator buttons 261 and (ii) a second end extending in another direction and coupled to the other one of the actuator buttons 261. As I discuss further in §§VIII.-V.IX. below, a POSITA would not have been motivated to modify Schaffer to change the form of the U-shaped actuating members to have one end extending in one direction to one of the actuator buttons and another end extending in another direction to the other one of the actuator buttons.
86. Moreover, a POSITA would understand that neither rigid actuating member 55 of Shaffer could have ends that extend in different directions and which are coupled to different first and second actuating members. Namely, because Shaffer’s actuating members 55 are rigid, each must be coupled to a single actuating member in one direction. Otherwise, the actuating members could not move as expressly required by claim 1. For example, claim 1 requires “the first member and the second member of the actuator are moveable

between (a) a first position wherein the filament circumferentially constricts the lumen to create a seal and (b) a second position wherein the filament is moved to at least partially open the lumen.” If one or both of the rigid actuating members 55 were coupled to both of the actuator buttons 261, the actuator buttons 261 would be rigidly coupled together and therefore not movable between a first position and a second position. That is, the actuator buttons 261 would be fixed in a single position relative to one another by the rigid actuating member(s) 55 extending therebetween.

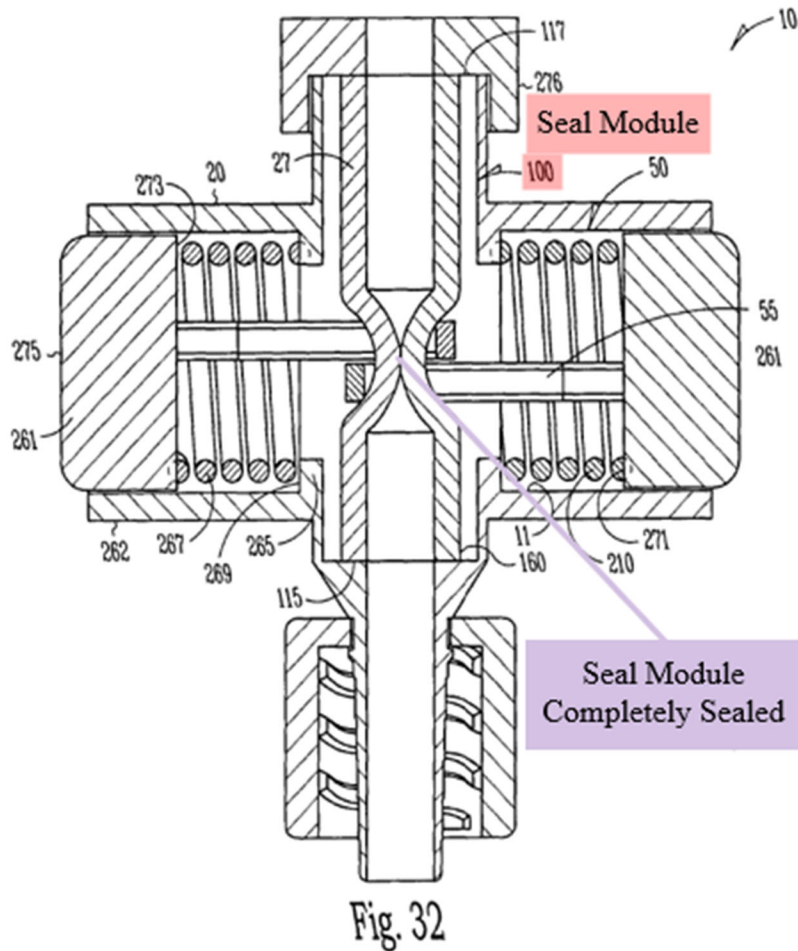
87. Petitioner asserts that “[e]ven if the Board were to conclude that Schaffer’s U-shaped actuating members do not ‘circumferentially constrict[] the lumen [of Schaffer’s valve] to create a seal’ as claimed in the ’011 patent, a POSITA would have found it obvious to modify the U-shaped actuating members to closely conform to the seal module to circumferentially constrict the lumen.” Petition, p. 32. More specifically, Petitioner states that (i) “POSITAs would have been motivated to do so to form a better seal and avoid the potential gaps discussed in the following section,” (ii) “POSITAs would have possessed the skill and knowledge to adjust the shape, material, and/or dimensions of Schaffer’s U-shaped actuating members to closely conform to the circumference of the cylindrical seal module,” and (iii) “[a]s an example, POSITAs could have

selected a thin, flexible sheet or flat ribbon of aluminum or plastic to form the actuating members.” *Id.*

88. I disagree with Petitioner’s assertion it would have been obvious to a POSITA to have modified Schaffer’s U-shaped actuating members 55 to be formed of a flexible material for at least the reasons set forth below.

A. Petitioner’s Stated Motivations to Modify Schaffer 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

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



Schaffer's device works to seal the seal module 100 as "[i]n the first position the actuating members 55 of the actuators 50 are ... disposed and at least partially circumferentially 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].

90. Schaffer describes in detail 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.*
91. Schaffer then describes 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).

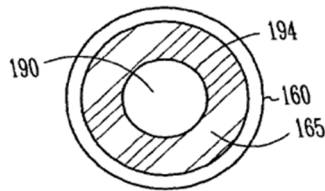


Fig. 16

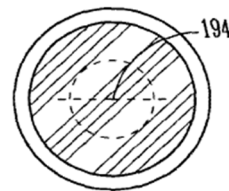


Fig. 17

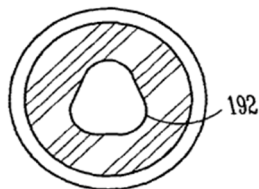


Fig. 18

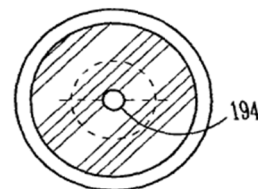


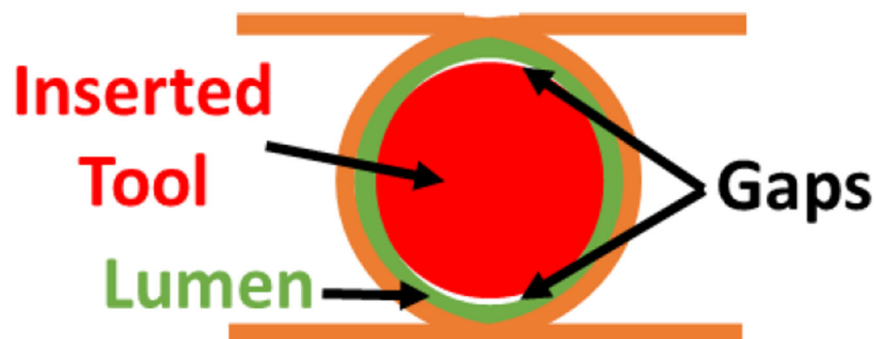
Fig. 19

92. 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].

93. 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.* In particular, the gelatinous, sticky, and extremely soft and compliant third seal member 165 can self-close under compression by sticking occlusively to itself to form “a nearly fluid/gas tight seal under very light compression” by the U-shaped actuating members 55. 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.
94. Petitioner’s expert ignores Shaffer’s express disclosure of how its rigid actuating members 55 operate in conjunction with the seal member 165 to form a complete seal around instruments of different shapes without the need for circumferential constriction such as with a filament garrote. Accordingly, a POSITA would not have been motivated to modify Schaffer to “form a better

seal” and “avoid the potential gaps” because Schaffer expressly discloses and illustrates that its valve performs both of these functions.

95. First, with regard to forming a better seal, Petitioner alleges that a POSITA would have been motivated to modify Schaffer to “seal more effectively across a wider range of diameters for the inserted devices (e.g., other catheters or tools) than Schaffer’s U-shaped actuators.” Petition, pp. 35-36. As explained above, Schaffer’s seal member 165 comprises a material that can conform to various shapes to form a seal. Forming a better seal around instruments would not have motivated a POSITA to modify Schaffer as claimed.
96. Second, with regard to “avoid[ing] the potential gaps,” Petitioner relies only 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”:

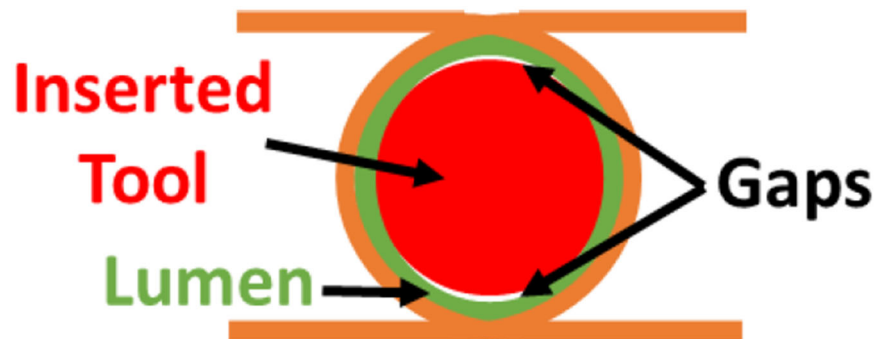


Id. at p. 36. However, Mr. Thornton’s figure is based on an incorrect understanding of Schaffer, and more specifically, the function of the seal member 165.

97. In fact, Schaffer recognizes that neither of Petitioner’s purported motivations would have motivated a POSITA to modify Schaffer to arrive at the claimed invention. 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 for “a durable stasis valve that **blocks the flow of gas or fluid completely** and immediately **with or without an instrument in place within the gas/fluid path.**” *Id.* at [0008] (emphasis added). Accordingly, a POSITA would understand that Schaffer’s valve is explicitly designed to seal effectively and completely (i.e., without gaps) in the presence of a wide range of different instruments, or without any instruments inserted thereto using the seal member 165. Petitioner’s stated motivations to modify Schaffer to “form a better seal” and “avoid the potential gaps” are based on an incorrect understanding of Schaffer.
98. For the foregoing reasons, Petitioner’s assertion that a POSITA would have been motivated to modify Schaffer’s U-shaped actuating members “to form a

better seal and avoid the potential 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.

99. 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:

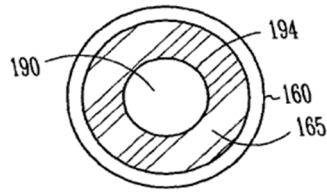


Fig. 16

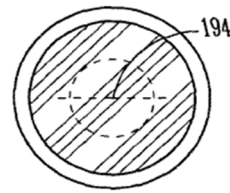


Fig. 17

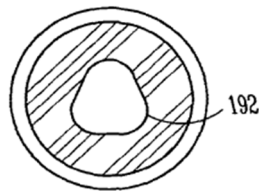


Fig. 18

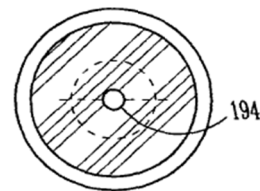


Fig. 19

100. Accordingly, a POSITA would not have been motivated to have modified Schaffer to make the U-shaped actuating members flexible, or otherwise have modified Schaffer, 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].

B. Modifying Schaffer to Replace Its Rigid U-Shaped Actuating Members with a Filament Would Change Schaffer's Principle of Operation and Reduce Durability and Easy Manufacturing

101. A POSITA would not have replaced the rigid actuating members 55 of Schaffer with a filament as claimed because doing so would make Schaffer's valve less durable and more difficult to manufacture. Petition, p. 32.
102. Regarding durability, Schaffer discloses the then-existing need for “a **durable stasis valve** that blocks the flow of gas or fluid completely and immediately with or without an instrument in place within the gas/fluid path.” EX1005, [0008] (emphasis added). Accordingly, a POSITA would understand durability, such as the ability to resist damage during operation, is a key feature of Schaffer's device. As I explain in §VI.A. above, Schaffer's actuating members 55 are rigid and “machined from aluminum” or “machined from plastic.” EX1005, [0082]. A POSITA would understand that forming the actuating members 55 to be “thin” and “flexible” would reduce the durability of these components—in direct contrast to Schaffer's intended purpose of having a durable valve. Petition, pp. 32-33.
103. Regarding manufacturability, and again as I explain in §VI.A. above, a POSITA would understand that flexible parts—such as Petitioner's proposed “thin, flexible sheet or flat ribbon of aluminum or plastic to form the actuating members”—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 a “thin, flexible sheet or flat ribbon of aluminum or plastic to form the actuating members” using machining as taught by Schaffer. Petition, p. 32. Accordingly, a POSITA would understand that modifying Schaffer to make the actuating members 55 thin and flexible would render the actuating members 55 unsuitable for their intended purpose of simple manufacturability via machining.

104. Further, Schaffer specifically describes how its stasis valve is assembled using rigid actuating 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:

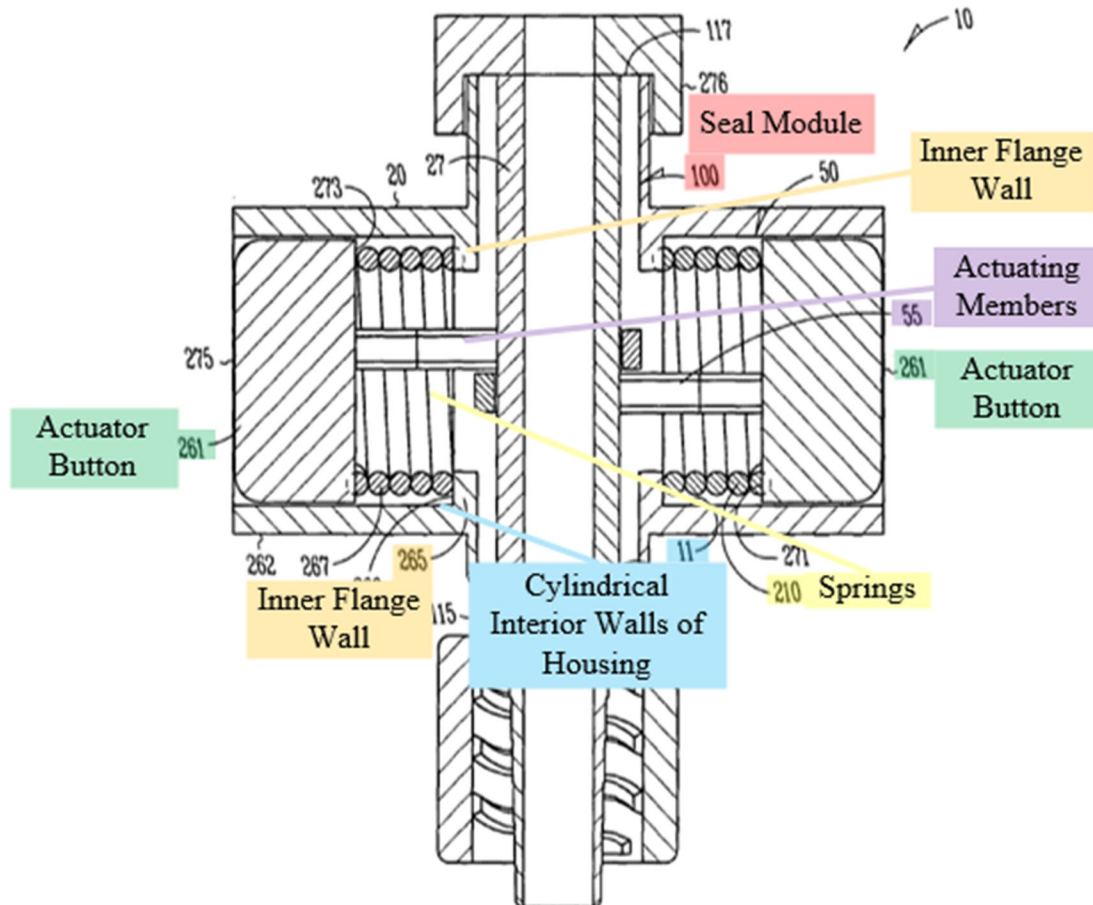


Fig. 34

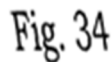
105. A POSITA would understand that modifying Schaffer to make the actuating members 55 thin and flexible as proposed by Petitioner would make it difficult to assemble Schaffer's valve in the simple manner taught by Schaffer that requires rigid actuating members 55 because thin flexible filament members would not provide a space through which the seal module 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 Schaffer's rigid actuating members 55 to permit positioning of the seal module 100 therethrough. Accordingly, a POSITA would understand that modifying Schaffer to make the actuating members 55 thin and flexible 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.

C. Modifying Schaffer to Make the U-Shaped Actuating Members Flexible 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

106. Additionally, a POSITA would not have replaced the rigid U-shaped actuating members 55 of Schaffer with a filament as claimed 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.
107. As I explain in §VI.A. above, in the second (open) position of Schaffer's valve, "each actuator button 261 is depressed" and "such movement allows each engaged actuating member 55 to **forcibly disengage** opposing outer walls 27 of the seal module 100 allowing the portion 108 of the containment

can pass therethrough”:



EX1005, [0077] (emphasis added). A POSITA would understand that for each of the actuating members 55 to “forcibly disengage” opposing outer walls 27 of the seal module, the actuating members 55 must be rigid. For example, if the actuating members 55 were made flexible as proposed by Petitioner, depressing the actuator buttons 261 to move the actuating members 55 may reduce a tension in the actuating members 55. But, a filament could

not “forcibly disengage” from the seal module 100. Accordingly, a POSITA would understand that modifying Schaffer to make the actuating members 55 thin and flexible would not allow the actuating members 55 to forcibly disengage the seal module, changing the principle of operation of Schaffer’s device. That is, the flexible actuating members 55 would remain in contact, or “float” in intervening space, with and never disengage the seal module 100.

108. Moreover, as I explain in greater detail above in §VII.A., 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.

VIII. GROUND 3: THE COMBINATION OF SCHAFFER AND HARTLEY DOES NOT RENDER CLAIMS 1-9 OBVIOUS

109. I understand that Petitioner and its expert, Mr. Thornton, allege that the Schaffer in combination with Hartley 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 have been motivated to or found it obvious to modify Schaffer in view of Hartley to arrive at the features of claim 1, for many of the same reasons I describe above in §VII. Therefore, the combination of Schaffer and Hartley 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.

110. 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.

111. Petitioner argues that “POSITAs would have found it obvious to substitute Hartley’s string for Schaffer’s U-shaped actuating members.” Petition, pp. 35-37.
112. I disagree that it would have been obvious to or that a POSITA would have substituted Hartley’s string 14 for Schaffer’s U-shaped actuating members 55 for at least the reasons set forth below.

A. Neither Schaffer nor Hartley Disclose a Single Continuous Flexible Filament Having a First End Coupled to a First Member and a Second End Coupled to a Second Member

113. As I explain in §VI. above, Schaffer does not disclose a single continuous 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 the 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. 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:

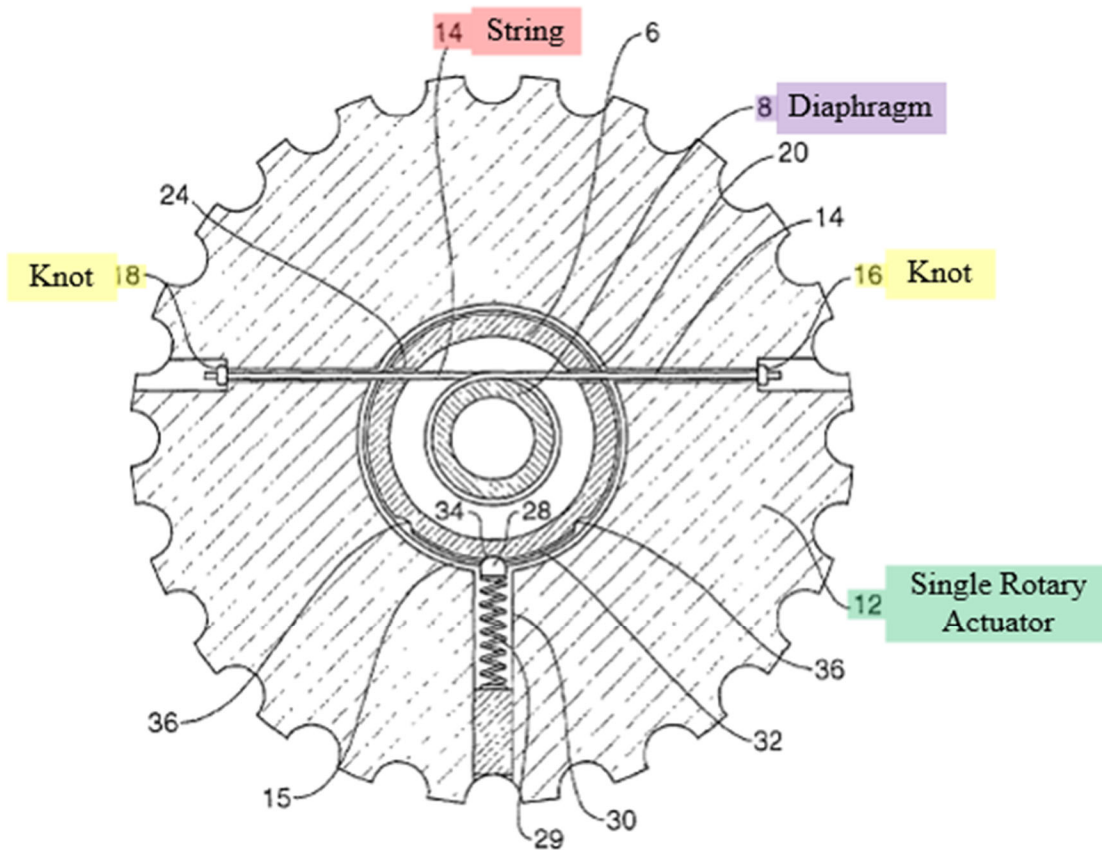


Fig 3

EX1006, [0031]. Even if Hartley's string 14 could be construed as a "filament," 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.

114. As such, even if a POSITA was motivated to substitute Hartley’s string 14 for Schaffer’s actuating members 55—a POSITA would not have been so motivated—that combination does not disclose 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 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,” as recited in claim 1. Instead, in that combination the alleged “filament” would have a first end and a second end, both extending in the same direction and both coupled to the same actuator button.

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

115. A POSITA would not have modified Schaffer in view of Hartley to improve sealing of Schaffer’s valve because Schaffer expressly discloses and illustrates the ability of its valve to seal completely across a wide range of instruments. Specifically, I disagree with Petitioner’s stated motivation to modify Schaffer in view of Hartley that “POSITAs would have recognized that Hartley’s string may seal more effectively across a wider range of diameters for the inserted devices (e.g., other catheters or tools) than Schaffer’s U-shaped actuating members” and “[d]epending on the diameter of the inserted device,

Schaffer's U-shaped actuating members may form small gaps between the valve's lumen and the outer surface of the device" as purportedly shown by Mr. Thornton's simple graphic. Petition, pp. 35-36. Petitioner's assertion that "Hartley's flexible string would not suffer from [the potential formation of small gaps] because the string encircles the central lumen and precisely conforms to the diameter of the inserted devices" is based on an incorrect understanding of Schaffer, and more specifically, Schaffer's sealing member 165.

116. As I explain in detail §VII.A. above, Petitioner's assertion that a POSITA would have been motivated to modify the U-shaped actuating members of Schaffer to "seal more effectively across a wider range of diameters for the inserted devices" without forming gaps is contradicted by the express disclosure of Schaffer. Schaffer describes a valve that addresses the then-existing need for complete sealing around a variety of instruments and specifically describes how the valve is configured to achieve such complete sealing by compression of the seal module 100 including the highly elastic, deformable, and compliant and self-closing third seal member 165. Likewise, contrary to Mr. Thornton's provided graphic and statement that "small gaps [may form] between the valve's lumen and the outer surface of the device," a POSITA would understand based on Schaffer's disclosure that such small gaps would not form.

117. Accordingly, a POSITA would not have been motivated to have substituted Hartley's string for Schaffer's U-shaped actuating members in view of Schaffer's express teachings that the seal module 100 completely seals around a variety of profile shapes and diameters of the lumen, around small instruments, around large instruments, in the absence of instruments, and even around irregularly shaped instruments. EX1005, [0060]. There was no need to change the sealing mechanism in Schaffer based on Schaffer's disclosure. Mr. Thornton is wrong that it would leave gaps.

C. Substituting Hartley's String for Schaffer's U-Shaped Actuating Members Would Render Schaffer's Valve Inoperable for Its Intended Purpose of Durability and Easy Manufacturing

118. It would not have been obvious to a POSITA to substitute Hartley's string for Schaffer's U-shaped actuating members because doing so would make Schaffer's valve less durable and more difficult to manufacture.
119. Regarding manufacturability, Petitioner contends that in its proposed combination "the first end of the string would be secured to the first actuator button (first actuator member), the string would loop at least once around the lumen of Schaffer's valve, and then the second end of the string would be secured to the second actuator button (second actuator member) on the opposite side of the valve." Petition. P 37. For example, "small holes could be made in each of Schaffer's actuator buttons, and each end of the string could be threaded

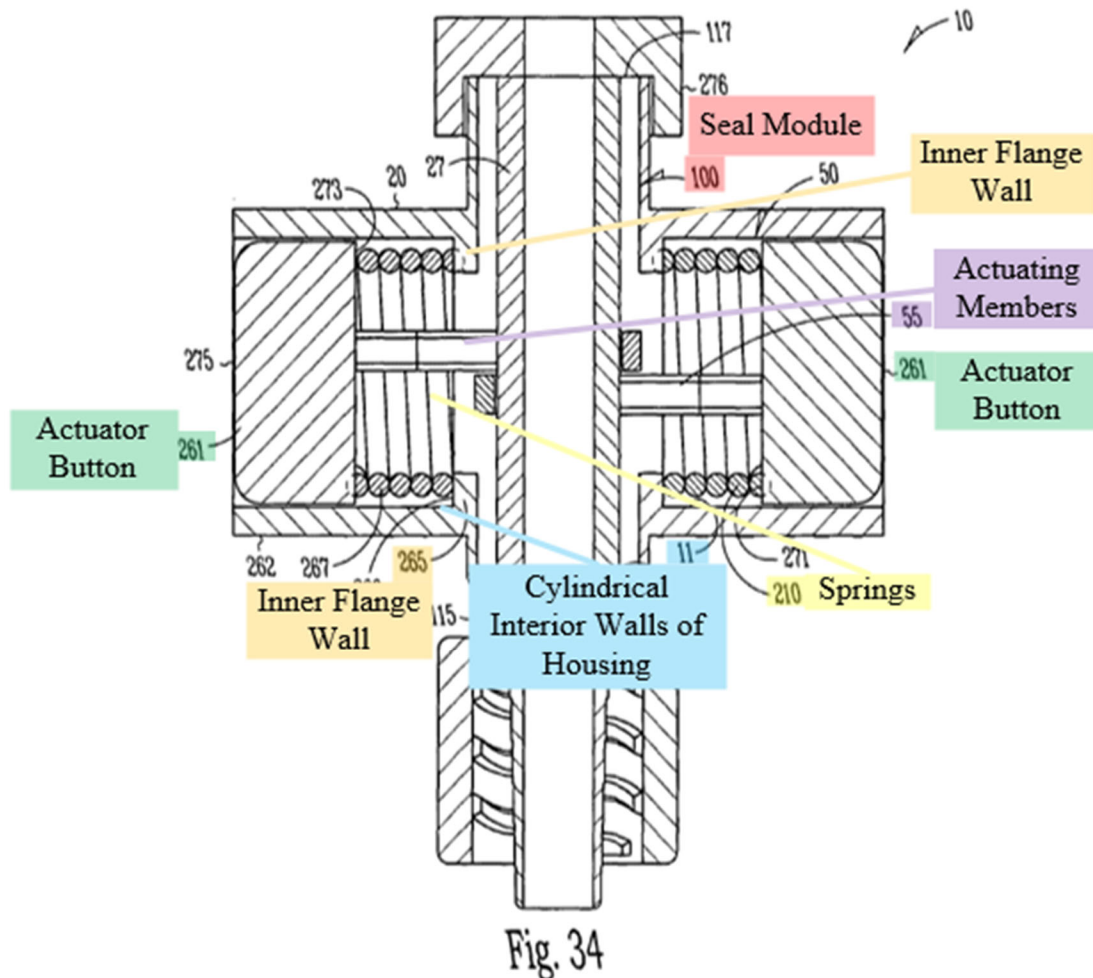
through the hole on the opposite buttons and knotted on the other side.” *Id.*

This is speculative and would remove the advantages Schaffer identifies its structure as providing.

120. 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.

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

combination the first end of Hartley's string is secured via a knot to one of Schaffer's actuator buttons 261 and the second end of Hartley's string is secured via a knot to the other one of Schaffer's actuator buttons 261. Petition, pp. 37-38. A POSITA would understand that to achieve this arrangement Hartley's string would either need to be (1) secured to the actuator buttons 261 before the actuator buttons 261 are inserted into the cylindrical openings in the housing 20 or (2) secured to the actuator buttons 261 after the actuator buttons 261 are inserted into the cylindrical openings.

122. However, the first method of assembly in which Hartley's string is secured to the actuator buttons 261 before their assembly into the valve would not be possible because the tethered actuator buttons 261 could not be inserted through the respective cylindrical openings on either side of the housing 20 while also positioning Hartley's string as alleged by Petitioner. Put differently, the inner flange wall 265 prevents either of Schaffer's actuator buttons 261 from passing entirely through the housing 20 as would be required to position Hartley's string around Schaffer's seal module 100 in Petitioner's combination.

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

actuator buttons 261 would block access to the interior of the housing 20 and inhibit or even prevent the positioning of Hartley's string in Petitioner's combination. That is, with the actuator buttons 261 inserted into the cylindrical openings in the housing 20, the interior of the housing 20 would be inaccessible for manipulating Hartley's string into position around the seal module 100.

124. Even if the first or second method of assembly was somehow workable, Schaffer teaches that the "[e]ach actuator button 261 is completely compressed and held while the seal module 100 is inserted through the housing 20 and between each actuator 50." EX1005, [0083]. The thin, flexible string of Hartley would be not tensioned (e.g., loose) when the actuator buttons 261 are compressed in Petitioner's proposed combination such that it would not provide a uniform opening like Schaffer's rigid actuating members 55 to permit positioning of the seal module 100 therethrough.
125. In sum, a POSITA would recognize the advantage of Schaffer's design when it comes to ease of assembly. Namely, each of the actuator buttons 261 is attached to a single one of the actuating members 55 to allow these individual components to be inserted into the cylindrical openings on either side of the housing 20. Tethering the actuator buttons 261 together with Hartley's string 14 would unduly complicate this simple assembly process.

126. Accordingly, for the foregoing reasons, a POSITA would understand that Petitioner's proposed substitution of Hartley's string 14 for Schaffer's actuating members 55 would make it much more difficult or even impossible to assemble Schaffer's valve in the simple manner taught by Schaffer.
127. Moreover, as I explain in §§VI.A. & VII.B. above, a POSITA would understand that flexible parts—such as Hartley's string—would be difficult or impossible to machine conventionally, as flexible materials will deform when force is applied during the machining process. This would inhibit or even prevent accurate manufacturing of Hartley's string using machining as taught by Schaffer. Accordingly, a POSITA would understand that replacing Schaffer's actuating members with Hartley's string would make Schaffer unsuitable for its intended purpose of simple manufacturability via machining.
128. Regarding durability, Schaffer explains that its invention addresses the then-existing need for “a **durable stasis valve** that blocks the flow of gas or fluid completely and immediately with or without an instrument in place within the gas/fluid path.” EX1005, [0008] (emphasis added). Accordingly, a POSITA would understand durability, such as the ability to resist damage during operation, is a key feature of Schaffer's device. As I explain in §§VI.A. & VII.B. above, Schaffer's actuating members 55 are rigid and “machined from aluminum” or “machined from plastic.” EX1005, [0082]. A POSITA would

understand that replacing Schaffer's actuating members 55 with Hartley's string 14 would make Schaffer's valve less durable—in direct contrast to Schaffer's intended purpose of having a durable valve. In particular, a POSITA would understand Hartley's thin and flexible string to be much more susceptible to damage, positioning errors, and the like during valve operation.

D. Substituting Hartley's String for Schaffer's U-Shaped Actuating Members Would Change the Principle of Operation of Schaffer's Valve in Which the U-Shaped Actuating Members Forcibly Disengage the Seal Module and Likely Render Schaffer's Valve Inoperable

129. It also would not have been obvious to a POSITA to substitute Hartley's string for Schaffer's U-shaped actuating members because doing so would change the stated principle of operation of Schaffer's valve in which the U-shaped actuating members 55 forcibly disengage the seal module 100.
130. As I explain in §§VI.A. & VII.C. above, in the second (open) position of Schaffer's valve, "each actuator button 261 is depressed" and "such movement allows each engaged actuating member 55 to **forcibly disengage** opposing outer walls 27 of the seal module 100 allowing the portion 108 of the containment structure 160 to retract to an uncollapsed configuration where gases and fluids can pass therethrough." EX1005, [0077] (emphasis added). Petitioner explains that in their proffered combination "the string would loop at least once around the lumen of Schaffer's valve." Petition, p. 37. As

explained by Petitioner, the seal module 100 would expand against Hartley's string to open when tension is released on the string: "pressing Schaffer's buttons inwardly (i.e., second position) would release the tension on the string, causing the string to loosen around the central lumen and allowing the lumen to at least partially open." *Id.* at p. 39. Thus, Hartley's string would never disengage—let alone forcibly disengage—Schaffer's seal module 100. That is, Hartley's string would remain in contact with and never disengage the seal module 100. Accordingly, a POSITA would understand that substituting Hartley's string for Schaffer's U-shaped actuating members 55 would cause the actuating member (i.e., Hartley's string) not to disengage or forcibly disengage Schaffer's seal module, changing the principle of operation of Schaffer's device.

131. Moreover, as I explain in greater detail above in §VII.A., 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, Hartley's string would not disengage the soft and sticky seal module 100 at all when the actuator buttons 261 are depressed such that the seal module 100 may stick to and

retain Hartley's string in the closed position—rendering Schaffer's valve inoperable by inhibiting or even preventing movement of the seal module 100 to the open position.

IX. GROUND 4: THE COMBINATION OF SCHAFFER AND ELLER DOES NOT RENDER CLAIMS 1-9 OBVIOUS

132. I understand that Petitioner and its expert, Mr. Thornton, allege that the Schaffer in combination with 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 have been motivated to or found it obvious to modify Schaffer in view of Eller to arrive at the features of claim 1, for many of the reasons I describe above in §§VII. & VIII. Therefore, the combination of Schaffer and 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 Eller.
133. 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.

134. Petitioner argues that a “POSITA would have found it obvious to substitute Eller’s wire member for Schaffer’s U-shaped actuating members.” Petition, pp. 44-46. Petitioner’s arguments closely track those made with reference to the combination of Schaffer and Hartley.

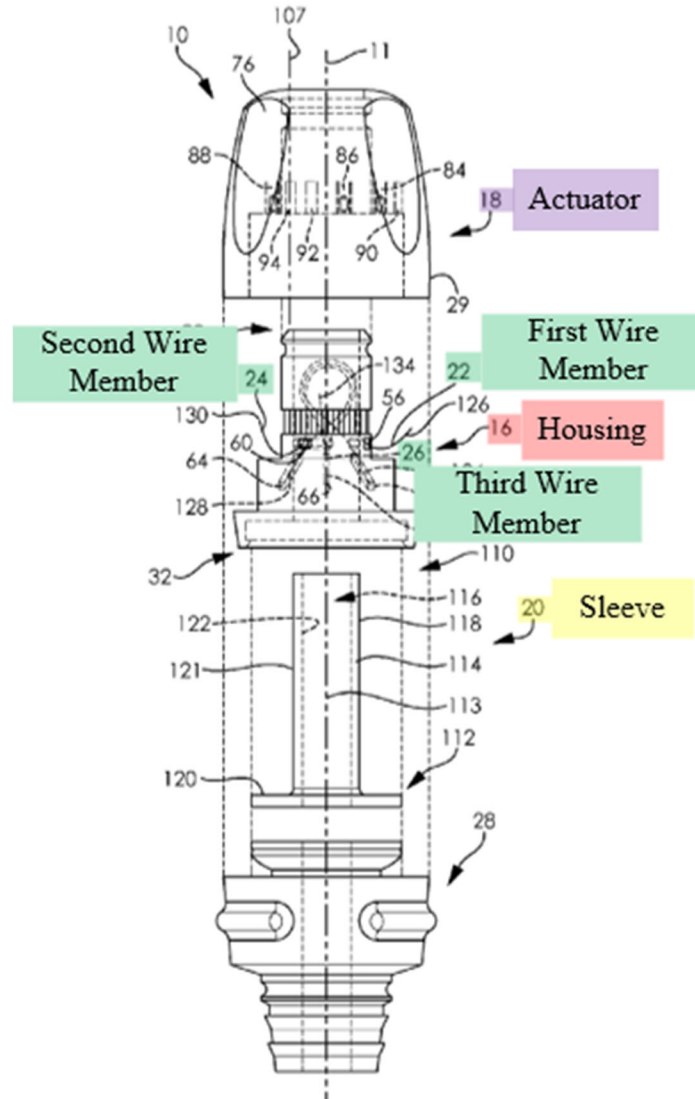
135. I disagree that it would have been obvious to or that a POSITA would have substituted Eller’s wire member for Schaffer’s U-shaped actuating members 55 for at least the reasons set forth below.

A. Neither Schaffer nor Eller Discloses a Single Continuous Flexible Filament or a Filament Having a First End Coupled to a First Member and a Second End Coupled to a Second Member

136. As I explain in §VI. above, Schaffer does not disclose an individual 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 the U-shaped actuating members have first and second ends extending in the **same**

direction and coupled to the **same** actuator button 261. 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.

137. 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:”



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.

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

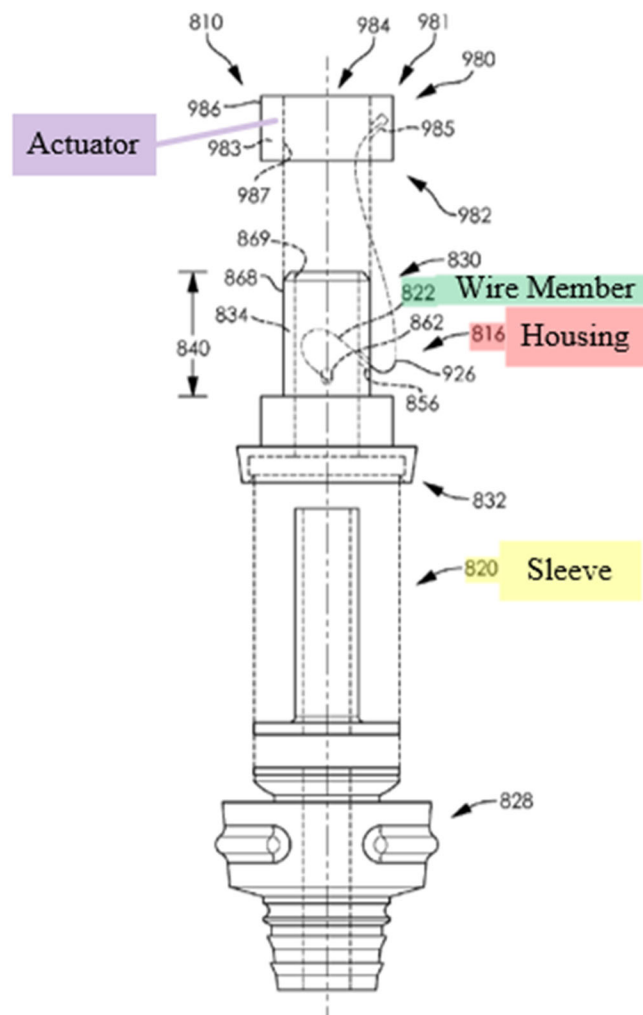


FIG. 20

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

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

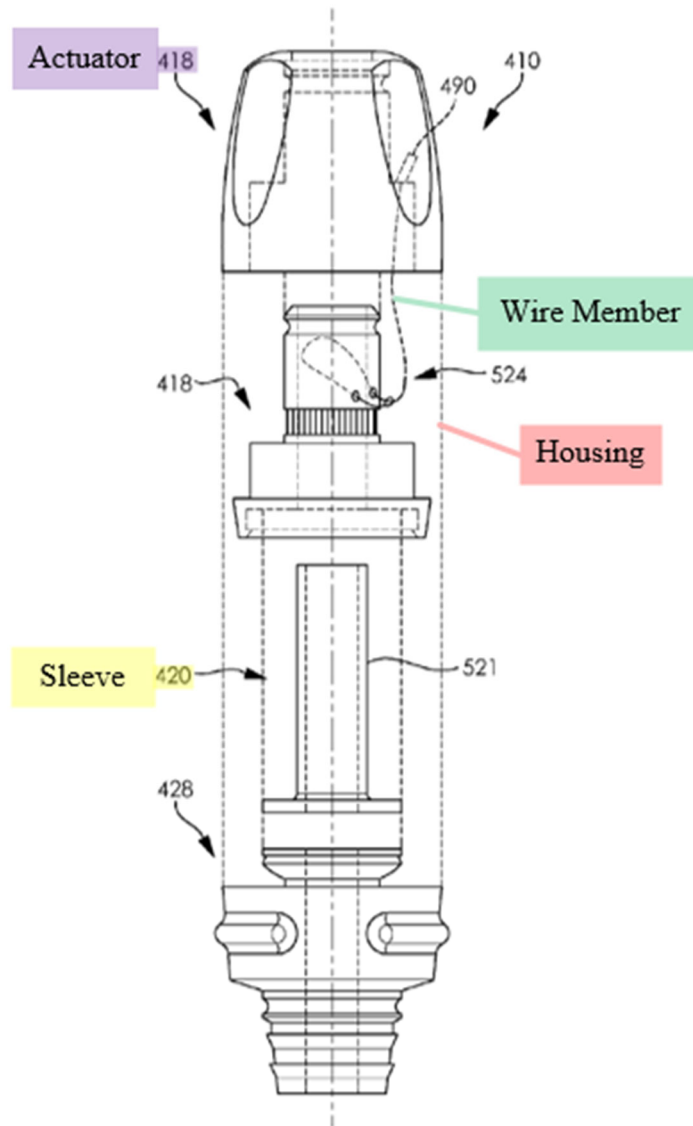


FIG. 15

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

140. 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. Even if one of Eller's wire members could be construed as a "filament," 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. Eller's wire members are designed to transfer force from the actuator to the housing, operating in a linear fashion that bears no resemblance to the claimed arrangement of a filament extending between two actuating members.

141. Despite the teachings of Eller, Petitioner's proposed combination asserts that a POSITA would have been motivated to substitute Eller's wire member for Schaffer's U-shaped members and attach one end of the wire member to one of Schaffer's actuator buttons 261 and the other end of Eller's wire member to the other one of Schaffer's actuator buttons 261. Petition, p. 26. Petitioner appears to rely on Eller's disclosure describing how its wire member is attached to support its conclusion that it would have been obvious to a POSITA to attach Eller's wire member at each end to one of Schaffer's actuator buttons. *Id.* The portion of Eller relied on by Petitioner provides that

“[a]ttachment between a wire member and a housing and/or an actuator can be accomplished using any suitable method or technique” and that “[e]xample methods and techniques considered suitable to attach a wire member to a housing and/or an actuator include using adhesives, welding, fusing, providing a friction fit between the wire member and the housing and/or actuator.” EX1007, 14:37-53. A POSITA would understand this disclosure to simply describe methods for attaching the wire members in Eller’s various embodiments to have one end attached to the actuator and the other end to the housing—and not that this disclosure suggests a complete redesign of the arrangement of Eller’s wire members to have their opposing ends both coupled to the actuator and not to the housing at all.

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

142. I understand that Petitioner’s stated motivations to modify Schaffer to include Eller’s wire member substantially track and refer back to Petitioner’s stated motivations for combining Schaffer and Hartley. Petition, p. 44.
143. As I explain in detail §§VII.A. & VIII.B. above, a POSITA would not have modified Schaffer in view of Eller to improve sealing of Schaffer’s valve because Schaffer expressly discloses and illustrates the ability of its valve to eliminate gaps and seal completely across a wide range of instruments.

Specifically, Petitioner's assertion that a POSITA would have been motivated to modify the U-shaped actuating members of Schaffer to "seal more effectively across a wider range of device diameters than Schaffer's U-shaped actuating members" is incorrect based upon the express disclosure of Schaffer. Schaffer describes a valve that addresses the then-existing need for complete sealing around a variety of instruments and specifically describes how the valve is configured to achieve such complete sealing by compression of the seal module 100 including the highly elastic, deformable, and compliant and self-closing third seal member 165. Likewise, contrary to Mr. Thornton's provided graphic and statement that "small gaps [may form] between the valve's lumen and the outer surface of the device," a POSITA would understand based on Schaffer's disclosure that such small gaps would not form.

144. Accordingly, a POSITA would not have been motivated to have substituted Eller's wire member for Schaffer's U-shaped actuating members in view of Schaffer's express teachings that the seal module 100 completely seals around a variety of profile shapes and diameters of the lumen, around small instruments, around large instruments, in the absence of instruments, and even around irregularly shaped instruments. EX1005, [0060]. There was no need to change the sealing mechanism in Schaffer based on Schaffer's disclosure. Mr. Thornton is wrong that it would leave gaps.

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

145. It would not have been obvious to a POSITA to substitute Eller's wire member for Schaffer's U-shaped actuating members because doing so would make Schaffer's valve less durable and more difficult to manufacture.
146. Regarding manufacturability, Petitioner contends that in its proposed combination "the first end of the wire member would be secured to the first actuator button (first actuator member), the wire member would loop at least once around the lumen of Schaffer's valve, and then the second end of the wire member would be secured to the second actuator button (second actuator member) on the opposite side of the valve." Petition. p 46. This is speculative and would remove the advantages Schaffer identifies its structure as providing. For the same reasons I describe in §VIII.C. above regarding the proposed substitution of Hartley's string for Schaffer's U-shaped actuating members, a POSITA would understand that Petitioner's proposed substitution of Eller's wire member for Schaffer's actuating members 55 would make it much more difficult to assemble Schaffer's valve in the simple manner taught by Schaffer and to manufacture Schaffer's valve components using a machining process.
147. Similarly, for the same reasons I describe in §VIII.C. above regarding the proposed substitution of Hartley's string for Schaffer's U-shaped actuating

members, a POSITA would understand that replacing Schaffer's actuating members with Eller's wire member would make Schaffer's valve less durable—in direct contrast to Schaffer's intended purpose of having a durable valve. In particular, a POSITA would understand Eller's thin and flexible wire member to be much more susceptible to damage, positioning errors, and the like during valve operation.

D. Substituting Eller's Wire Member for Schaffer's U-Shaped Actuating Members Would Change the Principle of Operation of Schaffer's Valve in Which the U-Shaped Actuating Members Forcibly Disengage the Seal Module and Likely Render Schaffer's Valve Inoperable

148. It also would not have been obvious to a POSITA to substitute Eller's wire member for Schaffer's U-shaped actuating members because doing so would change the stated principle of operation of Schaffer's valve in which the U-shaped actuating members 55 forcibly disengage the seal module 100. For example, for the same reasons I describe in §VIII.C. above regarding the proposed substitution of Hartley's string for Schaffer's U-shaped actuating members, a POSITA would understand that Eller's wire member substituted into Schaffer's valve would never disengage—let alone forcibly disengage—Schaffer's seal module 100. That is, Eller's wire member would remain in contact with and never disengage the seal module 100. Accordingly, a POSITA would understand that substituting Eller's wire member for

Schaffer's U-shaped actuating members 55 would cause the actuating member (i.e., Eller's wire member) not to disengage or forcibly disengage Schaffer's seal module, changing the principle of operation of Schaffer's device.

149. Moreover, as I explain in greater detail above in §VII.A., 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, Eller's wire member would not disengage the soft and sticky seal module 100 at all when the actuator buttons 261 are depressed such that the seal module 100 may stick to and retain Eller's wire member in the closed position—rendering Schaffer's valve inoperable by inhibiting or even preventing movement of the seal module 100 to the open position.

X. GROUND 5: THE COMBINATION OF HARTLEY AND ELLER DOES NOT RENDER CLAIMS 1-3, 5, 6, AND 9 OBVIOUS

150. 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.

151. 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

152. 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.
153. 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”:

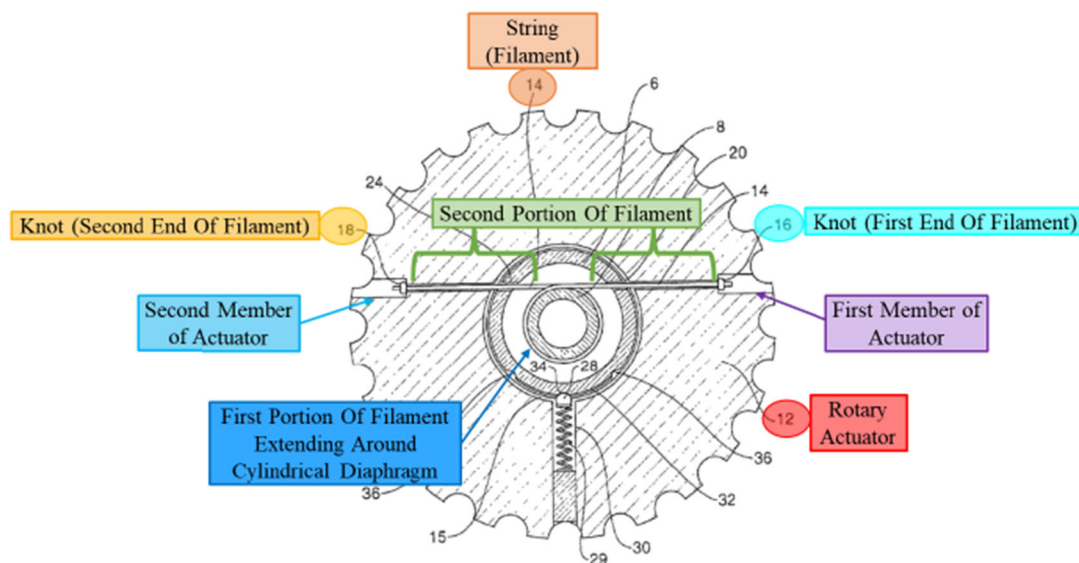


Fig 3

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.

154. 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:

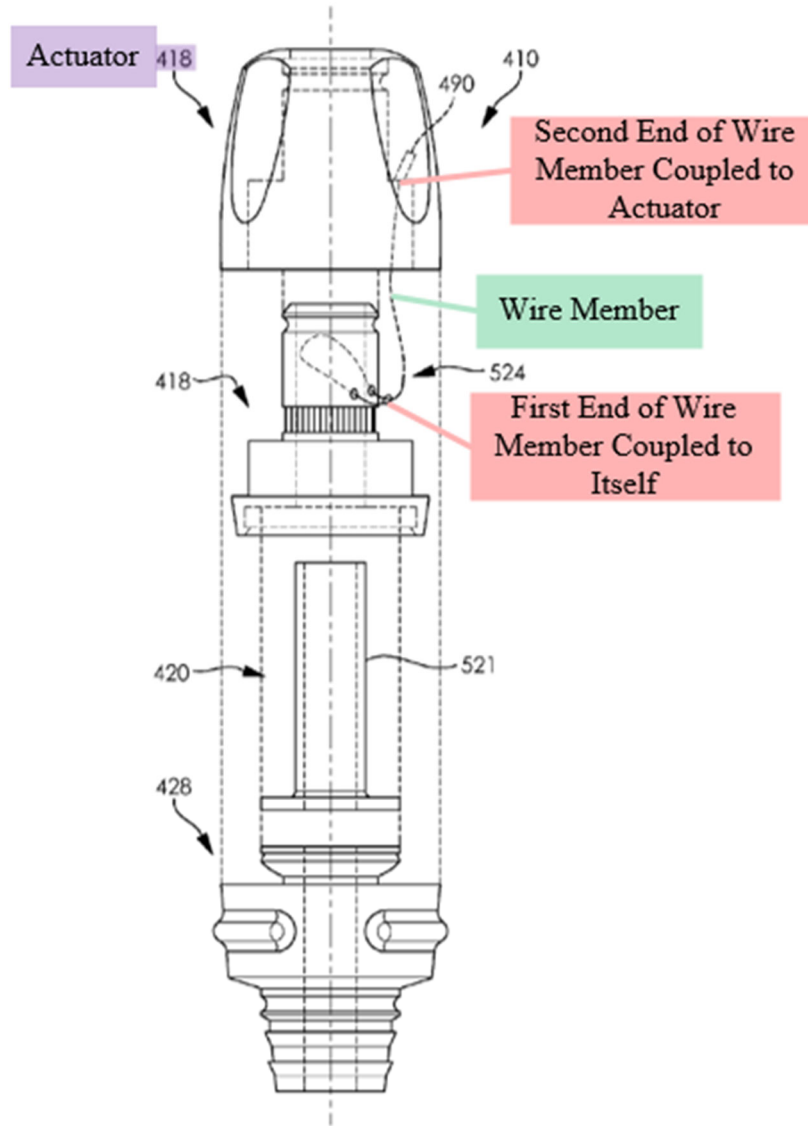
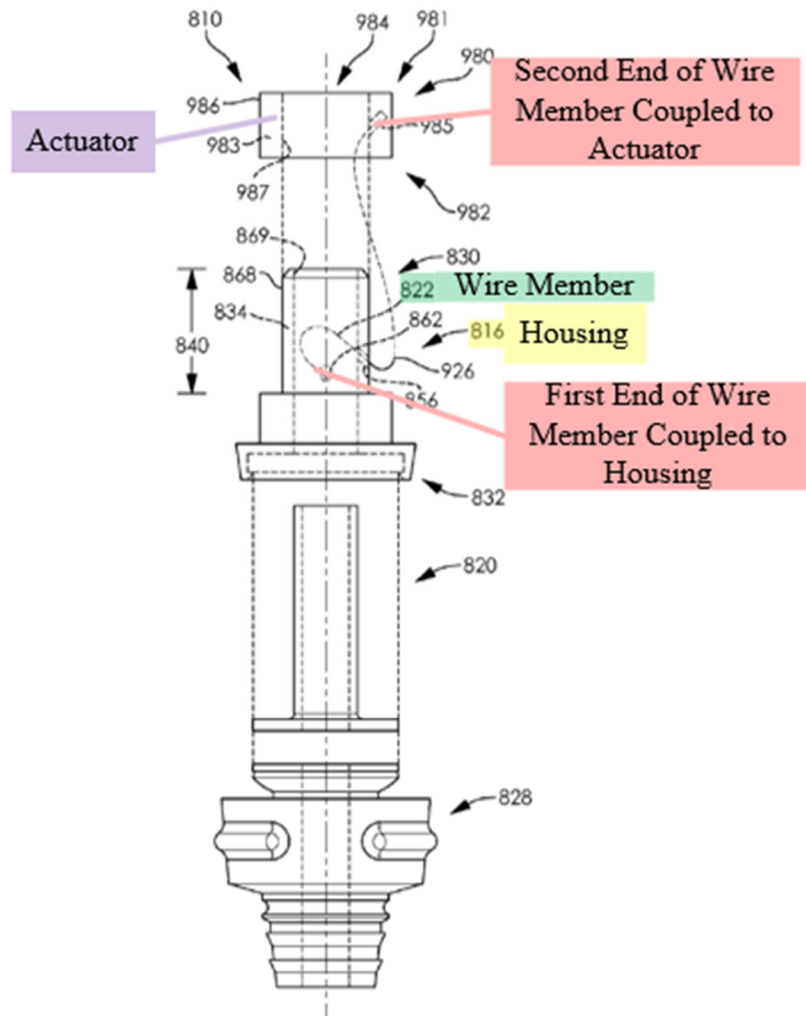


FIG. 15



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

155. 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

156. 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.
157. Hartley's valve includes a "detent arrangement having a ball 28 loaded by a spring 29 in an aperture 30 in the rotary actuator runs in a groove 32 in the cylindrical housing 6 ... [t]he groove 32 has a central recess 34 and end recesses 36":

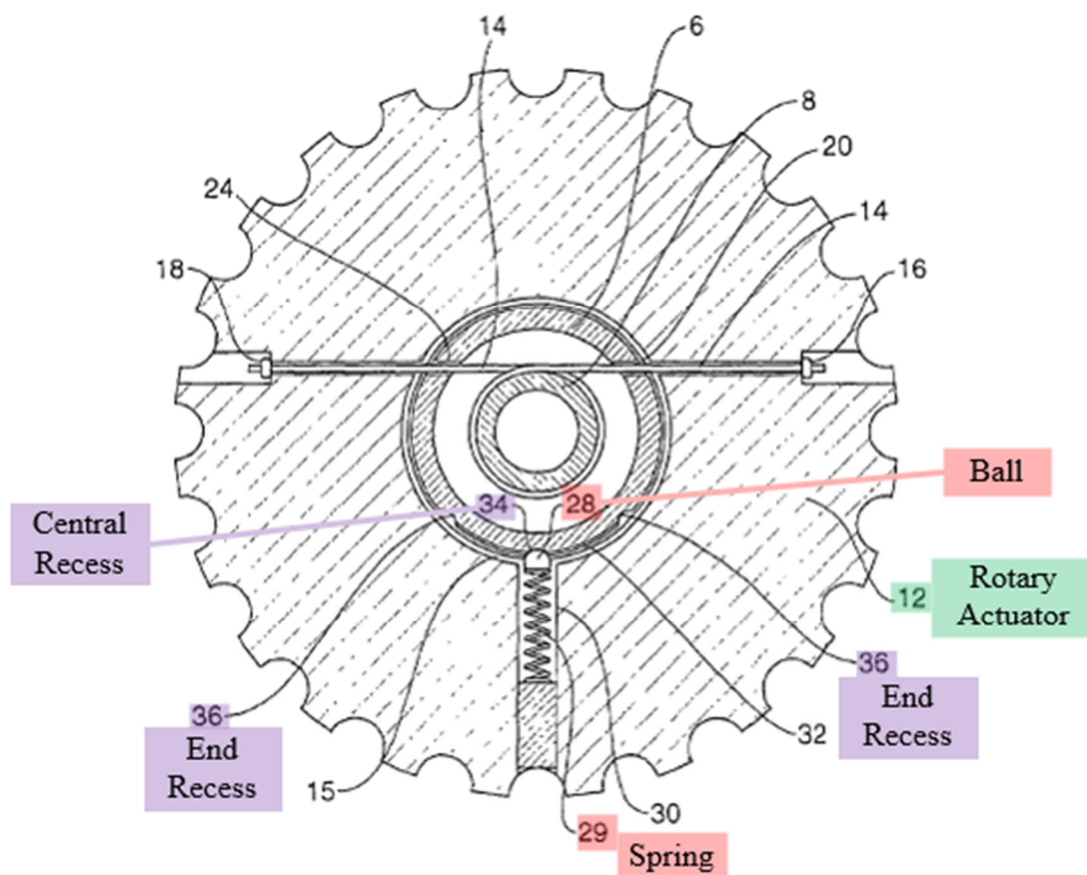
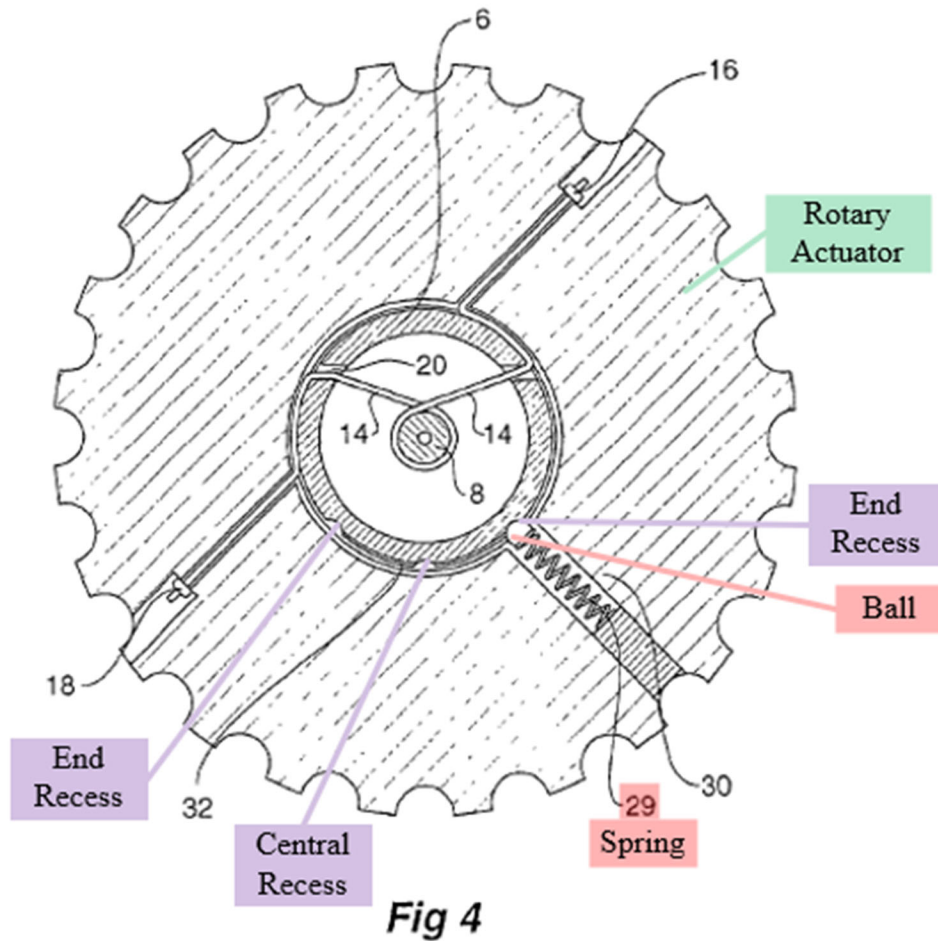


Fig 3



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

158. 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.
159. 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 §X.D. 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

160. 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.

161. 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 §X.C. above, incorporating Eller’s torsion spring into Hartley’s valve would render Hartley’s ball and detent arrangement inoperable for its intended purpose of retaining the rotary actuator in position and thereby maintaining the valve in a selected valve state (open, closed). A POSITA would understand that this functionality of the ball and detent arrangement to maintain the valve in an open state would be advantageous during insertion of instruments through Hartley’s valve.
162. 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.

163. 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.
164. 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.

165. 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.

166. 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.

XI. SECONDARY CONSIDERATIONS

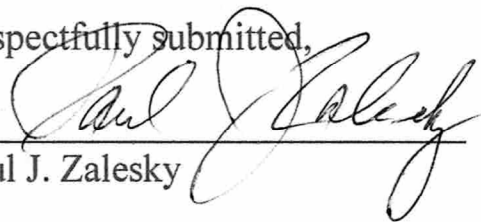
167. I have not rendered any opinions on secondary considerations of non-obviousness at this time, but reserve the right to do.

XII. CONCLUSION

168. 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.

I, Paul J. Zalesky, declare that all statements made herein of my knowledge are true, and that all statements made on information and belief are believed to be true, and that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Dated: October 29, 2024

Respectfully submitted,
By: 
Paul J. Zalesky

APPENDIX CV

Paul J Zalesky, PhD
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East Greenwich, RI 02818

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Education

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

Publications and Patents

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

Representative Publications:

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

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

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

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

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

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

Representative Patents:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Personal

Married with four children

Other

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

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

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

APPENDIX MATERIALS CONSIDERED

MATERIALS CONSIDERED

EXHIBIT/PAPER No.	DESCRIPTION
EX1001	U.S. Patent No. 11,697,011 (“the ’011 Patent”)
EX1002	’011 Patent Prosecution History Excerpt
EX1003	Thornton Expert Decl. ISO IPR Petition ’011 Patent
EX1004	Resume of Troy Thornton
EX1005	U.S. Patent Publication US 20030225379 A1 to Schaffer et al. (“Schaffer”)
EX1006	U.S. Patent Publication US 20030116731 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. 10371190
EX1009	U.S. Patent No. 5,429,616 to Schaffer (“Schaffer ’616”)
EX1010	U.S. Patent Publication US 20110144592 A1 to Wong et al. (“Wong”)
EX1011	U.S. Patent Publication US 20150173782 A1 to Garrison et al. (“Garrison”)
Paper 1	Petition for <i>Inter Partes</i> Review
EX2002	Merriam-Webster’s Collegiate Dictionary
EX2003	New Oxford American Dictionary
EX2004	U.S. Patent Application Publication No. 2018/0193043