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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
Patent No. 12,109,384

**PETITION FOR *INTER PARTES* REVIEW OF
U.S. PATENT NO. 12,109,384**

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LIST OF EXHIBITS

Exhibit 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”)
1011	RESERVED
1012	RESERVED
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”

Exhibit No.	Description
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
1019	RESERVED
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)
1021	RESERVED
1022	U.S. Patent No. 11,697,011 (“the ’011 patent”)
1023	U.S. Patent No. 11,697,012 (“the ’012 patent”)
1024	RESERVED
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.)

Exhibit No.	Description
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”)
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”)

Exhibit No.	Description
1043	U.S. Patent No. 8,808,350 B2 to Schreck (“Schreck”)

Petitioner Imperative Care, Inc. (“Petitioner”) requests *inter partes* review (“IPR”) of claims 1-4, 6-18, 20-30 (“the challenged claims”) of U.S. Patent No. 12,109,384 (“the ’384 patent,” Ex. 1001), which is assigned to Inari Medical, Inc. (“Patent Owner” or “PO”) and issued less than one year ago.

I. INTRODUCTION

Patent Owner asserts claims 1-4, 6-18, and 20-30 against Petitioner in the co-pending district court litigation (the “Litigation”). (*See* Ex. 1013 (PO’s infringement contentions).) The Court has not set a trial date and vacated the case schedule to hear argument on Petitioner’s motion to stay pending resolution of the IPRs. (*See e.g.*, Ex. 1020 (setting case schedule to only claim construction); Ex. 1028 (vacating claim construction schedule).) Given the early stage of the case and newness of the ’384 patent, Petitioner challenges the asserted claims in this IPR.

The ’384 patent has the same specification as two patents currently subject to instituted IPRs - U.S. Patent No. 11,697,011 (“the ’011 patent,” Ex. 1022) and 11,697,012 (“the ’012 patent,” Ex. 1023). (*See* Exs. 1025; Ex. 1026 (institution decisions).) The challenged claims share many common limitations with the claims in the instituted IPRs and, as shown below, are unpatentable over the same prior art.

Like the claims in the instituted IPRs, the challenged claims describe a known type of valve for sealing medical devices. Many medical procedures require physicians to insert tubes, such as catheters, into a patient’s vascular system.

However, once the catheter is placed inside the patient’s vasculature, the catheter fills with blood. If the end of the catheter nearest the physician is not sealed, blood can leak out of the catheter and into the operating room. Decades ago, medical device companies developed valves to seal the end of catheters and minimize blood loss during such procedures.

The challenged claims recite a valve having a “tubular member defining a lumen.” Figure 2 below illustrates “tubular member 132” and its “central lumen 138”:¹

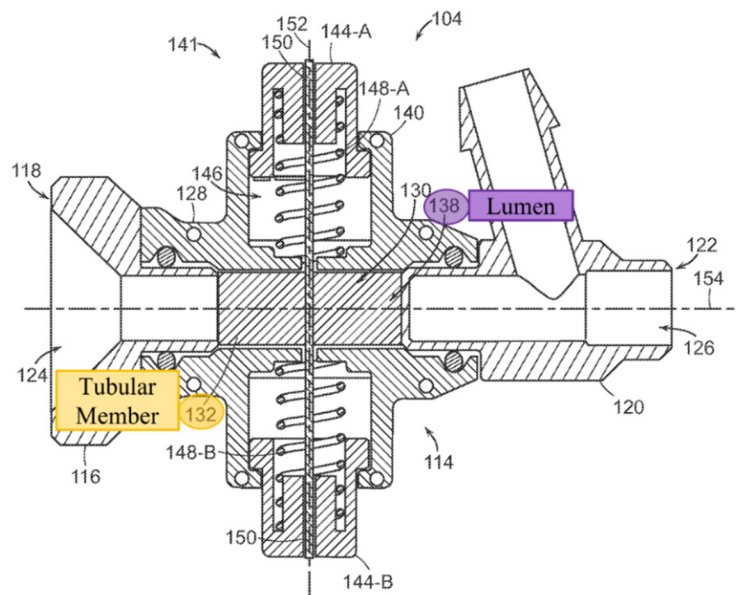
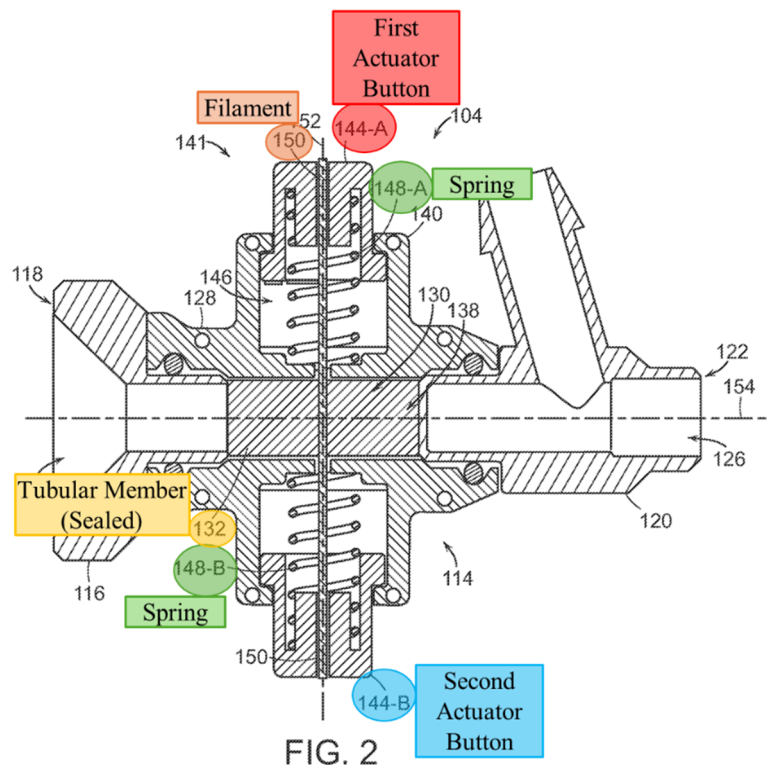


FIG. 2

(Ex. 1001, 7:11-45, Fig. 2.) The specification explains that the tubular member 132 “can comprise a compliant tubular structure” that “can facilitate the collapse” of the tubular member 132. (*Id.*, 7:17-31.)

¹ Petitioner added all colors and annotations except where otherwise noted.

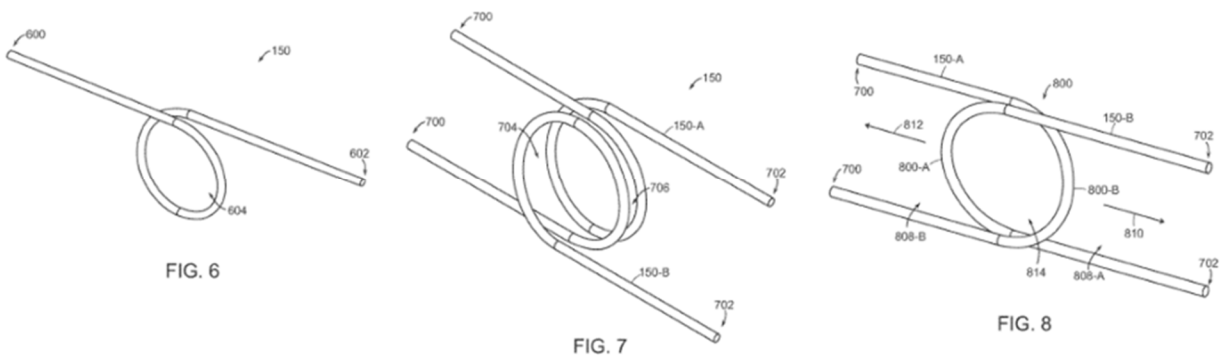
The challenged claims also require the valve to have a “pair of actuators” (i.e., buttons) that are “biased” by “springs” to a first position. Figure 2 illustrates the first position, in which the springs 148-A and 148-B bias the actuator buttons outwardly to pull on the filament and constrict the tubular member. (*Id.*, 8:38-56, Fig. 2.)



Alternatively, pushing on the buttons releases the tension on the filament, allowing the tubular member to expand and open the valve. (*Id.*, 9:54-62, Fig. 3.)

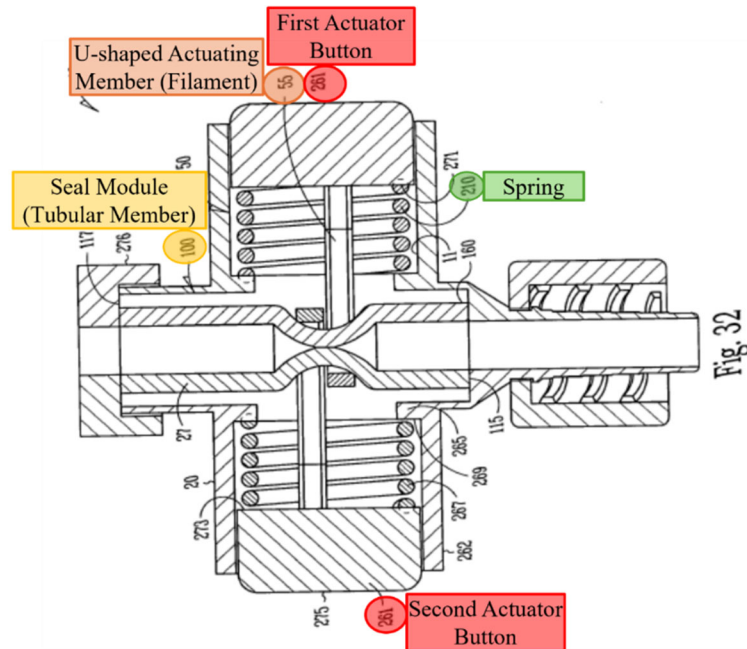
The primary difference between the independent claims in the previously instituted IPRs and the challenged claims is that the claims in the instituted IPRs require “at least one filament” or “at least ... a first filament” while the challenged claims require a “first filament” and a “second filament.”

The '384 patent describes several exemplary filament configurations (*see* figures below) but never describes any configuration as being novel or important to the invention. (*Id.*, 13:17-18.) In fact, the specification barely mentions embodiments having two filaments. Rather, the specification consistently describes the alleged invention as having “at least one filament” and describes the filament(s) as encircling the tubular member as shown in exemplary Figures 6-8 below:

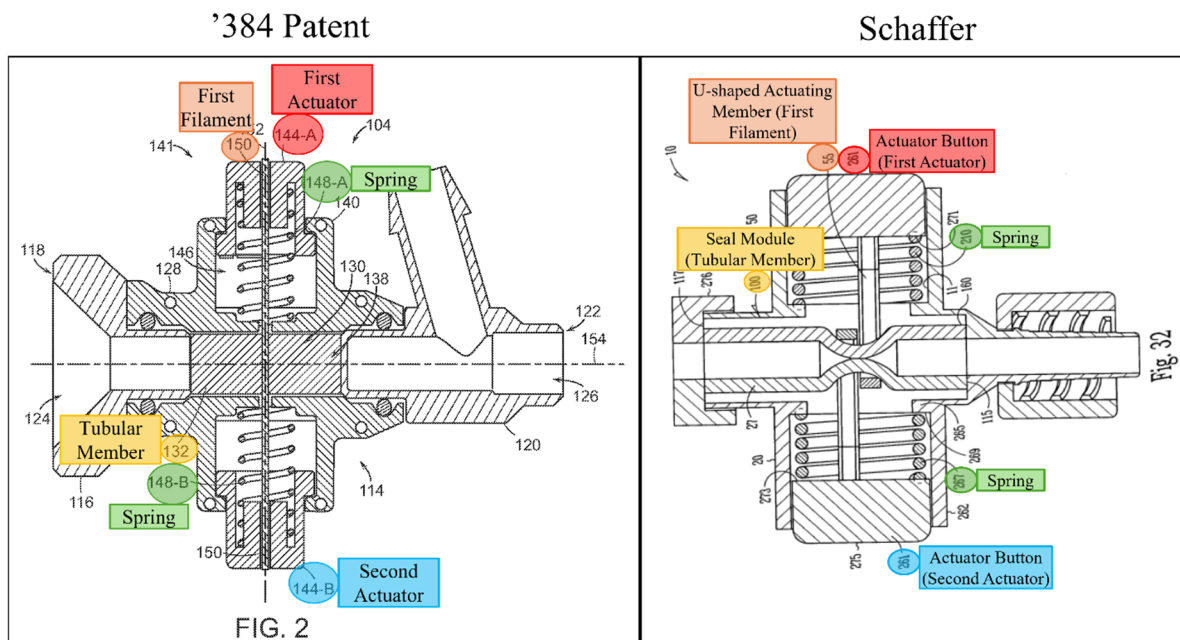


(*See e.g., id.*, 1:66-2:4, Figs. 6-8.)

Hemostasis valves having multiple filaments were well known before September 6, 2017, the earliest claimed priority date for the '384 patent. **Schaffer**, a patent application published in 2003, describes hemostasis valves for use with catheters during intravascular procedures. (Ex. 1005, [0002], [0008].) Like the claimed valves, Schaffer’s hemostasis valve includes opposing actuator buttons attached to springs that pull on two actuating members (filaments) to constrict a tube within the valve:



(*Id.*, Fig. 32.)² As shown below, Schaffer’s valve includes many of the same components, in the same arrangement, as the valve described in the ’384 patent.



² Petitioner uses the versions of Schaffer’s drawings submitted during prosecution on June 18, 2003 (Ex. 1008, 66-84) because they are clearer. The drawings became publicly available when Schaffer published on December 4, 2003. 37 C.F.R. §1.11.

Schaffer's two filaments are configured slightly differently than the filaments required by the challenged claims. While the challenged claims require two filaments that *each* form a loop around the tubular member, Schaffer's two u-shaped filaments *collectively* form a loop around the tubular member.

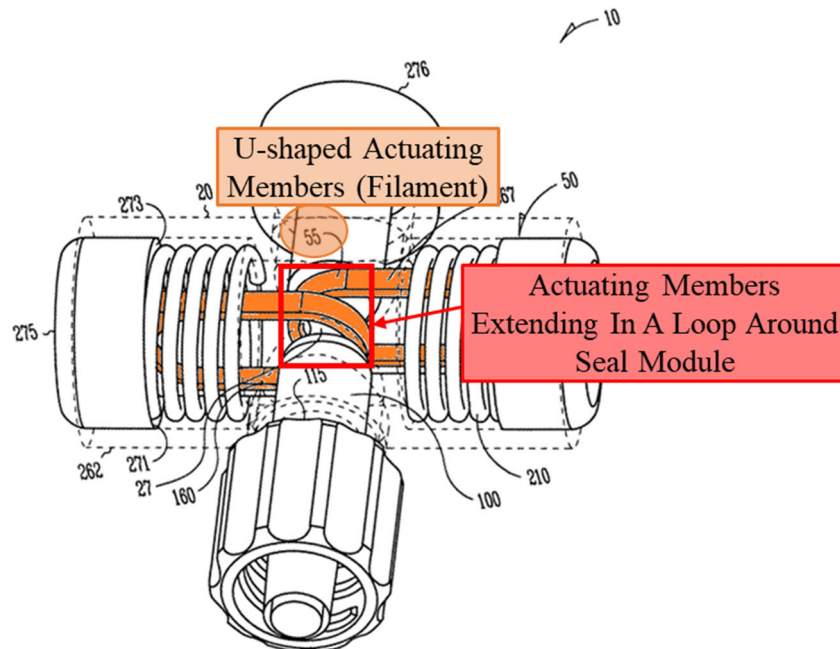


Fig. 31

(Ex. 1005, Fig. 31.) However, other prior art describes using a single filament to form a loop around and constrict a tubular member. **Hartley**, a patent application published in 2003, describes a hemostasis valve having a string that forms a loop around an elastomeric diaphragm (i.e., tubular member) to constrict the lumen of the elastomeric diaphragm:

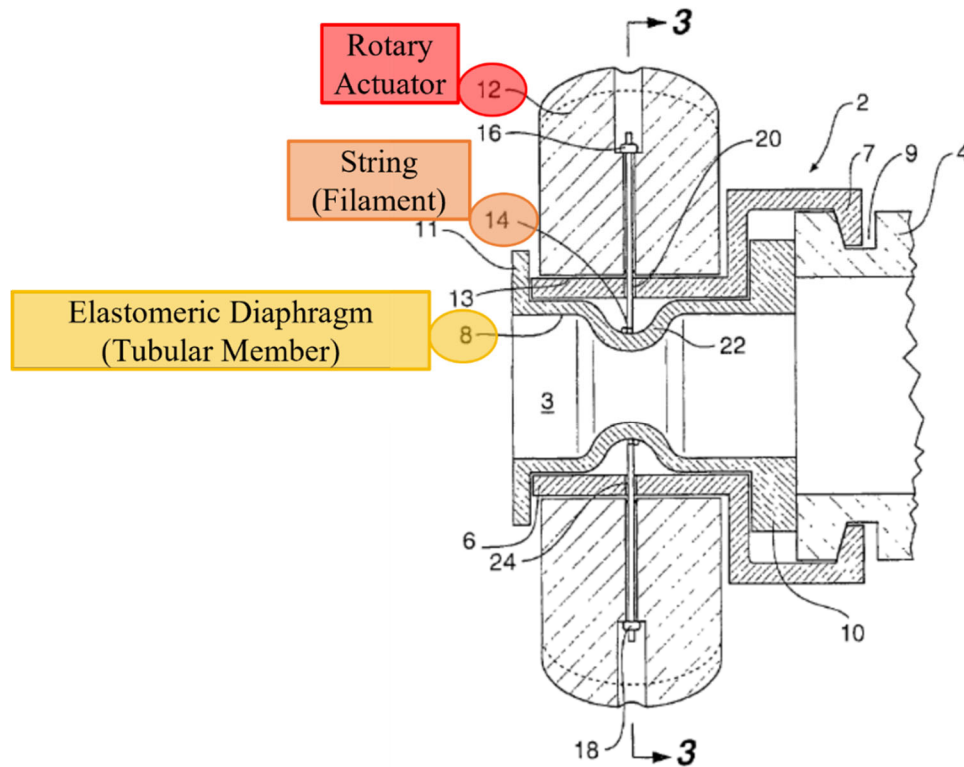
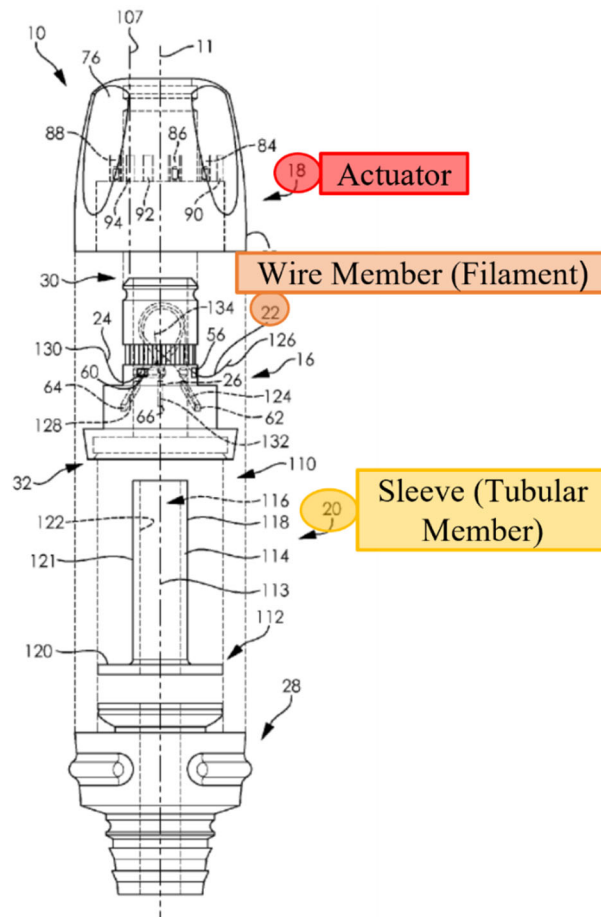


Fig 1

(Ex. 1006, [0031], Fig. 1.) Hartley’s string is attached to a “rotary actuator” that applies tension to the string. Rotation of the rotary actuator in one direction pulls on the ends of the string to reduce the diameter of the loop and constrict the lumen while rotation in the opposite direction releases tension on the ends of the string to relax the loop and open the lumen.

Similarly, **Eller**, a patent published in 2015, discloses a hemostasis valve with a rotatable actuator like the valve disclosed in Hartley. Eller’s hemostasis valve also includes filaments that loop around a collapsible sleeve (i.e., tubular member) to constrict the sleeve:



(Ex. 1007, 5:1-12, Fig. 2.) Eller discloses embodiments including one, two, or three filaments, and confirms that “[s]killed artisans will be able to select a suitable number of wire members [i.e., filaments] to include in a selective fluid barrier valve device” depending on the valve materials. (*Id.*, 16:7-19.)

A person of ordinary skill in the art (“POSITA”) would have found it obvious to replace Schaffer’s actuating members with one or two of the filaments disclosed in Hartley or Eller for the reasons discussed herein. The Board preliminarily addressed the combination of Schaffer with Hartley’s or Eller’s filaments in the

instituted IPRs.³ (Ex. 1025, 33-41; Ex. 1026, 34-48.) The Board found that “Petitioner advances multiple reasons why the skilled artisan would have been motivated to combine Schaffer and Hartley with a reasonable expectation of success.” (Ex. 1025, 36; *see also* Ex. 1026, 38 (“We find Petitioner’s argument and evidence summarized above sufficient, at this stage, to support the rationale for modifying Schaffer in view of Hartley as proposed with a reasonable expectation of success.”).)

For the reasons presented herein, Petitioner has demonstrated a reasonable likelihood that at least one claim of the ’384 patent is unpatentable. Accordingly, Petitioner requests that the Board institute this IPR to review the patentability of the ’384 patent.

II. THE ’384 PATENT

A. Overview

The ’384 patent describes hemostasis (or “garrote”) valves for use during minimally invasive intravascular procedures. (Ex. 1001, 5:55-6:6.) The hemostasis valve is used with a catheter inserted into the patient’s vasculature to provide a seal. (*Id.*, 1:42-:46.) The ’384 patent states that the hemostasis valve “can seal with or without a tool extending through the valve.” (*Id.*, 5:56-:58.)

³ The Board also preliminarily addressed the combination of Schaffer with Hartley and Eller in instituted IPR2025-00289 involving U.S. Patent No. 11,554,005. (Ex. 1029, 28-46 (institution decision).)

The described valve includes a “housing 128” that defines an “interior channel 130,” and a collapsible “elongate member 132” or “tubular member 132” that extends through the housing:

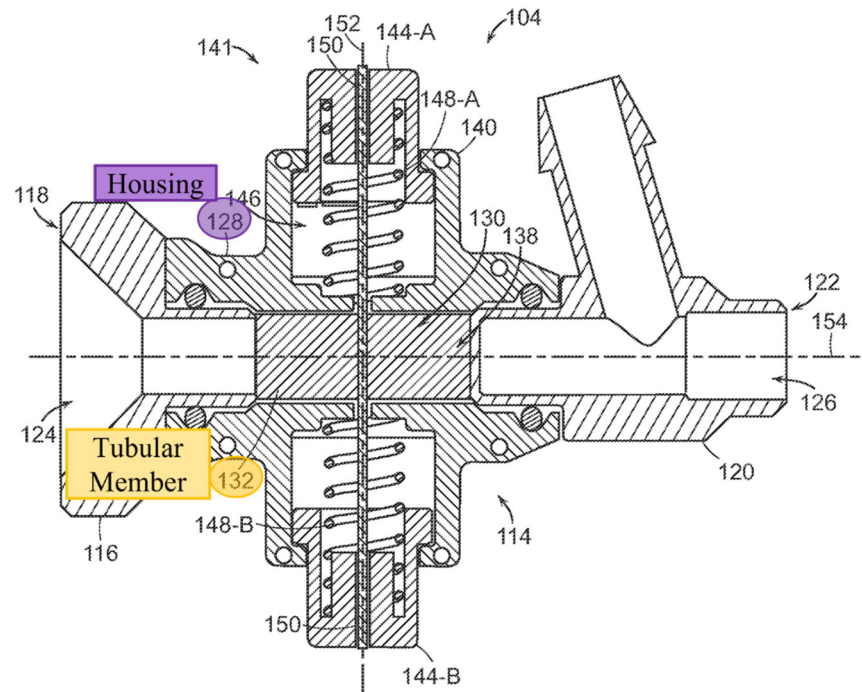


FIG. 2

(*Id.*, 6:56-7:31, Fig. 2.) The tubular member 132 has a “thin-walled compliant tubular structure” that helps facilitate “the uniform collapse of the elongate member 132 and the scaling of the elongate member 132.” (*Id.*, 7:17-23.)

The valve also includes a “constricting mechanism 141,” which can “collapse and seal the elongate member 132 via compression and/or constriction, and specifically via constriction with at least one filament 150”:

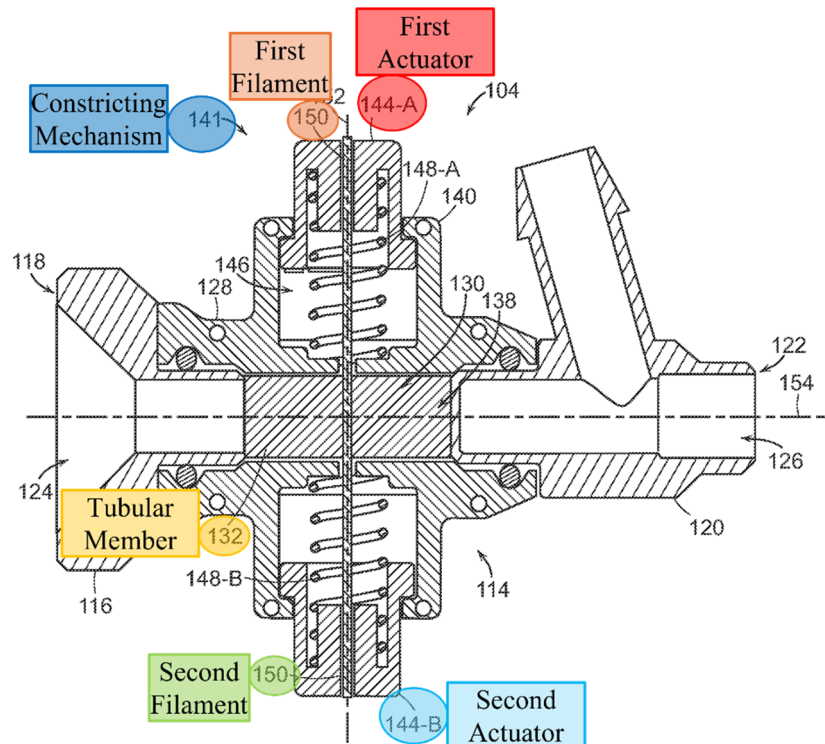


FIG. 2

(*Id.*, 8:5-8, Figs. 1, 2.) The constricting mechanism includes “an actuator 142 which can be a manual actuator such as one or several buttons 144; and the at least one filament 150 that can extend at least partially around the elongate member 132.”

(*Id.*, 8:5-12.) The “filament 150 can be coupled to the actuator 142 such that the filament 150 selectively constricts, collapses, and/or seals the elongate member 132 ... based on the movement and/or position of the actuator 142.” (*Id.*, 9:24-28.)

The valve also includes a “bias feature,” such as a spring (148-A and 148-B), which biases the actuator toward the open or closed configuration. (*Id.*, 8:38-56.)

In Figure 4, springs 148-A and 148-B bias the valve toward the closed configuration:

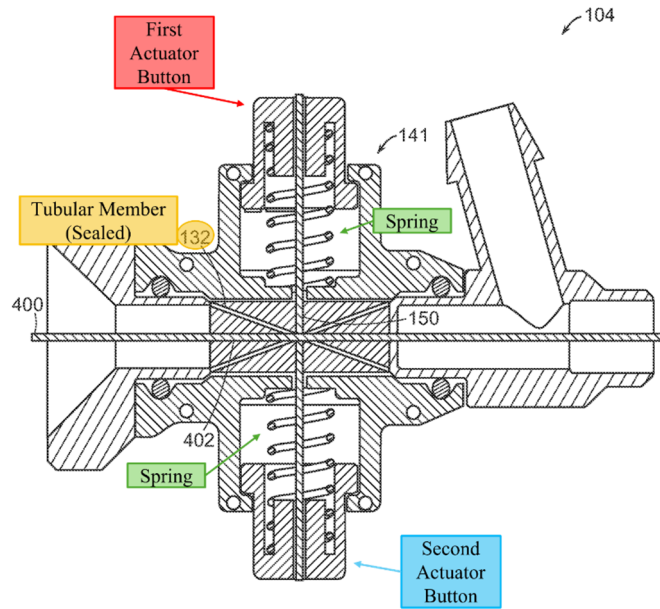


FIG. 4

(*Id.*, 8:38-56, Fig. 4.) Depressing the actuator buttons releases the tension on the filament, “thereby allowing the expansion of the elongate member 132 and the unsealing of the central lumen 138 of the elongate member 132”:

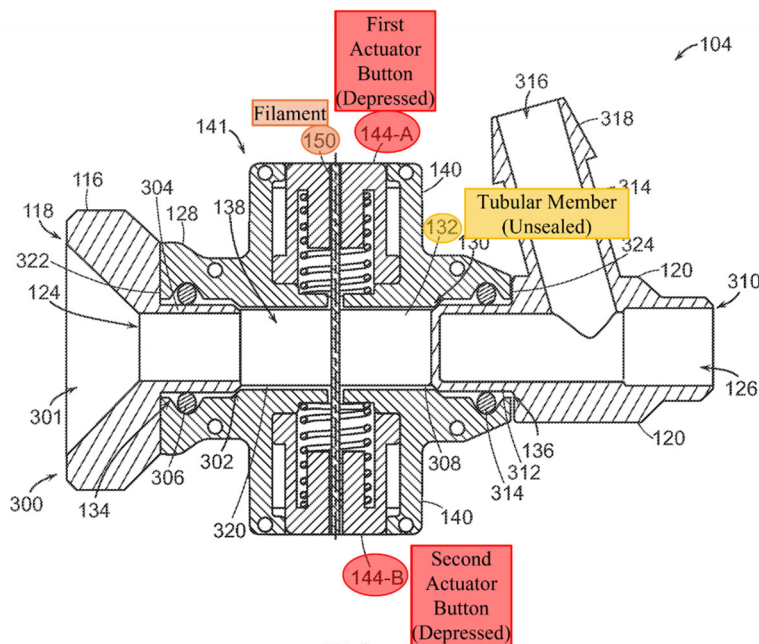


FIG. 3

(*Id.*, 9:44-62, Fig. 3.)

The filament can constrict the elongate member around a tool inserted through the central lumen of the tubular member, “creat[ing] a seal between the elongate member 132 [and the tool],” as illustrated in Figure 4:

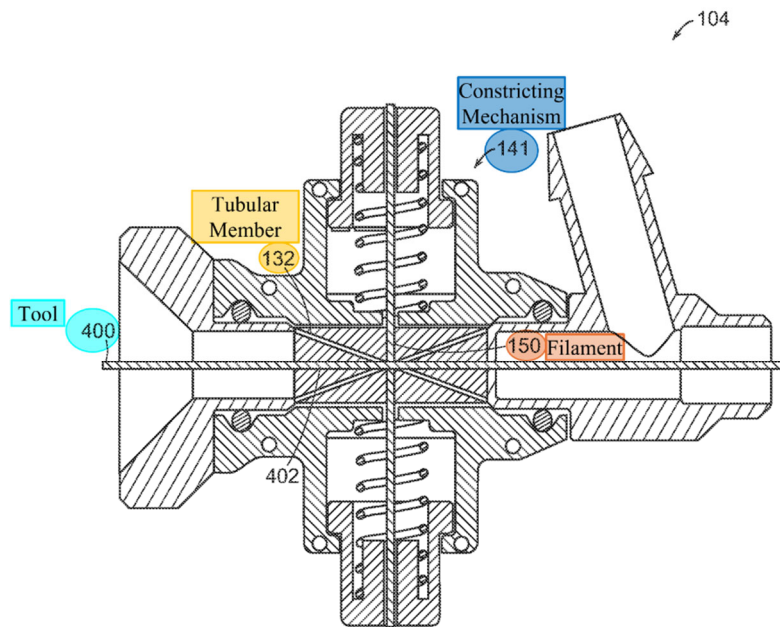


FIG. 4

(*Id.*, 12:4-:15, Fig. 4.)

The “filament 150 can be arranged in a variety of configurations” including a “single loop 604 that can extend around the elongate member 132” as shown in Figure 6, multiple loops as shown in Figure 7, or a “U-shaped section between the two ends of the filament 150” as shown in Figures 8 and 9:

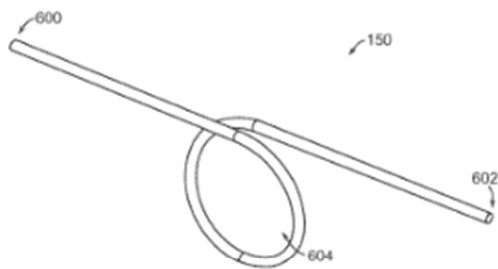


FIG. 6

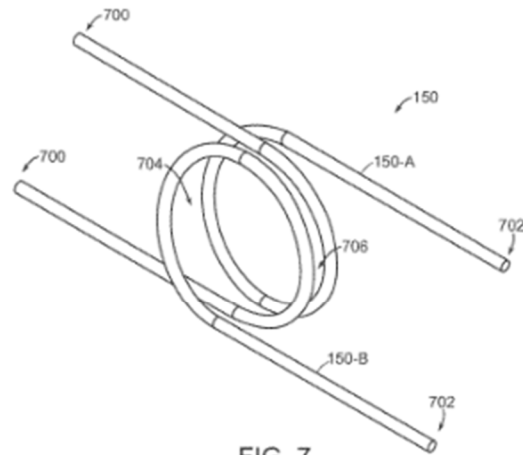


FIG. 7

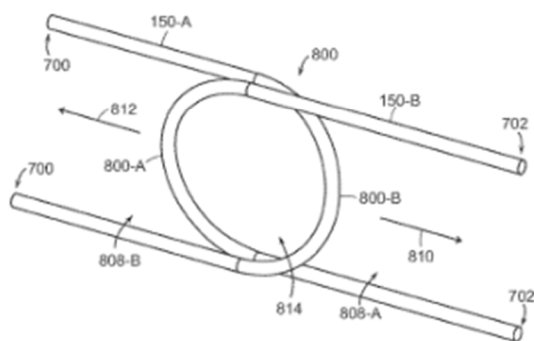


FIG. 8

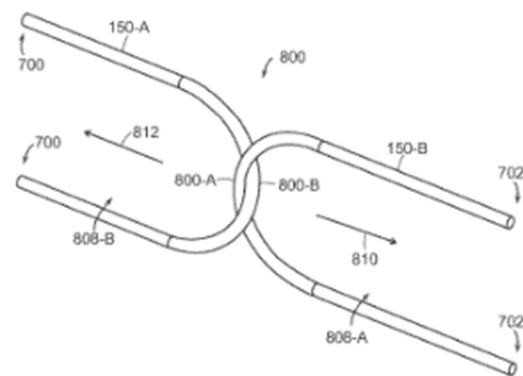
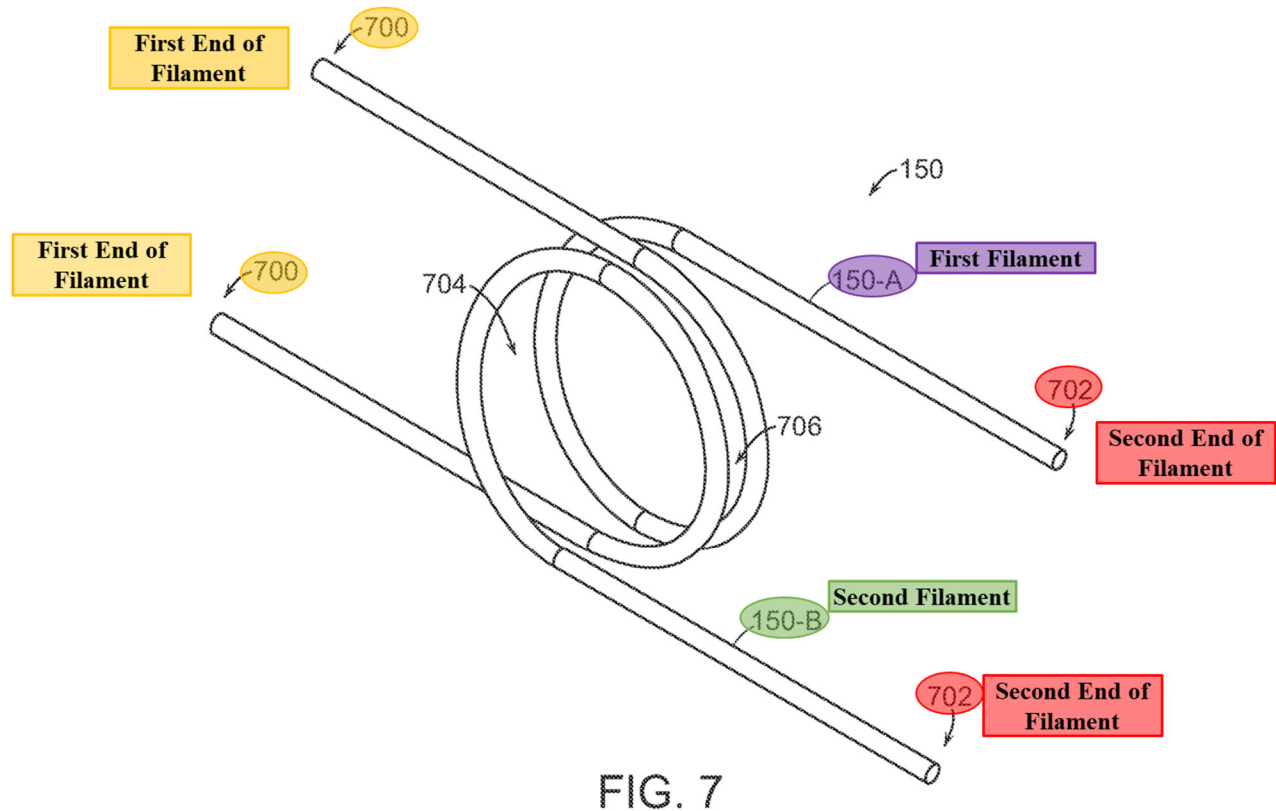


FIG. 9

(*Id.*, 13:17-14:34, Figs. 6-9.) The patent also discloses that “[t]he filament can be made from a variety of materials including, for example, a polymer, a synthetic, and/or a metal.” (*Id.*, 9:13-15.) The filament may also “comprise multiple filaments,” such as in Figures 7-9, where “each of the multiple filaments can have a first end 700 and a second end 702”:



(*Id.*, 12:61-67, Fig. 7.)

B. Prosecution History

The Examiner of the '384 patent did not issue any office actions and did not make any prior-art-based rejections. The Examiner issued a Restriction Requirement identifying three species and seven sub-species and requested that PO elect a species to pursue. (Ex. 1002, 229-234.) During a subsequent telephone interview, the Examiner purportedly acknowledged improperly identifying the sub-species. (*Id.*, 171-172.) Following the interview, PO elected Species I, sub-species A (Figures 1-4), and sub-species D (Figure 7). (*Id.*, 211-220.) However, in the Notice of Allowance, the Examiner withdrew the restriction and allowed claims to

all species and sub-species. (*Id.*, 18-21.) The Examiner provided no explanation for withdrawing the restriction.

In the Notice of Allowance, the Examiner also determined that the “closest prior art of record” was Hartley (Ex. 1006), Wong (Ex. 1010), and Eller (Ex. 1007). (Ex. 1002, 20.) The Examiner found that Hartley disclosed every limitation of the independent claims except “that the actuator is as [sic] a pair of actuators; a second filament.” (*Id.*) The Examiner also found that Eller disclosed every limitation of the independent claim except “that the actuator is as [sic] a pair of the actuator.” (*Id.*, 21.) The Examiner did not address the combination of any references.

C. The Earliest Possible Priority Date

The '384 patent claims priority to provisional application No. 62/554,931, filed September 6, 2017, which is the earliest possible priority date for the '384 patent. (Ex. 1001.) Petitioner applies this earliest priority date in this Petition; however, Petitioner reserves its right to challenge the priority date in subsequent proceeding(s).

III. LEVEL OF ORDINARY SKILL

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. (Ex. 1003, ¶32.) This is the same level of ordinary

skill that Petitioner proposed in the instituted IPRs and that was applied by PO and the Board. (Ex. 1025, 11; Ex. 1026, 11.)

IV. CLAIM CONSTRUCTION

The claim terms should receive their ordinary and customary meaning as understood by a POSITA at the time of filing and in accordance with the specification and the prosecution history. 37 C.F.R. §42.100(b); *see Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc). However, “the specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess [and] [i]n such cases, the inventor's lexicography governs.” *Id.* at 1316.

The challenged claims require a hemostasis valve having a “first filament” and a “second filament,” which each form a loop around the tubular member. Independent claim 1 recites that the first/second filaments are “flexible.” However, independent claims 15 and 23 do not recite that the filament is “flexible.” Rather, dependent claims 17 and 27, which depend from claims 15 and 23 respectively, add the “flexible” limitation, conveying that the filaments in claims 15 and 23 are not limited to “flexible” filaments.

In the instituted '011 and '012 Patent IPRs, the parties disputed the construction of “filament,” and specifically whether the “filament” recited in the '011 and '012 Patents is limited to a “flexible” filament. (Ex. 1025, 12-18; Ex. 1026,

13-21.) Because claims 1, 17, and 27 of the '384 patent expressly recite that the first/second filaments are “flexible,” Petitioner does not contest that flexibility is required for the filaments in those claims.⁴

Petitioner maintains that the filaments recited in claims 15 and 23 are not limited to “flexible” filaments. *See Bardford Co. v. Conteyor N. Am., Inc.*, 603 F.3d 1262, 1271 (Fed. Cir. 2010) (finding independent claim entitled to a broader construction because independent claim is “presumed to be broader” than dependent claim). If this were not the case, claims 17 and 27 would be superfluous. *See Ortho-McNeil Pharm., Inc. v. Mylan Lab'ys., Inc.*, 520 F.3d 1358, 1362 (Fed. Cir. 2008) (“Thus, this court strives to reach a claim construction that does not render claim language in dependent claims meaningless.”).

However, this issue is immaterial to Petitioner’s invalidity grounds herein, which rely upon Hartley and Eller for the “filament” limitations. PO has never disputed that Hartley and Eller disclose flexible filaments, and the Board has preliminarily found that both references disclose “flexible” filaments in the instituted IPRs. (Ex. 1025, 35-36; Ex. 1026, 34.) The Board needs to construe terms only to the extent necessary to resolve the controversy. *Realtime Data, LLC v. Iancu*, 912

⁴ Petitioner preserves its right to argue in future or related proceedings that the claims of the '384 patent are indefinite because a POSITA could not determine the scope of “flexible” with reasonable certainty.

F.3d 1368, 1375 (Fed. Cir. 2019). Here, a construction of “filament” is not necessary to resolve the controversy.

Petitioner does not believe any other terms require construction to resolve the patentability issues herein.

V. STATEMENT OF RELIEF REQUESTED

A. IPR Grounds

Petitioner asserts the following grounds of unpatentability:

Ground	Reference(s)	Basis	Challenged Claims
1	Schaffer + Hartley	35 U.S.C. § 103	1-4, 6-18, 20-30
2	Schaffer + Eller	35 U.S.C. § 103	1-4, 6-18, 20-30
3	Schaffer + Hartley + Eller	35 U.S.C. § 103	1-4, 6-18, 20-30
4	Hermann + Schaffer + Hartley	35 U.S.C. § 103	11-14, 20-22, 28-30
5	Hermann + Schaffer + Eller	35 U.S.C. § 103	11-14, 20-22, 28-30
6	Hermann + Schaffer + Hartley + Eller	35 U.S.C. § 103	11-14, 20-22, 28-30

B. The Asserted References Are Prior Art

The following references are prior art under at least 35 U.S.C. §102(a)(1):

- (1) Schaffer (Ex. 1005) published on December 4, 2003;
- (2) Hartley (Ex. 1006) published on June 26, 2003;

(3) Eller (Ex. 1007) published on October 29, 2015; and

(4) Hermann (Ex. 1009) issued on February 4, 1997.

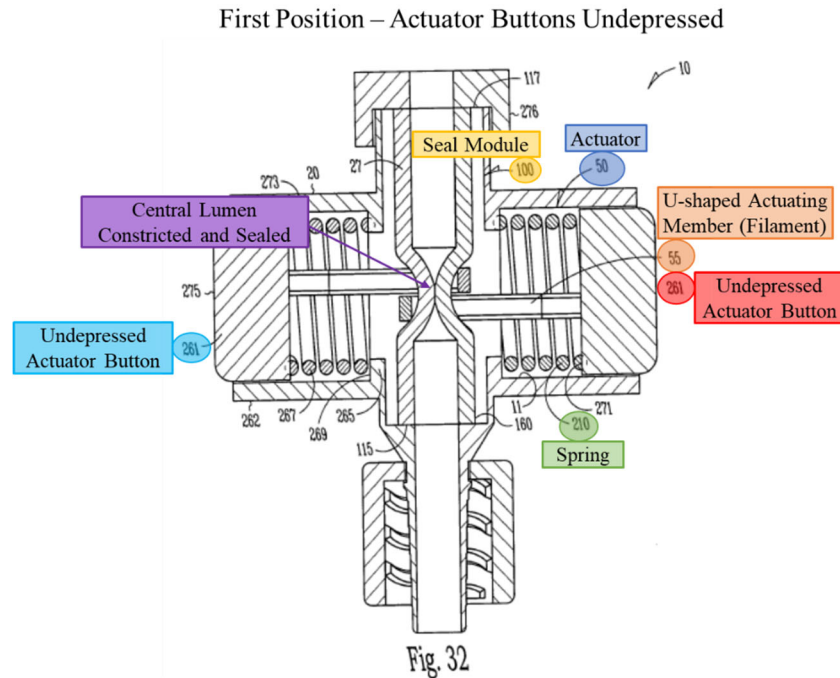
C. The Asserted References Are Analogous Art

The asserted references are analogous art that is usable in an obviousness combination. *Unwired Planet, LLC v. Google Inc.*, 841 F.3d 995, 1000 (Fed. Cir. 2016). The references are from the same field as the '384 patent, e.g., hemostasis valves for use during intravascular procedures. (Ex. 1003, ¶34.) The references are also pertinent to the problem the inventor was focused on, e.g., sealing a catheter during intravascular procedures to minimize blood leaks. (*Id.*) Accordingly, a POSITA is presumed to have been aware of these references. *In re Nilssen*, 851 F.2d 1401, 1403 (Fed. Cir. 1988).

VI. GROUNDS 1-2: CLAIMS 1-4, 6-18, AND 20-30 ARE OBVIOUS OVER SCHAFFER COMBINED WITH HARTLEY OR ELLER

Schaffer combined with Hartley or Eller renders claims 1-4, 6-18, and 20-30 obvious. (Ex. 1003, ¶¶51-195.) Schaffer discloses a hemostasis valve for use with catheters “that blocks the flow of gas or fluid completely and immediately with or without an instrument in place within the gas/fluid path.” (Ex. 1005, [0002], [0008].) Like the valve claimed in the '384 patent, Schaffer's valve includes a collapsible tubular member (“seal module 100”). (*Id.*, [0049].) Schaffer's valve also includes two actuating members 55 that constrict the elongate member to close the valve. (*Id.*, [0076]-[0077].) Also, like the '384 patent, Schaffer's actuating members 55

may be moved from a first position to a second position by depressing two actuator buttons 261 connected to two springs 210. (*Id.*)



(*Id.*, Fig. 32.)

Hartley and Eller disclose hemostasis valves having filaments that loop around and constrict the lumen of a tubular member to seal the valve. Hartley’s “filaments” are formed into a “string”:

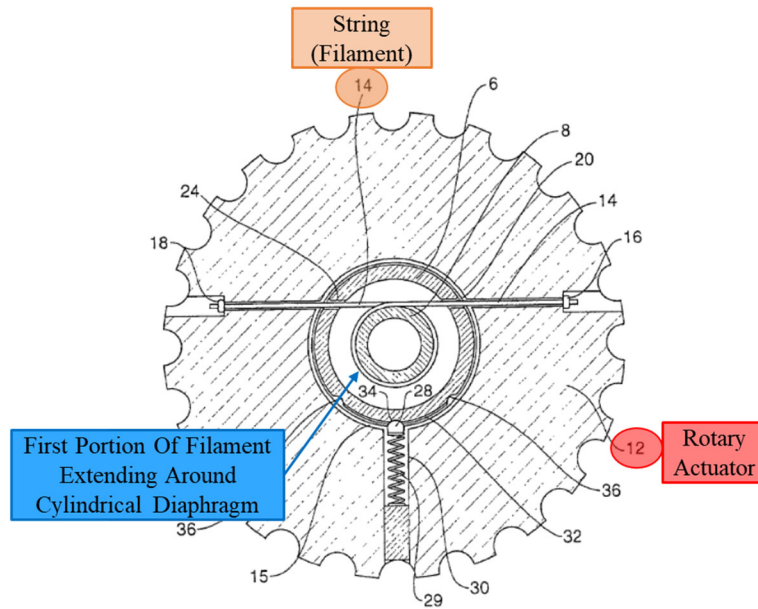
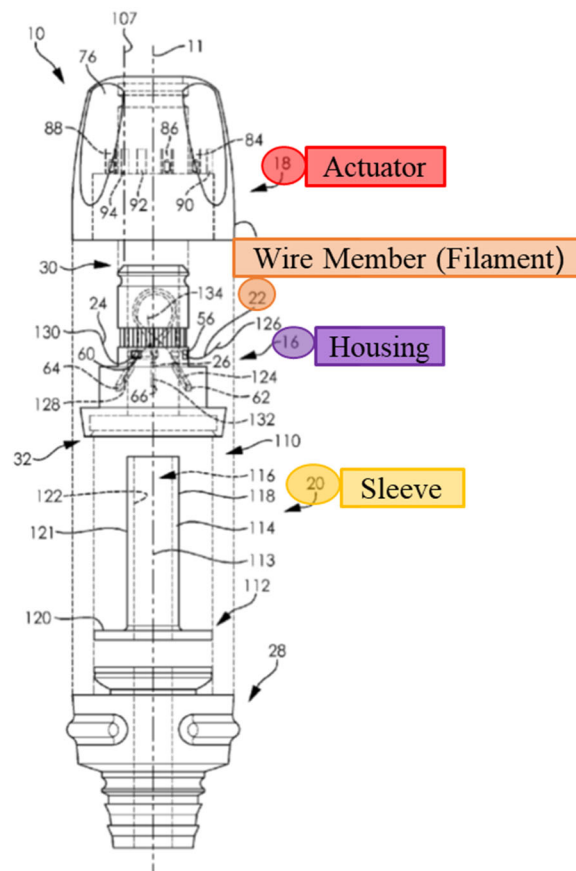


Fig 3

(Ex. 1006, [0031], Fig. 3.) Eller’s “filaments” are one or more “wire members”:



(Ex. 1007, 5:1-6, Fig. 2.) As the Board has preliminarily found in the instituted '011 and '012 Patent IPRs and as explained herein, a POSITA would have found it obvious to substitute Hartley's or Eller's filaments for Schaffer's actuating members. (Ex. 1025, 33-41; Ex. 1026, 34-48.) Further, a POSITA would have found it obvious, and been motivated, to use a first filament and a second filament in Schaffer's valve to, for example, increase the area of constriction.

A. Claim 1

Schaffer combined with Hartley *or* Eller renders claim 1 obvious. (Ex. 1003, ¶¶55-138.)

1. Preamble

If the preamble is limiting, Schaffer, Hartley, and Eller disclose a “valve assembly.” (Ex. 1003, ¶¶56-59.)

Schaffer discloses embodiments of a “fluid stasis valve” for use with catheters to prevent the flow of fluid and/or blood through the valve during medical procedures. (Ex. 1005, [0002], [0046], [0055].)

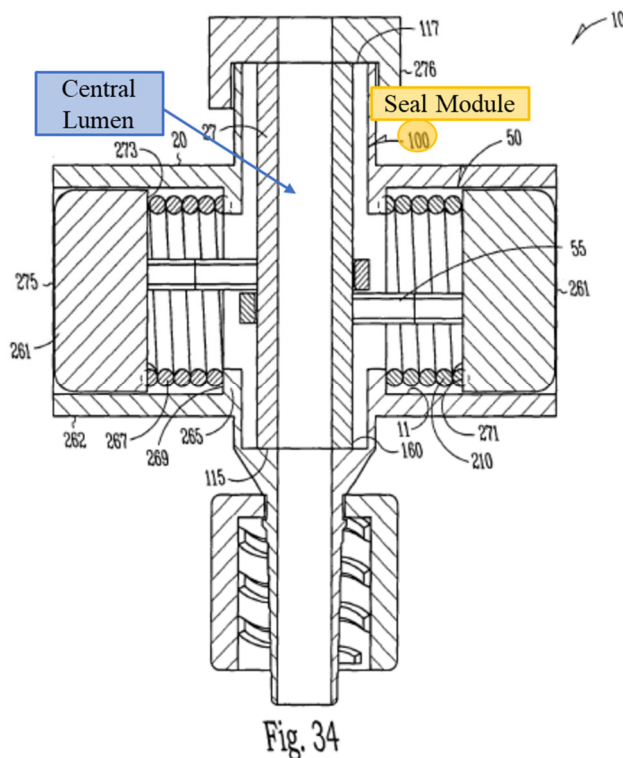
Hartley discloses “an access valve” for use in “medical applications ... where it is desired to seal around a catheter or other instrument ... to prevent loss of blood or other fluid.” (Ex. 1006, [0002]-[0004].)

Eller discloses “selective fluid barrier valve devices” for procedures “that require the percutaneous insertion of one or more interventional devices into a bodily passage, such as a portion of the vascular system.” (Ex. 1007, 1:14-23.)

2. Tubular Member

Schaffer discloses “a tubular member defining a lumen.” (Ex. 1003, ¶¶60-61.) Schaffer’s valve assembly includes a “seal module 100” that comprises “a flexible, elongate tubular structure 101.” (Ex. 1005, [0049], [0051], [0054], [0075].)

The seal module defines a central lumen:



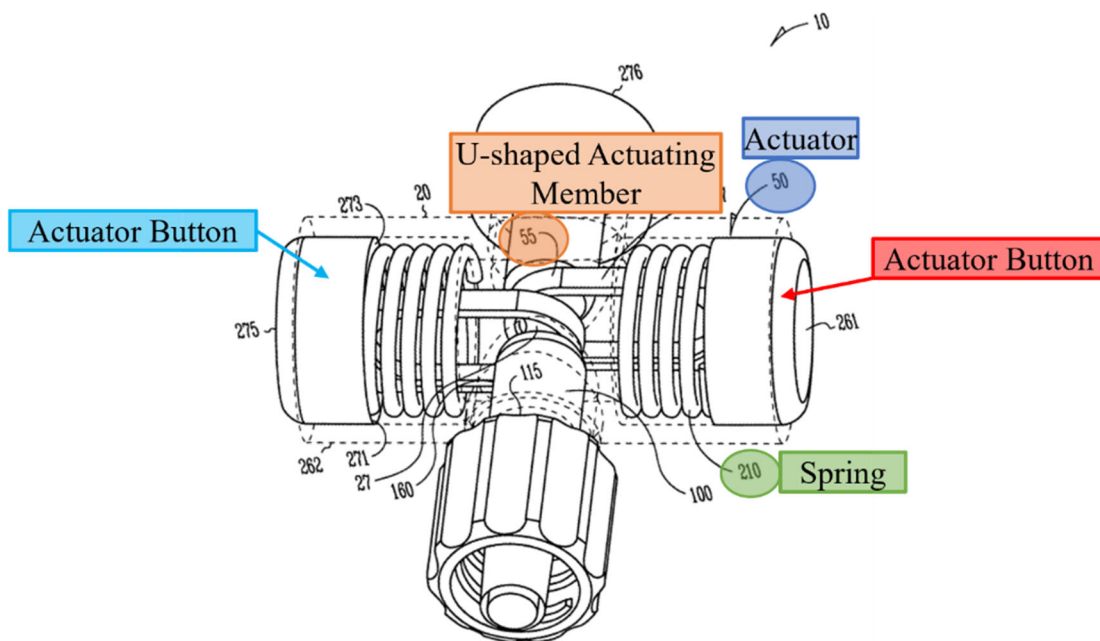
(*Id.*, [0075], Fig. 34.) Schaffer discloses that “a range of instruments [can be] used within the seal module,” such as “a catheter, guidewire, needle, or fiber.” (*Id.*,

[0056].) Schaffer’s seal module 100 is therefore “a tubular member defining a lumen.” (Ex. 1003, ¶61.)

3. Filaments

Claim 1 next recites “a first filament extending in a first loop around the tubular member, wherein the first filament is flexible; a second filament extending in a second loop around the tubular member, wherein the second filament is flexible.” Schaffer combined with Hartley *or* Eller renders these limitations obvious. (Ex. 1003, ¶¶62-124.)

Schaffer describes a valve having “two circular actuators 50” on opposite sides of the housing that are “movable from a first position to a second position”:



(Ex. 1005, [0075]-[0076], Figs. 31-32.) Each actuator 50 includes “an actuator button 261” and a “spring 210.” (*Id.*) Schaffer’s valve also includes two actuating members 55, which may be U-shaped, coupled to the actuator buttons and collectively forming a loop around Schaffer’s seal module 100 (tubular member):

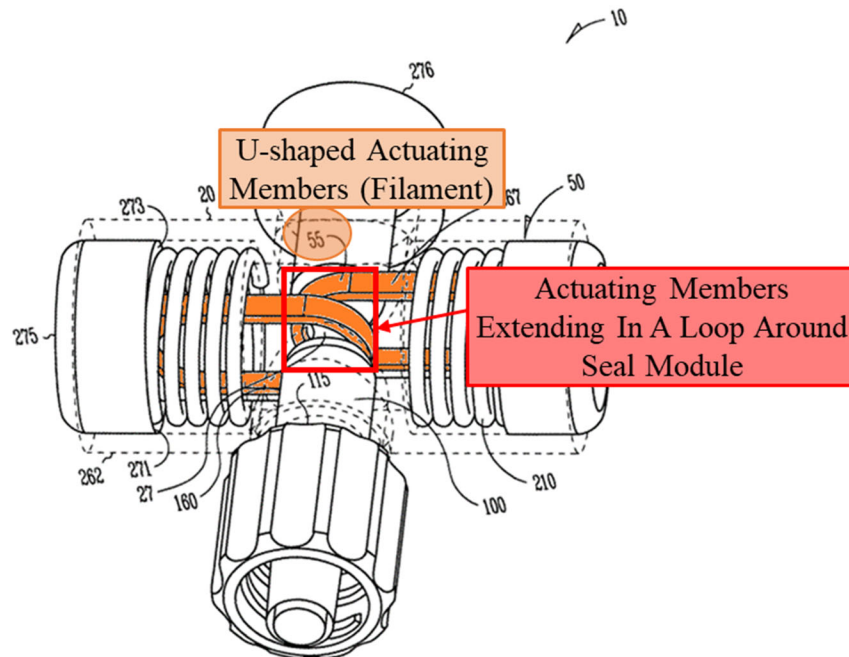


Fig. 31

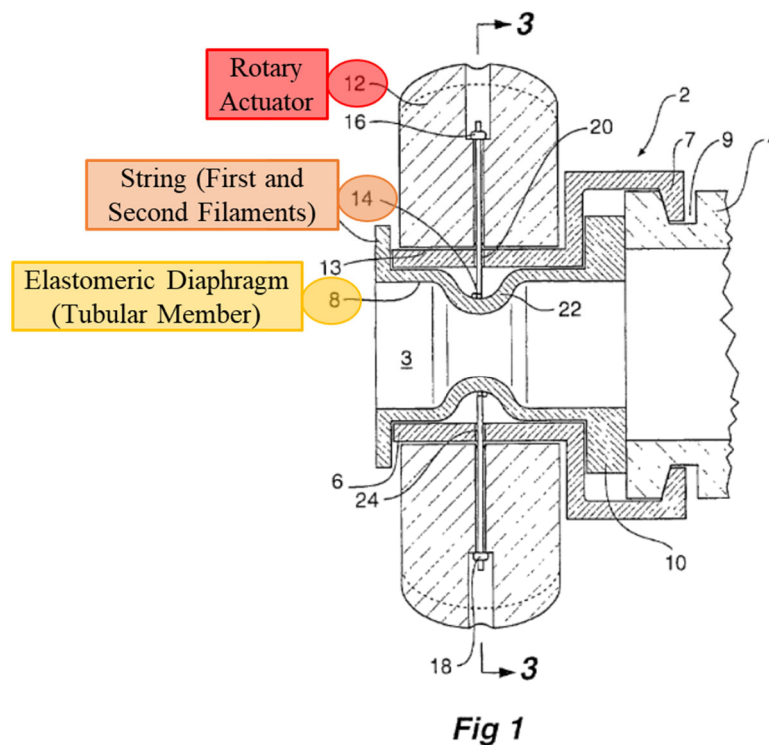
(*Id.*, [0076], Fig. 31; Ex. 1003, ¶63.)

Schaffer’s filament configuration is slightly different from the filament configuration recited in claim 1. Schaffer’s two U-shaped filaments collectively form a loop around the tubular member, as opposed to the claimed configuration that requires two filaments that each form a loop around the tubular member. However, as explained below, Hartley and Eller each disclose hemostasis valves with first and second filaments that form a loop around a collapsible tubular member. A POSITA

would have been motivated to substitute Hartley's or Eller's filaments for Schaffer's U-shaped actuating members with a reasonable expectation of success.

a. Hartley

Schaffer combined with Hartley renders this limitation obvious in two ways. **First**, Hartley discloses a “first filament” and “second filament” as recited in claim 1. (Ex. 1003, ¶¶66-77.) Hartley describes a hemostasis valve having a cylindrical housing that holds a “cylindrical elastomeric diaphragm,” and a rotatory actuator mounted to the housing:



(Ex. 1006, [0031], Fig. 1.) “A string 14 is mounted into the rotary actuator” and forms a loop around the elastomeric diaphragm. (*Id.*)

A POSITA would have understood that Hartley's string 14 would be formed from at least two threads twisted together. (Ex. 1014 (definition of string: "material consisting of threads of cotton, hemp, or other material twisted together to form a thin length"); Ex. 1015.) Each thread forming the string is a "filament" as described by the '384 patent and under the construction proposed by PO in related proceedings. (Ex. 1003, ¶67; Ex. 1001, 9:21-23 (stating that the filament "can comprise one or several threads, lines, cords, rope, ribbon, flat wire, sheet, or tape"); Ex. 1025, 12 ("Patent Owner argues that a 'POSA would understand that the term 'filament' ... as meaning 'a thin, flexible length of material formed by one or more strands of material.').) Thus, Hartley's string 14 comprises a "first filament" and a "second filament" as recited in claim 1. (Ex. 1003, ¶¶67-68.)

Claim 6 of the '384 patent confirms that the threads of Hartley's string are a "first filament" and "second filament" as recited in Claim 1. Claim 6 depends from Claim 1 and recites: "wherein the first filament and the second filament each comprise a plurality of strands woven together." Accordingly, the first and second filaments recited in Claim 1 are not limited to filaments formed from a plurality of woven strands and instead encompass the individual threads forming Hartley's string. *See Bardford Co.*, 603 F.3d at 1271 (holding that an independent claim is "presumed to be broader" than dependent claim); *Ortho-McNeil Pharm., Inc.*, 520

F.3d at 1362 (“Thus, this court strives to reach a claim construction that does not render claim language in dependent claims meaningless.”).

Hartley’s string is secured to the rotary actuator via knots 16 at the ends of the filament and “is wound preferably twice around the cylindrical diaphragm 8”:

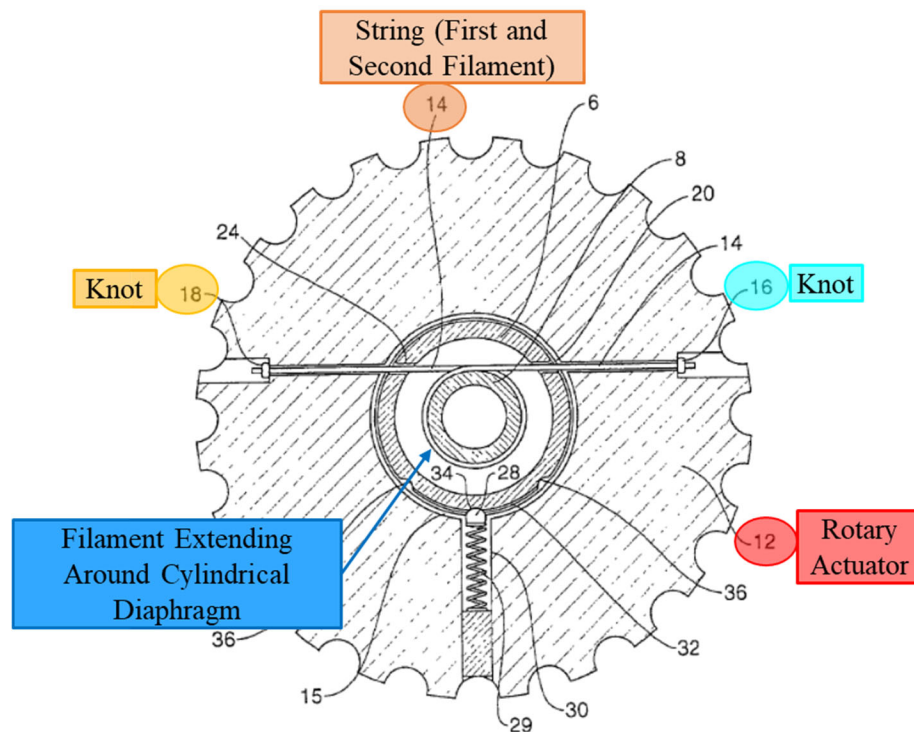


Fig 3

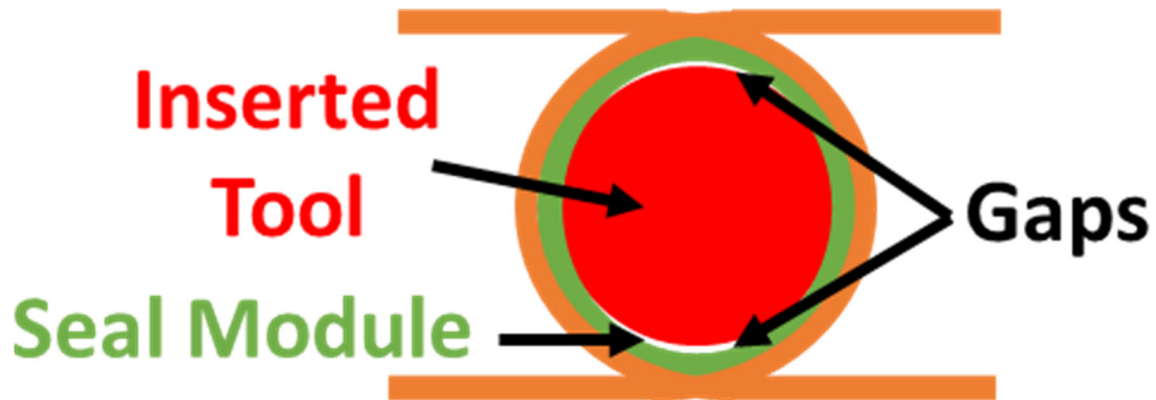
(Ex. 1006, [0031], Fig. 3.) Hartley’s string, and each of the filaments making up the string, therefore “extends in a loop around the tubular member.” (*Id.*; Ex. 1003, ¶69.)

Hartley discloses that “[r]otation of the rotary actuator 12 with respect to the cylindrical housing 6 will cause the string 14 to be pulled in both directions at once and hence the cylindrical diaphragm 8 to be constricted.” (Ex. 1006, [0031], [0034],

Fig. 4.) Hartley further discloses that its valve “will close over a range of diameters of devices passed through the valve or can close completely down to be self sealing.” (*Id.*, [0037].)

POSITAs would have found it obvious to substitute Hartley’s string for Schaffer’s actuating members. (Ex. 1003, ¶¶70-77.) The combination of Hartley’s string and Schaffer’s valve would have merely entailed substitution of one known element (Hartley’s string) for another (Schaffer’s actuating members) to yield the predictable result of sealing Schaffer’s valve. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, at 416 (2007).

Hartley’s disclosure that its string can “close over a range of diameters of devices passed through the valve or can close completely down to be self-sealing” would have further motivated POSITAs to substitute Hartley’s string for Shaffer’s actuating members. (Ex. 1006, [0037]; Ex. 1003, ¶71.) POSITAs would have recognized that Hartley’s string may seal more effectively across a wider range of tool diameters and shapes than Schaffer’s U-shaped actuating members. (Ex. 1003, ¶71.) Depending on the inserted tool, Schaffer’s actuating members may form small gaps between the valve’s seal module and the tool’s outer surface:



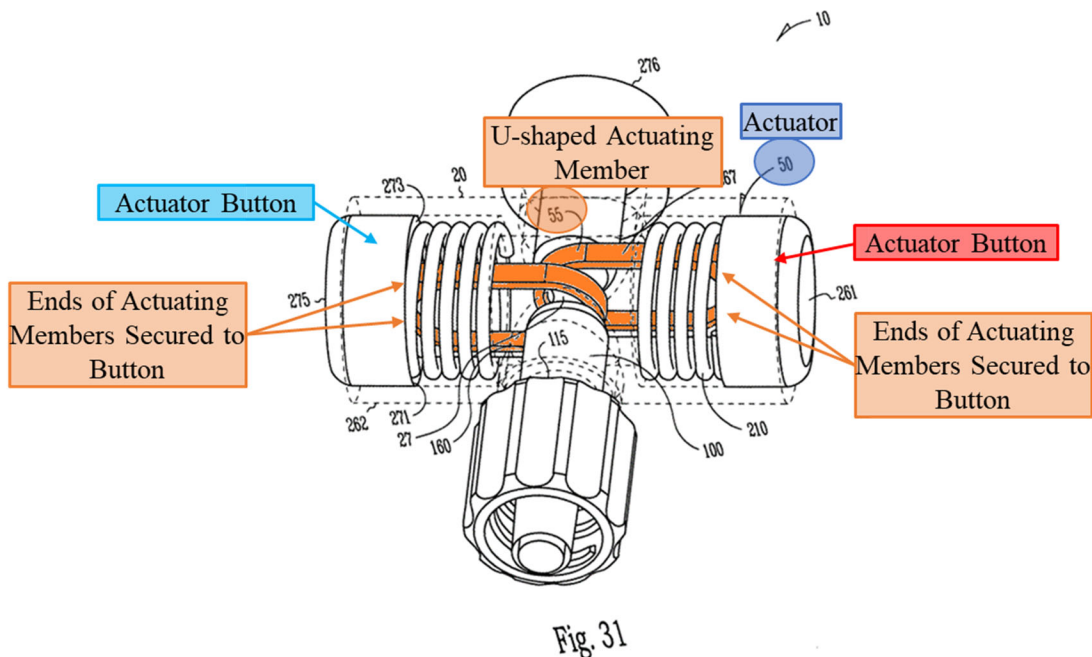
(*Id.*) Hartley’s string could improve upon this potential issue because the string more precisely conforms to the tool diameters and shapes. (*Id.*)

In the ’011 Patent IPR, PO argued that Schaffer’s valve would not create gaps. (*See* Ex. 1025, 37 (summarizing argument).) PO is incorrect. PO relied on a single embodiment in Schaffer that optionally uses a “gelatinous” or “sticky” seal module with “selfclosing” properties while ignoring other disclosures undermining its argument. (Ex. 1003, ¶¶107-112; *see also* Ex. 1025, 37 (explaining deficiencies in argument).)

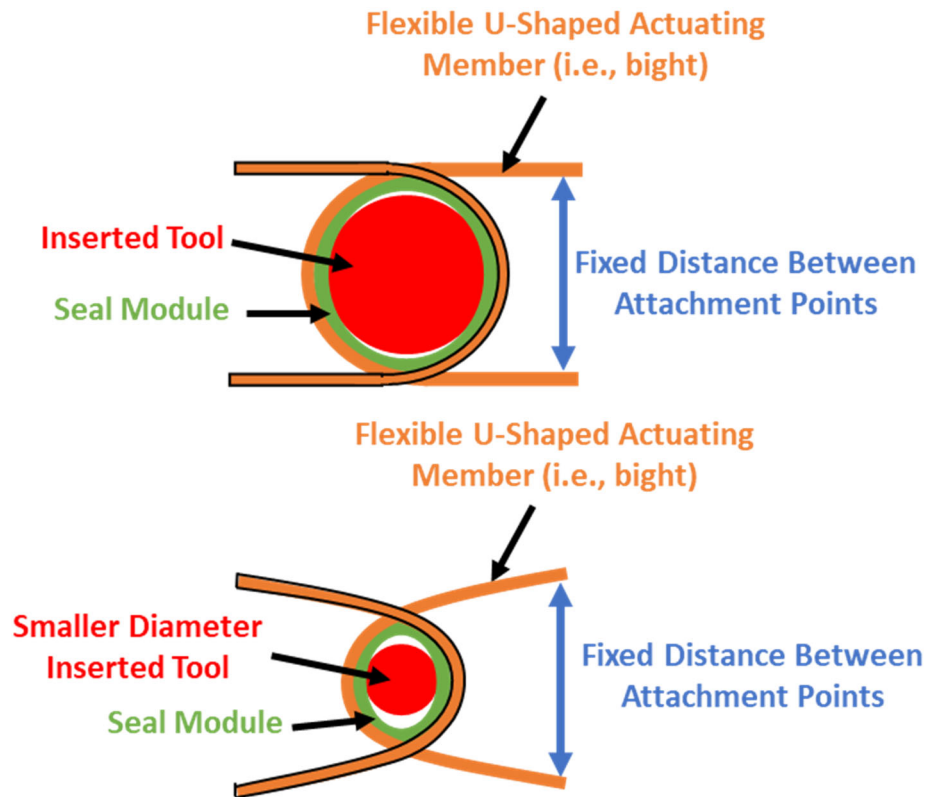
For example, Schaffer discloses that even the “sticky” or “gelatinous” seal module may not form a complete seal, stating that the valves form a “*nearly* fluid/gas tight seal.” (Ex. 1005, [0059] (emphasis added).) Further, Schaffer discloses that the “sticky” or “gelatinous” seal is an optional feature and does not suggest that the “sticky” or “gelatinous” seal is necessary for all embodiments, including the embodiment in Figures 30-34. (*Id.*, [0059], [0075], [0081].) In fact, Schaffer discloses many other seal materials that would not be “sticky” or “gelatinous.” (*Id.*,

[0059].) Further, Mr. Thornton explains that a POSITA would not have used a very “sticky” or “gelatinous” seal with the embodiment in Figures 30-34 because the seal in that embodiment must “retract to an uncollapsed configuration” when the tension on the seal is released by the actuating members. (Ex. 1003, ¶110.)

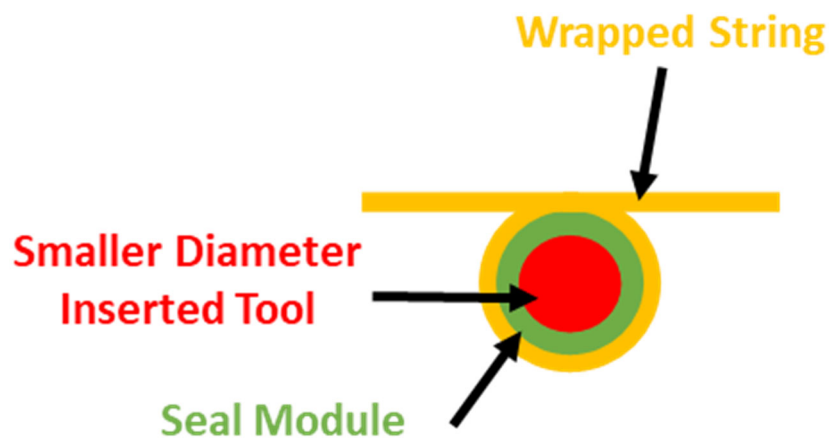
Mr. Thornton also explains that a POSITA would have understood that Schaffer’s valve may form gaps if the tool inserted through the valve does not match the size or shape of Schaffer’s U-shaped actuating members because each of the members is secured to the actuator buttons at two fixed, spaced-apart points:



(Ex. 1005, Fig. 31; Ex. 1003, ¶111.) A POSITA would have recognized that the fixed attachment points to the actuator buttons may prevent the U-shaped actuating members from completely conforming to the exterior of a tool with a smaller diameter than the distance between the attachment points:



(Ex. 1003, ¶111.) This would not be an issue with Hartley’s string, which would be wrapped around the seal module and conform to the varying diameter tools:



(*Id.*)

POSITAs also had a finite number of predictable materials to select from to constrict a tubular member in a hemostasis valve in September 2017. (Ex. 1003,

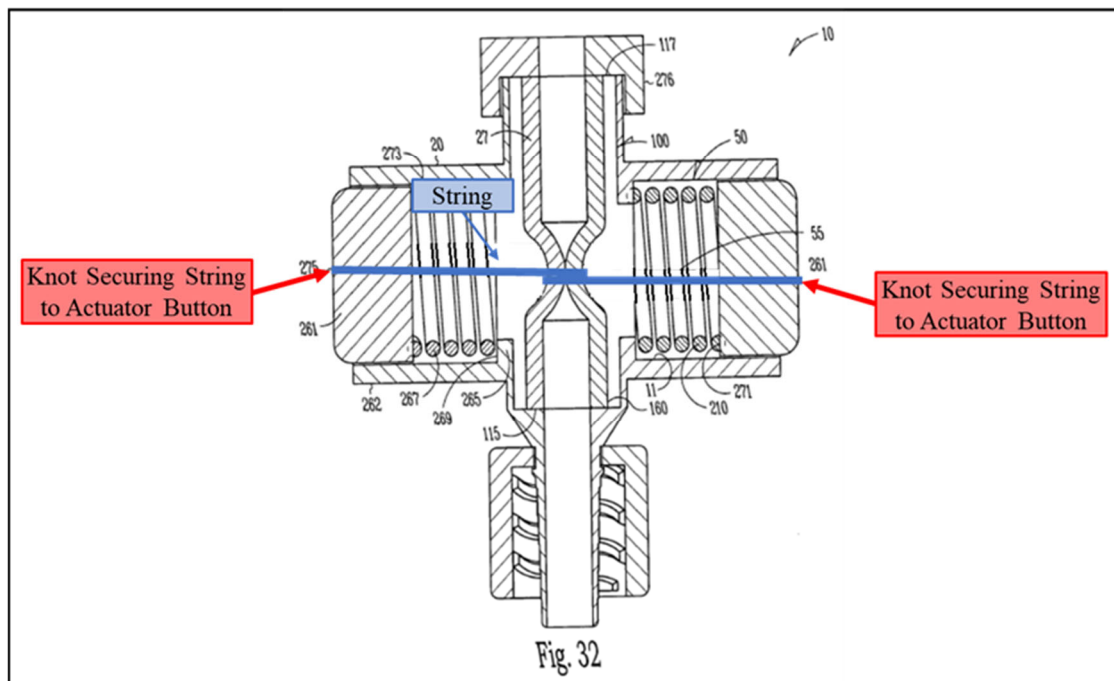
¶72.) Hartley and Schaffer disclose a few such materials: Hartley’s string and Schaffer’s actuating members (which can be plastic or metal). (*Id.*) Eller discloses another material: wire members (which can be metals or polymers). (*Id.*) A POSITA would have found it obvious to select from these finite, predictable materials for constricting a valve and, as discussed below, would have had a reasonable expectation of success in implementing them. (*Id.*); *KSR*, 550 U.S. at 421.

POSITAs also would have had a finite number of predictable filament configurations to select from to constrict a tubular member in a hemostasis valve in September 2017. (Ex. 1003, ¶73.) Hartley discloses a string that runs from one side of the valve to the other and forms a loop around the tubular member, while Schaffer discloses two u-shaped members that collectively form a loop around the tubular member. (*See above* (describing Schaffer and Hartley).) Eller also discloses wire members that loop around a tubular member to constrict the valve. (*See infra* §VI.A.3.b (describing Eller).) A POSITA would have found it obvious to select any of these finite, predictable configurations for constricting a valve and, as discussed below, would have had a reasonable expectation of success in implementing them. (Ex. 1003, ¶73); *KSR*, 550 U.S. at 421.

POSITAs would have reasonably expected success in substituting Hartley’s string for Schaffer’s two actuating members for several reasons. (Ex. 1003, ¶¶74-

77.) Hartley teaches using simple knots to attach the string to Hartley's rotary actuator. (Ex. 1006, [0031].) POSITAs would have reasonably expected that similar knots would secure Hartley's string to Schaffer's actuator buttons. (Ex. 1003, ¶74.) For example, each end of Hartley's string (and the filaments comprising the string) could be threaded through small holes drilled or otherwise created in Schaffer's buttons and knotted on the other side. (*Id.*) This simple modification would have been within a POSITA's skills:

Demonstrative Illustration
Schaffer + Hartley's String



(*Id.*)⁵

⁵ Petitioner created this demonstrative image.

Also, POSITAs would have recognized that Hartley's string and Schaffer's actuating members function in similar ways and, therefore, no other structural modifications to Schaffer's valve would be necessary. (*Id.*, ¶75.) Both valves collapse the tubular member's lumen by pulling the actuating members/string in opposite directions. (Ex. 1005, [0077]; Ex. 1006, [0031].) If Hartley's string were incorporated into Schaffer's valve, a POSITA would have reasonably expected Schaffer's springs to pull the ends of the strings in opposite directions to constrict Schaffer's seal module. (Ex. 1003, ¶75.)

Likewise, POSITAs would have reasonably expected that pressing Schaffer's buttons inwardly (i.e., second position) would release tension on the string, allowing the lumen to open. (*See* Ex. 1005, [0077]; Ex. 1006, [0034]; Ex. 1003, ¶76.) Schaffer's seal module is made from a "highly deformable, non-compressible material 166 (e.g., plastic)" and is "configured to maintain an open lumen 193 when no compressive force 67 is applied." (Ex. 1005, [0054].) Thus, Schaffer's seal module has the resilience to open when the tension on the string is released. (Ex. 1003, ¶76.)

Moreover, 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. (*Id.*) Schaffer and other prior art references disclose various materials for the seal module

that a POSITA could use to achieve the desired resiliency, including “modified vinyl, silicone, polyurethane or a combination thereof.” (Ex. 1005, [0081]; *see also* Ex. 1007, 36:27-60 (disclosing materials for seal modules).)

Second, if the Board finds that Hartley’s string does not constitute first and second filaments as recited in claim 1, a POSITA would have found it obvious to substitute two of Hartley’s strings for Schaffer’s U-shaped actuating members. (Ex. 1003, ¶¶78-84.)

A POSITA would have been motivated to use two strings with Schaffer’s valve based on Hartley’s teachings and to provide a more robust and reliable seal. (*Id.*, ¶79.) Hartley discloses that its string “is wound preferably twice around the cylindrical diaphragm.” (Ex. 1006, [0031].) A POSITA exchanging Hartley’s string for Schaffer’s two U-shaped actuating members would have recognized that another way to create two loops (or windings) around the tubular member would have been to use two strings, each string forming a single loop. (Ex. 1003, ¶79.) While Hartley does not explain why the string would be “preferably” wound twice around the tubular member, a POSITA would have understood that two loops of string would apply constricting force along a greater length of the tubular member, thereby creating a larger sealing area and a more robust seal. (*Id.*)

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. (*Id.*, ¶¶80-82.) First, a single string looped twice around the tubular member will create more friction because more of the string is in contact with the surface of the tubular member. (*Id.*, ¶80.) This increased friction means 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. (*Id.*) A POSITA would have been motivated to use two separate strings to reduce the friction while still accomplishing the same result (a larger sealing area). (*Id.*)

Second, using two separate strings allows the manufacturer to optimally space the strings to achieve the maximum sealing force. (*Id.*, ¶81) With only a single string, the loops formed by the string will tend to be immediately next to each other, particularly after the buttons have been depressed once or twice. (*Id.*) However, with two strings, the manufacturer can design a small gap between the strings that remains after use to ensure that the sealing area is wider. (*Id.*)

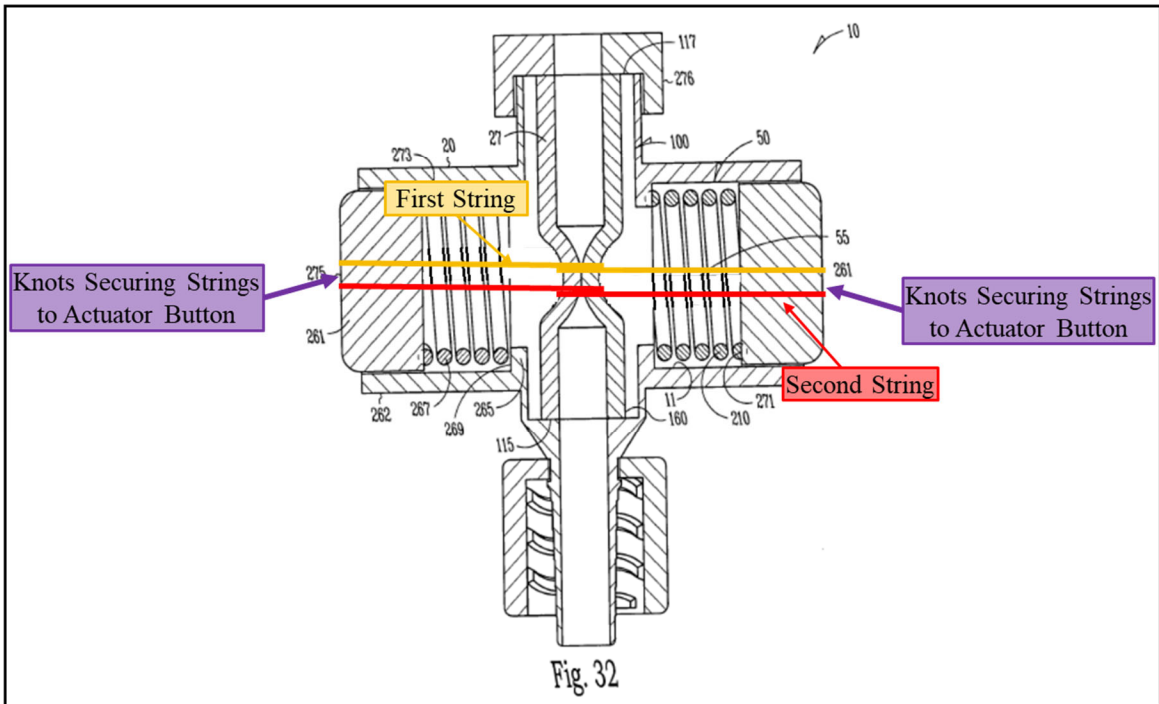
Third, a second string provides a redundancy to the valve that cannot be accomplished with a single string. (*Id.*, ¶82.) Using a second string ensures that the valve seals even if one string fails to tighten around the tubular member. (*Id.*) Such a backup would not exist with a single string looped twice around the tubular member. (*Id.*)

A POSITA would have reasonably expected success in substituting Schaffer's two actuating members with two of Hartley's strings because Schaffer already discloses a method of attaching two filament ends to each button. (Ex. 1005, [0075]-[0077], Figs. 30-34; Ex. 1003, ¶83.) In Schaffer, both ends of each U-shaped member are attached to the same button – thus, Schaffer describes a method of attaching two filament ends to a button. (Ex. 1005, [0075]-[0077], Figs. 30-34; Ex. 1003, ¶83.) Similarly, one end of each of Hartley's strings would be attached to Schaffer's buttons for a total of two filament ends attached to each button. (Ex. 1003, ¶83.)

Further, Hartley teaches using simple knots to attach the string to Hartley's rotary actuator. (Ex. 1006, [0031].) POSITAs would have reasonably expected that similar knots would secure Hartley's strings to Schaffer's actuator buttons. (Ex. 1003, ¶84.) For example, each end of Hartley's strings could be threaded through small holes drilled or otherwise created in Schaffer's buttons and knotted on the other side. (*Id.*) This simple modification would have been within a POSITA's skills:

Demonstrative Illustration

Schaffer + Hartley's Strings

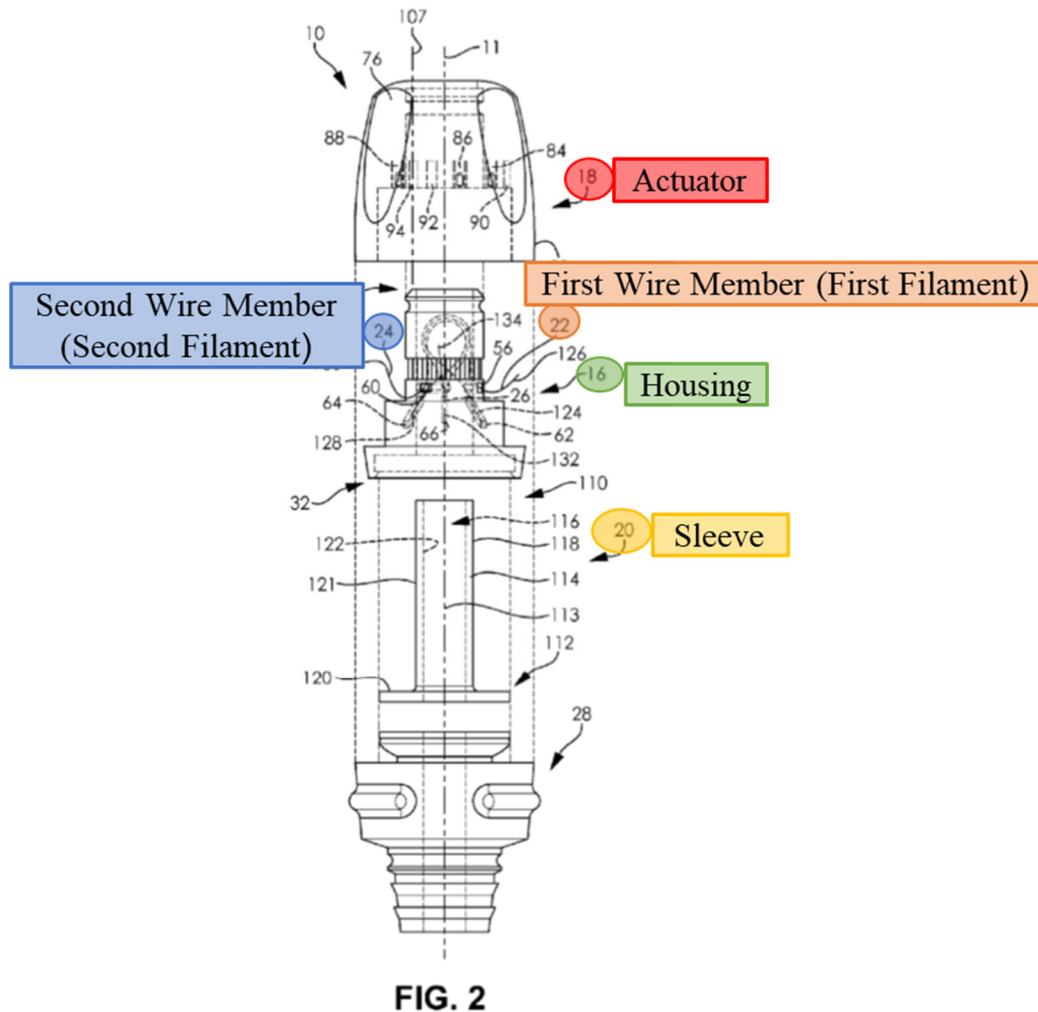


Thus, Schaffer combined with Hartley renders the first/second filaments recited in claim 1 obvious. (*Id.*)

b. Eller

Schaffer combined with Eller renders this limitation obvious in two ways.

First, Eller describes hemostasis valves having “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”:

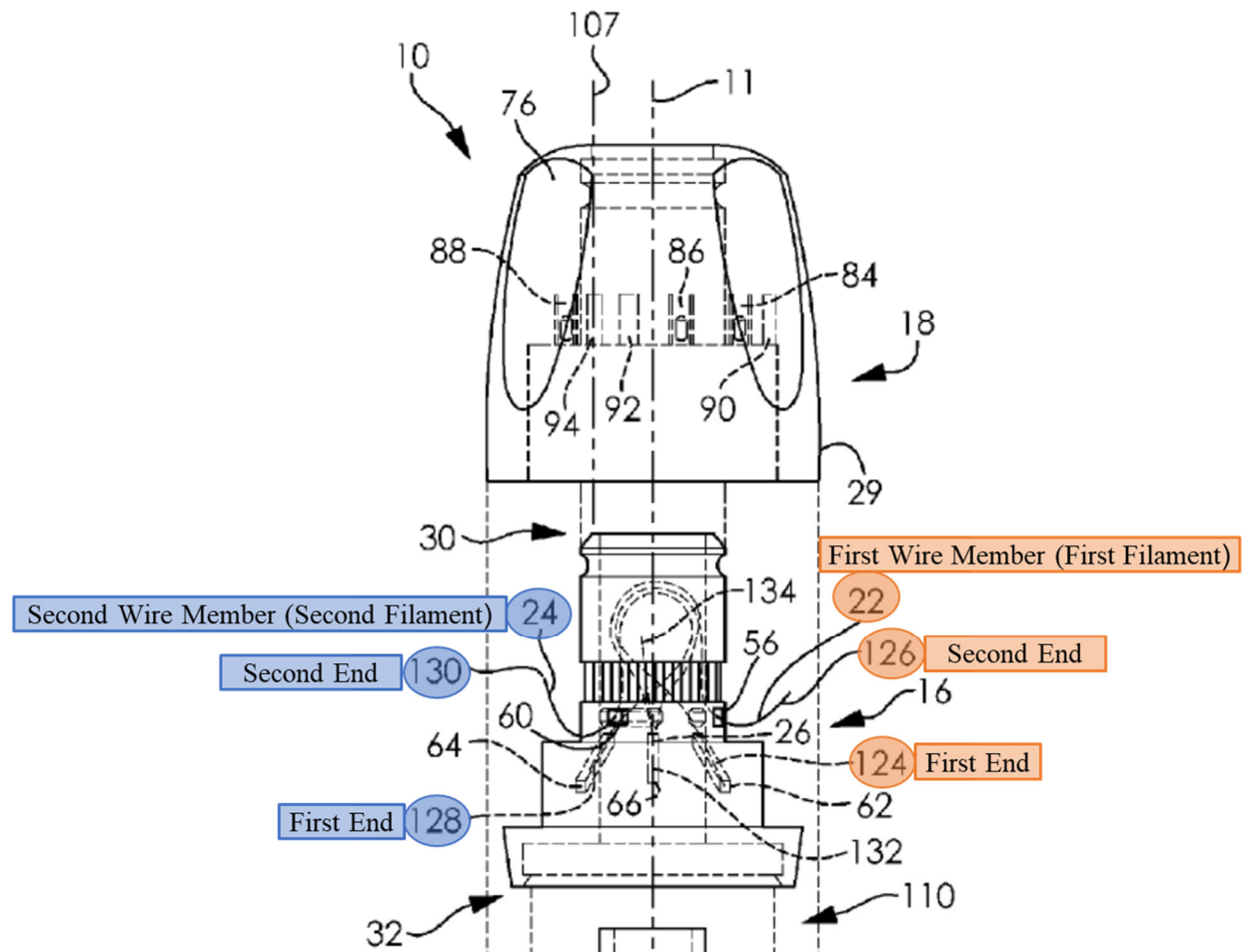


(Ex. 1007, 5:1-6, 16:7-19, Fig. 2⁶.) Eller states that the wire members may “comprise any suitable number of strands and/or fibers that are twisted, or otherwise interconnected to one another.” (*Id.*, 15:61-65.) A POSITA would have therefore understood that Eller’s wire member would be formed from at least two filaments twisted together. (Ex. 1003, ¶86.) Eller discloses that the wire member can be formed from various materials (e.g., “metals,” “polymers,” “polyester,” “[n]ylon,”

⁶ Eller’s Figure 2 shows an exploded view of the device. (Ex. 1007, 2:46-47.)

“flexible materials”), and thus the twisted “strands and/or fibers” comprising Eller’s wire member are each a flexible filament. (Ex. 1007, 15:41-65; Ex. 1003, ¶86; Ex. 1001, 9:21-23 (stating that the filament “can comprise one or several threads, lines, cords, rope, ribbon, flat wire, sheet, or tape”); Ex. 1025, 12 (“Patent Owner argues that a ‘POSA would interpret the term ‘filament’ ... as meaning ‘a thin, flexible length of material formed by one or more strands of material.’”).) Eller’s wire member therefore comprises a “first filament” and a “second filament” as recited in claim 1. (Ex. 1003, ¶¶86-87.)

Eller’s wire members extend around the valve’s “sleeve” so that a first end can attach to the housing 16 and a second end can attach to the actuator 18:



(Ex. 1007, 12:52-14:37, Fig. 2 (excerpt).) Eller also discloses that the “wire member can be positioned such that it extends at least one full revolution around the outer surface of the sleeve.” (*Id.*, 22:22-24.) When replacing Schaffer’s actuating members with Eller’s wire member, POSITAs would have been motivated to loop Eller’s wires at least one full revolution around Schaffer’s seal module to ensure the wires formed a constrictive seal. (Ex. 1003, ¶88.) POSITAs would have reasonably expected success because Eller encourages looping the wires one revolution around the sleeve and discloses that such a configuration forms a seal. (*Id.*)

Eller's actuator and wire members are "moveable between a first configuration and a second configuration." (Ex. 1007, 15:21-25.) In the first configuration, the actuator is rotated so that the wire members are in a relaxed state and fluid is permitted to flow through the sleeve. (*Id.*, 15:21-40, 17:38-43.) In the second configuration, the actuator is rotated to place the wire members under tension, causing the wire members to constrict the sleeve and prevent fluid from passing therethrough. (*Id.* 15:21-40, 17:62-67.)

A POSITA would have found it obvious to substitute Eller's wire member for Schaffer's two actuating members by attaching one end of the wire to Schaffer's first button, looping the wire around the seal module, and attaching the second end of the wire to Schaffer's second button. (Ex. 1003, ¶¶90-95.) The combination of Eller's wire member and Schaffer's valve would have entailed merely substituting one known element (Eller's wire member) for another (Schaffer's two actuating members) to yield the predictable result of constricting Schaffer's valve. *KSR*, 550 U.S. at 416.

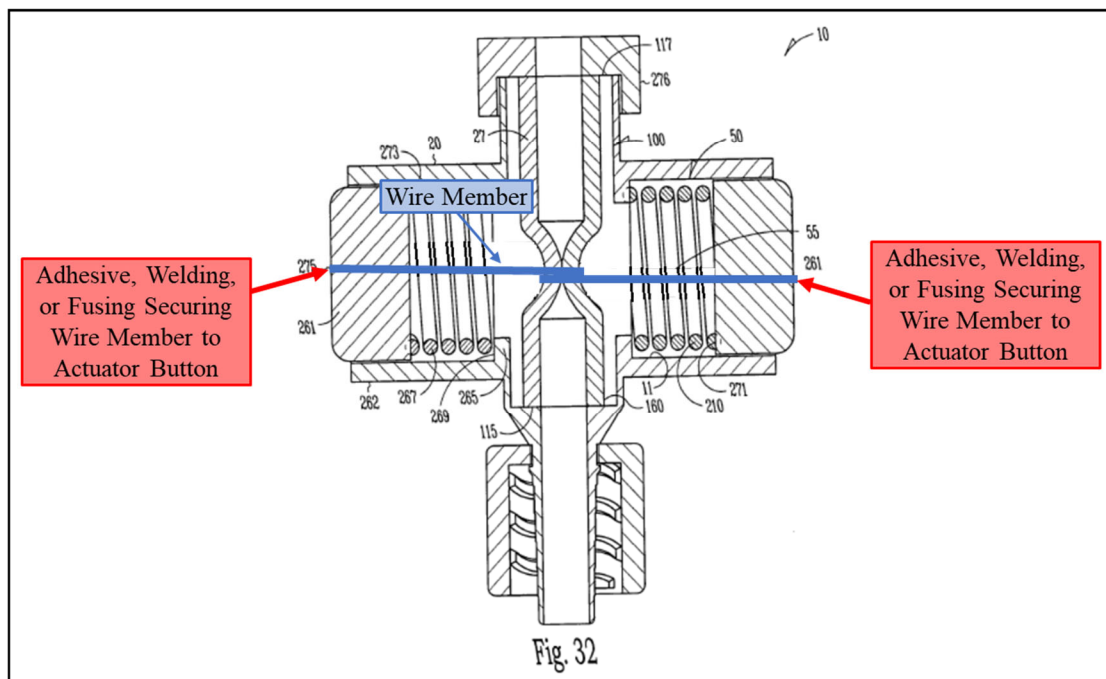
Eller's disclosure that the wire member can form a seal around one or more medical devices would have further motivated POSITAs to substitute Eller's wire member for Shaffer's actuating members. (Ex. 1007, 15:21-40, 17:38-43, 18:3-8; Ex. 1003, ¶91.) POSITAs would have recognized that Eller's wire may seal more effectively across more device diameters and shapes than Schaffer's actuating

members. (*Supra* §VI.A.3.a; Ex. 1003, ¶92.) Like Hartley’s string, Eller’s wire member could more closely conform to some devices. (Ex. 1003, ¶92.) PO’s argument that Schaffer would not form gaps is incorrect for the reasons explained above. (*Supra* §VI.A.3.a.)

POSITAs also had a finite number of predictable materials and a finite number of predictable filament configurations to use for constricting a tubular member within a hemostasis valve in September 2017. (*Supra* §VI.A.3.a; Ex. 1003, ¶¶94-95.) A POSITA would have found it obvious to select from these finite, predictable options, including Eller’s wire member, and would have reasonably expected success in implementing them, for the reasons discussed in the Schaffer-Hartley ground. (*Supra* §VI.A.3.a; Ex. 1003, ¶¶94-95.)

A POSITA would have reasonably expected success in substituting Eller’s wire member for Schaffer’s actuating members for several reasons. (Ex. 1003, ¶¶96-101.) First, Eller discloses that the “[a]ttachment between a wire member and a housing and/or an actuator can be accomplished using any suitable method or technique.” (Ex. 1007, 14:37-43.) Eller further identifies several means for securing its wire members to an actuator, including “using adhesives, welding, fusing.” (*Id.*, 14:43-49.) POSITAs would have reasonably expected success in securing Eller’s wire member to Schaffer’s actuator buttons using these simple methods. (Ex. 1003, ¶96.)

Demonstrative Illustration Schaffer + Eller's Wire Member



(*Id.*)⁷

Second, Eller teaches that its wire member may be used with “any suitable actuator capable of moving the selective fluid barrier valve device between a first configuration and a second configuration.” (Ex. 1007, 8:27–39.) Eller discloses that suitable actuators include “rotatable actuators, linear actuators, slidable actuators, pivotable actuators, levers, and any other actuator considered suitable for a particular embodiment.” (*Id.*, 8:39–44.) Given this disclosure, POSITAs would have reasonably expected Eller’s wire member to work with Schaffer’s buttons, which are linear and/or slidable actuators. (Ex. 1003, ¶97.)

⁷ Petitioner created this demonstrative image.

Third, Eller's wire member and Schaffer's actuating members function similarly to close the valves. (*Id.*, ¶98.) Both references disclose actuators that pull the wire/actuating members in opposite directions to constrict the valve's lumen. (Ex. 1005, [0077]; Ex. 1007, 15:21-40, 17:47-18:3.) POSITAs would have recognized that Eller's wire member would function the same way in Schaffer's valve. (Ex. 1003, ¶¶98-99.) In the first position, the springs coupled to Schaffer's actuator buttons would pull the ends of the wire member in opposite directions, thereby causing the wire member to constrict the seal module. (Ex. 1005, [0077]; Ex. 1007, 15:21-40, 17:47-18:3; Ex. 1003, ¶¶98-99.) When Schaffer's actuator buttons are pressed inwardly, the tension on the wire member would be relaxed, causing the wire member to loosen around the seal module. (Ex. 1003, ¶¶98-99.) As explained above, a POSITA would have expected Schaffer's seal module to have the resilience to return to its open configuration when "no compressive force [] is applied" to the seal. (*Supra* §VI.A.3.a; Ex. 1003, ¶100.) Further, if Schaffer's seal module required adjustment to function with Eller's wires, a POSITA would have possessed the knowledge to make the necessary adjustments, as explained in the Hartley ground. (*Supra* §VI.A.3.a; Ex. 1003, ¶101.)

Second, if the Board were to find that one of Eller's wire members does not constitute first and second filaments as recited in claim 1, a POSITA would have found it obvious to substitute two of Eller's wire members for Schaffer's two

actuator members. (Ex. 1003, ¶¶102-106.) A POSITA would have substituted two of Eller’s wire members for Schaffer’s two actuating members by attaching one end of the first and second wire members to Schaffer’s first button, looping the wire members around the seal module, and attaching the second end of the first and second wire members to Schaffer’s second button. (Ex. 1003, ¶102.)

A POSITA would have found it obvious to use two wire members with Schaffer’s valve based on the teachings of Eller. (*Id.*, ¶103.) Eller discloses that a hemostasis valve “can include any suitable number of wire members,” including “one, at least one, *two*, a plurality, three, four, five, or any other number considered suitable for a particular embodiment. (Ex. 1007, 16:7-19 (emphasis added).) Eller also recognizes that “[s]killed artisans will be able to select a suitable number of wire members to include in a selective fluid barrier valve device according to a particular embodiment based on various considerations, including the material(s) that forms the sleeve of an embodiment.” (*Id.*) Thus, Eller suggests varying the number of wire members (i.e., filaments) in a valve given the conditions and confirms a POSITA would have possessed the skills to make such routine adjustments. (Ex. 1003, ¶103.)

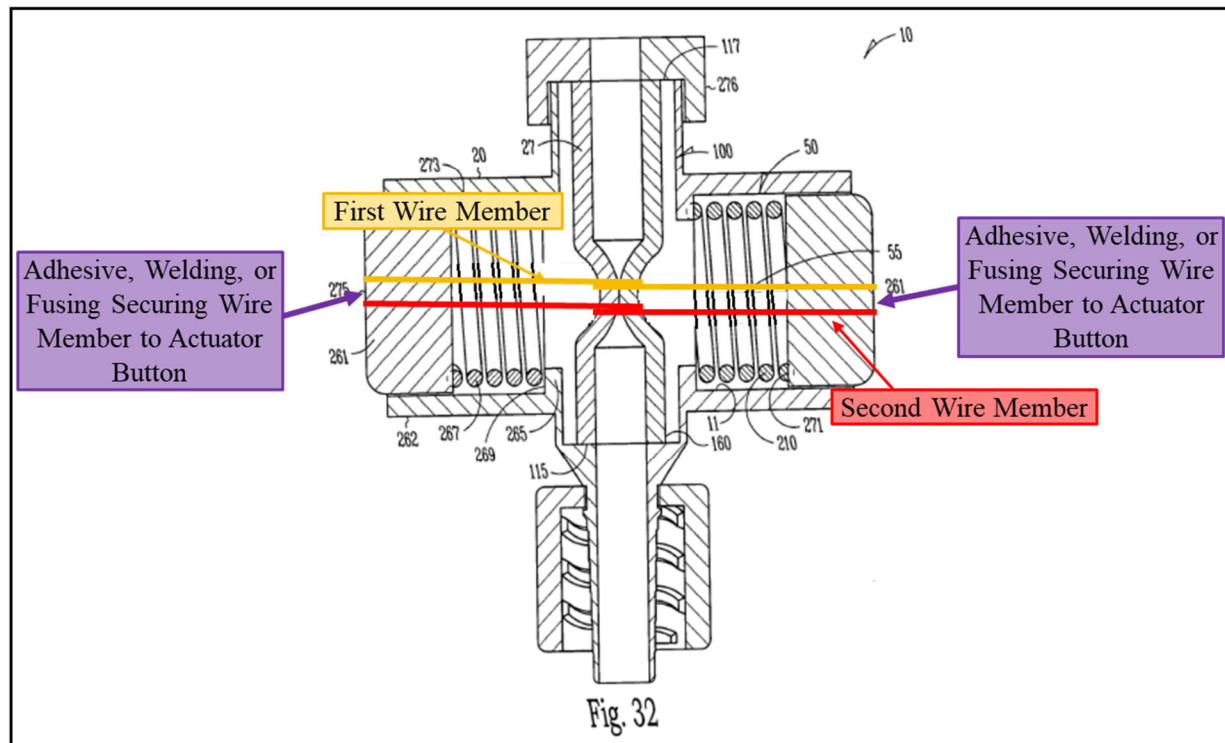
Further, the combination of Eller’s wire members and Schaffer’s valve would have entailed merely substituting one known element (Eller’s two wire members) for another (Schaffer’s two actuating members) to yield the predictable results of

constricting Schaffer's valve. *KSR*, 550 U.S. at 416. Moreover, 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). (*Supra* §VI.A.3.a.)

A POSITA would have reasonably expected success in substituting two of Eller's wire members for Schaffer's actuating members for several reasons. (Ex. 1003, ¶¶105-106.) First, as discussed for Hartley, Schaffer already discloses a method of attaching two ends of a filament with each button. (Ex. 1005, [0075]-[0077], Figs. 30-34; Ex. 1003, ¶105.) In Schaffer, both ends of each U-shaped member are attached to the same button – thus, Schaffer describes a method of attaching two filament ends to a button. (Ex. 1003, ¶105.) Similarly, one end of each of Eller's wire members would be attached to Schaffer's buttons for a total of two filament ends attached to each button. (*Id.*)

Second, as explained above, Eller discloses that the “[a]ttachment between a wire member and a housing and/or an actuator can be accomplished using any suitable method or technique” and identifies several means for securing its wire members to an actuator. (Ex. 1007, 14:37-49.) POSITAs would have reasonably expected success in securing Eller's wire members to Schaffer's actuator buttons using these simple methods. (Ex. 1003, ¶106.)

Demonstrative Illustration Schaffer + Eller's Wire Member



(*Id.*, ¶102)⁸

4. Actuators

Claim 1 next recites “a pair of actuators movable from a first position to a second position.” Schaffer discloses this limitation. (Ex. 1003, ¶¶125-127.)

Schaffer’s valve has “two circular actuators 50” on opposite sides of the housing that are “movable from a first position to a second position”:

⁸ Petitioner created this demonstrative image.

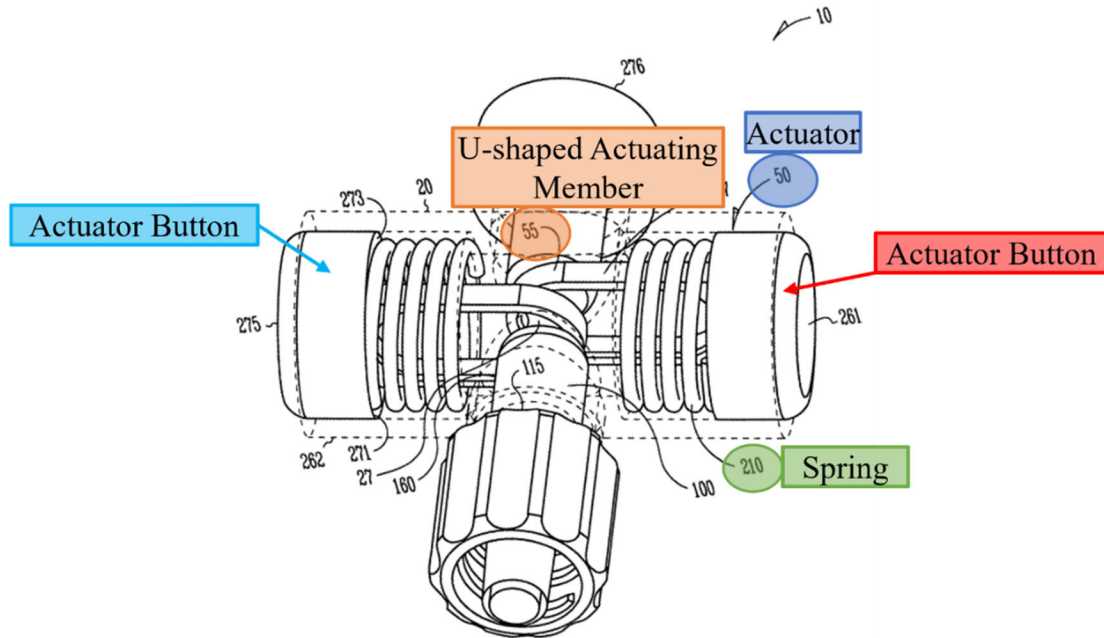
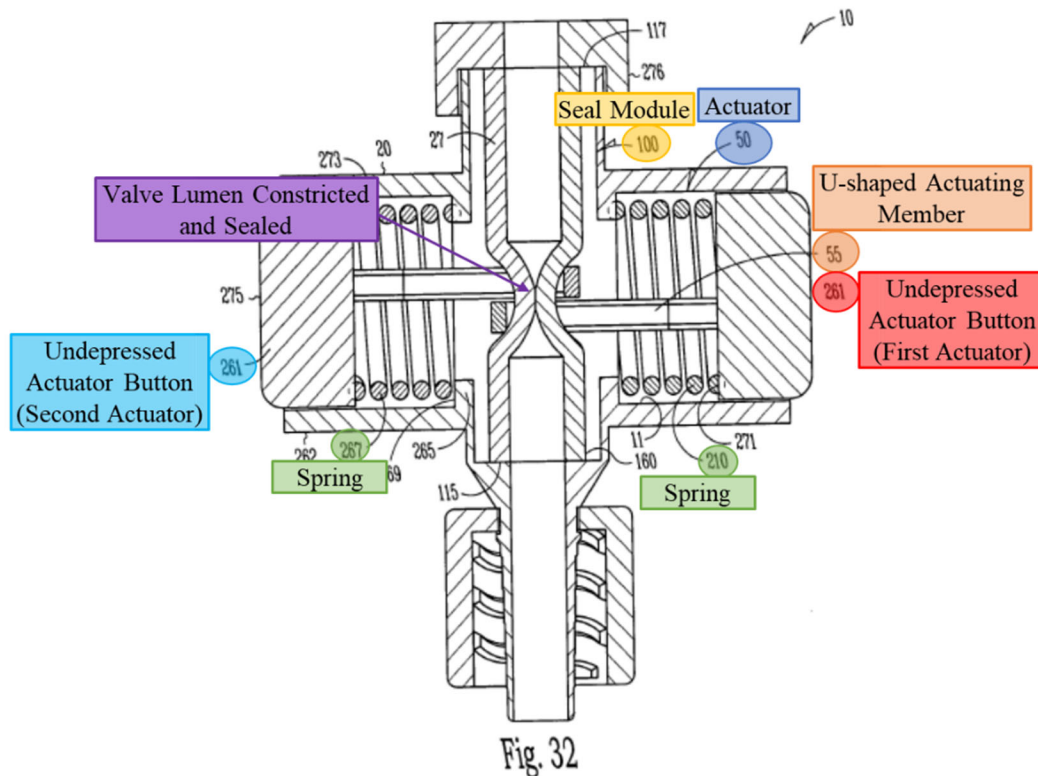


Fig. 31

(Ex. 1005, [0075]-[0076], Figs. 31-32.) Each actuator 50 includes “an actuator button 261” and a “spring 210.” (*Id.*)

Schaffer's actuators are movable from a first position to a second position. (Ex. 1003, ¶127.) In the first position, shown in Figure 32, the actuating members are “at least partially circumferentially disposed about the portion 108 of the seal module 100 depressing and at least partially collapsing a portion 108 of the containment structure 160 by a compressive force 67 (e.g. by a spring 210)”:

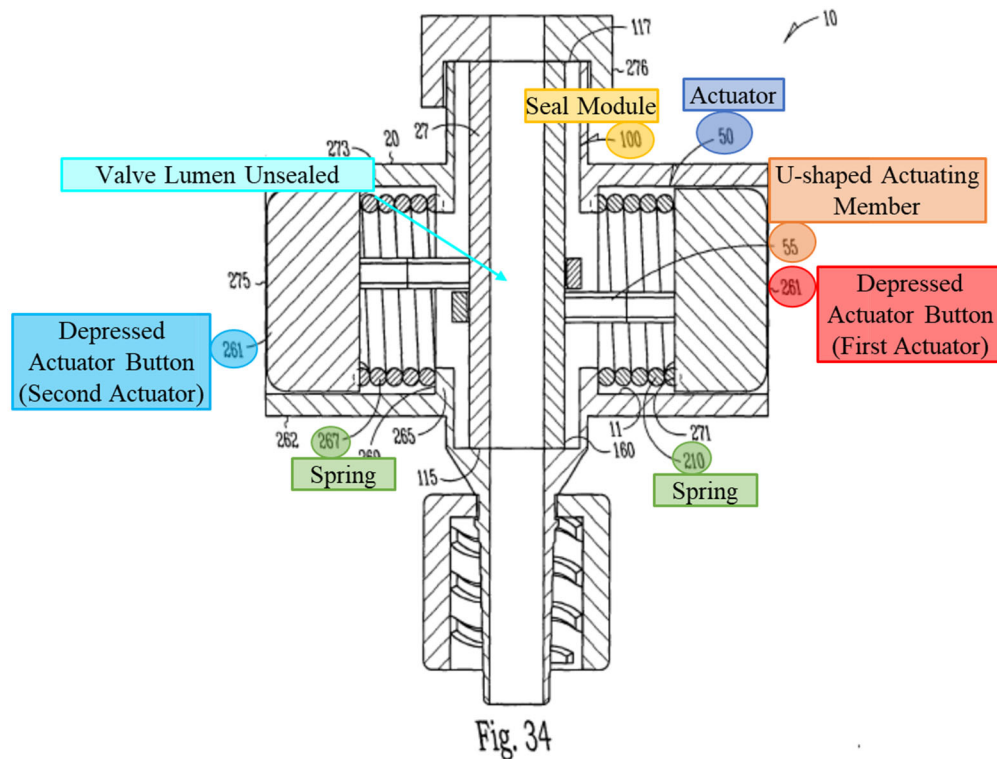
First Position – Actuator Buttons Undepressed



(Ex. 1005, [0077], Fig. 32.)

In the second position, shown in Figure 34, the actuator buttons are depressed, compressing the springs and allowing the actuator members to “disengage opposing outer walls 27 of the seal module 100 allowing the portion 108 of the containment structure 160 to retract to an uncollapsed configuration where gases and fluids can pass therethrough”:

Second Position – Actuator Buttons Depressed



(*Id.*, [0077], Fig. 34.)

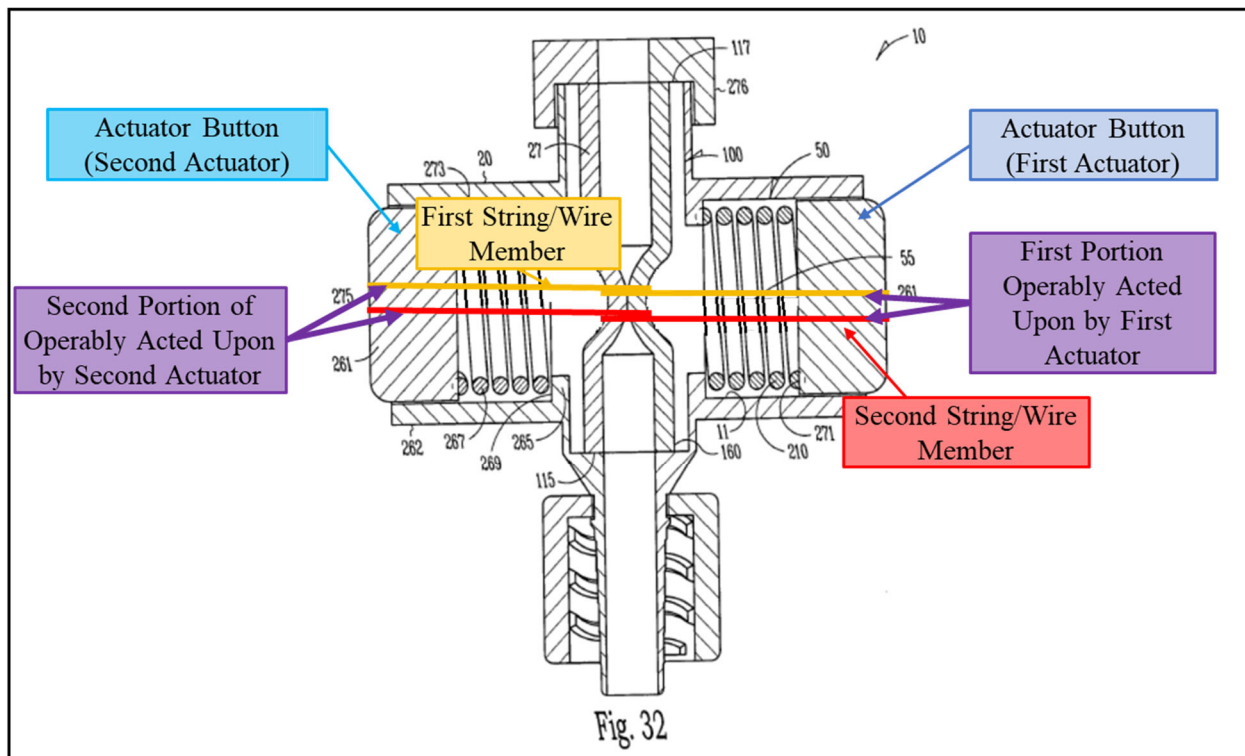
5. First And Second Filament Portions

Claim 1 next recites “the first 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; the second filament includes a first portion operably acted upon by the first one of the actuators and a second portion operably acted upon by the second one of the actuators.” Schaffer in combination Hartley *or* Eller renders these limitations obvious. (Ex. 1003, ¶¶128-130.)

As explained above, a POSITA would have been motivated to secure the first end of Hartley’s strings or Eller’s wire members to a first one of Schaffer’s buttons

using the conventional means disclosed in the references, including knots, adhesives, welding, or fusing. (*Supra* §VI.A.3; Ex. 1003, ¶129.) A POSITA would have similarly been motivated to secure the second end of Hartley’s strings or Eller’s wire members to a second one of Schaffer’s buttons on the opposite side of the tubular member using similar means:

Demonstrative Illustration Schaffer + Hartley’s String Or Eller’s Wire Member



(*Supra* §VI.A.3; Ex. 1003, ¶129.) Accordingly, a first portion of the strings/wire members would be attached to and “operably acted upon”⁹ by the first one of

⁹ Petitioner preserves its right to argue in future or related proceedings that the claims of the ’384 patent are indefinite because a POSITA could not determine the scope of “operably acted upon” with reasonable certainty.

Schaffer's actuators, and a second portion of the strings/wire members would be attached to and "operably acted upon" by a second one of Schaffer's actuators. (Ex. 1003, ¶130.)

6. First And Second Position

Claim 1 next recites: "in the first position, the actuators are positioned to tension the first filament and the second filament thereby decreasing a dimension of the first loop and a dimension of the second loop to constrict the lumen of the tubular member; in the second position, the actuators are positioned to loosen the first filament and the second filament thereby permitting the tubular member to expand against the first loop and the second loop to increase the dimension of the first loop and the dimension of the second loop to at least partially open the lumen of the tubular member." Schaffer in combination with Hartley *or* Eller renders these limitations obvious. (Ex. 1003, ¶¶131-135.)

Schaffer discloses that its valve has a first position, wherein the actuating members constrict and seal the valve, and a second position, wherein the actuator buttons are depressed to reduce constriction of the valve, as explained above. (*Supra* §VI.A.4.)

Similarly, Hartley discloses that "[r]otation of the rotary actuator 12 with respect to the cylindrical housing 6 will cause the string 14 to be pulled in both directions at once and hence the cylindrical diaphragm 8 to be constricted." (Ex.

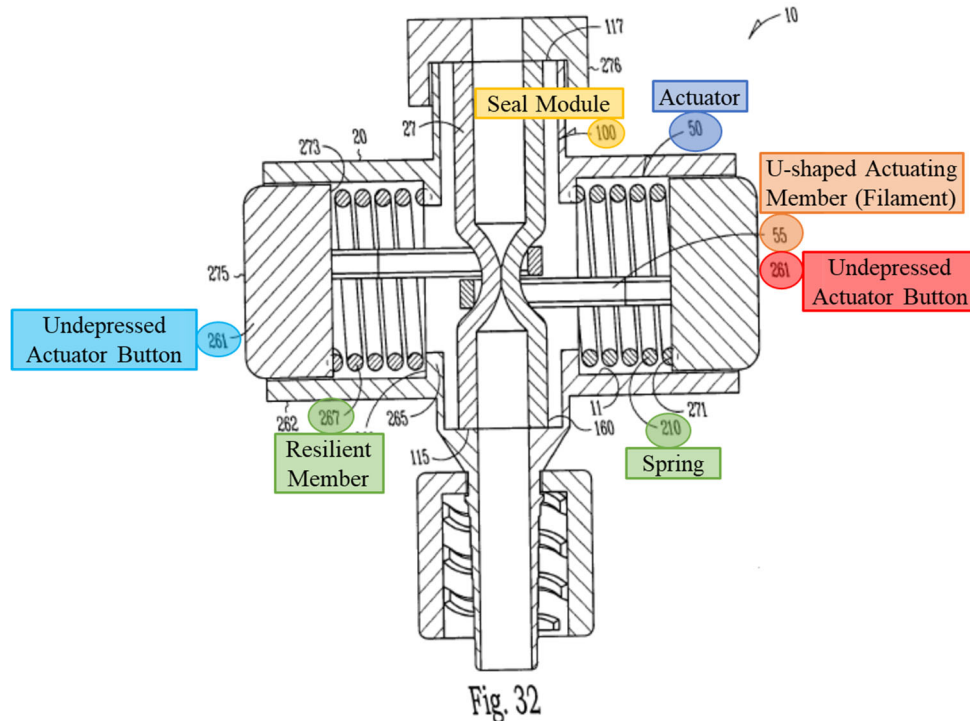
1006, [0031], [0034], Fig. 4.) Thus, tension placed on Hartley’s string by the actuator reduces the dimension of the loop to constrict and seal the valve as shown, for example, in Hartley’s Figures 3 and 4. (*Id.*, Figs. 3-4; Ex. 1003, ¶133.) Eller similarly discloses that rotation of its actuator places the wire members under tension, reducing the dimension of the wire loops and causing the wire members to constrict the sleeve and prevent fluid from passing therethrough. (Ex. 1007, 15:21-40, 17:62–67.)

Given these disclosures, a POSITA would have understood that when Schaffer’s actuating members are replaced with Hartley’s strings or Eller’s wire members (as discussed above, *supra* §VI.A.3), Schaffer’s actuators and springs would apply tension to the strings/wire members to decrease the dimensions of the loops formed by the strings/wire members to constrict and seal the valve. (Ex. 1003, ¶135.) A POSITA would have also understood that when Schaffer’s actuators are depressed to the second position, the tension on the strings/wire members would be relaxed, loosening the strings/wire members and allowing Schaffer’s seal module to expand to an opened configuration. (*Id.*)

7. Biased Actuators

Claim 1 finally recites “the actuators are biased to the first position.” Schaffer discloses this limitation. (Ex. 1003, ¶¶136-138.)

Schaffer's valve includes "two resilient members 267 (e.g., spring 210) disposed within the actuating member 55":



(Ex. 1005, [0076], Fig. 31.) Schaffer's resilient members bias Schaffer's actuator buttons (first and second actuators) toward the first (i.e., closed) position, which in turn causes the actuating members attached to the buttons to constrict the seal module, preventing the flow of fluid through the valve. (Ex. 1005, [0077]; Ex. 1003, ¶137.) Substitution of Schaffer's actuating members for Hartley's strings or Eller's wire members would not change the components or operation of the biasing system, as explained in the above sections. (Ex. 1003, ¶138; *supra* §§VI.A.3-6.)

B. Claim 2

Claim 2 recites “[t]he valve assembly of claim 1 wherein the first loop extends completely around the tubular member, and wherein the second loop extends completely around the tubular member.” Schaffer combined with Hartley *or* Eller renders claim 2 obvious. (Ex. 1003, ¶¶139-143.)

1. Schaffer + Hartley

Hartley’s string “is wound preferably twice around the cylindrical diaphragm”:

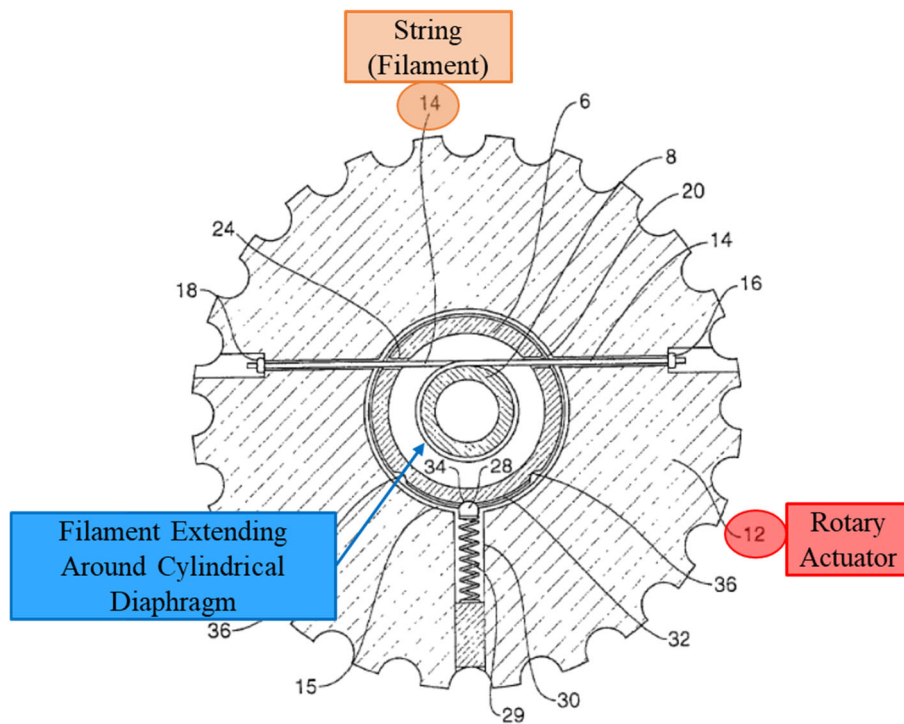


Fig 3

(Ex. 1006, [0031], Fig. 3.) Hartley’s string therefore includes a loop that “extends completely around the tubular member.” (*Id.*; Ex. 1003, ¶140.)

Hartley discloses that looping the string around the central lumen forms an effective seal. (Ex. 1006, [0031], [0037].) When replacing Schaffer’s actuating members with one or two of Hartley’s strings, POSITAs would have been motivated to loop the strings around Schaffer’s seal module at least once to form a constrictive seal, as taught in Hartley. (Ex. 1003, ¶141.) POSITAs would have reasonably expected success because Hartley encourages looping a filament around the tubular member and teaches that such a configuration forms an effective seal. (*Id.*)

2. Schaffer + Eller

Eller discloses that its “wire member can be positioned such that it extends at least one full revolution around the outer surface of the sleeve.” (Ex. 1007, 22:18-24; *see also id.*, 12:52-64, 24:50-57, Fig. 21; *supra* §VI.A.3.b.) Thus, Eller’s wire members may form a loop completely around the tubular member. (Ex. 1003, ¶142.) When replacing Schaffer’s actuating members with Eller’s wire members, POSITAs would have been motivated to loop Eller’s wires at least one revolution around Schaffer’s seal module to ensure the wire formed a constrictive seal. (*Id.*, ¶143; *supra* §VI.A.3.b.) POSITAs would have reasonably expected success because Eller encourages looping the wire one revolution around the sleeve and discloses that such a configuration is effective. (Ex. 1003, ¶143.)

C. Claim 3

Claim 3 recites “[t]he valve assembly of claim 1 wherein the first portion of the first filament is a first end portion of the first filament, wherein the second portion of the first filament is a second end portion of the first filament, wherein the first portion of the second filament is a first end portion of the second filament, and wherein the second portion of the second filament is a second end portion of the second filament.” Schaffer combined with Hartley *or* Eller renders claim 3 obvious for the reasons explained for claim 1. (*Supra* §VI.A.3-5; Ex. 1003, ¶144.)

D. Claim 4

Claim 4 recites “the valve assembly of claim 3 wherein the first end portion of [sic] first filament is directly attached to the first one of the actuators, wherein the second end portion of the first filament is directly attached to the second one of the actuators, wherein the first end portion of the second filament is directly attached to the first one of the actuators, and wherein the second end portion of the second filament is directly attached to the second one of the actuators.” Schaffer combined with Hartley *or* Eller renders claim 4 obvious for the reasons explained for claim 1. (*Supra* §§VI.A.3-5; Ex. 1003, ¶145.)

E. Claim 6

Claim 6 recites “the valve assembly of claim 1 wherein the first filament and the second filament each comprise a plurality of strands woven together.” Schaffer combined with Hartley *or* Eller renders claim 6 obvious. (Ex. 1003, ¶¶146-148.)

As explained above for claim 1, a POSITA would have understood that Hartley’s string would be formed of a “plurality of strands woven together”. (*Supra* §VI.A.3.a; Ex. 1003, ¶147; Ex. 1014; Ex. 1015.) As also explained above for claim 1, Eller discloses that its wire members can have various compositions (e.g., “braided materials,” “twisted materials”), be formed from various materials (e.g., “metals,” “polymers,” “polyester,” “nylon,” “flexible materials”), and have different shapes (e.g., “round,” “rectangular”). (*Supra* §VI.A.3.b; Ex. 1007, 15:41-16:6.) A POSITA would have understood that Eller’s wire members formed of “braided” or “twisted” materials would “each comprise a plurality of strands woven together.” (Ex. 1003, ¶148.) Thus, if a POSITA substituted two of Hartley’s strings or Eller’s wire members for Schaffer’s actuating members, the resulting valve would have a first and second filaments comprising a plurality of strands woven together. (*Id.*, ¶¶147-148.)

F. Claim 7

Claim 7 recites “the valve assembly of claim 1 wherein the tubular member is elastically deformable.” Schaffer combined with Hartley *or* Eller renders claim 7 obvious. (Ex. 1003, ¶¶149-150.)

Schaffer’s seal module (i.e., tubular member) “includes a flexible, elongate tubular structure 101 having an outer wall 27 which includes a material 166 that is highly elastic, deformable, compliant and yet virtually non-compressible.” (Ex. 1005, [0054].) Thus, Schaffer’s tubular member is elastically deformable. (Ex. 1003, ¶150.)

G. Claim 8

Claim 8 recites “the valve assembly of claim 1 wherein the tubular member is configured to resiliently expand.” Schaffer combined with Hartley *or* Eller renders claim 8 obvious. (Ex. 1003, ¶¶151-152.)

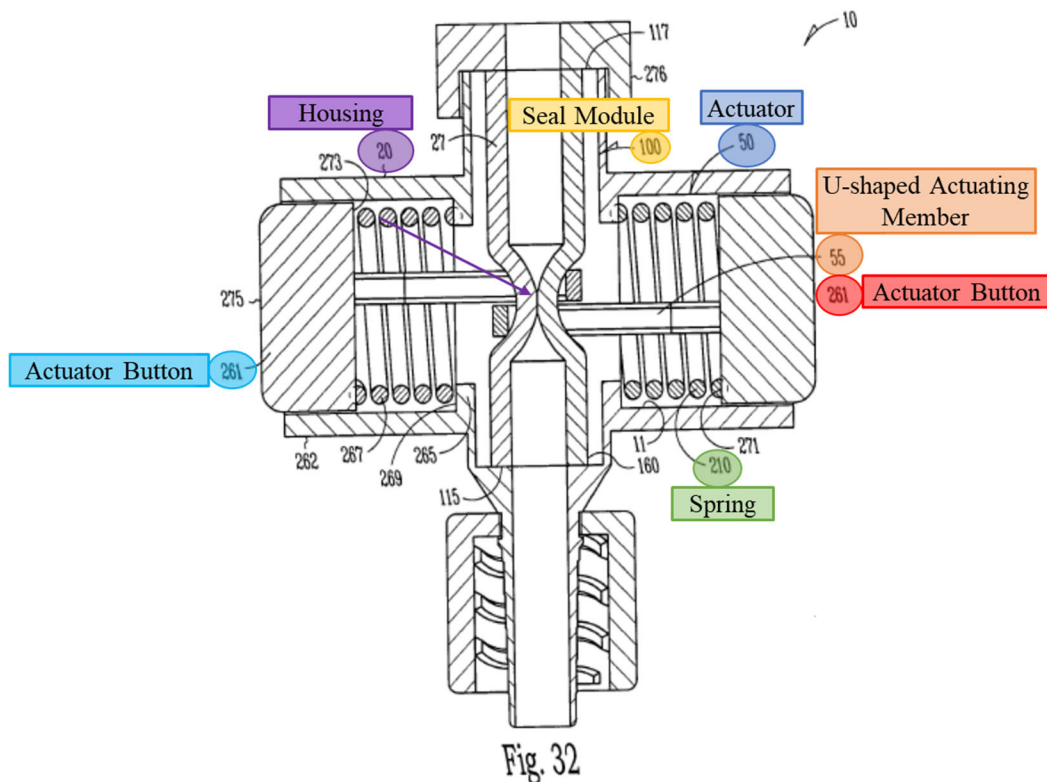
Schaffer discloses that its seal module (i.e., tubular member) “is sized and configured to maintain an open lumen 193 when no compressive force 67 is applied.” (Ex. 1005, [0054].) Schaffer also discloses that depressing the actuator buttons “allows each engaged actuating member 55 to forcibly disengage opposing outer walls 27 of the seal module 100 allowing the portion 108 of the containment structure 160 to retract to an uncollapsed configuration where gases and fluids can pass therethrough.” (*Id.*, [0077]; *see also id.* (“the lumen 193 of the third seal

member 165 is able to retract to an unsealed configuration”).) Schaffer’s tubular member is therefore “configured to resiliently expand.” (Ex. 1003, ¶152.)

H. Claim 9

Claim 9 recites “the valve assembly of claim 1 further comprising a rigid housing, wherein the tubular member, the first filament, and the second filament are positioned within the housing, and wherein the actuators are movably coupled to the housing.” Schaffer combined with Hartley *or* Eller renders claim 9 obvious. (Ex. 1003, ¶¶153-156.)

Schaffer’s hemostasis valve includes a housing 20:



(Ex. 1005, [0076], Fig. 32.) “[T]he housing 20 is sized and configured to hold and control a composite seal module 100, a portion of an actuator 50, and an actuating member 55.” (*Id.*, [0046].) Thus, Schaffer’s tubular member is located within the housing, and Hartley’s strings or Eller’s wire members would be similarly located within the housing. (*Id.*; Ex. 1003, ¶154.) Schaffer discloses that “the actuators 50 are configured cylindrically to slide along the cylindrical interior wall 11 of the housing 20 from a first position to a second position.” (Ex. 1005, [0076].) The actuators are therefore “movably coupled to the housing.” (Ex. 1003, ¶155.)

The ‘384 patent does not explain the level of flexibility or composition necessary for a “rigid” housing.¹⁰ However, Schaffer discloses that the “housing 20, in one option, is made of ABS plastic.” (Ex. 1005, [0081].) Moreover, the housing 20 can “provide an opposing support for the resilient member 267 (e.g. spring 210)”. (*Id.*, [0078].) A housing 20 that is constructed from ABS plastic and provides sufficient support for the springs would be “rigid” as recited in claim 9. (Ex. 1003, ¶156.)

I. Claim 10

Claim 10 recites “wherein the actuators are depressed toward one another in the second position, and wherein the actuators are moved away from one another in

¹⁰ Petitioner preserves its right to argue in future or related proceedings that claim 9 of the ‘384 patent are indefinite because a POSITA could not determine the scope of “rigid” with reasonable certainty.

the first position.” Schaffer combined with Hartley *or* Eller renders claim 10 obvious for the reasons explained for claim 1. (*Supra* §VI.A.6; Ex. 1003, ¶157.)

J. Claim 11

Claim 11 recites “the valve assembly of claim 1 wherein, in the second position, the tubular member has a diameter of at least 14 French.” Schaffer combined with Hartley *or* Eller renders claim 11 obvious. (Ex. 1003, ¶¶158-167.)

Schaffer’s hemostasis valve is intended “for use with catheters.” (Ex. 1005, [0002].) Schaffer’s valve includes a seal module 100 defining a central lumen 193 and further discloses that “a range of instruments [can be] used within the seal module,” such as “a catheter, guidewire, needle, or fiber,” and that “a guidewire and catheter may be placed into the same lumen 193 for extension into a body passage.” (*Id.*, [0056], [0074]; *see also id.*, [0047] (“The second end-wall 22 of the housing 20 is sized and configured to receive an inserted instrument, catheter or guide wire through a receiving member 45.”).)

A POSITA would have understood that the lumen of Schaffer’s hemostasis valve must be at least as large as the outer diameter of any catheter or tool inserted through the valve. (Ex. 1003, ¶160.) Mr. Thornton and Dr. Zalesky, PO’s expert in related IPRs, agree that POSITAs routinely optimized the size of hemostasis valves to match the outer diameter of the tools inserted through the valve. (Ex. 1016, 35:20-36:3, 44:12-21, 45:6-15, 46:8-21, 66:9-19; Ex. 1017, 136:13-139:13; Ex. 1018, 19:1-

22:22, 25:21-26:2, 31:4-32:24.) POSITAs would have therefore found it obvious and been motivated to size the hemostasis valve to fit the size of catheter or instrument inserted through the tubular member, and they would have reasonably expected success in doing so due to the frequency of this practice. (Ex. 1003, ¶162.)

Moreover, hemostasis valves with lumen diameters ranging from 14-24Fr were well known and used to endovascularly treat medical conditions before 2017. (Ex. 1003, ¶¶163-165.) For example, introducer sheaths with integrated hemostasis valves having diameters up to 24Fr were commercially available from several manufacturers before September 2017. (Ex. 1032 (describing Gore DrySeal Sheath with hemostasis valve); Ex. 1033 (describing use of 26Fr Gore DrySeal Sheath during blood clot aspiration procedure); Ex. 1034, 239 (disclosing 20-24Fr Gore introducer sheath with silicone pinch valve); Ex. 1035 (12-26Fr Medtronic Sentrant Sheath with a “rigid seal housing containing the hemostatic valve assembly”); Ex. 1036 (10-24Fr Cook Check Flo introducer sheath with hemostatic valve); Ex. 1037 (22Fr Z-Trak introducer sheath with a Captor Hemostatic Valve).

In addition, Eller describes testing the performance of tubular members (i.e., sleeves) in Eller’s hemostasis valve by inserting different tools through the valve. (Ex. 1007, 36:25-45.) In one test, Eller describes testing a “14 French dilator disposed within sleeve passageway.” (*Id.*) A POSITA would have understood that

the diameter of the sleeve must have been at least 14 French to accommodate the dilator. (Ex. 1003, ¶164.)

Many additional prior art references also disclose hemostasis valves designed to accommodate tools with diameters up to 26Fr. (*See, e.g.*, Ex. 1009, 7:25-39; Ex. 1038, 10:24-49; Ex. 1039, [0024], [0046]; Ex. 1040, 6:17-20; Ex. 1041, 6:30-40; Ex. 1042, 7:6-22; Ex. 1043, 10:44-65.) The common use of hemostasis valves with lumen diameters of at least 14-24Fr in the prior art would have further motivated a POSITA to optimize the diameter of Schaffer's tubular member to be at least 14Fr, or at least 16Fr, or at least 20Fr, or at least 24Fr, depending on the diameter of the catheters used in the standard procedure. (Ex. 1003, ¶166.)

Such an adjustment to the valve would have involved merely applying a known technique (optimizing the tubular member diameter) to a known device (Schaffer's valve) ready for improvement to yield predictable results (inserting a tool having a diameter of at least 14Fr-24Fr). *KSR*, 550 U.S. at 416; (Ex. 1003, ¶166.) Additionally, as the literature and patents cited above show, a finite number of predictable diameters existed for catheters inserted into a patient's vasculature (i.e., approximately 3Fr to 36Fr). (Ex. 1003, ¶167.) Correspondingly, a finite number of similar diameters also existed for the hemostasis valves designed to accommodate those catheters. (*Id.*) A POSITA would have found it obvious to choose from this finite number of identified and predictable sizes for the hemostasis

valve. (*Id.*) Further, as the literature and patents cited above demonstrate, POSITAs had demonstrated the hemostasis valves having sizes ranging specifically from 3Fr to 36Fr worked effectively to prevent blood leakage. These successes would have given a POSITA a reasonable expectation of success in optimizing Schaffer’s valve to have a lumen diameter ranging from at least 14Fr to 24Fr. (*Id.*)

K. Claim 12

Claim 12 recites “the valve assembly of claim 1 wherein, in the second position, the tubular member has a diameter of at least 16 French.” Schaffer combined with Hartley *or* Eller renders claim 12 obvious for the reasons explained for claim 11. (*Supra* §VI.J; Ex. 1003, ¶168.)

L. Claim 13

Claim 13 recites “the valve assembly of claim 1 wherein, in the second position, the tubular member has a diameter of at least 20 French.” Schaffer combined with Hartley *or* Eller renders claim 13 obvious for the reasons explained for claim 11. (*Supra* §VI.J; Ex. 1003, ¶169.)

M. Claim 14

Claim 14 recites “the valve assembly of claim 1 wherein, in the second position, the tubular member has a diameter of at least 24 French.” Schaffer combined with Hartley *or* Eller renders claim 14 obvious for the reasons explained for claim 11. (*Supra* §VI.J; Ex. 1003, ¶170.)

N. Claim 15

Claim 15 recites similar limitations as claims 1, 2, and 7 and is therefore rendered obvious by Schaffer combined with Hartley *or* Eller for the reasons set forth in those claims and described below. (*Supra* §§VI.A, VI.B, VI.F; Ex. 1003, ¶¶171-177.)

1. Preamble

If the preamble is limiting, Schaffer, Hartley, and Eller disclose a “valve assembly” for the reasons explained for claim 1. (*Supra* §VI.A.1; Ex. 1003, ¶172.)

2. Tubular Member

Claim 15 next recites “a tubular member defining a lumen, wherein the tubular member is elastically deformable from a first position in which the lumen is constricted to a second position in which the lumen is at least partially open.” Schaffer discloses these limitations for the reasons explained for claims 1 and 7. (*Supra* §§VI.A.2, VI.F; Ex. 1003, ¶173.)

3. Actuators and Filaments

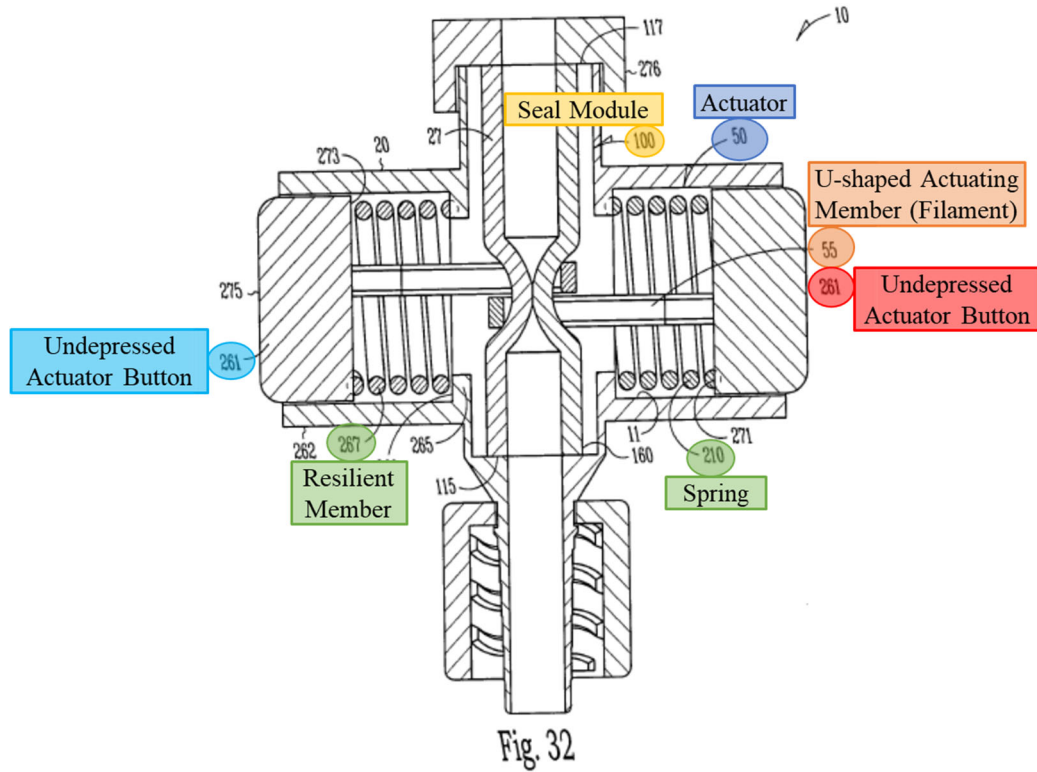
Claim 15 next recites “a first actuator; a second actuator; a first filament configured in a first loop completely around the tubular member and having a first portion extending from the first loop toward the first actuator and a second portion extending from the first loop toward the second actuator; and a second filament configured in a second loop completely around the tubular member and having a

first portion extending from the second loop toward the first actuator and a second portion extending from the second loop toward the second actuator.” Schaffer combined with Hartley *or* Eller renders these limitations obvious for the reasons explained for claims 1 and 2. (*Supra* §§VI.A.3-5, VI.B; Ex. 1003, ¶174.)

4. Biased Actuators

Claim 15 next recites “wherein– the first actuator and the second actuator are biased away from one another to elastically deform the tubular member to the first position by (a) increasing a tension in the first filament to decrease a dimension of the first loop and (b) increasing a tension in the second filament to decrease a dimension of the second loop; and the first actuator and the second actuator are movable toward one another to permit the tubular member to return to the second position by (a) decreasing the tension in the first filament and (b) decreasing the tension in the second filament.” Schaffer combined with Hartley *or* Eller renders these limitations obvious for the reasons explained below. (Ex. 1003, ¶¶175-177.)

Schaffer’s valve includes “two resilient members 267 (e.g., spring 210) disposed within the actuating member 55”:



(Ex. 1005, [0076], Fig. 32.) Schaffer's resilient members bias Schaffer's actuator buttons (first and second actuators) away from each other to the first (i.e., closed) position, which in turn causes the actuating members attached to the buttons to deform and constrict the seal module, preventing the flow of fluid through the valve. (Ex. 1005, [0077]; Ex. 1003, ¶176.) Schaffer also discloses that moving the actuators towards one another depresses the springs and relieves tension on the actuating members, allowing the lumen to retract to an open, unsealed state. (Ex. 1005, [0077]; Ex. 1003, ¶176.)

Accordingly, a POSITA would have understood that when Schaffer's U-shaped actuating members are replaced with Hartley's strings or Eller's wire

members, the actuators/springs would increase tension on the first/second strings/wire members in the first position (i.e., when the actuators are biased away from each other) to decrease the dimension of the loops and deform the lumen of the valve. (Ex. 1003, ¶177; *supra* §§VI.A.3, 7.) Then, when the actuators are depressed toward one another, tension would be relieved on the strings/wire members, allowing the lumen to expand. (Ex. 1003, ¶177.)

O. Claim 16

Claim 16 recites “the valve assembly of claim 15 wherein the first actuator and the second actuator each comprise a button.” Schaffer combined with Hartley *or* Eller renders claim 16 obvious. (Ex. 1003, ¶¶178-179.)

Each of Schaffer’s actuators comprises an actuator button:

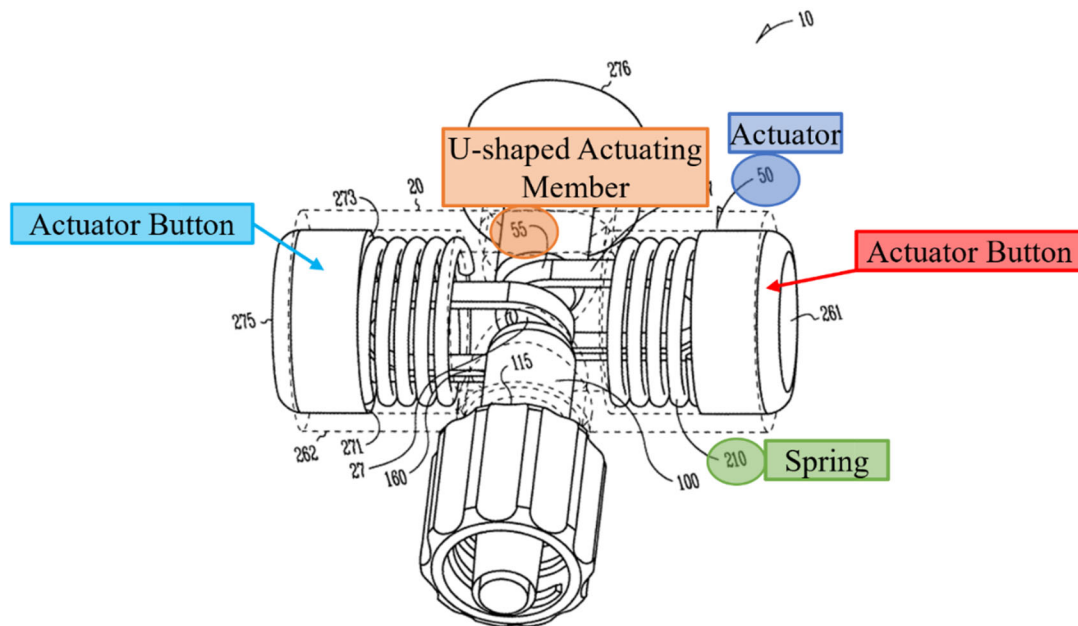


Fig. 31

(Ex. 1005, [0075]-[0076], Figs. 31-32.)

P. Claim 17

Claim 17 recites “the valve assembly of claim 15 wherein the first filament is flexible, and wherein the second filament is flexible.” Schaffer combined with Hartley *or* Eller renders claim 17 obvious for the reasons explained for claim 1 and 15. (*Supra* §§VI.A.3, VI.N.3; Ex. 1003, ¶180.)

Q. Claim 18

Claim 18 recites “the valve assembly of claim 15 wherein the first portion of first filament is directly attached to the first actuator, wherein the second portion of the first filament is directly attached to the second actuator, wherein the first portion of the second filament is directly attached to the first actuator, and wherein the second portion of the second filament is directly attached to the second actuator.” Schaffer combined with Hartley *or* Eller renders claim 18 obvious for the reasons explained for claims 4 and 15. (*Supra* §§VI.D, VI.N.3; Ex. 1003, ¶181.)

R. Claim 20

Claim 20 recites “the valve assembly of claim 15 wherein, in the second position, the tubular member has a diameter of at least 16 French.” Schaffer combined with Hartley *or* Eller renders claim 20 obvious for the reasons explained for claims 11 and 15. (*Supra* §§VI.J, VI.N; Ex. 1003, ¶182.)

S. Claim 21

Claim 21 recites “the valve assembly of claim 15 wherein, in the second position, the tubular member has a diameter of at least 20 French.” Schaffer combined with Hartley *or* Eller renders claim 21 obvious for the reasons explained for claims 11 and 15. (*Supra* §§VI.J, VI.N; Ex. 1003, ¶183.)

T. Claim 22

Claim 22 recites “the valve assembly of claim 15 wherein, in the second position, the tubular member has a diameter of at least 24 French.” Schaffer combined with Hartley *or* Eller renders claim 22 obvious for the reasons explained for claims 11 and 15. (*Supra* §§VI.J, VI.N; Ex. 1003, ¶184.)

U. Claim 23

Claim 23 recites the same limitations as claims 1 and 7 and is therefore rendered obvious by Schaffer alone or combined with Hartley *or* Eller for the reasons provided in those claims and described below. (*Supra* §§VI.A, VI.F; Ex. 1003, ¶¶185-188.)

1. Preamble

If the preamble is limiting, Schaffer, Hartley, and Eller disclose a “valve assembly” for the reasons explained for claim 1. (*Supra* VI.A.1; Ex. 1003, ¶186.)

2. Tubular Member

Claim 23 recites “a tubular member defining a lumen.” Schaffer discloses this limitation for the reasons explained for claim 1. (*Supra* §VI.A.2; Ex. 1003, ¶187.)

3. Filaments and Actuators

Claim 23 next recites “a first filament extending in a first loop around the tubular member; a second filament extending in a second loop around the tubular member; and a pair of actuators biased to circumferentially constrict the first loop and the second loop to elastically deform the tubular member to a first position in which the lumen is constricted, wherein at least one the actuators is movable to decrease a level of tension in the first filament and a level of tension in the second filament to permit the tubular member to expand against the first loop and the second loop to a second position in which the lumen of the tubular member is at least partially open.” Schaffer combined with Hartley *or* Eller renders these limitations obvious for the reasons explained for claims 1 and 15. (*Supra* §§VI.A.3-6, VI.N.3; Ex. 1003, ¶188.)

V. Claim 24

Claim 24 recites “the valve assembly of claim 23 wherein the actuators each comprise a button.” Schaffer combined with Hartley *or* Eller renders claim 24

obvious for the reasons explained for claims 1, 15, and 16. (*Supra* §§VI.A.4, VI.N.3, VI.O; Ex. 1003, ¶189.)

W. Claim 25

Claim 25 recites “the valve assembly of claim 23 wherein the first filament includes a first portion operably coupled to a first one of the actuators and a second portion operably coupled to a second one of the actuators, and wherein the second filament includes a first portion operably coupled to the first one of the actuators and a second portion operably coupled to the second one of the actuators.” Schaffer combined with Hartley *or* Eller renders claim 25 obvious for the reasons explained for claims 1 and 23. (*Supra* §§VI.A.5, VI.U.3; Ex. 1003, ¶190.)

X. Claim 26

Claim 26 recites “the valve assembly of claim 25 wherein the first portion of first filament is directly attached to the first one of the actuators, wherein the second portion of the first filament is directly attached to the second one of the actuators, wherein the first portion of the second filament is directly attached to the first one of the actuators, and wherein the second portion of the second filament is directly attached to the second one of the actuators.” Schaffer combined with Hartley *or* Eller renders claim 26 obvious for the reasons explained for claims 1 and 23. (*Supra* §§VI.A.3-5, VI.U.3; Ex. 1003, ¶191.)

Y. Claim 27

Claim 27 recites “the valve assembly of claim 23 wherein the first filament is flexible, and wherein the second filament is flexible.” Schaffer combined with Hartley *or* Eller renders claim 27 obvious for the reasons explained for claims 1 and 23. (*Supra* §§VI.A.3, VI.U.3; Ex. 1003, ¶192.)

Z. Claim 28

Claim 28 recites “the valve assembly of claim 23 wherein, in the second position, the tubular member has a diameter of at least 16 French.” Schaffer combined with Hartley *or* Eller renders claim 28 obvious for the reasons explained for claims 11 and 23. (*Supra* §§VI.J, VI.U; Ex. 1003, ¶193.)

AA. Claim 29

Claim 29 recites “the valve assembly of claim 23 wherein, in the second position, the tubular member has a diameter of at least 20 French.” Schaffer combined with Hartley *or* Eller renders claim 29 obvious for the reasons explained for claims 11 and 23. (*Supra* §§VI.J, VI.U; Ex. 1003, ¶194.)

BB. Claim 30

Claim 30 recites “the valve assembly of claim 23 wherein, in the second position, the tubular member has a diameter of at least 24 French.” Schaffer combined with Hartley *or* Eller renders claim 30 obvious for the reasons explained for claims 11 and 23. (*Supra* §§VI.J, VI.U; Ex. 1003, ¶195.)

**VII. GROUND 3: CLAIMS 1-4, 6-18, AND 20-30 ARE OBVIOUS OVER
SCHAFFER COMBINED WITH HARTLEY AND ELLER**

As explained in Ground 1, a POSITA would have been motivated to replace Schaffer’s U-shaped actuating members with two of Hartley’s strings and would have had a reasonable expectation of success in doing so. (*Supra* §VI.A.3.a.) Eller would have provided a POSITA with even further motivation to combine two of Hartley’s strings with Schaffer’s valve. (Ex. 1003, ¶¶196-200.)

Eller describes hemostasis valves having “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”:

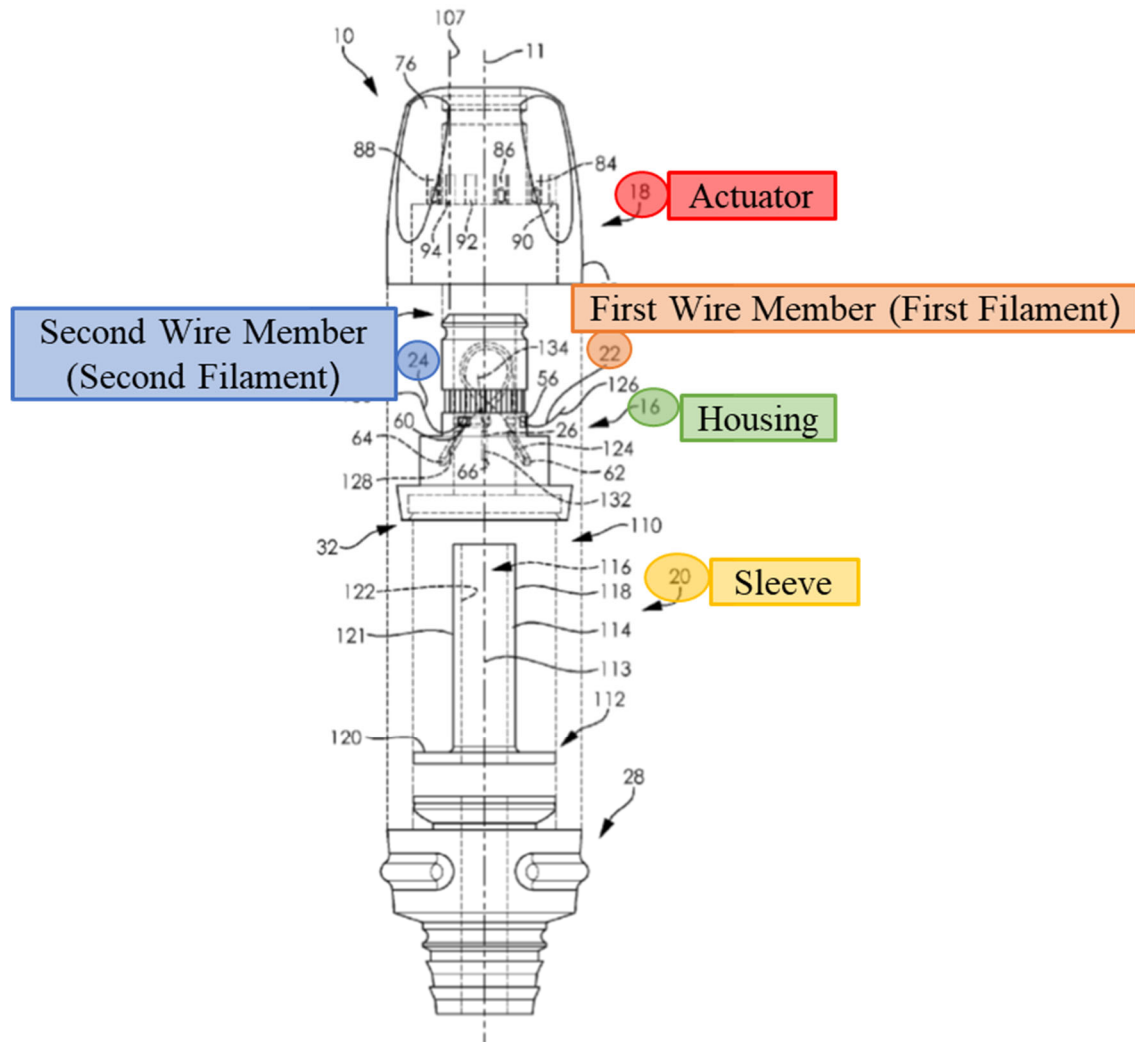


FIG. 2

(Ex. 1007, 5:1-5, 16:7-19, Fig. 2.) Eller explains that its valve “can include any suitable number of wire members” and recognizes that “[s]killed artisans will be able to select a suitable number of wire members to include in a selective fluid barrier valve device according to a particular embodiment.” (*Id.*, 16:7-19.)

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. (Ex. 1003, ¶198.) Moreover, Eller’s recognition that “[s]killed artisans will be able to select a suitable number of wire members to include in a selective fluid barrier valve device according to a particular embodiment” confirms that POSITAs would have found it obvious to adjust the number of filaments used to constrict a hemostasis valve according to the needs of a particular valve. (*Id.*) POSITAs would have been motivated to combine the teachings of Schaffer, Hartley, and Eller because all three references concern hemostasis valves used to prevent blood leaks during intravascular procedures and use similar mechanisms to constrict the lumen of the valve to create a seal. (*Id.*, ¶199.)

Accordingly, the challenged claims would have been obvious to a POSITA in September 2017 in view of Schaffer combined with Hartley and Eller. (*Id.*, ¶200.)

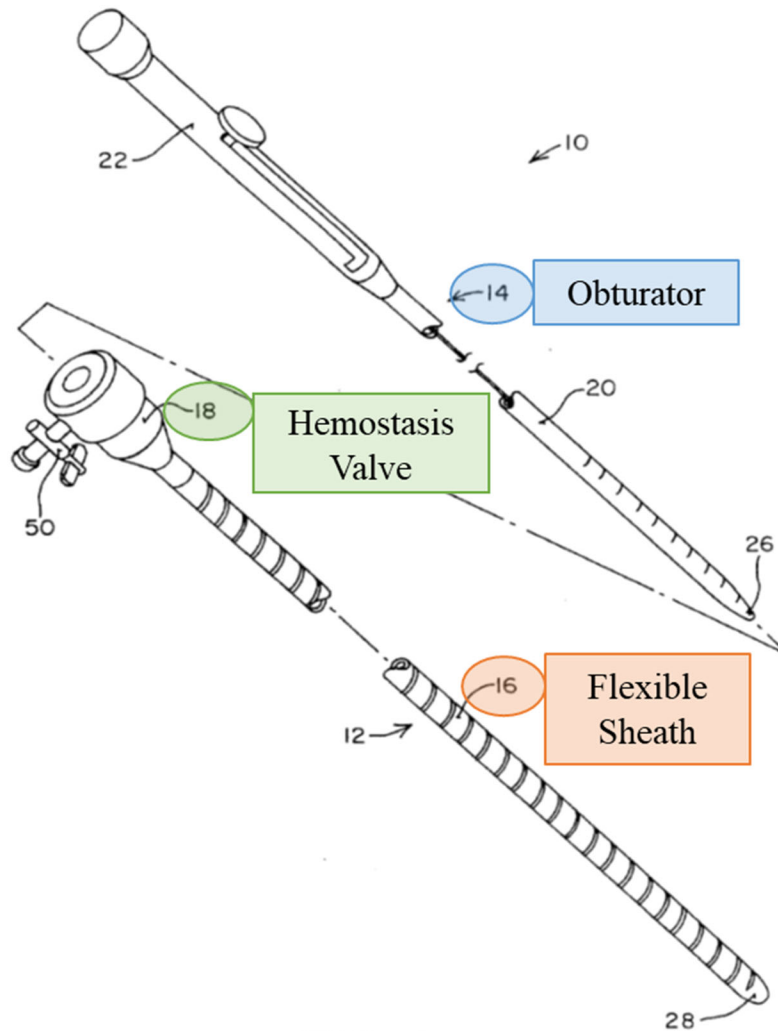
**VIII. GROUNDS 4-6: CLAIMS 11-14, 20-22, AND 28-30 ARE OBVIOUS
OVER SCHAFFER AND HERMANN COMBINED
WITH HARTLEY AND/OR ELLER**

Challenged claims 11-14, 20-22, and 28-30 recite that the lumen of the hemostasis valve has a diameter in the second (opened) position ranging from at least 14 French to at least 24 French. Schaffer and Hermann combined with Hartley and/or Eller render these claims obvious. (Ex. 1003, ¶¶201-211.)

Schaffer does not expressly disclose the diameter of the tubular member lumen in its hemostasis valve, but Schaffer discloses that the valve is intended “for use with catheters.” (Ex. 1005, [0002].) Schaffer also discloses that “a range of

instruments [can be] used within [its] seal module,” such as “a catheter, guidewire, needle, or fiber,” and that “a guidewire and catheter may be placed into the same lumen 193 for extension into a body passage.” (*Id.*, [0056], [0074].) As explained in Grounds 1-2, a POSITA would have understood that the diameter of Schaffer’s lumen must be at least as large as the outer diameter of any catheter or instrument inserted through the lumen, and that the disclosed devices would each have different diameters. (*Supra* §VI.J.) As also explained in Grounds 1-2, catheters with hemostasis valves ranging from 14-24F were known and used to endovascularly treat medical conditions before September 2017. (*Id.*; Ex. 1003, ¶¶163-165.) Hermann discloses one such system.

Hermann is titled “Large-Diameter Introducer Sheath Having Hemostasis Valve and Removable Steering Mechanism” and discloses a catheter introduction system having a flexible introducer sheath, an obturator, and a hemostasis valve:



(Ex. 1009, 9:41-45, Fig. 1.) Hermann states that a “wide variety of hemostasis valves would be suitable” for use with its introducer sheath. (*Id.*, 7:28-29.) Hermann further states that its system “preferably employs a hemostasis valve construction which provides for tight lateral sealing against catheters having a wide range of outside diameters, e.g., from guide wires to catheters as large as 30 French ... often as large as 26 F, and preferably as large as 22 F.” (*Id.*, 7:34-39.)

A POSITA would have been motivated, and found it obvious, to use Schaffer’s valve, as modified in view of Hartley and/or Eller, as the hemostasis valve in Hermann’s introducer system. (Ex. 1003, ¶¶205-209.) First, Schaffer discloses that its hemostasis valve is “for use with catheters” and “blocks the flow of gas or fluid completely and immediately with or without an instrument in place within the gas/fluid path.” (Ex. 1005, [0002], [0008], [0047], [0049].) Schaffer further discloses that a range of instruments can be used within the valve, such as “a catheter, guidewire, needle, or fiber.” (*Id.*, [0056], [0074].) Thus, Schaffer’s valve would permit the insertion of the tools identified in Hermann through Hermann’s flexible sheath while preventing blood leaks. (Ex. 1003, ¶206.)

Second, POSITAs would have recognized that Schaffer’s hemostasis valve could seal more effectively around a wider range of device diameters than Hermann’s valve. (*Id.*, ¶207.) The physician can adjust the diameter of the opening in Schaffer’s valve by pressing the buttons so that it more nearly matches the size of the inserted device. (*Id.*) This feature allows the valve to accommodate a wider range of devices and allows the user to reduce the insertion friction by opening the valve wider. (*Id.*) A POSITA would have therefore been motivated to implement Schaffer’s valve in Hermann’s system to achieve this benefit. (*Id.*)

Third, the combination of Schaffer’s valve (as modified in view of Hartley and/or Eller) with Hermann’s introducer system would have merely entailed the

substitution of one known element (Schaffer's valve) with another (Hermann's valve) according to known methods (attaching or forming integrally the valve with a port/hub) to yield the predictable result of minimizing blood loss through the catheter. *See KSR*, 550 U.S. at 416; (Ex. 1003, ¶208.)

Fourth, POSITAs in September 2017 had a finite number of predictable hemostasis valves to select. (Ex. 1003, ¶209.) Generally, the art consisted of static valves (*see e.g.*, Schaffer Figures 12-15) and adjustable-opening valves (*see e.g.*, Schaffer Figures 30-34, Hartley Figures 3-4). Further, within the variable opening valves, the art disclosed two general configurations: valves that pinch an internal tube from two sides to close the valve (*see e.g.*, Schaffer Figures 5-7) and valves that circumferentially constrict an internal tube to close the valve (*see e.g.*, Schaffer Figures 30-34; Hartley Figures 3-4). A POSITA would have found it obvious to try any of these hemostasis valves with the prior art aspiration systems. (*Id.*); *KSR*, 550 U.S. at 417. The known valves, like Schaffer's adjustable-opening hemostasis valve, were simple mechanical structures that operate in a predictable way. (Ex. 1003, ¶209.) Hermann also reflects a POSITA's level of understanding, and particularly the understanding that a POSITA could use different valves interchangeably with the same systems, stating that a "wide variety of hemostasis valves would be suitable" for its introducer system. (Ex. 1009, 7:28-29.) POSITAs would have

therefore reasonably expected success in combining Schaffer's valve with Hermann's system. (Ex. 1003, ¶209)

When combining Schaffer's hemostasis valve with Hermann's introducer system, a POSITA would have been motivated to size Schaffer's valve to accommodate catheters as large as 30 French in view of Hermann's express suggestion to do so. (Ex. 1003, ¶210; Ex. 1009, 7:25-39.) A POSITA would have reasonably expected success in optimizing the diameter of Schaffer's valve to accommodate such catheters based on Hermann's disclosure and based on the many other prior art references disclosing similarly sized valves. (*Supra* §VI.J (claim 11).)

Accordingly, claims 11-14, 20-22, and 28-30 would have been obvious to a POSITA in view of Schaffer and Hermann combined with Hartley and/or Eller. (Ex. 1003, ¶211.)

IX. SECONDARY CONSIDERATIONS

Petitioner is not aware of any evidence of secondary considerations. (Ex. 1003, ¶¶212-213.) If PO identifies evidence of secondary considerations, Petitioner respectfully requests an opportunity to respond.

X. SOTERA STIPULATION

Petitioner hereby stipulates that if the Board institutes this IPR based on the grounds and claims raised in the Petition, Petitioner will not pursue in district court the grounds asserted in the IPR Petition or any other ground that could have been

reasonably raised in this IPR. Thus, there will be no “overlap between issues raised in the petition and in the parallel proceeding.” *Apple v. Fintiv*, IPR2020-00019, Paper 11 at 6 (PTAB Mar. 20, 2020) (precedential).

**XI. MANDATORY NOTICES, GROUNDS FOR STANDING,
AND FEE PAYMENT**

A. Real Parties-In-Interest (37 C.F.R. §42.8(b)(1))

Imperative Care, Inc. is the real parties in interest for Petitioner.

B. Related Matters (37 C.F.R. §42.8(b)(2))

In the Litigation, PO filed a Third Amended Complaint alleging that Petitioner’s Symphony system infringes the ’910 patent, as well as U.S. Patent Nos. 11,969,333; 11,554,005; 11,744,691; 11,697,012; 11,844,921, 11,865,291, 12,016,580; 12,109,384; 12,156,669; and 12,239,333. *Inari Medical, Inc. v. Imperative Care, Inc.*, No. 24-cv-3117 (N.D. Cal., filed May 22, 2024). In its Second Amended Complaint, Petitioner also dropped its infringement allegations regarding U.S. Patent No. 11,697,011, which is the subject of an instituted IPR. (Ex. 1025.) The Court vacated the claim construction schedule and stated that it would revisit scheduling after a hearing on Petitioner’s Motion to Stay the Litigation pending resolution of the IPRs. (Ex. 1028.) The court has not set a trial date in the Litigation. (Ex. 1020.) The district court held a hearing on Petitioner’s Motion to Stay the Litigation pending resolution of the IPRs on July 16, 2025. (Ex. 1027-1028.)

Petitioner has filed nine IPRs against patents asserted by PO in the Litigation:

(1) *Imperative Care, Inc. v. Inari Medical, Inc.*, IPR2024-01157 requesting review of U.S. Patent No. 11,697,011 (Filed July 8, 2024); (2) *Imperative Care, Inc. v. Inari Medical, Inc.*, IPR2024-01257 requesting review of U.S. Patent No. 11,744,691 (Filed August 12, 2024); (3) *Imperative Care, Inc. v. Inari Medical, Inc.*, IPR2025-00156 requesting review of U.S. Patent No. 11,697,012 (Filed November 8, 2024); (4) *Imperative Care, Inc. v. Inari Medical, Inc.*, IPR2025-00289 requesting review of U.S. Patent No. 11,554,005 (Filed December 13, 2024); (5) *Imperative Care, Inc. v. Inari Medical, Inc.*, IPR2025-00728 requesting review of U.S. Patent No. 11,844,921 (Filed March 13, 2025); (6) *Imperative Care, Inc. v. Inari Medical, Inc.*, IPR2025-00989 requesting review of U.S. Patent No. 11,865,291 (Filed May 9, 2025); (7) *Imperative Care, Inc. v. Inari Medical, Inc.*, IPR2025-01021 requesting review of U.S. Patent No. 11,969,333 (Filed May 19, 2025); (8) *Imperative Care, Inc. v. Inari Medical, Inc.*, IPR2025-01025 requesting review of U.S. Patent No. 11,974,910 (Filed May 20, 2025); and (9) *Imperative Care, Inc. v. Inari Medical, Inc.*, IPR2025-01264 requesting review of U.S. Patent No. 12,016,580 (filed July 8, 2025). The Board granted institution of the '011, '012 and '005 patent IPRs and denied institution of the '691 patent IPR for reasons not relevant to this IPR.

C. Lead and Backup Counsel (37 C.F.R. §42.8(b)(3))

Petitioner provides the following designation of counsel, all of whom are included in Customer No. 20,995 identified in Petitioner's Power of Attorney.

Lead Counsel	Back-up Counsel
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D. Service Information (37 C.F.R. §42.8(b)(4))

Please direct all correspondence to lead counsel and back-up counsel at the addresses shown above. Petitioner also consents to electronic service by email to BoxImperative384@knobbe.com.

E. Grounds for Standing (37 C.F.R. §42.104)

Petitioner certifies that the '384 patent is available for IPR and that Petitioner is not barred or estopped from requesting IPR on the identified grounds. This Petition is being filed within one year of service of the Complaint that first asserted the '384 patent in the Litigation.

F. Payment of Fees (37 C.F.R. §42.15(a))

The fee for this petition has been paid. Additional fees may be charged to Deposit Account 11-1410.

XII. CONCLUSION

For the reasons above, Petitioner has established a reasonable likelihood of prevailing in showing that at least one or more claims are unpatentable as obvious and, therefore, requests that the Board institute an *inter partes* review.

Respectfully submitted,

KNOBBE MARTENS OLSON & BEAR, LLP

Dated: September 19, 2025 By: / Joshua J. Stowell/

Joshua J. Stowell (Reg. No. 64,096)

Joseph R. Re (Reg. No. 31,291)

Brian C. Barnes (Reg. No. 75,805)

Attorneys for Petitioner Imperative Care, Inc.

CERTIFICATE OF COMPLIANCE

Pursuant to 37 C.F.R. § 42.24(d), the undersigned certifies that this PETITION FOR INTER PARTES REVIEW OF U.S. PATENT NO. 12,109,384 contains 13,427 words according to the word-processing program used to prepare this paper. The foregoing word count complies with the 14,000-word type-volume limit specified by 37 C.F.R. § 42.24(a)(1).

Dated: September 19, 2025

By: /Joshua J. Stowell/

Joshua J. Stowell (Reg. No. 64,096)

KNOBBE MARTENS OLSON & BEAR, LLP

CERTIFICATE OF SERVICE

The undersigned hereby certifies that on the date below a copy of this
**PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 12,109,384
AND EXHIBITS 1001-1043**, were served by Priority Mail Express on the Patent
Owner at the correspondence address of record for the subject patent as follows:

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Dated: September 19, 2025

By: /Joshua J. Stowell/

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