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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. IPR2025-00989
Patent No. 11,865,291

**PETITION FOR *INTER PARTES* REVIEW OF
U.S. PATENT NO. 11,865,291**

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35 U.S.C. §112	45
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LIST OF EXHIBITS

Exhibit No.	Description
1001	U.S. Patent No. 11,865,291 (“the ’291 patent”)
1002	Prosecution History of the ’291 Patent
1003	Expert Declaration of Troy Thornton
1004	Resume of Troy Thornton
1005	U.S. Patent Publication US 2003/0225379 A1 to Schaffer et al. (“Schaffer”)
1006	U.S. Patent Publication US 2003/0116731 A1 to Hartley (“Hartley”)
1007	U.S. Patent No. 9,980,813 B1 to Eller (“Eller”)
1008	Certified File History of U.S. Patent Application 10/371,190 (Schaffer File History)
1009	U.S. Patent No. 5,429,616 to Schaffer (“Schaffer ’616”)
1010	RESERVED
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	New Oxford American Dictionary, 3rd ed. (2010) – definitions of “diameter,” “filament,” and “loop”
1015	RESERVED
1016	U.S. Patent No. 12,109,384 B2 to Merritt et al.

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 Trerotola
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)
1022	U.S. Patent No. 11,697,012 B2 (“the ’012 patent”)
1023	Decision Granting Institution of <i>Inter Partes</i> Review for U.S. Patent No. 11,697,012 (Paper 6) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-00156 (P.T.A.B. Apr. 22, 2025)
1024	Imperative Care’s Opposition to Inari’s Motion for Leave to File Third Amended Complaint (Dkt. #98) in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 24-cv-03117-EKL (N.D. Cal.) (filed March 26, 2025)
1025	Imperative Care’s Notice of Motion and Motion to Stay Pending <i>Inter Partes</i> Review (Dkt. #100) in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 24-cv-03117-EKL (N.D. Cal.) (filed April 2, 2025)
1026	Patent Owner’s Exhibit 2002 filed in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-00289 (P.T.A.B.)
1027	Claim Construction Excerpt Report of Troy Thornton in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 24-cv-03117-EKL (N.D. Cal.)

Petitioner Imperative Care, Inc. (“Petitioner”) requests *inter partes* review (“IPR”) of claims 1-8, and 12-19 (“the challenged claims”) of U.S. Patent No. 11,865,291 (“the ’291 patent,” Ex. 1001), which is assigned to Inari Medical, Inc. (“Patent Owner” or “PO”).

I. INTRODUCTION

Patent Owner has asserted claims 1-8, 12-17, and 19 against Petitioner in the co-pending district court litigation (the “Litigation”). *See* Ex. 1013 (PO’s infringement contentions). The Litigation is in its early stages and no trial date has been set. (*See* Ex. 1019 at 2 (representing to Court that “discovery is at an early stage); Ex. 1021 (setting case schedule to claim construction).) Therefore, Petitioner challenges the patentability of those asserted claims, and the claims from which they may¹ depend, in this IPR.

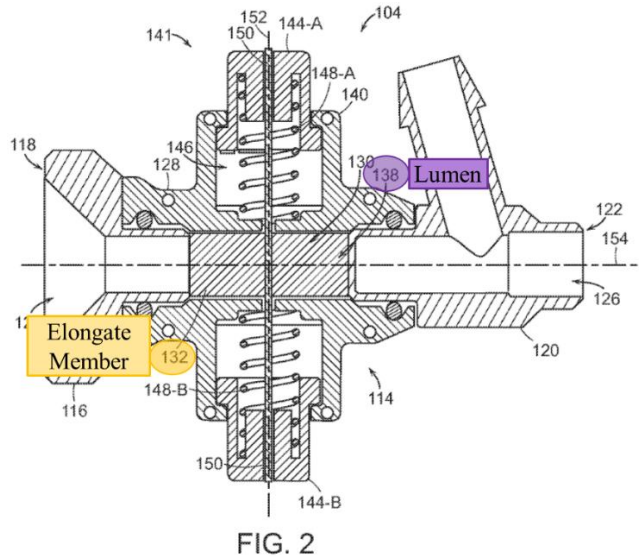
Additionally, the challenged ’291 patent is a divisional of U.S. Patent No. 11,697,011 (“the ’011 patent,” Ex. 1012) and the parent of U.S. Patent No. 11,697,012 (“the ’012 patent,” Ex. 1022). The Board instituted Petitioner’s IPRs challenging the patentability of the ’011 and ’012 patents. (Ex. 1017; Ex. 1023.) In the institution decisions, the Board preliminarily addressed claim limitations similar to those found in the ’291 patent.

¹ Claim 19 includes an error so it is not clear whether the claim depends from claim 1 or claim 18. *Infra* §VI.O.

The challenged claims in the '291 patent describe a known type of “hemostasis 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 hemostasis valves to seal the end of catheters and minimize blood loss during such procedures.

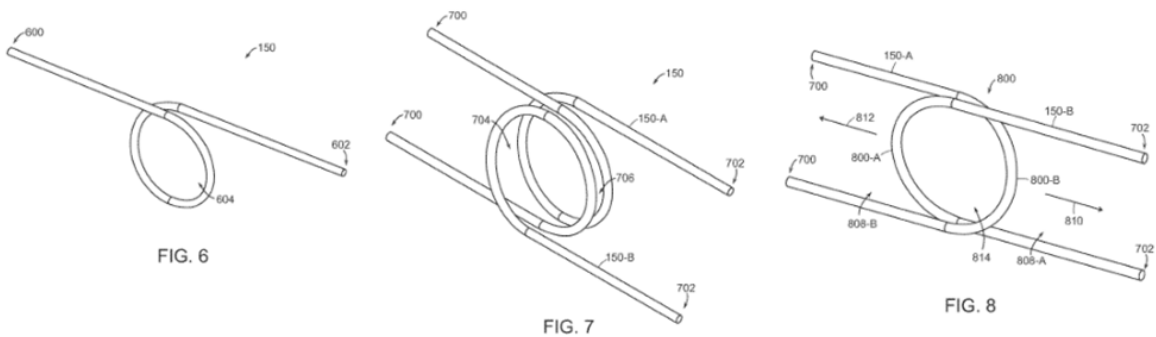
The challenged claims describe a hemostasis valve that includes a “collapsible tubular sidewall defining a lumen.” The term “collapsible tubular sidewall” does not appear in the '291 patent specification and, therefore, it is not specifically identified in any figures. Rather, the specification describes hemostasis valves having an “elongate member 132” or “tubular member 132” with a “central lumen 138”:²

² Petitioner added all colors and annotations except where otherwise noted.



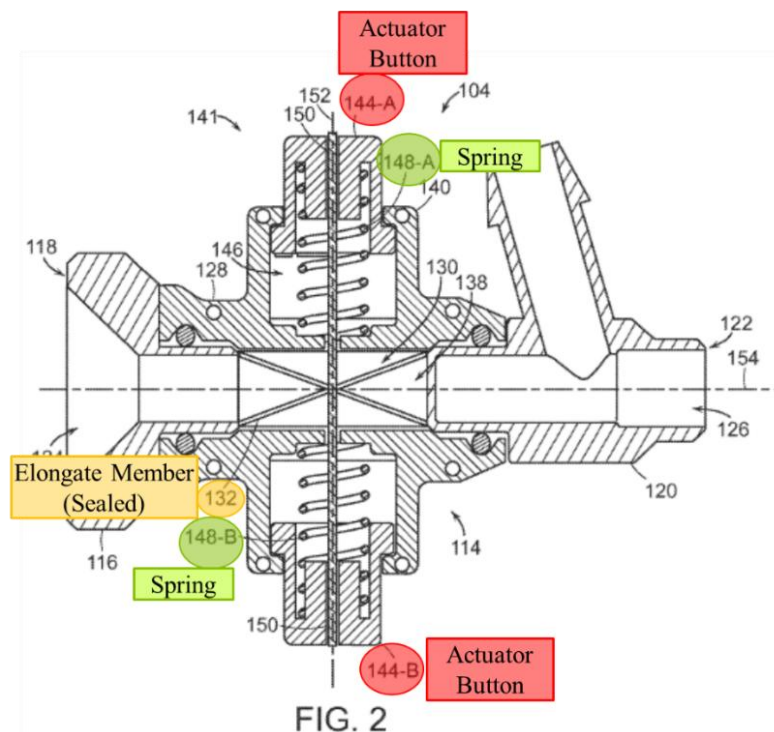
(Ex. 1001, 7:11-45, Fig. 2.) The specification explains that the “elongate member 132 can comprise a compliant tubular structure” that “can facilitate the collapse” of the elongate member 132. (*Id.*, 7:17-31.)

The claimed hemostasis valve also includes an “actuator” having a “first member” (i.e., a button) and a “filament formed in a loop around the tubular sidewall” and connected to the button. The specification explains that when tension is applied to the ends of the filament, the filament constricts the elongate member, collapsing and sealing the lumen of the tubular member. The filament can have a variety of configurations, as shown below.



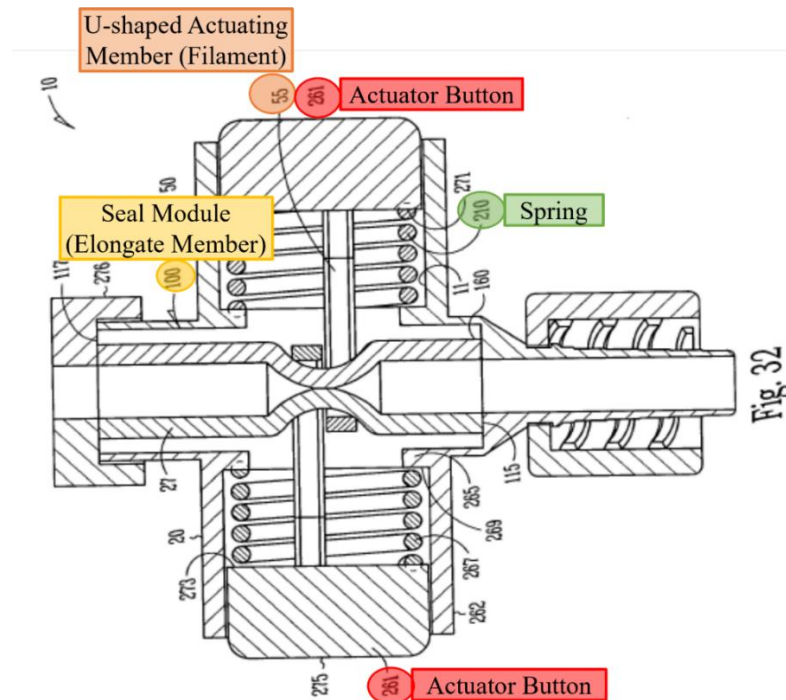
(*Id.*, Figs. 6-8.)

The claimed hemostasis valve also includes a “spring” that moves the first member (i.e., button) in a direction that pulls on the filament to reduce the diameter of the filament loop. (*Id.*, 8:38-56, Fig. 2.) In Figure 2, springs 148-A and 148-B move the actuator buttons to close the valve. (*Id.*)



Hemostasis valves having a filament looped around a collapsible tube and springs to move a button to close a valve were well known before September 6, 2017, the earliest claimed priority date for the '291 patent. **Schaffer**, a patent application published in 2003, describes hemostasis valves for use with catheters during intravascular procedures. (Ex. 1005, [0002], [0008].) Schaffer was **not** before the Examiner during prosecution of the '291 patent. Like the claimed valves, Schaffer's

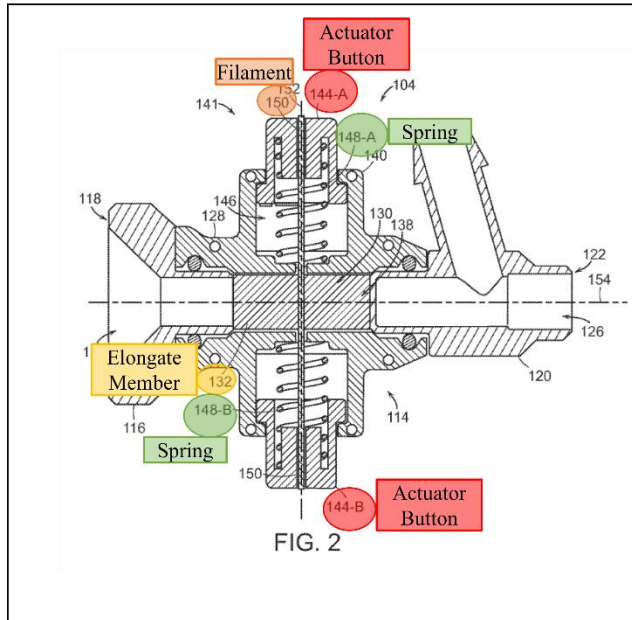
hemostasis valve includes opposing actuator buttons attached to springs that apply or release tension on a filament (e.g., actuating members) to collapse a tube (e.g., seal module) within the valve:



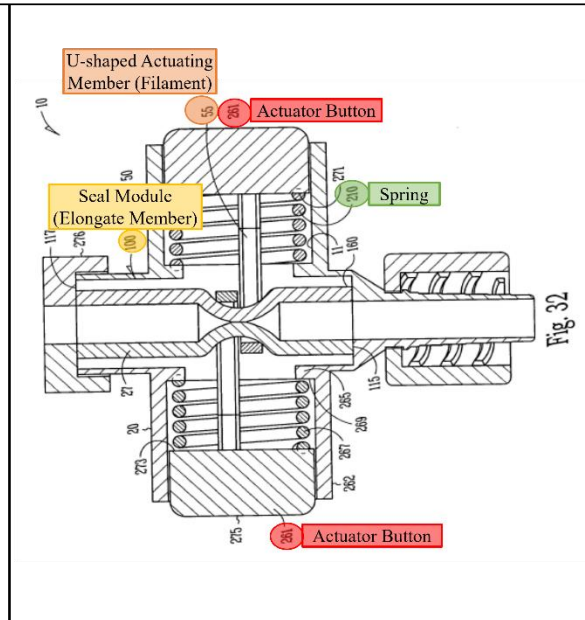
(*Id.*, Fig. 32.)³ As shown below, Schaffer’s valve has the same components, in the same arrangement, as the valve claimed in the ’291 patent. Thus, Schaffer anticipates or renders obvious the challenged claims.

³ Petitioner uses the versions of Schaffer’s drawings submitted during prosecution on June 18, 2003 (Ex. 1008) because they are clearer. The drawings became publicly available when Schaffer published on December 4, 2003. 37 C.F.R. §1.11.

'291 Patent



Schaffer



Schaffer also renders the challenged claims obvious in combination with the “filaments” described in Hartley or Eller. In the IPR institution decisions for both the ’011 patent and ’012 patent, the Board found a reasonable likelihood that Petitioner will prevail in showing that at least claim 1 of the challenged patents unpatentable based on the combination of Schaffer and Hartley. (Ex. 1017, 35, 41; Ex. 1023, 48.) Notably, claim 1 of the ’011 and ’012 patents includes similar limitations to those in independent claims 1 and 18 of the ’291 patent.

Hartley, a patent application published in 2003, describes a hemostasis valve having a filament that constricts the lumen of an elongate member:

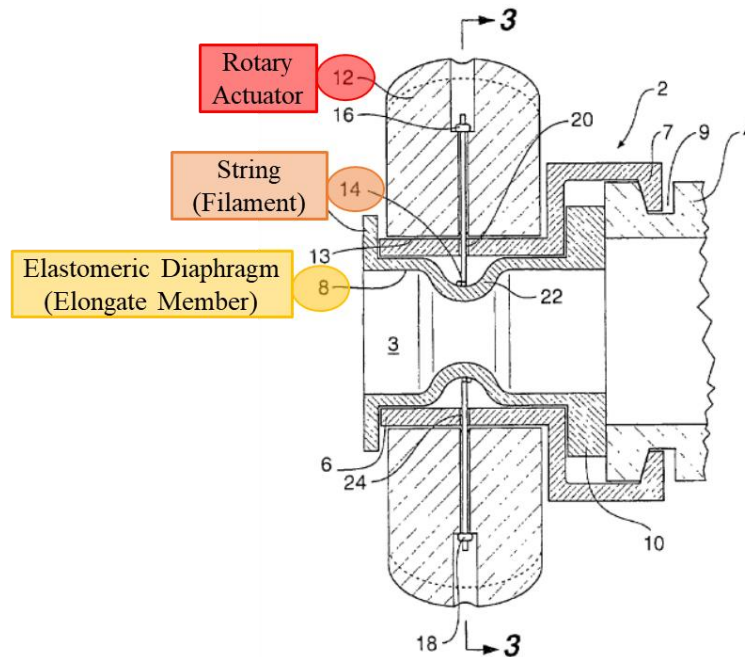
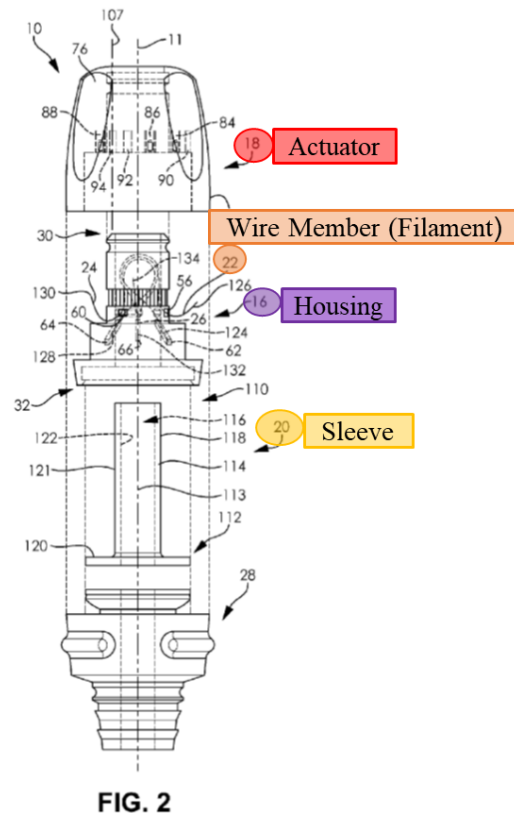


Fig 1

(Ex. 1006, [0031], Fig. 1.) Hartley’s filament is attached to a “rotary actuator” that applies tension to the filament. Rotation of the rotary 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 loops around a collapsible sleeve to constrict the lumen of the sleeve:



(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. As discussed above, the Board preliminarily addressed the combination of Schaffer with Hartley’s or Eller’s filaments in the institution decisions for the ’011 patent and ’012 patent IPRs. (Ex. 1017, 33-41; Ex. 1023, 34-48.) The Board found that “Petitioner advances multiple reasons why the skilled artisan would have been motivated to combine Schaffer and Hartley with a reasonable expectation of success.” (Ex. 1017, 36; *see also* Ex. 1023, 38 (“We find

Petitioner’s argument and evidence summarized above sufficient, at this stage, to support the rationale for modifying Schaffer in view of Hartley as proposed with a reasonable expectation of success”).)

For the reasons presented herein, Petitioner has demonstrated a reasonable likelihood that at least one claim of the ’291 patent is unpatentable. Accordingly, Petitioner requests that the Board institute this IPR to review the patentability of the ’291 patent.

II. THE ’291 PATENT

A. Overview

The ’291 patent describes hemostasis (or “garrote”) valves for use during minimally invasive intravascular procedures. (Ex. 1001, 5:55-6:6.) The hemostasis valve is used with a catheter inserted into the patient’s vasculature to provide a seal. (*Id.*, 1:41-1:44.) The ’291 patent states that the hemostasis valve “can seal with or without a tool extending through the valve.” (*Id.*, 5:56-5:58.)

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

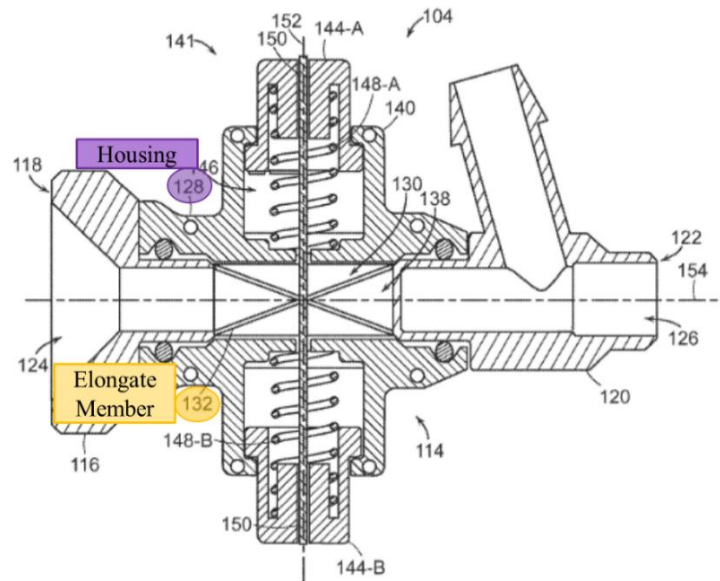


FIG. 2

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

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

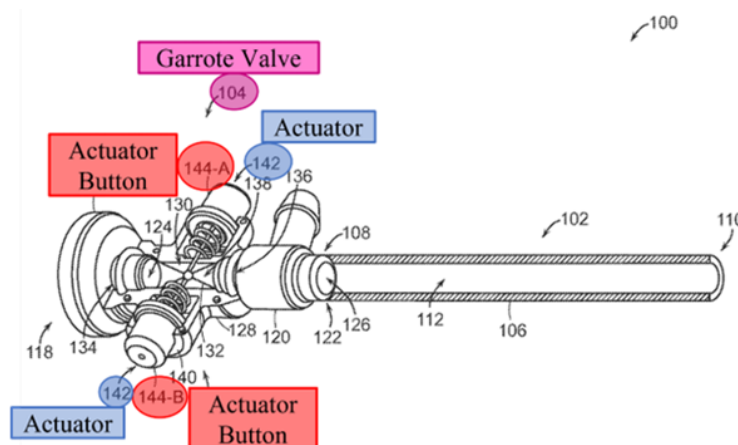
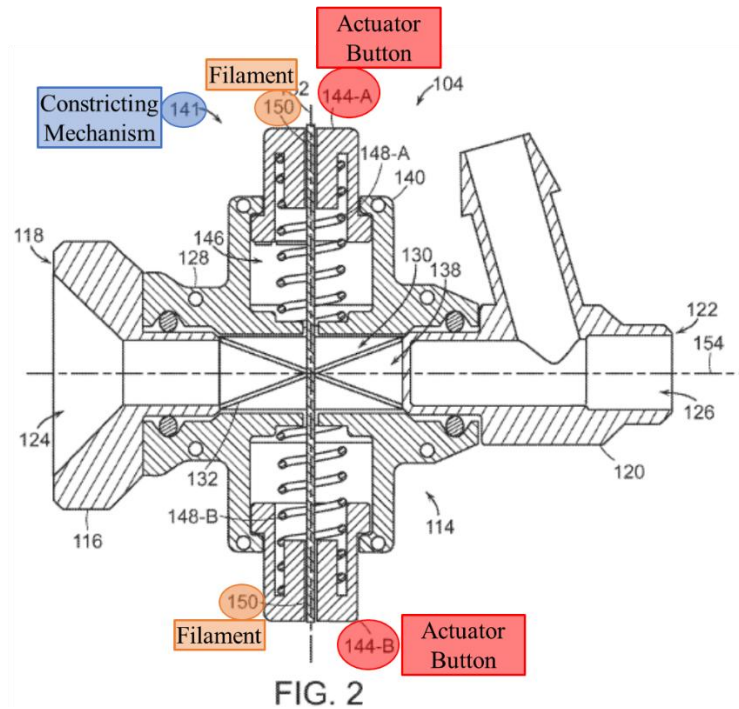


FIG. 1



(*Id.*, 8:5-8, Figs. 1, 2.) The constricting mechanism includes “an actuator 142 which can be a manual actuator such as one or several buttons 144; and the at least one filament 150 that can extend at least partially around the elongate member 132.” (*Id.*, 8:5-12.) The “filament 150 can be coupled to the actuator 142 such that the filament 150 selectively constricts, collapses, and/or seals the elongate member 132 ... based on the movement and/or position of the actuator 142.” (*Id.*, 9:24-28.)

The valve also includes a “bias feature,” such as a spring (148-A and 148-B), which biases the actuator toward the open or closed configuration. (*Id.*, 8:38-56.) In Figure 4, springs 148-A and 148-B bias the valve toward the closed configuration:

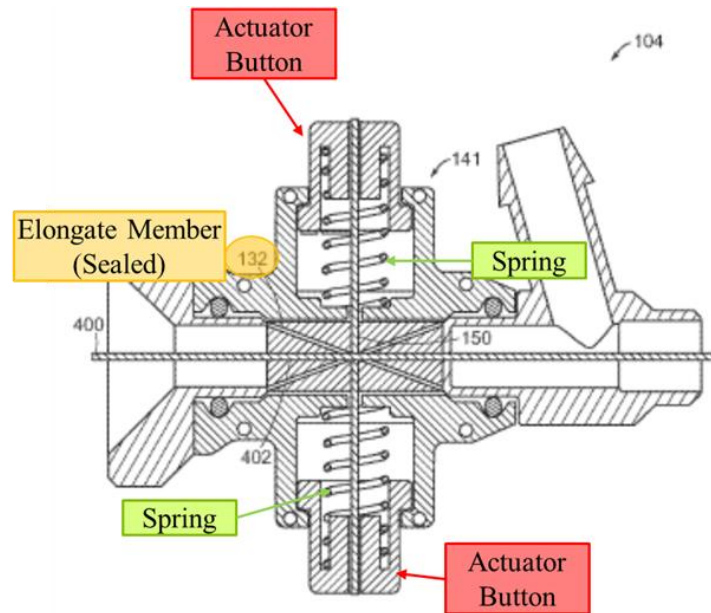


FIG. 4

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

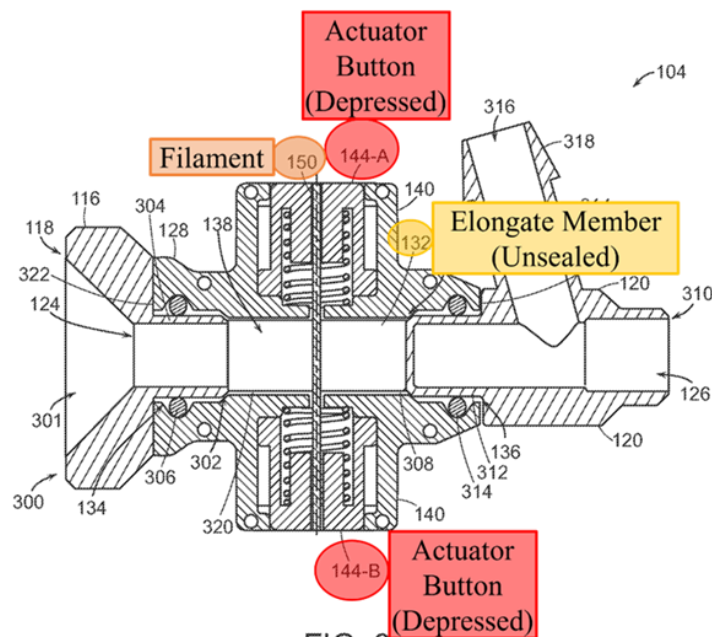


FIG. 3

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

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

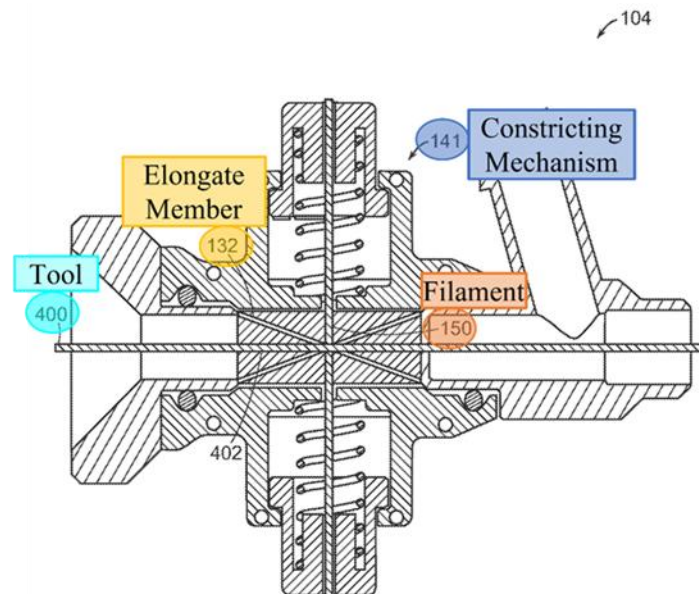


FIG. 4

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

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

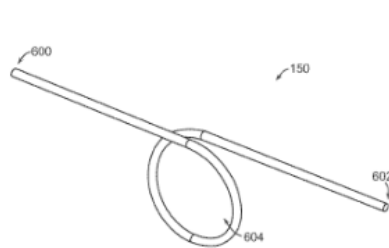


FIG. 6

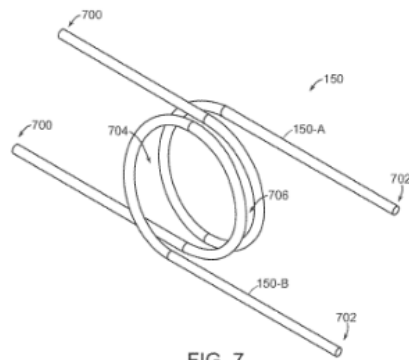


FIG. 7

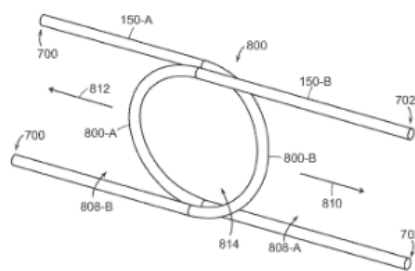


FIG. 8

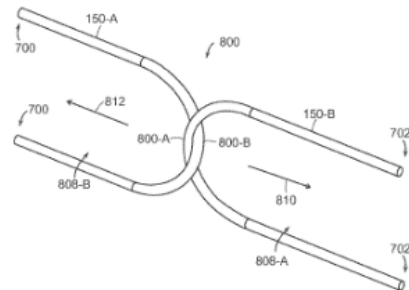


FIG. 9

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

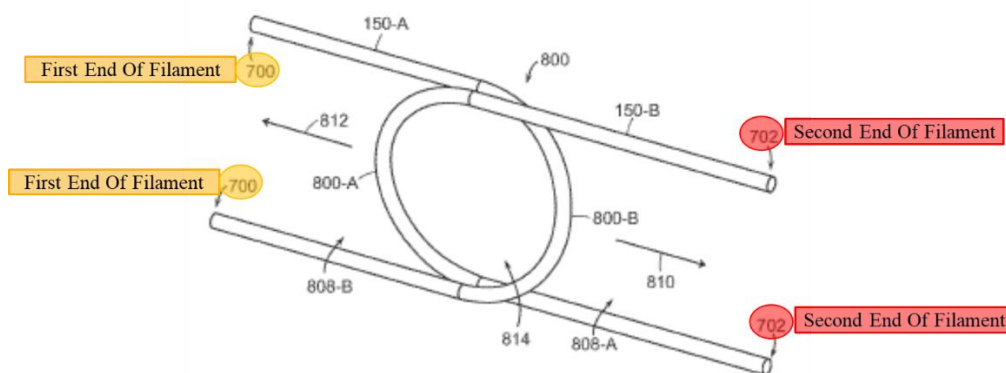


FIG. 8

(*Id.*, 12:61-67, Fig. 8.)

B. Prosecution History

The Examiner of the '291 patent did not issue any office actions and did not make any prior-art based rejections. In the Notice of Allowance, the Examiner stated that Hartley (Ex. 1006) was the “closest prior art of record.” (Ex. 1002, 393.) The Examiner found that Hartley disclosed every limitation of the independent claims except a spring that “perform[s] a function required in the claimed invention, i.e. the spring configured to move the first member in a direction that pulls the first end portion away from the tubular sidewall, reducing a diameter of the lumen in response to reducing a diameter of the loop.” (*Id.*, 393-394.) The Examiner did not address the combination of any references.

C. The Earliest Possible Priority Date

The '291 patent claims priority to provisional application No. 62/554,931, filed September 6, 2017, which is the earliest possible priority date for the '291 patent. (Ex. 1001.) Petitioner applies this earliest priority date in this Petition; however, Petitioner reserves its right to challenge the priority date in subsequent proceeding(s).

III. LEVEL OF ORDINARY SKILL

A POSITA in September 2017 would have had an undergraduate degree in mechanical engineering or a related engineering discipline and 2-4 years of product design or engineering experience. (Ex. 1003, ¶36.) This is the same level of ordinary

skill that Petitioner proposed in the '011 and '012 patent IPRs and that was applied by PO and the Board. (Ex. 1017, 11; Ex. 1023, 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” in the '291 patent to mean at least “one or more threads, lines, cords, ropes, ribbons, flat wires, sheets, or tapes” based on the intrinsic record. (Ex. 1003, ¶¶50-72.) This is the same construction of “filament” that Petitioner proposed in the '011 and '012 patent IPRs. (Ex. 1017, 12; Ex. 1023, 14.)

In those prior IPRs, PO argued that Petitioner's construction was incomplete because it did not limit the claims to “flexible” filaments. (Ex. 1023, 21, n.13.) PO also sought to import other limitations into the construction of “filament” (e.g., “thin”). (*Id.*, 14.) Importantly, however, the construction of “filament” potentially

impacts only whether Schaffer anticipates the claims or renders them obvious. (Ex. 1023, 21, n.13.) The construction does not impact whether Schaffer in combination with Hartley or Eller renders the claims obvious because PO “does not dispute that Hartley and/or Eller disclose a flexible filament (e.g., flexible string or flexible wire).” (*Id.*)

1. Support for Petitioner’s Construction of “Filament”

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 structure forming the “filament.” For example, claim 1 recites “a filament formed in a loop around the tubular sidewall, the filament having at least a first end portion extending away from the loop to the first member.” Dependent claim 3 adds that the filament can optionally include a second end portion extending away from the loop to a second member. Dependent claim 4 adds that “the first end portion, the loop, and the second end portion are one continuous filament.” While the dependent claims identify some optional features of a filament, they do not define the scope of structures that comprise the “filament” in claim 1.

However, the ’291 patent specification (like the ’011 patent) identifies express examples of “filaments.” The ’291 patent states, “the filament 150 can comprise one

or several threads, lines, cords, rope, ribbon, flat wire, sheet, or tape.” (Ex. 1001, 9:21-23.) 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.*, 9:13-15.) 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.*, 9:16-21.) 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.*, 12:61-64.)

In the ’011 patent IPR, the Board preliminarily found that it did not need to “expressly construe the term ‘filament’ in the manner urged by Petitioner.” (Ex. 1017, 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.*) Similarly, in the ’012 patent IPR, the Board stated, “We agree with Petitioner that a ‘filament’

may encompass one or several threads, lines, cords, robes [sic], ribbons, flat wires, sheets or tapes. The Specification supports such interpretation.” (Ex. 1023, 15.)

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 identified herein, even if a full construction of “filament” would include additional structures.

2. The Board’s Prior Analysis of PO’s Attempt to Limit Claims to “Flexible” Filaments

The Board addressed PO’s attempts to limit the claims of the ’011 and ’012 patents to “flexible” filaments in the prior IPRs. In the ’011 patent IPR, PO argued 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 relative terms” because “flexibility and rigidity exist along a spectrum” (*Id.*)

The Board reached a different preliminary construction in the ’012 patent IPR. There, the Board found that the “claims, as understood by the POSA, suggest that

the filament must be flexible.”⁴ (Ex. 1023, 15.) The Board focused on the limitations in the ’012 patent claims reciting “a first filament formed into a loop around the collapsible tubular sidewall” and that the “diameter of the valve lumen decreases in response to reducing a diameter of the loop.” (*Id.*) The Board credited an argument by PO’s expert that the loop must be flexible to have its diameter reduced. (*Id.*) The Board also preliminarily found that the ’012 patent specification suggests that filaments that form loops “are not the same” as filaments that form bights defining an encircled area. (*Id.*, 18-19.) The Board also cited PO’s response to a restriction requirement during prosecution of the ’012 patent as supporting an argument that the ’012 patent claims are limited to a filament that forms a “loop,” as shown in Figure 6 of the ’012 patent, and not a filament that forms “bights,” as shown in Figures 8 and 9. (*Id.*, 20.)

The Board also stated that “[t]here is no irreconcilable inconsistency” between its preliminary constructions in the ’011 and ’012 patent IPRs. (*Id.*, 18.) The Board explained that claim 1 of the ’011 patent “does not require that the ‘filament forms into a loop’ where the ‘diameter of the loop’ reduces when the end portion(s) of the filament are pulled,” unlike the challenged claims in the ’012 patent. (*Id.*) Thus, the Board found that “Claim 1 in the [’011 patent IPR] is arguably broader concerning

⁴ The Board did not address the other portions of PO’s claim construction (e.g., “thin”) in the ’012 patent IPR.

the ‘filament’ and would purport to encompass, for example, both loop and bight embodiments.” (*Id.*)

3. The ’291 Patent Claims Are Not Limited To “Flexible” Filaments

The ’291 patent claims are not limited to “flexible” filaments for several reasons. (Ex. 1003, ¶¶64-72.) First, as the Board recognized in the ’011 patent IPR, the ’291 patent specification does not use the word “flexible” to describe the filament. (Ex. 1017, 15.) Likewise, the ’291 patent does not provide any objective measurements or boundaries that would permit a POSITA to determine where along the spectrum of flexibility a given material becomes a “filament” with reasonable certainty. (*Id.*; Ex. 1003, ¶64); *Nautilus, Inc. v. BiosigInstruments, Inc.*, 572 U.S. 898, 910 (2014). Consequently, the importation of “flexible” into the ’012 patent claims would render the claims indefinite, a result that is to be avoided where possible. *See Ruckus Wireless, Inc. v. Innovative Wireless Sols., LLC*, 824 F.3d 999, 1004 (Fed. Cir. 2016) (relying on “canon favoring constructions that preserve claim validity” to construe claims).

Second, the Board preliminarily limited the ’012 patent claims to “flexible” filaments based, in part, on the ’012 patent claim language. However, the ’291 patent claims differ in meaningful ways.⁵ Like the ’012 patent claims, the

⁵ Petitioner does not concede that the Board’s construction of “filament” in the ’012 patent is correct and will address the construction in that IPR.

independent claims of the '291 patent require “a filament formed in a loop around the tubular sidewall” and that pulling on the first end of the filament results in “reducing a diameter of the lumen in response to reducing a diameter of the loop.” (Ex. 1001, claim 1.) However, dependent claim 4 of the '291 patent recites, “the first end portion, the loop, and the second end portion are one continuous filament.” The '012 patent does not include this claim.

The embodiment in Figure 6 depicts “one continuous filament”:

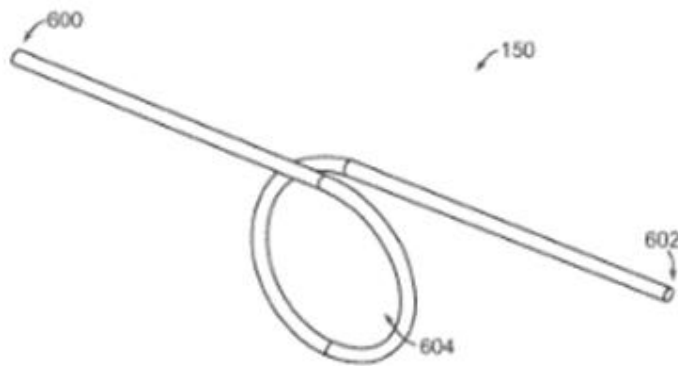
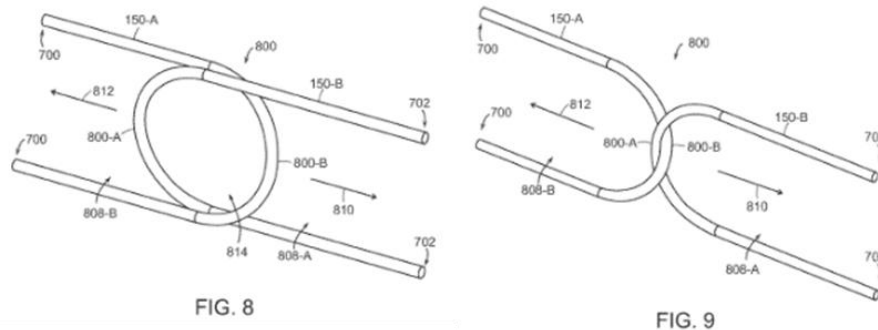


FIG. 6

(*Id.*, Fig. 6.) However, claim 1 is necessarily broader than dependent claim 4 (and Figure 6) and encompasses filaments that are not “one continuous filament.” See *Bardford Co. v. Conteyor N. Am., Inc.*, 603 F.3d 1262, 1271 (Fed. Cir. 2010) (finding independent claim entitled to a broader construction because independent claim is “presumed to be broader” than dependent claim). If this were not the case, claim 4 would be superfluous. See *Ortho-McNeil Pharm., Inc. v. Mylan Lab ’ys., Inc.*, 520 F.3d 1358, 1362 (Fed. Cir. 2008) (“Thus, this court strives to reach a claim

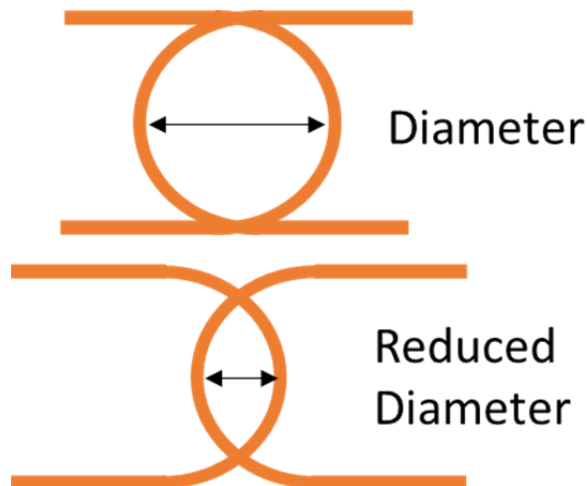
construction that does not render claim language in dependent claims meaningless.”).

The only embodiments in the '291 patent that do not include “one continuous filament” are the “bight” embodiments in Figures 8 and 9:



(Ex. 1001, Figs. 8-9.) Thus, claim 1 presumably encompasses these embodiments.

Additionally, the “bight” embodiments in Figures 8-9 meet the claim limitations because the bights collectively form a loop and pulling on the ends of the bights reduces the loop diameter. This is illustrated by the demonstrative below:



(Ex. 1003, ¶67.) Notably, a “diameter” is not limited to circular objects but includes irregular shapes like the lower demonstrative above. (Ex. 1014, 3.)

In the '012 patent IPR, the Board focused on the portion of the specification describing Figure 6 as having a “loop” and Figure 8 as having an “encircled area” to suggest that a “loop” is distinct from an “encircled area.” (Ex. 1023, 18-19.) While the words are different, “loop” means to “encircle.” (Ex. 1014, 5.) Further, the specification describes the filaments in Figures 6 and 8-9 as behaving the same way. The specification explains that “a diameter or **size** of the loop ... can **decrease** when the constricting mechanism 141 is moved” (Ex. 1001, 13:24-29 (emphasis added).) Similarly, the specification explains movement of the constricting mechanism “**decreases** the **size** of the encircled area 814” (*Id.*, 14:2-5 (emphasis added).) Thus, in view of claim 4 and the meaning of “loop” and “encircle,” the specification does not clearly and unmistakably disavow the “bight” embodiments from the scope of “filament.”

Third, the Board preliminarily limited the '012 patent claims to “flexible” filaments based, in part, on the '012 patent prosecution history. However, the '291 patent prosecution is different and does not include any restriction requirement response like the one provided in the '012 patent. (Ex. 1002.) Thus, the prosecution history does not support a narrower interpretation of “filament” here.

Fourth, PO has obtained patent claims in related patents that specifically require a “flexible” filament. PO’s U.S. Patent No. 12,109,384 includes claims reciting, “a first filament extending in a first loop around the tubular member,

wherein the first filament **is flexible.**” (Ex. 1016, claim 1 (emphasis added).) The claim further recites that the actuator can apply tension to the filament to “decreas[e] [the] dimension of the first loop.” (*Id.*) Thus, the claim further establishes that flexibility is **not** a requirement of a filament that forms a loop, otherwise the limitation stating “the first filament is flexible” would be superfluous. See *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1119 (Fed. Cir. 2004) (rejecting construction that read term out of claim).

Finally, in a more recent POPR, PO has argued that the description of the embodiment in Figure 3 requires a “flexible” filament. *Imperative Care, Inc. v. Inari Medical, Inc.*, IPR2025-00289, Paper 5 at 22. The specification states that when the buttons in the embodiment are depressed, “the filament 150 is loosened, thereby allowing the expansion of the elongate member 132” (Ex. 1001, 9:58-62, Fig. 3.) PO attempts to equate “loosened” with “flexible,” but PO’s argument fails for several reasons. First, the word “loosened” is not synonymous with “flexible.” The term “loosen” in the dictionary submitted by PO means “to release from restraint.” (Ex. 1026, 7.) Many inflexible items can be loosened, such as screws and bolts. Likewise, the “bight” embodiments in Figures 8 and 9 are also “loosened” to allow expansion of the elongate member, even if they are inflexible. (Ex. 1003, ¶72.) Second, the word “loosened” appears only once in the ’291 patent concerning Figure 3. The patent does not describe all filaments as being “loosened.” Thus, even if

“loosened” were synonymous with “flexible,” PO has failed to show the patent uses words of manifest exclusion or restriction to limit the meaning of “filament.” See *Innova/Pure Water*, 381 F.3d at 1117 (“even where a patent describes only a single embodiment, claims will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using words or expressions of manifest exclusion or restriction”) (internal citations omitted).

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	1-3, 5-8, 12-17, 19
2	Schaffer	35 U.S.C. § 103	1-3, 5-8, 12-17, 19
3	Schaffer + Hartley	35 U.S.C. § 103	1-8, 12-17, 19
4	Schaffer + Eller	35 U.S.C. § 103	1-8, 12-17, 19
5	Garrison + Schaffer	35 U.S.C. § 103	18-19
6	Garrison + Schaffer + Hartley	35 U.S.C. § 103	18-19
7	Garrison + Schaffer + Eller	35 U.S.C. § 103	18-19

B. The Asserted References Are Prior Art

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

- (1) Schaffer (Ex. 1005) published on December 4, 2003;
- (2) Hartley (Ex. 1006) published on June 26, 2003;
- (3) Eller (Ex. 1007) published on October 29, 2015; and
- (4) Garrison (Ex. 1011) published on June 25, 2015.

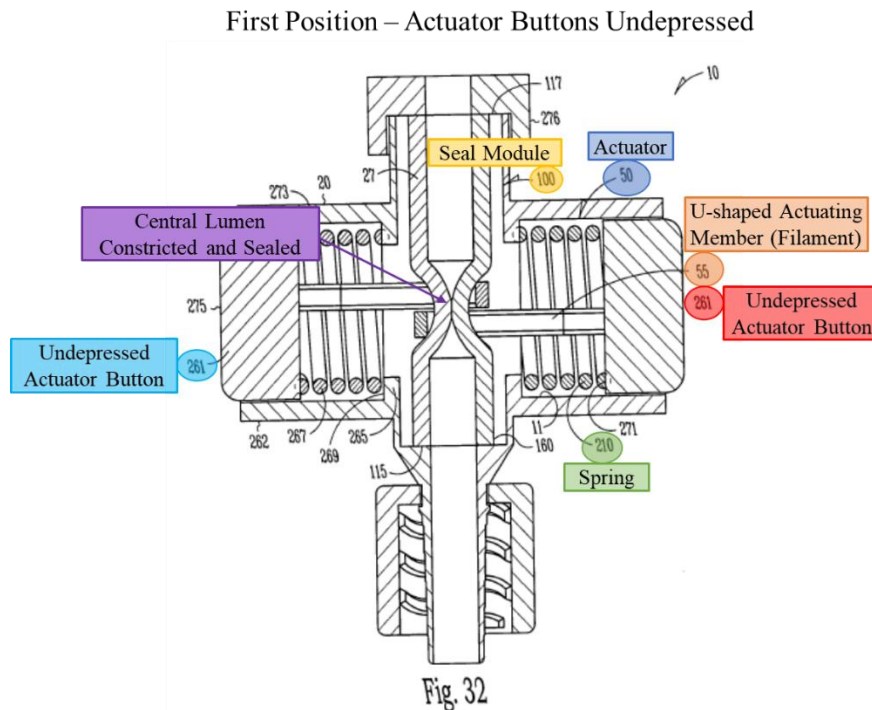
C. The Asserted References Are Analogous Art

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 '291 patent, e.g., hemostasis valves for use during intravascular procedures. (Ex. 1003, ¶27.) 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. GROUND 1-4: CLAIMS 1-8 AND 12-17, AND 19 ANTICIPATED BY SCHAFFER OR OBVIOUS OVER SCHAFFER ALONE OR IN COMBINATION WITH HARTLEY OR ELLER

Schaffer anticipates claims 1-3, 5-8, 12-17, and 19 or renders them obvious. (Ex. 1003, ¶¶74182.) Schaffer discloses a hemostasis valve for use with catheters “that blocks the flow of gas or fluid completely and immediately with or without an

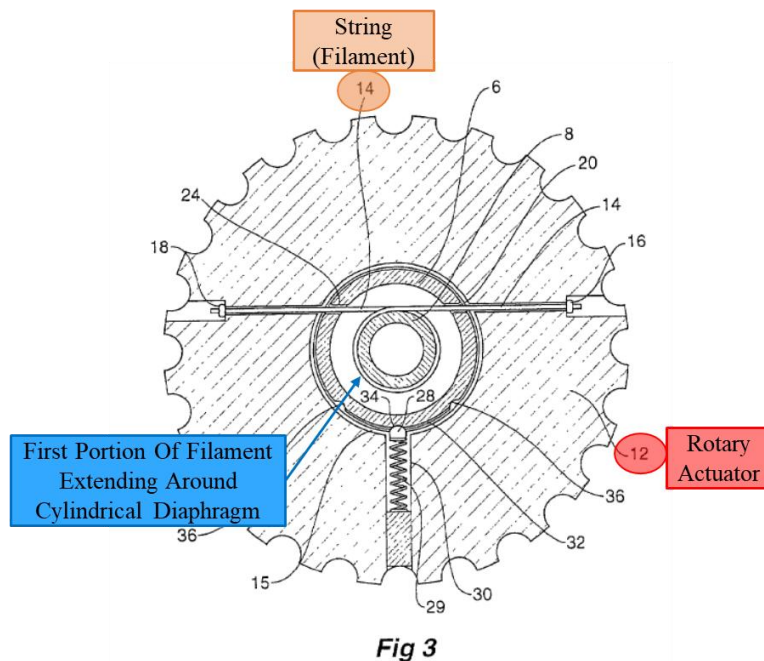
instrument in place within the gas/fluid path.” (Ex. 1005, [0002], [0008].) Like the valve in the ’291 patent, Schaffer’s valve includes a collapsible elongate member (“seal module 100”). (*Id.*, [0049]) Schaffer’s valve also includes a filament (actuating members 55) that can constrict the elongate member to close the valve. (*Id.*, [0076]-[0077].) Also, like the ’291 patent, Schaffer’s actuating members 55 may be moved from a first position to a second position by depressing two actuator buttons 261 connected to two springs 210. (*Id.*)



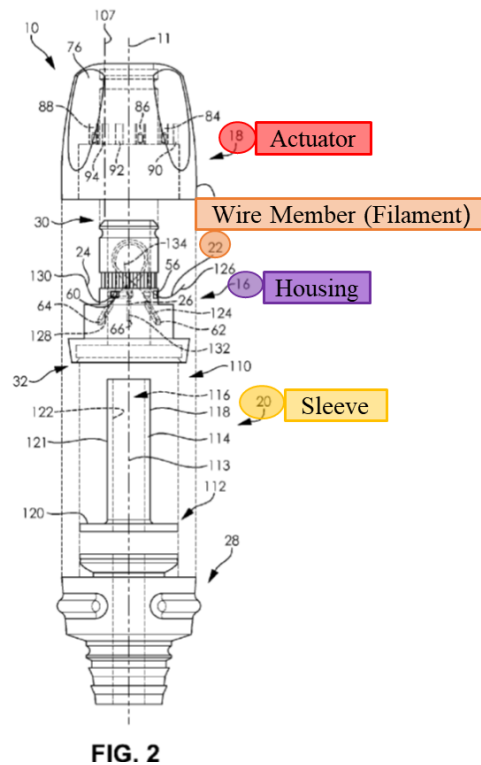
(*Id.*, Fig. 32.) Thus, Schaffer discloses the claimed valve.

If the Board limits the claims to a “flexible” filament and finds that Schaffer discloses **only** “rigid” actuating members, a POSITA would have found it obvious to make Schaffer’s actuating members more flexible. (Ex. 1003, ¶¶95-98.)

Moreover, regardless of whether the “filament” is flexible, Schaffer combined with Hartley or Eller renders claims 1-8, 12-17, and 19 obvious. (Ex. 1003, ¶¶103-131.) Hartley and Eller disclose hemostasis valves having filaments that loop around and constrict the lumen of an elongate member to seal the valve. Hartley’s “filament” is a “string”:



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



(Ex. 1007, 5:1-6, Fig. 2.) As the Board has preliminarily found in the '011 and '012 patent IPRs and as explained herein, a POSITA would have found it obvious to substitute Hartley's or Eller's filaments for Schaffer's actuating members. (Ex. 1017, 33-41; Ex. 1023, 34-48.)

A. Claim 1

Schaffer anticipates claim 1 or renders claim 1 obvious alone⁶ or in view of Hartley *or* Eller. (Ex. 1003, ¶¶78-135.)

⁶ “[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.

1. Preamble

If the preamble is limiting, Schaffer, Hartley, and Eller disclose a “hemostasis valve.” (Ex. 1003, ¶¶79-82.)

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].)

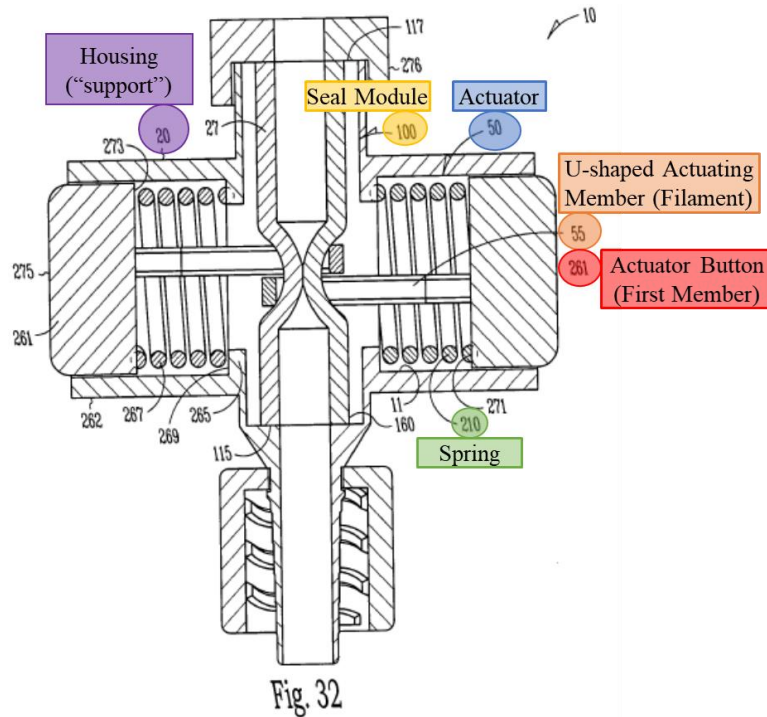
Hartley discloses “an access valve” for use in “medical applications ... where it is desired to seal around a catheter or other instrument ... to prevent loss of blood or other fluid.” (Ex. 1006, [0002]-[0004].)

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. Support

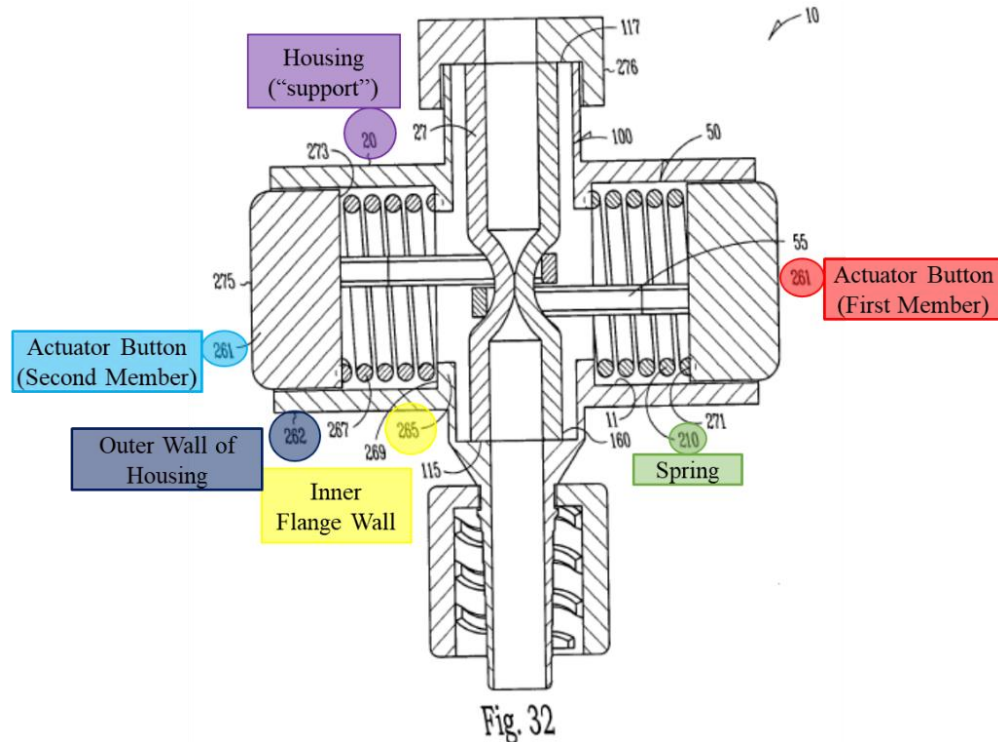
Claim 1 recites that the hemostasis valve comprises “a support.” Schaffer discloses “a support.” (Ex. 1003, ¶¶83-86.)

Schaffer’s hemostasis valve includes housing 20:



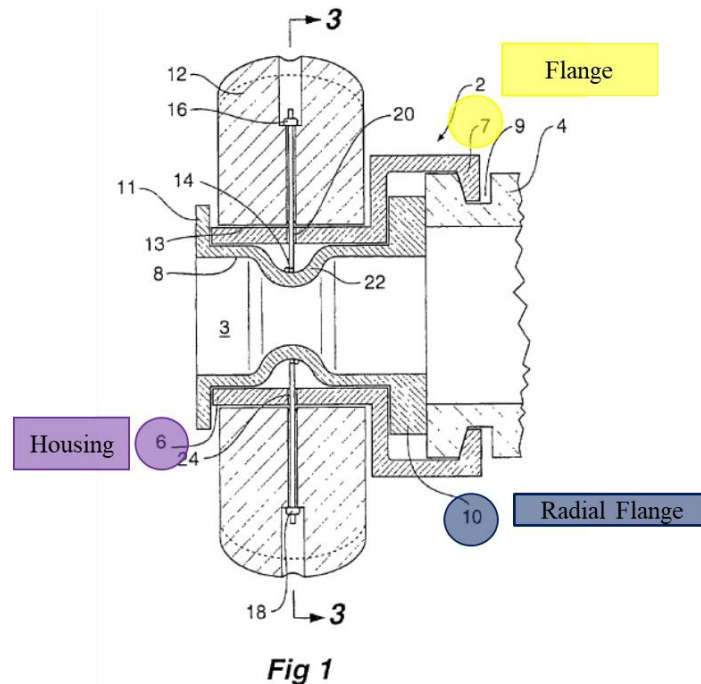
(Ex. 1005, [0076], Fig. 32.) Schaffer discloses that the housing supports other parts of the valve. Specifically, Schaffer explains that the “outer wall 262 of the housing 20 and the inner flange wall 265 of the housing 20 provides opposing **support** for two resilient members 267 (e.g., spring 210) disposed within the actuating member 55.” (*Id.*, [0076] (emphasis added).) Schaffer’s housing also meets the other limitations in claim 1 that reference the “support.” As shown in the next section, Schaffer’s first member is “movably coupled to the support [i.e., housing].” (*Infra* §VI.A.3.) Likewise, as discussed further below, Schaffer’s collapsible tubular member is “carried by the support [i.e., housing].” (*Infra* §VI.A.4.) Schaffer’s housing also satisfies the limitation in Claim 9, which is not challenged in this IPR, that requires: “the spring is positioned between the first member and the support.”

As shown below, Schaffer's springs are positioned between the first/second members (actuator buttons) and the inner flange wall 265 of the housing 20:



(Ex. 1005, Fig. 32.)

Additionally, during prosecution of the '291 patent, the examiner found that Hartley's hemostasis valve included a "support." Specifically, the examiner found three elements satisfied the "support" limitation: (1) Hartley's housing 6, (2) flange 7 on Hartley's housing, and (3) radial flange 10 on Hartley's cylindrical diaphragm:



(Ex. 1002, 393-395; Ex. 1006, [0031], Fig. 1.) As shown in Schaffer’s Figure 32 above, Schaffer’s valve also includes a housing 20 and an inner flange wall 265 on the housing similar to the ones in Hartley so at least these features satisfy the “support” limitation, as required by claim 1. (Ex. 1003, ¶185.)

In the co-pending Litigation, Petitioner argues that the term “support” is indefinite because PO has failed to “inform those skilled in the art about the scope of the invention with reasonable certainty.” *Nautilus*, 572 U.S. at 910. While the claims discussed above provide some information about the “support,” they fail to provide objective boundaries that would enable a competitor to, for example, design around the “support.” (See Ex. 1027 (Thornton Expert Report).)

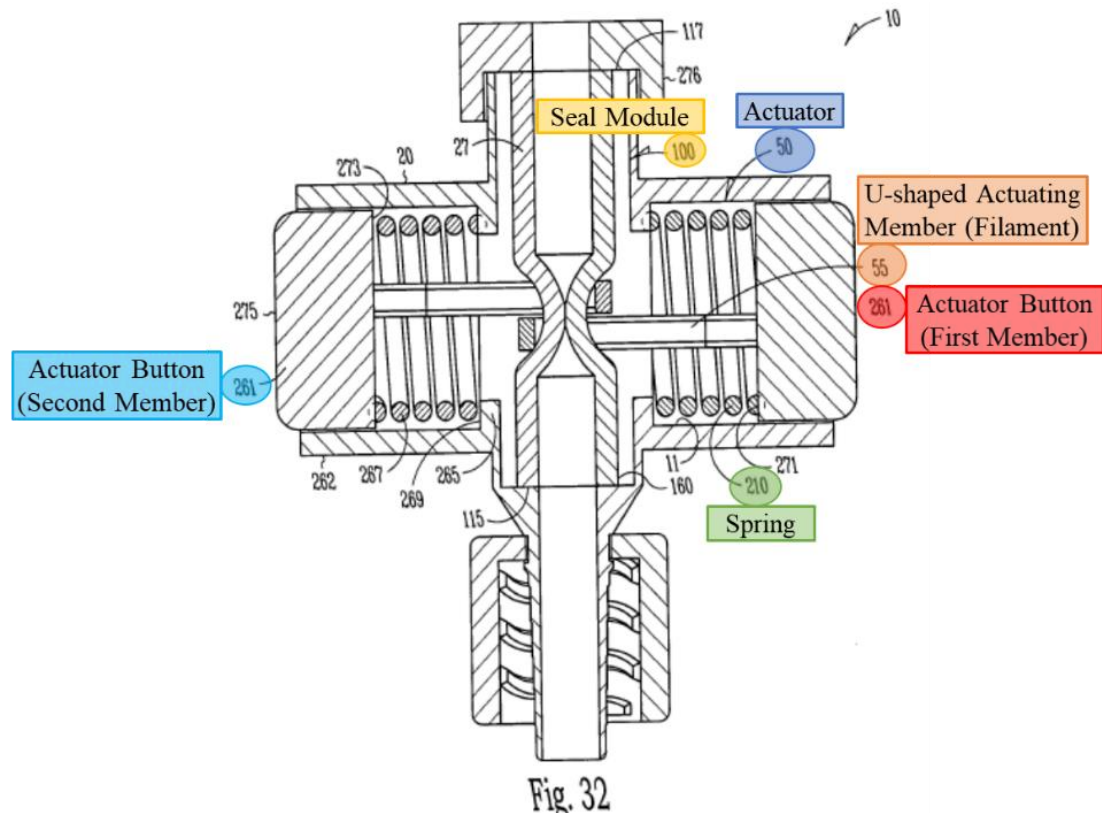
Similarly, the '291 patent specification does not use the term “support,” and does not describe any part of the hemostasis valve as a “support.” Thus, the specification does not provide any guidance on the scope of “support.”

The prosecution history also does not provide objective boundaries for the term “support.” While the examiner’s statements help identify some features of a valve that fall within the scope of the claim, the examiner and PO never define what structures would fall outside the term. As shown above, Schaffer’s valve includes the feature (e.g., Schaffer’s housing and flange) described in the prosecution history as satisfying the “support” limitation and, therefore, discloses a “support.” Consequently, the Board can resolve this IPR without addressing whether “support” is indefinite. *Realtime Data*, 912 F.3d at 1375.

3. Actuator

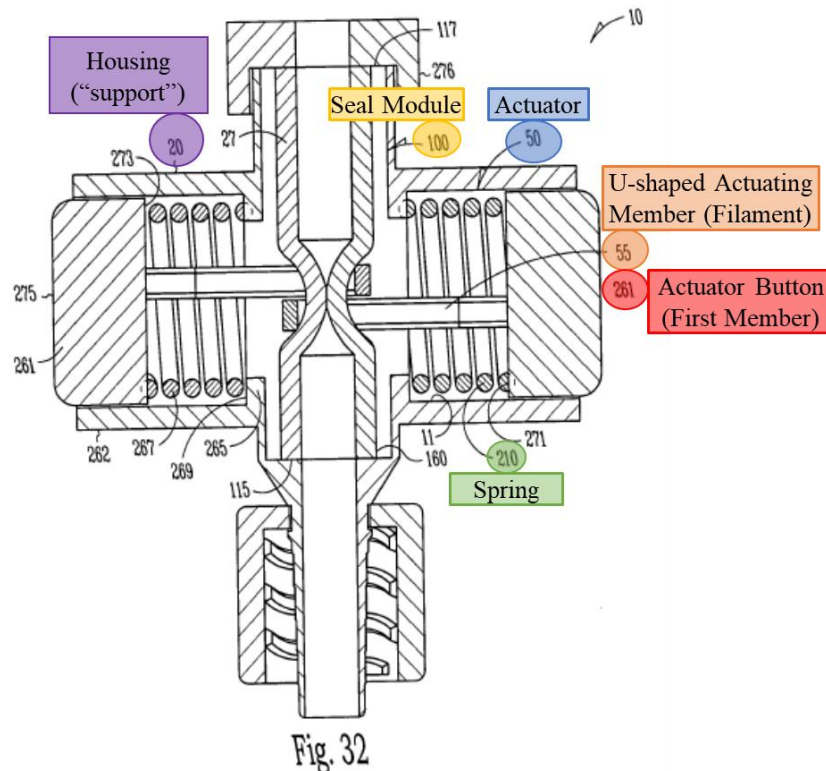
Claim 1 recites that the hemostasis valve comprises “an actuator having at least a first member movably coupled to the support.” Schaffer discloses this limitation. (Ex. 1003, ¶¶87-89.)

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” attached to a “spring 210.” (*Id.*) Petitioner has designated the right actuator button (shown above) as the “first member,” although the left actuator button could also serve as the “first member.” (Ex. 1003, ¶88.)

Schaffer’s “actuators 50 are configured cylindrically to slide along the cylindrical interior wall 11 of the housing 20 from a first position to a second position.”

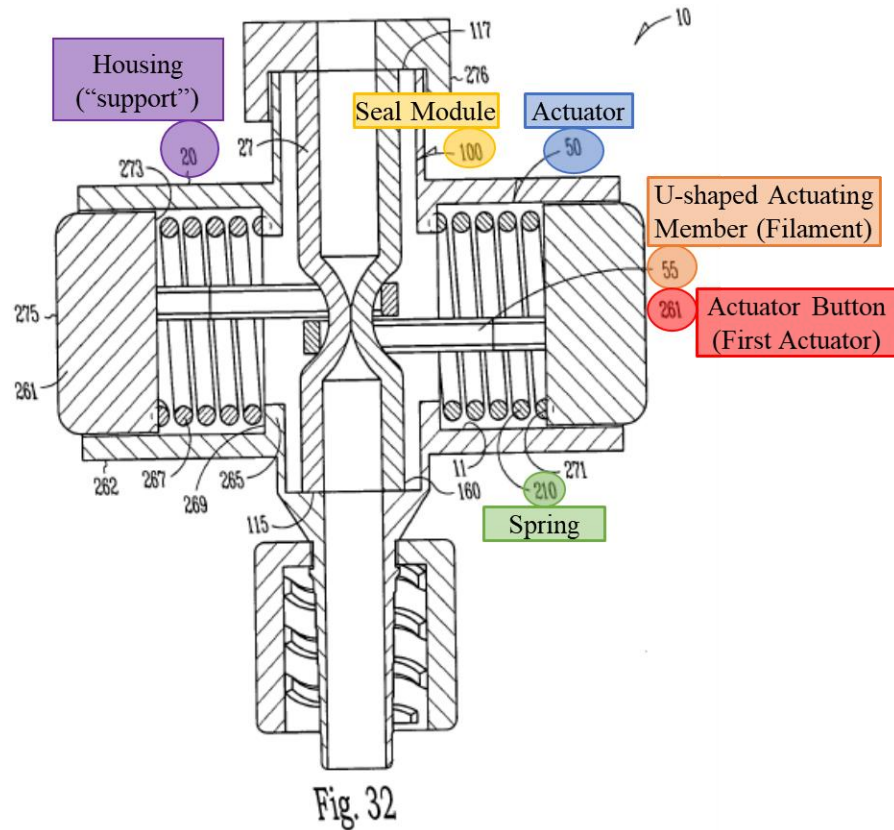


(Ex. 1005, [0076], Fig. 32; *see also id.*, [0083] (the actuator button 261 is inserted into the housing during assembly).) Thus, Schaeffer’s actuator button (first member) is movably coupled to the housing (support). (Ex. 1003, ¶89.)

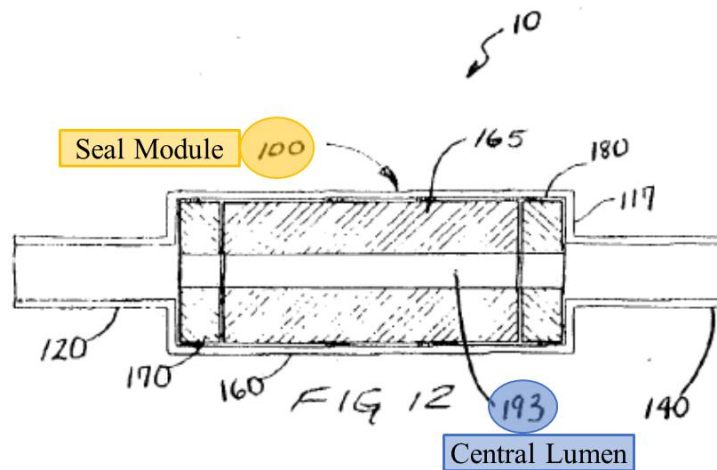
4. Collapsible Tubular Sidewall

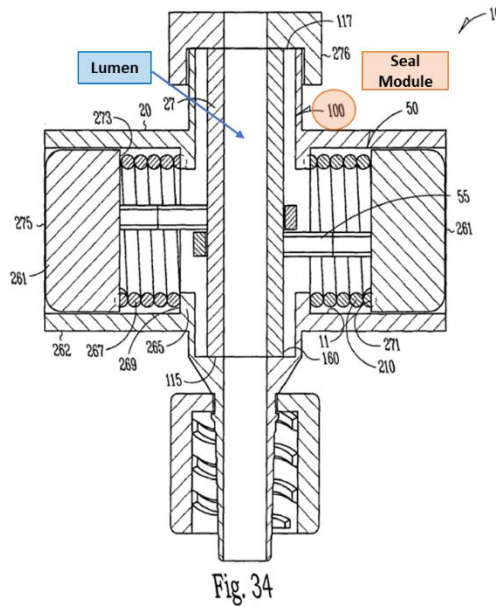
Claim 1 recites that the hemostasis valve comprises “a collapsible tubular sidewall defining a lumen carried by the support.” Schaffer discloses this limitation. (Ex. 1003, ¶¶90-92.)

Schaffer’s valve includes a “seal module 100” that comprises “a flexible, elongate tubular structure 101.” (Ex. 1005, [0049], [0051], [0054], [0075].) The seal module can be “at least partially collaps[ed] ... by a compressive force.” (*Id.*, [0077].) In Figure 32 below, the seal module is entirely collapsed:



(*Id.*, Fig. 32.) The seal module 100 (collapsible tubular sidewall) defines a lumen 193:





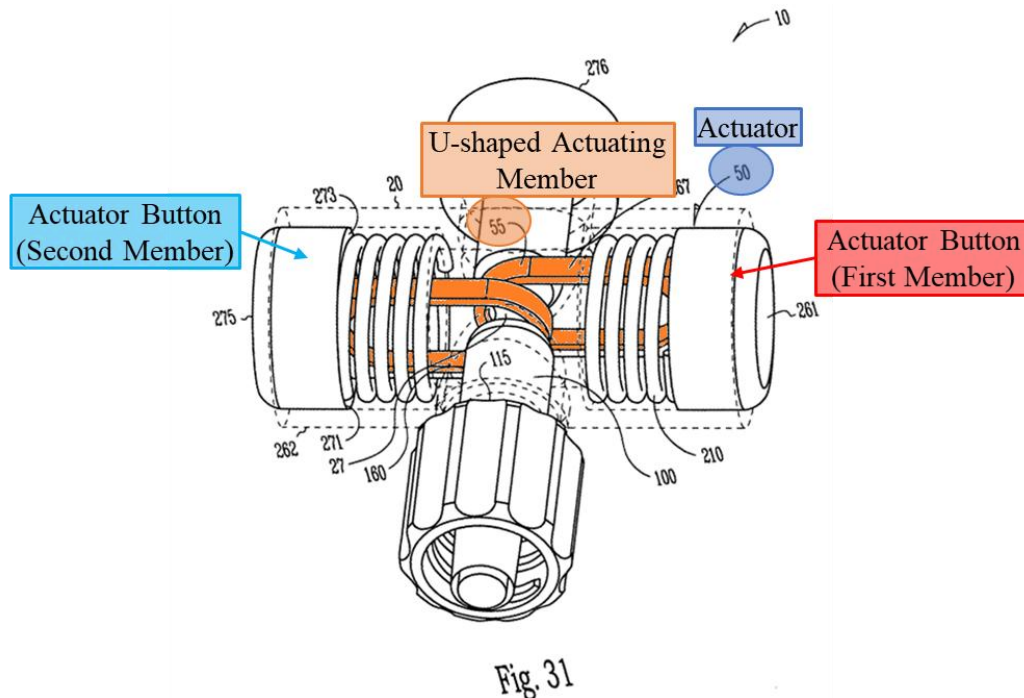
(*Id.*, [0058], [0075], Figs. 12, 32, 34.) As shown in Figure 32 above, the seal module is carried by the housing 20 (support) because the seal module is enclosed within the housing. (*Id.*; see also *id.*, [0083] (“the seal module 100 is inserted through the housing 20 and between each actuator”); claim 3 (“wherein the seal module is enclosed in a housing”).) Thus, Schaeffer’s seal module is “a collapsible tubular sidewall defining a lumen carried by the support.” (Ex. 1003, ¶¶90-92.)

5. Filament

Claim 1 recites that the hemostasis valve comprises “a filament formed in a loop around the tubular sidewall, the filament having at least a first end portion extending away from the loop to the first member.” Schaffer discloses this limitation or renders the limitation obvious alone or in combination with Hartley or Eller. (Ex. 1003, ¶¶93-131.)

a. Schaffer

Schaffer discloses a “filament.” (Ex. 1003, ¶¶94-1024.) 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 a “filament” as claimed in the ’291 patent. (Ex. 1003, ¶94; *supra* §IV.) Schaffer discloses the actuating members may be formed from metal or plastic, and, as shown in Figure 31 above, resemble a ribbon, flat wire, sheet, or tape. (Ex. 1005, [0081]-[0082], Figs. 31-34; Ex. 1003, ¶94.) Schaffer’s actuating members are therefore encompassed by the ’291 patent’s description of filaments. For example, the ’291 patent discloses that filaments may

be made from a polymer, which includes Schaffer’s plastic actuating members, or a metal, which includes Schaffer’s metal or aluminum actuating members. (*Supra* §IV.) Likewise, the ’291 patent states that a filament may be a ribbon, flat wire, sheet, or tape, which includes Schaffer’s actuating members. (*Id.*; Ex. 1003, ¶94.)

In the ’011 and ’012 patent IPRs, PO argued that Schaffer’s actuating members are “rigid” and, therefore, not a filament. (Ex. 1017, 38; Ex. 1023, 32.) In the ’011 patent institution decision, the Board did not adopt a position on whether Schaffer was limited to “rigid” actuating members, stating “even assuming [PO’s] characterization of Schaffer’s U-shaped actuating members as being ‘rigid’ is correct, that does not necessarily foreclose Petitioner’s anticipation challenge.” (Ex. 1017, 32.)

In the ’012 patent institution decision, the Board stated that “a skilled artisan would more likely understand the U-shaped actuating members described in Schaffer as being substantially ‘rigid.’” (Ex. 1023, 32.) As support, the Board cited testimony from PO’s expert arguing that Schaffer’s example of machining the members from plastic or metal indicates a “rigid” material. (*Id.*) There are several problems with PO’s expert testimony.

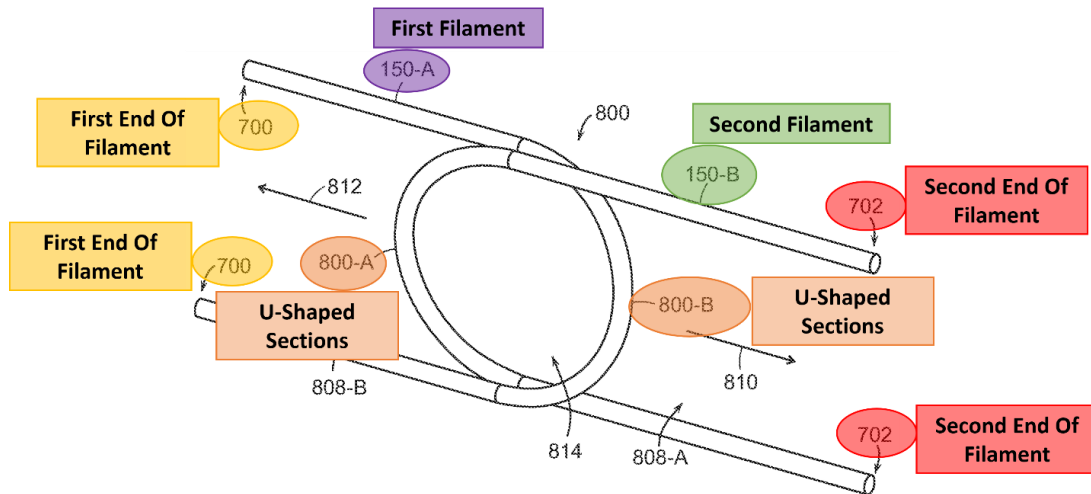
First, as previously recognized by the Board, rigidity exists along a spectrum. (*Supra* §IV.2.) Schaffer does not mention rigidity and does not identify any dimensions or physical properties that would lead a POSITA to believe that the

actuating members must be rigid. (Ex. 1003, ¶95.) On the contrary, a POSITA would have recognized that Schaffer’s actuating members would have some flexibility. (*Id.*) Even the Board’s statement that the actuating members would be “**substantially** rigid” recognizes that the members would have some flexibility. The problem with importing the term “flexible” into the construction of “filament” is that the ’291 patent provides no guidance as to how “flexible” a material must be to meet the claims.

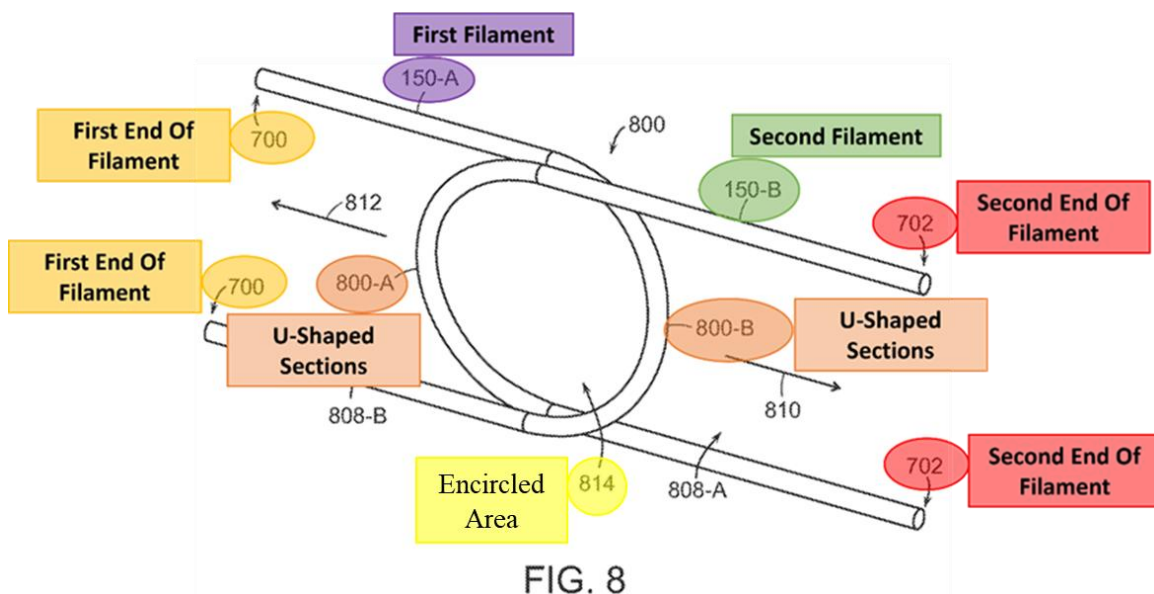
Second, the description of a device as “made from machining” is not dispositive of whether the finished product is “flexible” or “rigid.” (Ex. 1003, ¶96.) As more metal or plastic is removed during the machining process, the material will have increased flexibility. (*Id.*) Third, Schaffer offers “machining” as “one option” for making the actuating members. (Ex. 1005, [0082].) A POSITA would have known that the U-shaped actuating members could be made using a variety of manufacturing techniques, including extrusion and drawing, which could result in flexible members. (Ex. 1003, ¶96.) Fourth, Schaffer’s actuating members would work if they were flexible. A metal having the dimensions in a paper clip, for example, would unquestionably be flexible, and even flexible enough to form a loop, and would work perfectly well in Schaffer’s valve. (*Id.*) Thus, PO’s attempts to limit Schaffer to only “rigid” actuating members is unsupported.

However, even if Schaffer’s actuating members were “rigid,” a POSITA would have found it obvious to use “flexible” materials to form the actuating members. (Ex. 1003, ¶98.) A POSITA would have understood that a thin, flexible material would have allowed the actuating members to conform as much as possible to the outer surface of the seal module and the tool inserted therethrough. (*Id.*) Not all tools have a circular profile so using more flexible actuating members allows the members to more closely conform to the tools. (*Id.*) As discussed below, a POSITA would have reasonably expected flexible materials, like a string or wire, to work in Schaffer’s device. (*Infra* §§VI.A.5.b-c.)

Schaffer’s actuating members also satisfy the limitation requiring a “filament formed in a loop around the tubular sidewall.” (Ex. 1003, ¶¶99-102.) The ’291 patent specifically discloses that two sub-filaments, like Schaffer’s two U-shaped actuating members 55, can form “a filament,” as required by claim 1. The ’291 patent states that the “**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”:



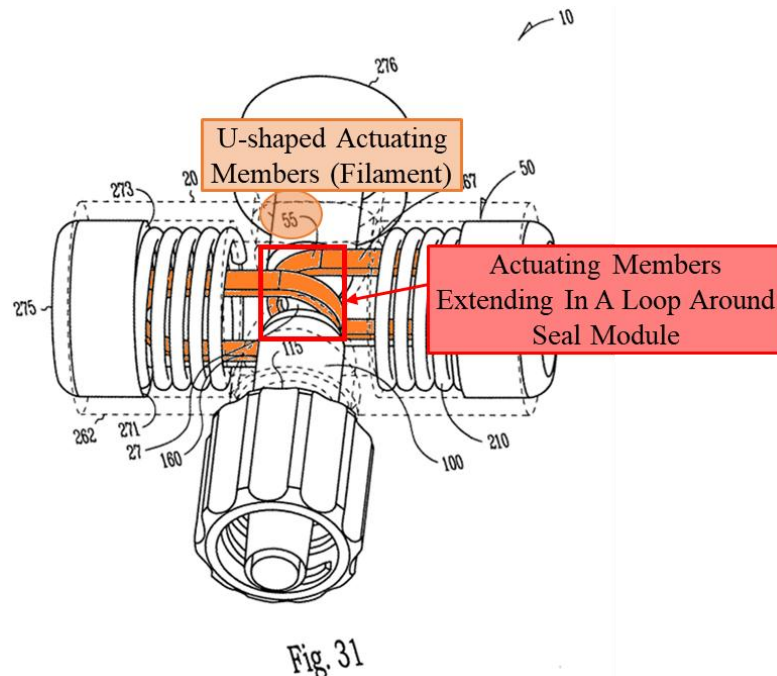
(Ex. 1001, 12:61-64, Fig. 8 (emphasis added).) The '291 patent also discloses that “different embodiments and/or configurations of the filament 150 are shown” in Figures 6 through 9. (*Id.*, 12:44-46 (emphasis added).) Likewise, the '291 patent explains that the sub-filaments illustrated in Figure 8 form a loop, specifically describing the area between the u-shaped sections as an “encircled area 814.” (*Id.*, 13:57-61.)



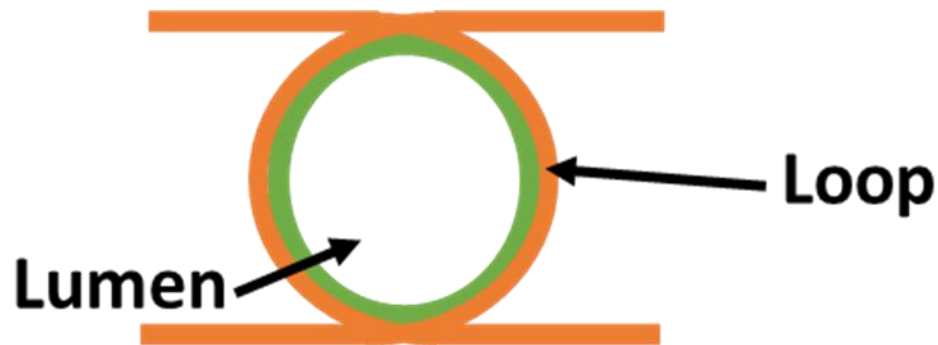
(*Id.*, Fig. 8.)

Similarly, the claims of the '291 patent confirm that the loop in claim 1 may be formed by multiple sub-filaments. Dependent claim 4 requires the filament's first end portion, second end portion, and loop to be "one continuous filament." Thus, the "filament" in claim 1 does not **not** need to be one continuous filament, otherwise claim 4 would not narrow the independent claim. See 35 U.S.C. § 112(d) (requiring dependent claim to "specify a further limitation of the subject matter claimed"). Accordingly, Schaffer's U-shaped actuating members collectively constitute the "filament formed in a loop around the tubular sidewall" recited in claim 1 of the '291 patent. (Ex. 1003, ¶¶99-100); see also *SanDisk Corp. v. Kingston Tech. Co., Inc.*, 695 F.3d 1348, 1360 (Fed. Cir. 2012) ("the later use of 'the' ... to refer back to an earlier claim term does not limit that claim term to the singular"); *Biagro W. Sales, Inc. v. Grow More, Inc.*, 423 F.3d 1296, 1304 (Fed. Cir. 2005).

Schaffer's Figure 31 illustrates that the actuating members 55 form a loop around the seal module 100 (collapsible tubular sidewall):



(Ex. 1005, [0076], Fig. 31; Ex. 1003, ¶99.) The demonstrative below illustrates the loop formed by the U-shaped actuating members:



(Ex. 1003, ¶99.) Schaffer’s specification further confirms that each actuating member is “at least partially circumferentially [sic] disposed about the portion 108 of the seal module” to collectively form a loop. (Ex. 1005, [0077].)

Further, the right actuating member includes a first end portion extending away from the loop:

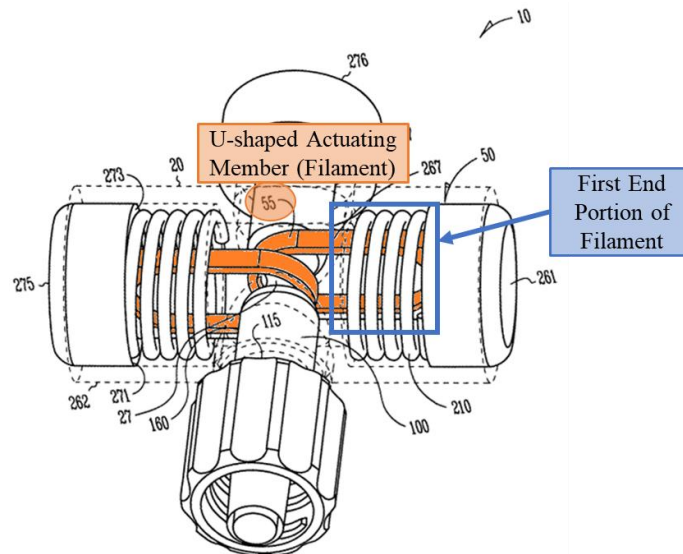
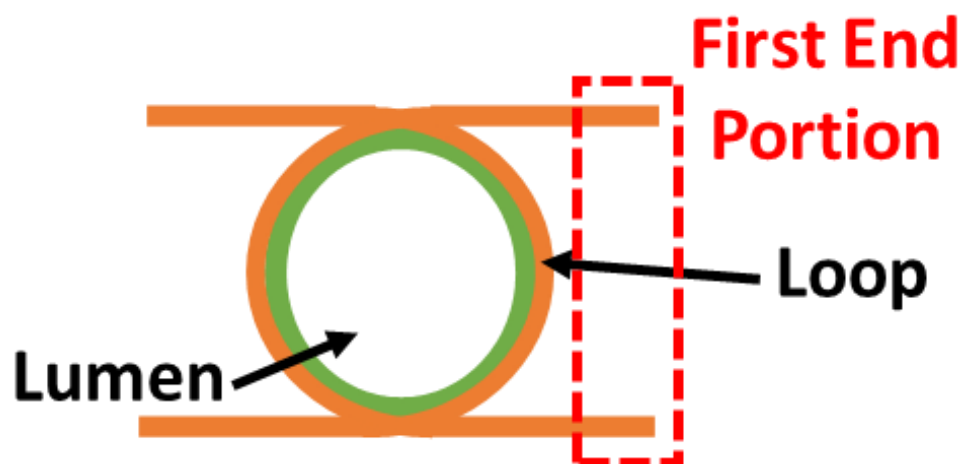


Fig. 31

(Ex. 1005, Fig. 31; Ex. 1003, ¶¶100-102.) The first end portion is also identified in the demonstrative below by the red box:



(Ex. 1003, ¶101.)

The identification of Schaffer's first end portion above is consistent with the '291 patent. The '291 patent discloses that where "the filament 150 comprises

multiple filaments, each of the multiple filaments can have a **first end 700** and a **second end 702**”:

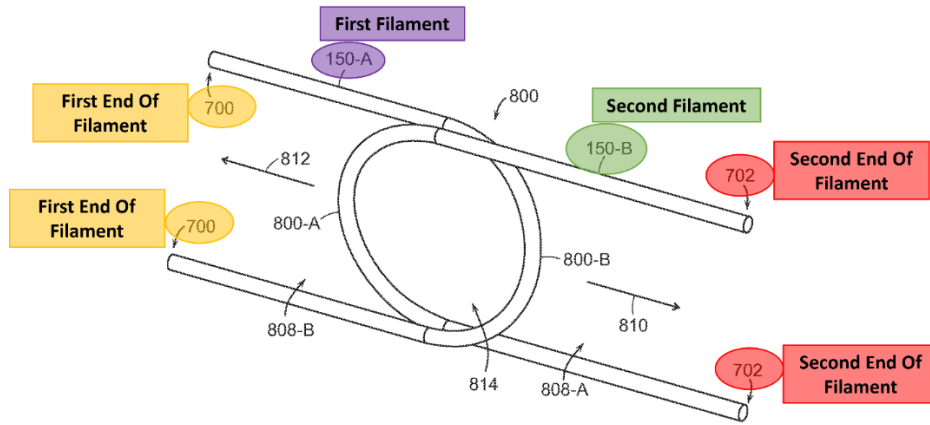


FIG. 8

(Ex. 1001, 12:64-67, Fig. 8 (emphasis added).) Consistent with this disclosure, the first end portion of Schaffer’s U-shaped actuating members extends away from the loop and attaches to the first actuator button (first member):

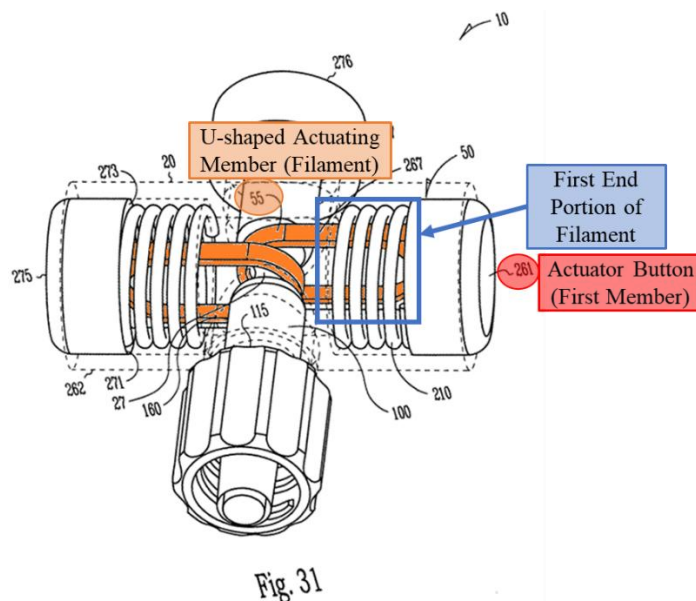


Fig 31

(Ex. 1005, [0076], Figs. 31-32; Ex. 1003, ¶102.) Thus, Schaeffer discloses the “filament” required by claim 1 or renders it obvious. (Ex. 1003, ¶¶94-102.)

b. Hartley

Hartley also discloses a filament. (Ex. 1003, ¶¶103-117.) Hartley describes a hemostasis valve having a cylindrical housing that holds a “cylindrical elastomeric diaphragm,” and a rotary actuator mounted to the housing:

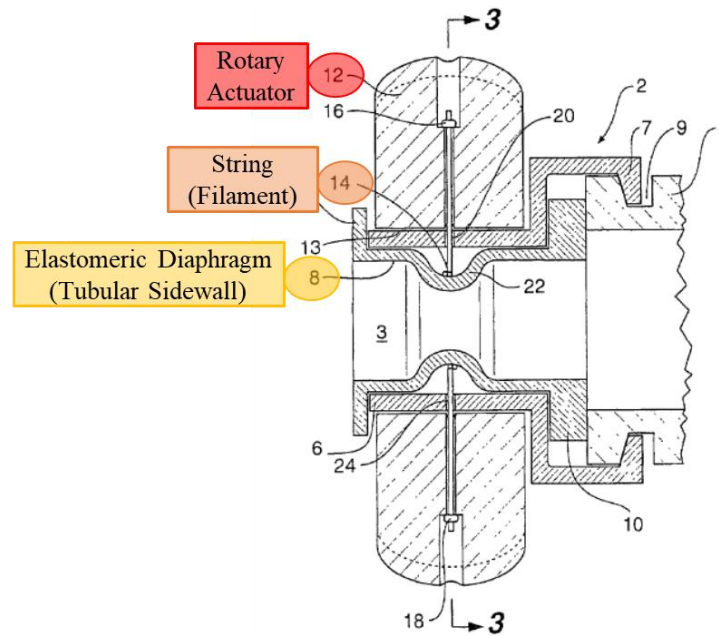


Fig 1

(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, ¶103.)

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”:

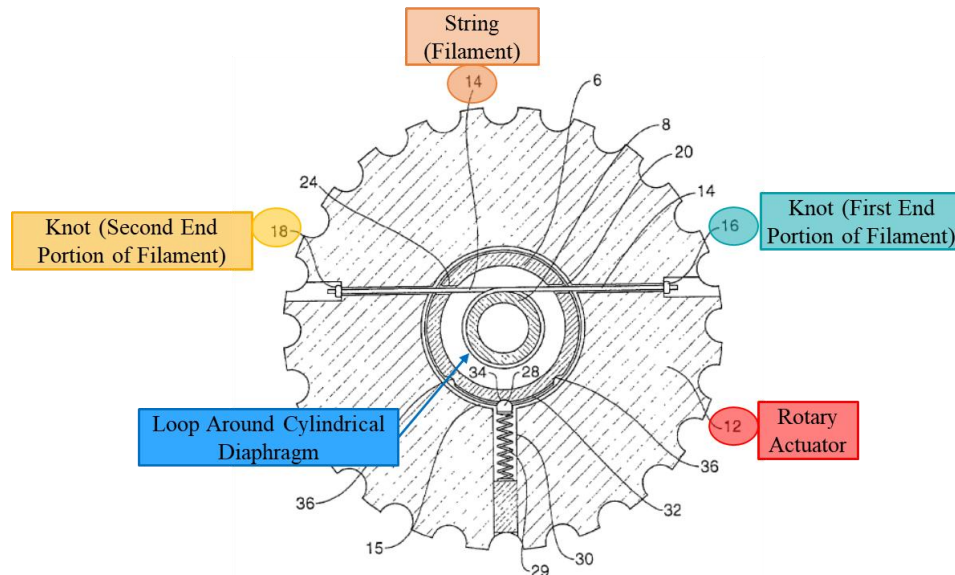


Fig 3

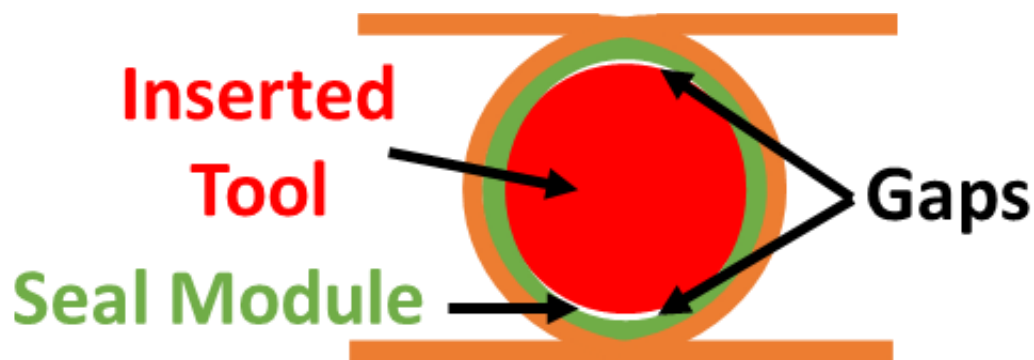
(Ex. 1006, [0031], Fig. 3.) As shown above, Hartley’s string forms a loop around the cylindrical diaphragm (tubular sidewall) and has a first end portion extending away from the loop. (Ex. 1003, ¶104.)

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 the 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 Schaffer’s first button, looping the string around Schaffer’s seal module, and

attaching the string to Schaffer’s second button. (Ex. 1003, ¶¶106-117.) This combination of Hartley’s string and Schaffer’s valve would have merely entailed substitution of one known element (Hartley’s string) for another (Schaffer’s actuating members) to yield the predictable result of sealing Schaffer’s valve. *KSR Int’l Co. v. Teleflex, Inc.*, 550 U.S. 398, 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, ¶106.) 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, ¶107.) 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:



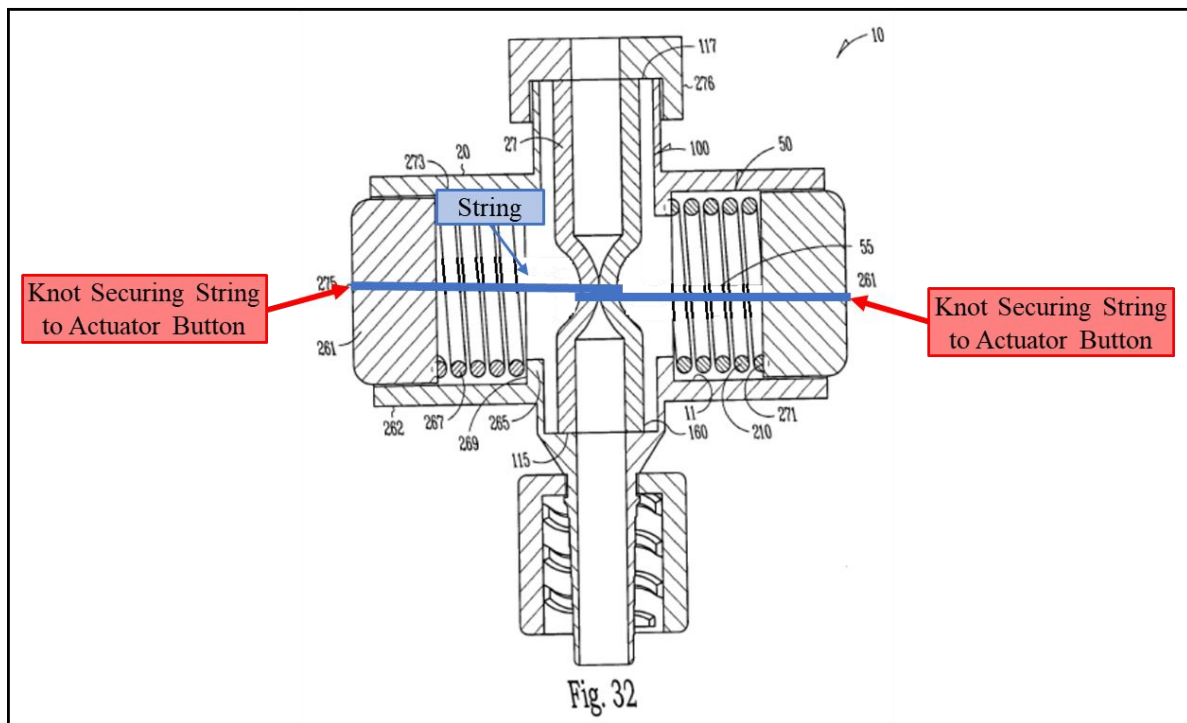
(*Id.*) Hartley’s string could improve upon this potential issue because the string more precisely conforms to the tool diameters and shapes. (*Id.*) In the ’011 patent IPR,

PO argued that Schaffer's valve would not create gaps. (See Ex. 1017, 37 (summarizing argument).) However, PO's argument depended on a single embodiment in Schaffer while ignoring other disclosures undermining the argument. (See Ex. 1003, ¶108 (explaining deficiencies in argument); see also Ex. 1017, 37 (same).)

POSITAs also had a finite number of materials to use for constricting a tubular member in a hemostasis valve in 2017. (Ex. 1003, ¶110.) 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, ¶¶112-117.) 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, ¶112.) 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.*)⁷

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.*, ¶113.) 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 pull the ends of the string in opposite directions to constrict

⁷ This image is a demonstrative prepared by Petitioner.

Schaffer's seal module. (Ex. 1003, ¶¶113-114.) Further, if Schaffer's springs did not initially exert sufficient force to pull Hartley's string and constrict the valve, a POSITA 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 a person of ordinary skill in the art in September 2017. (*Id.*)

Likewise, POSITAs would have reasonably expected that pressing Schaffer's buttons inwardly would release tension on the string, allowing the lumen to open. (See Ex. 1005, [0077]; Ex. 1006, [0034]; Ex. 1003, ¶¶115-117.) 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, ¶115.) 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.*, ¶116.) 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).)

Further, Hartley discloses that looping the string around the central lumen 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 similarly loop Hartley’s string around Schaffer’s seal module. (Ex. 1003, ¶117.) POSITAs would have reasonably expected success in using this configuration because Hartley teaches the configuration forms an effective seal. (*Id.*) Thus, Schaffer combined with Hartley renders claim 1 obvious. (*Id.*)

c. Eller

Eller also discloses a “filament.” (Ex. 1003, ¶118-131.) Eller describes hemostasis valves having “a housing 16, an actuator 18, a sleeve 20, [and] a first wire member 22”:

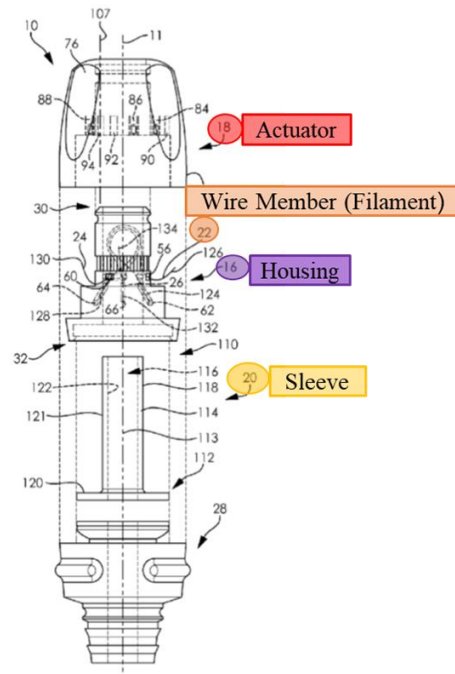


FIG. 2

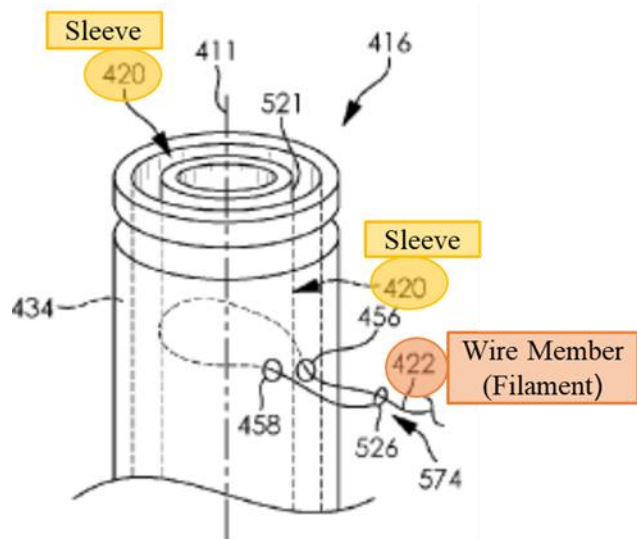


FIG. 16

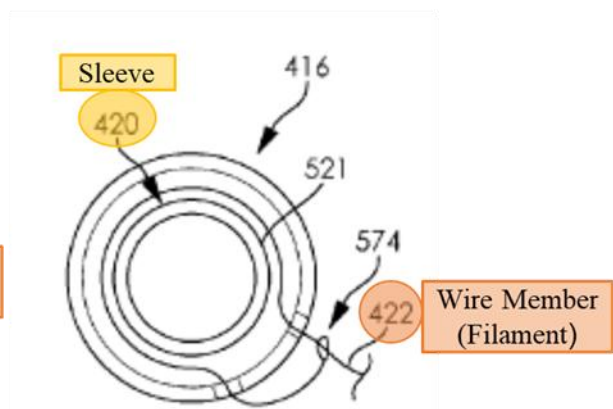


FIG. 17

(Ex. 1007, 5:1-5, 16:7-19, 21:37-22:31, 23:50-25:9, Fig. 2,⁸ 16-17.) Eller's wire member is a "filament" at least because it is made of at least one or more threads,

⁸ Eller's Figure 2 shows an exploded view of the device. (Ex. 1007, 2:46-47.)

lines, cords, rope, ribbon, flat wire, sheet, or tape. (Ex. 1003, ¶119; *supra* §IV.) Eller discloses 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.)

The wire member loops 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:

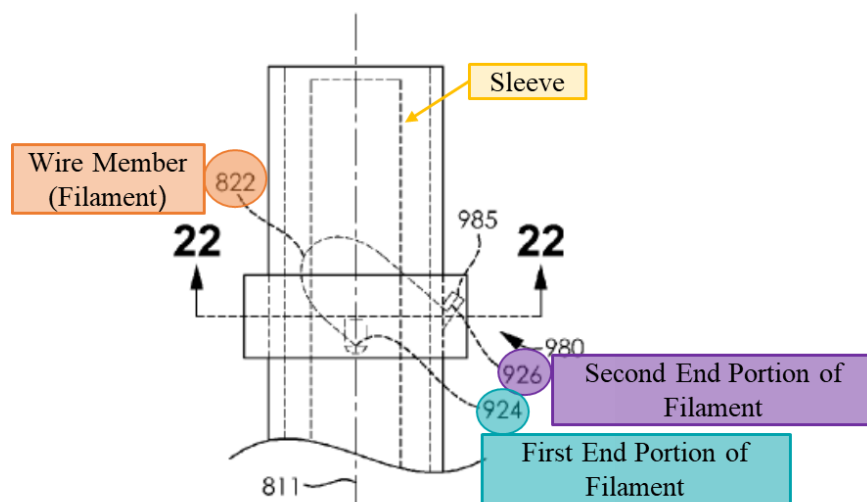


FIG. 21

(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, 18:3-8.)

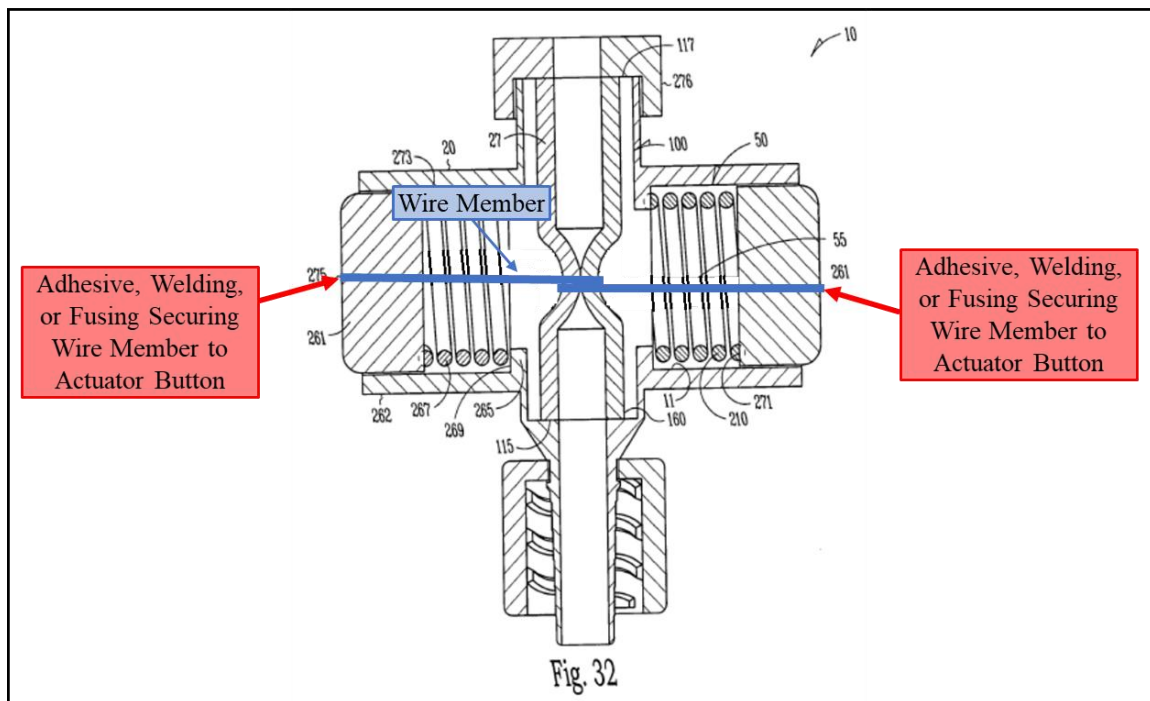
A POSITA would have found it obvious to substitute Eller’s wire member for Schaffer’s two actuating members by attaching one end of the wire to Schaffer’s first button, looping the wire around the seal module, and attaching the second end of the wire to Schaffer’s second button. (Ex. 1003, ¶¶123-131.) A POSITA would have been motivated to loop the wire around the seal module because Eller describes that configuration, and the configuration would maximize the constrictive seal around the module. (*Id.*, ¶131.) The combination of Eller’s wire member and Schaffer’s valve would have entailed merely substituting one known element (Eller’s wire member) for another (Schaffer’s two actuating members) to yield the predictable result of constricting Schaffer’s valve. *See 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 two actuating members. (Ex. 1007, 15:21-40, 17:38-43, 18:3-8; Ex. 1003, ¶123.) 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.5.b; Ex. 1003, ¶124.) 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 the lumen of a collapsible tubular sidewall in September 2017, as discussed in the previous section. (*Supra* § VI.A.5.b; Ex. 1003, ¶126.) 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 two actuating members for several reasons. (Ex. 1003, ¶¶127-131.) First, Eller discloses that the “[a]ttachment between a wire member and a housing and/or actuator can be accomplished using any suitable method or technique.” (Ex. 1007, 14:37-43.) Eller identifies several exemplary ways to secure its wire member to an actuator, including “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, ¶127.)

Demonstrative Illustration Schaffer + Eller's Wire Member



(*Id.*)⁹

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 teaches 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, ¶128.)

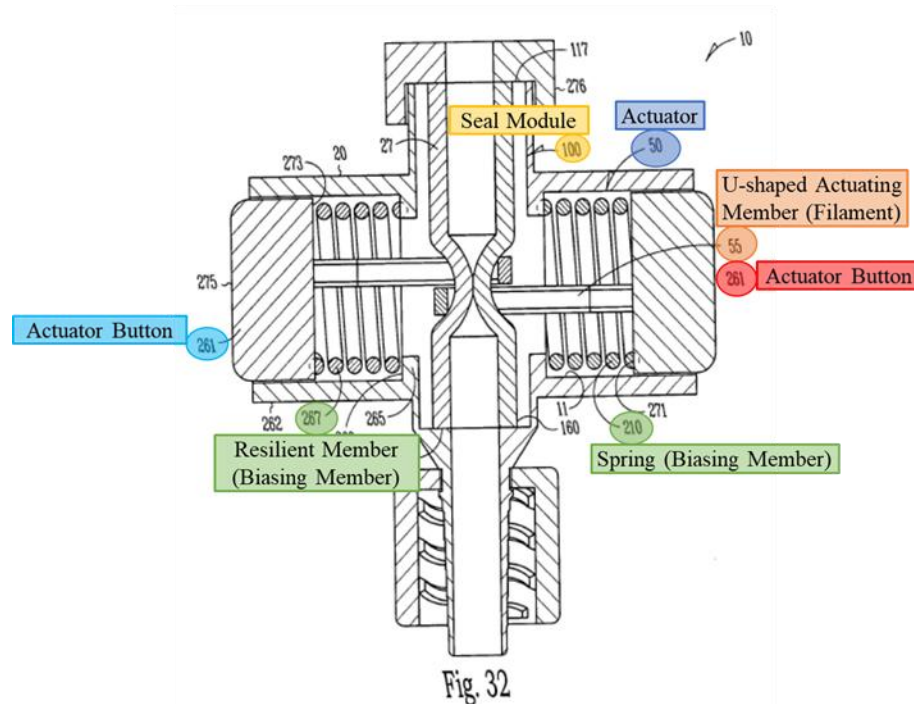
⁹ This image is a demonstrative prepared by Petitioner.

Third, Eller's wire member and Schaffer's actuating members function similarly to close the valves. (*Id.*, ¶129.) 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, ¶130.) 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 Schaffer's seal module. (See Ex. 1005, [0077]; Ex. 1007, 15:21-40, 17:47-18:3; Ex. 1003, ¶130.) 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. (See Ex. 1005, [0077]; Ex. 1007, 15:21-40, 17:47-18:3; Ex. 1003, ¶130.) 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.5.b; Ex. 1003, ¶130.) Further, if Schaffer's seal module or springs 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 claim 1 obvious.

6. Spring

Claim 1 finally recites that the hemostasis valve comprises “a spring configured to move the first member in a direction that pulls the first end portion away from the tubular sidewall, reducing a diameter of the lumen in response to reducing a diameter of the loop.” Schaffer discloses this limitation. (Ex. 1003, ¶¶132-134.)

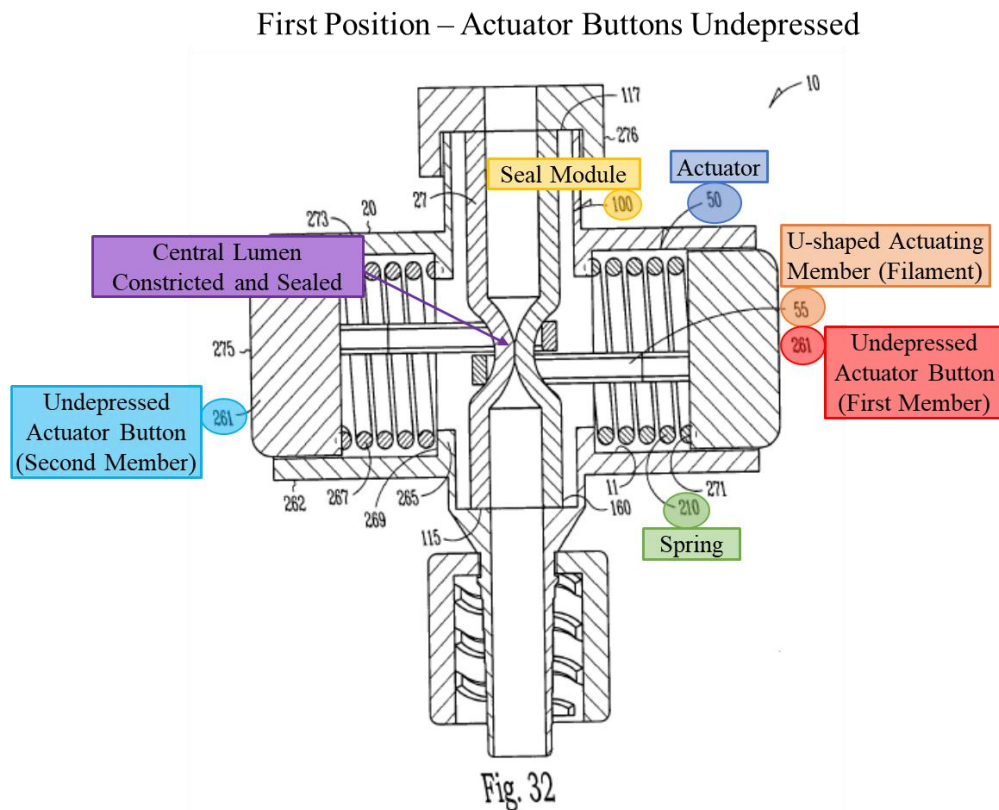
Schaffer’s hemostasis valve includes “two resilient members 267 (e.g., spring 210) disposed within the actuating member 55”:



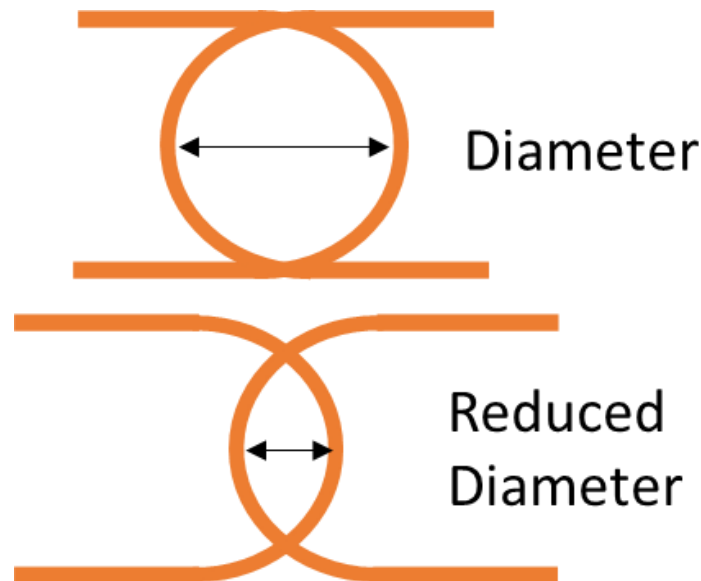
(Ex. 1005, [0076], Fig. 32.)

Schaffer’s actuator buttons are “movable from a first position to a second position.” (*Id.*) In Schaffer’s first position, shown in Figure 32, the spring moves

the first buttons outwardly (or away from the tubular sidewall). This movement causes the first member to pull the first end portion of the actuating member (filament) to reduce the diameter of the seal module lumen and constrict the valve:



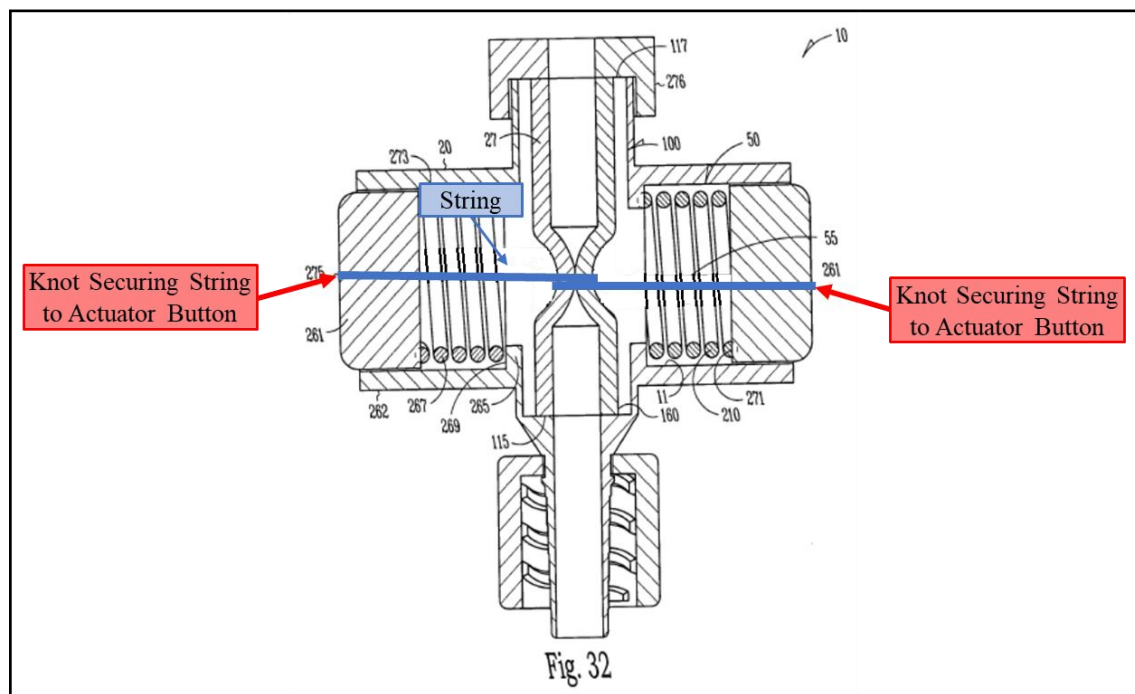
(*Id.*, [0008], [0077], Fig. 32; *see also* §VI.A.4; Ex. 1003, ¶134.) As illustrated in the demonstrative below, pulling on the ends of the filament reduces the diameter of the loop formed by the filament. (Ex. 1005, [0077], Figs. 31-34; Ex. 1003, ¶134.)



(Ex. 1003, ¶134.) Consequently, Schaffer discloses each limitation of claim 1 and anticipates claim 1. (*Id.*)

If Schaffer's two actuating members were replaced with Hartley's string or Eller's wire member, pulling on the ends of the string/wire would also reduce the diameter of the lumen in response to reducing the diameter of the loop formed by the string/wire. (Ex. 1003, ¶135.) As discussed in the prior sections, Hartley and Eller each disclose looping a filament around a collapsible tubular sidewall and pulling on the ends of the filament to reduce the diameter of the loop to constrict the tubular sidewall. (*Supra* §§VI.A.5b-c.) If Hartley's string and Eller's wire member were combined with Schaffer's valve, Schaffer's spring would move the buttons outwardly (away from the collapsible tubular sidewall), thereby pulling on the ends of the string/wire member to reduce the diameter of Schaffer's seal module (tubular sidewall) and the diameter of the loop, as demonstrated below:

Demonstrative Illustration Schaffer + Hartley's String

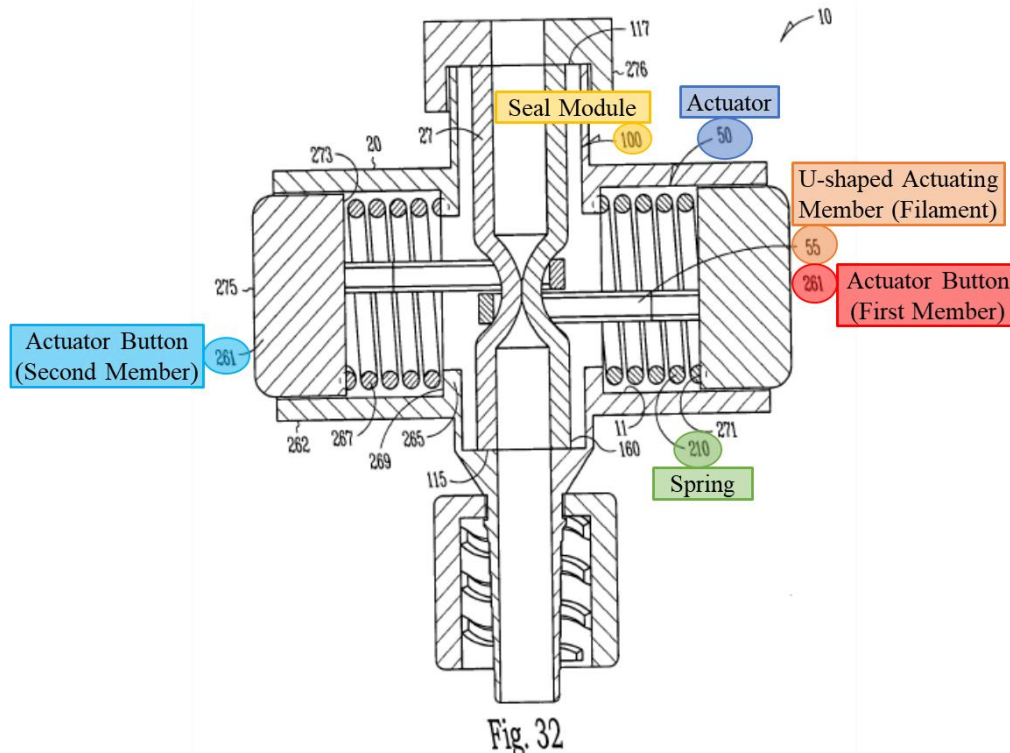


(Ex. 1003, ¶135.) A POSITA would have been motivated to combine Hartley's string or Eller's wire member with Schaffer's valve, and reasonably expected success in doing so, for the reasons provided previously. (*Supra* §§VI.A.5.b-c.) Thus, Schaffer combined with Hartley or Eller renders claim 1 obvious.

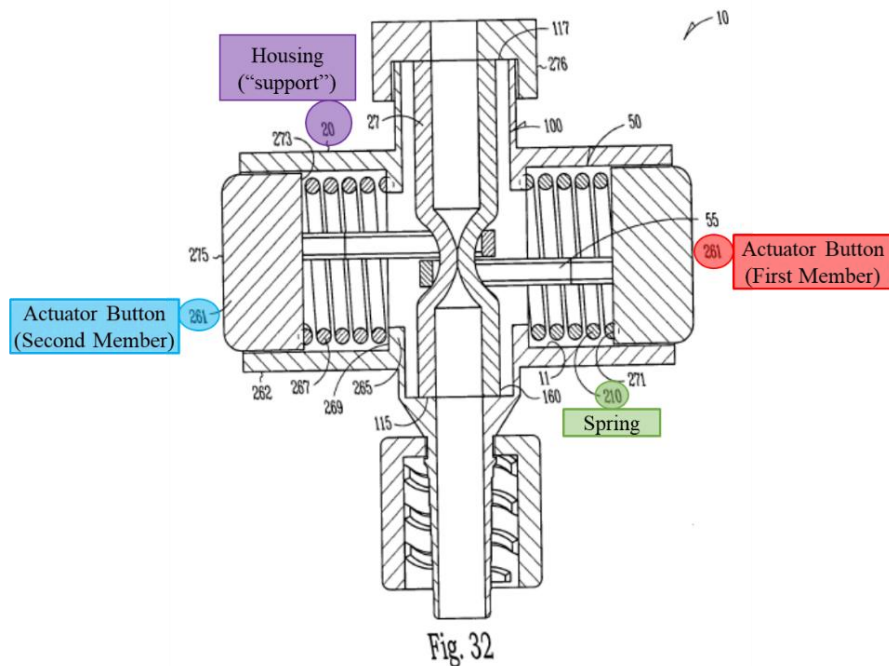
B. Claim 2

Claim 2 recites “[t]he hemostasis valve of claim 1, further comprising a second member movably coupled to the support.” Schaffer anticipates claim 2 or renders claim 2 obvious alone or in combination with Hartley or Eller. (Ex. 1003, ¶¶136-138.)

Schaffer's valve includes two actuator buttons 261. (Ex. 1005, [0075]-[0076], Figs. 31-32.) As explained in claim 1, the right actuator button is a “first member movably coupled to the support.” (*Supra* §VI.A.3.) Similarly, the left actuator button is a “second member movably coupled to the support”:



(Ex. 1005, [0075]-[0076], Figs. 31-32.) As with the first actuator button, the second actuator button (member) is “configured cylindrically to slide along the cylindrical interior wall 11 of the housing 20 from a first position to a second position.”

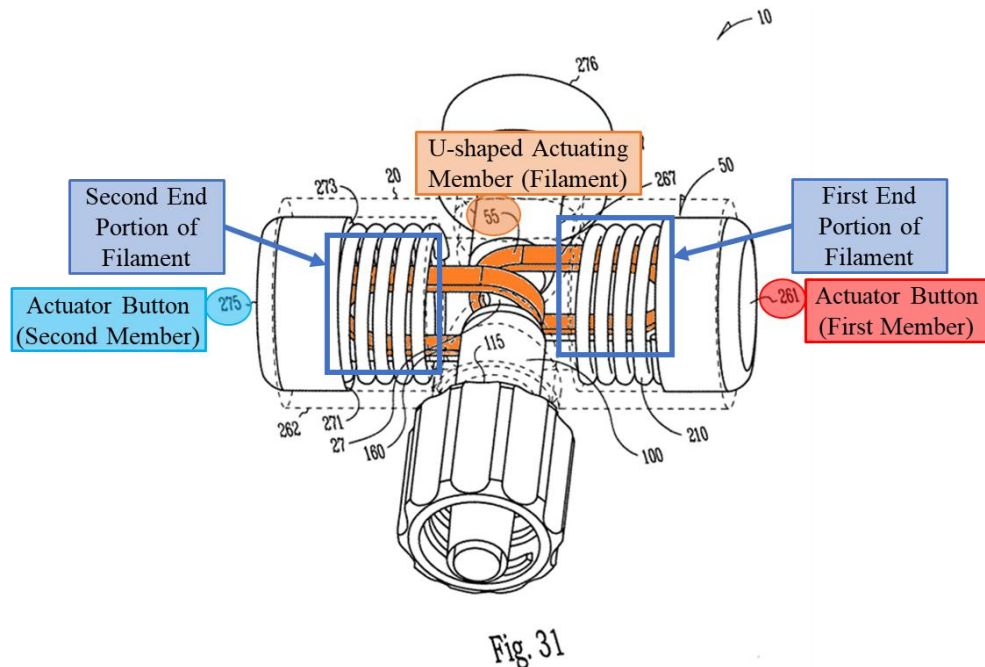


(*Id.*, [0076], Fig. 32; *see also id.*, [0083] (the actuator button 261 is inserted into the housing during assembly).) Thus, Schaeffer’s left actuator button (second member) is movably coupled the housing (support). (Ex. 1003, ¶138.)

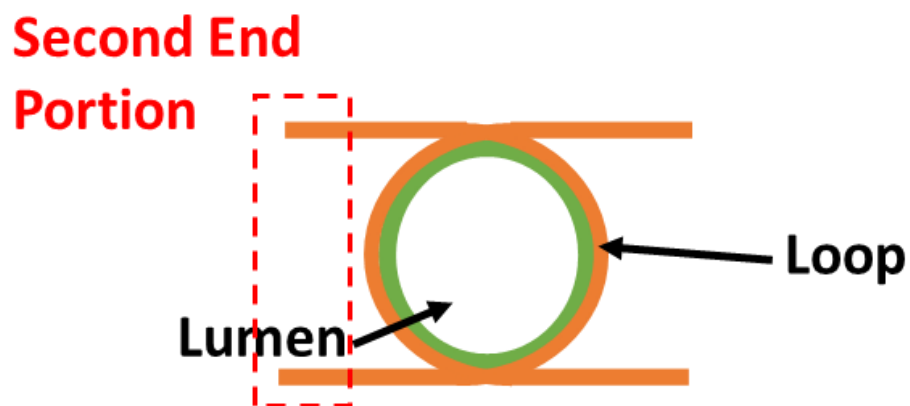
C. Claim 3

Claim 3 recites the “hemostasis valve of claim 2 wherein the filament further comprises a second end portion extending away from the loop to the second member.” Schaffer anticipates claim 3 or renders claim 3 obvious alone or combined with Hartley *or* Eller. (Ex. 1003, ¶¶139-145.)

As shown below, Schaffer’s left actuating member includes a second end portion extending away from the loop:



(Ex. 1005, Fig. 31; Ex. 1003, ¶140.) The second end portion of the filament is also identified in the demonstrative below by the red box:

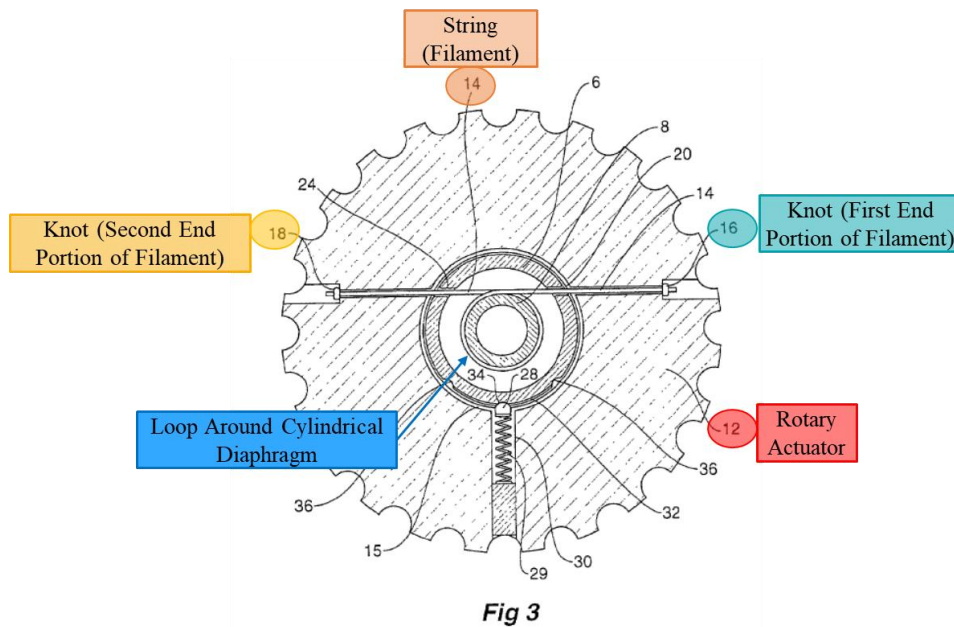


(Ex. 1003, ¶141.)

The identification of Schaffer's second end portion above is consistent with the '291 patent for the reasons provided concerning the first end portion in claim 1. (*Supra* §VI.A.5.a.) As illustrated, the second end portion of Schaffer's U-shaped

actuating members extends away from the loop (encircled area) and attaches to Schaffer's second actuator button (second member). (Ex. 1005, [0076], Figs. 31-32; Ex. 1003, ¶142; *supra* §VI.A.5.a.) Thus, Schaeffer discloses this limitation.

Hartley's string and Eller's wire member also have a second end portion extending away from the loop. (Ex. 1003, ¶143.) 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":



(Ex. 1006, [0031], Fig. 3.) As shown above, the left end of the string forms a second end portion extending away from the loop. (Ex. 1003, ¶143.)

Similarly, Eller's wire member loops 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:

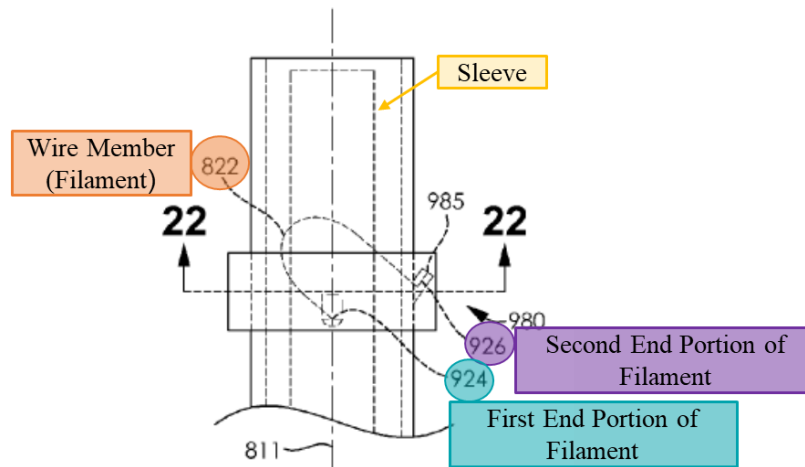


FIG. 21

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

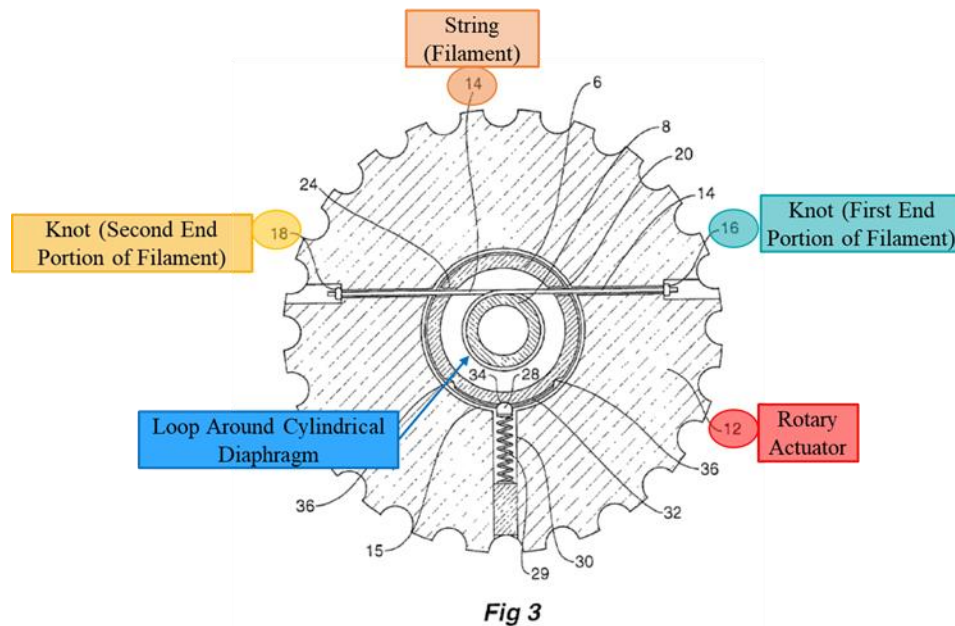
A POSITA would have been motivated to replace Schaffer's U-shaped actuating members with Hartley's string or Eller's wire member, and reasonably expected success in doing so, for the reasons provided in claim 1. (*Supra* §§VI.A.5.b-c.) In such an arrangement, the second end portion of Hartley's string or Eller's wire member would attach to Schaffer's second actuator button (second member). (*Id.*) Therefore, Schaffer combined with Hartley or Eller renders this claim obvious. (Ex. 1003, ¶145.)

D. Claim 4

Claim 4 recites the "hemostasis valve of claim 3 wherein the first end portion, the loop, and the second end portion are one continuous filament." Schaffer in combination with Hartley or Eller renders claim 4 obvious. (Ex. 1003, ¶¶146-150.)

1. Schaffer-Hartley

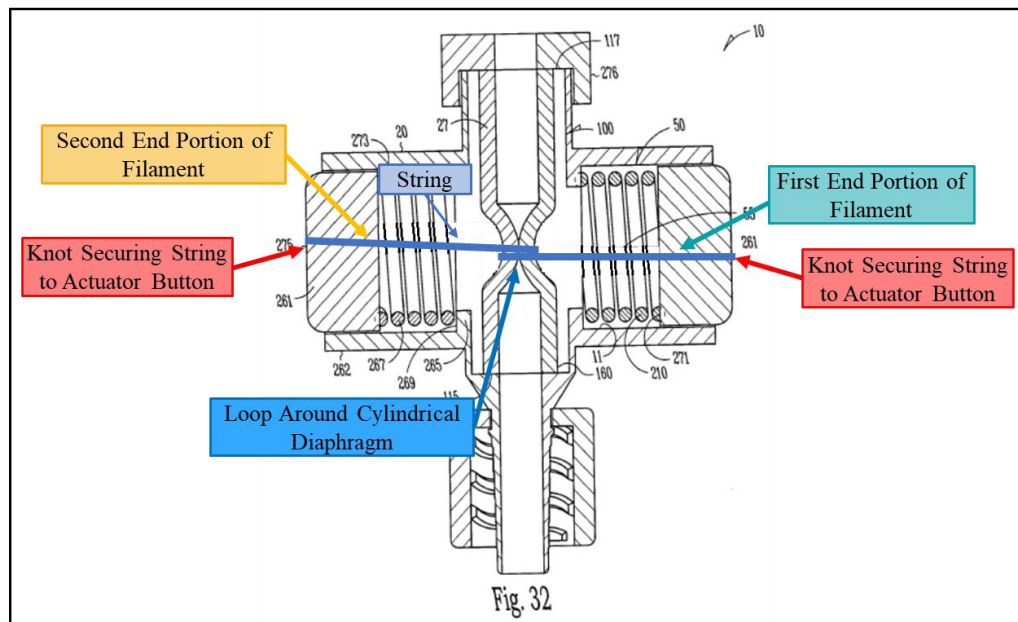
Hartley discloses a continuous string (i.e., filament) that has first and second end portions and forms a loop around the outer surface of a cylindrical diaphragm (i.e., collapsible tubular sidewall):



(Ex. 1006, [0031], Figs. 1, 3.)

As explained in claim 1, a POSITA would have been motivated to substitute Hartley's string for Schaffer's two U-shaped actuating members, and reasonably expected success in doing so. (*Supra* §VI.A.5.b). In that combination, the portions of the string forming the loop, first end portion, and second end portion would be a continuous filament:

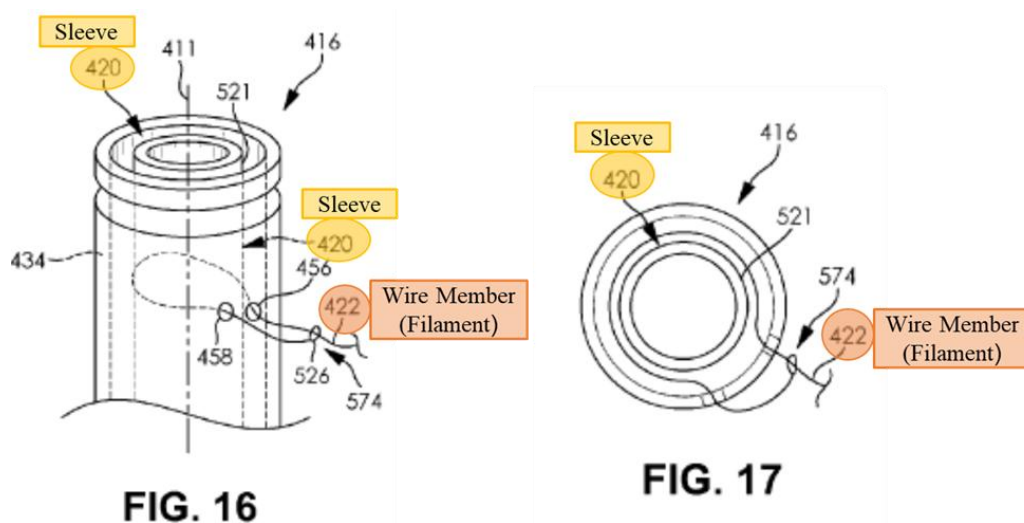
Demonstrative Illustration
Schaffer + Hartley's String



(Ex. 1003, ¶148.)

2. Schaffer-Eller

Eller discloses a continuous wire member (i.e., filament) that forms a loop around the outer surface of a sleeve (i.e., collapsible tubular member).

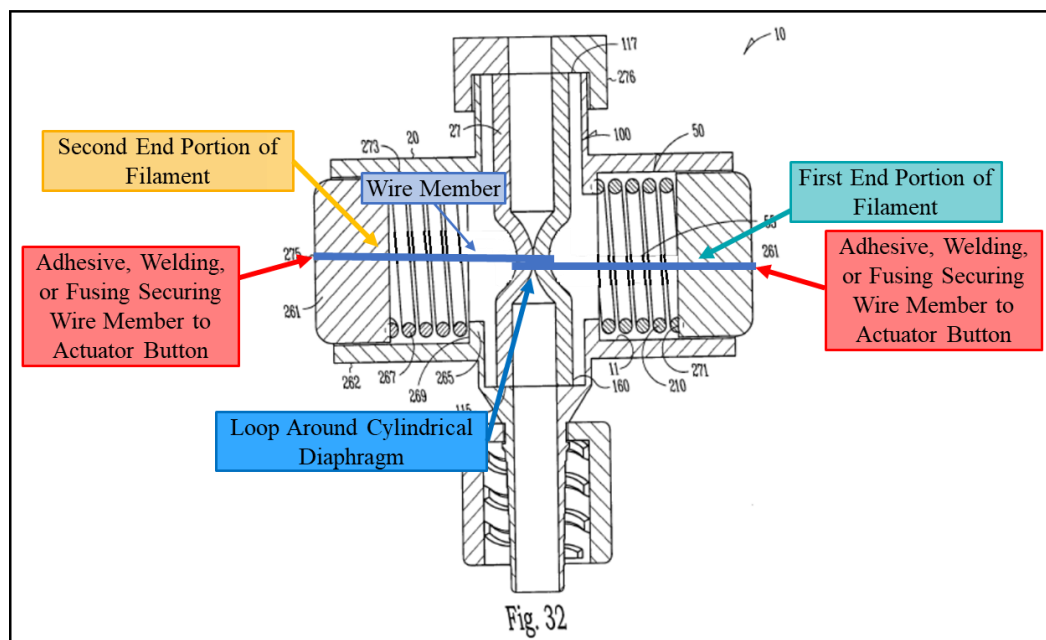


(Ex. 1007, 5:1-5, 16:7-19, 21:37-22:31, 23:50-25:9, Fig. 2, 16-17.)

As explained in claim 1, a POSITA would have been motivated to substitute Hartley's string for Schaffer's two U-shaped actuating members, and reasonably expected success in doing so. (*Supra* §VI.A.5.c). In that combination, the portions of the wire member forming the loop, first end portion, and second end portion would be a continuous filament:

Demonstrative Illustration

Schaffer + Eller's Wire Member



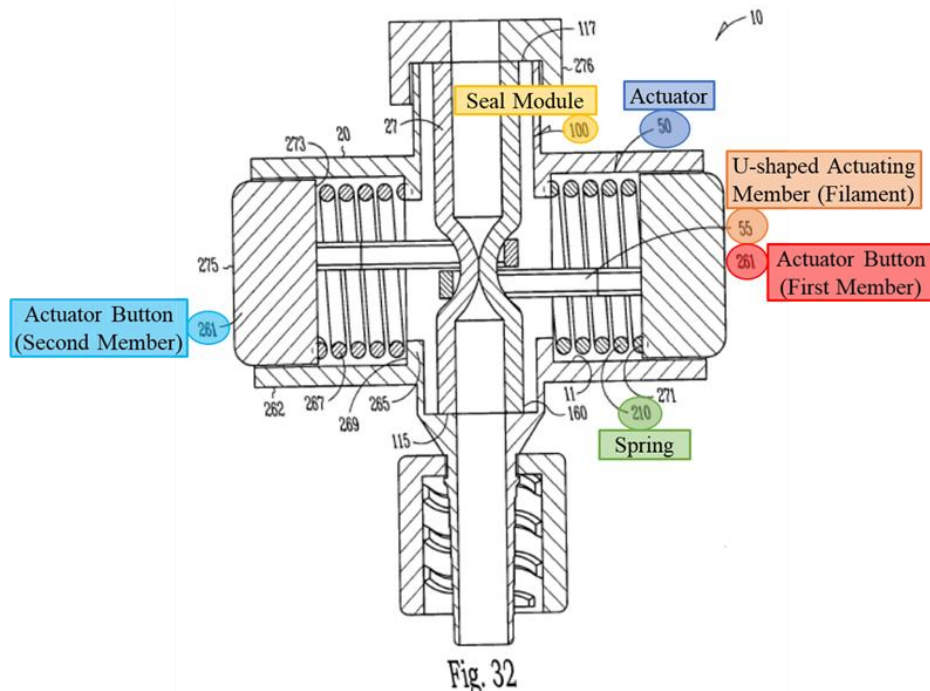
(Ex. 1003, ¶150.)

E. Claim 5

Claim 5 recites the “hemostasis valve of claim 3 wherein first member and the second member are biased in a direction that places the first end portion and the second end portion under sufficient tension to reduce the diameter of the lumen and

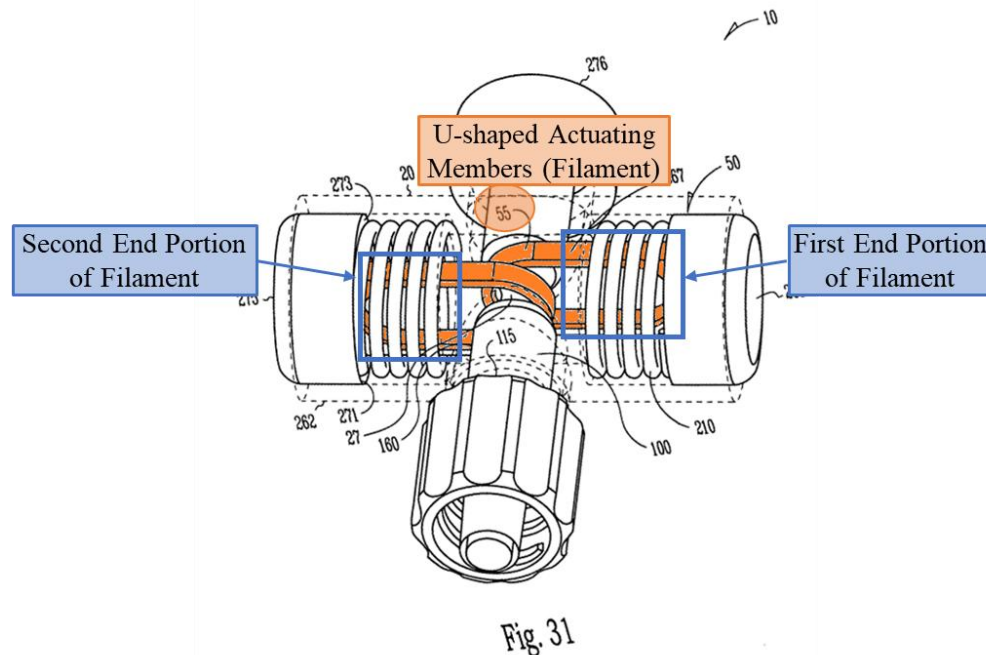
provide a seal around a device extending through the lumen.” Schaffer discloses this limitation. (Ex. 1003, ¶¶151-156.)

As discussed in claims 1 and 2, Schaffer discloses a hemostasis valve having a first actuator button (first member) and a second actuator button (second member):



(Ex. 1005, [0075]-[0076], Figs. 31-32; *supra* §§VI.A.3, VI.B; Ex. 1003, ¶152.)

Each actuator button is attached to a spring. (*Id.*) As shown in Figure 32 above and Figure 31 below, the spring biases the actuator buttons in a direction that places the first and second end portions of the filament under sufficient tension to reduce the diameter of the seal module lumen:

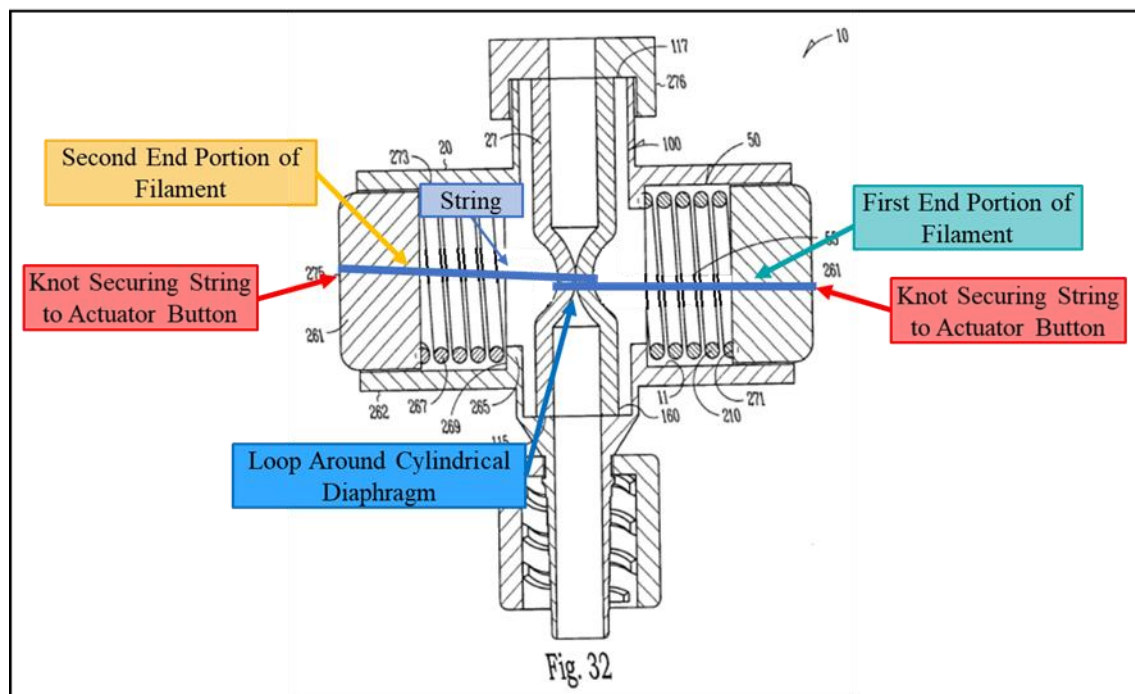


(Ex. 1005, Fig. 31; *supra* §VI.A.3-4; Ex. 1003, ¶153.) Schaffer expressly discloses that the described valve “blocks the flow of gas or fluid completely and immediately with or without an instrument in place within the gas/fluid path.” (Ex. 1005, [0008].) Therefore, Schaffer’s valve places the actuating members under sufficient tension to provide a seal around a device extending through the lumen, and Schaffer anticipates this claim. (Ex. 1003, ¶154.)

Schaffer’s valve would also place the first and second end portions of Hartley’s string or Eller’s wire member under sufficient tension to reduce the diameter of the lumen and provide a seal around a device extending through the lumen. (Ex. 1003, ¶155.) As explained in claims 1 and 3, each end of Hartley’s string or Eller’s wire member would be attached to one of Schaffer’s buttons. (*Supra* §§VI.A.5.b-c, VI.C.) Schaffer’s springs would bias the actuator buttons to provide

sufficient tension on the filament to seal the valve, as shown in the demonstrative below:

Demonstrative Illustration Schaffer + Hartley's String



(Ex. 1003, ¶155.) If Schaffer's valve did not initially seal when combined with Hartley's string or Eller's wire member, a POSITA would have possessed the knowledge to modify the material used in the collapsible tubular sidewall or adjust the spring material or configuration to ensure a seal, as described in claim 1. (*Supra* §§VI.A.5.b-c; Ex. 1003, ¶156.) Therefore, Schaffer in combination with Hartley or Eller renders claim 5 obvious.

F. Claim 6

Claim 6 recites the “hemostasis valve of claim 3 wherein the first member and the second member are biased in a direction that places the first end portion and the second end portion under sufficient tension to close the lumen.” Schaffer anticipates claim 6 or renders it obvious alone or in combination with Hartley or Eller. (Ex. 1003, ¶¶157-159.)

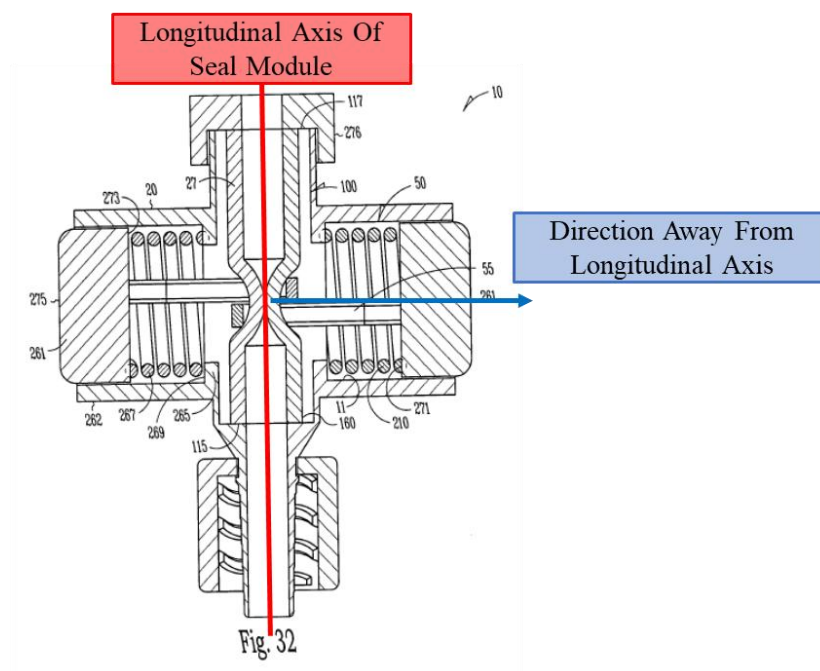
As explained in claims 1 and 5, Schaffer’s actuator buttons are biased to place the first and second end portions of the filament under tension to close the lumen of the seal module. (*Supra* §§VI.A.5-6, VI.E.) Schaffer expressly discloses that its valve “blocks the flow of gas or fluid completely and immediately with ***or without*** an instrument in place within the gas/fluid path.” (Ex. 1005, [0008] (emphasis added), Fig. 32.) Thus, Schaffer discloses this limitation. (Ex. 1003, ¶158.)

As also explained in claims 1 and 5, if Hartley’s string or Eller’s wire member were substituted for Schaffer’s U-shaped actuating member, Schaffer’s springs and actuator buttons would place the first and second end portions of the string/wire member under tension to close the lumen of the seal module. (*Supra* §§VI.A.5-6, VI.E; Ex. 1003, ¶159.) Further, POSITAs would have possessed the motivation and skill to adjust Schaffer’s seal module or springs to ensure the valve sealed completely when using Hartley’s string or Eller’s wire member. (*Id.*) Thus, Schaffer in combination with Hartley or Eller renders this claim obvious.

G. Claim 7

Claim 7 recites the “hemostasis valve of claim 1 wherein the lumen extends along a longitudinal axis, and wherein the direction is a direction away from the longitudinal axis.” Schaffer anticipates this claim or renders it obvious alone or in combination with Hartley or Eller. (Ex. 1003, ¶¶160-161.)

Schaffer’s springs bias the actuator buttons to create tension on the filament. (*Supra* §VI.A.3.) As shown below, the direction of force is a direction away from the longitudinal axis of the seal module’s lumen:



(Ex. 1005, [0077], Figs. 31-34; Ex. 1003, ¶161.)

H. Claim 8

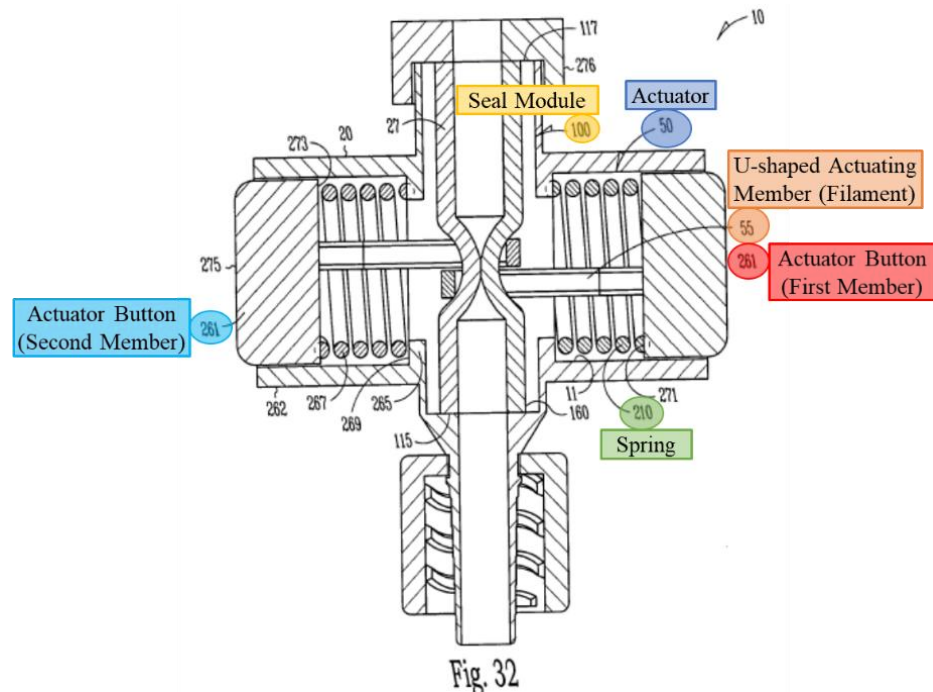
Claim 8 recites the “hemostasis valve of claim 1 wherein the lumen extends along a longitudinal axis, and wherein the direction is a direction orthogonal to the

longitudinal axis.” Schaffer anticipates this claim or renders it obvious alone or in view of Hartley *or* Eller. (Ex. 1003, ¶¶162-163.) As shown in claim 7, Schaffer’s buttons are biased in a direction orthogonal to the longitudinal axis of the seal module lumen. (*Supra* §VI.G.)

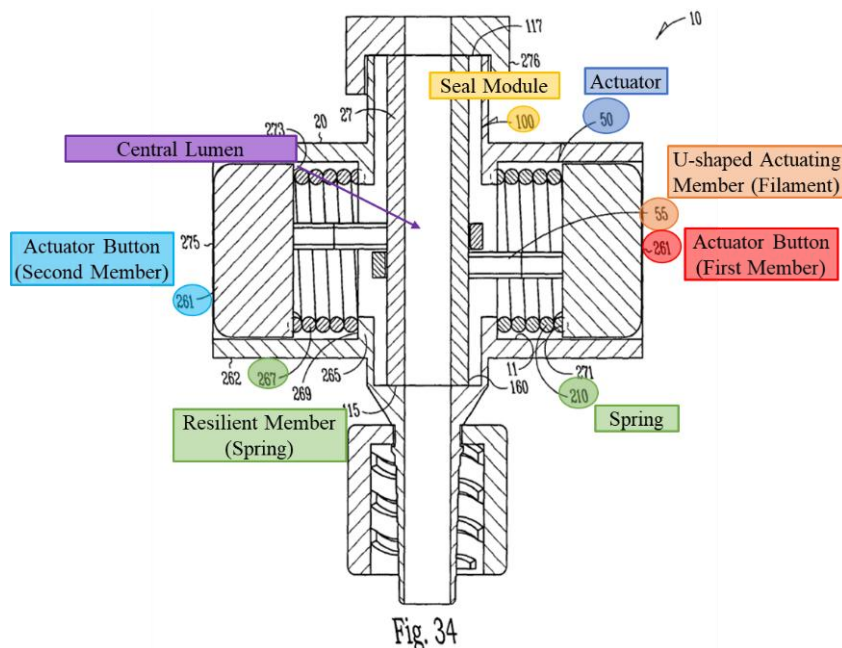
I. Claim 12

Claim 12 recites the “hemostasis valve of claim 1 wherein the direction is a first direction, and wherein the first member is actuatable in a second direction to move the first end portion toward the tubular sidewall to increase the diameter of the lumen in response to increasing the diameter of the loop.” Schaffer anticipates claim 12 or renders it obvious alone or in combination with Hartley or Eller. (Ex. 1003, ¶¶164-166.)

As explained in claim 1, 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.) In the second position, the buttons are pushed inward (i.e., in a second direction) to move the first end portion of the filament toward the seal module (tubular sidewall) to increase the diameter of the lumen in response to increasing the diameter of the loop:

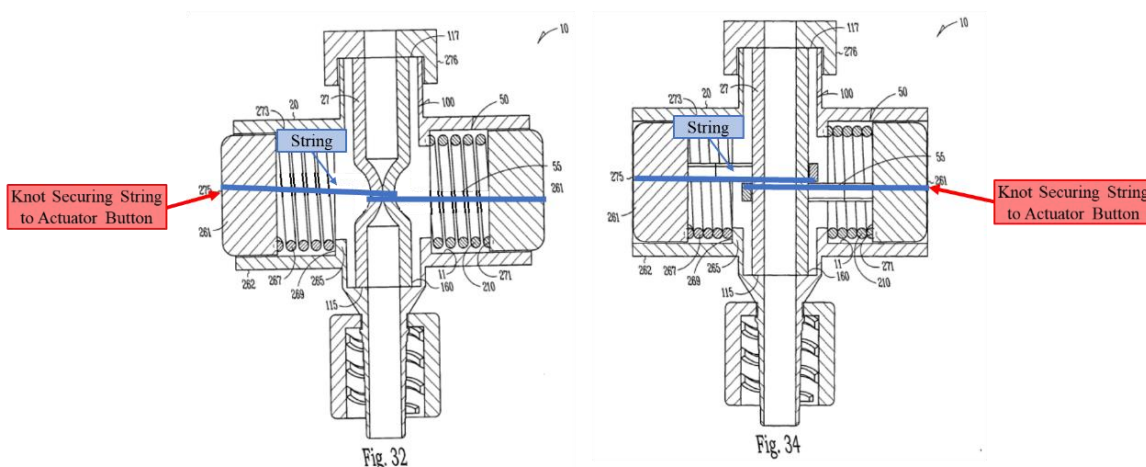


(*Id.*, [0077], Fig. 34; Ex. 1003, ¶165.) Thus, Schaffer anticipates this claim.

Similarly, if Schaffer's actuating members were replaced with Hartley's string or Eller's wire member, pushing the buttons inward (i.e., in a second direction) would move the first end portion of the string/wire member toward the seal module (tubular member):

Demonstrative Illustration

Schaffer + Hartley's String



(Ex. 1003, ¶166.) A POSITA would have been motivated to combine Hartley's string or Eller's wire member with Schaffer's valve, and reasonably expected success in doing so, for the reasons provided in claim 1. (*Supra* §§VI.A.5.b-c.)

J. Claim 13

Claim 13 recites the “hemostasis valve of claim 12 wherein the first direction is opposite the second direction.” Schaffer anticipates this claim or renders it obvious alone or in combination with Hartley or Eller. (Ex. 1003, ¶¶167-168.)

As shown in claim 12, the first direction is outward from the longitudinal axis of the seal module (collapsible tubular member) while the second direction is inward toward the longitudinal axis of the seal module. (*Supra* §VI.I.) Thus, the first direction is opposite the second direction. (Ex. 1003, ¶168.)

K. Claim 14

Claim 14 recites the “hemostasis valve of claim 13 wherein the lumen extends along a longitudinal axis, and wherein the first direction and the second direction are orthogonal to the longitudinal axis.” Schaffer anticipates claim 14 or renders it obvious alone or in combination with Hartley or Eller. (Ex. 1003, ¶¶169-170.)

As shown in claims 7, 8, 12, and 13, the first and second directions are orthogonal to the longitudinal axis of the seal module lumen. (*Supra* §§VI.G-J.)

L. Claim 15

Claim 15 first recites the “hemostasis valve of claim 1 wherein the actuator further comprises a second member movably coupled to the support, wherein the filament further comprises a second end portion extending away from the loop to the second member, wherein the spring is a first spring, wherein the direction is a first direction, and further comprising a second spring configured to move the second member in a second direction that pulls the second end portion away from the tubular sidewall, reducing the diameter of the lumen in response to reducing the diameter of

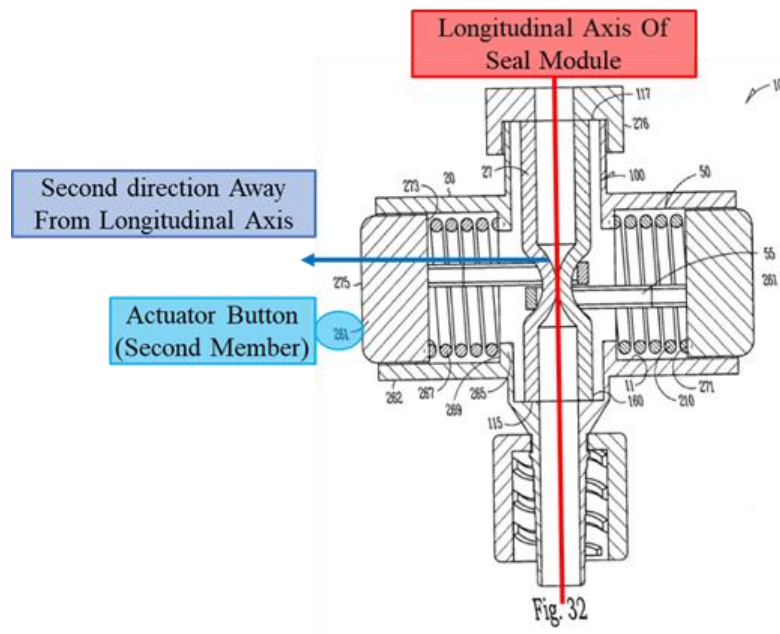
the loop.” Claim 15 is anticipated by Schaffer or rendered obvious by Schaffer alone or in combination with Hartley or Eller. (Ex. 1003, ¶¶171-174.)

Schaffer discloses an actuator comprising a second member movably coupled to the support for the reasons provided in claim 2. (*Supra* §VI.B; Ex. 1003, ¶172.)

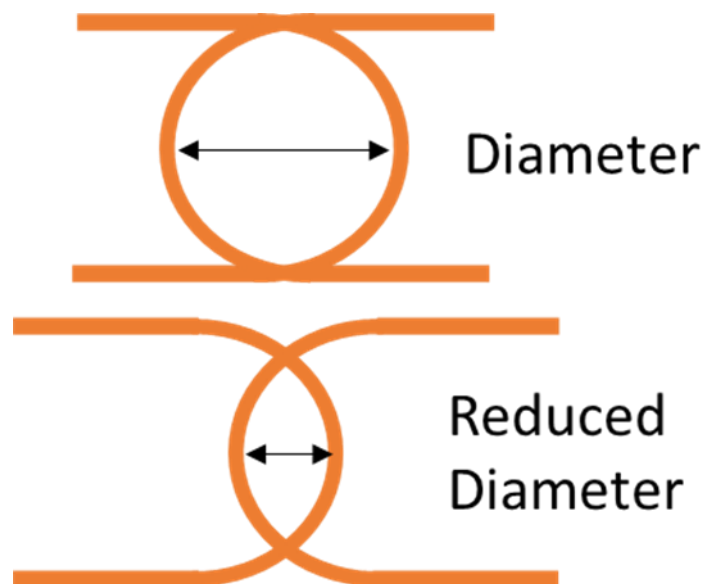
Similarly, Schaffer, or Schaffer in combination with Hartley’s string or Eller’s wire member, discloses a filament comprising a second end portion extending away from the loop to the second member for the reasons provided in claim 3. (*Supra* §VI.C; Ex. 1003, ¶172.)

Schaffer also discloses a first spring that biases the actuator button to a first direction that pulls on the first end portion of the filament for the reasons provided in Claims 1 and 5. (*Supra* §§VI.A.6, VI.E; Ex. 1003, ¶172.)

Schaffer also discloses a second spring configured to move the second member in a second direction that pulls the second end portion away from the tubular sidewall:



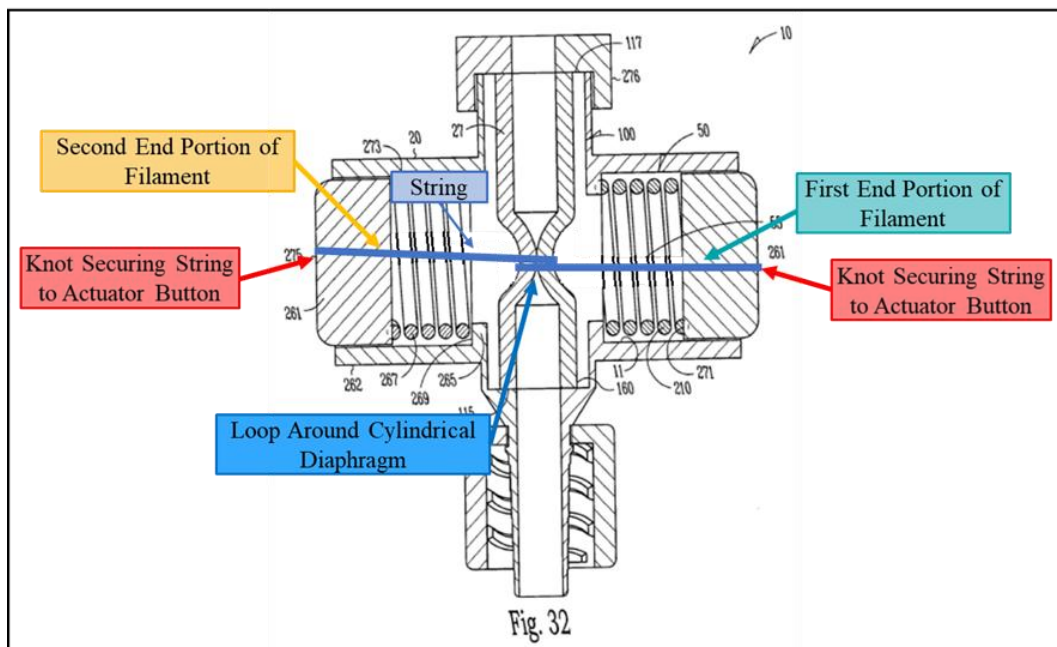
(Ex. 1005, Fig. 32; *supra* §§VI.E-F.) As shown below, pulling the second end portion of the filament away from the tubular sidewall reduces the diameter of the lumen in response to reducing the diameter of the loop:



(Ex. 1005, [0077], Fig. 32; Ex. 1003, ¶173; *supra* §VI.A.6.)

Schaffer combined with Hartley’s string or Eller’s wire member renders this claim obvious. As illustrated by the demonstrative below, pulling on the second end portion of Hartley’s string or Eller’s wire member away from the seal module’s lumen reduces the diameter of the lumen in response to reducing the diameter of the loop:

Demonstrative Illustration
Schaffer + Hartley’s String

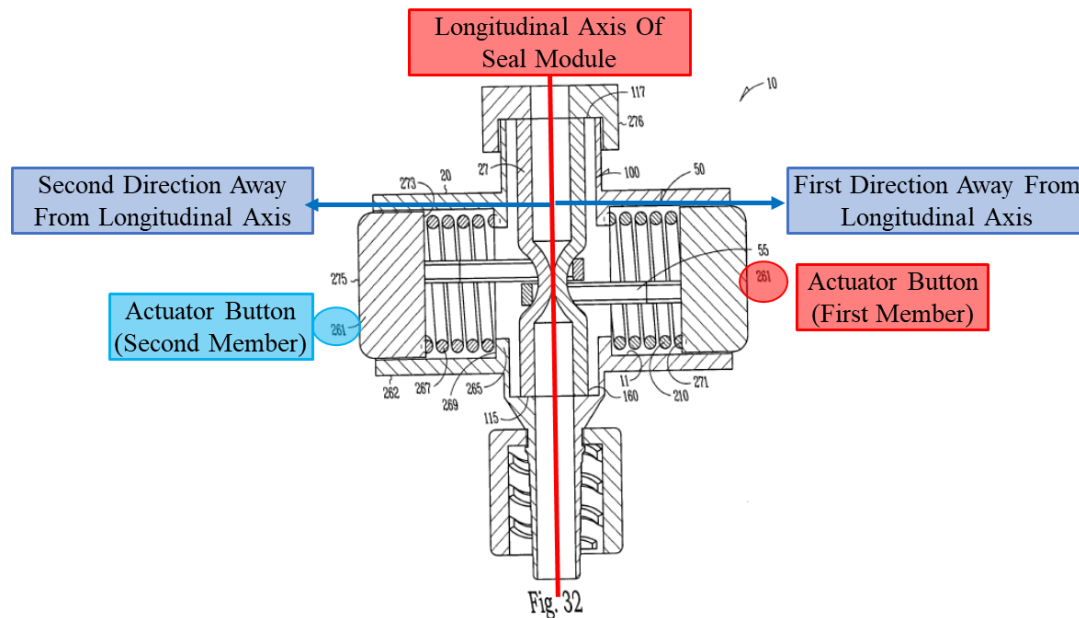


(Ex. 1003, ¶174; *supra* §§VI.E-F.)

M. Claim 16

Claim 16 recites the “hemostasis valve of claim 15 wherein the first direction is opposite to the second direction.” Schaffer anticipates this claim or renders it obvious alone or in combination with Hartley or Eller. (Ex. 1003, ¶¶175-176.)

As shown below, Schaffer's actuator buttons are both biased outwards from the seal module in a first position. As shown, the first direction is opposite the second direction:



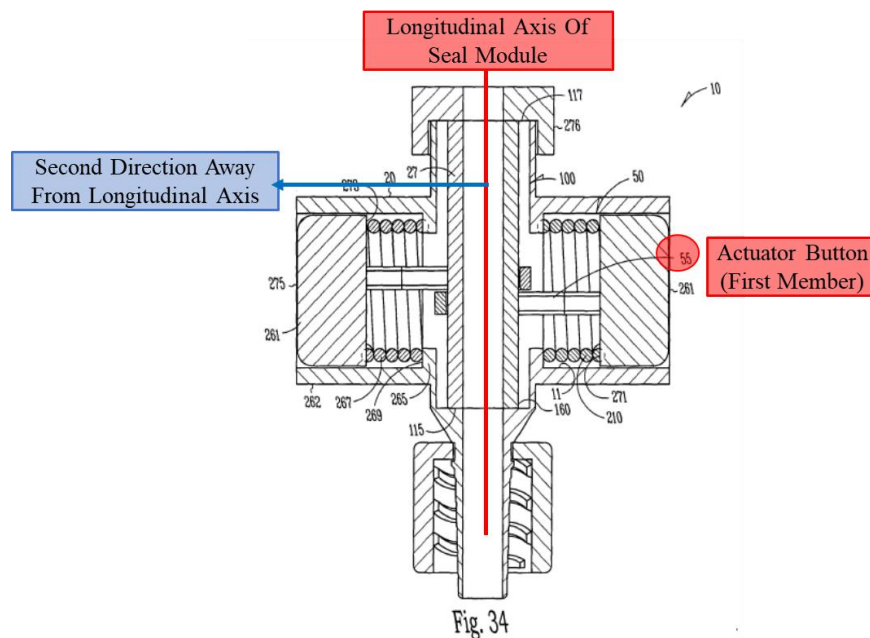
(Ex. 1005, [0077], Fig. 32; Ex. 1003, ¶176.) The first and second directions would be the same if Schaffer's actuating members were replaced with Hartley's string or Eller's wire member. (Ex. 1003, ¶176.)

N. Claim 17

Claim 17 recites the “hemostasis valve of claim 15 wherein the first member is actuatable in the second direction and/or the second member is actuatable in the first direction to move the first end portion toward the tubular sidewall to increase the diameter of the lumen in response to increasing the diameter of the loop.”

Schaffer anticipates this claim or renders it obvious alone or in combination with Hartley or Eller. (Ex. 1003, ¶¶177-178.)

When Schaffer’s right actuator button (first member) is pushed inward (i.e., in the second direction), the first end portion of the filament is moved toward the seal module (tubular sidewall) to increase the diameter of the lumen in response to increasing the diameter of the loop:



(Ex. 1005, [0077], Fig. 34; Ex. 1003, ¶178.) This is true whether the filament is Schaffer’s U-shaped actuating members, Hartley’s string, or Eller’s wire member. (Ex. 1003, ¶178; *supra* §VI.A.)

O. Claim 19

Claim 19 recites the “aspiration catheter system of claim 1 wherein the direction is a first direction, and wherein the first member is actuatable in a second

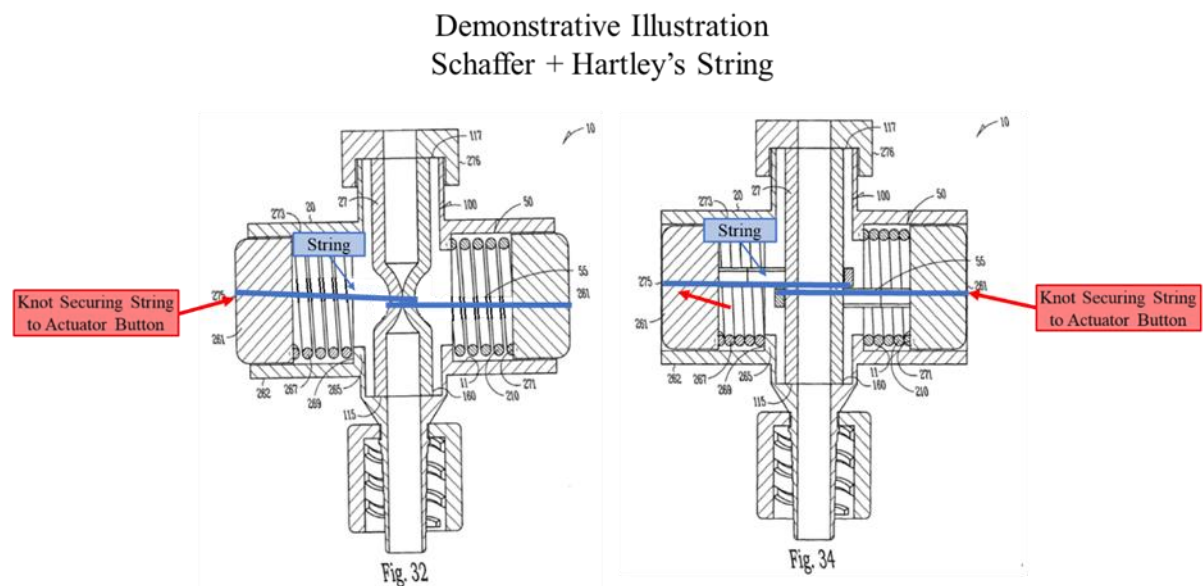
direction to move the first end portion toward the tubular sidewall to increase the diameter of the lumen in response to increasing the diameter of the loop to fluidly couple the lumen of the tubular sidewall to the lumen of the aspiration catheter.”

Claim 19 includes a mistake, although the source of the mistake is not conspicuous or undisputable. *Fitbit, Inc. v. Valencell, Inc.*, 964 F.3d 1112, 1119 (Fed. Cir. 2020). Claim 19 recites “the aspiration catheter system of claim 1,” yet claim 1 does not include such a system. Instead, independent claim 18 recites “An aspiration catheter system.” Given the conflict, a POSITA could not determine whether claim 19 should depend from claim 1 or claim 18. (Ex. 1003, ¶180.) If claim 19 depends from claim 1, then Schaffer anticipates claim 19 or renders the claim obvious alone or combined with Hartley or Eller. (Ex. 1003, ¶¶180-182.)

As explained in claim 17, Schaffer’s actuator button (first member) is actuatable in a second direction to move the first end portion of the filament. (*Supra* §VI.N.) Moving the actuator button in the second direction opens the valve and fluidly couples the lumen of Schaffer’s seal module (tubular sidewall) to the lumen of any attached catheter, including an aspiration catheter. (See Ex. 1005, [0077] (pushing the buttons allows “the portion 108 of the containment structure 160 to retract to an uncollapsed configuration where gases and fluids can pass therethrough”), Fig. 34; Ex. 1003, ¶181.) Schaffer expressly “relates to catheters, in particular to a composite fluid-stasis valve for use with catheters” and more

specifically discloses connecting a syringe to the valve for creating an aspiration catheter. (Ex. 1005, [0002]-[0003], [0049]; Ex. 1003, ¶181.) Thus, Schaffer discloses this limitation even if “the aspiration catheter,” which lacks antecedent basis, is a limitation.

Further, pressing Schaffer’s actuator button inward (in the second direction) would also move the first end portion of Hartley’s string or Eller’s wire member toward the tubular sidewall to increase the diameter of the lumen in response to increasing the diameter of the loop. (Ex. 1003, ¶182; *supra* §VI.I.) The figure on the right illustrates pushing the actuator buttons inward and the associated increase in the lumen diameter:



(Ex. 1005, [0077], Figs. 32, 34; Ex. 1003, ¶182.) Thus, Schaffer combined with Hartley or Eller renders this claim obvious.

**VII. GROUNDS 5-7: CLAIMS 18-19 OBVIOUS OVER GARRISON
COMBINED WITH SCHAFFER AND OPTIONALLY HARTLEY OR
ELLER**

A. Claim 18

Claim 18 is an independent claim that requires “An aspiration catheter system, comprising: an aspiration catheter defining a lumen and having a proximal end portion; and” the hemostasis valve described in claim 1. Garrison combined with Schaffer and optionally Hartley or Eller renders claim 18 obvious. (Ex. 1003, ¶¶183-200.)

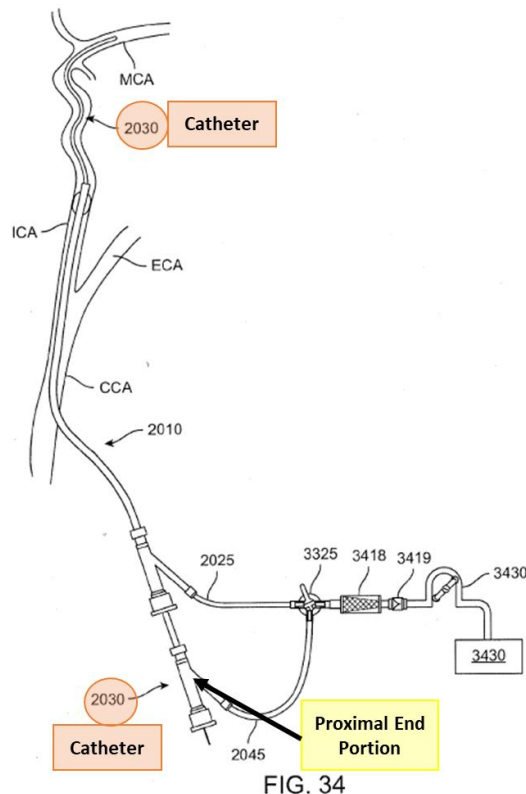
1. Preamble

The preamble recites an “aspiration catheter system.” If the preamble is limiting, Garrison discloses this limitation. (*Id.*, ¶184.) Garrison discloses an aspiration catheter system “to provide aspiration ... for the purpose of facilitating removal of the occlusion as well as minimizing distal emboli.” (Ex. 1011, [0007]; *see also id.*, [0029] (“FIGS. 32-35 show examples of systems for treating an artery with active aspiration”); [0048] (similar).) Garrison’s aspiration source creates a vacuum that aspirates (i.e., suctions) blood clots from the patient’s vessel through a catheter. (*Id.*, Abstract, [0097]-[0098]; Ex. 1003, ¶184.) Thus, Garrison discloses an “aspiration catheter system.”

2. Aspiration Catheter

Claim 18 next recites “an aspiration catheter defining a lumen and having a proximal end portion.” Garrison discloses this limitation. (Ex. 1003, ¶185.)

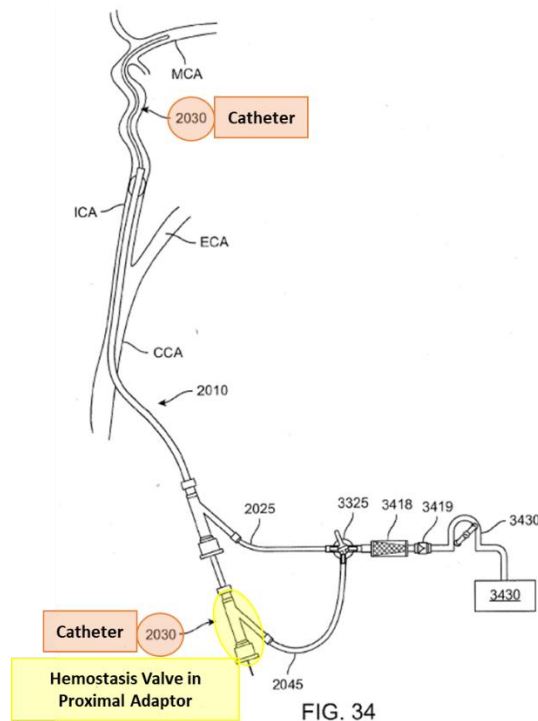
Garrison discloses an aspiration catheter 2030 [orange]:



(Ex. 1011, [0054], Figs. 1-3, 34.) The aspiration catheter 2030 includes a lumen that can “provide distal access for additional devices, localized fluid or contrast delivery or localized aspiration at a location distal of the distal-most end of the arterial access device 2010.” (*Id.*, [0054]; *see also id.* (“The catheter 2030 may then be used to apply aspiration to the occlusion.”).) As shown above, the aspiration catheter has a proximal end portion. (Ex. 1003, ¶185.)

3. Hemostasis Valve

Garrison discloses a first catheter 2030 having a “proximal hub 2065” or “proximal adaptor” and explains that “a separate hemostasis valve may be attached to proximal hub 2065” or “the hemostasis valve may be integral to the catheter proximal adaptor”:



(Ex. 1011, [0098], Fig. 34.)

Garrison also explains that catheter 2030 can include different types of hemostasis valves, including, for example, “an adjustable-opening valve such as a Tuohy-Borst or rotating hemostasis valve (RHV).” (*Id.*, [0098].) However, Garrison does not expressly describe the structure of the hemostasis valves, instead

presuming that POSITAs would have been familiar with such valves. (Ex. 1003, ¶187.)

Schaffer discloses an adjustable-opening “fluid stasis valve.” (Ex. 1005, [0002], [0046], [0055].) A POSITA would have been motivated, and found it obvious, to use Schaffer’s valve (with or without Hartley’s or Eller’s filaments) as the hemostasis valve on Garrison’s catheter for several reasons. (Ex. 1003, ¶¶188-200.)

First, Garrison teaches that the hemostasis valves used with its system “can be ... an adjustable-opening valve.” (Ex. 1011, [0062], [0065], [0098].) Schaffer discloses an adjustable-opening valve and, therefore, a POSITA would have been motivated to combine, and reasonably expected success in combining, Schaffer’s valve with Garrison. (Ex. 1003, ¶189.)

Second, Schaffer discloses that its hemostasis valve is “for use with catheters” and “blocks the flow of gas or fluid completely and immediately with or without an instrument in place within the gas/fluid path.” (Ex. 1005, [0002], [0008], [0047], [0049].) Schaffer further discloses that a range of instruments can be used within the valve, such as “a catheter, guidewire, needle or fiber.” (*Id.*, [0056], [0074].) Thus, Schaffer’s valve performs the function of Garrison’s “hemostasis valve” — to “allow introduction of devices ... while preventing or minimizing blood loss during the procedure.” (Ex. 1011, [0098].) For this added reason, a POSITA would have

been motivated to combine, and reasonably expected success in combining, Schaffer's valve with Garrison. (Ex. 1003, ¶190.)

Third, POSITAs would have recognized that Schaffer's hemostasis valve could simplify operation of Garrison's system. (Ex. 1003, ¶191.) For example, Schaffer's springs bias the valve toward the closed position, eliminating the need to manually seal the valve during procedures as occurred with some prior-art valves. (*Id.*; *supra* §VI.A.5.)

Fourth, the combination of Schaffer's valve with Garrison's aspiration catheter would merely entail the combination of known elements (Schaffer's valve and catheter 2030) according to known methods (attaching the valve to a catheter's proximal hub) to yield the predictable result of minimizing blood loss through the catheter. *See KSR*, 550 U.S. at 416; (Ex. 1003, ¶192.)

Fifth, POSITA's in September 2017 had a finite number of predictable hemostasis valves to select, including an "adjustable-opening valve" or RHV. (Ex. 1003, ¶193.) A POSITA would have found it obvious to try any of these hemostasis valves with Garrison's catheter 2030. (*Id.*); *KSR*, 550 U.S. at 417. The known valves, like Schaffer's adjustable-opening hemostasis valve, were simple mechanical structures that operate in a predictable way. (Ex. 1003, ¶193.)

A POSITAs would have reasonably expected success in combining Schaffer's valve with Garrison. (*Id.*, ¶¶194-195.) Garrison discloses that its aspiration system

can be used with a variety of hemostasis valves including adjustable opening valves. Ex. 1011, [0062]. Schaffer discloses an adjustable opening valve and further explains that its valve is intended for use with catheters. Ex. 1005, [0002], [0047], [0049]. Given these disclosures, a POSITA would have reasonably expected that Schaffer's valve would allow the tools in Garrison's system to pass through the valve into the patient's vasculature while also preventing blood from leaking around those tools. (Ex. 1003, ¶195.)

a. Support and Actuator

Schaffer discloses “a support” and “an actuator having at least a first member movably coupled to the support” for the reasons explained in claim 1. (*Supra* §§VI.A.2-3.)

b. Tubular Sidewall

Schaffer discloses “a collapsible tubular sidewall defining a lumen carried by the support” for the reasons explained in claim 1. (*Supra* §VI.A.4.) Garrison in combination with Schaffer also discloses “wherein the lumen of the tubular sidewall is selectively fluidly couplable to the lumen of the aspiration catheter.” (Ex. 1003, ¶198.) Schaffer's valve includes a “connecting member 35 sized and configured to attach in fluid communication to a fluid delivery supply or a body passage such as a blood vessel.” (Ex. 1005, [0047].) Depressing Schaffer's actuator buttons (first/second members) allows the lumen to open allowing gases and fluids to pass

through the valve to any attached catheter, including Garrison’s catheter 2030. (*Id.*, [0077]; Ex. 1003, ¶198.)

c. Filament

Schaffer, or Schaffer in combination with Hartley or Eller, discloses “a filament formed in a loop around the tubular sidewall, the filament having at least a first end portion extending away from the loop to the first member” for the reasons explained for claim 1. (*Supra* §VI.A.5.)

d. Spring

Schaffer discloses “a spring configured to move the first member in a direction that pulls the first end portion away from the tubular sidewall, reducing a diameter of the lumen in response to reducing a diameter of the loop to fluidly decouple the lumen of the tubular sidewall from the lumen of the aspiration catheter” for the reasons explained for claim 1. (*Supra* §VI.A.6.) Schaffer explains that when the springs move the buttons outward, the lumen of the seal module is closed preventing the flow of fluids or gases through connecting member to any catheter, including Garrison’s aspiration catheter 2030. (Ex 1005, [0049]; Ex. 1003, ¶200.)

B. Claim 19

If claim 19 depends from claim 18, then Garrison in combination with Schaffer and optionally Hartley or Eller renders the claim obvious. (Ex. 1003, ¶¶201-202.) As explained above, Schaffer’s actuator buttons (first/second members)

may be depressed to open the lumen of the seal module (tubular sidewall) to couple the lumen of the tubular sidewall to the lumen of Garrison’s aspiration catheter.
(*Supra* §§VI.O, VII.A.3.c.)

VIII. SECONDARY CONSIDERATIONS

Petitioner is not aware of any evidence of secondary considerations.
(Ex. 1003, ¶¶203-204.) If PO identifies evidence of secondary considerations, Petitioner respectfully requests an opportunity to respond.

IX. SOTERA STIPULATION

Petitioner hereby stipulates that if the Board institutes this IPR based on the grounds and claims raised in the Petition, Petitioner will not pursue in district court the grounds asserted in the IPR Petition or any other ground that could have been reasonably raised in this IPR. Thus, there will be no “overlap 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).

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 ’291 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.*) PO has also filed a Motion for Leave to File a Third Amended Complaint, which would add U.S. Patent No. 12,239,333 to the litigation. (Ex. 1019.) Petitioner has opposed the Motion and requested that the Court vacate the case schedule until PO is done asserting additional patents. (Ex. 1024.) The motion is scheduled for hearing on May 28, 2025. Petitioner has also filed a Motion to Stay the Litigation pending resolution of the IPRs. (Ex. 1025.) The motion is schedule for hearing on July 16, 2025.

Petitioner has filed five IPRs against patents asserted by PO in the Litigation: (1) *Imperative Care, Inc. v. Inari Medical, Inc.*, IPR2024-01157 requesting review of U.S. Patent No. 11,697,011 (Filed July 8, 2024); (2) *Imperative Care, Inc. v. Inari Medical, Inc.*, IPR2024-01257 requesting review of U.S. Patent No. 11,744,691 (Filed August 12, 2024); (3) *Imperative Care, Inc. v. Inari Medical, Inc.*, IPR2025-00156 requesting review of U.S. Patent No. 11,697,012 (Filed November 8, 2024);

(4) *Imperative Care, Inc. v. Inari Medical, Inc.*, IPR2025-00289 requesting review of U.S. Patent No. 11,554,005 (Filed December 13, 2024); and (5) *Imperative Care, Inc. v. Inari Medical, Inc.*, IPR2025-00728 requesting review of U.S. Patent No. 11,844,921 (Filed March 13, 2025). The Board granted institution of the '011 and '012 patent IPRs and denied institution of the '691 patent IPR for reasons not relevant to this IPR.

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

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

Lead Counsel	Back-up Counsel
Joshua J. Stowell (Reg. No. 64,096) Joshua.Stowell@knobbe.com BoxImperative291@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 BoxImperative291@knobbe.com.

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

Petitioner certifies that the '291 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.

Respectfully submitted,

KNOBBE MARTENS OLSON & BEAR, LLP

Dated: May 8, 2025

By: /Joshua J. Stowell/
Joshua J. Stowell (Reg. No. 64,096)
Joseph R. Re (Reg. No. 31,291)
Brian C. Barnes (Reg. No. 75,805)

Attorneys for Petitioner Imperative Care, Inc.

CERTIFICATE OF COMPLIANCE

Pursuant to 37 C.F.R. § 42.24(d), the undersigned certifies that this PETITION FOR INTER PARTES REVIEW OF U.S. PATENT NO. 11,865,291 contains 13,625 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: May 9, 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. 11,865,291 AND EXHIBITS 1001-1027**, were served by Priority Mail Express on the Patent Owner at the correspondence address of record for the subject patent as follows:

Joseph Hamiltion
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:

Amanda Tessar Perkins Coie LLP 1900 Sixteenth Street Suite 1400 Denver, CO 80202 303-291-2357 Email: atessar@perkinscoie.com	Ramsey M. Al-Salam Perkins Coie LLP 1201 Third Avenue Suite 4000 Seattle, WA 98101-3099 206-359-8000 Email: ralsalam@perkinscoie.com
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Dated: May 9, 2025

By: /Joshua J. Stowell/

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