

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

IMPERATIVE CARE, INC.,
Petitioner,

v.

INARI MEDICAL, INC.,
Patent Owner.

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

DECLARATION OF PAUL J. ZALESKY

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

I. INTRODUCTION

1. I have been retained by counsel for Patent Owner Inari Medical, Inc., (“Patent Owner” or “Inari”) as an independent expert consultant in this proceeding in connection with the *inter partes* review (IPR) proceeding IPR2025-01562 concerning U.S. Patent No. 12,109,385 (“the ’384 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 for *inter partes* review before the Board asserting:

Ground 1: Claims 1-4, 6-18, and 20-30 of the ’384 Patent are unpatentable under 35 U.S.C. § 103 as obvious over U.S. Patent Application Publication No. 2003/0225379 to Schaffer et al. (“Schaffer”) in combination with U.S. Patent Application Publication No. 2003/0116731 to Hartley (“Hartley”);

Ground 2: Claims 1-4, 6-18, and 20-30 of the ’384 Patent are unpatentable under 35 U.S.C. § 103 as obvious over Schaffer in combination with U.S. Patent No. 9,980,813 to Eller (“Eller”);

Ground 3: Claims 1-4, 6-18, and 20-30 of the '384 Patent are unpatentable under 35 U.S.C. § 103 as obvious over Schaffer in combination Hartley and Eller;

Ground 4: Claims 11-14, 20-22, and 28-30 of the '384 Patent are unpatentable under 35 U.S.C. § 103 as obvious over Schaffer in combination with Hartley and U.S. Patent No. 5,599,305 to Hermann (“Hermann”);

Ground 5: Claims 11-14, 20-22, and 28-30 of the '384 Patent are unpatentable under 35 U.S.C. § 103 as obvious over Schaffer in combination with Eller and Hermann; and

Ground 6: Claims 11-14, 20-22, and 28-30 of the '384 Patent are unpatentable under 35 U.S.C. § 103 as obvious over Schaffer in combination with Hartley, Eller, and Hermann.

3. I have been asked by counsel for Inari to opine on the patentability of the claims of the '384 Patent and, in particular, the patentability of independent Claims 1, 15, and 23 with respect to grounds 1-3 (the grounds for those independent Claims).
4. Along with my years of education, research, and experience, my opinions are based on investigation and study of relevant materials. The materials that I

evaluated in support of this Declaration include all exhibits cited in this Declaration and in the Petition.

5. I may rely upon these materials, my knowledge and experience, and/or additional materials to rebut arguments raised by Petitioner. Further, I may also consider additional documents and information in forming any necessary opinions, including documents that may not yet have been provided to me.
6. My analysis of the materials produced in this matter is ongoing, and I will continue to review any new material as it is provided. This Declaration represents only those opinions I have formed to date. I reserve the right to revise, supplement, and/or amend my opinions stated herein based on new information and on my continuing analysis of the materials already provided.
7. My work in this case is being billed at my normal hourly consulting rate, with reimbursement for actual expenses. My compensation is not related to the outcome of this proceeding. I have no personal interest in the outcome of the case.

II. BACKGROUND AND QUALIFICATIONS

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

9. I received my Ph.D. in Biomedical Engineering from the University of Michigan. My doctoral research focused on the prediction of optimal surgical timing for the repair of congenital heart defects. I received an undergraduate degree in Aerospace Engineering from the University of Notre Dame. I also received a Master of Science in Aerospace Engineering from the University of Michigan.
10. My industrial career has been focused on the development and commercialization of specialty medical devices for the diagnosis and treatment of heart disease, encompassing more than 30 years of management/engineering positions in both large and small companies. As outlined below, I have been directly involved with the development and clinical use of various interventional catheters and devices, all requiring the insertion and use of a hemostatic valve to minimize or prevent back bleeding.
11. Following the initiation of “interventional” cardiology by Dr. Andreas Gruntzig in the late 1970’s, when he pioneered coronary balloon angioplasty, the 1980’s saw the evolution of less invasive treatments of cardiovascular disease. Today, those treatments are generally referred to as interventional cardiology or radiology. Early on, I became directly involved in the development of devices associated with interventional cardiology and related cardiovascular disciplines. Such devices range from simple, diagnostic catheters to

complex electromechanical systems used for cardiovascular disease and associated issues, including thrombosis. In 1986, I led Boston Scientific's entry into the coronary angioplasty (PTCA) market as the Director of R&D, presenting device efficacy data to the FDA Panel towards a soon-approved Pre-Market Application (PMA). In that role I also supervised the development of guide catheters and guidewires needed as accessories to the diagnosis and treatment of cardiovascular disorders.

12. In 1986, I co-founded InterTherapy with cardiologist Dr. Walt Henry. InterTherapy was focused on the development of intravascular ultrasound for assessment of coronary and peripheral vascular disease that directed subsequent therapy. The disposable component of the product was a 5 French catheter with design and materials that enabled its passage through standard guide catheters into the branches of the coronary artery or peripheral arteries. From 1986 through 1990 I managed all company operations, with emphasis on device use in the cardiac catheterization and special procedure labs of center-of-excellence hospitals.
13. I recruited, and worked closely with, Dr. Martin Leon, then a Fellow at the National Institutes of Health, and collaborated with Dr. Leon on the creation of a new, interventional cardiology symposium, Transcatheter Cardiovascular Therapeutics, which subsequently evolved into the largest and most

comprehensive symposium in the field of interventional cardiology. I also collaborated closely with cardiologists, vascular and cardiac surgeons, and interventional radiologists from multiple U.S. and European Centers of Excellence, including the Mayo Clinic, Mass General Hospital, UCLA, Rhode Island Hospital, Emory University, Stanford University, Clinico Cardiologica in Milan, Italy, and many others. In this, and subsequent professional positions, I participated in hundreds of patient cases in the cardiac catheterization lab and operating room, donning protective lead aprons and masks while assisting or observing patient cases. The InterTherapy technology effectively enabled the development and evolution of coronary and peripheral vascular stents, as the real time, intravascular imaging enabled review and optimization of treatment with specialized catheters or stents.

14. In the early 1990's I served as a VP R&D for a division of Baxter International, where I led the development of and presented the corporation's interventional cardiology and cardiopulmonary bypass product portfolio to cardiologists and surgeons and associated symposia, including the development of critical devices for treatment of cardiovascular disease.
15. In 1995 I co-founded, with cardiologist Dr. J. Richard Spears, TherOx. TherOx was focused on the development of oxygen supersaturated solutions to the coronary artery, following acute myocardial infarction (heart attack). The

primary product included a sub-selective catheter that could access distal segments of the coronary branches, for fluid delivery. By sub-selective, I mean a catheter that can be placed into and advanced through a larger catheter, sometimes referred to as a “mother-and-child” catheter configuration.

16. In the 1995-2005 time period, myriad guide catheter configurations were developed and tested by many different companies, including multi-hardness bodies, multi-flexibility properties, various tip geometries and materials, and various lumen geometries. Simultaneously, variations on angioplasty, thrombectomy, atherectomy, and other devices were developed and tested, including catheters with active energy capability for lesion (disease) ablation or removal, miniature balloons on wires, and selective pharmacologic infusions. I was directly involved with physician use and assessment of these and related devices while directing and participating in formal clinical studies in the U.S., Europe, Canada, and Israel.
17. During my time with Volcano Corporation (now Philips) I supervised coronary and peripheral artery catheter development, manufacture, and clinical use.
18. Since 2013, I have focused on consulting and have provided expert advice or opinion on numerous projects, including such areas as algorithms for cardiac arrhythmia diagnosis, implantable cardiac defibrillators, blood oxygen

diagnostic devices, and cardiovascular devices and processes associated with vascular disease or obstruction treatment. For 1½ years, I served as interim CEO for Keystone Medical, an Israel-based start-up for the development of cerebral protection devices for use with transcatheter heart valve replacement. Our product development activities included cardiac delivery catheters, guide-wires, and associated catheterization lab procedures for device insertion, deployment, use, and removal.

19. In many of my management positions, I was responsible for development and maintenance of intellectual property, including both direct management of in-house patent counsel and collaboration with outside patent counsel. I am a named co-inventor on more than 20 issued U.S. patents, almost all focused on cardiovascular, coronary artery devices.
20. I have devoted most of my 35 plus years in product development to diagnosis and treatment of cardiovascular disease. Multiple experiences provided me with keen insights into the various aspects of heart disease, the optimized use of least invasive therapies, and the underlying pathophysiology of cardiovascular disease. I observed or participated in several hundred patient cases in the special procedure labs across the U.S. and Europe. I co-pioneered Intra-vascular Ultrasound, utilized to characterize vascular disease, guide treatment, and confirm therapeutic efficacy via complete stent deployment or other

treatment at the lesion site. I co-pioneered the use of Aqueous Oxygen in patients with acute myocardial infarctions (heart attacks), providing resuscitation of ischemic, stunned or damaged cardiac muscle. Both of these technologies are currently part of the interventional cardiologist armamentarium for heart disease diagnosis and treatment.

III. BASES OF MY OPINION

A. Materials Considered

21. The opinions included in this Declaration are based on the documents I reviewed, my professional judgment, and my education and experience.
22. In forming my opinion expressed in this Declaration, I reviewed all the materials listed in the attachment hereto, and any other material I refer to in this Declaration in support of my opinion.

B. Relevant Legal Principles

23. I am not an attorney, but in preparing and forming my opinions, I have been informed of certain legal principles. I have applied my understanding of those principles and taken them into account when forming the opinions I describe. My understanding of the relevant legal principles is summarized below.
24. I understand that claim terms are generally given their ordinary and customary meaning as understood by a person of ordinary skill in the art at the time of the invention when read in the context of the specification and prosecution

history unless a patentee sets out a different definition or clearly disavows claim scope.

25. I further understand that extrinsic evidence such as expert and inventor testimony, dictionaries, and learned treatises can help determine the meaning of claim terms, although that evidence is less significant than the claims, specification, and prosecution history.
26. I have been informed that Imperative bears the burden of proving unpatentability by a preponderance of evidence. I have been told that this means that Imperative must prove that more likely than not that the claims of the '384 Patent are obvious over the combination of Schaffer and Hartley, obvious over the combination of Schaffer and Eller, obvious over the combination of Schaffer, Hartley, and Eller, obvious over the combination of Schaffer, Hartley, and Hermann, obvious over the combination of Schaffer, Eller, and Hermann, or obvious over the combination of Schaffer, Hartley, Eller, and Hermann.
27. I understand that my opinions regarding patentability are from the viewpoint of a person having ordinary skill in the field of the technology of the patent as of the time of the invention. For the purposes of this Declaration, I have assumed that date is the earliest priority date of the '384 Patent which is September 6, 2017. Petitioner also applies September 6, 2017, as the priority date for the '384 Patent. Petition, p. 16.

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 '384 Patent are not rendered obvious by Schaffer in combination with Hartley and/or Eller, and are not rendered obvious by any combination of the prior art asserted in the Petition.

V. THE '384 PATENT

A. Overview

33. The '384 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, 1:52-56. The '384 Patent addresses those drawbacks by providing a hemostasis valve (i.e., a valve that inhibits or prevents blood from flowing through the valve) that provides for easy one-handed operation and strong sealing around a variety of different sized instruments, both of which are particularly important for hemostasis valves for use with thrombectomy systems, an embodiment of the '384 Patent. *Id.* at 16:7-31 (incorporating by

reference, e.g., U.S. Patent Application 15/498,320, which published as U.S. Patent Application Publication No. 2018/0193043 and issued as U.S. Patent No. 10,098,651). 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 '384 Patent discloses that “[t]he present disclosure relates to a valve that can be used [as] a hemostasis valve.” EX1001, 5:55-56. This valve, also referred to in the '384 Patent as a garrote valve, can seal with or without a tool extending through the valve. *Id.* at 5:56-58. I understand that the '384 Patent uses the term “garrote valve” to evoke the mechanism and action of the valve in which one or multiple filaments are looped around a flexible tubular member and pulled tightly to shrink the loop(s) to thereby collapse and seal the flexible tubular member.
35. The design and functionality of this hemostasis valve enables medical professionals to operate the valve with one hand while maintaining a robust seal to prevent blood loss during procedures. *Id.* at 5:57-67. Specifically, the design enables such ease of use while maintaining an effective and strong seal under the high-pressure differential caused by vacuum aspiration during aspiration

thrombectomy procedures. *Id.* at 2:12-14, 5:17-20, & 5:67-6:6. This type of valve, because of its strong seal and ability to minimize patient blood loss, is particularly well-suited for medical procedures involving the use of large-bore catheters, where the risk of blood loss is generally greater and the need for a tight valve is critical.

36. When utilizing the garrote valve in a thrombectomy procedure, for example, the garrote valve can be coupled to a proximal end of a catheter and used to seal a lumen of the catheter and maintain hemostasis (i.e., inhibit or prevent blood flow from the catheter through the valve) when an instrument (e.g., catheter, wire, thrombectomy device) extends through the garrote valve and the lumen of the catheter, and when no instruments extend through the garrote valve. *Id.* at 5:55-67. The garrote valve provides for convenient single-handed operation to open and close the garrote valve while also providing robust sealing with or without an instrument inserted therethrough during various catheter operations, such as vacuum aspiration of the catheter. *Id.* at 5:64-6:6.
37. In an embodiment, the '384 Patent discloses a garrote valve 104 on a proximal end 108 of a catheter 102. *Id.* at 6:28-35. The catheter 102 can comprise an elongate flexible shaft 106 that defines a central lumen 112 and a distal end 110 of the catheter 102:

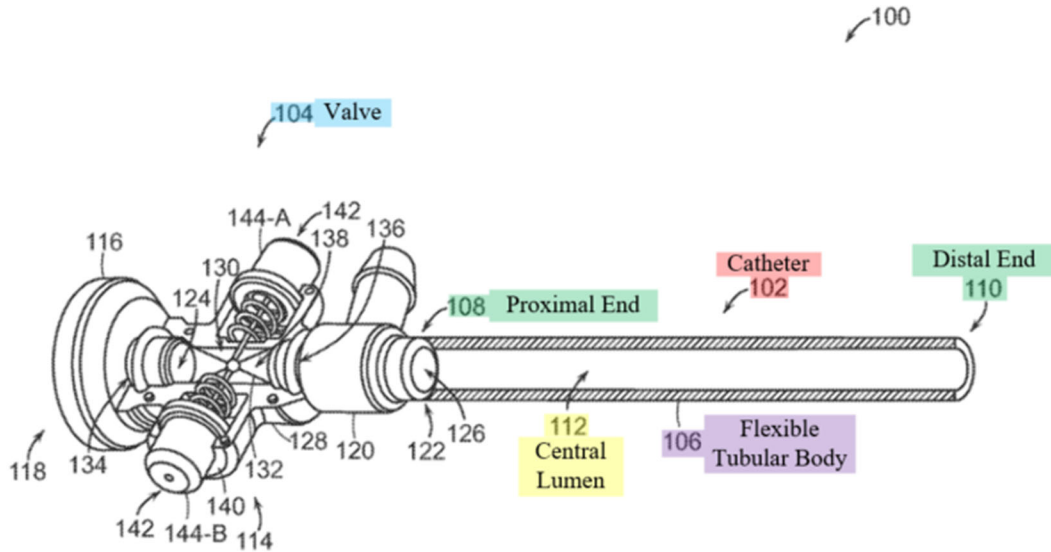


FIG. 1

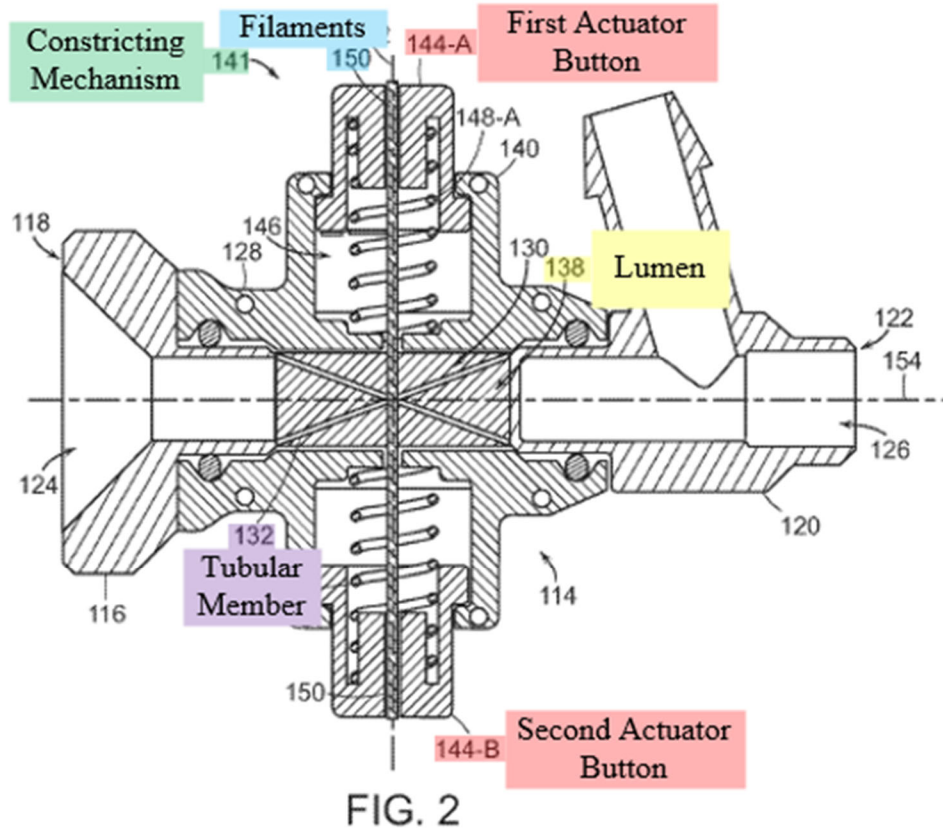
Id. at 6:30-41.

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

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

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

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



Id. at 8:8-12 & 9:28-38.

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

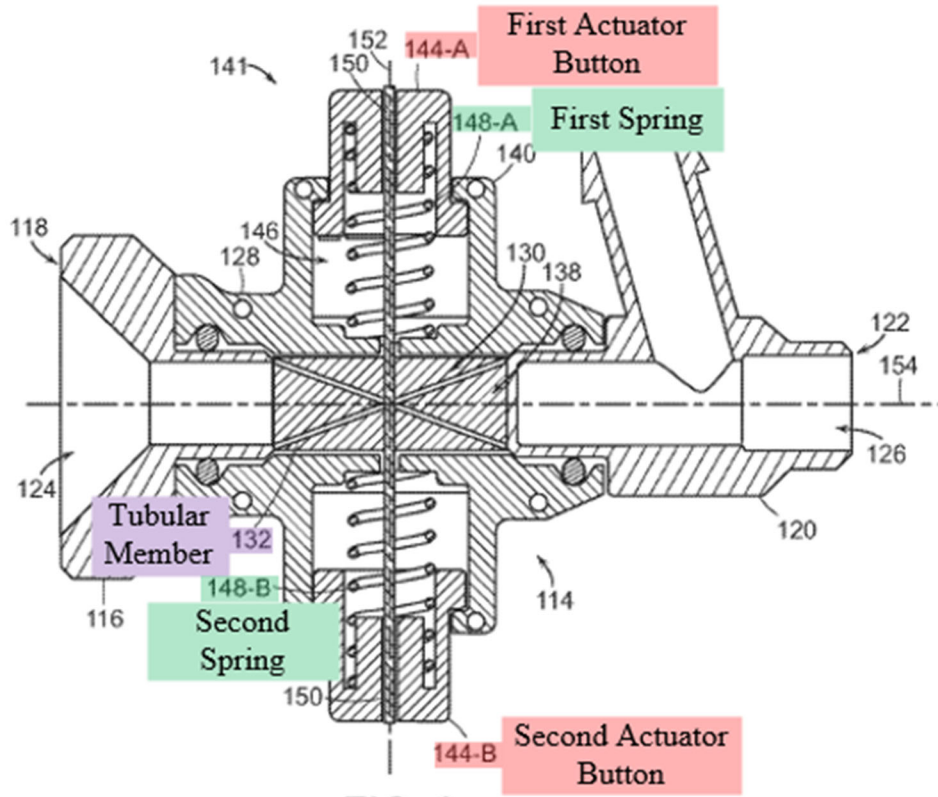


FIG. 2

Id. at 8:38-56. The actuator 142 can be actuated to move the garrote valve to a second (open) configuration shown in Figure 3 wherein the tubular member 132 is expanded and the central lumen 138 of the tubular sidewall 132 is unsealed:

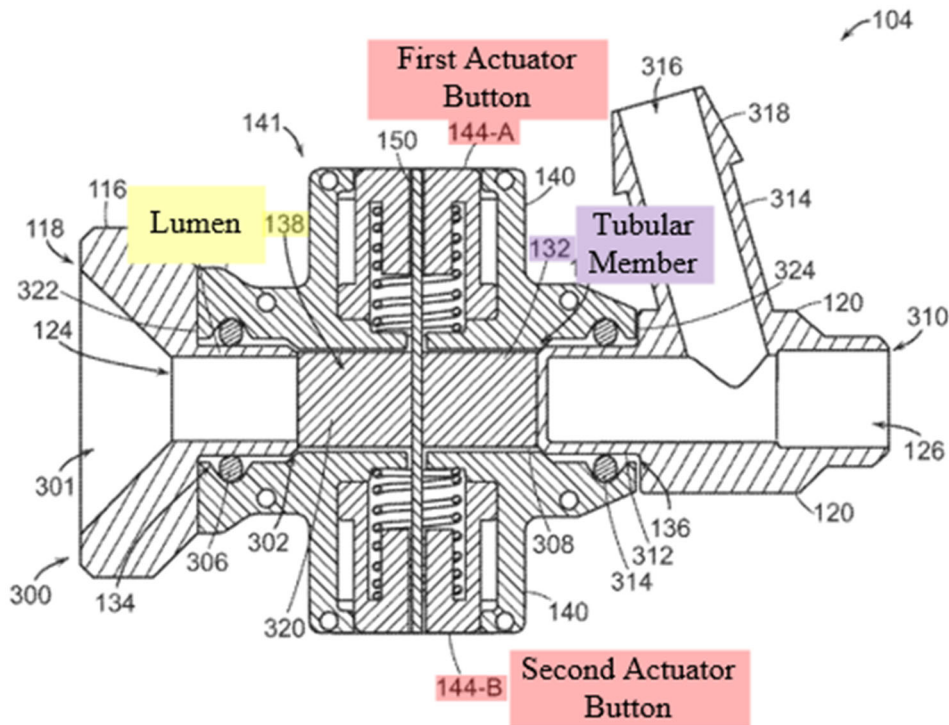


FIG. 3

Id. at 9:54-62. For example, the first and second buttons 144-A, 144-B can be depressed against the first and second springs 148-A, 148-B, respectively, in the second configuration. *Id.* In this position, the filament 150 is loosened, thereby allowing the expansion of the tubular member 132 and the unsealing of the central lumen 138 thereof. *Id.* This arrangement of the constricting mechanism 141 can facilitate sealing of the garrote valve around tools or instruments of a wide range of sizes and/or diameters that fit through the tubular member 132. *Id.* at 8:12-16.

41. The filament 150 can be made from various materials, including a polymer, a synthetic, a metal, nylon, stainless steel, nitinol, silicone, or the like. *Id.* at

- 9:13-16. The filament 150 can comprise a single strand or a plurality of strands, and therefore can comprise one or several threads, lines, cords, rope, ribbon, flat wire, sheet, or tape. *Id.* at 9:16-23.
42. The filament 150 “can comprise a single filament 150” as shown in Figure 6. *Id.* at 12:46-48. The filament 150 can also “comprise multiple filaments” such as a first filament 150-A and a second filament 150-B as shown in Figures 7-9. *Id.* at 12:61-64.
43. The filament 150 can have different configurations as shown in Figures 6-9 of the '384 Patent. For example, as shown in Figure 6, the filament 150 can comprise a single filament configured to form a single loop 604 that extends around the tubular member 132:

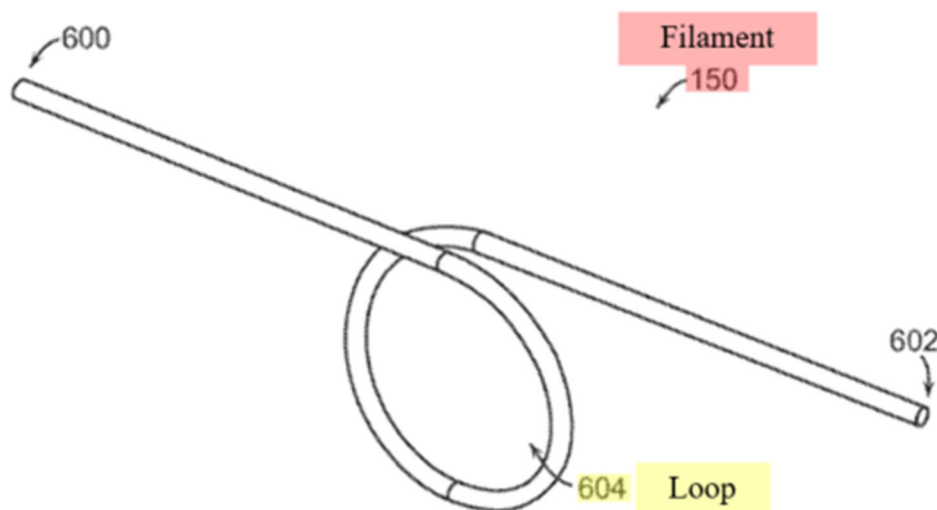


FIG. 6

Id. at 13:18-21. For example, as shown in Figure 7, the filament 150 can comprise a first filament 150-A and a second filament 150-B that each form an individual loop—a first loop 704 and a second loop 706, respectively—around the tubular member 132:

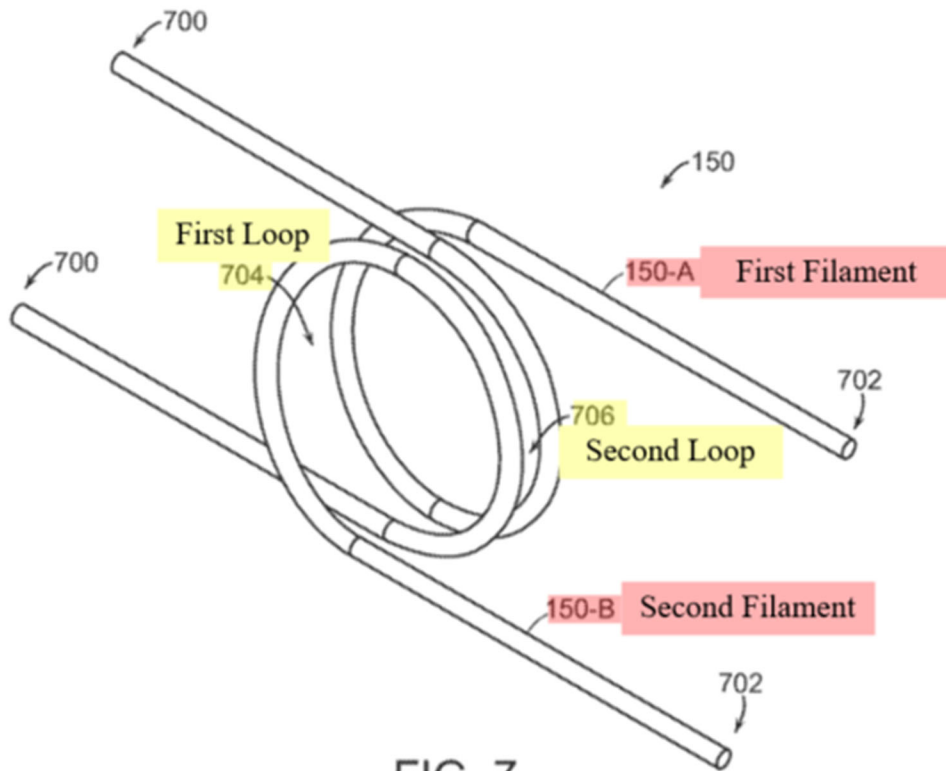
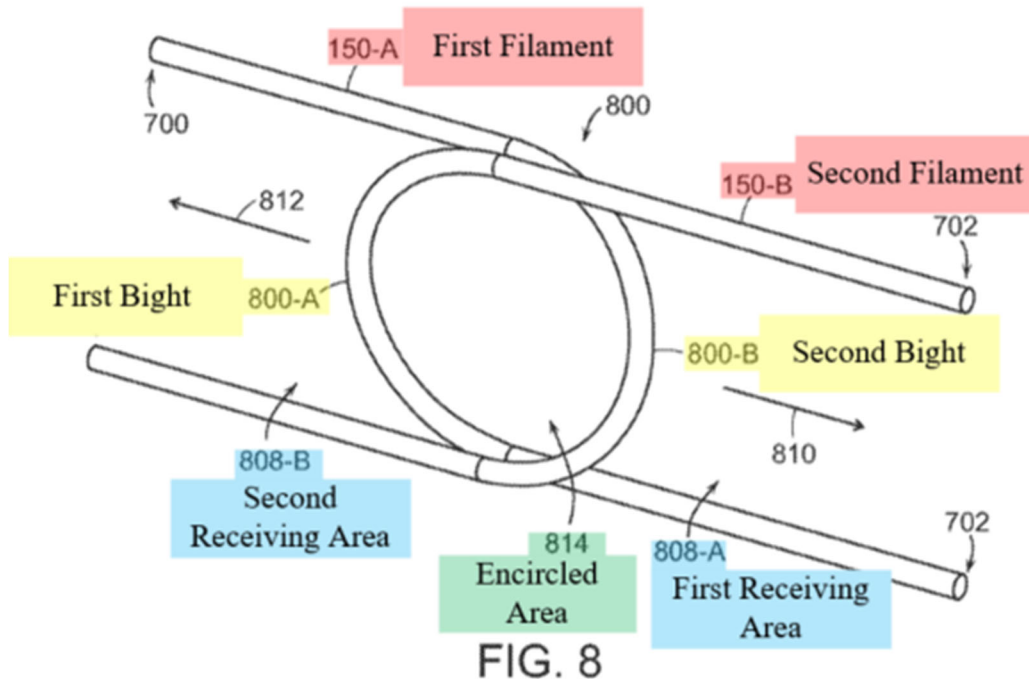


FIG. 7

Id. at 13:21-25.

44. For the filament loop embodiments shown in Figures 6 and 7, the constricting mechanism 141 acts to decrease a diameter or size of the loop 604 (Figure 6), or the first and second loops (Figure 7), when the constricting mechanism 141 is moved from the second (open) configuration to the first (closed configuration) as shown in Figures 2 and 3. *Id.* at 13:26-29.

45. As shown in Figures 8 and 9, in other non-loop embodiments of the '384 Patent the filament 150 can be formed into a single bight or multiple bights. *Id.* at 13:30-32. The '384 Patent specifies that in contrast to a loop, the term “bight” refers to a U-shaped section between the two ends of the filament 150.” *Id.* at 13:32-33. Figures 8 and 9 show the first and second filaments 150-A and 150-B each forming an individual U-shaped bight—a first bight 800-A and a second bight 800-B, respectively:



Id. at 13:34-36.

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

800-B, respectively, for receiving the tubular member 132. *Id.* at 47-51. As further shown above, the first and second receiving areas 808-A and 808-B overlap to define a constricting area 814. *Id.* at 13:57-61. The movement of the constricting mechanism 141 to the first (closed) configuration moves the bights 800-A, 800-B to decrease the size of the encircled area 814 and constrict, collapse, and/or seal the elongate member 132 extending through the encircled area 814, as shown in Figure 9:

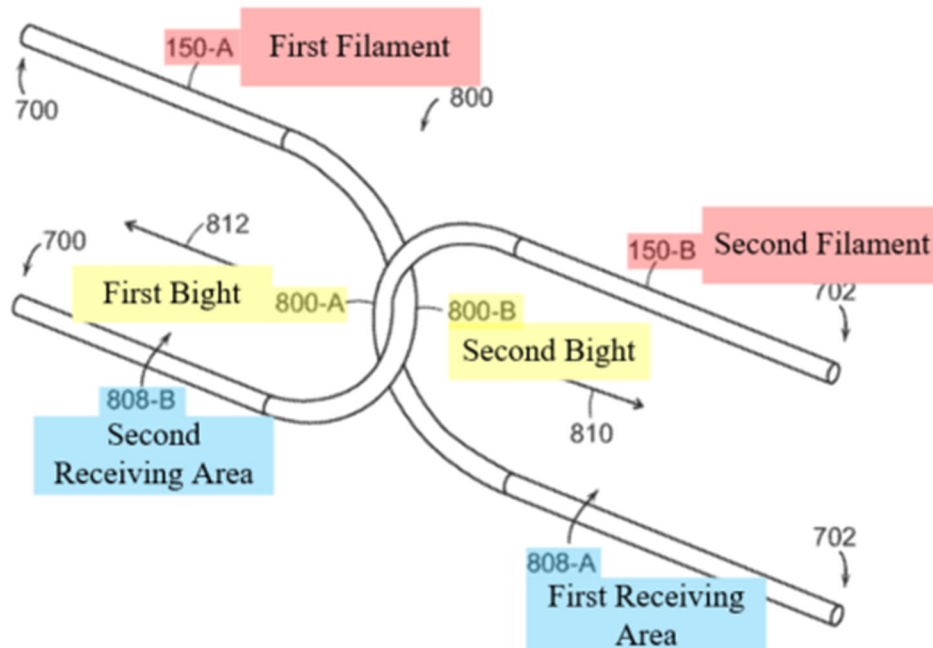


FIG. 9

Id. 13:62-14:5.

47. As I note above, the easy one-handed operation and strong seal of the garrote valve is particularly useful in vacuum thrombectomy procedures. Figure 11 of the '384 Patent discloses one example of a thrombectomy system 1100

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

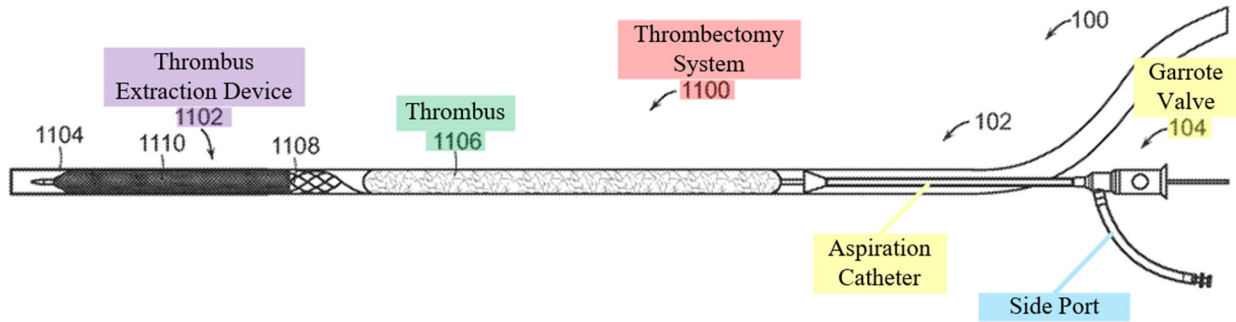


FIG. 11

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

48. For example, the aspiration catheter 102 can have an outer diameter of “at least 18 French, at least 20 French, at least 22 French.” *Id.* at 6:41-45. Sealing a large-bore catheter is particularly challenging because of the large lumen size and the additional polymer material inherent to the larger catheter, requiring additional and focused material collapse/compression. A garrote valve that essentially “cinches” at a particular point is necessarily more effective in this setting than alternative valve configurations imposing diffuse sealing force. Thus, a POSITA would understand, for example, the garrote valve to be particularly useful in thrombectomy procedures using large-bore catheters to apply significant vacuum pressure, such as thrombectomy procedures used to treat pulmonary embolism or deep vein thrombosis.
49. Overall, the garrote valve’s design prioritizes user control, allowing for single-handed operation while maintaining the integrity of the catheter system, including in the face of significant pressure differentials applied during aspiration thrombectomy procedures. In particular, the design allows for quicker and more effective sealing of large-bore catheters used for aspiration thrombectomy in large veins and pulmonary arteries, such as for treating deep vein thrombosis or pulmonary embolism. These features are important to treating physicians and critical to patient health. A robust seal and quick, self-closing valve are critical to reduce patient blood loss during procedures, which can be

significant through a large catheter. Traditional rotating hemostasis valves take many turns to seal the larger bore catheters used in such procedures. The incorporation of bias features and springs ensures that the actuator can quickly and easily function effectively, providing a reliable and efficient means of achieving hemostasis.

B. Prosecution History

50. I have reviewed the prosecution history of the '384 Patent, including the Requirement for Restriction mailed May 8, 2024 (EX1002, pp. 229-234), Inari's response to the Requirement for Restriction filed July 1, 2024 (*id.* at pp. 211-220), and the Notice of Allowance mailed July 26, 2024 (*id.* at 13-22).
51. In the Requirement for Restriction, the Examiner required an election between different species and between different sub-species. *Id.* at pp. 231-232. The species were identified as:
- I) claims 1-14;
 - II) claims 15-22; and
 - III) claims 23-30.

Id. at p. 231. The Examiner identified the sub-species as:

- 1) Figs. 1-4¹;
- 2) Fig. 5;
- 3) Fig. 6;
- 4) Fig. 7;
- 5) Fig. 8;
- 6) Fig. 9; and
- 7) Fig. 12.

Id. at p. 232.

52. Before filing a response to the Requirement for Restriction, Inari and the Examiner conferred in an interview. *Id.* at pp. 171-172. As summarized by the Examiner, “[b]oth [Patent Owner’s attorney] and examiner Vu agreed that the sub-species (filament) in either one of the Figs 6-9 should be examined or combined into the delivery device system in Figs. 1-4.” *Id.* at p. 172. “For example: if the sub-species – filament 150 in Fig. 6 [were] elected, then, the filament 150 in Fig. 6 are combined in the delivery device system 100, in Figs. 1-4,” “[o]r if the sub-species – filament 150 in Fig. 7 [were] elected, in that

¹ As I explain below, later the Examiner acknowledged that this sub-species was not separate from the embodiments in Figures 6-9 but instead worked with those embodiments.

case, the filament 150 in Fig. 7 are combined in the delivery device system 100 in Figs. 1-4,” and likewise for the sub-species identified by the Examiner in Figures 8-9. *Id.* That agreement comports with what a POSITA would understand—the specific and different filament arrangements in Figures 6-9 of the ’384 Patent would be incorporated into the more general valve of, for example, Figures 1-4.

53. Based on that understanding, Inari elected species I (claims 1-14) and sub-species 4) directed to Figure 7, and withdrew claims 15-30 in view of the then-pending Restriction Requirement. *Id.* at p. 220. As I explained above, the embodiment in Figure 7 discloses two filaments: a first filament 150-A and a second filament 150-B each separately forming an individual loop—a first loop 704 and a second loop 706, respectively:

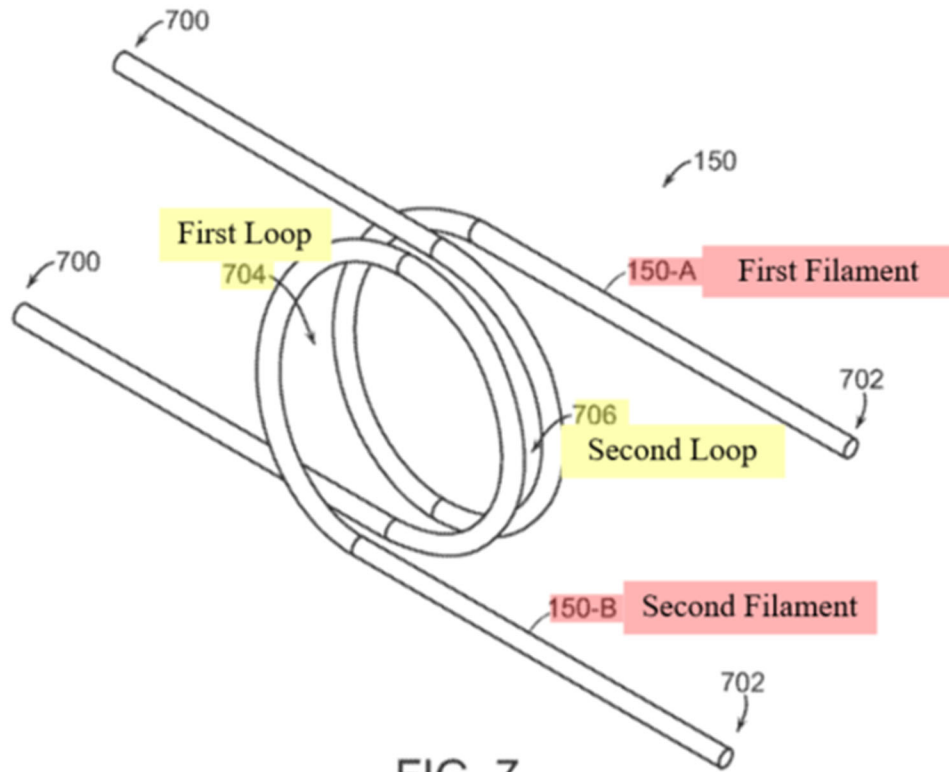


FIG. 7

EX1001, 13:21-25. In contrast, the non-elected embodiment in Figure 6 of the '384 Patent discloses a single filament forming a single loop, and the non-elected embodiment in Figures 8-9 of the '384 Patent discloses two filaments each forming an individual bight. *Id.* at 13:18-21 & 13:34-36.

54. In the Notice of Allowance, the Examiner found claims 1-14 allowable and withdrew the restriction of claims 15-30 because those claims “require[] all the limitations of an allowable claim,” such that each of claims 1-30 were indicated to be allowable. EX1002, p. 18. The Examiner further identified Hartley and Eller (the same references applied by Petitioner here) as the “closest prior art of record” before finding that both references fail to “disclose the

device” recited in the claims that issued in the ’384 Patent and challenged here. *Id.* at pp. 20-21. Specifically, the Examiner explained that Hartley “fails to disclose that the actuator is as a pair of actuators; a second filament” and that Eller “fails to disclose that the actuator is a pair” *Id.* That is, the Examiner expressly found that Hartley fails to disclose a second filament and a pair of actuators, and that Eller fails to disclose a pair of actuators. I agree with the Examiner’s conclusions regarding Hartley and Eller.

C. Person of Ordinary Skill in the Art

55. A POSITA in September 2017 would have had an undergraduate degree in mechanical engineering or a related engineering discipline and 2 to 4 years of product design or engineering experience designing medical devices in the field of the ’384 Patent. A person with less education but more relevant practical experience, or more relevant education but less practical experience, may also meet this standard.
56. Petitioner asserts that a “POSITA in September 2017 would have had an undergraduate degree in mechanical engineering or a related engineering discipline and 2-4 years of product design or engineering experience.” Petition, p. 16. I disagree—Petitioner’s suggested definition is insufficient to qualify as a POSITA because, although Petitioner’s suggested definition of a POSITA includes a comparable level of education to mine, it does not include any

experience in designing medical devices, particularly in the context of the '384 Patent. Having experience in the relevant field is important for designing hemostasis valves.

57. Nevertheless, I apply Petitioner's definition throughout my declaration as, even under this too-low definition of ordinary skill, a POSITA would have understood the Claims of '384 Patent to be patentable over the prior art references cited in grounds 1-6. I was also at least a person of ordinary skill in the art as of the priority date of the '384 Patent according to this standard.

D. Claim Construction

58. 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).
59. Here, Petitioner proposes a construction only for the term "filament" recited in each of independent Claims 1, 15, and 23. The '384 patent uses and applies the plain and ordinary meaning for the term "filament"—a "thin, flexible

length of material formed by one or more strands of material”—as would be understood by a person of ordinary skill in the art as of September 6, 2017, for the reasons I have explained in my declarations in IPRs for related U.S. Patent No. 11,697,011 (*Imperative Care, Inc. v. Inari Medical, Inc.*, IPR2024-01157, EX2001 & EX2008), U.S. Patent No. 11,697,012 (*Imperative Care, Inc. v. Inari Medical, Inc.*, IPR2025-00156, EX2001 & EX2008), U.S. Patent No. 11,844,921 (*Imperative Care, Inc. v. Inari Medical, Inc.*, IPR2025-00728, EX2024), and U.S. Patent No. 11,554,005 (*Imperative Care, Inc. v. Inari Medical, Inc.*, IPR2025-00186, EX2001 & EX2026). (I collectively refer to those IPRs as the “related IPRs” in my Declaration here.) Here, however, my analysis of the patentability of independent Claims 1, 15, and 23 does not depend on the construction of “filament” regarding its flexibility. Accordingly, I have not provided or repeated my reasons for the proper construction of “filament” in this Declaration, but reserve my right to do so.

VI. GROUND 1—THE COMBINATION OF SCHAFFER AND HARTLEY DOES NOT RENDER OBVIOUS INDEPENDENT CLAIMS 1, 15, AND 23

60. Petitioner and its expert, Mr. Thornton, allege that Schaffer in combination with Hartley renders obvious independent Claims 1, 15, and 23 of the '384 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 the independent Claims including, for example, the “first filament [configured/extending] in a first loop” and the “second filament [configured/extending] in a second loop.” Therefore, the combination of Schaffer and Hartley does not render obvious independent Claims 1, 15, and 23.

61. I understand that for a patent claim to be rendered obvious, the differences between the claimed invention and the prior art must be such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains, the claimed invention is obvious. Even if all limitations of a claimed invention are disclosed by the prior art combination, Petitioner must demonstrate an apparent reason to combine the known elements in the fashion of the patent claim at issue and that a person of ordinary skill in the art would have reasonable expectation of success in pursuing that combination. A prior art reference teaches away from a modification of a prior art reference when a person of ordinary skill in the art would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path followed by and claimed in the patent.
62. Petitioner asserts that Hartley discloses a hemostasis valve “with first and second filaments that form a loop around a collapsible tubular member” and that

a “POSITA would have been motivated to substitute Hartley’s ... filaments for Schaffer’s U-shaped actuating members with a reasonable expectation of success.” Petition, pp. 26-27, 69-70, & 75. More specifically, Petitioner asserts that Schaffer combined with Hartley renders obvious the limitations of a “first filament” and a “second filament” required by independent Claims 1, 15, and 23 “in two ways”: (1) Hartley’s single string includes two filaments (*id.* at pp. 27-37) and (2), if not, a POSITA “would have found it obvious to substitute two of Hartley’s strings for Schaffer’s U-shaped actuating members” (*id.* at pp. 37-40).

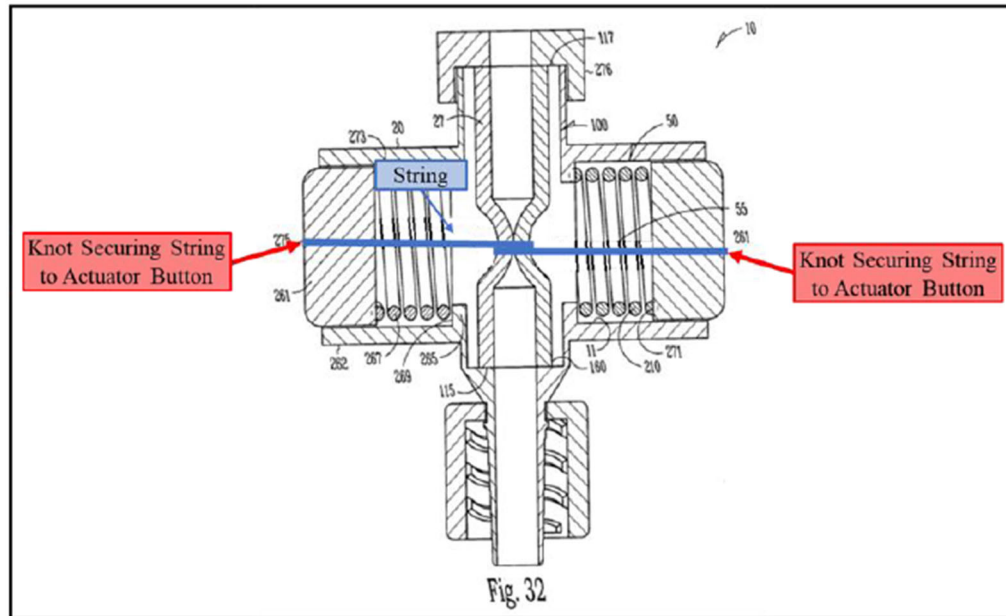
63. I disagree that Hartley discloses a “first filament” and a “second filament” as required by independent Claims 1, 15, and 23 and also that it would have been obvious to duplicate Hartley’s string and replace Schaffer’s U-shaped members with two of Hartley’s strings for at least the reasons set forth below.

A. Petitioner is Incorrect that Hartley’s String Includes Two Filaments as Required by Independent Claims 1, 15, and 23

64. Petitioner’s “first way” that Schaffer in combination with Hartley renders obvious independent Claims 1, 15, and 23 is incorrect because Hartley’s single string 14 is not a “first filament” and a “second filament” as required by those Claims. Petitioner contends that in its proposed combination the first end of Hartley’s string would be secured to Schaffer’s first actuator button, Hartley’s string would loop around Schaffer’s seal module, and the second end of

Hartley's string would be secured to Schaffer's second actuator button, as shown in Petitioner's demonstrative illustration of the proposed substitution:

Demonstrative Illustration
Schaffer + Hartley's String

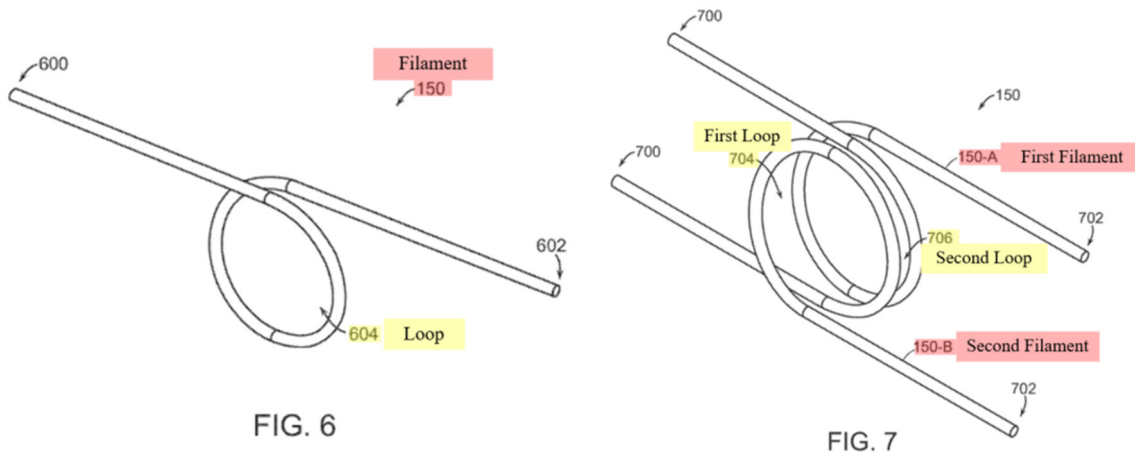


Petition, p. 35. Petitioner further alleges that in that combination, Hartley's string 14 is a "first filament" and a "second filament" because a "POSITA would have understood that Hartley's string 14 would be formed from at least two threads twisted together" and that "[e]ach thread forming the string is a 'filament.'" *Id.* at p. 28.

65. I disagree that a POSITA would have been motivated to substitute Hartley's string 14 into Schaffer's valve for at least the reasons I explained in my declarations in the related IPRs. Nevertheless, even assuming that a POSITA would have been motivated to substitute one of Hartley's strings, Hartley's

single string 14 does not comprise a “first filament” and a “second filament” as required by the Claims.

66. First, as I explain in §V.A. above, the '384 Patent discloses in Figure 6 an embodiment including a single filament 150 forming a single loop 604 and in Figure 7 an embodiment including two filaments: a first filament 150-A and a second filament 150-B each forming an individual first loop 704 and a second loop 706, respectively:



EX1001, 13:18-25. A POSITA would understand based on that disclosure that the “first filament [configured/extending] in a first loop” and the “second filament [configured/extending] in a second loop” as recited in the independent Claims requires separate first and second filaments as shown in Figure 7 rather than a single filament composed of different threads like Figure 6 as Petitioner alleges. What’s more, in response to the Requirement for Restriction, Inari expressly elected the embodiment in Figure 7 of the '384 Patent

having two filaments each forming a loop as opposed to the embodiment in Figure 6 having a single filament formed in a single loop. EX1002, p. 220. A POSITA would further understand based on that election that the “first filament” and the “second filament” recited in the Claims are separate filaments forming separate loops as shown in Figure 7 of the ’384 Patent and not a single filament forming a single loop as shown in Figure 6 and in Petitioner’s proposed combination.

67. Second, a POSITA would also not have understood Hartley’s single string 14 to include a “first filament” and a “second filament” because such a finding would be directly contrary to the Patent Office’s finding in the Notice of Allowance that Hartley “fails to disclose ... a second filament.” EX1002, p. 20. That is, the Patent Office correctly understood Hartley’s string 14 as a single filament rather than multiple filaments as recited in the Claims of the ’384 Patent.
68. Third, Petitioner’s reliance on Claim 6 of the ’384 Patent as “confirm[ing] that the threads of Hartley’s string are a ‘first filament’ and ‘second filament’” is misplaced. Petition, p. 28. Claim 6 simply clarifies that the first filament and second filament “each comprise a plurality of strands woven together.” That recitation confirms the disclosure of the ’384 Patent which distinguishes different embodiments in which each filament “can comprise a single strand such

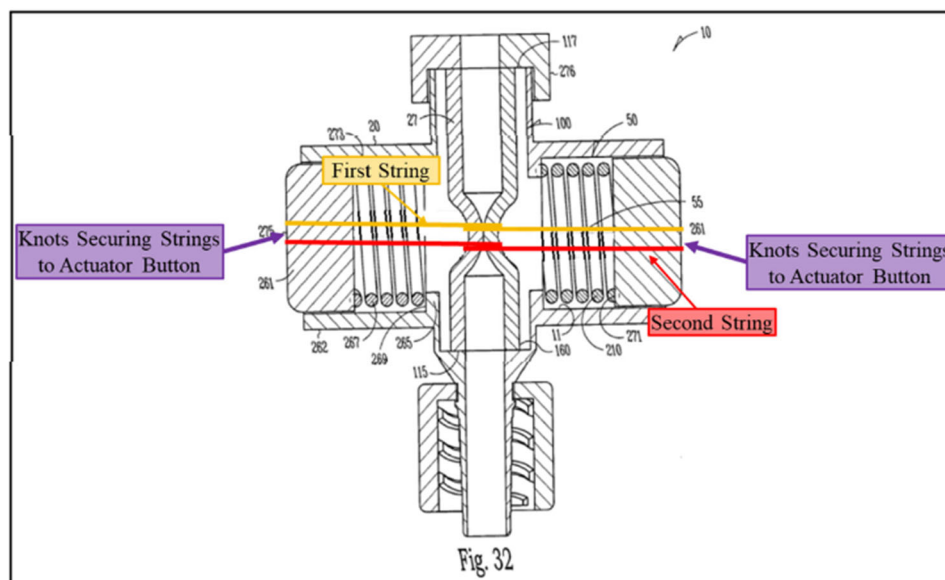
as, for example, a monofilament” or “a plurality of strands that can be, for example, twisted, woven, grouped, and/or fused to form the filament.” EX1001, 9:16-21. That is, a POSITA would understand based on Claim 6 that the “first filament” and the “second filament” recited in Claim 1 could each either be a monofilament (i.e., single strand) or multiple strands woven together, and that Claim 6 narrows Claim 1 by requiring that the “first filament” and the “second filament” each comprise multiple strands woven together. The ’384 Patent is explicit that a single filament can be a monofilament or it can include a “plurality of strands,” but a single filament does not become both a first and second filament simply because of multiple strands twisted together. EX1001, 9:16-21 (“In some embodiments, the filament can comprise a single strand such as, for example, a monofilament, and in some embodiments, the filament can comprise a plurality of strands that can be, for example, twisted, woven, grouped, and/or fused to form the filament.”). Accordingly, Claim 6 does not mean that a single string made up of twisted or woven fibers comprises both the first and second filaments and the first and second loops recited in the Claims.

69. For those reasons, Hartley’s single string 14 is not “a first filament [configured/extending] in a first loop” and “a second filament [configured/extending] in a second loop” as recited in the independent Claims.

B. It Would Not Have Been Obvious to a POSITA to Have Substituted Two of Hartley's Strings for Schaffer's U-Shaped Actuating Members

70. Petitioner's "second way" that Schaffer in combination with Hartley renders obvious independent Claims 1, 15, and 23 is incorrect because it would not have been obvious to a person of ordinary skill in the art to have substituted two of Hartley's strings for Schaffer's U-shaped actuating members. Petitioner contends that in that alternative combination two of Hartley's strings would be included in Schaffer's valve and the first end of each string would be secured to Schaffer's first actuator button, each string would loop around Schaffer's seal module, and the second end of each string would be secured to Schaffer's second actuator button, as shown in Petitioner's demonstrative illustration of the proposed substitution:

Demonstrative Illustration
Schaffer + Hartley's Strings



Petition, p. 40.

71. But, nowhere does Hartley disclose or suggest using two of the strings 14 in its valve. Instead, every embodiment of Hartley includes only the single string 14. And, while Schaffer’s valve has two actuating members 55—those actuating members 55 are not “filaments” (let alone filaments formed in a loop) and the configuration of the actuating members is “*opposed* to the claimed configuration that requires two filaments that each form a loop around the tubular member” as Petitioner correctly concedes. Petition, p. 26 (my emphasis added). Accordingly, neither Schaffer nor Hartley disclose “a first filament [configured/extending] in a first loop” and “a second filament [configured/extending] in a second loop” as recited in the independent Claims.
72. Despite those differences, Petitioner and its expert assert that a POSITA would have duplicated Hartley’s single string 14 and included those two strings in Schaffer’s valve to “provide a more robust and reliable seal” based on Hartley’s disclosure that its string 14 “is wound preferably twice around the cylindrical diaphragm.” Petition, p. 37; EX1003, ¶ 79; EX1007, ¶ [0031]. Specifically, Petitioner and its expert argue that a POSITA “would have been motivated to use two separate strings, each looped once around the tubular member, as opposed to a single string looped twice around the tubular member, for a few reasons”: (1) “to reduce friction,” (2) “to ensure that the sealing

area is wider,” and (3) to “provide[] a redundancy to the valve that cannot be accomplished with a single string.” Petition, pp. 37-38; EX1003, ¶¶ 80-82.

73. I disagree that a POSITA would have been motivated to substitute Hartley’s string 14—let alone two of them—into Schaffer’s valve for at least the reasons I explained in my declarations in the related IPRs. Nevertheless, even assuming that a POSITA would have been motivated to include Hartley’s single string 14 in Schaffer’s valve, a POSITA would not have been motivated to include two of Hartley’s strings 14 in Schaffer’s valve—an arrangement not disclosed by Hartley—based on any of Petitioner’s “few reasons.”
74. First, Petitioner’s purported reason to modify that a “POSITA would have been motivated to use two separate strings to reduce the friction” because “a single string looped twice around the tubular member will create more friction [than two separate strings] because more of the string is in contact with the surface of the tubular member” such that “the springs will need to exert more pulling force on the string to constrict the tubular member, and the tubular member will need greater resiliency to overcome the friction and return to its expanded configuration” is inaccurate and would not have motivated a POSITA. Petition, p. 37.
75. In Petitioner’s purported arrangement adding two of Hartley’s single string 14 in Schaffer, each of the two strings extends in a loop around Schaffer’s seal

module 160. *Id.* at p. 40. Each string contacts Schaffer's tubular seal module along its loop. Likewise, in Hartley where the string 14 "is wound preferably twice around the cylindrical diaphragm," the string 14 contacts the tubular diaphragm along each of the two windings. Accordingly, in Petitioner's purported arrangement including two strings and in Hartley's express disclosure of the single string 14 wound "twice around" the tubular diaphragm, the same total amount of string contacts the tubular member. Therefore, a POSITA would understand that the friction is the same in Petitioner's proposed two-string arrangement as in Hartley's single-string arrangement such that a POSITA would not have been motivated to use two of Hartley's string 14 instead of one to reduce friction.

76. Additionally, even if there were more friction (which there is not) using a single, twice-wound string, a POSITA would not have been motivated to deviate from Hartley's disclosure of a single string because Schaffer's springs may "need to exert more pulling force on the string to constrict the tubular member, and the tubular member will need greater resiliency to overcome the friction and return to its expanded configuration" based on Petitioner and its expert's own statements. In particular, Petitioner and its expert allege for its "first way" of obviousness that "if the resiliency of Schaffer's lumen required adjustment to function with Hartley's string, a POSITA would have possessed

the skills and knowledge to select an appropriate material with the proper resiliency.” Petition, p. 36; EX1003, ¶ 76. Likewise, in the related IPRs, Petitioner and its expert have similarly asserted that “POSITAs would have found it obvious to make adjustments ... including ... adjusting Schaffer’s spring strength to apply additional force” and to “exert more tension on the filament by, for example, changing the spring material or adjusting the springs coils.” See, e.g., *Imperative Care, Inc. v. Inari Medical, Inc.*, IPR2025-00156, Paper 2, p. 71. That is, Petitioner and its expert contradictorily explain for different arguments in the same and other IPRs that a POSITA would easily be able to adjust the resiliency of Schaffer’s lumen and/or the strength of its springs to function with Hartley’s string and any friction therefrom—without the need to introduce two separate strings in an arrangement not taught by Hartley or Schaffer.

77. Second, Petitioner’s purported reason to modify Schaffer to include two of Hartley’s strings 14 “to ensure that the sealing area is wider” is again based on an inaccurate understanding of the physics of Hartley’s single double-wound string and Petitioner’s proposed arrangement. As I explain above, in Petitioner’s purported arrangement each of the two strings extends in a loop around Schaffer’s seal module 160 and contacts the seal module along its loop. Likewise, in Hartley the string 14 contacts the tubular diaphragm along

each of its two windings when it “is wound preferably twice around the cylindrical diaphragm.” EX1007, ¶ [0031]. Petitioner and its expert allege that Hartley’s string 14 seals where it contacts the tubular containment structure: “Hartley’s string may seal more effectively across a wider range of tool diameters and shapes than Schaffer’s U-shaped actuating members ... because the string more precisely conforms to the tool diameters and shapes.” Petition, pp. 30-31; EX1003, ¶ 71. Thus, the purported “sealing area” in Petitioner’s proposed substitution is not “wider” than the sealing area of Hartley’s single string 14 wound twice around the tubular diaphragm. Instead, the sealing area is the same as the single string 14 of Hartley—Hartley’s single string seals where the two windings contact the tubular diaphragm and Petitioner’s purported two strings seal where the loops contact Schaffer’s seal module. That is, whether wound twice or formed into two loops, the windings and loops have the same sealing width. Accordingly, a POSITA would not have been motivated to duplicate Hartley’s string 14 to arrive at an arrangement not found in Hartley to widen the sealing area because Hartley’s disclosure of a single string 14 wound twice has the same sealing width.

78. Moreover, a POSITA would understand that forming a “small gap between the strings that remains after use,” as Petitioner proposes, would introduce a region for stagnant blood formation that could complicate any procedure

using the valve. Petition, p. 38. Namely, the gap between the strings would create a stagnant blood pool from back bleed, that in turn can lead to thrombus (clot) formation. A POSITA would not have been motivated to arrive at Petitioner's proposed combination for that additional reason.

79. Third and finally, Petitioner's purported reason to modify Schaffer to include two of Hartley's strings 14 to "provide a redundancy" that "ensures that the valve seals even if one string fails to tighten around the tubular member" would not have sufficiently motivated a POSITA to modify Schaffer and Hartley in a manner not taught by any of those references. Petition, p. 38; EX1003, ¶ 82. For example, a POSITA would understand that, in Petitioner's purported modification to Schaffer's valve using two strings instead of one, the two strings might interfere with one another, especially after Schaffer's actuator buttons are depressed one or more times and if the valve were tilted relative to gravity such that one string moves toward the other along the seal module. Specifically, when Schaffer's actuator buttons are depressed one of Hartley's strings might move underneath the loop of the other string, potentially reducing the sealing effectiveness of the loops. Thus, a POSITA would understand that any redundancy of using two strings may be offset by the possibility of failure or reduced sealing effectiveness where the two strings interfere with one another. Indeed, Petitioner's proposed arrangement would increase the

cost and complexity of the proposed valve without any of Petitioner's proposed advantages.

80. Additionally, Petitioner's reason to "provide a redundancy" in the case of failure of Hartley's string 14 is directly contrary to their arguments in the related IPRs. For example, as I explained in my declarations in the related IPRs, a POSITA would not have substituted Hartley's single string for Schaffer's actuating members at least in part because such a substitution would undermine the durability of Schaffer's valve. *See, e.g., Imperative Care, Inc. v. Inari Medical, Inc.*, IPR2025-00156, EX2008, ¶¶ 143-154. In response, Petitioner and its expert argued that Hartley does not "suggest[] that durability is an issue," that "durable strings and wire materials for medical devices would have been available to POSITAs before 2017," and that "durability would not have dissuaded POSITAs from combining Hartley's string ... with Schaffer's valve." *Id.* at Paper 17, p. 11; *id.* at EX1020, ¶¶ 48-49. Accordingly, based on those assertions of Petitioner and its expert that Hartley's string is sufficiently durable, a POSITA would not have been motivated to duplicate Hartley's single string 14 and include that duplication in Schaffer's valve to provide redundancy in the case of failure of the string 14—according to Petitioner and its expert, Hartley's single string would suffice.

C. Neither Schaffer nor Hartley Disclose Any Filament Acted Upon by a Pair of Actuators, e.g., Opposing Actuators

81. Independent Claim 1 of the '384 Patent requires a “pair of actuators movable from a first position to a second position” wherein each of the first filament and the second filament “includes a first portion operably acted upon by a first one of the actuators and a second portion operably acted upon by a second one of the actuators.” Neither Schaffer nor Hartley disclose any U-shaped member, string, or other member with different portions operably acted upon by a pair of actuators as required by independent Claim 1.
82. For example, in Schaffer each of the actuating members 55 is attached to only one of the actuator buttons 261 (e.g., at a first portion and at a second portion) such that each of the two actuator buttons 261 operably acts on only one of the actuating members 55:

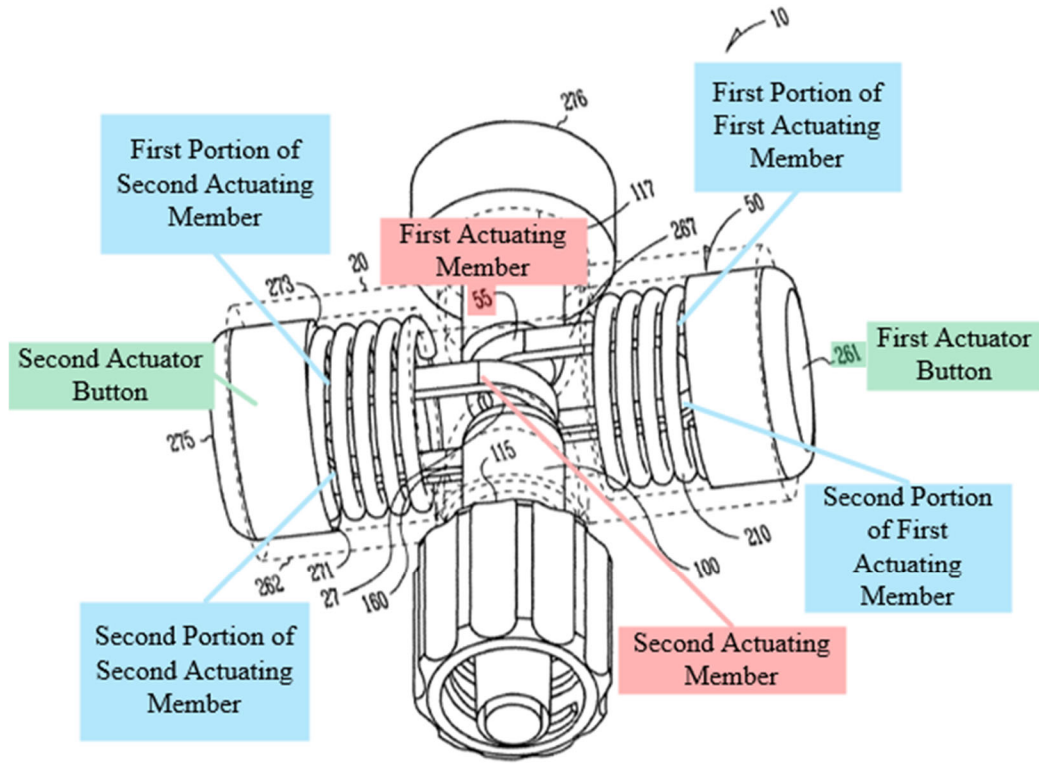


Fig. 31

EX1005, Fig. 31.

83. In Hartley's valve, the *single* string 14 extends around a cylindrical elastomeric diaphragm 8 and is attached by knots 16 and 18 at each end to a *single* rotary actuator 12 that controls movement of both ends of the string 14:

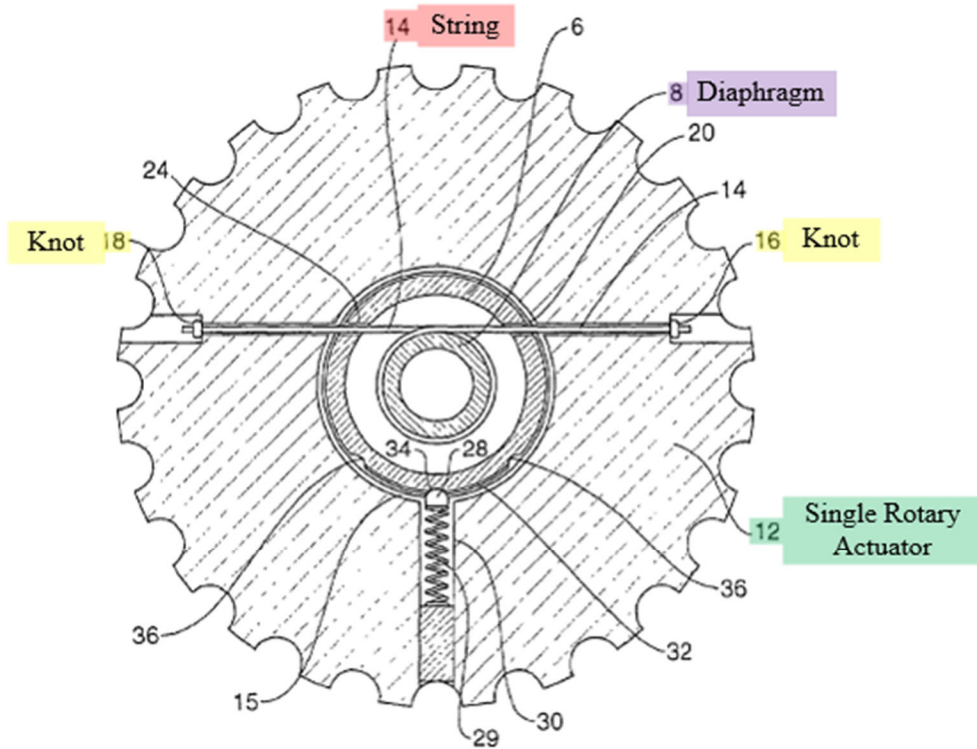


Fig 3

EX1006, ¶ [0031]. Thus, Hartley discloses a single actuator 12 that operably acts on the single string 14.

84. Accordingly, independent Claim 1 is not rendered obvious by the combination of Schaffer and Hartley because neither Schaffer nor Hartley disclose any filament—let alone a first filament and a second filament—having “a first portion operably acted upon by a first one of the actuators and a second portion operably acted upon by a second one of the actuators,” as required by independent Claim 1. Independent Claims 15 and 23 are also not rendered obvious by the combination of Schaffer and Eller for the same reasons.

VII. GROUND 2—THE COMBINATION OF SCHAFFER AND ELLER DOES NOT RENDER OBVIOUS INDEPENDENT CLAIMS 1, 15, AND 23

85. Petitioner and its expert, Mr. Thornton, allege that Schaffer in combination with Eller renders obvious independent Claims 1, 15, and 23 of the '384 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 the independent Claims including the “first filament [configured/extending] in a first loop” and “second filament [configured/extending] in a second loop.” Therefore, the combination of Schaffer and Hartley or Eller does not render obvious independent Claims 1, 15, and 23.

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

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

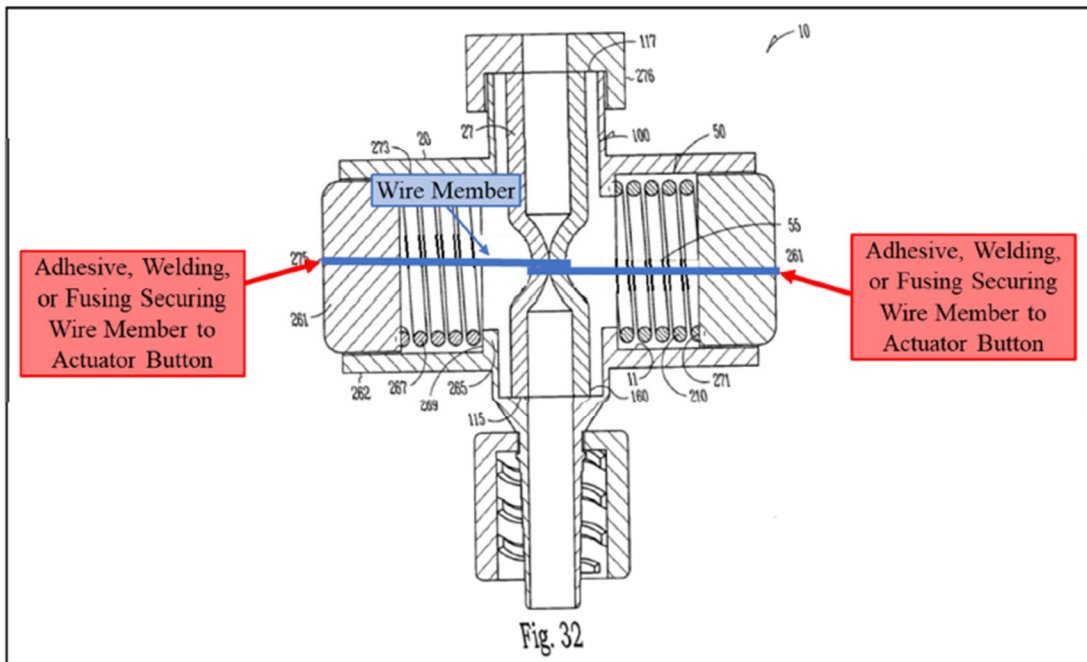
87. Petitioner argues for ground 2 that Eller discloses a hemostasis valve “with first and second filaments that form a loop around a collapsible tubular member” and that a “POSITA would have been motivated to substitute ... Eller’s filaments for Schaffer’s U-shaped actuating members with a reasonable expectation of success.” Petition, pp. 26-27, 69-70, & 75. More specifically, Petitioner argues that Schaffer combined with Eller renders obvious the limitation of a “first filament” and a “second filament” as required by independent Claims 1, 15, and 23 and “in two ways”: (1) Eller’s wire member includes two filaments (*id.* at pp. 40-47) and (2), if not, a POSITA “would have found it obvious to substitute two of Eller’s wire members for Schaffer’s two actuator members” (*id.* at pp. 47-50).
88. I disagree that Eller discloses a “first filament” and a “second filament” as required by independent Claims 1, 15, and 23 and also disagree that it would have been obvious to substitute two of Eller’s wire members into Schaffer’s

valve and arrange them both in loops with ends connected to different actuators for at least the reasons set forth below.

A. Petitioner is Incorrect that a Single One of Eller's Wire Members Includes Two Filaments as Required by Independent Claims 1, 15, and 23

89. Petitioner's "first way" that Schaffer in combination with Eller renders obvious independent Claims 1, 15, and 23 is incorrect because a single one of Eller's wire members is not a "first filament" and a "second filament" as required by those Claims. Petitioner contends that in its proposed combination the first end of Eller's wire member would be attached to Schaffer's first actuator button, Eller's wire member would loop around Schaffer's seal module, and the second end of Eller's wire member would be attached to Schaffer's second actuator button, as shown in Petitioner's demonstrative illustration of the proposed substitution:

Demonstrative Illustration Schaffer + Eller's Wire Member



Petition, pp. 44-46. Petitioner further alleges that in that combination, Eller's wire member is a "first filament" and a "second filament" because a "POSITA would have ... understood that Eller's wire member would be formed from at least two filaments twisted together" and that "the twisted 'strands and/or fibers' comprising Eller's wire member are each a flexible filament.'" *Id.* at pp. 41-42.

90. I disagree that a POSITA would have been motivated to substitute Eller's wire member into Schaffer's valve for at least the reasons I explained in my declarations in the related IPRs. Nevertheless, even assuming that a POSITA would have been motivated to substitute one of Eller's wire members, a single

one of Eller's wire members **does not** include a "first filament" and a "second filament" as required by the Claims for the same reasons I explain in §VI.A. above related to the purported combination of Schaffer and Hartley.

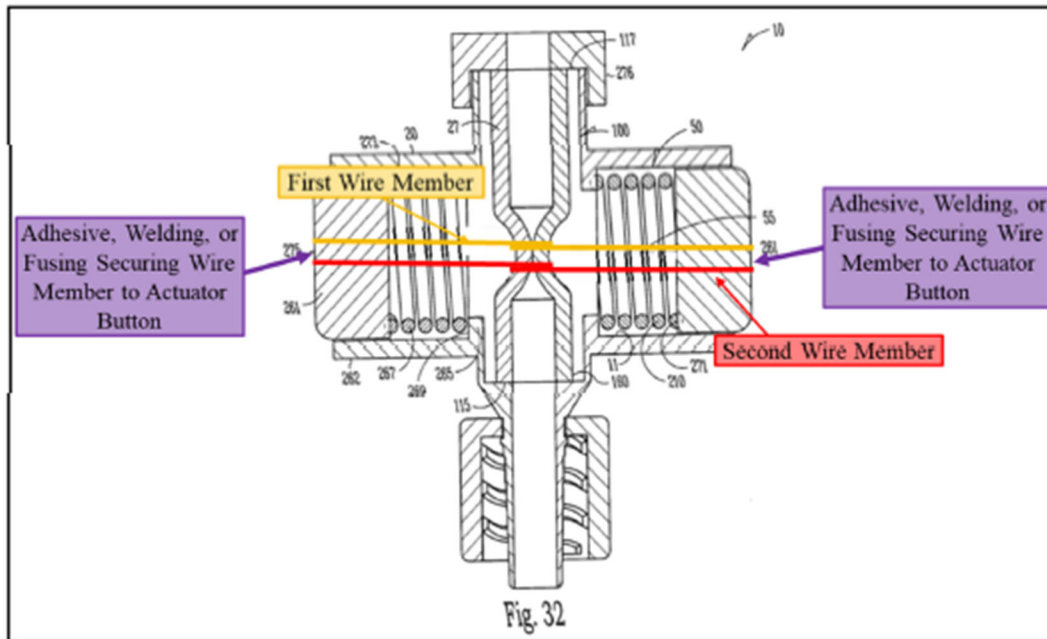
91. Namely, a POSITA would understand based on the disclosure and prosecution history of the '384 Patent that the "first filament [configured/extending] in a first loop" and the "second filament [configured/extending] in a second loop" required by the independent Claims require *separate* first and second filaments as shown in Figure 7 rather than a single filament composed of different strands and/or fibers as Petitioner alleges. For those reasons, a single one of Eller's wire members does not comprise "a first filament [configured/extending] in a first loop" and "a second filament [configured/extending] in a second loop" as recited in the independent Claims.

B. It Would Not Have Been Obvious to a POSITA to Have Substituted Two of Eller's Wire Members for Schaffer's U-Shaped Actuating Members

92. Petitioner's "second way" that Schaffer in combination with Eller renders obvious independent Claims 1, 15, and 23 is incorrect because it would not have been obvious to a POSITA to have substituted two of Eller's wire members for Schaffer's U-shaped actuating members such that the wire members are "[configured/extending] in a first loop" and "[configured/extending] in a second loop" as required by those Claims. Petitioner contends that in its proposed

combination two of Eller's wire members would be included in Schaffer's valve, the first end of each wire member would be attached to Schaffer's first actuator button, each wire member would loop around Schaffer's seal module, and the second end of each wire member would be secured to Schaffer's second actuator button, as shown in Petitioner's demonstrative illustration of the proposed substitution:

Demonstrative Illustration Schaffer + Eller's Wire Member



Petition, pp. 48-50.

93. Petitioner provides three theories as to why their combination of Schaffer and Eller is obvious: (1) Eller discloses the use of multiple wire members, (2) the combination is a simple substitution, and (3) a POSITA would have been motivated to use two wire members with Schaffer's valve to "provide a more

robust and reliable seal for the reasons explained above with respect to Hartley.” *Id.* at pp. 48-49. I disagree because Eller does not disclose any embodiment including more than one, single wire member forming a loop, and the proposed combination does not involve the substitution of a known element for another but, instead, a new construction that differs from the arrangements taught by both Schaffer and Eller.

1. Eller does not disclose or suggest a valve including more than one wire member extending in or configured in a loop.

94. A POSITA would not have found it obvious to arrive at Petitioner’s purported combination based on Eller’s disclosure that its hemostasis valve “can include any suitable number of wire members” because Eller does not disclose any embodiment including multiple wire members that form first and second loops as required by the Claims. Petition, p. 48; EX1007, 16:7-19. For example, the disclosure of Eller relied on by Petitioner that its hemostasis valve “can include any suitable number of wire members” relates to the embodiment illustrated in Figures 1-10C of Eller.
95. Figures 1-10C of Eller illustrate a “selective fluid barrier valve device 10 that has ... a housing 16, an actuator 18, a sleeve 20, a first wire member 22, a second wire member 24, [and] a third wire member 26”:

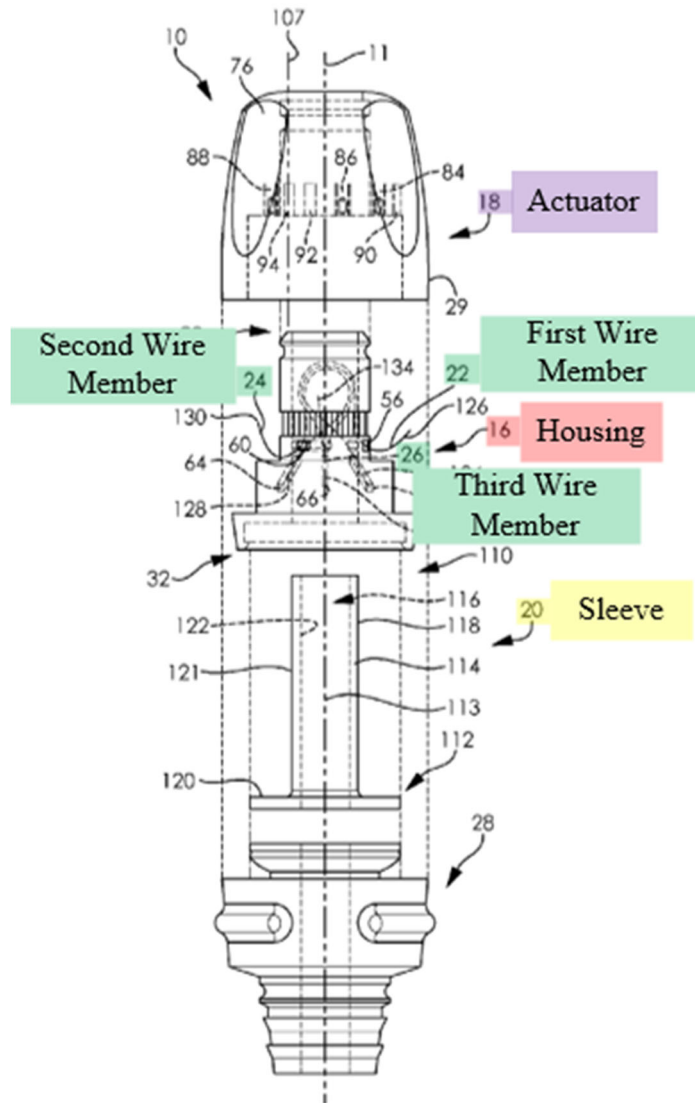
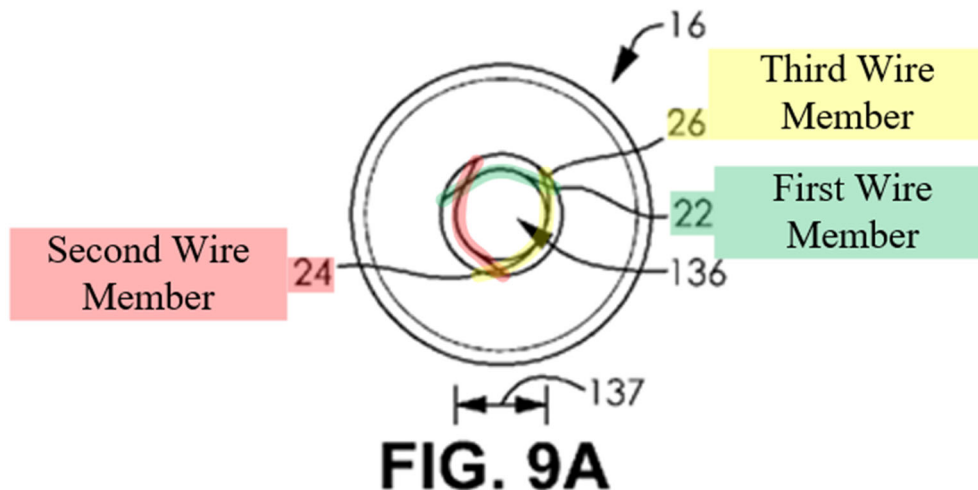


FIG. 2

EX1007, 5:2-6. The “wire member has a first end 124 attached to the housing 16 and a second end 126 attached to the actuator 18.” EX1007:12:52-58. The second wire member 24 and the third wire member 26 likewise have a first end attached to the housing 16 and a second end attached to the actuator 18. *Id.* at 12:21-14:27. As best seen in Figures 9A-10C of Eller (Figure 9A annotated below) (i) the “first wire member 22 extends ... around *a portion* of the

outer surface 121 of the sleeve 20,” (ii) the “second wire member 24 extends ... around *a portion* of the outer surface 121 of the sleeve 20,” and (iii) the “third wire member 26 extends ... around *a portion* of the outer surface 121 of the sleeve 20”:



Id. at 12:58-64, 13:27-33, & 13:64-14:3 (my emphasis added). None of the wire members 22-26 in this embodiment extend in a “loop” because each of the wire members extends only partially around “a portion” of the sleeve 20. Accordingly, the embodiment relied on by the Petitioner fails to disclose or suggest any wire member “extending in” or “configured in” a loop—let alone a “first filament [configured/extending] in a first loop” and a “second filament [configured/extending] in a second loop” as required by the Claims.

96. Figures 11-14 of Eller illustrate “another selective fluid barrier valve device 210 ... similar to the selective fluid barrier valve device 10 illustrated in FIGS.

1, 2, 3, 4, 5, 6, 7, 8A, 8B, 8C, 9A, 9B, 9C, 10A, 10B, and 10C.” *Id.* at 20:12-

17. The wire members 22-26 have the same configuration in Figures 11-14 such that this embodiment of Eller also fails to disclose any wire member “extending in” or “configured in” a loop—let alone a “first filament [configured/extending] in a first loop” and a “second filament [configured/extending] in a second loop” as required by the Claims. *Id.* at 20: 17-27.

97. Figures 15-17 of Eller illustrate “another selective fluid barrier valve device 410 ... similar to the selective fluid barrier valve device 10 illustrated in FIGS. 1, 2, 3, 4, 5, 6, 7, 8A, 8B, 8C, 9A, 9B, 9C, 10A, 10B, and 10C.” *Id.* at 21:37-42. In this embodiment, “the selective fluid barrier valve device 410 omits the inclusion of a second wire member (e.g., second wire member 24) and a third wire member (e.g., third wire member 26)” and:

The first wire member 422 has a first end 524 attached to the actuator 418 within the first cavity 490 and a second end 526 attached to the first wire member 422 between the first end 524 and the second end 526. The first wire member 422 extends from the first end 524 disposed within the first cavity 490 defined by the actuator 418, through the first opening 456 defined by the housing 416, around the outer surface 521 of the sleeve 420, through the second opening 458 defined by the housing 416, around the outer surface of the first wire member 422 and is attached to itself between the first end 524 and the second end 526. Thus, the first wire member 422 defines a loop 574 at its second end 526 through which the first wire member 422 is disposed.

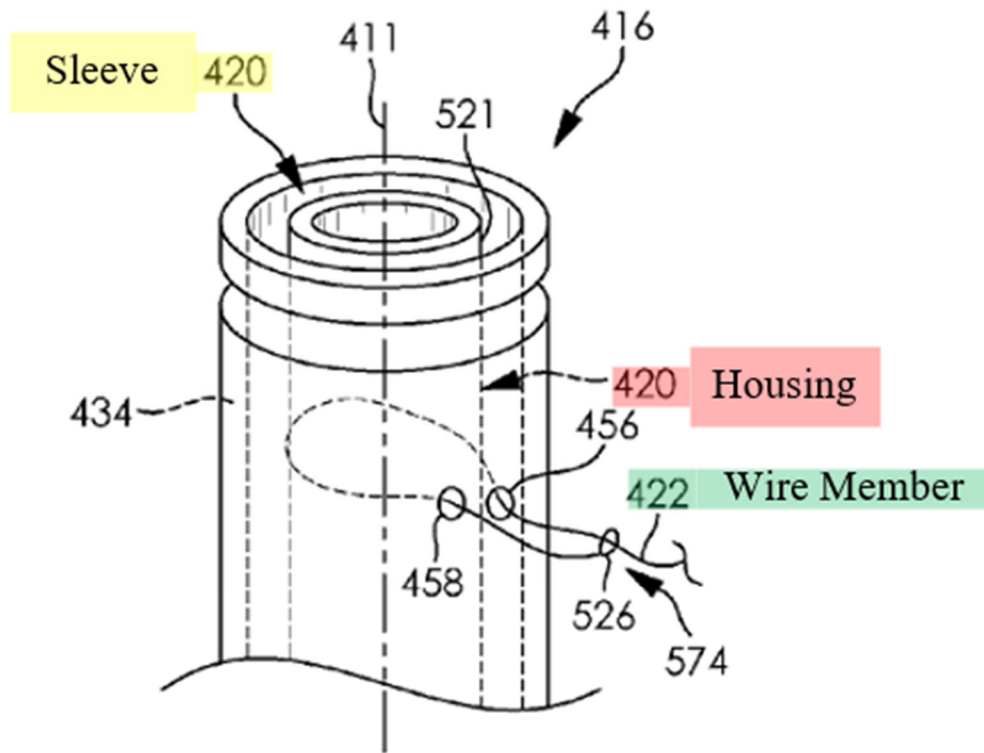
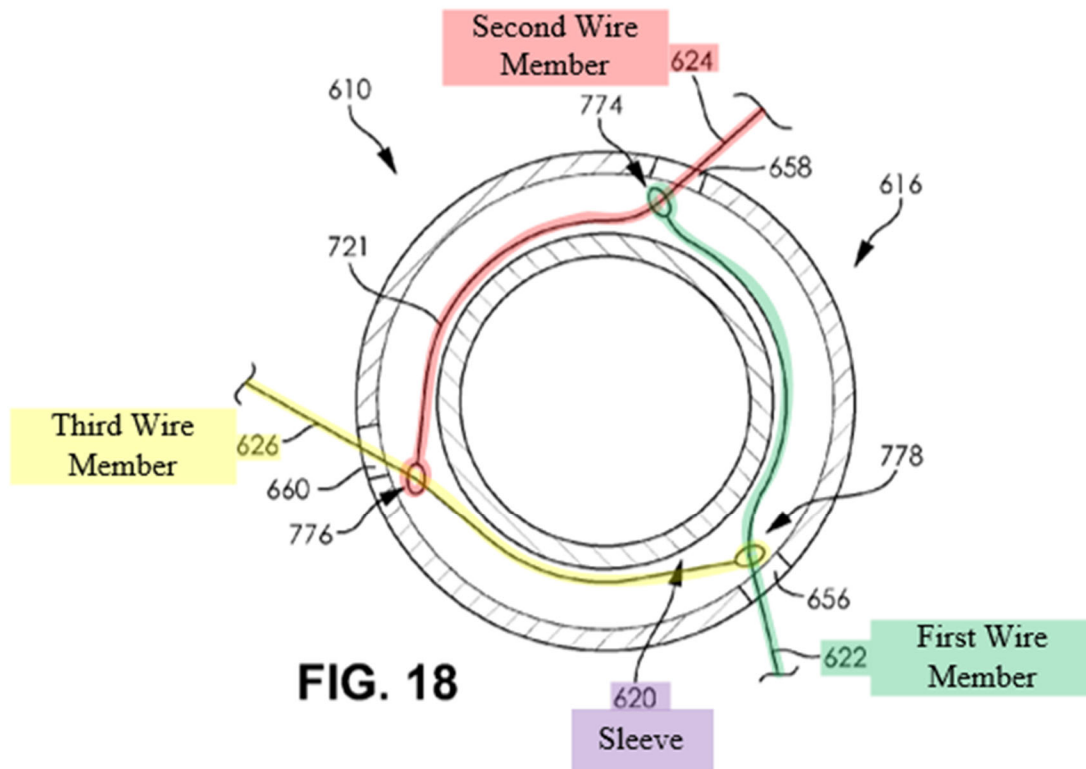


FIG. 16

Id. at 21:49-22:10. In this embodiment, the “*single* wire member” is “disposed around more than 50% of the outer surface 521 of the sleeve 42[0]” and in “alternative embodiments can include a single wire member that is disposed around more than 75% of the outer surface of the sleeve or that is disposed around more than 100% of the outer surface of the sleeve ... [f]or example, the wire member can be positioned such that it extends at least one full revolution around the outer surface of the sleeve.” *Id.* at 22:11-24 (my emphasis added). Accordingly, the embodiment in Figures 15-17 of Eller discloses that

a valve having a *single* wire member can be positioned to extend a full revolution around the sleeve. But, this embodiment fails to disclose more than a single wire member, let alone a “first filament [configured/extending] in a first loop” and a “second filament [configured/extending] in a second loop” as required by the Claims.

98. Figures 18 and 19 of Eller illustrate “another selective fluid barrier valve device 610 ... similar to the selective fluid barrier valve device 10 illustrated in FIGS. 1, 2, 3, 4, 5, 6, 7, 8A, 8B, 8C, 9A, 9B, 9C, 10A, 10B, and 10C.” *Id.* at 22:32-37. The valve device 610 has a first wire member 622, a second wire member 624, and a third wire member 626 that, like the embodiment in Figures 1-10C, each extend only partially around a sleeve 620:



Id. at 22:52-23:23. Accordingly, this embodiment of Eller fails to disclose or suggest any wire member “extending in” or “configured in” in a loop—let alone a “first filament [configured/extending] in a first loop” and a “second filament [configured/extending] in a second loop” as required by the Claims.

99. Figures 20-22 of Eller illustrate “another selective fluid barrier valve device 810 ... similar to the selective fluid barrier valve device 10 illustrated in FIGS. 1, 2, 3, 4, 5, 6, 7, 8A, 8B, 8C, 9A, 9B, 9C, 10A, 10B, and 10C.” *Id.* at 23:50-55. The valve device 810 includes 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”:

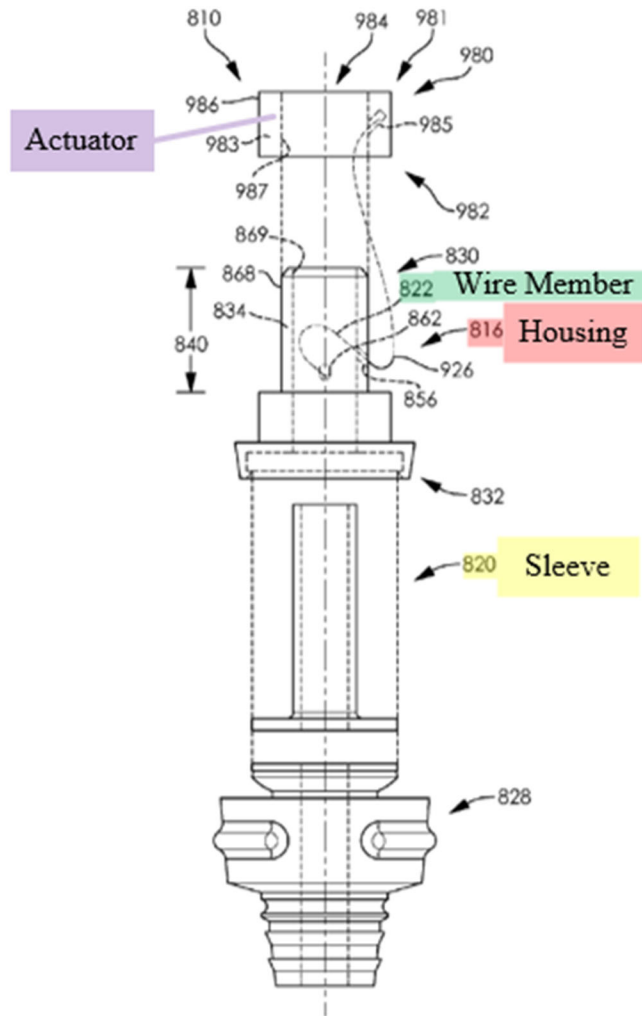


FIG. 20

Id. at 23:50-62 & 24:50-52. The single wire member 822 in this embodiment does not extend fully around the sleeve 820 as best seen in Figure 22 of Eller. Accordingly, this embodiment of Eller fails to disclose or suggest any wire member “extending in” or “configured in” in a loop—let alone a “first filament [configured/extending] in a first loop” and a “second filament [configured/extending] in a second loop” as required by the Claims.

100. Finally, Figures 24-27 of Eller illustrate “another selective fluid barrier valve device 1110 ... similar to the selective fluid barrier valve device 10 illustrated in FIGS. 1, 2, 3, 4, 5, 6, 7, 8A, 8B, 8C, 9A, 9B, 9C, 10A, 10B, and 10C.” *Id.* at 31:29-34. The valve device 1110 includes a first wire member 1122, a second wire member 1124, and a third wire member 1124 that have the same configuration as in Figures 1-10C such that this embodiment of Eller also fails to disclose any wire member “extending in” or “configured in” in a loop—let alone a “first filament [configured/extending] in a first loop” and a “second filament [configured/extending] in a second loop” as required by the Claims. *Id.* at 31: 40-44.

101. Accordingly, despite Eller’s disclosure of multiple wire members, Eller does not disclose any embodiment including two wire members configured in or extending in a loop as required by the Claims. In each embodiment including multiple wire members, each of the multiple wire members extends only partially around the sleeve and not in a loop. And, Eller discloses only a single embodiment in Figures 15-17 in which a “*single* wire member ... can be positioned such that it extends at least one full revolution around the outer surface of the sleeve.” *Id.* at 22:11-24 (my emphasis added). Therefore, a POSITA would not have found it obvious to “use two wire members with Schaffer’s valve based on the teachings of Eller” in the arrangement Petitioner

suggests, because Eller does not disclose any embodiment including a first wire member “[configured/extending] in a first loop” and a second wire member “[configured/extending] in a second loop” as required by the Claims. Petition, p. 48.

2. Petitioner’s proposed combination incorporating Eller’s wire members into Schaffer’s valve is not a simple substitution.

102. A POSITA would not have found it simple to have substituted two of Eller’s wire members for Schaffer’s U-shaped actuating members and form each of those wires in a loop around Schaffer’s seal module. First, as I explain above, neither Schaffer nor Eller disclose a “first filament [configured/extending] in a first loop” and a “second filament [configured/extending] in a second loop” as required by the Claims. At most, Eller discloses one embodiment with a *single* wire member that can extend a full revolution around a sleeve. In each embodiment including multiple wire members, each of the multiple wire members extends only partially around the sleeve and not in a loop. Thus, the proposed substitution does not merely entail the substitution of a known element for another—multiple wire members formed into multiple individual loops were not known from Petitioner’s references.
103. Second, as I explained in my declarations for the related IPRs, in Schaffer each of the actuating members 55 is attached to only one of the actuator

buttons 261 such that movement of a single one of the actuator buttons 261 controls movement of a single one of the actuating members 55. And, 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. In Petitioner's purported simple substitution each wire member (e.g., different ends thereof) is controlled by both of Schaffer's two actuator buttons 261. Petition, pp. 47-50. Accordingly, Petitioner's proposed substitution is not simple because it requires significant additional modification and departs from the intended purpose and express disclosure of each of Schaffer and Eller in which a single U-shaped actuating member 55 or wire member, respectively, are controlled by a single actuator. If anything, Petitioner's proposed combinations appear to be based on hindsight in view of the '384 Patent.

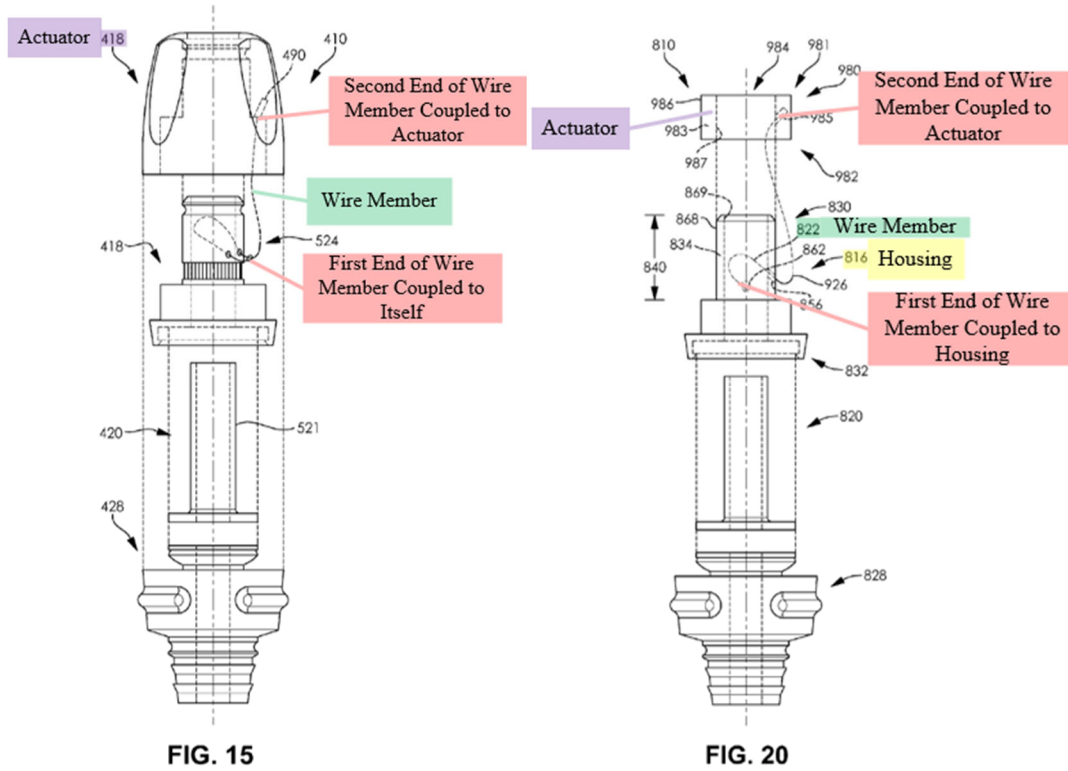
3. Petitioner's purported motivations to create a larger sealing area, allow the manufacturer to optimally space the strings, and add redundancy to the system would not have motivated a POSITA.

104. Petitioner's argument that "a POSITA would have been motivated to use two wire members with Schaffer's valve to provide a more robust and reliable seal for the reasons explained above with respect to Hartley (e.g., creating a larger sealing area, allowing the manufacturer to optimally space the strings, adding

redundancy to the system)” fails for the same reasons I describe above in §VI.B with respect to Hartley. Petition, p. 49.

C. Neither Schaffer nor Eller Disclose Any Filament Acted Upon by a Pair of Actuators, e.g., Opposing Actuators

105. Independent Claim 1 of the '384 Patent requires a “pair of actuators movable from a first position to a second position” wherein each of the first filament and the second filament “includes a first portion operably acted upon by a first one of the actuators and a second portion operably acted upon by a second one of the actuators.” Neither Schaffer nor Eller disclose any U-shaped member, wire member, or other member with different portions operably acted upon by a pair of actuators as required by independent Claim 1.
106. For example, as I explain above in §VI.C., in Schaffer each of the actuating members 55 is attached to only one of the actuator buttons 261 such that each actuator button 261 operably acts on only one of the actuating members 55. Eller discloses various selective fluid barrier devices that include one or more wire members each having one end coupled to an actuator and the other end coupled to itself or a housing—not to the same or different actuator:



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

107. Accordingly, independent Claim 1 is not rendered obvious by the combination of Schaffer and Eller because neither Schaffer nor Eller disclose any filament—let alone a first filament and a second filament—having “a first portion operably acted upon by a first one of the actuators and a second portion operably acted upon by a second one of the actuators,” as required by independent Claim 1. Independent Claims 15 and 23 are also not rendered obvious by the combination of Schaffer and Eller for the same reasons.

VIII. GROUND 3—THE COMBINATION OF SCHAFFER, HARTLEY, AND ELLER DO NOT RENDER OBVIOUS INDEPENDENT CLAIMS 1, 15, AND 23

108. Petitioner and its expert, Mr. Thornton, allege that Schaffer in combination with Hartley and Eller renders obvious independent Claims 1, 15, and 23 of the '384 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 and Eller to arrive at the features of the independent Claims including the “first filament [configured/extending] in a first loop” and “second filament [configured/extending] in a second loop.” Therefore, the combination of Schaffer and Hartley or Eller does not render obvious independent Claims 1, 15, and 23.
109. As I explained above, I understand that for a patent claim to be rendered obvious, the differences between the claimed invention and the prior art must be such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains, the claimed invention is obvious. Even if all limitations of a claimed invention are disclosed by the prior art combination, Petitioner must demonstrate an apparent reason to combine the known elements in the fashion of the patent claim at issue and that a person of ordinary skill in the art would have reasonable expectation of

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

110. Petitioner argues that “Eller’s disclosure of a hemostasis valve having first and second wire members that constrict the lumen to form a seal would have further motivated a POSITA to use a similar configuration when replacing Schaffer’s actuating members with Hartley’s strings.” Petition, pp. 79-80. I disagree for at least the reasons I explain above in §§VI-VII. In particular, Hartley discloses only a single string 14 and, while Eller describes valves having multiple wire members, Eller fails to disclose any embodiment including a first wire member “[configured/extending] in a first loop” and a second wire member “[configured/extending] in a second loop” as required by the Claims. In every embodiment of Eller having multiple wire members, each of the wire members extends only partially—and not in a loop—around Eller’s tubular sleeve rather than in a loop.

IX. DEPENDENT CLAIMS 2-4, 6-14, 16-18, 20-22, AND 24-30 ARE NOT OBVIOUS OVER SCHAFFER IN COMBINATION WITH HARTLEY, ELLER, AND/OR HERMANN

111. Petitioner and its expert, Mr. Thornton, allege that Schaffer in combination with Hartley (ground 1), Eller (ground 2), or Hartley and Eller (ground 3) render obvious dependent Claims 2-4, 6-14, 16-18, 20-22, and 24-30 of the '384 Patent. Petitioner and its expert also allege that Schaffer in combination with Hartley and Hermann (ground 4), Eller and Hermann (ground 5), or Hartley, Eller, and Hermann (ground 6) render obvious dependent Claims 11-14, 20-22, and 28-30.
112. For all the reasons discussed above, dependent claims 2-4, 6-14, 16-18, 20-22, and 24-30, which depend from one of independent Claims 1, 15, or 23, are also not rendered obvious by Schaffer in combination with Hartley and/or Eller (grounds 1-3).
113. Petitioner relies on Hermann only for disclosing various diameters of the claimed valve assemblies. Petition, pp. 80-85. Because of the deficiencies of Schaffer, Hartley, and Eller I explain above with reference to grounds 1-3, I do not analyze the details of Hermann herein. Nevertheless, I reserve my right to further review and assess any independent reasons of patentability for the claims in view of Hermann.

X. SECONDARY CONSIDERATIONS

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

XI. CONCLUSION

115. For all the above reasons, it is my opinion that the claims of the '384 Patent are not invalid based on the prior art grounds asserted by Petitioner and Mr. Thorton.

IPR2025-01562

Declaration of Paul J. Zalesky

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

Respectfully submitted,

Dated: 29 Dec 2025

By:

Paul J. Zalesky

A handwritten signature in black ink, appearing to read "Paul J. Zalesky", written over a horizontal line. The signature is cursive and stylized.

ATTACHMENT 1

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Education

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

Publications and Patents

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

Representative Publications:

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

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

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

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

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

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

Representative Patents:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Personal

Married with four children

Other

During the past 10 years (2015 – 2025), testified in depositions and court settings regarding specialized medical technologies and various aspects of their commercialization. Examples:

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

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

ATTACHMENT 2

MATERIALS CONSIDERED

EXHIBIT/PAPER No.	DESCRIPTION
1001	U.S. Patent No. 12,109,384 (“the ’384 patent”)
1002	Prosecution History of the ’384 Patent
1003	Expert Declaration of Troy Thornton
1004	Resume of Troy Thornton
1005	U.S. Patent Publication US 2003/0225379 A1 to Schaffer et al. (“Schaffer”)
1006	U.S. Patent Publication US 2003/0116731 A1 to Hartley (“Hartley”)
1007	U.S. Patent No. 9,980,813 B1 to Eller (“Eller”)
1008	Certified File History of U.S. Patent Application 10/371,190 (Schaffer File History)
1009	U.S. Patent No. 5,599,305 to Hermann (“Hermann”)
1010	U.S. Patent Publication US 2011/0144592 A1 to Wong et al. (“Wong”)
1013	Inari’s Supplemental Infringement Contentions (without claim charts) from <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , No. 24-cv-3117 (N.D. Cal.) (served February 7, 2025).
1014	Google Dictionary Definition of “String”
1015	Cambridge Dictionary Definition of “String”
1016	Deposition Transcript of PO’s Expert Paul Zalesky, Ph.D. dated June 23, 2025
1017	Deposition Transcript of PO’s Expert Paul Zalesky, Ph.D. dated August 27, 2025
1018	Deposition Transcript of Troy Thornton dated March 19, 2025
1020	Case Management & Scheduling Order (Dkt. #54) in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 24-cv-03117-EKL (N.D. Cal.) (issued December 19, 2024)
1022	U.S. Patent No. 11,697,011 (“the ’011 patent”)

EXHIBIT/PAPER No.	DESCRIPTION
1023	U.S. Patent No. 11,697,012 (“the ’012 patent”)
1025	Decision Granting Institution of <i>Inter Partes</i> Review for U.S. Patent No. 11,697,011 (Paper 7) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2024-01157 (P.T.A.B. Jan. 23, 2025)
1026	Decision Granting Institution of <i>Inter Partes</i> Review for U.S. Patent No. 11,697,012 (Paper 6) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-00156 (P.T.A.B. Apr. 22, 2025)
1027	Imperative Care, Inc.’s Notice of Motion and Motion to Stay Pending <i>Inter Partes</i> Review in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 5:24-cv-03117-EKL (N.D. Cal.)
1028	Order Regarding Case Schedule and Motion to Stay in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 5:24-cv-03117-EKL (N.D. Cal.)
1029	Decision Granting Institution of <i>Inter Partes</i> Review for U.S. Patent No. 11,554,005 (Paper 10) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-00289 (P.T.A.B. June 18, 2025)
1030	Patent Owner Response for <i>Inter Partes</i> Review for U.S. Patent No. 11,697,011 (Paper 3) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2024-01157 (P.T.A.B. Apr. 18, 2025)
1031	Supplemental Declaration of Paul J. Zalesky submitted in IPR2024-01157
1032	Robert C. Allen, <i>The Gore DrySeal Sheath</i> , Supp. Endovascular Today (Feb. 2011) (“Allen”)
1033	Cara M. Michelson, et al., <i>Use of a Modified Cardiopulmonary Bypass Circuit for Suction Embolectomy with the Angiovac Device</i> , 49 J. Extra Corpor. Tech., 299-303 (2017) (“Michelson”)
1034	Jacques Kpodonu, <i>Manual of Thoracic Endoaortic Surgery</i> (2010) (“Kpodonu”)
1035	510(k) Summary – K123990, Sentrant Introducer Sheath with Hydrophilic Coating (Apr. 26, 2013) (“Sentrant”)
1036	Matthew Kruse, <i>Thoracic Endovascular Aortic Repair (TEVAR) Sheaths</i> , CTSNet (Jan. 18, 2011) (“Kruse”)
1037	Cook Medical, <i>Endovascular Aortic Repair – Abdominal: Zenith Endovascular Grafts</i> (2012) (“Zenith Brochure”)
1038	U.S. Patent No. 8,137,321 B2 to Argentine (“Argentine”)

EXHIBIT/PAPER No.	DESCRIPTION
1039	U.S. Patent Pub. No. 2017/0080200 A1 (“Bickhart”)
1040	U.S. Patent No. 11,730,942 B2 to Fantuzzi (“Fantuzzi”)
1041	U.S. Patent No. 8,777,893 B2 to Malewicz (“Malewicz”)
1042	U.S. Patent No. 5,125,903 to McLaughlin (“McLaughlin”)
1043	U.S. Patent No. 8,808,350 B2 to Schreck (“Schreck”)
Paper 2	Petition for <i>Inter Partes Review</i> of U.S. Patent No. 12,109,384
2002	Merriam-Webster’s Collegiate Dictionary (11th ed. 2014)
2003	Declaration of Troy L. Thornton in Support of <i>Inter Partes Review</i> of U.S. Patent No. 11,697,011