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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. IPR2025-00728
Patent No. 11,844,921

**PETITION FOR *INTER PARTES* REVIEW OF
U.S. PATENT NO. 11,844,921**

TABLE OF CONTENTS

	Page No.
I. INTRODUCTION	1
II. THE '921 PATENT	9
A. Overview	9
B. Prosecution History	16
C. The Earliest Possible Priority Date	16
III. LEVEL OF ORDINARY SKILL	16
IV. CLAIM CONSTRUCTION	17
V. STATEMENT OF RELIEF REQUESTED	20
A. IPR Grounds	20
B. The Asserted References Are Prior Art	20
C. The Asserted References Are Analogous Art	21
VI. GROUNDS 1-4: CLAIMS 1-7, 9-10, 15-18, 20-24 ANTICIPATED BY SCHAFFER OR OBVIOUS OVER SCHAFFER ALONE OR IN COMBINATION WITH HARTLEY OR ELLER.....	21
A. Claim 1	24
1. Preamble.....	24
2. Elongate Member	24
3. Tensioning Mechanism	26
a. Actuator	26
b. Filament	29

TABLE OF CONTENTS

(*cont'd*)

	Page No.
i. Schaffer	29
ii. Hartley	33
iii. Eller	40
4. Biasing Member	46
B. Claim 2	47
C. Claim 3	47
1. Schaffer	47
2. Hartley	49
3. Eller	51
D. Claim 4	52
E. Claim 5	53
1. Schaffer	53
2. Hartley	56
3. Eller	57
F. Claim 6	58
G. Claim 7	63
H. Claim 9	63
I. Claim 10	64
1. Schaffer	65
2. Hartley	66

TABLE OF CONTENTS

(cont'd)

	Page No.
3. Eller	69
J. Claim 15	71
K. Claim 16	72
L. Claim 17	72
M. Claim 18	72
N. Claim 20	72
O. Claim 21	73
P. Claim 22	74
Q. Claim 23	74
R. Claim 24	74
VII. GROUNDS 5-7: CLAIMS 1-3, 5-6, 9, 15-18, AND 21-24 OBVIOUS OVER HARTLEY IN COMBINATION WITH ELLER	76
A. Claim 1	76
1. Preamble.....	77
2. Elongate Member	77
3. Tensioning Mechanism	78
a. Actuator	79
b. Filament	80
4. Biasing Member	81

TABLE OF CONTENTS
(cont'd)

	Page No.
B. Claim 2	86
C. Claim 3	86
D. Claim 5	87
E. Claim 6	88
F. Claim 9	90
G. Claim 15	90
H. Claim 16	91
I. Claim 17	91
J. Claim 18	91
K. Claim 21	91
L. Claim 22	92
M. Claim 23	92
N. Claim 24	92
VIII. SECONDARY CONSIDERATIONS	92
IX. THE BOARD SHOULD NOT DENY INSTITUTION UNDER §314(a) OR §325(d)	93
X. MANDATORY NOTICES, GROUNDS FOR STANDING, AND FEE PAYMENT	95
A. Real Parties-In-Interest (37 C.F.R. §42.8(b)(1))	95
B. Related Matters (37 C.F.R. §42.8(b)(2))	95

TABLE OF CONTENTS
(cont'd)

	Page No.
C. Lead and Backup Counsel (37 C.F.R. §42.8(b)(3))	96
D. Service Information (37 C.F.R. §42.8(b)(4))	96
E. Grounds for Standing (37 C.F.R. §42.104)	96
F. Payment of Fees (37 C.F.R. §42.15(a))	97
XI. CONCLUSION.....	97

TABLE OF AUTHORITIES

Page No(s).

<i>Apple v. Fintiv</i> , IPR2020-00019, Paper 11 (PTAB Mar. 20, 2020)	93
<i>Comcast Cable Commc'ns LLC v. Promptu Sys. Corp.</i> , IPR2018-00342, Paper 13 (P.T.A.B. July 19, 2018)	94
<i>Imperative Care v. Inari Medical, Inc.</i> , IPR2024-01157, Paper 5 (Oct. 29, 2024)	85
<i>KSR Int'l Co. v. Teleflex, Inc.</i> , 550 U.S. 398 (2007)	<i>passim</i>
<i>In re Nilssen</i> , 851 F.2d 1401 (Fed. Cir. 1988)	21
<i>Phillips v. AWH Corp.</i> , 415 F.3d 1303 (Fed. Cir. 2005) (en banc)	17
<i>Realtime Data, LLC v. Iancu</i> , 912 F.3d 1368 (Fed. Cir. 2019)	18, 24
<i>SanDisk Corp. v. Kingston Tech. Co., Inc.</i> , 695 F.3d 1348 (Fed. Cir. 2012)	49
<i>Unwired Planet, LLC v. Google Inc.</i> , 841 F.3d 995 (Fed. Cir. 2016)	21
<i>Vitronics Corp. v. Conceptronic, Inc.</i> , 90 F.3d 1576 (Fed. Cir. 1996)	19

OTHER AUTHORITIES

35 U.S.C. § 102	20, 24
35 U.S.C. § 103	20, 24

TABLE OF AUTHORITIES
(cont'd)

	Page No(s).
35 U.S.C. §314.....	93, 94
35 U.S.C. §325.....	93, 94
37 C.F.R. §1.11	4
37 C.F.R. §42.100	17

LIST OF EXHIBITS

Exhibit No.	Description
1001	U.S. Patent No. 11,844,921 (“the ’921 patent”)
1002	’921 Patent Prosecution History Excerpt
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. 5,429,616 to Schaffer (“Schaffer ’616”)
1010	U.S. Patent No. 3,438,607 to Williams et al.
1011	U.S. Patent Publication US 2015/0173782 A1 to Garrison et al. (“Garrison”)
1012	U.S. Patent No. 11,697,011 (“the ’011 patent”)
1013	Inari’s Supplemental Infringement Contentions (without claim charts) from <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , No. 24-cv-3117 (N.D. Cal.) (served February 7, 2025).
1014	Google Dictionary Definition of “String”
1015	Cambridge Dictionary Definition of “String”
1016	U.S. Patent No. 12,109,384 B2 to Merritt et al.

IPR Petition – Patent 11,844,921
Imperative Care, Inc. v. Inari Medical Inc.

Exhibit No.	Description
1017	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)
1018	PCT Patent Publication WO 2018/019829 A1 to Brady et al.
1019	Inari’s Notice of Motion and Motion for Leave to File Third Amended Complaint (Dkt. #88) in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 24-cv-03117-EKL (N.D. Cal.) (filed March 5, 2025)
1020	U.S. Patent No. 6,776,770 B2 to Treretola
1021	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)

Petitioner Imperative Care, Inc. (“Petitioner”) requests *inter partes* review (“IPR”) of claims 1-7, 9-10, and 15-18, and 20-24 (“the challenged claims”) of U.S. Patent No. 11,844,921 (“the ’921 patent,” Ex. 1001), which is assigned to Inari Medical, Inc. (“Patent Owner” or “PO”).

I. INTRODUCTION

Patent Owner has asserted claims 1-3, 5-7, and 9-10 against Petitioner in the co-pending district court litigation (the “Litigation”). See Ex. 1013 (contentions). In this IPR, Petitioner challenges the patentability of those asserted claims, as well claims having similar limitations.

The challenged ’921 patent is the parent of U.S. Patent No. 11,697,011 (“the ’011 patent,” Ex. 1012). The Board recently instituted Petitioner’s IPR challenging the patentability of the ’011 patent. (Ex. 1017.) In that institution decision, the Board preliminarily addressed the same or similar claim limitations to those included in the ’921 patent.

The challenged claims in both the ’011 and ’921 patents 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 medical procedures.

The challenged claims require a valve having a collapsible “elongate member” that extends through the center of the valve. The elongate member has a “lumen.”¹

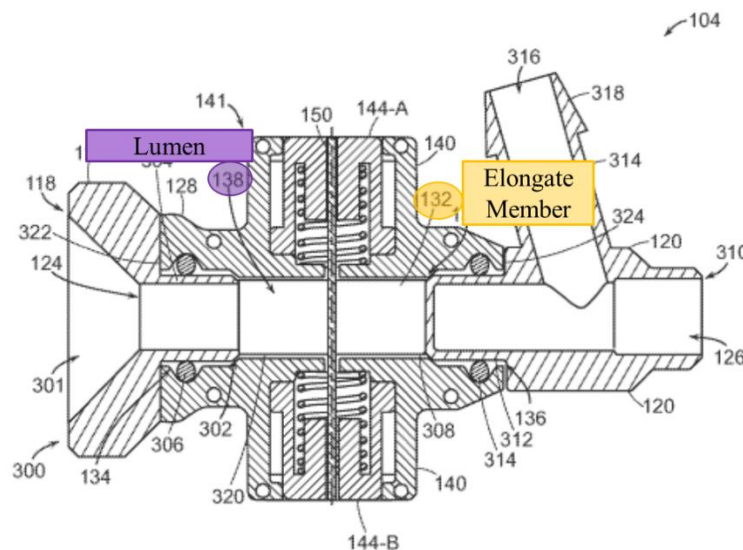
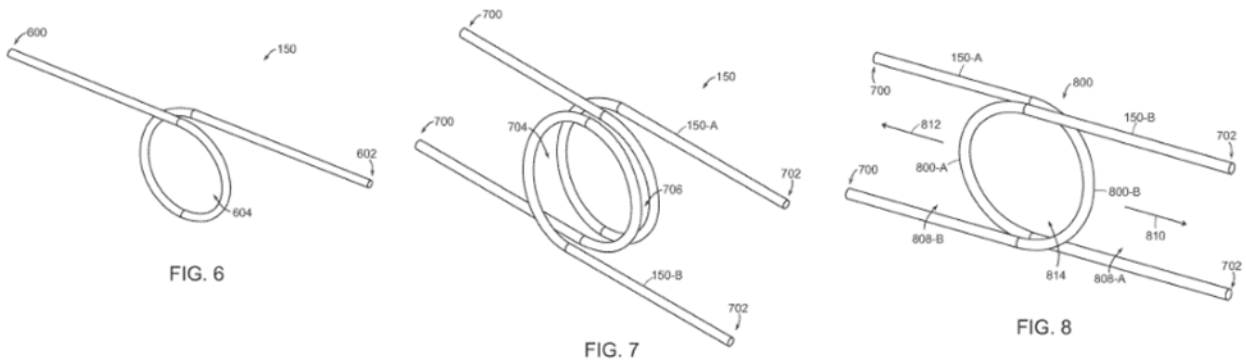


FIG. 3

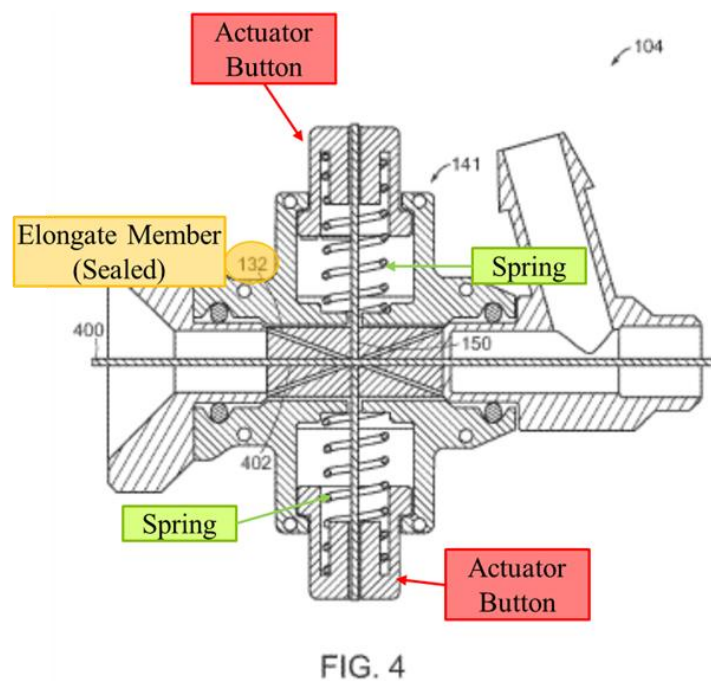
(Ex. 1001, Fig. 2.) The claimed valve also includes an actuator (e.g., button) and a “filament” extending around the elongate member. When the actuator applies tension to the ends of the filament, the filament constricts the elongate member to seal the lumen. The filament can have a variety of configurations, as shown below.

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



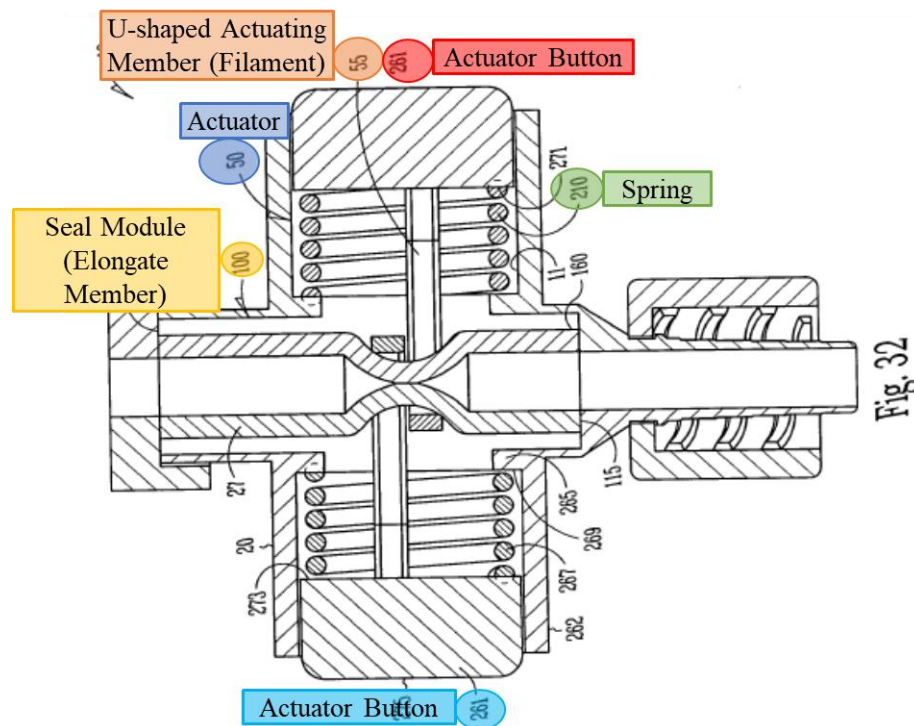
(*Id.*, Figs. 6-8.)

The claimed valve also includes a “biasing member” (e.g., spring) that biases the actuator toward a first position wherein the valve is constricted:



Valves having a filament looped around a collapsible tube and springs to bias the valve toward its closed configuration were well known before September 6, 2017, the earliest claimed priority date for the '921 patent. **Schaffer**, a patent application published in 2003, describes a hemostasis valve for use during minimally

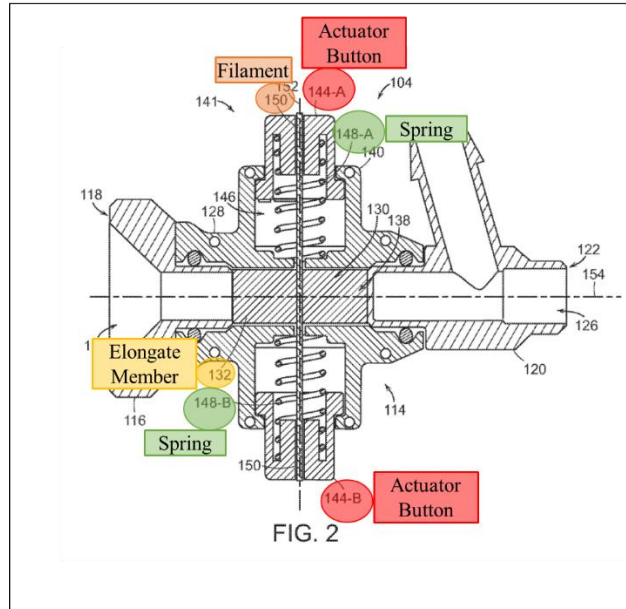
invasive intravascular procedures. Schaffer was **not** before the Examiner during prosecution of the '921 patent. Like the claimed valves, Schaffer's valve includes an elongate member having a lumen, an actuator (e.g., button) coupled to a filament (e.g., actuating members), and a biasing system (e.g., spring):



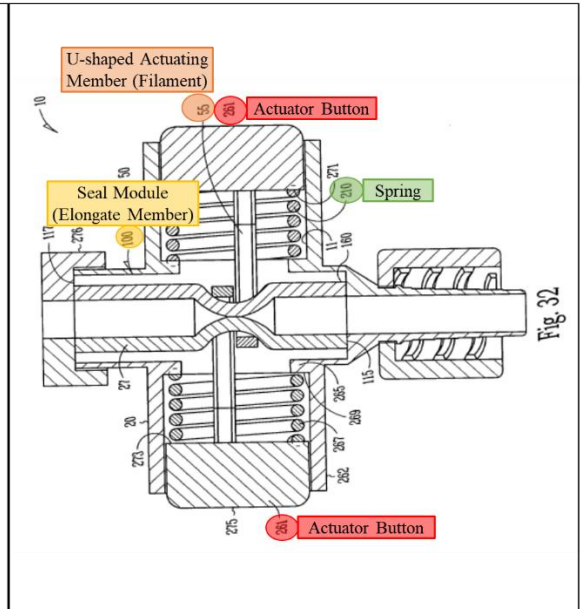
(*Id.*, Fig. 32.)² As illustrated below, Schaffer's valve has the same components, in the same arrangement, as the valve claimed in the '921 patent. Thus, Schaffer anticipates or renders obvious the challenged claims.

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.

'921 Patent



Schaffer



In the IPR institution decision for the '011 patent, the Board found, “based on the preliminary record,” “that Petitioner has established a reasonable likelihood that it will prevail in showing that at least claim 1 [of the '011 patent] is anticipated by Schaffer.” (Ex. 1017 at 33.) Notably, claim 1 of the '011 patent includes similar limitations to those in claim 1 of the '921 patent.

Schaffer also renders the challenged claims obvious in combination with the “filaments” described in Hartley or Eller. **Hartley**, another patent application published in 2003, describes a hemostasis valve having a filament that constricts the lumen of an elongate member:

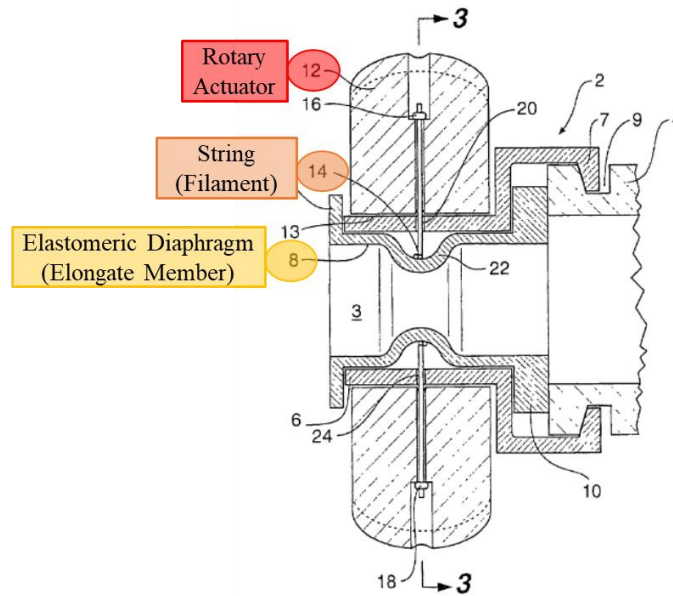
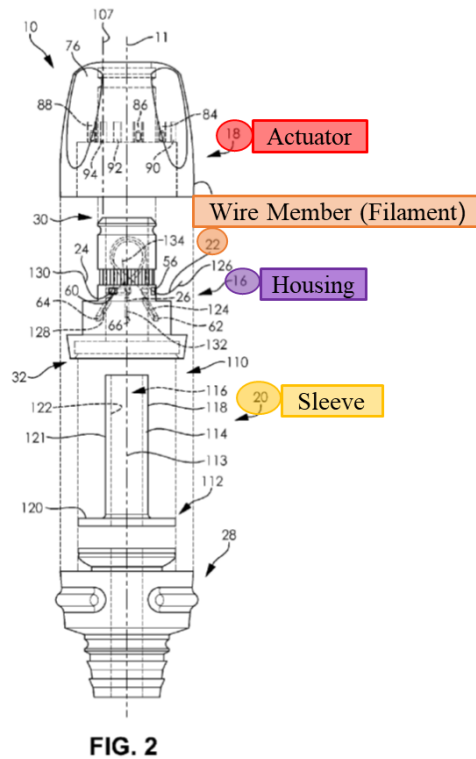


Fig 1

(Ex. 1006, [0031], Fig. 3.) Hartley's filament is attached to a rotary actuator that applies tension to the filament. Rotation of the actuator in one direction constricts the lumen while rotation in the opposite direction opens the lumen.

Eller, a patent published in 2015, discloses a rotatable hemostasis valve like the valve disclosed in Hartley. Eller's hemostasis valve also includes a filament that constricts the lumen of an elongate member:



(Ex. 1007, 5:1-12, Fig. 2.)

If Schaffer does not disclose the “filament” required by the challenged claims, a person of ordinary skill in the art (“POSITA”) would have found it obvious to replace Schaffer’s actuating members with the filaments in Hartley or Eller for the reasons discussed herein. The Board preliminarily addressed the combination of Schaffer and Hartley or Eller in the ’011 patent IPR. (Ex. 1017 at 33-41.) There, PO argued that a POSITA would not have been motivated to combine Schaffer and Hartley or Eller with a reasonable expectation of success. *Id.* at 36. The Board preliminarily rejected PO’s argument, finding that “Petitioner advances multiple reasons why the skilled artisan would have been motivated to combine Schaffer and Hartley with a reasonable expectation of success.” *Id.*

Hartley combined with Eller also renders many of the challenged claims obvious. The Examiner of the '921 patent did not issue any office actions or make any prior-art based rejections. However, in the Notice of Allowance, the Examiner concluded that Hartley taught each limitation of the '921 patent's independent claims except the "biasing member." (Ex. 1002, 25.) The Examiner never addressed whether a POSITA would have found it obvious to combine a biasing mechanism with Hartley. Yet, valves combining a biasing mechanism with a rotating actuator were known by September 2017.

Eller, for example, combines a torsion spring with a rotating actuator to bias Eller's valve toward the closed position. (Ex. 1007, 19:22-30.) As explained herein, a POSITA would have found it obvious to combine Eller's torsion spring with Hartley's rotatable hemostasis valve. While Eller was listed in an Information Disclosure Statement ("IDS") during prosecution, it was not discussed or applied by the Examiner.

The Board preliminarily addressed the combination of Hartley and Eller in the '011 patent IPR institution decision. Ex. 1017 at 42. The Board was unpersuaded at that time that Hartley and Eller rendered the claims of the '011 patent unpatentable. The '011 patent claims required an actuator with a "first member" and "second member." The Board was not convinced that Hartley and Eller disclosed

two members. However, the challenged claims in this IPR do not require two members. Therefore, the Board is addressing a new issue in this IPR.

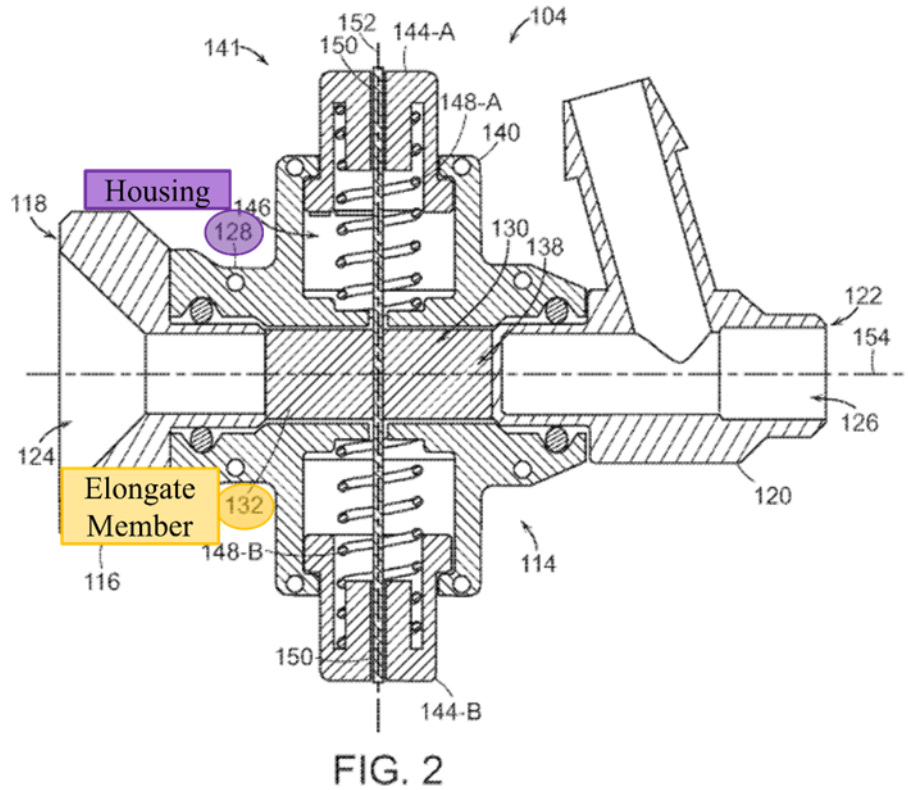
For the reasons presented herein, Petitioner has demonstrated a reasonable likelihood that at least one claim of the '921 patent is unpatentable. Accordingly, Petitioner requests that the Board institute this IPR to review the patentability of the '921 patent.

II. THE '921 PATENT

A. Overview

The '921 patent describes hemostasis (or “garrot”) valves for use during minimally invasive intravascular procedures. (Ex. 1001, 5:49-67). The hemostasis valve is used with a catheter inserted into the patient’s vasculature to provide a seal. (*Id.* at 1:35-38). The '921 patent states that the valve “can seal with or without a tool extending through the valve.” (*Id.*, 5:50-52.)

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



(*Id.*, 6:49-7:24, Fig. 2.) The elongate member 132 has a “thin-walled compliant tubular structure,” which helps facilitate “the uniform collapse of the elongate member 132 and the sealing of the elongate member 132.” (*Id.*, 7:10-16.)

The valve also has a “constricting mechanism,” which can “collapse and seal the elongate member 132 via compression and/or constriction, and specifically via constriction with at least one filament 150.” (*Id.*, 8:1-4.)

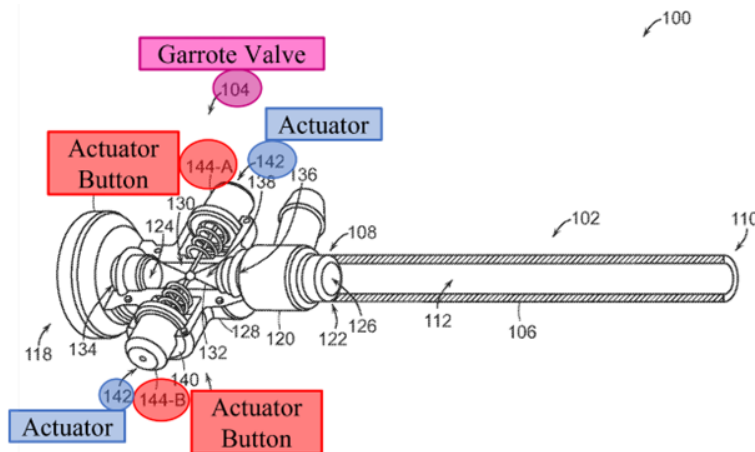


FIG. 1

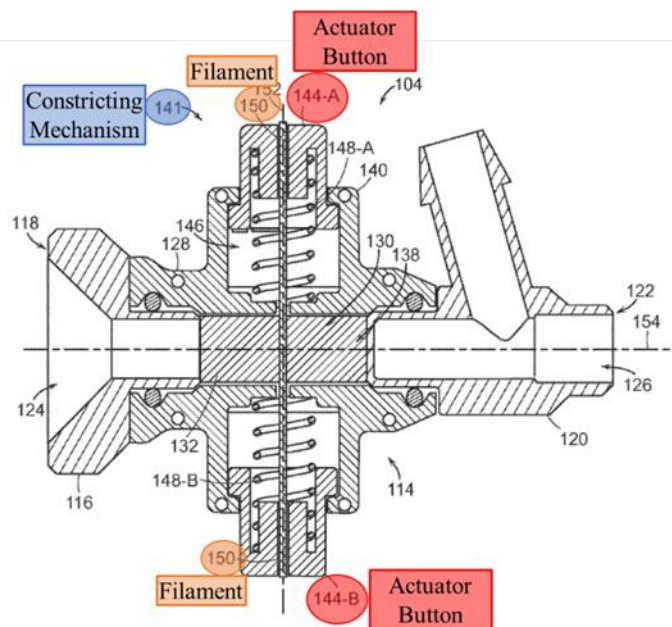


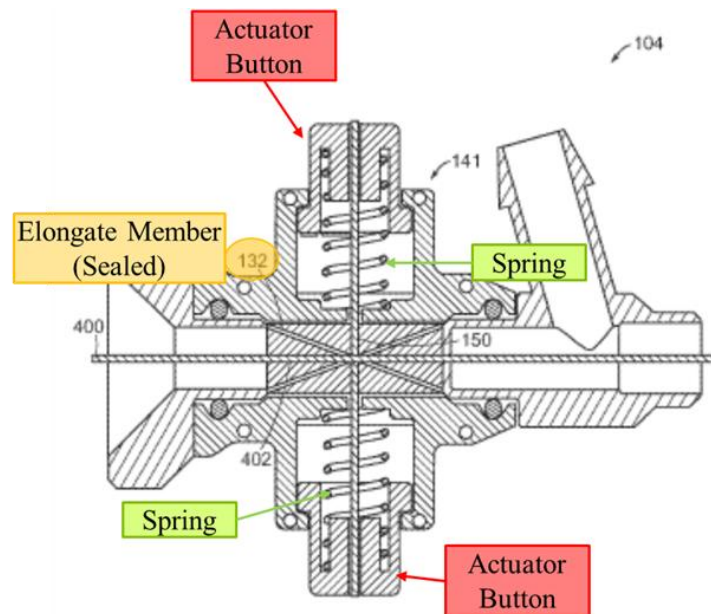
FIG. 2

(*Id.*, 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.*, 8:1-5.) The “filament 150 can be coupled to the actuator 142 such that the filament 150

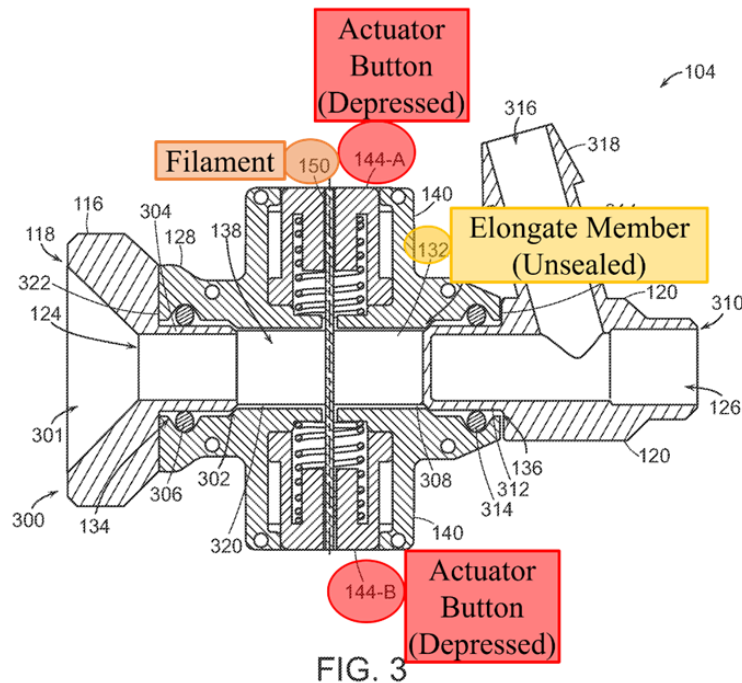
selectively constricts, collapses, and/or seals the elongate member 132 ... based on the movement and/or position of the actuator 142.” (*Id.*, 9:18-22.)

The valve also includes a “bias feature,” such a spring (148-A and 148-B), which biases the actuator toward the open or closed configuration. (*Id.*, 8:32-51.)

Figure 4 shows the valve biased toward a first, closed position:



(*Id.*, 8:32-51, Fig. 2.) Depressing the actuator buttons releases 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”:



(*Id.*, 9:48-56, Fig. 3).

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

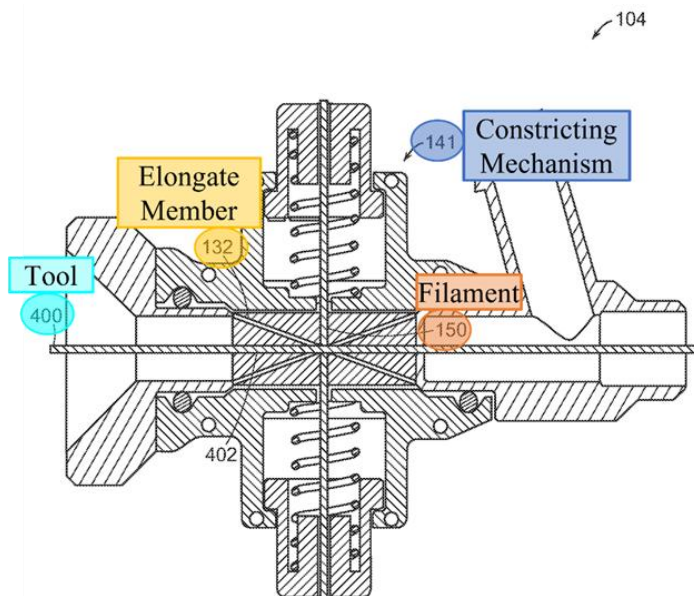


FIG. 4

(*Id.*, 11:64-12:8, 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 8-9:

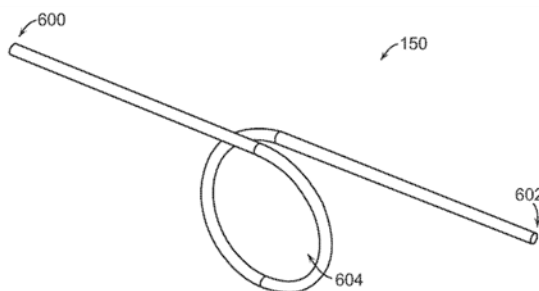


FIG. 6

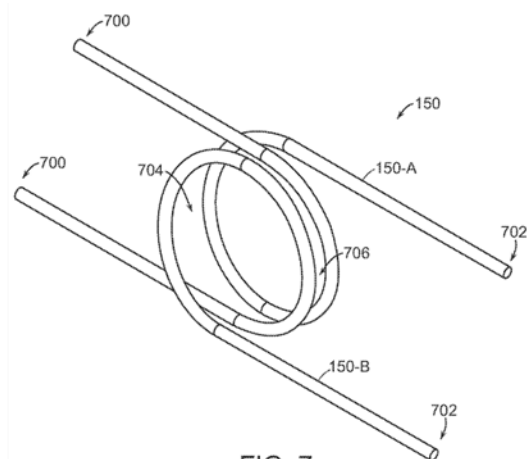


FIG. 7

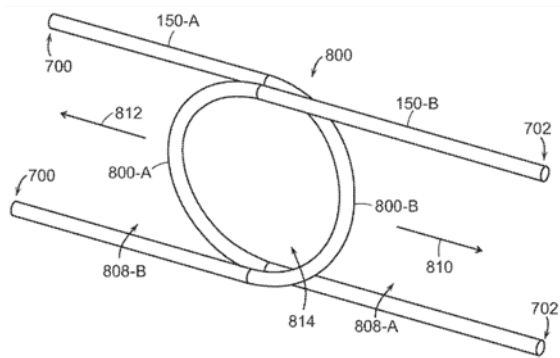


FIG. 8

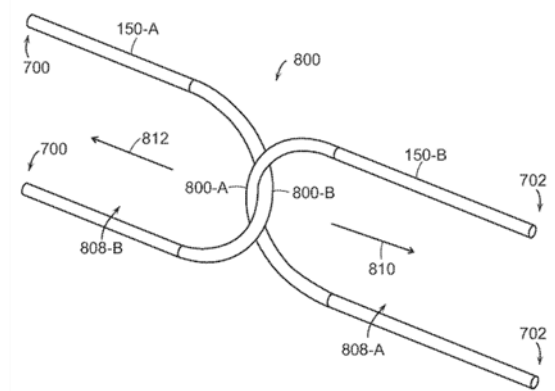


FIG. 9

(*Id.*, 13:10-14:27, 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”:

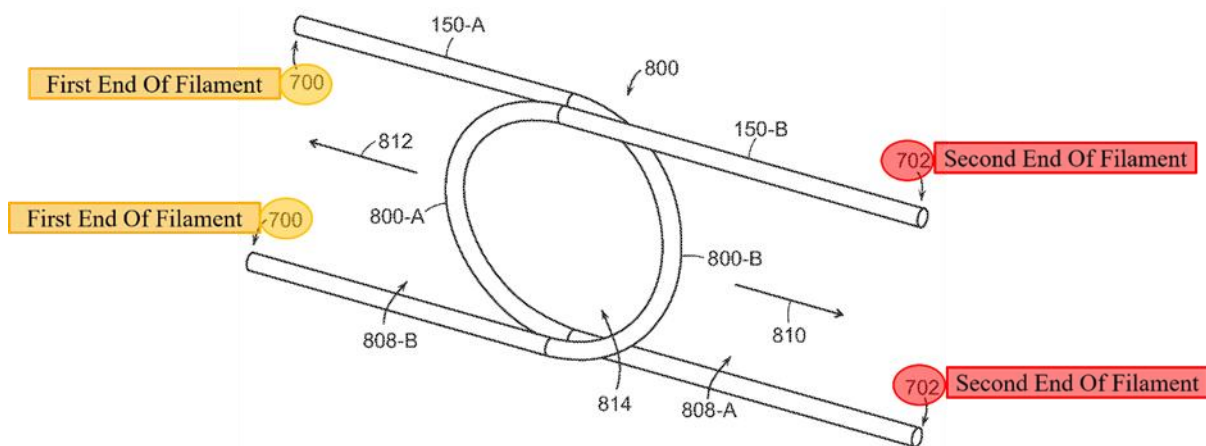


FIG. 8

(*Id.*, 13:1-9, Fig. 8.)

B. Prosecution History

In the Notice of Allowance, the Examiner stated that Hartley and Williams (Ex. 1010) were the “closest prior art of record.” (Ex. 1002, 25.) The Examiner found that Hartley disclosed every limitation of several claims except “a biasing member configured to bias the actuator to the first position.” (*Id.*) While the Examiner found that Williams disclosed a biasing member, the Examiner concluded that Williams failed to disclose “a filament extending around the elongate member.” (*Id.*, 26.) The Examiner did not address the combination of any references.

C. The Earliest Possible Priority Date

The '921 patent claims priority to provisional application No. 62/554,931, filed September 6, 2017, which is the earliest possible priority date for the '921 patent. (Ex. 1001.) Petitioner applies this earliest priority date in this Petition; however, Petitioner preserves its right to challenge the priority date in subsequent proceedings.

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, ¶35.) This is the same level of ordinary skill that Petitioner proposed in the '011 patent IPR and that was applied by PO and the Board. (Ex. 1017, 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 “filament.” A POSITA would have understood the term “filament” to mean at least “one or more threads, lines, cords, ropes, ribbons, flat wires, sheets, or tapes” based on the intrinsic record. (Ex. 1003, ¶¶49-59.) This is the same construction of “filament” that Petitioner proposed in the ’011 patent IPR. (Ex. 1017, 12.) There, the Board preliminarily found that it did not need to “expressly construe the term ‘filament’ in the manner urged by Petitioner.” (*Id.*, 13.) However, the Board agreed with “Petitioner that a filament as claimed *encompasses* one or more threads, lines, cords, ropes, ribbons, flat wires, sheets, or tapes.” (*Id.* (emphasis in original).) The Board correctly observed that the ’011 patent “lists those structures explicitly, but suggests that those are only examples and, thus, the term ‘filament’ may be broader than those structures.” (*Id.*) Petitioner agrees with the Board that “filament” may be construed

more broadly. However, the Board needs to construe the terms only to the extent necessary to resolve the controversy. *Realtime Data, LLC v. Iancu*, 912 F.3d 1368, 1375 (Fed. Cir. 2019). Here, Petitioner’s construction of “filament” resolves the dispute because the structures listed in the construction (e.g., threads, flat wires) are found in the prior art references, even if a full construction of “filament” would include additional structures.

The Board also addressed PO’s argument in the ’011 patent IPR that the “filament” must be “thin and flexible.” (Ex. 1017, 13.) The Board did not adopt PO’s construction in the institution decision. (*Id.*, 15.) The Board observed that “the ’011 patent never uses the words ‘thin’ or ‘flexible’ to describe the ‘filament.’” (*Id.*) The Board also observed that “the words ‘thin’ and ‘flexible’ inject potential ambiguities as a relative term” because “flexibility and rigidity exist along a spectrum” (*Id.*) Petitioner agrees that PO’s proposed construction is incorrect for these reasons and others. (Ex. 1003, ¶¶51-54.) For example, in a related patent, PO specifically claims a filament that “is flexible,” demonstrating that flexibility is not an inherent property of the filament. (Ex. 1016, claim 1.) PO’s proposed construction in the ’011 patent IPR also required “one or more strands,” which would improperly exclude specific “filaments” identified in the ’921 application, such as a “sheet” of metal.” (Ex. 1003, ¶52.) For at least these reasons, PO’s previously proposed construction is incorrect.

Petitioner's construction of "filament" is supported by the intrinsic record. Claim construction generally begins with the claim language. *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). Here, however, the claims provide little information regarding the "filament." For example, claim 1 recites "a filament ... extending at least partially around the elongate member." Claims 15 and 21 require "a filament coupled to the elongate member." Claim 25 requires "a first filament" and "a second filament" where a first actuator is "coupled to the elongate member via a first filament" and a second actuator is "coupled to the elongate member via a second filament." This claim language does not provide a POSITA with guidance on the "filament" structure.

However, the '921 patent specification (like the '011 patent) identifies examples of "filaments." The '921 patent states, "the filament 150 can comprise one or several threads, lines, cords, rope, ribbon, flat wire, sheet, or tape." (Ex. 1001, 9:15-17.) Petitioner has adopted this description for its construction of "filament."

The remainder of the specification is consistent with this description, stating that, "[t]he filament can be made from a variety of materials including, for example, a polymer, a synthetic, and/or a metal." (*Id.*, 9:7-9.) The specification also discloses, "the filament can comprise a single strand such as, for example, a monofilament, [or] the filament can comprise a plurality of strands that can be, for example, twisted, woven, grouped, and/or fused to form the filament." (*Id.*, 9:10-15.) Additionally,

the specification explains that “the filament 150 can comprise multiple filaments, and specifically, as shown in FIGS. 7 through 9, the filament 150 can comprise a first filament 150-A and a second filament 150-B.” (*Id.*, 12:54-57.)

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	35 U.S.C. § 102	1-7, 9-10, 15-18, 20-24
2	Schaffer	35 U.S.C. § 103	1-7, 9-10, 15-18, 20-24
3	Schaffer + Hartley	35 U.S.C. § 103	1-7, 9-10, 15-18, 20-24
4	Schaffer + Eller	35 U.S.C. § 103	1-7, 9-10, 15-18, 20-24
5	Hartley + Eller	35 U.S.C. § 103	1-3, 5-6, 9-10, 15-18, 21-24

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

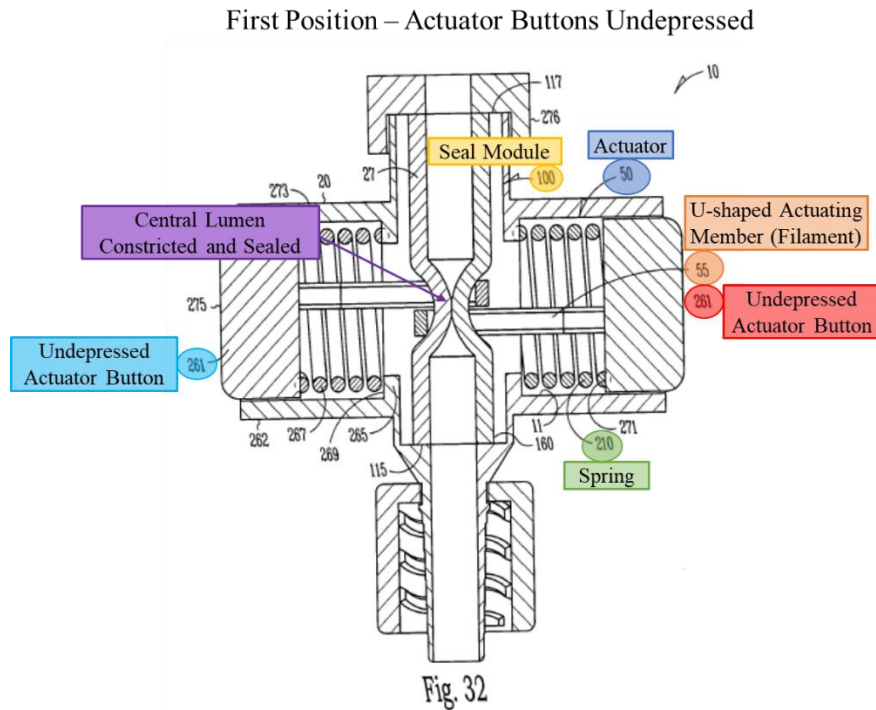
C. The Asserted References Are Analogous Art

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 '921 patent, e.g., hemostasis valves for use during intravascular procedures. (Ex. 1003, ¶26.) 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 1-4: CLAIMS 1-7, 9-10, 15-18, 20-24 ANTICIPATED BY SCHAFFER OR OBVIOUS OVER SCHAFFER ALONE OR IN COMBINATION WITH HARTLEY OR ELLER

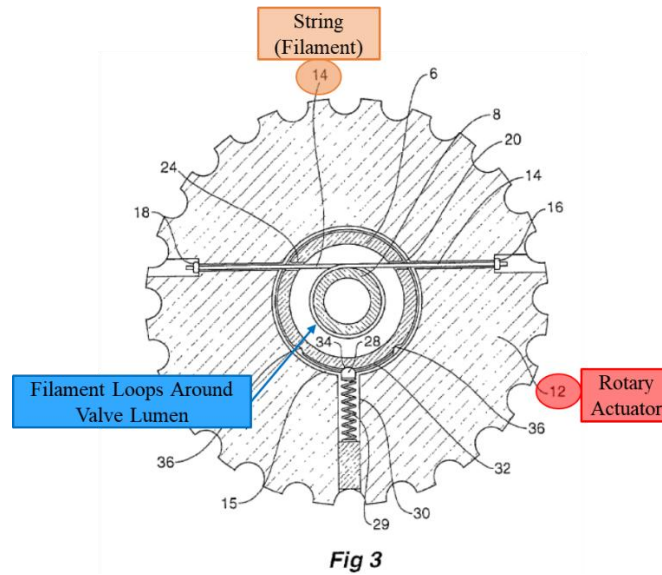
Schaffer anticipates claims 1-7, 9-10, 15-18, and 20-24 or renders them obvious. (Ex. 1003, ¶¶61-173.) Schaffer discloses a hemostasis valve for use with catheters “that blocks the flow of gas or fluid completely and immediately with or without an instrument in place within the gas/fluid path.” (Ex. 1005, [0002], [0008].) Like the valve described in the '921 patent, Schaffer's valve includes a collapsible elongate member (called a “seal module 100”). (*Id.*) Schaffer's valve also includes filaments (“actuating member 55”) that can collapse the elongate member to close the valve. (*Id.*, [0076]-[0077].) Also, like the '921 patent, Schaffer's actuating

members 55 (i.e., filaments) may be moved from a first position to a second position by depressing two actuator buttons 261 connected to two springs 210. (*Id.*)

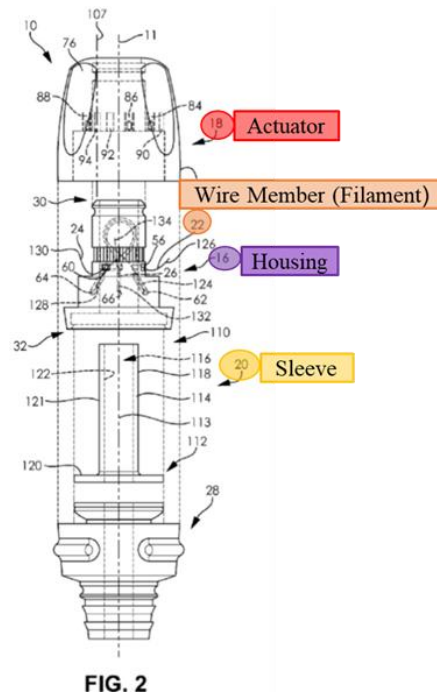


Thus, Schaffer discloses the claimed valve.

If, however, the Board finds that Schaffer’s actuating members 55 are not “filaments,” as PO has previously argued, Schaffer combined with Hartley or Eller renders the challenged claims obvious. (Ex. 1003, ¶¶62-64.) Hartley and Eller disclose hemostasis valves having filaments that loop around and constrict the lumen of an elongate member to seal a valve. Hartley’s “filament” is a “string”:



(Ex. 1006, [0017], [0031], Fig. 3.) Eller’s “filament” is a “wire member”:



A. Claim 1

Schaffer anticipates claim 1 or renders claim 1 obvious alone³ or combined with Hartley *or* Eller. (Ex. 1003, ¶¶65-109.)

1. Preamble

If the preamble is limiting, Schaffer, Hartley, and Eller disclose a “valve.” (Ex. 1003, ¶¶66-69.)

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].)

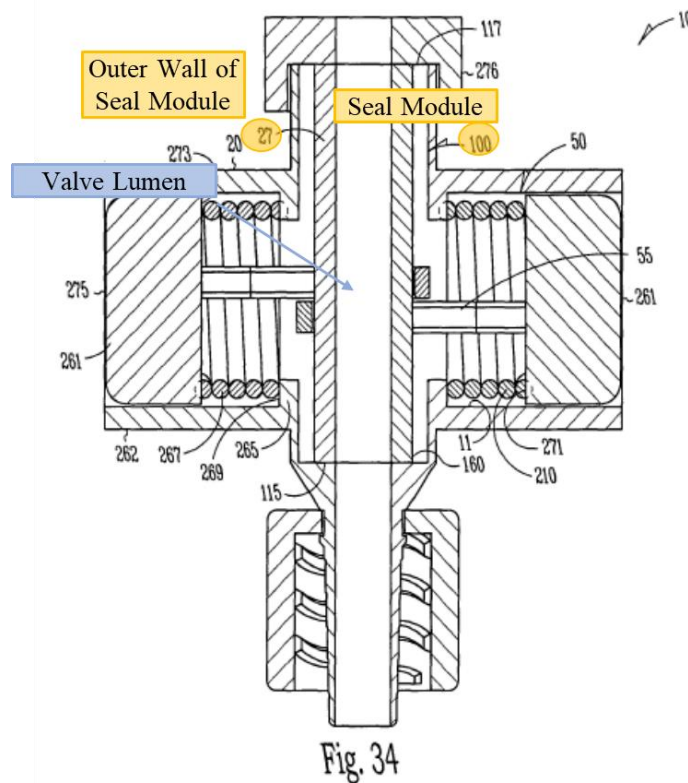
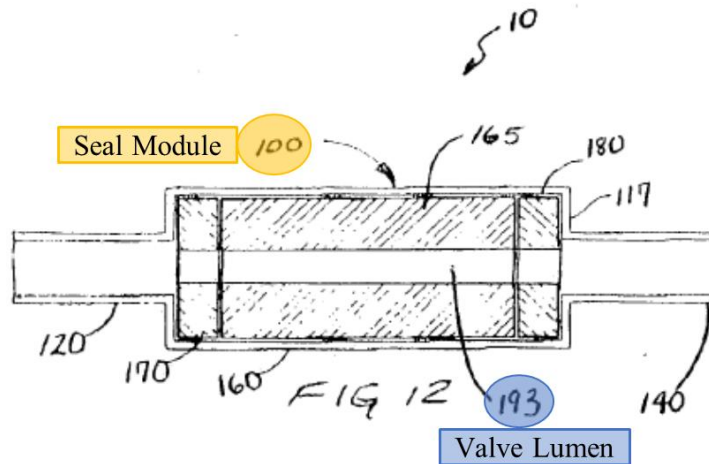
Eller discloses “selective fluid barrier valve devices” for procedures “that require the percutaneous insertion of one or more interventional devices into a bodily passage, such as a portion of the vascular system.” (Ex. 1007, 1:14-23.)

2. Elongate Member

Claim 1 next recites “an elongate member defining a lumen.” Schaffer discloses this limitation. (Ex. 1003, ¶¶70-71.)

³ “[I]t is well settled that a ‘disclosure that anticipates under §102 also renders the claim invalid under §103, for anticipation is the epitome of obviousness.’” *Realtime Data*, 912 F.3d at 1373.

Schaffer's valve includes a "seal module 100" having "a flexible, elongate tubular structure 101." (Ex. 1005, [0049], [0051], [0054], [0075].) The elongate tubular structure 101 defines a lumen 193:



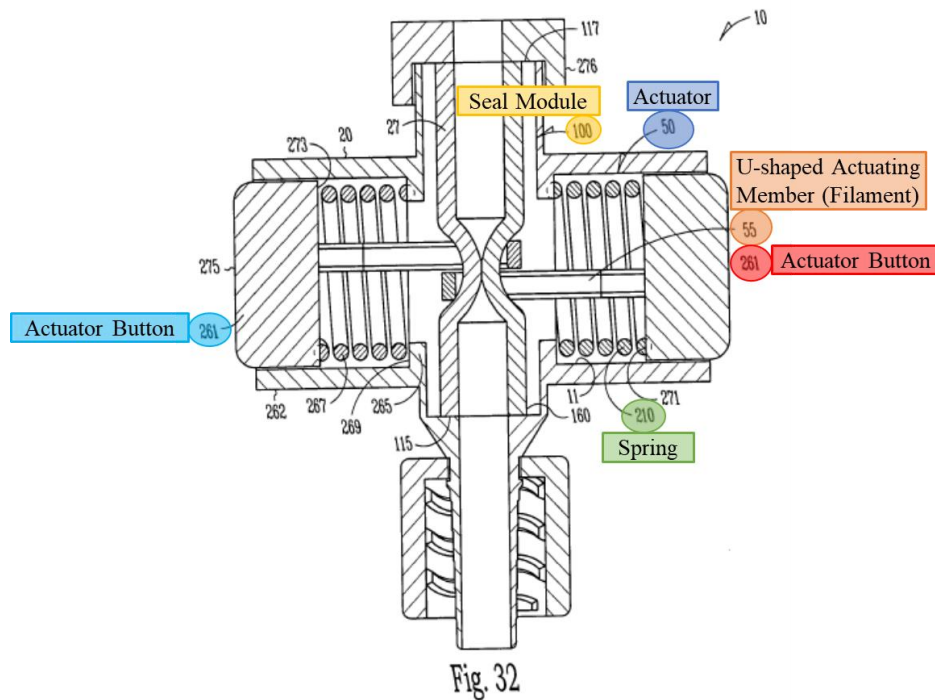
(*Id.*, [0058], Figs. 12, 34). Thus, Schaffer’s seal module 100 is “an elongate member defining a lumen.” (Ex. 1003, ¶71.)

3. Tensioning Mechanism

Claim 1 next recites “an active tensioning mechanism including an actuator coupled to the elongate member via a filament extending at least partially around the elongate member, wherein the actuator is movable between (a) a first position wherein the lumen is constricted and sealed and (b) a second position wherein the lumen is at least partially open.” Schaffer discloses these limitations or renders them obvious in view of Hartley *or* Eller. (Ex. 1003, ¶¶72-106.)

a. Actuator

Schaffer discloses the actuator required by claim 1. (Ex. 1003, ¶¶73-77.) 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”:

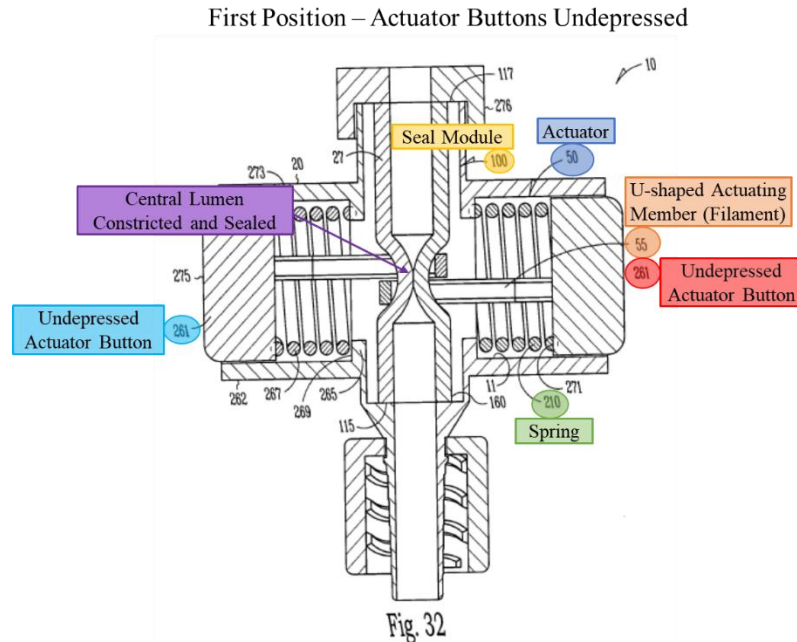


(Ex. 1005, [0075]-[0076], Figs. 31-32). Each actuator 50 includes “an actuator button 261.” (*Id.*).

Schaffer’s actuator buttons are each coupled to “an actuating member 55 which, in one option, is U-shaped.” (Ex. 1005, [0076]). As explained below, each actuating member is a filament under the correct construction of that term. (*Infra* §VI.A.3.b.i.) The actuating members couple the actuator buttons to the elongate member. (See Ex. 1005, Fig. 32 (above).)

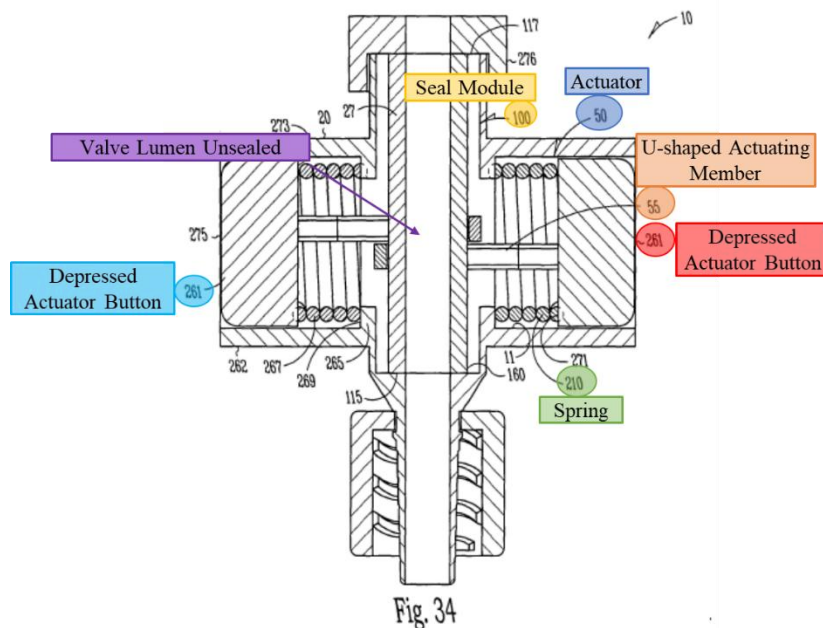
Each actuator button is movable between a first position wherein the lumen is constricted to create a seal and a second position wherein the lumen is at least partially open. (Ex. 1003, ¶75.) Schaffer discloses that in a first position, shown in

Figure 32, the actuator buttons pull on the actuating members, which collapses the lumen of the seal module to create a seal:



(Ex. 1005, [0077], Fig. 32; *see also id.*, [0008] (Schaffer’s valve “blocks the flow of gas or fluid completely and immediately with or without an instrument in place within the gas/fluid path”).) In a second position, shown in Figure 34 below, the actuator buttons are pressed inwardly, compressing the springs and permitting the seal module’s lumen to return to its uncollapsed configuration:

Second Position – Actuator Buttons Depressed

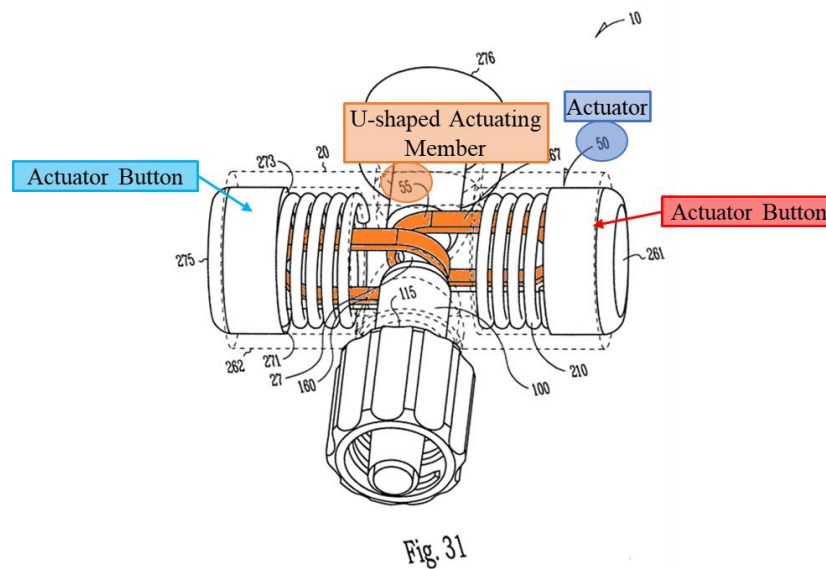


(Ex. 1005, [0077], Fig. 34.) The user of Schaffer’s valve can actively depress the actuator buttons to open and close the valve. Moreover, Schaffer’s actuator buttons actively apply tension to the actuating members, via the springs, to seal the valve. For these reasons, a POSITA would have understood that Schaffer’s actuators and actuating members form “an active tensioning mechanism.” (Ex. 1003, ¶76.)

b. Filament

i. Schaffer

Schaffer discloses a “filament.” (Ex. 1003, ¶¶78-81.) Schaffer’s valve includes two actuating members, which may be U-shaped, coupled to the actuator buttons:



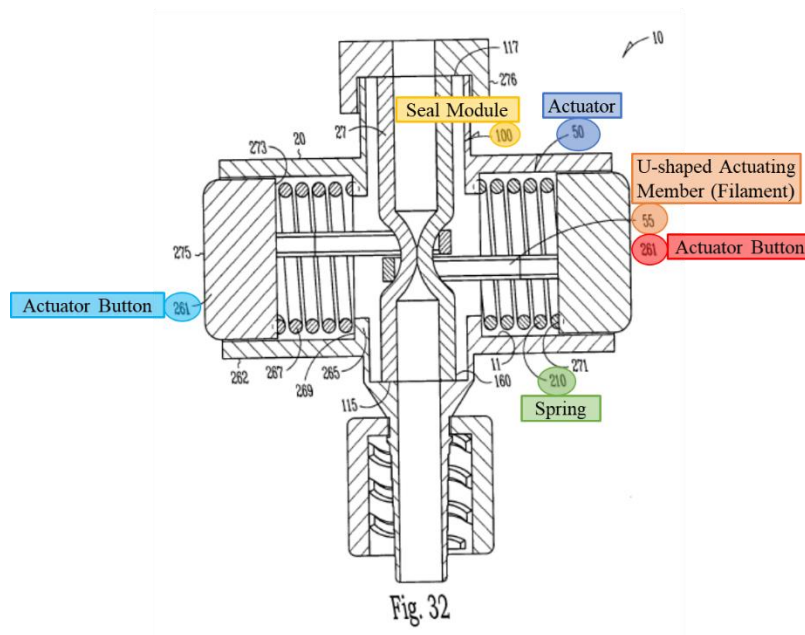
(Ex. 1005, [0076], Fig. 31.)

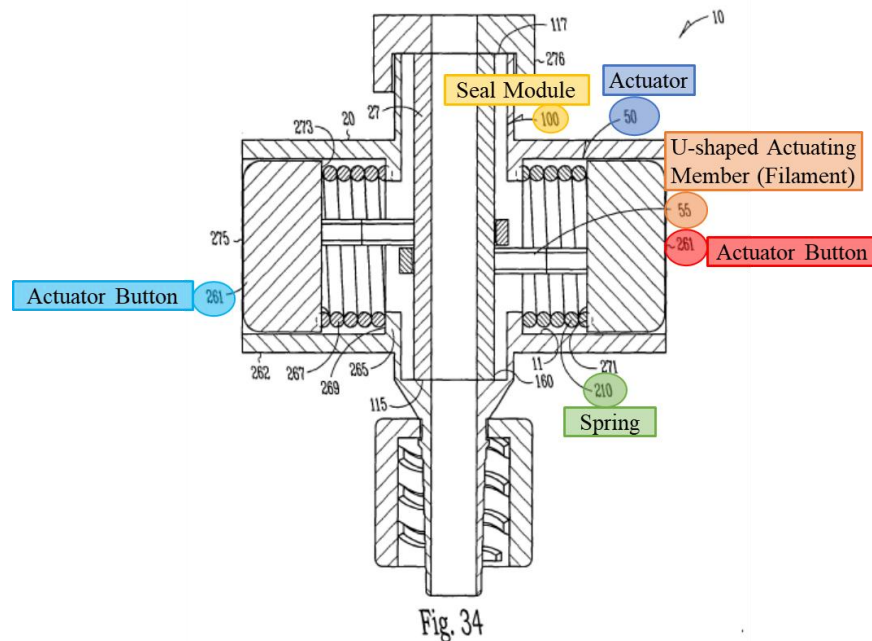
Schaffer’s actuating members are “filaments.” (*Supra* §IV.) Schaffer discloses the actuating members may be formed from aluminum or plastic, and they resemble a ribbon, flat wire, sheet, or tape. (Ex. 1005, [0081], Figs. 31-34.) Schaffer’s actuating members are encompassed by the ’921 patent’s description of filaments. For example, the ’921 patent discloses that filaments may be made from a polymer, which includes Schaffer’s plastic, or a metal, which includes Schaffer’s aluminum. (*Supra* §IV.) Likewise, the ’921 patent states that a filament may be a ribbon, flat wire, sheet, or tape, which includes Schaffer’s actuating members. (*Id.*; Ex. 1003, ¶79.)

In the ’011 Patent IPR, PO argued that Schaffer’s actuating members are “rigid.” (Ex. 1017, 38.) This is inaccurate. Schaffer does not describe the actuating members as “rigid,” nor does it contain disclosure suggesting rigidity. (Ex. 1003,

¶79.) Moreover, even if the actuating members were “rigid,” they would still form a “filament” under the correct construction of that term. (*Id.*; *supra* §IV; Ex. 1017, 32 (“even assuming Patent Owner’s characterization of Schaffer’s U-shaped actuating members as being ‘rigid’ is correct, that does not necessarily foreclose Petitioner’s anticipation challenge”).)

Schaffer discloses that its actuating members are “at least partially circumferentially [sic] disposed about the portion of the seal module 100.” (Ex. 1005, [0076].) Schaffer explains that the actuating members are “coupled” to the actuator buttons, and as shown in Figures 32 and 34, Schaffer’s actuating members are in contact with the elongate member (seal module) in both the sealed and unsealed positions:





(Ex. 1005, [0076]-[0077], Figs. 31-34.) Schaffer’s actuator buttons are therefore coupled to the elongate member (seal module) via the actuating members (filaments). (Ex. 1003, ¶80.) The actuating members also extend at least partially around the elongate member, as illustrated in Figures 32-34. (*Id.*)

Further, even if Schaffer’s lumen were not “constricted and sealed” by the actuating members in the first position, as claimed in the ’921 patent, a POSITA would have found it obvious to modify the actuating members to closely conform to the seal module to constrict and seal the lumen. (Ex. 1003, ¶81.) POSITAs would have been motivated to do so to form a better seal and avoid the potential gaps discussed in the following section. (*Infra* §VI.A.3.b.ii.) A POSITA would have possessed the skill and knowledge to adjust the shape, material, and/or dimensions

of Schaffer’s U-shaped actuating members to closely conform to the circumference of the cylindrical seal module. (Ex. 1003, ¶81.) POSITAs would have had extensive experience with the materials (e.g., plastic, aluminum) and components (e.g., ribbon, flat wire) described in Schaffer and these simple components would have behaved predictably. (*Id.*) As an example, POSITAs could have selected a thin, flexible sheet or flat ribbon of aluminum or plastic to form the actuating members. (*Id.*) Such members would have conformed to the outer surface of the cylindrical seal module and circumferentially constricted the lumen when pulled in opposite directions by the actuator buttons to seal the valve. (*Id.*)

ii. Hartley

Hartley also discloses a “filament.” (Ex. 1003, ¶¶82-84.) Hartley describes a hemostasis valve having a cylindrical housing that holds a “cylindrical elastomeric diaphragm,” and a rotatory actuator mounted to the housing:

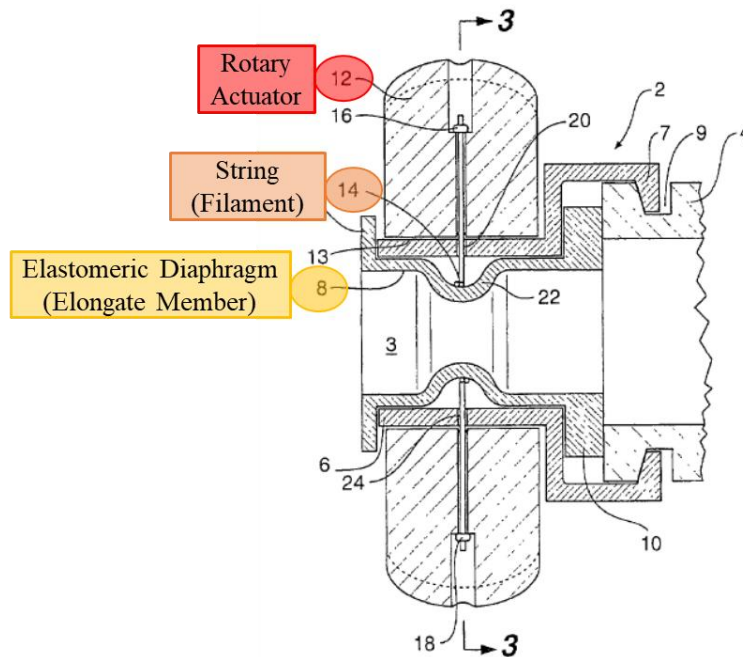


Fig 1

(Ex. 1006, [0031], Fig. 1.) Hartley’s valve also includes a “string 14 ... mounted into the rotary actuator.” (*Id.*) Hartley’s string 14 is a “filament” because the string is made of at least one or more threads, lines, or cords. (Ex. 1003, ¶82.)

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”:

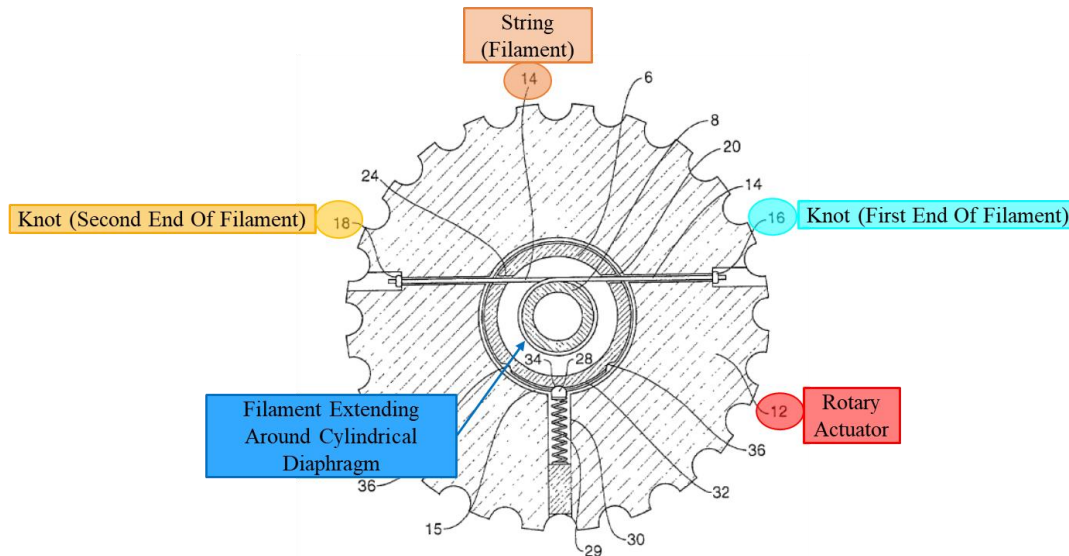


Fig 3

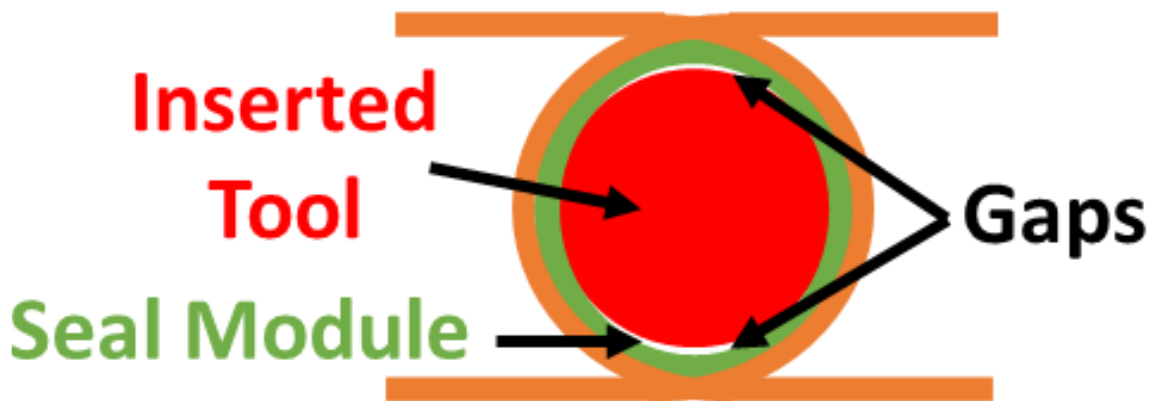
(Ex. 1006, [0031], Fig. 3). Thus, Hartley’s string extends at least partially around the elongate member. (Ex. 1003, ¶83.)

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].)

A POSITA would have found it obvious to substitute Hartley’s string for Schaffer’s two U-shaped actuating members by, for example, attaching the string to one button, wrapping the string around the seal module, and attaching the string to the second button. (Ex. 1003, ¶¶85-94.) This combination of Hartley’s string and Schaffer’s valve would merely entail substitution of one known element (Hartley’s

string) for another (Schaffer’s actuating members) to yield the predictable results of sealing Schaffer’s valve. *KSR Int’l Co. v. Teleflex, Inc.*, 550 U.S. 398, 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, ¶86.) 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, ¶86.) 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:



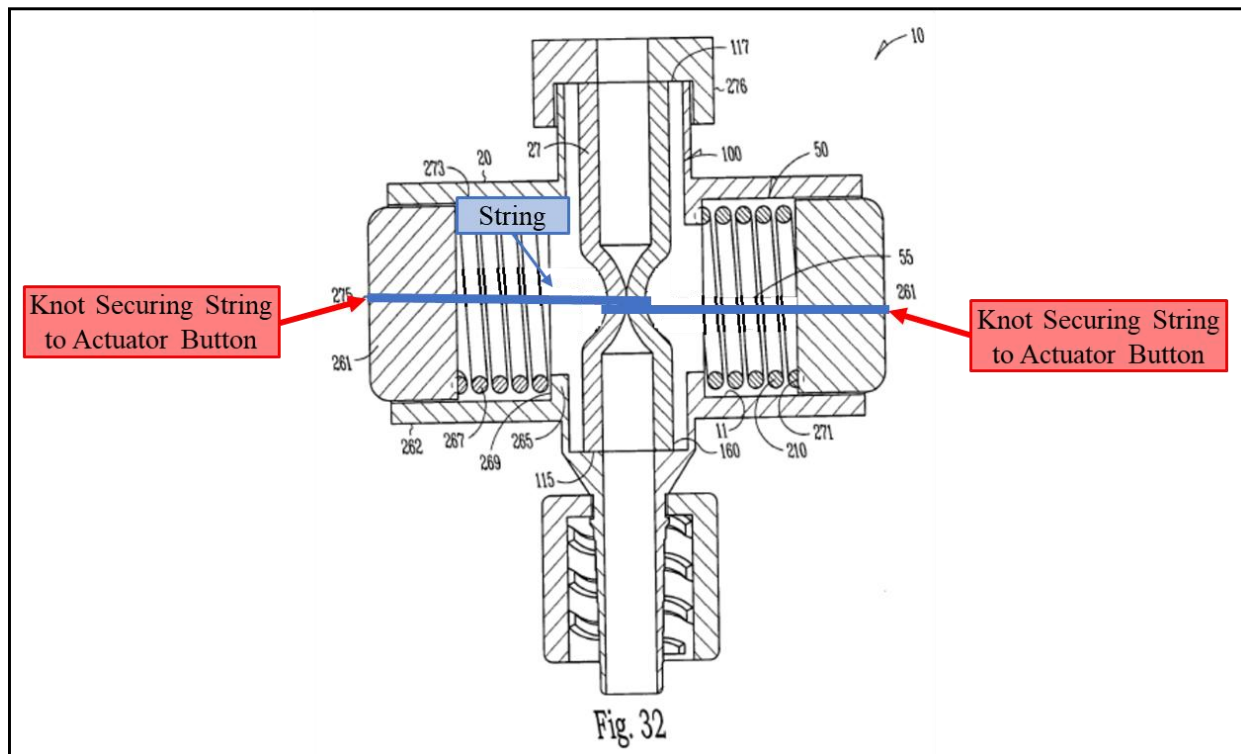
(*Id.*) Hartley’s string could improve upon this potential issue because the string more precisely conforms to the tool diameters and shapes. (*Id.*) In the ’011 patent IPR, PO argued that Schaffer’s valve would not create gaps. (See Ex. 1017, 37 (summarizing argument).) However, PO’s argument relied on a single embodiment

in Schaffer while ignoring other disclosures undermining the argument. (Ex. 1003, ¶86; *see also* Ex. 1017, 37 (explaining deficiencies in argument).)

POSITAs also had a finite number of materials to use for constricting a tubular member in a hemostasis valve in 2017. (Ex. 1003, ¶88.) Hartley and Schaffer disclose two such options: Hartley’s string and Schaffer’s actuating members. (*Id.*) Eller discloses a third option: wire members. A POSITA would have found it obvious to select from these finite, predictable options and, as discussed below, would have had a reasonable expectation of success in implementing them. (*Id.*); *KSR*, 550 U.S. at 421.

POSITAs would have reasonably expected success in substituting Hartley’s string for Schaffer’s two actuating members. (Ex. 1003, ¶¶89-94.) 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, ¶90.) For example, each end of Hartley’s 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.*)⁴

Also, POSITAs would have recognized that Hartley's string and Schaffer's actuating members function in similar ways and, therefore, no other modifications to Schaffer's valve would be necessary. (*Id.*, ¶91.) Both valves collapse the elongate 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

⁴ Petitioner created this demonstrative image.

pull the ends of the string in opposite directions to constrict Schaffer's seal module.
(Ex. 1003, ¶91.)

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, ¶¶92-93.) 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, ¶93.) 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.*, ¶94.) Schaffer and other prior art references disclose various materials for the seal module that a POSITA could try 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).)

Thus, Schaffer combined with Hartley renders claim 1 obvious. (Ex. 1003, ¶94.)

iii. **Eller**

Eller also discloses a “filament.” (Ex. 1003, ¶¶95-96.) Eller describes hemostasis valves having “a housing 16, an actuator 18, a sleeve 20, [and] a first wire member 22”:

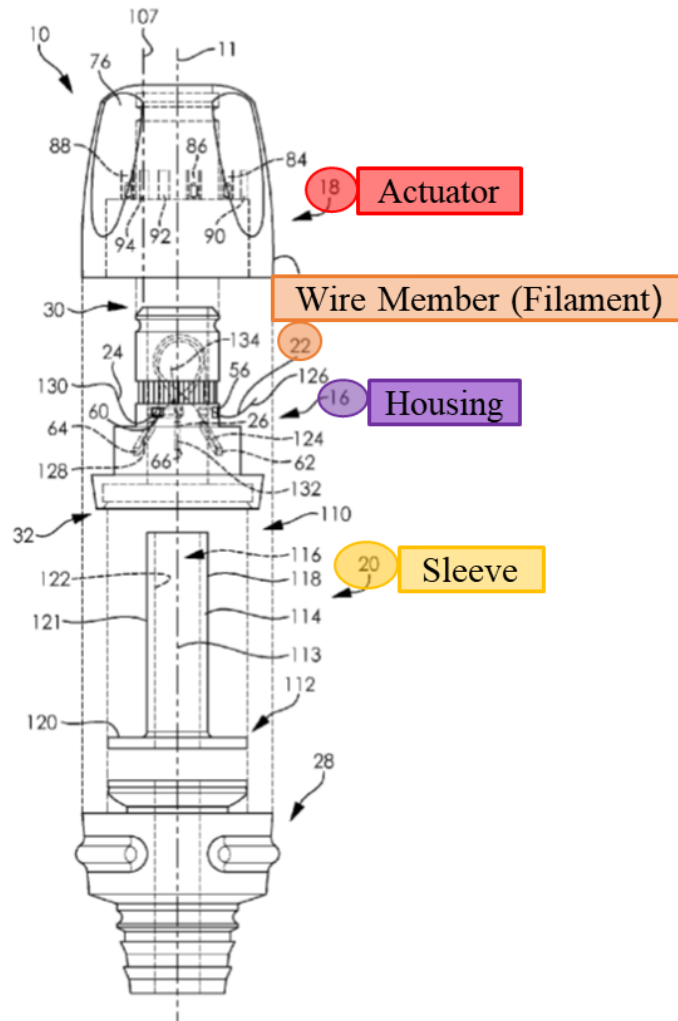
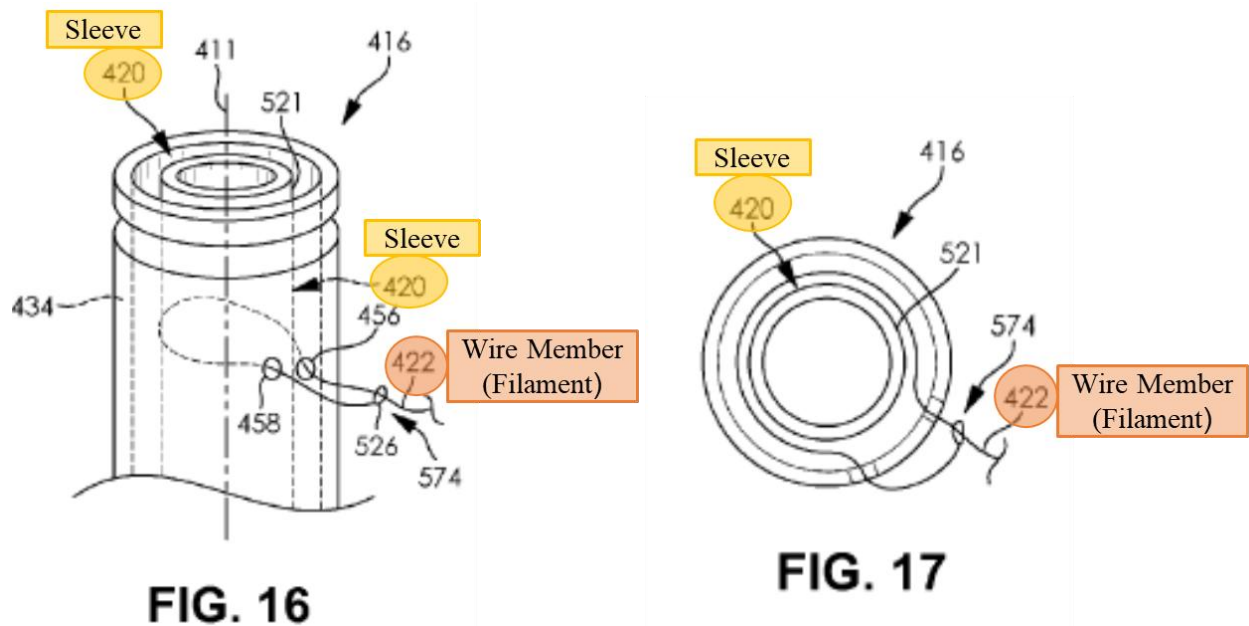


FIG. 2



(Ex. 1007, 5:1-5, 16:7-19, 21:37-22:31, 23:50-25:9, Figs. 2,⁵ 15-16.) Eller's wire member is a filament. (Ex. 1003, ¶¶95-96; *supra* §IV.) The wire member 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"). (Ex. 1007, 15:41-16:6.) Thus, the wire member is a "filament" at least because it is made of at least one or more threads, lines, cords, rope, ribbon, flat wire, sheet, or tape. (Ex. 1003, ¶96.)

The wire member extends at least partially around the valve's "sleeve" so that a first end 124 can attach to the housing 16 and a second end 126 can attach to the actuator 18:

⁵ Eller's Figure 2 shows an exploded view of the device. (Ex. 1007, 2:46-47.)

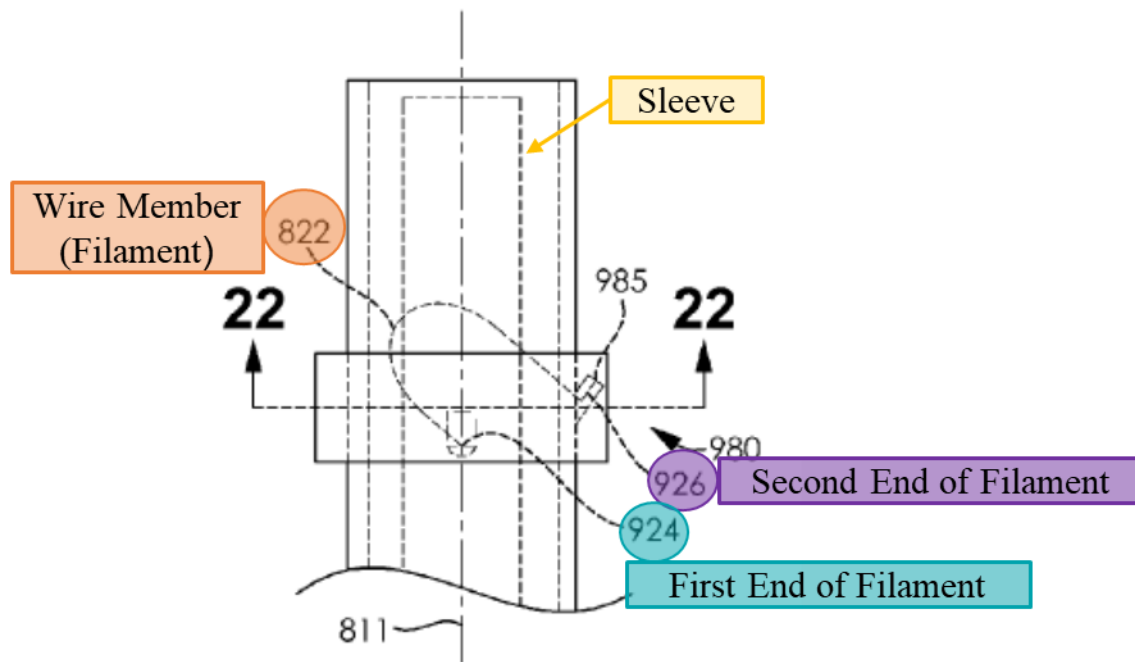


FIG. 21

(Ex. 1007, 12:52-64, 24:50-57, Fig. 21.)

Eller's actuator and wire member is "moveable between a first configuration and a second configuration." (*Id.*, 15:21-25.) In the first configuration, the actuator is rotated so that the wire member is 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 member under tension, causing the wire member 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, ¶¶99-106.) 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 results of constricting Schaffer’s valve. *KSR*, 550 U.S. at 416.

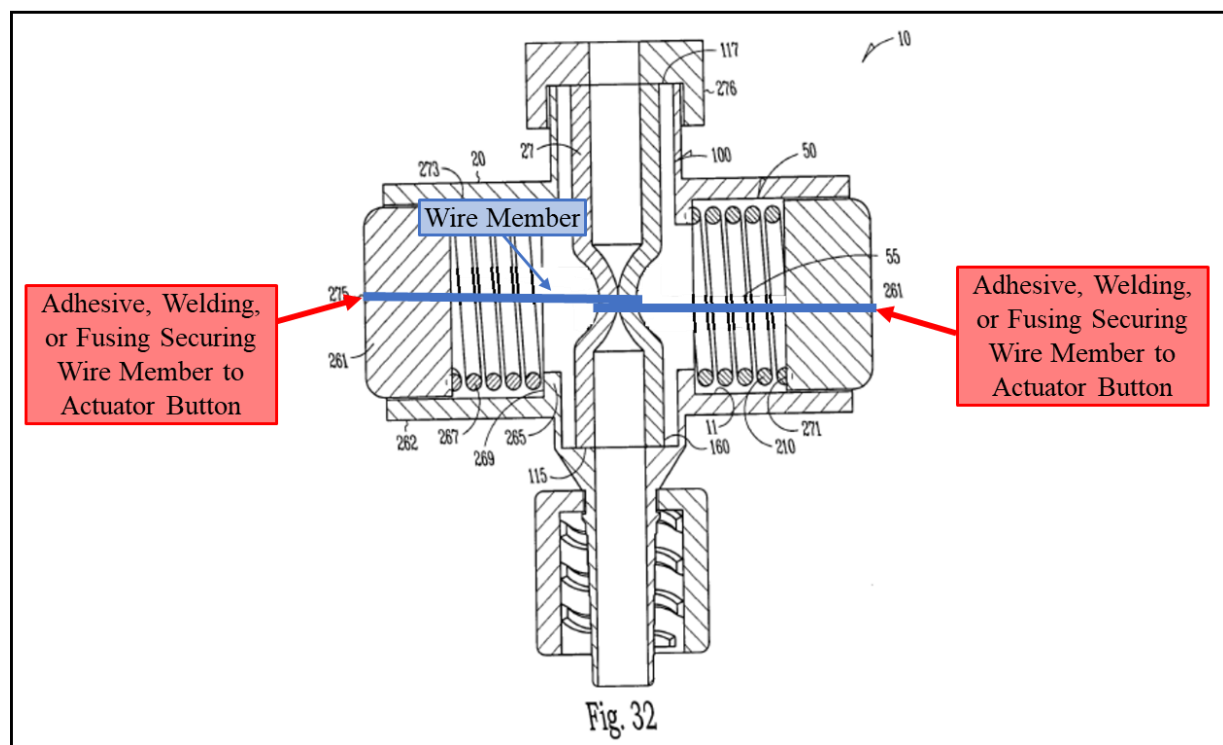
Eller’s disclosure that the wire member can form a seal around one or more medical devices would have further motivated POSITAs to substitute Eller’s wire member for Shaffer’s actuating members. (Ex. 1007, 15:21-40, 17:38-43, 18:3-8; Ex. 1003, ¶¶99.) POSITAs would have recognized that Eller’s wire may seal more effectively across more device diameters and shapes than Schaffer’s actuating members. (*Supra* §VI.A.3.b.i; Ex. 1003, ¶¶99-100.) Like Hartley’s string, Eller’s wire member could more closely conform to some devices. *Id.*

POSITAs also had a finite number of materials to use for constricting an elongate member in September 2017. (*Supra* §VI.A.3.b.ii; Ex. 1003, ¶¶102.) 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 previously discussed. (*Id.*)

A POSITA would have reasonably expected success in substituting Eller’s wire member for Schaffer’s actuating members for several reasons. (Ex. 1003, ¶¶103-106.) 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 member 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, ¶103.)

Demonstrative Illustration Schaffer + Eller’s Wire Member



(*Id.*)⁶

⁶ Petitioner created this demonstrative image.

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, ¶104.)

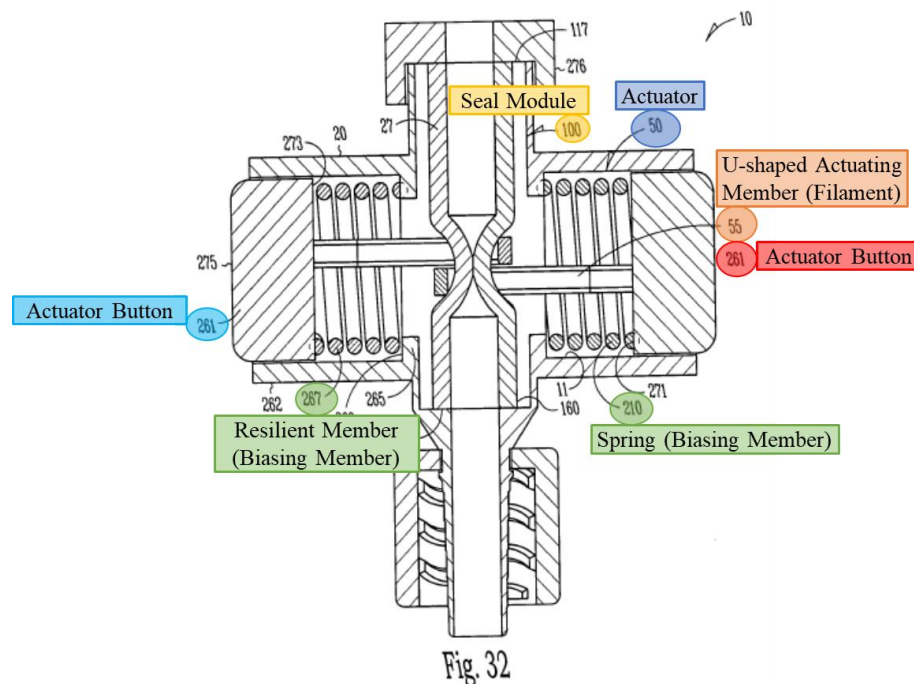
Third, Eller’s wire member and Schaffer’s actuating members function similarly to close the valves. (*Id.*, ¶105.) Both references disclose actuators that pull the wire/actuating members in opposite directions to constrict the valve’s lumen. (Ex. 1005, [0077], Ex. 1007, 15:21-40, 17:47-18:3.) POSITAs would have recognized that Eller’s wire member would function the same way in Schaffer’s valve. (Ex. 1003, ¶105.) 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, ¶¶105-106.) 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. (*Id.*) 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.b.ii; Ex. 1003, ¶106.) Further, if Schaffer’s seal module required adjustment to function with Eller’s wire, a POSITA would have possessed the knowledge to make the necessary adjustments, as explained in the Hartley ground. (*Id.*)

Thus, Schaffer combined with Eller renders this claim obvious. (Ex. 1003, ¶106.)

4. **Biasing Member**

Schaffer discloses “a biasing member configured to bias the actuator to the first position.” (Ex. 1003, ¶¶107-109.) 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/springs bias Schaffer’s actuators toward the first (i.e., closed) position. (*Id.*, [0077].) Therefore, Schaffer’s resilient members/springs meet this limitation. (Ex. 1003, ¶¶108-109.)

B. Claim 2

Claim 2 recites the “valve of claim 1 wherein the elongate member is pliable.” Schaffer anticipates claim 2 or renders claim 2 obvious alone or combined with Hartley *or* Eller. (Ex. 1003, ¶¶110-111.)

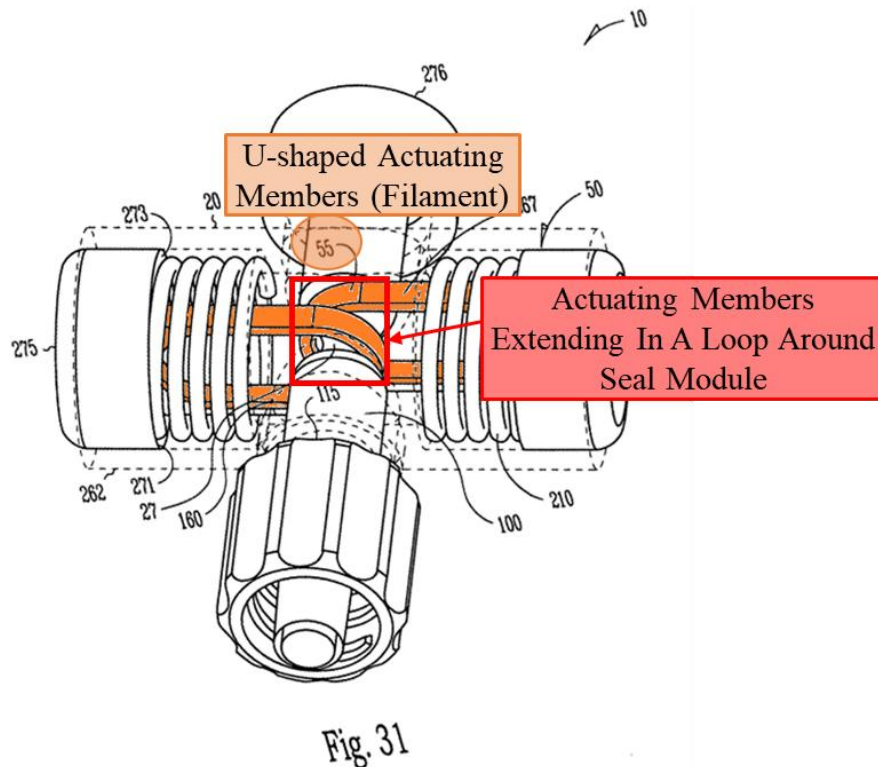
Schaffer’s valve “includes a flexible, elongate tubular structure 101 [i.e., elongate member] having an outer wall 27 which includes a material 166 that is highly elastic, deformable, compliant and yet virtually non-compressible.” (Ex. 1005, [0054].) Thus, Schaffer’s elongate member is pliable. (Ex. 1003, ¶111.)

C. Claim 3

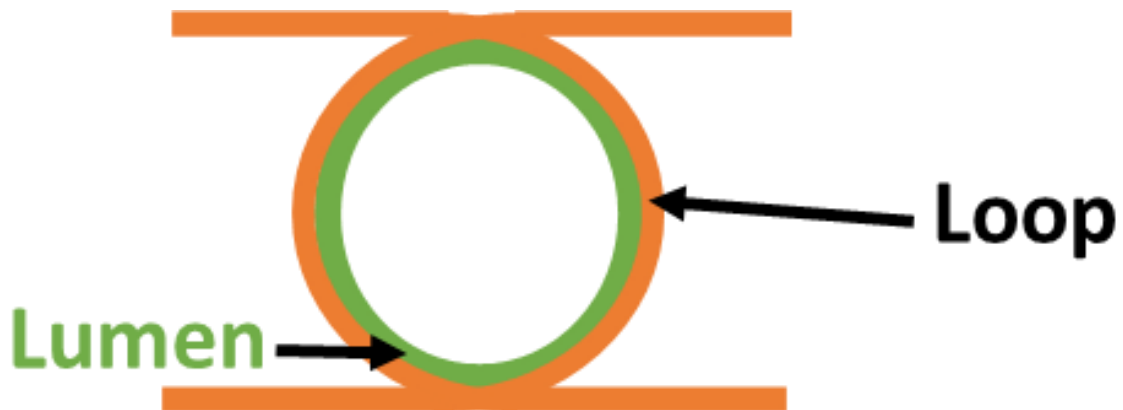
Claim 3 recites the “valve of claim 1 wherein the filament extends in a loop around the elongate member.” Schaffer anticipates claim 3 or renders claim 3 obvious alone or combined with Hartley *or* Eller. (Ex. 1003, ¶¶112-120.)

1. Schaffer

Schaffer’s Figure 31 illustrates that the actuating members collectively form a loop around seal module 100:



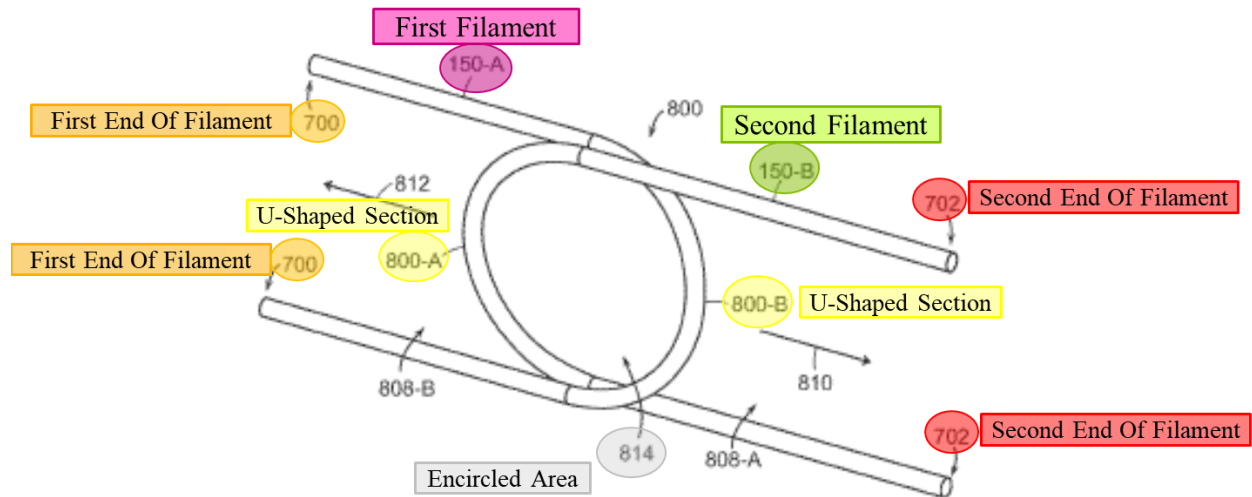
(Ex. 1005, [0076], Fig. 31; Ex. 1003, ¶113.) The demonstrative below further shows the loop formed by the actuating members:



(Ex. 1003, ¶113.)

That Schaffer depicts two actuating members that collectively form a loop around the elongate member is not a basis to distinguish Schaffer. The '921 patent

discloses that the “*the filament 150* can comprise multiple filaments,” including filaments (150-A and 150-B) forming two U-shaped sections:



(Ex. 1001, 12:54-13:65, Fig. 8 (emphasis added).) The '921 patent describes the area formed by the two U-shaped actuating members forming the “filament 150” as an “encircled area 814.” (*Id.*) Accordingly, Schaffer’s U-shaped actuating members also collectively form a “filament” that extends in a loop around the elongate member. (Ex. 1003, ¶114); *see also SanDisk Corp. v. Kingston Tech. Co., Inc.*, 695 F.3d 1348, 1360 (Fed. Cir. 2012) (explaining that “the later use of ‘the’ ... to refer back to an earlier claim term does not limit that claim term to the singular”).

2. Hartley

Schaffer combined with Hartley renders this claim obvious. (Ex. 1003, ¶¶115-117.) Hartley’s string “is wound preferably twice around the cylindrical diaphragm”:

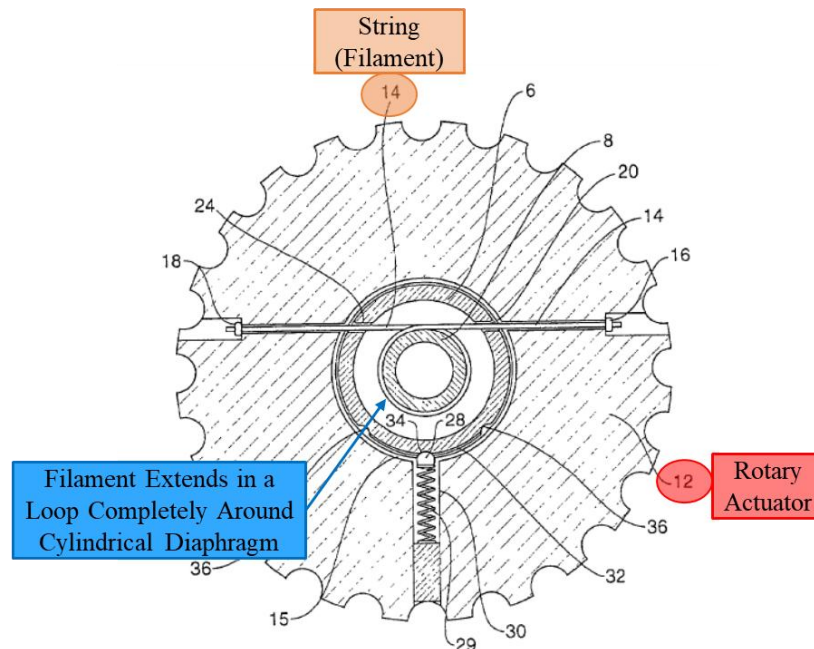


Fig 3

(Ex. 1006, [0031], Fig. 3.) Hartley’s string therefore “extends in a loop around the elongate member.” (*Id.*; Ex. 1003, ¶115.)

Hartley discloses that looping the string around the elongate member forms an effective seal. (Ex. 1006, [0031], [0037].) Thus, when replacing Schaffer’s actuating members with Hartley’s string, POSITAs would have been motivated to loop Hartley’s string around Schaffer’s seal module. (Ex. 1003, ¶116.) POSITAs would have reasonably expected success in using this configuration because the configuration works to form a seal (per Hartley). (*Id.*, ¶¶116-117.)

3. Eller

Schaffer combined with Eller also renders this claim obvious. (Ex. 1003, ¶¶118-120.) Eller explicitly discloses, “the wire member can be positioned such that it extends at least one full revolution around the outer surface of the sleeve”:

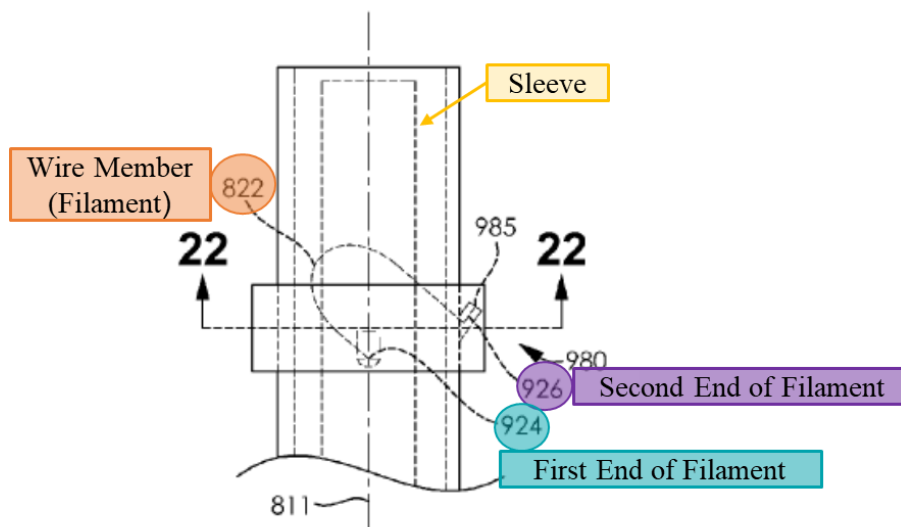


FIG. 21

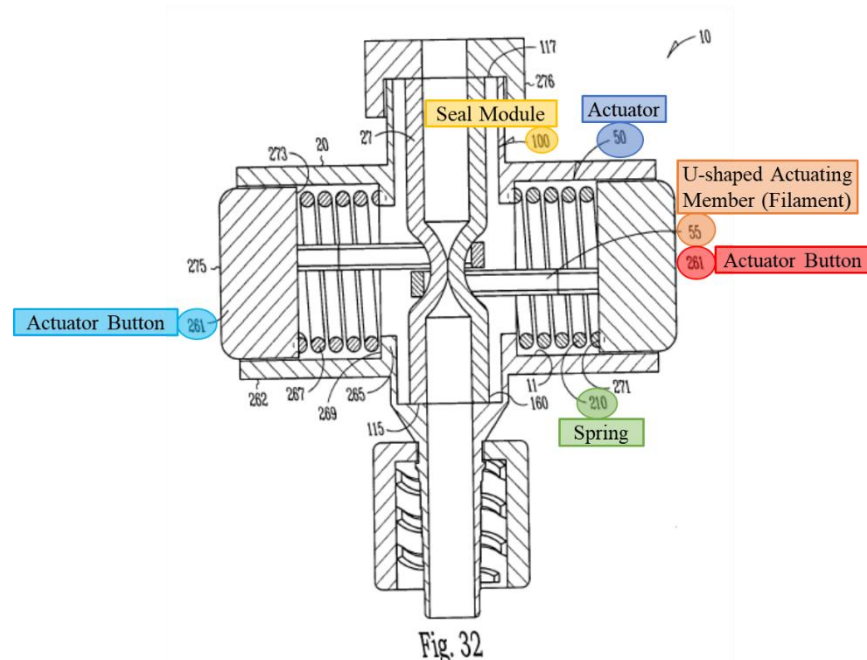
(Ex. 1007, 22:18-24; *see also id.*, 12:52-64, 24:50-57, Fig. 21.)

Thus, the wire member extends in a loop around the elongate member. (Ex. 1003, ¶118.) When replacing Schaffer’s actuating members with Eller’s wire member, POSITAs would have been motivated to loop Eller’s wire at least one revolution around Schaffer’s seal module to ensure the wire formed a constrictive seal. (*Id.*, ¶119.) 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. (*Id.*, ¶¶119-120.)

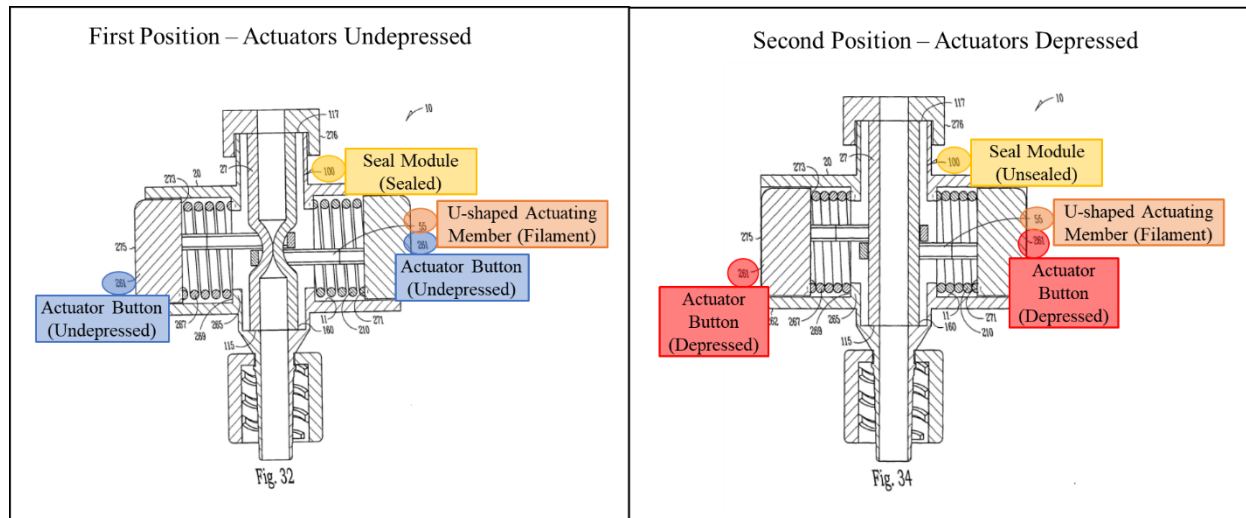
D. Claim 4

Claim 4 recites the “valve of claim 1 wherein the actuator is a button, wherein the button is undepressed in the first position, and wherein the button is depressed in the second position.” Schaffer anticipates claim 4 or renders claim 4 obvious alone or combined with Hartley *or* Eller. (Ex. 1003, ¶¶121-122.)

Schaffer’s valve includes two spring-loaded actuator buttons 261 “movable from a first position to a second position on opposing sides of the housing”:



(Ex. 1005, [0075]-[0076], Figs. 31-32.) Schaffer’s actuator buttons are undepressed when the valve is in the first (closed) position and depressed when the valve is in the second (open) position as illustrated by Figure 32 and 34:



(*Id.*, [0077], Figs. 32, 34; Ex. 1003, ¶122.)

E. Claim 5

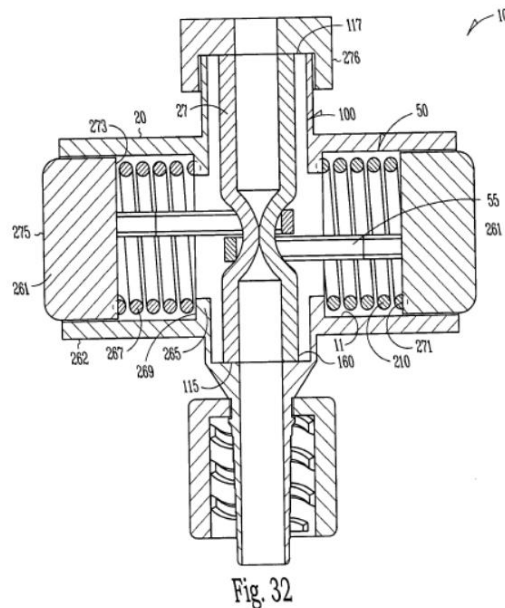
Claim 5 recites the “valve of claim 1 wherein, when the actuator is in the first position, the lumen is configured to remain constricted and sealed when a pressure differential exists between (a) a first volume outside the lumen and adjacent to a first end of the elongate member and (b) a second volume outside the lumen and adjacent to a second end of the elongate member.” Schaffer anticipates claim 5 or renders claim 5 obvious alone or combined with Hartley *or* Eller. (Ex. 1003, ¶¶123-137.)

1. Schaffer

Schaffer’s valve is sealed when the actuator buttons are in the first, undepressed position. (Ex. 1005, [0008]; *Supra* §VI.A.3.a-b.) Schaffer’s valve is “for use with catheters” inserted into the patient’s vasculature. (Ex. 1005, [0002].) When a catheter is inserted into the patient’s vasculature, the pressure within the catheter’s distal end (the portion of catheter in the patient) and adjacent the distal

side of the valve is the blood pressure. (Ex. 1003, ¶¶124-125.) Conversely, the pressure outside the valve’s proximal end is the air pressure, which is less than the blood pressure. (*Id.*) This pressure difference between the blood and air is one reason blood spurts out of wounds. (*Id.*)

Second End Subject to Air Pressure



First End Subject to Blood Pressure

(Ex. 1005, [0075], Fig. 32.)

All hemostasis valves, including Schaffer’s valve, are designed to remain closed against the pressure differential between the blood pressure and the air pressure. (Ex. 1003, ¶124.) If Schaffer’s valve did not remain closed, blood would leak out of the catheter and the valve would not be a “hemostasis” valve (i.e., a valve that stops blood loss). (*Id.*, ¶¶124-127.) Yet, Schaffer’s valve blocks “the flow of gas or fluid” during such medical procedures and, therefore, remains closed when a

pressure differential exists between the two ends of the valve. (*Id.*; Ex. 1005, Abstract, [0008], [0077].)

Moreover, if Schaffer's valve did not remain sealed when a pressure differential exists, POSITAs would have been motivated to make adjustments to the valve to maintain the seal, including adjusting Schaffer's spring strength to apply additional force, adjusting the resilience and compressibility of the seal module that forms the valve's lumen, and/or adjusting the shape, flexibility, and/or dimensions of the actuating members to more closely conform to the shape of the seal module and any tool(s) inserted therethrough. (Ex. 1003, ¶¶128-129; *see also* Ex. 1007, 15:41-60 (identifying different filament materials).) POSITAs would have been motivated to adjust Schaffer's hemostasis valve to prevent blood leaks because that is the valve's purpose. (Ex. 1003, ¶¶128-129.)

POSITAs would have reasonably expected success in adjusting the spring strength to exert more tension on the filament by, for example, changing the spring material or adjusting the springs coils. (*Id.*) Springs are simple, predictable mechanical devices that would have been well understood by POSITAs. (*Id.*) Additionally, POSITAs would have reasonably expected success in selecting an appropriate material for the elongate member in view of the range of suitable materials disclosed in the prior art. (*Id.*) POSITAs would have also reasonably expected success in adjusting the shape or orientation of Schaffer's actuating

members to increase their compliance and improve the seal around the seal module.
(*Id.*)

2. **Hartley**

Hartley's valve is also intended to "permit[] [a] catheter or other instrument to be passed through the access valve and the valve to form a seal against the walls of the catheter or other instrument to prevent loss of blood or other fluid." (Ex. 1006, [0003].) "Depending on how much the flexible member [i.e., string] is pulled radially and/or tangentially the cylindrical diaphragm can be completely constricted to prevent fluid flow through the valve or can be constricted to the extent that it closes around an instrument, for instance a catheter, passed through the valve." (*Id.*, [0006].)

A POSITA would have recognized that Hartley's string constricts and seals the lumen of the hemostasis valve where a pressure differential (blood vs. air) exists across the valve for the same reasons as Schaffer's valve. (*Supra* §VI.E.1; Ex. 1003, ¶¶130-131.) POSITAs would have reasonably expected Hartley's string to constrict and seal Schaffer's seal module when Schaffer's actuator buttons are in the first, undepressed position, even when a pressure differential exists between the proximal and distal ends of the lumen because that is the purpose of the string. (*Id.*)

Moreover, if Schaffer's valve and Hartley's string did not seal the lumen when a pressure differential exists, a POSITA would have found it obvious to make one

or more adjustments to the valve to maintain the seal, as discussed in the Schaffer ground. (*Supra* §VI.E.1; Ex. 1003, ¶132.)

3. Eller

Eller's hemostasis valve prevents fluid flow through the sleeve when the actuator is in the closed position. (Ex. 1007, Abstract, 12:14-17, 15:21-40, 17:47-18:8, Figs. 10A-10C.) Eller discloses tests performed on its valves having different sleeves that show no leaks despite a pressure difference across the valve (*see* highlighted examples):

Material of Sleeve	Empty Sleeve Passageway	0.018"Wire disposed within sleeve passageway	0.035" Wire disposed within sleeve passageway	14 French dilator disposed within sleeve passageway	Rating:
80% - 4755	3 g	5.4 g	50 g	4.9 g	+
20% - 4765					
100% - 4755	14.3 g	2.8 g	25.4 g	11 g	+
90% - 4755	0	0	1.4 g	0	++
10% - 4014					
80% - 4755	0	0	0	0	++++
20% - 4014					
70% - 4755	0	0	0	0	++++
30% - 4014					
60% - 4755	0	0	Trace	0	+++
40% - 4014					

(*Id.*, 36:26-37:27.) Eller's results confirm that Eller's wire member constricts and seals the valve lumen, even when a pressure differential exists between the proximal and distal ends of the lumen. (Ex. 1003, ¶¶133-136.)

POSITAs would have reasonably expected Eller's wire member to behave in the same way to seal Schaffer's seal module when Schaffer's actuator buttons are in

the first, undepressed position, even when a pressure differential exists between the proximal and distal ends of the lumen due to similarities between the sleeve and seal module. (*Id.*; *supra* §VI.E.1.)

Moreover, if Schaffer’s valve and Eller’s wire member did not maintain a seal when a pressure differential exists, a POSITA would have found it obvious to make the valve adjustments described in the Schaffer ground. (*Supra* §VI.E.1; Ex. 1003, ¶137.)

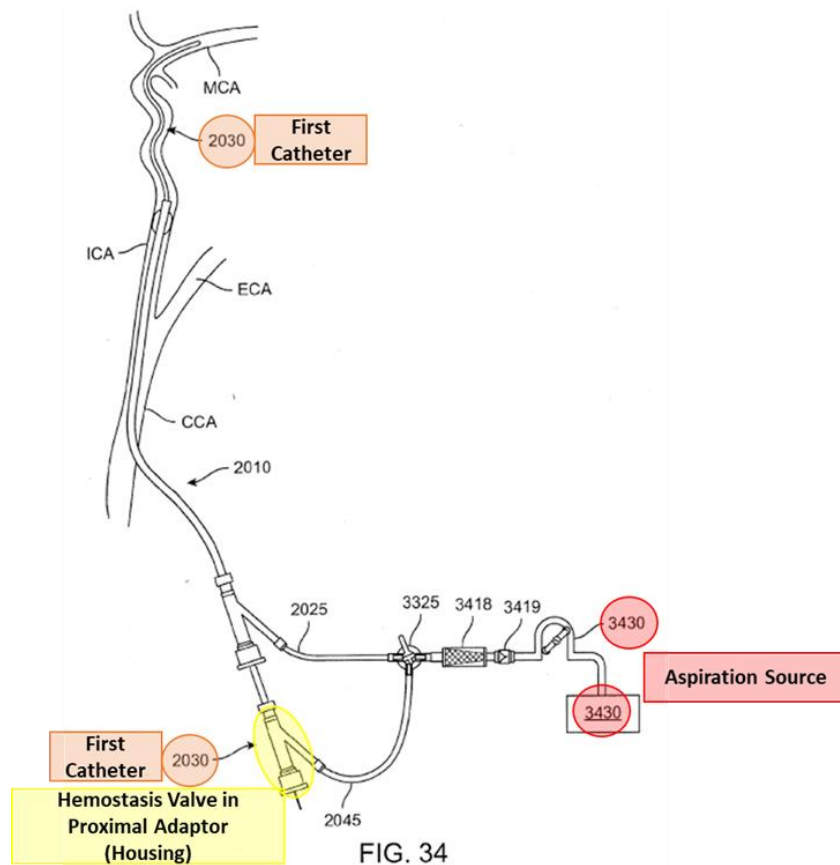
F. Claim 6

Claim 6 recites the “valve of claim 1 wherein, when the actuator is in the first position, the lumen is configured to remain constricted and sealed when vacuum pressure is applied to a volume outside the lumen and adjacent to either a first end or a second end of the elongate member.” Schaffer anticipates claim 6 or renders claim 6 obvious alone or combined with Hartley *or* Eller. (Ex. 1003, ¶¶138-144.)

Schaffer, Hartley, and Eller disclose hemostasis valves that prevent blood leaks during intravascular procedures. Schaffer’s valve is also configured to connect to “a fluid or gas delivery system or device such as a syringe, intravenous system or the like.” (Ex. 1005, [0049].) POSITAs in September 2017 would have understood that syringes were used to generate negative pressure for aspiration. (*See e.g.*, Ex. 1011, [0071] (“The flow line 905 may also be connected to an aspiration source such as a pump or syringe.”); Ex. 1018, 3:9-18 (describing use of syringe to create

vacuum); Ex. 1020, 1:28-45, 4:37-40 (describing prior art uses of syringes to provide suction); Ex. 1003, ¶139.)

Schaffer further discloses that its valve prevents leakage across “a range of instruments,” such as “a catheter, guidewire, needle or fiber.” (Ex. 1005, [0056].) Aspiration catheters were commonly used with hemostasis valves prior to September 2017 to apply vacuum pressure through the catheter. (Ex. 1003, ¶140.) For example, Garrison discloses an aspiration catheter 2030 having a proximal hub 2065 that may include a “separate hemostasis valve ... attached to proximal hub 2065, to allow introduction of devices such as a microcatheter, guide wire, or thrombectomy device while preventing or minimizing blood loss during the procedure. Alternately, the hemostasis valve may be integral to the catheter proximal adaptor”:

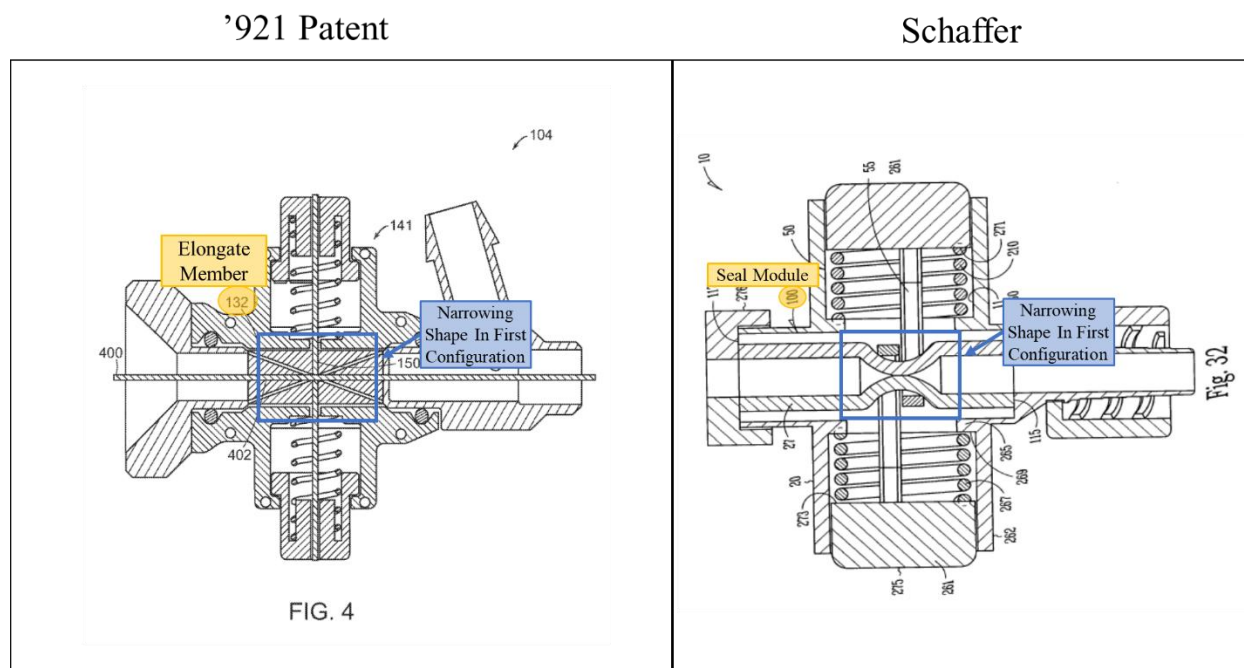


(Ex. 1011, [0098]; *see also id.*, [0130]-[0132], Fig. 34; *see also* Ex. 1018, abstract; Ex. 1020, 2:26-35.)

Given the common practice of using hemostasis valves with vacuum sources in September 2017 (such as Schaffer’s syringe) and Schaffer’s disclosures discussed in claim 5, POSITAs would have understood that, when Schaffer’s actuator buttons remain in the first, undepressed position, the lumen of the elongate member would remain constricted and sealed, even when a vacuum pressure is applied to a volume outside of the valve’s lumen and adjacent to the end of the elongate member. (Ex. 1003, ¶141; Ex. 1005, [0008], [0077]; *supra* §VI.E.) The lumen on Schaffer’s valve

is held in the closed position by the springs/buttons pulling on the actuating members. A POSITA would not have expected the vacuum pressure applied through a catheter inserted into a patient to be strong enough to overwhelm this spring force. (Ex. 1003, ¶¶141-142.) Further, the force from the vacuum pressure would be perpendicular to the actuating members and, therefore, a POSITA would not expect the vacuum to push/force the actuating members apart. (*Id.*)

Moreover, the only disclosure in the '921 patent regarding sealing under vacuum pressure attributes the ability to maintain a seal to the narrowing shape of the valve. (Ex. 1001, 10:50-56.) Schaffer's elongate member (seal module 100) also has a "narrowing shape" when the actuator buttons are in the first position:



(*Id.*, Fig. 4 (left); Ex. 1005, [0077], Fig. 32 (right).) Because Schaffer discloses the same structure that the '921 patent claims to enable sealing under vacuum pressure, PO cannot genuinely argue that Schaffer fails to disclose this limitation.

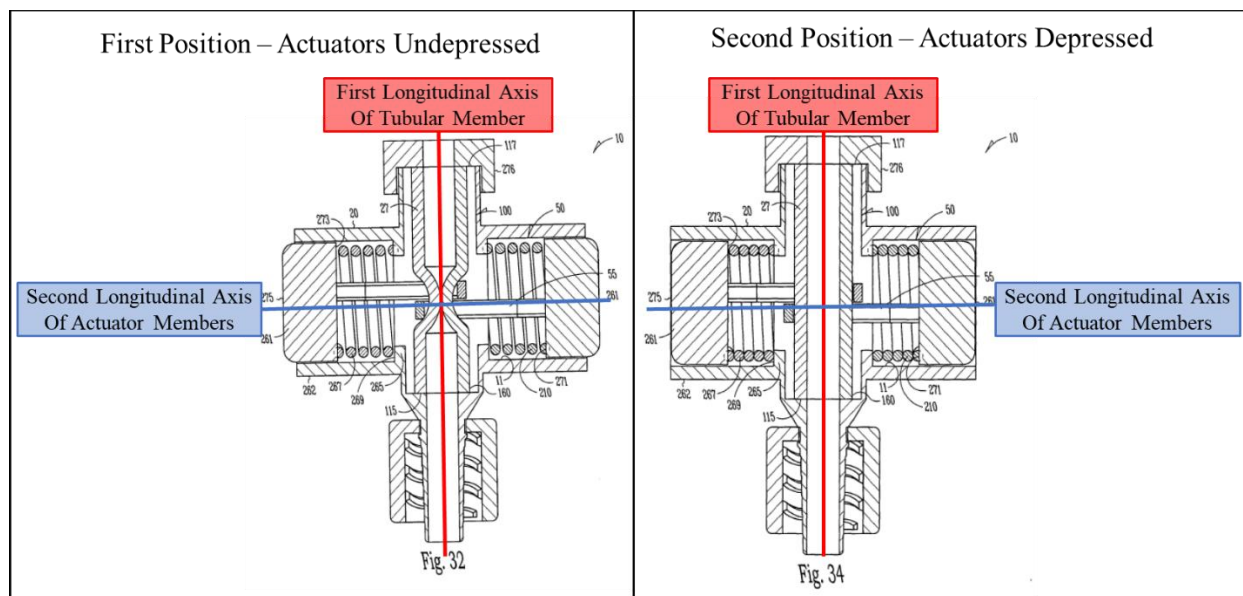
In addition, given the disclosures of Schaffer, Hartley, and Eller discussed for claim 5, a POSITA would have reasonably expected that Hartley's string or Eller's wire member would constrict and seal Schaffer's elongate member when Schaffer's actuator buttons are in the first position, even when a vacuum pressure is applied to a volume outside of the valve's lumen. (Ex. 1003, ¶143; Ex. 1005, [0008], [0077]; Ex. 1006, [0003], [0006]; Ex. 1007, 27:44-50, 36:46-37:3.) Like Schaffer, Hartley's string and Eller's wire member are pulled perpendicularly to the direction of suction. (Ex. 1003, ¶143.) A POSITA would not have expected the vacuum to exert enough force on the string/wire member and springs to open the valve. (*Id.*)

Moreover, if Schaffer's valve would not maintain its seal under vacuum pressure (either alone or with Hartley's or Eller's filament), a POSITA would have found it obvious to make one or more adjustments to the valve to ensure a seal as described in claim 5. (*Supra* §VI.E.1; Ex. 1003, ¶144.) POSITAs would have been motivated to do so because the purpose of Schaffer's valve is to prevent leaks when a catheter is inserted into a patient, including aspiration catheters. (*Id.*) POSITAs would have reasonably expected success in making these adjustments for the reasons explained in claim 5. (*Id.*)

G. Claim 7

Claim 7 recites the “valve of claim 1 wherein the lumen extends a long [sic] a first longitudinal axis, wherein the actuator is movable between the first and second positions along a second longitudinal axis, and wherein the first longitudinal axis is orthogonal to the second longitudinal axis.” Schaffer anticipates claim 7 or renders claim 7 obvious alone or combined with Hartley *or* Eller. (Ex. 1003, ¶¶145-146.)

Schaffer’s actuator buttons are movable between a first and second position along a longitudinal axis that is orthogonal to the longitudinal axis of the tubular member:



(Ex. 1005, [0077], Figs. 31-34.)

H. Claim 9

Claim 9 recites the “valve of claim 1 wherein, in the first position, the actuator pulls the filament to circumferentially constrict the elongate member such that the

lumen is constricted and sealed.” Schaffer anticipates claim 9 or renders claim 9 obvious, alone or combined with Hartley *or* Eller. (Ex. 1003, ¶¶147-148.)

When Schaffer’s actuator buttons are in the first, undepressed position, the springs coupled to Schaffer’s actuator buttons pull the U-shaped actuating members to circumferentially constrict the seal module 100. (Ex. 1005, [0076]-[0077]; Ex. 1003, ¶148.) The ’921 patent teaches that two u-shaped members may be a “filament” that defines an “encircled area” or “constricting area.” (Ex. 1001, 13:50-54.) Thus, Schaffer’s two U-shaped actuating members also circumferentially constrict the elongate member by encircling the elongate member. (Ex. 1003, ¶148.) If Schaffer’s U-shaped actuating members were replaced with Hartley’s string or Eller’s wire member, Schaffer’s actuator buttons would similarly pull the string/wire member to circumferentially constrict the seal module 100. (*Id.*)

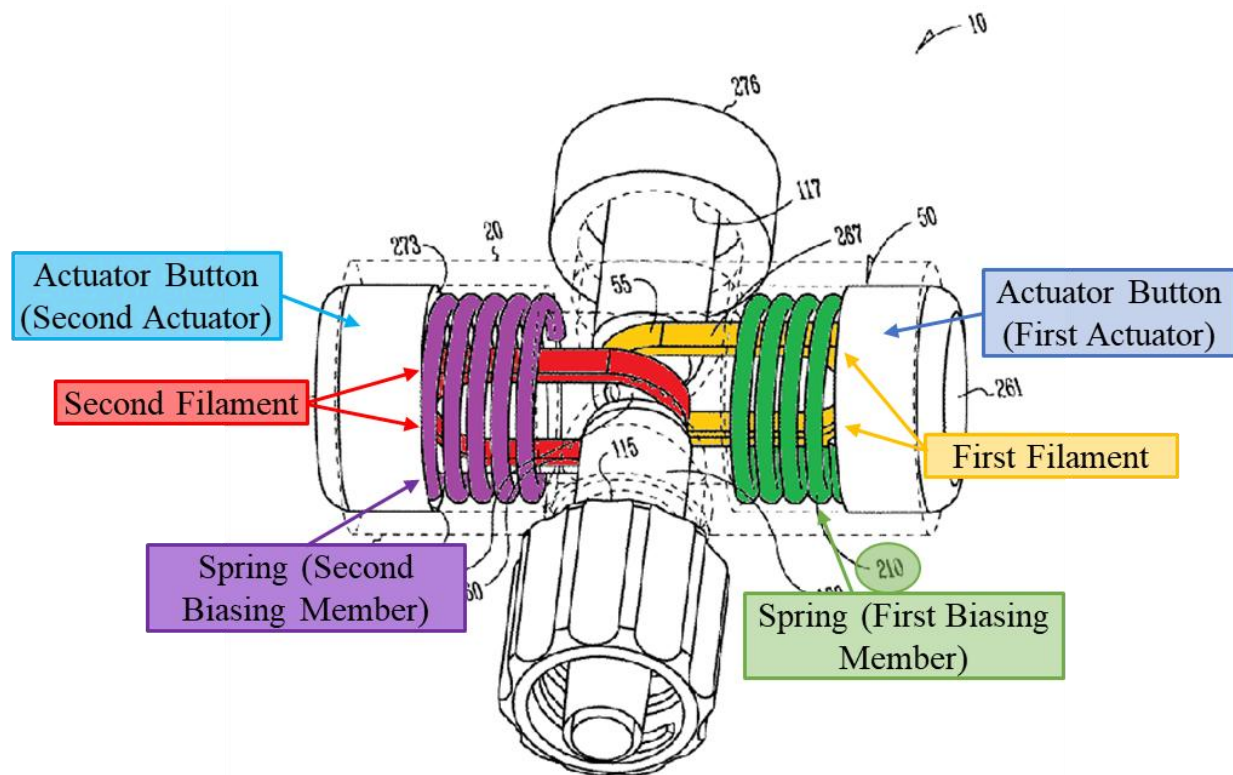
I. Claim 10

Claim 10 recites the “valve of claim 1 wherein the actuator is a first actuator, wherein the filament is a first filament, wherein the biasing member is a first biasing member, and wherein the active tensioning mechanism further comprises: a second actuator coupled to the elongate member via a second filament extending at least partially around the elongate member, wherein the second actuator is moveable between (a) a first position wherein the lumen is constricted and sealed and (b) a second position wherein the lumen is at least partially open; and a second biasing

member configured to bias the second actuator to the first position.” Schaffer anticipates claim 10 or renders claim 10 obvious, alone or combined with Hartley *or* Eller. (Ex. 1003, ¶149-159.)

1. Schaffer

Schaffer discloses a first actuator (i.e., button), a first filament, and a first biasing member (i.e., spring) as explained in claim 1. (*Supra* §VI.A.) Schaffer’s valve further includes a second actuator (i.e., second button), second filament, and second biasing member positioned on the opposite side of the elongate member:



(Ex. 1005, [0075]-[0077], Fig. 31.) Each of Schaffer’s actuating members (i.e., filament) extends partially around the elongate member. (*Id.*; Ex. 1003, ¶150.)

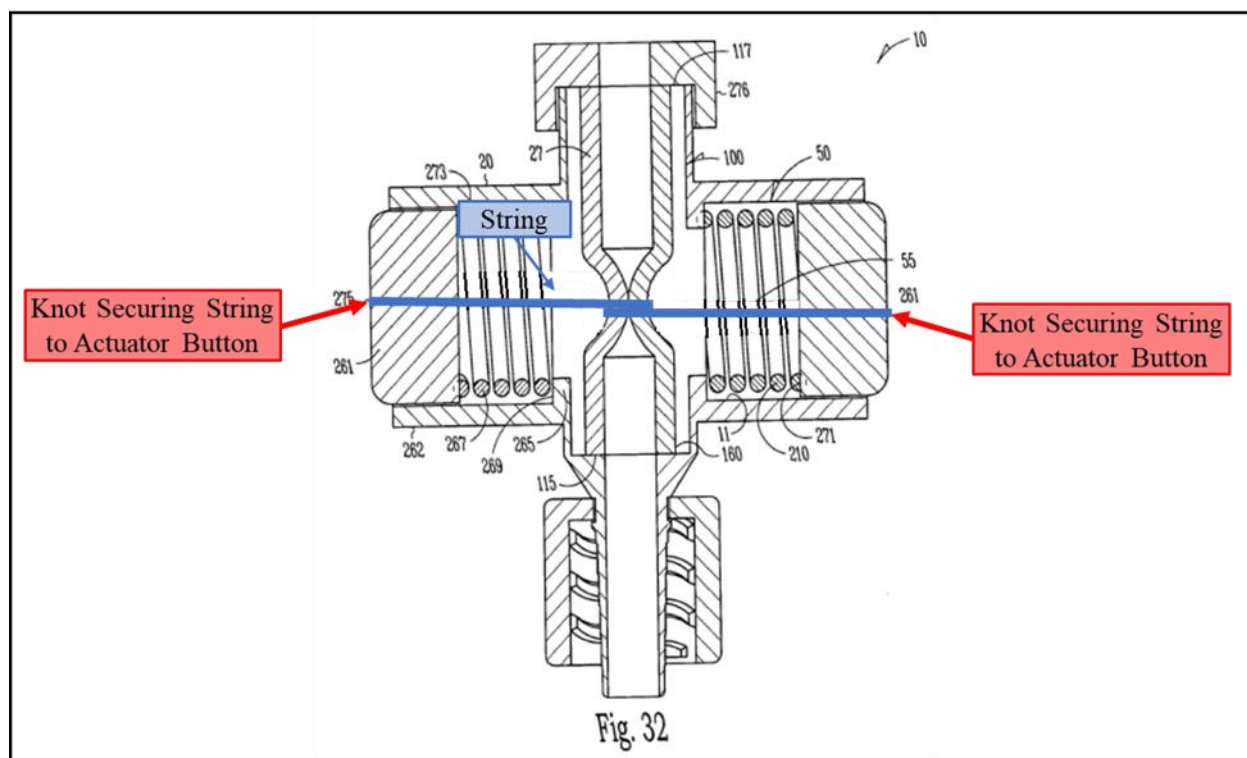
Schaffer's second actuator is coupled to the elongate member via the second filament in the same way that the first actuator is coupled to the elongate member via the first filament. (*Supra* §VI.A.3.) Similarly, Schaffer's second actuator is "moveable between (a) a first position wherein the lumen is constricted and sealed and (b) a second position wherein the lumen is at least partially open" in the same way as the first actuator. (*Supra* §VI.A.2.) Schaffer's second biasing member (i.e., second spring) biases the second actuator toward the first position in the same way as the first biasing member described in claim 1. (*Supra* §VI.A.4.)

2. **Hartley**

Schaffer combined with Hartley renders this claim obvious in two ways. **First**, Hartley discloses a string 14 mounted to the rotary actuator. (Ex. 1006, [0031].) POSITAs would have understood that strings typically include several threads twisted together. (See Ex. 1014 (definition of string: "material consisting of threads of cotton, hemp, or other material twisted together to form a thin length"); Ex. 1015; Ex. 1007, 15:61-16:6 (wire member "can have any suitable structure and comprise any suitable number of strands and/or fibers that are twisted").) Consequently, POSITAs would have recognized that Hartley's string 14 encompasses strings having two or more threads, lines, or cords twisted together and therefore includes at least a first and second filament. (Ex. 1003, ¶152.)

If a POSITA substituted Hartley's string for Schaffer's U-shaped actuating members, the two or more threads, lines or cords making up the string would begin at the first actuator button, wrap around the elongate member at least once, and end at the second actuator button:

Demonstrative Illustration Schaffer + Hartley's String



(*Supra* §VI.A.3.b.ii; Ex. 1003, ¶153.) The string, comprised of at least first and second filaments, would also tighten to collapse and seal the elongate member in a first position and relax to unseal the elongate member in a second position. (*Id.*)

POSITAs would have been motivated to substitute Hartley's string for Schaffer's actuating members, and expected success in doing so, for the reasons explained in claim 1. (*Supra* §VI.A.3.b.ii; Ex. 1003, ¶153.)

Second, rather than replace Schaffer's U-shaped actuating members with a single string extending from the first actuator to the second actuator, POSITAs would have also found it obvious to replace each U-shaped actuating member with a string. (Ex. 1003, ¶154.) Hartley shows that the string has sufficient strength to constrict a tube extending through a hemostasis valve, which is the very function of Schaffer's U-shaped actuating members. (Ex. 1006, *abstract*.) POSITAs would have been motivated to substitute Hartley's string for the actuating members, and reasonably expected success in doing so, because the string can constrict a tube and conform to tools having various sizes and shapes. POSITAs also would have been motivated to try a string, and expected success in doing so, because strings are readily available, predictable, and inexpensive options for use in a valve. (Ex. 1003, ¶154.)

Further, in September 2017, a finite number of predictable materials existed for use as actuating members. (*Id.*, ¶155.) Schaffer discloses two such options, plastic or aluminum members. (Ex. 1005, [0081].) Hartley discloses additional options, a string, suture, or band. (Ex. 1006, [0017].) Eller discloses another option, wire members. (Ex. 1007, *abstract*.) A POSITA would have found it obvious to try

any of these materials in Schaffer's valve because the materials are commonly used in medical devices, simple, and predictable. (Ex. 1003, ¶155.) In fact, Eller confirms that POSITAs possessed the necessary skill and knowledge to use different materials and configurations to constrict a tube in a valve. (Ex. 1007, 15:61-16:6.) Further, the replacement of Schaffer's actuating members with string would merely entail substitution of one known element (Hartley's string) for another (plastic or aluminum members) to yield the predictable results of sealing Schaffer's valve. *KSR*, 550 U.S. at 416.

For each of these reasons, Schaffer combined with Hartley renders this claim obvious. (Ex. 1003, ¶155.)

3. Eller

Eller discloses embodiments having a first wire member, a second wire member, and a third wire member. (Ex. 1007, 5:1-6.) Eller further explains that its valve “can include any suitable number of wire members” and 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.*, 16:7-15.) Eller discloses that “[e]xample number of wire members considered suitable to include in a selective fluid barrier valve device include ... two” wire members. (*Id.*, 16:15-19.)

As in the Hartley ground, POSITAs would have found it obvious to use a wire member made from multiple filaments twisted together (i.e., strands or fibers) that extends from the first actuator button, around the elongate member, and to the second actuator button. (Ex. 1003, ¶157.) Eller expressly explains that each wire member can include two or more strands or fibers. (Ex. 1007, 15:61-16:6.) Alternatively, POSITAs would have found it obvious to replace each of Schaffer's U-shaped actuating members with a wire member. (Ex. 1003, ¶158.) POSITAs would have been motivated to use Eller's wire members in either configuration, and reasonably expected success in doing so, based on the teachings in Eller that broadly describe many configurations for the wires. Eller also confirms the wires perform the same constricting function as Schaffer's actuating members. Further, the wire members are readily available to engineers, predictable, and inexpensive options to incorporate into the valve. (*Id.*; Ex. 1007, 15:61-16:19.)

Also, as discussed above, POSITAs had a finite number of predictable options to use for constricting the lumen of an elongate member in a valve in September 2017. (*Supra* §VI.I.2; Ex. 1003, ¶158.); *KSR*, 550 U.S. at 421. Further, the replacement of Schaffer's actuating members with wire members would merely entail substituting one known element (Eller's wire members) for another (plastic or aluminum members) to yield the predictable result of sealing Schaffer's valve. *KSR*, 550 U.S. at 416.

J. Claim 15

Claim 15 recites a “valve, comprising: an elongate member defining a lumen; a filament coupled to the elongate member; an actuator coupled to the filament, wherein the actuator is moveable between (a) a first position wherein the lumen is constricted and sealed and (b) a second position wherein the lumen is at least partially open; and a biasing member configured to bias the actuator to the first position.” Claim 15 largely repeats claim 1. But claim 15 requires a filament “coupled to the elongate member” and “coupled to” the actuator, whereas claim 1 requires an actuator “coupled to the elongate member via a filament.” Claim 15 also lacks the “active tensioning mechanism” limitation from claim 1.

Schaffer’s U-shaped actuating members (filaments) are coupled to the elongate member and the actuators, as shown for example in Figures 31-34, for the reasons explained in claim 1. (*Supra* §VI.A.3.) If Schaffer’s actuating members were replaced with Hartley’s string or Eller’s wire member, the string/wire would also be coupled to the elongate member and actuators. (*Id.*) Schaffer, Hartley, and Eller disclose the remaining limitations of claim 15 for the reasons provided in claim 1. (*Supra* §VI.A.) Schaffer therefore anticipates claim 15 or renders it obvious, alone or combined with Hartley **or** Eller. (Ex. 1003, ¶¶160-162.)

K. Claim 16

Claim 16 recites the “valve of claim 15 wherein the filament extends at least partially around the elongate member.” This limitation also appeared in claim 1. Consequently, Schaffer anticipates claim 16 or renders it obvious, alone or combined with Hartley *or* Eller as explained in claim 1. (*Supra* §VI.A.3.b.; Ex. 1003, ¶163.)

L. Claim 17

Claim 17 recites the “valve of claim 16 wherein, in the first position, the actuator pulls the filament to circumferentially constrict the elongate member such that the lumen is constricted and sealed.” This limitation also appeared in claim 9. Consequently, Schaffer anticipates claim 17 or renders it obvious, alone or combined with Hartley *or* Eller as explained in claim 9. (*Supra* §VI.H.; Ex. 1003, ¶164.)

M. Claim 18

Claim 18 recites the “valve of claim 15 wherein the elongate member is pliable.” This limitation also appeared in claim 2. Consequently, Schaffer anticipates claim 18 or renders it obvious, alone or combined with Hartley *or* Eller as explained in claim 2. (*Supra* §VI.B.; Ex. 1003, ¶165.)

N. Claim 20

Claim 20 recites the “valve of claim 15 wherein the actuator is a button that is undepressed in the first position and depressed in the second position, wherein the button is movable between the first and second positions along a first longitudinal

axis, and wherein the first longitudinal axis is orthogonal to the second longitudinal axis.” These limitations also appeared in claims 4 and 7. Consequently, Schaffer anticipates claim 20 or renders it obvious, alone or combined with Hartley *or* Eller as explained in those claims. (*Supra* §§VI.D, VI.G.; Ex. 1003, ¶166.)

O. Claim 21

Claim 21 recites a “valve, comprising: an elongate member defining a lumen; a filament coupled to the elongate member; and an actuator coupled to the elongate member, wherein the actuator is moveable between (a) a first position in which the actuator pulls the filament to collapse the elongate member such that the lumen is constricted and sealed and (b) a second position wherein the lumen is at least partially open; a biasing member configured to bias the actuator to the first position.” Thus, claim 21 is similar to claim 15, except that claim 21 recites that the actuator is “coupled to the elongate member” and that the “actuator pulls the filament.”

Schaffer’s actuators are coupled to the elongate member via the filament as explained in claim 1. (*Supra* §VI.A.3.) Schaffer’s actuator also pulls the filament as described in claim 9. (*Supra* §VI.H.) Schaffer discloses the remaining limitations of claim 21 or renders them obvious, both alone and combined with Hartley *or* Eller, for the reasons provided in claim 1. (*Supra* §VI.A.) Schaffer therefore anticipates claim 21 or renders it obvious, alone or combined with Hartley *or* Eller. (Ex. 1003, ¶¶167-168.)

P. Claim 22

Claim 22 recites the “valve of claim 21 wherein the elongate member is pliable, and wherein the filament extends at least partially around the elongate member.” These limitations also appear in claims 1-2. Consequently, Schaffer anticipates claim 22 or renders it obvious, alone or combined with Hartley *or* Eller as explained in those claims. (*Supra* §§VI.A-VI.B.; Ex. 1003, ¶169.)

Q. Claim 23

Claim 23 recites the “valve of claim 21 wherein the elongate member is pliable, and wherein the filament is looped around the elongate member.” These limitations also appear in claims 2-3. Consequently, Schaffer anticipates claim 23 or renders it obvious, alone or in view of Hartley *or* Eller as explained in those claims. (*Supra* §§VI.B-VI.C.; Ex. 1003, ¶170.)

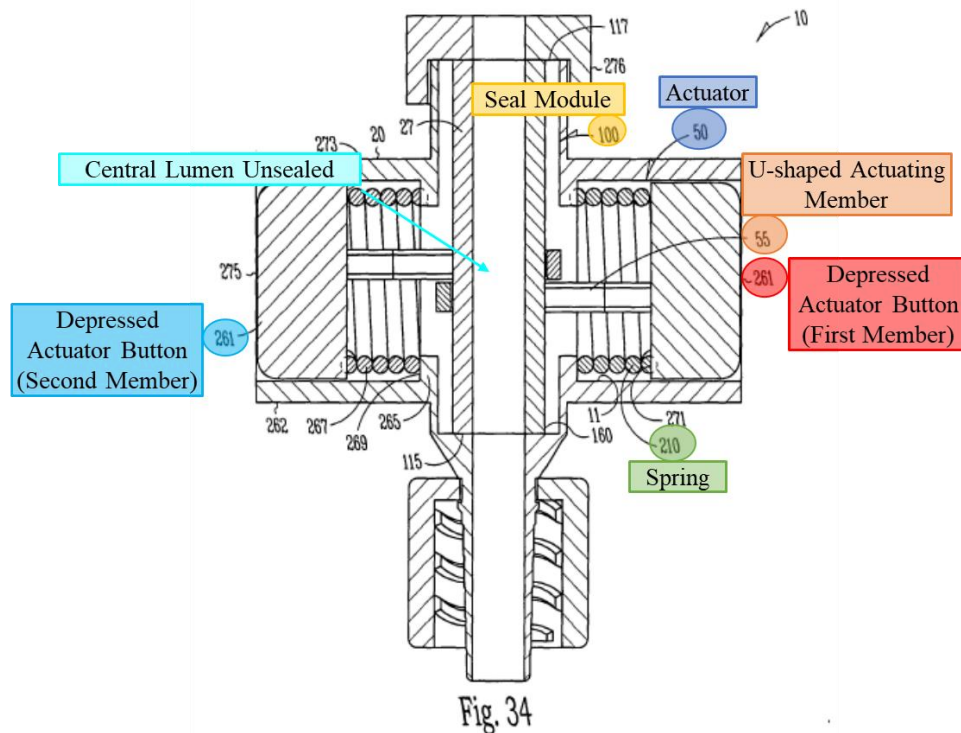
R. Claim 24

Claim 24 recites the “valve of claim 21 wherein the actuator does not substantially pull the filament in the second position such that the elongate member can expand.” Schaffer discloses this limitation and therefore anticipates claim 24 or renders it obvious, alone or combined with Hartley *or* Eller. (Ex. 1003, ¶¶171-173.)

Schaffer discloses that in a second position, shown in Figure 34 below, the actuator buttons are pressed inwardly, 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 gasses and fluids can pass therethrough”:

Second Position – Actuator Buttons Depressed



(Ex. 1005, [0077], Fig. 34). Accordingly, Schaffer’s actuators do not substantially pull the filament when in the second position, allowing the elongate member to expand to an uncollapsed configuration. (Ex. 1003, ¶¶172-173.)

If Schaffer’s actuating members were replaced with Hartley’s string or Eller’s wire members, pushing the buttons would similarly cause the string/wire member to disengage the elongate member to permit the elongate member to assume its uncollapsed configuration. (*Id.*; *supra* §VI.A.)

**VII. GROUNDS 5-7: CLAIMS 1-3, 5-6, 9, 15-18, AND 21-24 OBVIOUS
OVER HARTLEY IN COMBINATION WITH ELLER**

During prosecution of the '921 patent, the examiner found that Hartley discloses every limitation of claim 1 (and others) except “a biasing member configured to bias the actuator to the first position.” (Ex. 1002, 25.) The examiner overlooked, however, that such biasing members were well known in the prior art and would have been obvious to combine with Hartley in September 2017. (Ex. 1003, ¶¶174-175.)

For example, Eller discloses a biasing member for a hemostasis valve in the form of a torsion spring placed between the valve’s housing and rotating actuator such that “when no outside forces are applied to the ... valve device, the spring positions the actuator” in the closed position. (Ex. 1007, 19:22-30.) As explained below, a POSITA would have recognized that Eller’s torsion spring would be well-suited for use with Hartley’s rotational actuator, and a POSITA would have found it obvious to combine Eller’s biasing member with Hartley’s valve. (Ex. 1003, ¶175.) Therefore, Hartley combined with Eller renders obvious claims 1-3, 5-6, 9, 15-18, and 21-24. (*Id.*)

A. Claim 1

Hartley combined with Eller renders claim 1 obvious. (Ex. 1003, ¶¶176-193.)

1. Preamble

If the preamble is limiting, Hartley and Eller disclose a “valve” for the reasons explained in Grounds 1-4. (*Supra* §VI.A.1.)

2. Elongate Member

Hartley discloses “an elongate member defining a lumen.” (Ex. 1003, ¶¶178-179.) The examiner correctly found that Hartley discloses this limitation during prosecution. (Ex. 1002, 25.)

Hartley discloses an “access valve which can be controlled to vary the size of the aperture through the valve and be flexible so that a seal may be formed against an instrument or other object inserted through the access valve.” (Ex. 1006, [0004].) Hartley’s valve includes a “cylindrical housing 6 into which is received a cylindrical elastomeric diaphragm 8 ... [that] defines a cylindrical aperture 3 therethrough”:

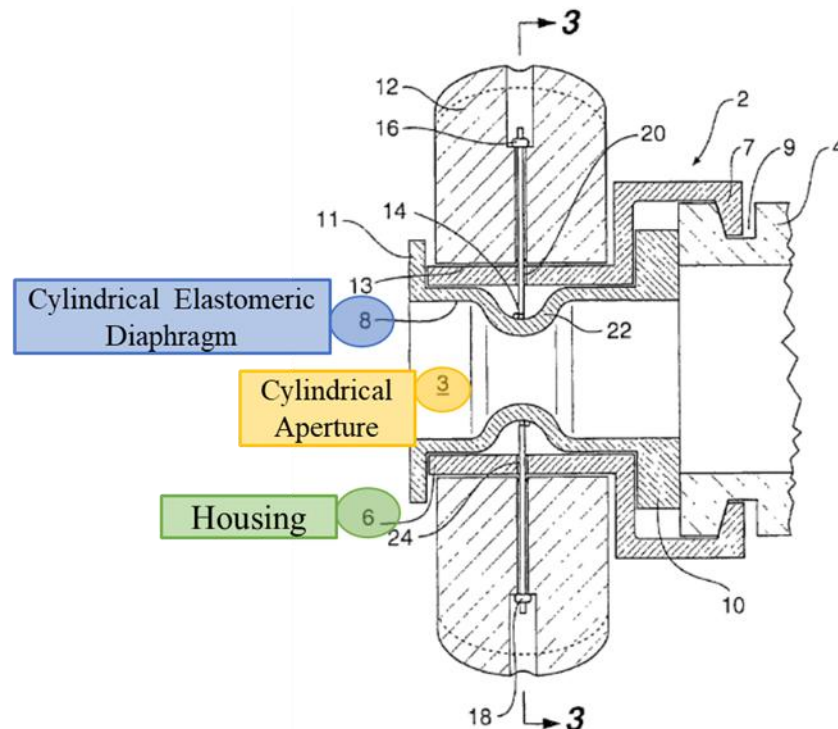


Fig 1

(*Id.*, [0031], Fig. 1.) Hartley’s “cylindrical diaphragm can be completely constricted to prevent fluid flow through the valve or can be constricted to the extent that it closes around an instrument, for instance a catheter, passed through the valve.” (*Id.*, [0006].) Accordingly, Hartley’s elastomeric diaphragm is “an elongate member defining a lumen.” (Ex. 1003, ¶179.)

3. Tensioning Mechanism

Hartley discloses the active tensioning mechanism recited in claim 1. (Ex. 1003, ¶¶180-184.) The examiner correctly found that Hartley discloses this limitation during prosecution. (Ex. 1002, 25.)

a. Actuator

Hartley's valve includes a cylindrical housing that holds a “cylindrical elastomeric diaphragm,” and a rotatory actuator mounted onto the housing:

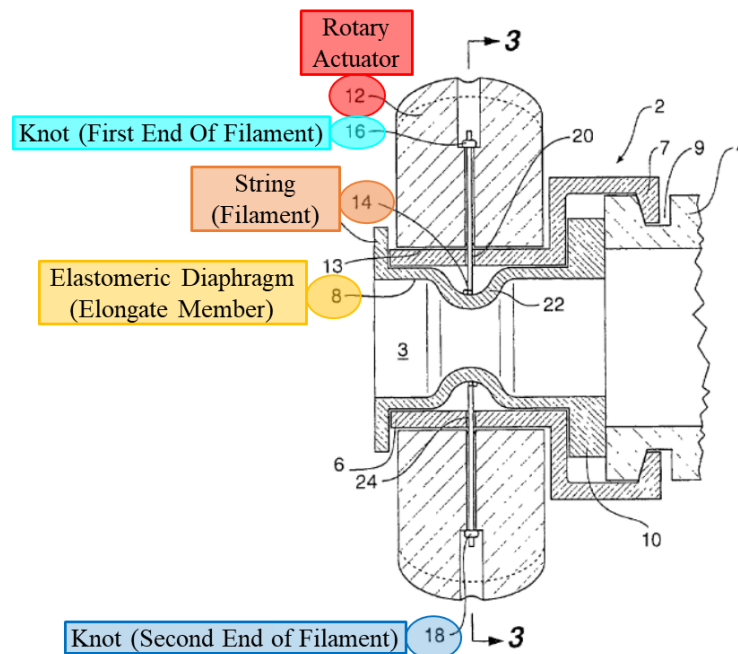


Fig 1

(Ex. 1006, [0031], Fig. 1.)

As discussed below, Hartley's actuator is coupled to the cylindrical diaphragm (elongate member) via the string 14 (i.e., filament). (*Infra* §VII.A.3.b.) Hartley's actuator is “moveable between (a) a first position wherein the lumen is constricted and sealed and (b) a second position wherein the lumen is at least partially open.” (Ex. 1003, ¶182.) 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 “[r]otation of the rotary actuator back to the central position where the detent ball 28 is received in depression 34 will cause the sutures to loosen again so that the resilient cylindrical diaphragm will retain its original shape as shown in FIGS. 1 and 3.” (*Id.*, [0034].) Thus, Hartley discloses the actuator required by claim 1. (Ex. 1003, ¶182.)

b. Filament

Hartley’s valve includes a “string 14 ... mounted into the rotary actuator.” (Ex. 1006, [0031].) Hartley’s string 14 is a filament. (Ex. 1003, ¶183; *supra* §VI.A.3.b.ii.)

As illustrated in Figure 3, Hartley’s string is secured to the rotary actuator at a first end via a knot 16, is wound preferably twice around the cylindrical diaphragm 8, before being fixed by knot 18 again to the rotary actuator:

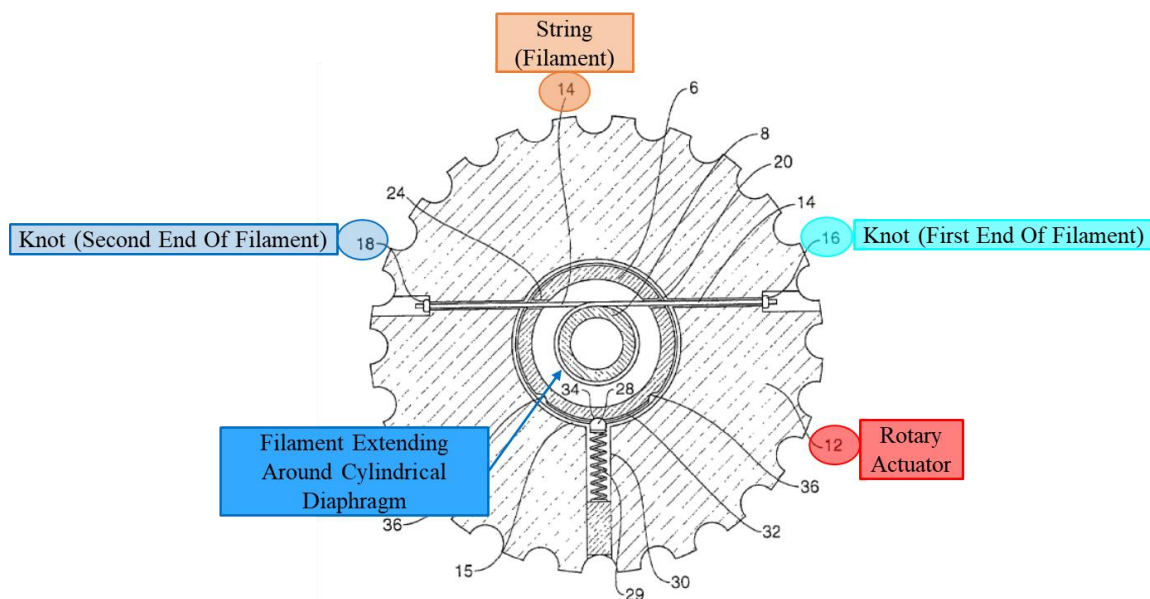


Fig 3

(Ex. 1006, [0031], Fig. 3.) Hartley’s string therefore extends at least partially around the elongate member, and Hartley’s actuator is “coupled” to the elongate member via the string. (*Id.*; Ex. 1003, ¶184.) Thus, Hartley discloses the filament required by claim 1.

4. Biasing Member

Hartley in combination with Eller renders the biasing member recited in claim 1 obvious. (Ex. 1003, ¶¶185-193.)

Eller discloses valves that include “a housing 16, an actuator 18, a sleeve 20, [and] a first wire member 22”:

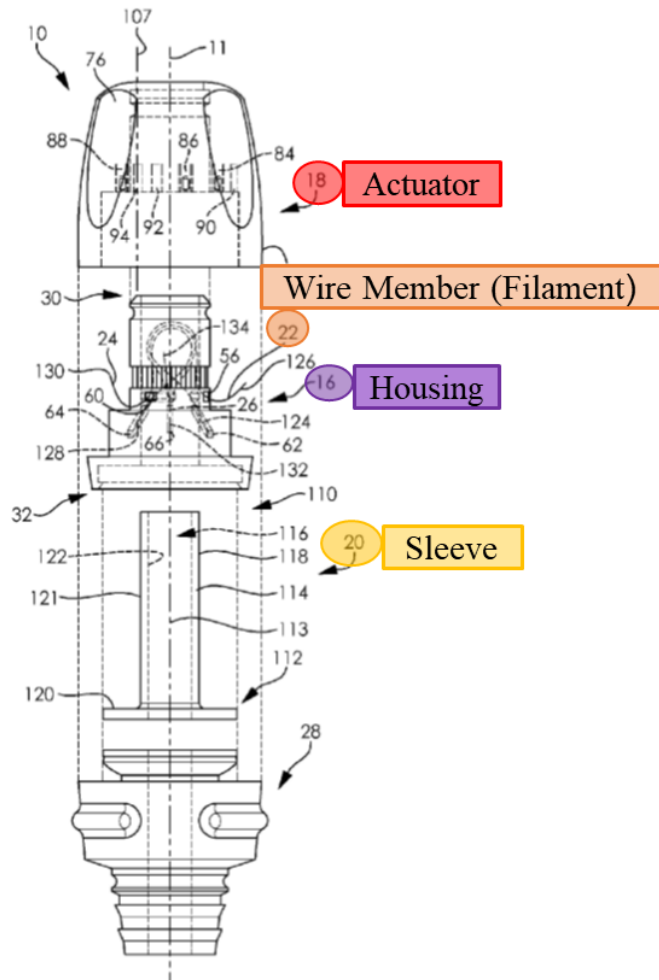


FIG. 2

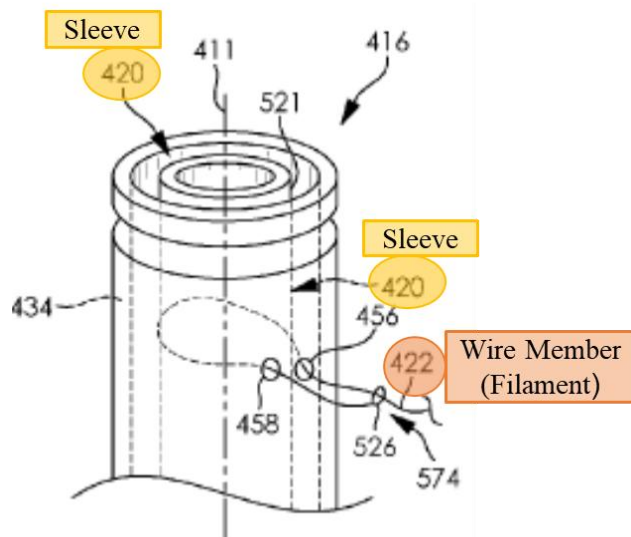


FIG. 16

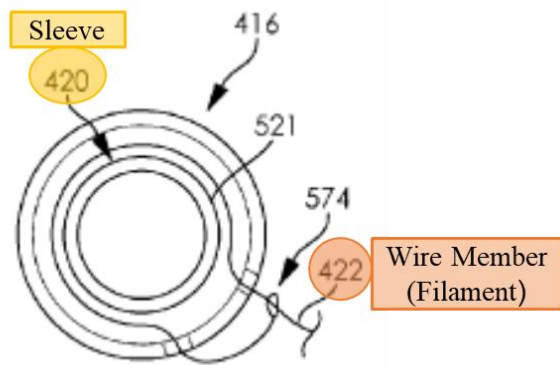


FIG. 17

(Ex. 1007, 5:1-5, Figs. 2, 16-17.) Eller’s fluid barrier valve has two configurations. “In the first configuration, the passageway 116 defined by the sleeve 20 is open such that fluid can pass through the passageway. In the second configuration, the passageway 116 defined by the sleeve 20 is closed such that fluid is prevented from passing through the passageway 116.” (*Id.*, 12:13-18.) Eller further discloses that the valve “can be biased to the second configuration” using, for example, “a torsion spring ... positioned between the housing and the actuator.” (*Id.*, 19:22-30 (emphasis added).) Eller therefore discloses a biasing member configured to bias an actuator to a position wherein the lumen of a hemostasis valve is sealed. (Ex. 1003, ¶186.)

POSITAs would have been motivated to combine Eller’s torsion spring with Hartley’s fluid control valve for several reasons. (*Id.*, ¶¶187-193.) First, the biasing member ensures that Hartley’s valve seals quickly when a device is removed through the valve, which minimizes blood loss. (*Id.*, ¶187.) Further, the biasing system ensures that the physician cannot inadvertently leave the valve open after removing a device, which could lead to unwanted blood loss. (*Id.*)

Second, the biasing member simplifies Hartley’s valve by reducing the steps required to seal the valve. (*Id.*, ¶188.) For example, the biasing member eliminates the need for the operator to manually seal the valve prior to or during the procedure.

(*Id.*) Eliminating this step can make the procedure easier for the physician and save time. (*Id.*)

Third, adding the biasing member to Hartley's valve would merely entail the combination of known elements (Hartley's valve and Eller's torsion spring) according to known methods (positioning a torsion spring between the valve housing and actuator) to yield the predictable result of reducing leakage of fluid through the valve. *See KSR*, 550 U.S. at 416; (Ex. 1003, ¶189.)

POSITAs would have had a reasonable expectation of success in combining Eller's torsion spring with Hartley's valve because Hartley and Eller are from the same field of endeavor and share the same objective of providing a fluid control valve suitable to seal around tools inserted through the valve during intravascular procedures. (Ex. 1006, [0004]; Ex. 1007, Abstract, 12:15-18, 15:21-40, 17:47-18:8; Ex. 1003, ¶¶190-192.) Additionally, the valves in Hartley and Eller share many common features, including: a housing, a rotational actuator mounted to the housing, a tubular sleeve/diaphragm extending through the actuator, and a constricting string/wire extending circumferentially around the sleeve/diaphragm. (*See, e.g.*, Ex. 1006, [0031], Figs. 1-3; Ex. 1007, 5:1-12, Figs. 1-10; Ex. 1003, ¶191.) Eller also explains that the torsion spring of the biasing system "can be positioned between the housing and the actuator and can be attached to the housing and the actuator such that when no outside forces are applied to the selective fluid barrier valve device,

the spring positions the actuator in the second position.” (Ex. 1007, 19:26-30.) The positioning of a torsion spring between two components that rotate with respect to each other was conventional in September 2017 and would have been well within the skill and understanding of a POSITA. (Ex. 1003, ¶192.) Consequently, POSITAs would have reasonably expected that a similar arrangement could be successfully used to attach a torsion spring to Hartley’s housing and rotary actuator to bias the actuator toward the closed position. (*Id.*)

In the ’011 patent IPR, PO argued that POSITAs would not have been motivated to combine Eller’s torsion spring with Hartley’s valve because “that modification would eliminate the object of Hartley’s invention.” *Imperative Care v. Inari Medical, Inc.*, IPR2024-01157, Paper 5 at 48-49 (Oct. 29, 2024). PO argued that Hartley satisfied its objective (i.e., sealing around instruments) through a “detent arrangement.” *Id.* However, Hartley is not that narrow. (Ex. 1003, ¶193.) Hartley’s detent mechanism (*see e.g.*, Fig. 3-4) would offer benefits even with a torsion spring because it would provide “tactical feedback” as the user opens the valve. (Ex. 1003, ¶193.) Thus, PO’s argument that a torsion spring is “not compatible with Hartley’s detent system and would render the system inoperable” is incorrect. (*Id.*) As explained above, POSITAs would have had many motivations to combine Eller’s torsion spring with Hartley’s valve and would have reasonably expected success in doing so.

B. Claim 2

Hartley combined with Eller renders claim 2 obvious. (Ex. 1003, ¶¶194-195.)

Hartley’s cylindrical diaphragm (i.e., tubular member) “may be constructed from a [sic] elastomeric material such as silicone rubber” and can be constricted by the string. (Ex. 1006, [0016].) Thus, the cylindrical diaphragm is pliable. (Ex. 1003, ¶195.)

C. Claim 3

Hartley combined with Eller renders claim 3 obvious. (Ex. 1003, ¶¶196-197.)

As illustrated in Figure 3, Hartley’s string “is wound preferably twice around the cylindrical diaphragm”:

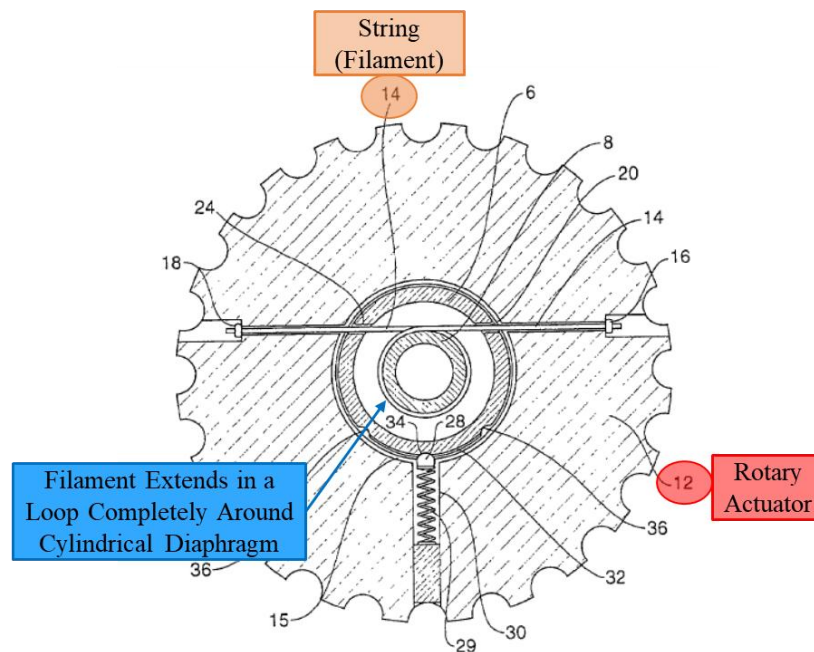


Fig 3

(Ex. 1006, [0031], Fig. 3.) Hartley’s string therefore “extends in a loop around the elongate member.” (*Id.*; Ex. 1003, ¶197.)

D. Claim 5

Hartley combined with Eller renders claim 5 obvious. (Ex. 1003, ¶¶198-201.) Hartley’s valve “can be controlled to vary the size of the aperture through the valve and be flexible so that a seal may be formed against an instrument or other object inserted through the access valve.” (Ex. 1006, [0004].) Hartley teaches that “[d]epending on how much the flexible member is pulled radially and/or tangentially the cylindrical diaphragm can be completely constricted to prevent fluid flow through the valve or can be constricted to the extent that it closes around an instrument, for instance a catheter, passed through the valve.” (*Id.*, [0006].)

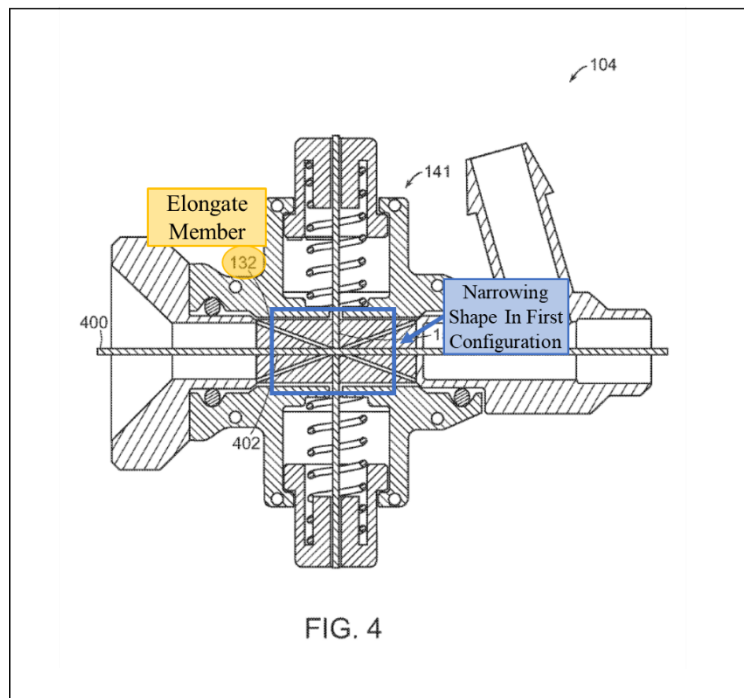
As explained in Grounds 1-4, a pressure differential exists between the proximal and distal ends of a catheter inserted into a patient’s vasculature. (*Supra* §VI.E.) The purpose of Hartley’s valve is to maintain a seal when devices are inserted through the valve into the patient’s vasculature. (Ex. 1003, ¶200.) Thus, POSITAs would have reasonably expected that Hartley’s valve would maintain the lumen of the cylindrical diaphragm in a constricted, sealed state when the actuator is in the first, closed position, even when a pressure differential exists between the proximal and distal ends of the lumen. (*Id.*, ¶¶200-201.)

E. Claim 6

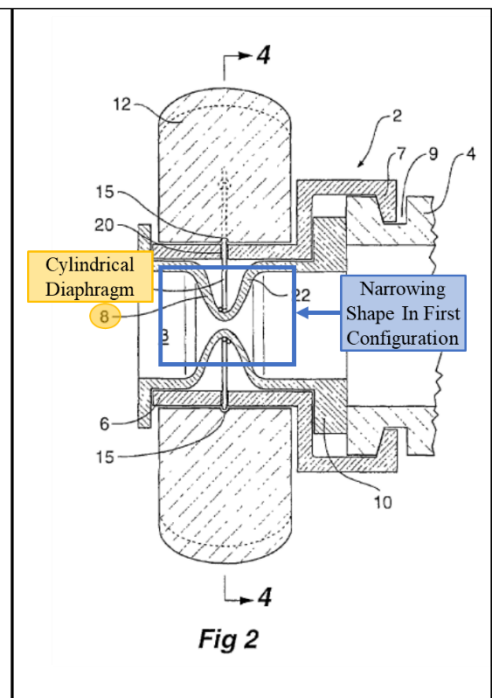
Hartley combined with Eller renders claim 6 obvious. (Ex. 1003, ¶¶202-206.) As explained in Grounds 1-4, POSITAs commonly used hemostasis valves with suction devices, such as syringes, in September 2017 to create a seal during intravascular procedures. (*Supra*, §VI.F.) Given this common practice and Hartley’s disclosures discussed previously for claim 5, POSITAs would have understood that Hartley’s valve would maintain the lumen of the cylindrical diaphragm in a constricted, sealed state when the actuator is in the first, closed position, even when a vacuum pressure is applied to a volume outside of the valve’s lumen. (Ex. 1003, ¶¶203-204; Ex. 1006, [0003], [0006].)

Moreover, the only disclosure in the ’921 patent regarding the valve’s ability to seal in the presence of a vacuum attributes the ability to the “narrowing shape” of the valve. (Ex. 1001, 10:50-56.) Hartley also discloses that its elongate member (cylindrical diaphragm 8) has a “narrowing shape” when the actuator is in in the first (i.e., closed) configuration:

'921 Patent



Hartley



(*Id.*, Fig. 4 (left); Ex. 1006, [0031], Fig. 2⁷ (right).) Because Hartley discloses the same structure disclosed in the '921 patent, PO cannot argue that Hartley's valve does not meet this limitation.

Moreover, if Hartley's valve did not maintain its seal under vacuum pressure, a POSITA would have found it obvious to adjust the torsion spring strength to apply additional force to seal the valve, adjust the resilience and compressibility of the cylindrical diaphragm that forms the valve's lumen, and/or adjust the shape, flexibility, and/or dimensions of the string to more closely conform to the shape of

⁷Figure 2 of Hartley depicts the valve in a "partially constricted position." (Ex. 1006, [0026].) The cylindrical diaphragm would have an even narrower shape in the fully constricted position. (Ex. 1003, ¶205.)

the seal module and any tool(s) inserted through the valve. (Ex. 1003, ¶206.) POSITAs would have been motivated to do so because the purpose of Hartley’s hemostasis valve is to prevent leakage when other devices, such as aspiration catheters, are inserted through the valve. (*Id.*) POSITAs would have had a reasonable expectation of success in making such adjustments for the same reasons discussed previously in Grounds 1-4. (*Supra* §VI.E-F.)

F. Claim 9

Hartley combined with Eller renders claim 9 obvious. (Ex. 1003, ¶¶207-208.) 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].) Hartley therefore discloses the additional limitations of claim 9. (Ex. 1003, ¶208.)

G. Claim 15

Hartley’s string is coupled to the elongate member (by wrapping around the member) and the actuator (via knots) for the reasons explained in claim 1. (*Supra* §VII.A.3.) Hartley combined with Eller renders the remaining limitations of claim 15 obvious for the reasons provided in claim 1. (*Supra* §VII.A.) Hartley combined with Eller therefore renders claim 15 obvious. (Ex. 1003, ¶¶209-210.)

H. Claim 16

Hartley discloses the limitations of claim 16 for the reasons explained for claim 1. (*Supra* §VII.A.3.) Hartley combined with Eller therefore renders claim 16 obvious. (Ex. 1003, ¶211.)

I. Claim 17

Hartley discloses the limitations of claim 17 for the reasons explained for claim 1. (*Supra* §VII.A.3.) Hartley combined with Eller therefore renders claim 17 obvious. (Ex. 1003, ¶212.)

J. Claim 18

Hartley discloses the limitations of claim 18 for the reasons explained for claim 2. (*Supra* §VII.B.) Hartley combined with Eller therefore renders claim 18 obvious. (Ex. 1003, ¶213.)

K. Claim 21

Hartley's actuators are coupled to the elongate member through the string (filament), which wraps around the elongate member and is attached by knots to the actuators, as explained in claim 1. (*Supra* §VII.A.3.) Hartley combined with Eller renders the remaining limitations of claim 21 obvious for the reasons provided in claim 1. (*Supra* §VII.A.) Hartley combined with Eller therefore renders claim 21 obvious. (Ex. 1003, ¶¶214-215.)

L. Claim 22

Hartley discloses the limitations of claim 22 for the reasons explained for claim 2. (*Supra* §VII.B.) Hartley combined with Eller therefore renders claim 22 obvious. (Ex. 1003, ¶216.)

M. Claim 23

Hartley discloses the limitations of claim 23 for the reasons explained for claims 2 and 3. (*Supra* §§VII.B-C.) Hartley combined with Eller therefore renders claim 23 obvious. (Ex. 1003, ¶217.)

N. Claim 24

Hartley combined with Eller renders claim 24 obvious. (Ex. 1003, ¶¶218-219.) Hartley discloses that “[r]otation of the rotary actuator back to the central position where the detent ball 28 is received in depression 34 will cause the sutures to loosen again so that the resilient cylindrical diaphragm will retain its original shape as shown in FIGS. 1 and 3.” (Ex. 1007, [0034].) Accordingly, Hartley’s actuators do not substantially pull the filament when in the second position, allowing the elongate member to expand to an uncollapsed configuration. (Ex. 1003, ¶219.)

VIII. SECONDARY CONSIDERATIONS

Petitioner is not aware of any evidence of secondary considerations. (Ex. 1003, ¶¶220-221.) If PO identifies evidence of secondary considerations, Petitioner respectfully requests an opportunity to respond.

**IX. THE BOARD SHOULD NOT DENY INSTITUTION
UNDER §314(a) OR §325(d)**

The Board should not exercise its discretion to deny institution under §314(a). First, 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. Therefore, there will be no “overlap in the issues raised in the petition and in the parallel proceeding.” *Apple v. Fintiv*, IPR2020-00019, Paper 11 at 6 (PTAB Mar. 20, 2020) (precedential).

Second, the parallel Litigation is in its early stages. *Id.* PO recently admitted in a motion to amend the complaint that “[d]iscovery is this case is in at [sic] an early stage” and emphasizing that the “Court has not even set a date for the close of fact discovery.” (Ex. 1019 at 6.) PO is correct; the Court has set a case schedule through only the claim construction hearing. (Ex. 1021.) The Court has not set any deadlines thereafter, and the Court will not set such deadlines until after issuing a claim construction ruling. Thus, any trial date is likely fall well after any final written decision in this IPR.

Third, Petitioner has informed the Court, and the Court expects, that Petitioner will move to stay the litigation pending resolution of the IPRs once the Court has addressed a pending Motion for Preliminary Injunction filed by PO. Thus, the Board

should not discretionarily deny institution under § 314(a) based on the parallel Litigation.

Additionally, denial of institution under 325(d) would also be unwarranted because Schaffer, which forms the basis for Grounds 1-4 herein, was not of-record during prosecution of the '921 patent.

Additionally, the examiner never considered the combination of Hartley and Eller set forth herein. (*See* Ex. 1002.) As explained in the introduction, the examiner found that Hartley disclosed every limitation of issuing independent claims 1, 15, and 21 except a “biasing system configured to bias the actuator to the first position.” Yet, a POSITA would have found it obvious to combine Hartley’s valve with the biasing system disclosed by Eller. (*Supra* §VII.) The examiner therefore materially erred in allowing the challenged claims over Hartley and Eller. While Eller was cited on an IDS during prosecution, the examiner never discussed Eller or addressed the combination of Eller’s torsion spring with Hartley. Accordingly, the Board should not deny institution based on the citation of Hartley and Eller in IDS’s because, as shown above, the references render the challenged claims unpatentable, and the Examiner never applied them. (Ex. 1002); *see e.g., Comcast Cable Commc’ns LLC v. Promptu Sys. Corp.*, IPR2018-00342, Paper 13 (P.T.A.B. July 19, 2018) (declining to deny institution under §325(d) because prior art was not applied).

**X. 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))

PO recently filed a Second Amended Complaint alleging that Petitioner's Symphony system infringes the '921 patent, as well as U.S. Patent Nos. 11,974,910; 11,969,333; 11,554,005; 11,744,691; 11,697,012; 11,865,291, 12,016,580; 12,109,384; and 12,156,669. *Inari Medical, Inc. v. Imperative Care, Inc.*, No. 24-cv-3117 (N.D. Cal., filed May 22, 2024). In the 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. 1017.) The court has set a case schedule only through the claim construction hearing, currently set for July 24, 2025. (Ex. 1021.) The court has not set a trial date in the litigation. (*Id.*)

In addition to the Petition for IPR of U.S. Patent No. 11,697,011, Petitioner has also filed three additional IPRs against patents asserted by PO in the Litigation: (1) *Imperative Care, Inc. v. Inari Medical, Inc.*, IPR2024-01257 requesting review of U.S. Patent No. 11,744,691 (Filed August 12, 2024); (2) *Imperative Care, Inc. v. Inari Medical, Inc.*, IPR2025-00156 requesting review of U.S. Patent No. 11,697,012 (Filed November 8, 2024); (3) *Imperative Care, Inc. v. Inari Medical, Inc.*, IPR2025-00289 requesting review of U.S. Patent No. 11,554,005 (Filed

December 13, 2024). The Board 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
Joshua J. Stowell (Reg. No. 64,096) Joshua.Stowell@knobbe.com BoxImperative921@knobbe.com Knobbe, Martens, Olson, & Bear, LLP <u>Postal and Hand-Delivery Address:</u> 2040 Main St., 14 th Floor Irvine, CA 92614 Telephone: 949-760-0404 Facsimile: 949-760-9502	Joseph R. Re (Reg. No. 31,291) Joe.Re@knobbe.com Brian C. Barnes (Reg. No. 75,805) Brian.Barnes@knobbe.com Knobbe, Martens, Olson, & Bear, LLP <u>Postal and Hand-Delivery Address:</u> 2040 Main St., 14 th Floor Irvine, CA 92614 Telephone: 949-760-0404 Facsimile: 949-760-9502

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 BoxImperative921@knobbe.com.

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

Petitioner certifies that the '921 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 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.

XI. 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 anticipated or obvious and, therefore, requests that the Board institute an *inter partes* review.

Dated: March 13, 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)

KNOBBE MARTENS OLSON & BEAR, LLP
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. 11,844,921** contains 13,865 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: March 13, 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. 11,844,921 and EXHIBITS 1001-1021**, were served by Priority Mail Express on the Patent Owner at the correspondence address of record for the subject patent as follows:

Joseph Hamilton
PERKINS COIE LLP
P.O. BOX 1247
PATENT PROCUREMENT
SEATTLE, WA 98111-1247

A courtesy copy is being sent by email on this day to Patent Owner's counsel of record in the Litigation as follows:

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