

Filed: November 8, 2024

On behalf of **Imperative Care, Inc.**

By: Joshua J. Stowell (Reg. No. 64,096)  
Joseph R. Re (Reg. No. 31,291)  
Brian C. Barnes (Reg. No. 75,805)  
KNOBBE, MARTENS, OLSON & BEAR, LLP  
2040 Main Street, 14th Floor  
Irvine, CA 92614  
Tel.: (949) 760-0404  
Fax: (949) 760-9502  
Email: BoxImperative012@knobbe.com

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. IPR2025-00156  
Patent No. 11,697,012

---

**PETITION FOR *INTER PARTES* REVIEW OF  
U.S. PATENT NO. 11,697,012**

## TABLE OF CONTENTS

### Page No.

|      |                                                                                                                                    |    |
|------|------------------------------------------------------------------------------------------------------------------------------------|----|
| I.   | SUMMARY OF THE ARGUMENT .....                                                                                                      | 1  |
| II.  | THE '012 PATENT .....                                                                                                              | 8  |
| A.   | Overview .....                                                                                                                     | 8  |
| B.   | Prosecution History.....                                                                                                           | 14 |
| C.   | The Earliest Possible Priority Date.....                                                                                           | 15 |
| III. | LEVEL OF ORDINARY SKILL .....                                                                                                      | 15 |
| IV.  | CLAIM CONSTRUCTION .....                                                                                                           | 15 |
| A.   | Filament.....                                                                                                                      | 16 |
| B.   | “Aspiration” In The Preamble Is Not Limiting.....                                                                                  | 18 |
| V.   | STATEMENT OF RELIEF REQUESTED.....                                                                                                 | 20 |
| A.   | IPR Grounds .....                                                                                                                  | 20 |
| B.   | The Asserted References Are Prior Art.....                                                                                         | 21 |
| C.   | The Asserted References Are Analogous Art.....                                                                                     | 21 |
| VI.  | GROUND 1-4: CLAIMS 1-9 ANTICIPATED BY SCHAFFER<br>OR RENDERED OBVIOUS BY SCHAFFER ALONE OR<br>COMBINED WITH HARTLEY OR ELLER ..... | 22 |
| A.   | Claim 1 .....                                                                                                                      | 24 |
| 1.   | Preamble .....                                                                                                                     | 24 |
| 2.   | Tubular Body .....                                                                                                                 | 27 |

**TABLE OF CONTENTS**  
**(cont'd)**

|                                       | <b>Page No.</b> |
|---------------------------------------|-----------------|
| 3. Hemostasis Valve .....             | 29              |
| 4. Collapsible Tubular Sidewall ..... | 32              |
| 5. Constricting Mechanism .....       | 33              |
| a. First Actuator .....               | 34              |
| b. Filament .....                     | 35              |
| i. Schaffer .....                     | 35              |
| ii. Hartley .....                     | 40              |
| iii. Eller .....                      | 47              |
| c. First Spring .....                 | 54              |
| B. Claim 2 .....                      | 57              |
| 1. Tubular Member .....               | 57              |
| 2. Constricting Mechanism .....       | 58              |
| 3. Filament .....                     | 60              |
| a. Schaffer .....                     | 60              |
| b. Hartley .....                      | 65              |
| c. Eller .....                        | 66              |
| C. Claim 3 .....                      | 67              |
| D. Claim 4 .....                      | 68              |

**TABLE OF CONTENTS**  
**(cont'd)**

|                                                                                                                       | <b>Page No.</b> |
|-----------------------------------------------------------------------------------------------------------------------|-----------------|
| E. Claim 5 .....                                                                                                      | 69              |
| 1. Schaffer .....                                                                                                     | 69              |
| 2. Hartley .....                                                                                                      | 72              |
| 3. Eller .....                                                                                                        | 73              |
| F. Claim 6 .....                                                                                                      | 75              |
| G. Claim 7 .....                                                                                                      | 80              |
| H. Claim 8 .....                                                                                                      | 81              |
| I. Claim 9 .....                                                                                                      | 82              |
| VII. GROUNDS 5-7: CLAIMS 1-9 OBVIOUS OVER SCHAFFER<br>COMBINED WITH GARRISON AND OPTIONALLY<br>HARTLEY OR ELLER ..... | 83              |
| A. Claim 1 .....                                                                                                      | 85              |
| 1. Preamble .....                                                                                                     | 85              |
| 2. Tubular Body .....                                                                                                 | 86              |
| 3. Hemostasis Valve .....                                                                                             | 89              |
| 4. Remaining Claim 1 Limitations .....                                                                                | 94              |
| B. Claims 2-9 .....                                                                                                   | 94              |
| VIII. SECONDARY CONSIDERATIONS .....                                                                                  | 94              |
| IX. THE BOARD SHOULD NOT DENY INSTITUTION UNDER<br>§325(D) .....                                                      | 94              |

**TABLE OF CONTENTS**  
**(cont'd)**

|                                                                      | <b>Page No.</b> |
|----------------------------------------------------------------------|-----------------|
| X. MANDATORY NOTICES, GROUNDS FOR STANDING,<br>AND FEE PAYMENT ..... | 95              |
| A. Real Parties-In-Interest (37 C.F.R. §42.8(b)(1)) .....            | 95              |
| B. Related Matters (37 C.F.R. §42.8(b)(2)) .....                     | 95              |
| C. Lead and Backup Counsel (37 C.F.R. §42.8(b)(3)) .....             | 96              |
| D. Service Information (37 C.F.R. §42.8(b)(4)) .....                 | 96              |
| E. Grounds for Standing (37 C.F.R. §42.104) .....                    | 97              |
| F. Payment of Fees (37 C.F.R. §42.15(a)) .....                       | 97              |
| XI. CONCLUSION .....                                                 | 97              |

## TABLE OF AUTHORITIES

### Page No(s).

|                                                                                                                 |            |
|-----------------------------------------------------------------------------------------------------------------|------------|
| <i>Allen Eng'g Corp. v. Bartell Indus., Inc.</i> ,<br>299 F.3d 1336 (Fed. Cir. 2002).....                       | 18         |
| <i>Am. Med. Sys., Inc. v. Biolitec, Inc.</i> ,<br>618 F.3d 1354 (Fed. Cir. 2010).....                           | 19         |
| <i>Biagro W. Sales, Inc. v. Grow More, Inc.</i> ,<br>423 F.3d 1296 (Fed. Cir. 2005).....                        | 37         |
| <i>Bicon, Inc. v. Straumann Co.</i> ,<br>441 F.3d 945 (Fed. Cir. 2006).....                                     | 18         |
| <i>Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc.</i> ,<br>289 F.3d 801 (Fed. Cir. 2002).....              | 18, 19     |
| <i>Comcast Cable Commc'ns LLC v. Promptu Sys. Corp.</i> ,<br>IPR2018-00342, Paper 13 (PTAB July 19, 2018) ..... | 95         |
| <i>In re Gleave</i> ,<br>560 F.3d 1331 (Fed. Cir. 2009).....                                                    | 86         |
| <i>Imperative Care, Inc. v. Inari Med., Inc.</i> ,<br>IPR2024-01157, Paper 5 (P.T.A.B. Oct. 29, 2024) .....     | 17, 36, 43 |
| <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> ,<br>IPR2024-01157, Paper 1 (P.T.A.B. July 8, 2024).....    | 96         |
| <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> ,<br>IPR2024-01257, Paper 1 (P.T.A.B. Aug. 12, 2024) .....  | 96         |
| <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> ,<br>No. 24-cv-3117 (N.D. Cal., filed May 22, 2024).....    | 95, 97     |
| <i>Ex Parte Klop</i> ,<br>Appeal 2019-006763, 2020 WL 2473929 (P.T.A.B. May 7, 2020) .....                      | 86         |

## TABLE OF AUTHORITIES (*cont'd*)

|                                                                                           | Page No(s).   |
|-------------------------------------------------------------------------------------------|---------------|
| <i>KSR Int’l Co. v. Teleflex Inc.</i> ,<br>550 U.S. 398 (2007).....                       | <i>passim</i> |
| <i>Marrin v. Griffin</i> ,<br>599 F.3d 1290 (Fed. Cir. 2010).....                         | 18            |
| <i>In re Nilssen</i> ,<br>851 F.2d 1401 (Fed. Cir. 1988).....                             | 22            |
| <i>Phillips v. AWH Corp.</i> ,<br>415 F.3d 1303 (Fed. Cir. 2005) (en banc) .....          | 15            |
| <i>Sandisk Corp. v. Kingston Tech. Co., Inc.</i> ,<br>695 F.3d 1348 (Fed. Cir. 2012)..... | 37            |
| <i>Seachange Int’l, Inc. v. C-COR, Inc.</i> ,<br>413 F.3d 1361 (Fed. Cir. 2005).....      | 19            |
| <i>TomTom, Inc. v. Adolph</i> ,<br>790 F.3d 1315 (Fed. Cir. 2015).....                    | 20            |
| <i>Unwired Planet, LLC v. Google Inc.</i> ,<br>841 F.3d 995 (Fed. Cir. 2016).....         | 21            |
| <i>Vitronics Corp. v. Conceptronic, Inc.</i> ,<br>90 F.3d 1576 (Fed. Cir. 1996).....      | 16            |

## OTHER AUTHORITIES

|                       |        |
|-----------------------|--------|
| 35 U.S.C. § 102 ..... | 21     |
| 35 U.S.C. § 103 ..... | 21     |
| 35 U.S.C. §325 .....  | 94, 95 |

**TABLE OF AUTHORITIES**  
**(*cont'd*)**

|                        | <b>Page No(s).</b> |
|------------------------|--------------------|
| 37 C.F.R. §42.8.....   | 96                 |
| 37 C.F.R. §42.15.....  | 97                 |
| 37 C.F.R. §42.100..... | 15                 |
| 37 C.F.R. §42.104..... | 97                 |

**LIST OF EXHIBITS**

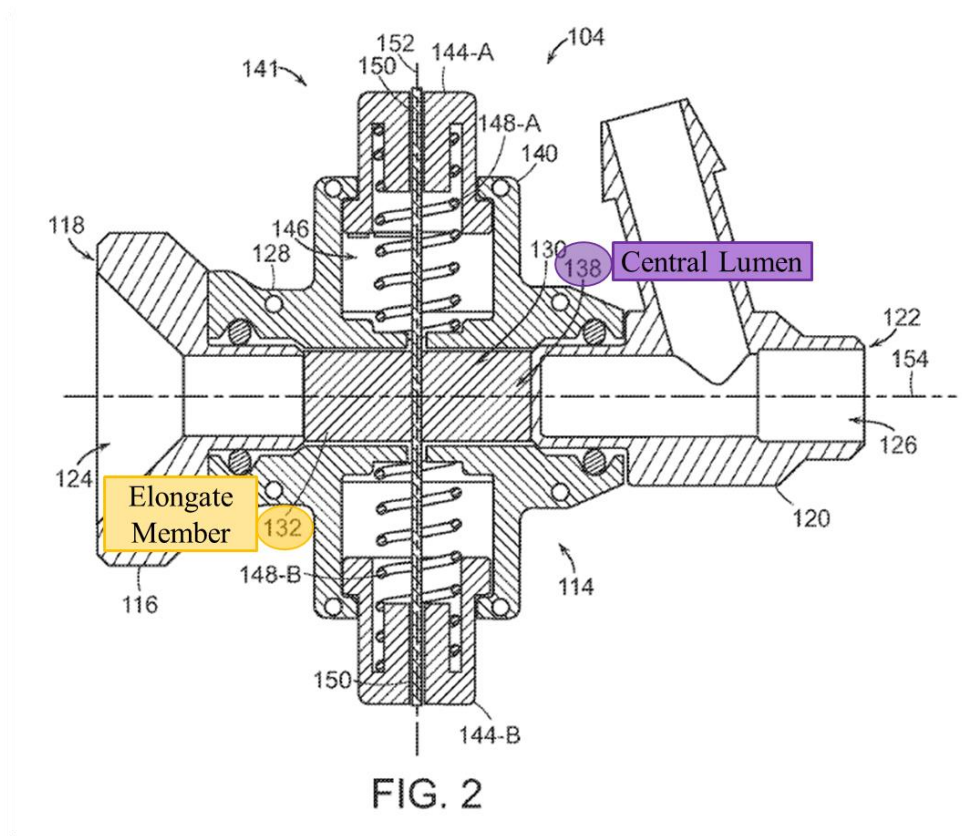
| <b>Exhibit No.</b> | <b>Description</b>                                                                                  |
|--------------------|-----------------------------------------------------------------------------------------------------|
| 1001               | U.S. Patent No. 11,697,012 (“the ’012 patent”)                                                      |
| 1002               | Excerpts from the prosecution history of the ’012 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               | Drawings Submitted During Prosecution of U.S. Patent Application No. 10/371,190 dated June 18, 2003 |
| 1009               | U.S. Patent No. 5,429,616 to Schaffer (“Schaffer ’616”)                                             |
| 1010               | U.S. Patent Publication US 2011/0144592 A1 to Wong et al. (“Wong”)                                  |
| 1011               | U.S. Patent Publication US 2015/0173782 A1 to Garrison et al. (“Garrison”)                          |
| 1012               | U.S. Patent No. 9,216,277 B2 to Myers (“Myers”)                                                     |
| 1013               | Dorland’s Illustrated Medical Dictionary, 32 <sup>nd</sup> ed. (2012) - Definition of “Catheter”    |
| 1014               | U.S. Patent No. 4,723,550 to Bales et al.                                                           |
| 1015               | U.S. Patent No. 5,895,376 to Schwartz et al.                                                        |
| 1016               | U.S. Patent No. 12,109,384 B2 to Merritt et al.                                                     |

Petitioner Imperative Care, Inc. (“Petitioner”) requests *inter partes* review (“IPR”) of claims 1-9 (“the challenged claims”) of U.S. Patent No. 11,697,012 (“the ’012 patent”), which is assigned to Inari Medical, Inc. (“Patent Owner” or “PO”).

## **I. SUMMARY OF THE ARGUMENT**

A variety of 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 medical procedures.

The challenged claims recite an “aspiration catheter” having a specific type of hemostasis valve. The claimed hemostasis valve has a “collapsible tubular sidewall” defining a “valve lumen.” The term “collapsible tubular sidewall” does not appear in the ’012 patent specification and, therefore, it is not identified in any figures. Instead, the specification describes valves having “an elongate member 132” or “tubular member 132” with a “central lumen 138”:

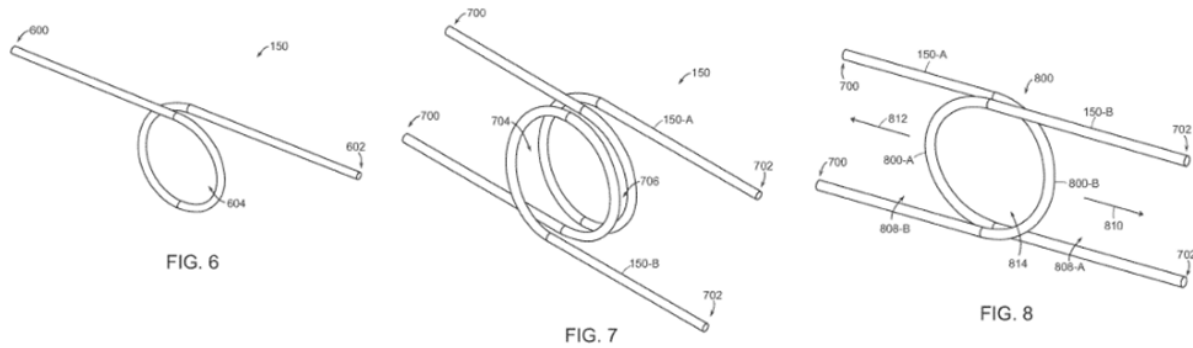


(Ex. 1001, 7:11-57, Fig. 2.) The “elongate member 132 can comprise a compliant tubular structure” that “can facilitate the collapse” of the elongate member 132.<sup>1</sup> (*Id.*) Further, dependent claim 2 of the ’012 patent recites that “the collapsible tubular sidewall comprises a tubular member defining a valve lumen.”

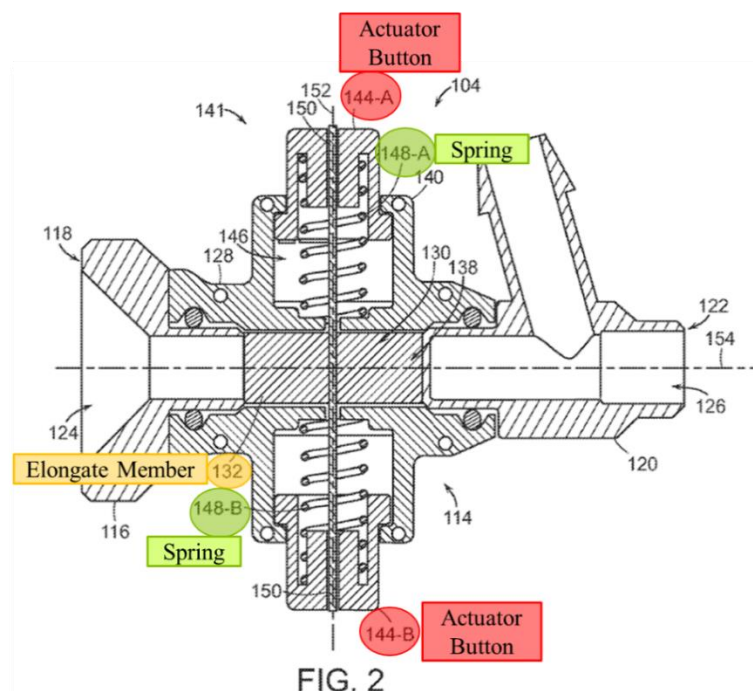
The challenged claims also recite a “constricting mechanism” having “a first filament formed into a loop around the collapsible tubular sidewall.” When tension is applied to the ends of the filament, the filament constricts the collapsible tubular

<sup>1</sup> Colors and annotations added by Petitioner except where noted.

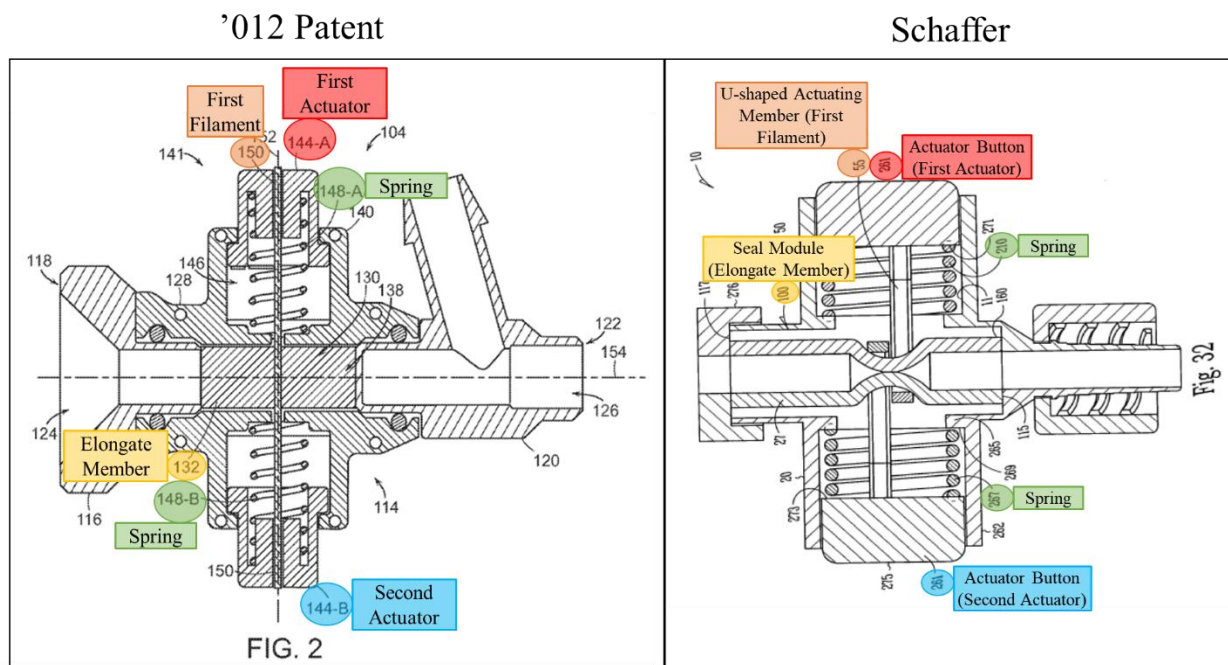
sidewall, thereby causing the diameter of the valve's lumen to decrease. (*Id.*, 8:5-16.) The specification describes various filament configurations:



(*Id.*, Figs. 6-8.) The challenged claims further recite that the “constricting mechanism” includes “at least a first actuator” and “first spring.” The actuator and spring apply tension to the filament in a first position to constrict the valve and release tension on the filament in a second position to open the valve. Figure 2 illustrates actuator buttons (144A, 144B) and springs (148-A, 148-B):



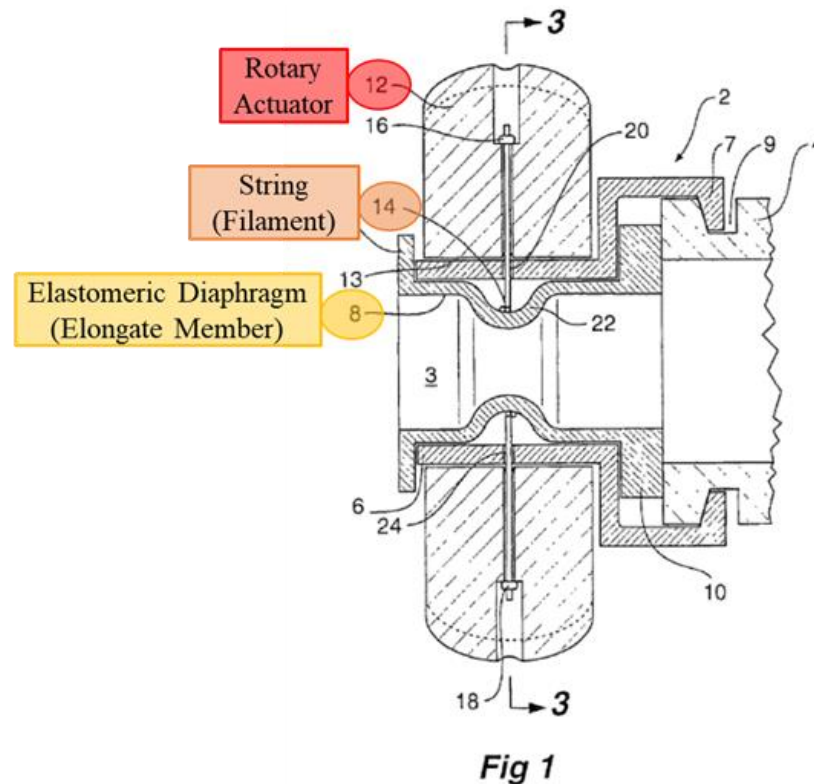
Hemostasis valves that included a filament looped around a collapsible tube to open and close the valve were well known before September 6, 2017, the earliest possible priority date for the '012 patent. **Schaffer**, a patent application published in 2003, describes hemostasis valves for use with catheters during intravascular procedures. (Ex. 1005, [0002], [0008].) Schaffer's valve includes opposing actuator buttons attached to springs that apply or release tension on a filament to collapse a tube within the valve. As shown below, Schaffer's valve has the same components, in the same arrangement, as the valve claimed in the '012 patent:



Schaffer was not before the Examiner during prosecution of the '012 patent and anticipates the challenged claims.

**Hartley**, a patent application published in 2003, describes a hemostasis valve for use with catheters to prevent blood loss. (Ex. 1006, [0002]-[0003].) Hartley's

valve also includes an actuator that applies tension to a filament looped around a collapsible tube to open and close the valve:



(*Id.*, [0031], Fig. 1.) Hartley was discussed by the Examiner during prosecution but was not combined with any other references, such as Schaffer, as in this Petition.

**Eller**, a patent published in 2015, also describes a hemostasis valve for use with catheters to prevent blood loss during medical procedures. (Ex. 1007, 1:20-50.) Eller's valve also includes an actuator that applies tension to a filament looped around a collapsible tube to open and close the valve:

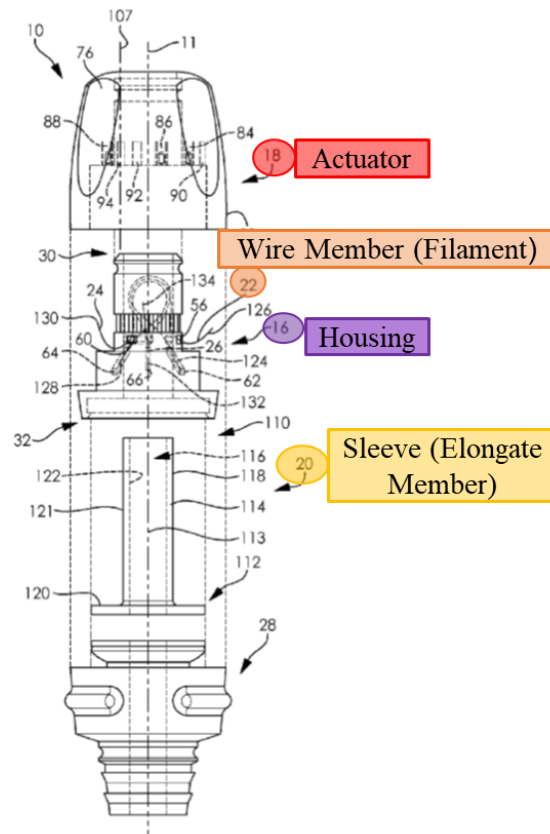
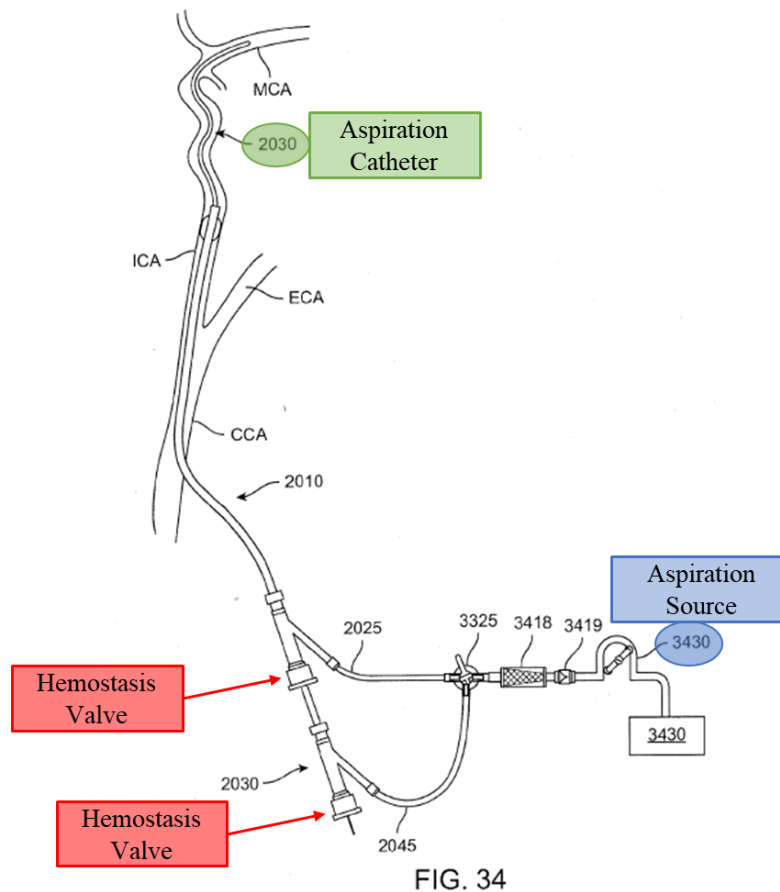


FIG. 2

(Ex. 1007, 5:1-12, Fig. 2.) Eller was listed in an Invention Disclosure Statement (“IDS”) but was not substantively discussed or applied during prosecution.

The preamble of the challenged claims also recites an “aspiration catheter.” As discussed below, the preamble term “aspiration” is not limiting. However, even if the preamble were limiting, combining a hemostasis valve, like the valves described above, with an “aspiration catheter” was well known before September 2017. **Garrison**, a patent application published in 2015, discloses aspiration catheters having hemostasis valves to seal the aspiration catheter and permit the introduction of other devices through the catheter:



(Ex. 1011, [0098], Fig. 34.) If the preamble were limiting, persons of ordinary skill in the art (“POSITAs”) would have found it obvious to combine these known aspiration catheters (e.g., Garrison) with the known filament-based hemostasis valves (e.g., Schaffer), as demonstrated in this Petition.

The grounds identified herein demonstrate a reasonable likelihood that at least one claim of the ’012 patent is unpatentable. Accordingly, Petitioner requests that the Board institute this IPR to reconsider the patentability of the ’012 patent.

## II. THE '012 PATENT

### A. Overview

The '012 patent describes a delivery system 100 that includes a catheter 102 and a hemostasis (or “garrote”) valve 104 for use during intravascular procedures.

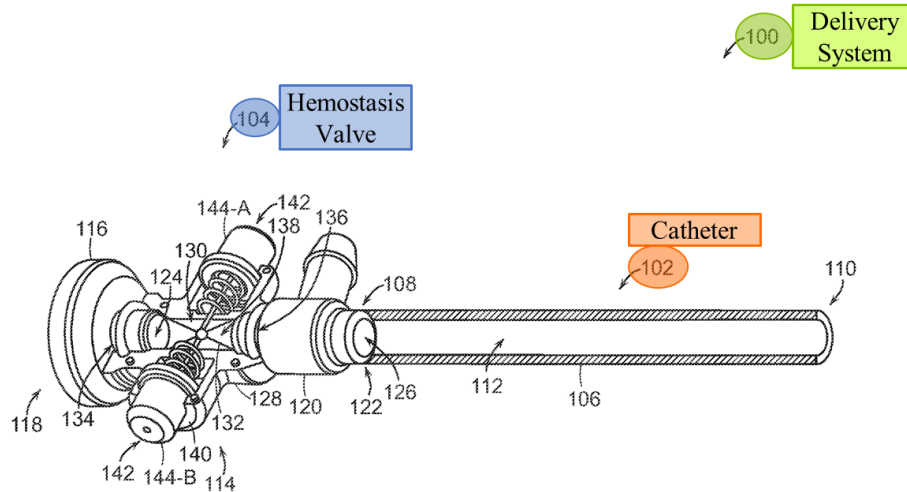
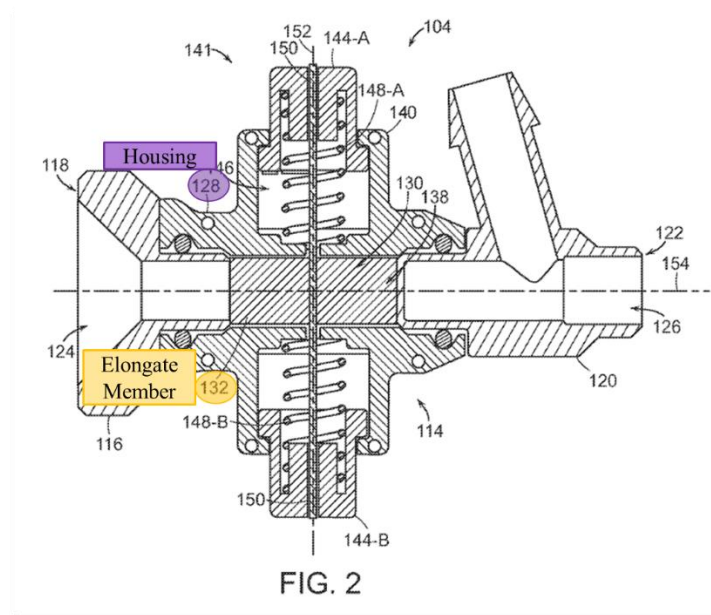


FIG. 1

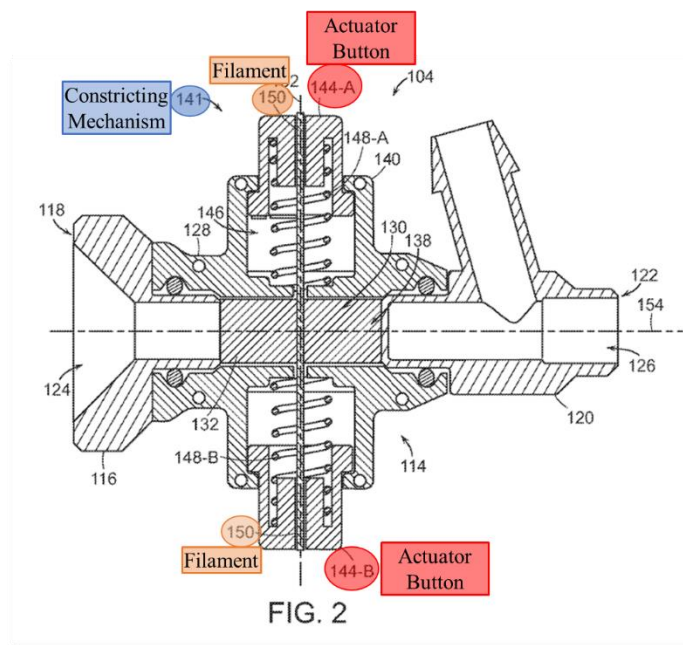
(Ex. 1001, 6:26-47, Fig. 1.) The catheter is inserted into the patient’s vasculature and the hemostasis valve helps provide a seal to minimize blood loss. (*Id.*, 1:41-44.) The valve “can seal with or without a tool extending through the valve.” (*Id.*, 5:55-58.)

The hemostasis valve includes an “elongate member 132” that extends through the interior of the valve housing 128. (*Id.*, 7:1-31.) The elongate member has a “thin-walled compliant tubular structure” that facilitates “the uniform collapse of the elongate member 132 and the sealing of the elongate member 132”:



(*Id.*, 7:17-23, Fig. 2.)

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



(*Id.*, 8:5-8, Fig. 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.*, 8:8-12.) 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, that biases the actuator toward the open or closed configuration. (*Id.*, 8:38-56.) In Figure 4, the springs bias the valve toward the closed configuration:

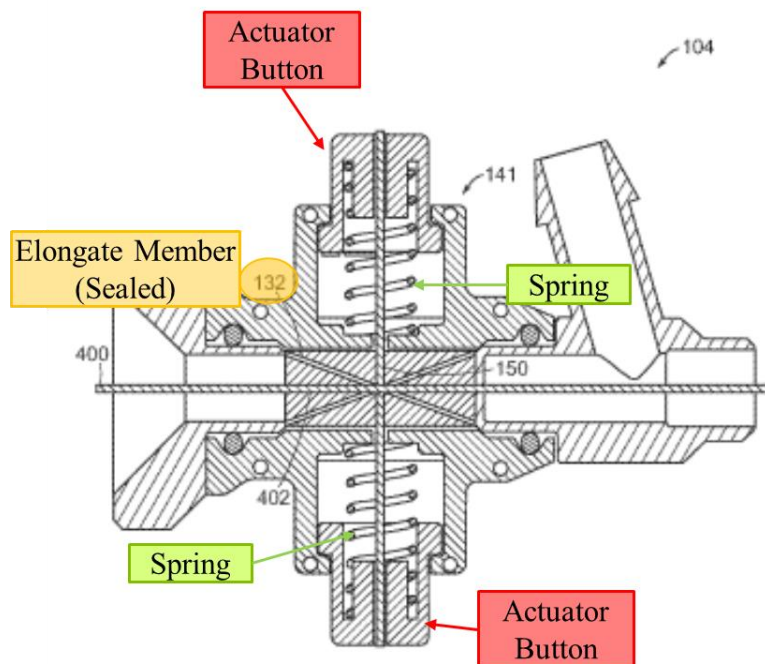
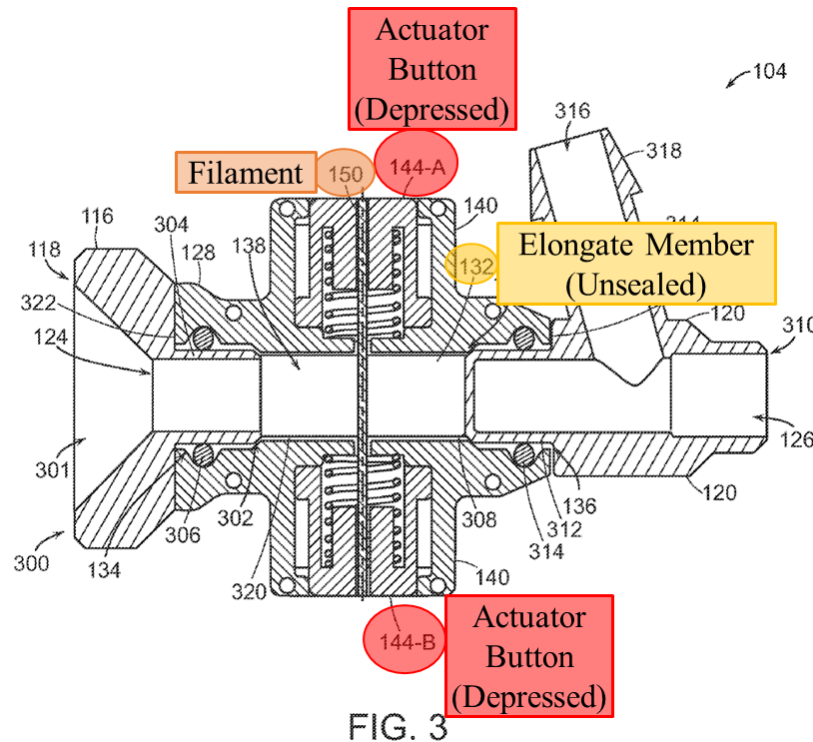


FIG. 4

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



(*Id.*, 9:54-62, 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:

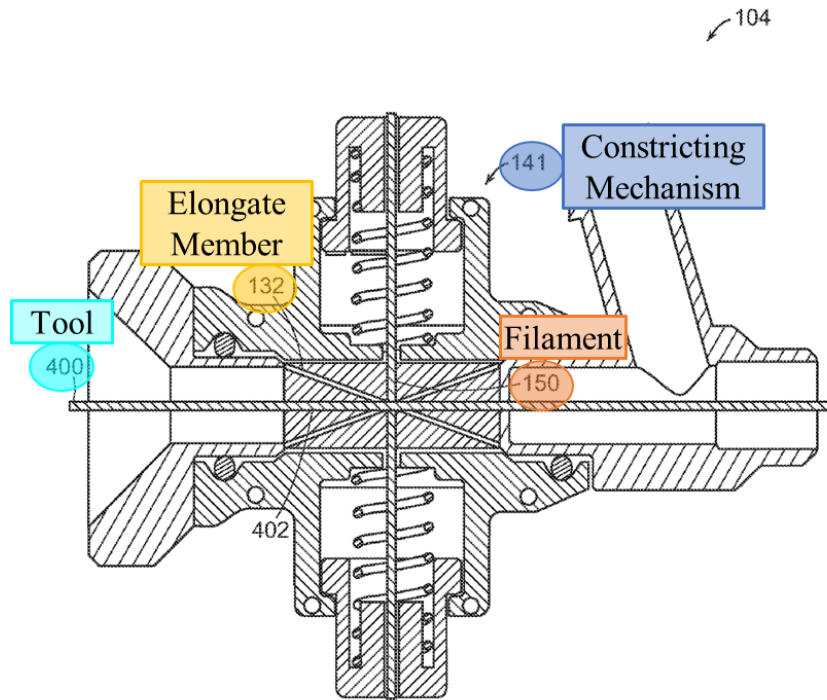


FIG. 4

(*Id.*, 12:4-15, 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 8-9:

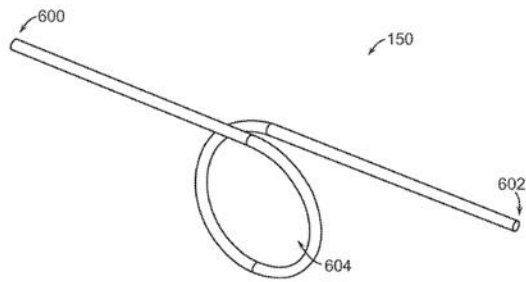


FIG. 6

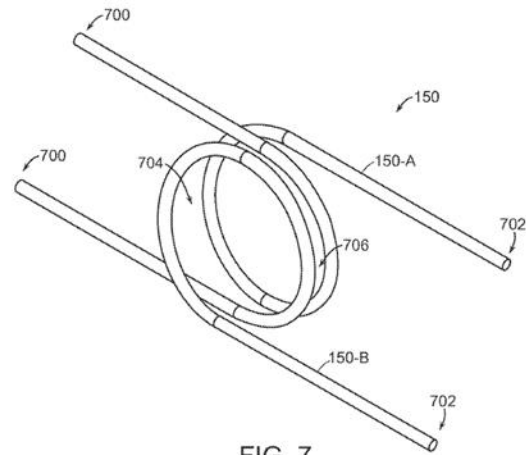


FIG. 7

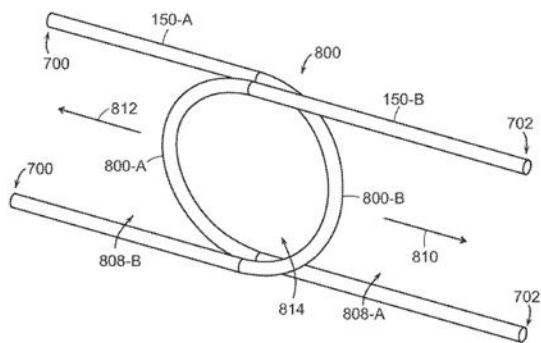


FIG. 8

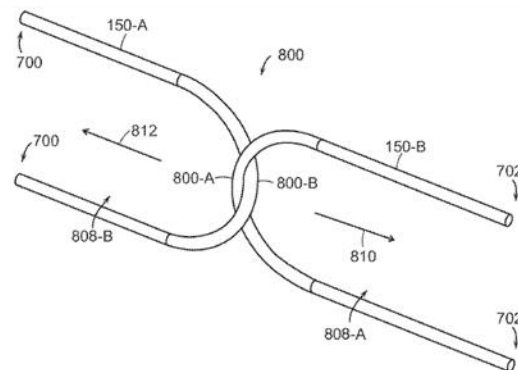


FIG. 9

(*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”:

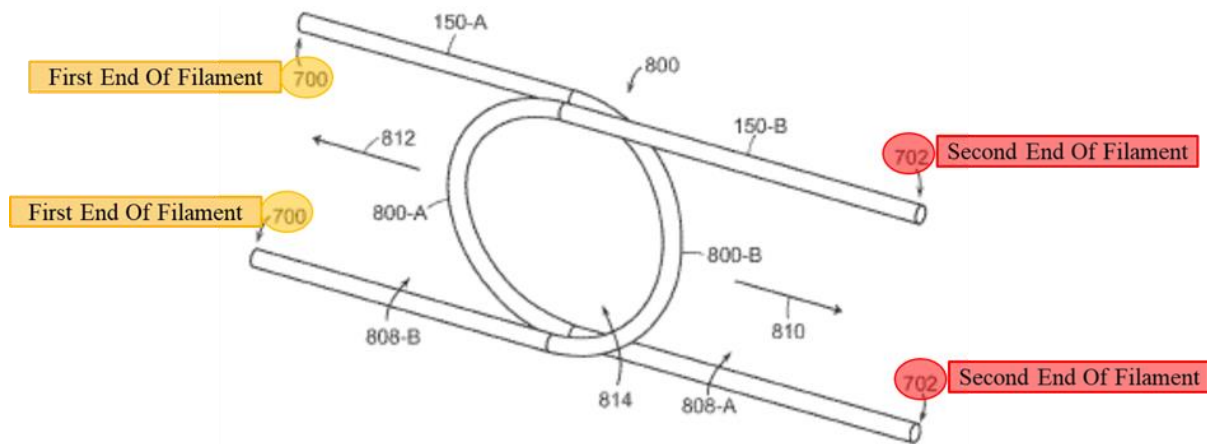


FIG. 8

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

## B. Prosecution History

The examiner of the '012 patent did not make any prior-art based rejections. In the Notice of Allowance, the examiner found that the closest prior art of record was Hartley (US 2003/0116731), Wong (U.S. 2011/0144592) (Ex. 1010), and Myers (U.S. 9,216,277) (Ex. 1012). (Ex. 1002, 85.) The examiner found that Hartley disclosed every limitation of allowed claim 1 except “a first spring configured to move the first actuator in a direction that pulls the first end portion such that the diameter of the valve lumen decreases in response to reducing a diameter of the loop.” (*Id.*) The examiner concluded that Wong and Myers both disclose a hemostasis valve with a spring configured to move the valve to a closed position. (*Id.*, 85-86.) Yet, the examiner found that “the spring in Wong or Myers is inapplicable to add into the device of Hartley.” (*Id.*, 86.) The examiner did not explain this finding.

**C. The Earliest Possible Priority Date**

The '012 patent claims priority to provisional application No. 62/554,931, filed September 6, 2017, which is the earliest possible priority date for the '012 patent. (Ex. 1001.) Petitioner applies this earliest possible priority date in this Petition; however, Petitioner preserves 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, ¶35.)

**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); *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (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.” *Phillips*, 415 F.3d at 1316.

**A. Filament**

The challenged claims require “a first filament.” A POSITA would have understood the term “filament” to mean at least “one or more threads, lines, cords, ropes, ribbons, flat wires, sheets, or tapes” based on the intrinsic record. (Ex. 1003, ¶¶48-54.)

Claim construction generally begins with the claim language. *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). Here, however, the claims provide little information regarding the “filament.” Claim 1 recites “a first filament formed into a loop around the collapsible tubular sidewall” having “at least a first end portion extending away from the loop and connected to the first actuator.” (Ex. 1001, claim 1.) Other than clarifying that the filament has a “first end portion” and forms a loop, the claims do not provide a POSITA with guidance on the meaning of “filament.”

The specification, however, provides explicit examples of “filaments.” The ’012 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.)

The examiner mentioned the “filament” in the Notice of Allowance, concluding that Hartley describes a “first filament 14 formed into a loop around the collapsible tubular sidewall 8, see Figs. 3-4.” (Ex. 1002, 85.) Hartley refers to item 14 as a “string,” which comports with Petitioner’s construction of “filament.” (Ex. 1006, [0017], [0031].) The “filament” was not otherwise discussed during prosecution.

In related proceedings, PO argued that “filament” means “a thin, flexible length of material formed by one or more strands of material.” *Imperative Care, Inc. v. Inari Med., Inc.*, IPR2024-01157, Paper 5 at 16 (P.T.A.B. Oct. 29, 2024). Yet, the ’012 patent does not describe the “filament” as “thin” or “flexible.” Further, PO’s definition would exclude specific “filaments” identified in the patent, such as a “sheet” of metal, which would not have “one or more strands of material.” Moreover, in related patents, PO has specifically claimed a filament that “is flexible,” demonstrating that flexibility is not an inherent property of the filament.

(Ex. 1016, claim 1.) For at least these reasons, PO’s proposed construction is incorrect. (Ex. 1003, ¶54.)

**B. “Aspiration” In The Preamble Is Not Limiting**

The preamble of claim 1 recites “[a]n aspiration catheter.” The term “aspiration” describes an intended use for the device defined in the claim body and is not limiting. *Catalina Mktg. Int’l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 809 (Fed. Cir. 2002).

The general rule is that the preamble does not limit the claims. *Allen Eng’g Corp. v. Bartell Indus., Inc.*, 299 F.3d 1336, 1346 (Fed. Cir. 2002). A preamble may be limiting, however, “if it recites essential structure or steps” or otherwise “is necessary to give life, meaning, and vitality to the claim.” *Catalina*, 289 F.3d at 808 (internal quotations omitted). But the preamble is “not limiting when the claim body describes a structurally complete invention such that deletion of the preamble phrase does not affect the structure or steps of the claimed invention.” *Id.* at 809. Likewise, a preamble that merely describes the intended use or purpose of the claimed invention is not limiting. *Marrin v. Griffin*, 599 F.3d 1290, 1294 (Fed. Cir. 2010); *Bicon, Inc. v. Straumann Co.*, 441 F.3d 945, 952 (Fed. Cir. 2006).

Here, the claim body describes a structurally complete invention. The preamble term “aspiration” does not provide any essential structure and is not necessary to give life, meaning, and vitality to the claims. Notably, the ’012 patent

specification does not mention “aspiration,” much less disclose any structural features unique to an “aspiration catheter.” (Ex. 1003, ¶55.) In addition, the applicant did not “clearly and unmistakably” rely on the preamble to distinguish the prior art during prosecution, and therefore, this is not one of the “rare instances” in which a statement of intended use in a preamble may be limiting. *Catalina*, 289 F.3d at 809.

While the preamble of claim 1 provides antecedent basis for “the catheter” in the claim body, the term “aspiration” does not appear elsewhere in the claims. Further, providing antecedent basis for a term in the claim body does not make the preamble limiting unless the preamble also provides “context essential to understand[ing] the meaning” of the term. *Am. Med. Sys., Inc. v. Biolitec, Inc.*, 618 F.3d 1354, 1359 (Fed. Cir. 2010). For example, in *American Medical*, the preamble recited “photoselective vaporization of tissue” and the claim body recited “the tissue.” *Id.* The Federal Circuit held that the preamble was not limiting because “the generic term ‘tissue’ in the preamble [did not] provide any ‘context essential to understand[ing]’ the meaning of ‘the tissue’ in the body of each claim.” *Id.* (quoting *Seachange Int’l, Inc. v. C-COR, Inc.*, 413 F.3d 1361, 1376 (Fed. Cir. 2005)). The same is true here – the preamble term “aspiration” does not provide any context essential to understanding “catheter.” Moreover, even if the preamble term “catheter” were limiting, the mere fact that one portion of a claim’s preamble

“provides a necessary structure for [the claim] does not necessarily convert the entire preamble into a limitation, particularly one that only states the intended use of the invention.” *TomTom, Inc. v. Adolph*, 790 F.3d 1315, 1323-1324 (Fed. Cir. 2015).

Further, the examiner did not find that the term “aspiration” added any context essential to understanding the claim. Rather, the examiner found, “Hartley discloses a catheter [that] is capable for aspiration therefore, it can be called as an aspiration catheter.” (Ex. 1002, 85-86.) Similarly, the examiner found Wong and Meyers disclose catheters “capable of using for aspiration” and, therefore, concluded the catheters could be called “an aspiration catheter.” (*Id.*) Notably, Hartley, Wong, and Meyers do not mention aspiration. Rather, the examiner presumed any “catheter” was capable of being an “aspiration catheter,” demonstrating that the term “aspiration” was not treated as limiting.

In the event the Board disagrees and finds the preamble term “aspiration” limiting, Petitioner has presented unpatentability grounds where the term (1) is not limiting, and (2) is limiting.

## **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 | 1-9               |
| 2      | Schaffer                      | 35 U.S.C. § 103 | 1-9               |
| 3      | Schaffer + Hartley            | 35 U.S.C. § 103 | 1-9               |
| 4      | Schaffer + Eller              | 35 U.S.C. § 103 | 1-9               |
| 5      | Schaffer + Garrison           | 35 U.S.C. § 103 | 1-9               |
| 6      | Schaffer + Hartley + Garrison | 35 U.S.C. § 103 | 1-9               |
| 7      | Schaffer + Eller + Garrison   | 35 U.S.C. § 103 | 1-9               |

The Petition is supported by the expert declaration of Troy Thornton (Ex. 1003).

**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**

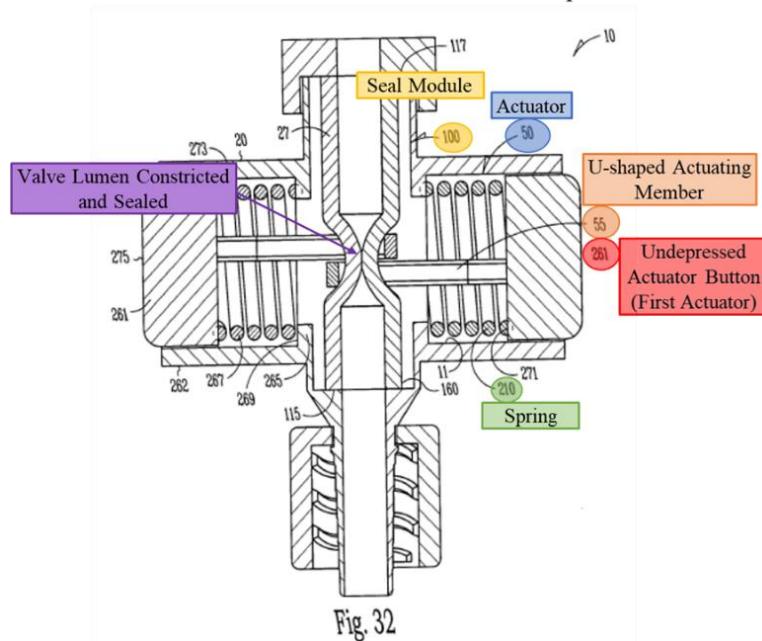
The asserted references are analogous art that is usable in an obviousness combination. *Unwired Planet, LLC v. Google Inc.*, 841 F.3d 995, 1000 (Fed. Cir.

2016). The references are from the same field as the '012 patent, e.g., hemostasis valves for use during intravascular procedures. (Ex. 1003, ¶26.) The references are also pertinent to the problem the inventor was focused on, e.g., sealing a catheter during intravascular procedures to minimize blood leaks. (*Id.*) Accordingly, a POSITA is presumed to have been aware of these references and the teachings may be combined to support an obviousness rejection. *In re Nilssen*, 851 F.2d 1401, 1403 (Fed. Cir. 1988).

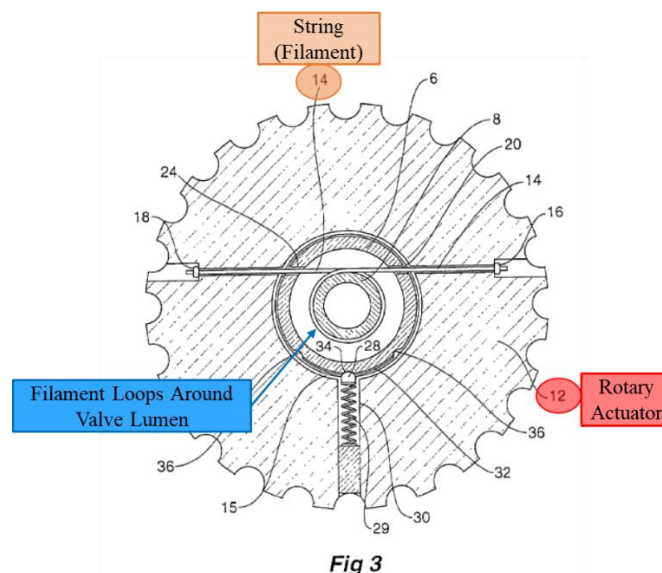
**VI. GROUNDS 1-4: CLAIMS 1-9 ANTICIPATED BY SCHAFFER OR  
RENDERED OBVIOUS BY SCHAFFER ALONE OR COMBINED WITH  
HARTLEY OR ELLER**

Schaffer anticipates claims 1-9 or renders the claims obvious. (Ex. 1003, ¶¶57-171.) Schaffer discloses a hemostasis valve for use with catheters “that blocks the flow of gas or fluid completely and immediately with or without an instrument in place within the gas/fluid path.” (Ex. 1005, [0002], [0008].) Like the valve described in the '012 patent, Schaffer's valve includes a collapsible tubular sidewall (called a “seal module 100”) within the valve that can receive other catheters. (*Id.*) Schaffer's valve also includes a filament (called “actuating member 55”) that can collapse the tubular sidewall to close the valve. (*Id.*, [0076]-[0077].) Also, like the '012 patent, Schaffer's actuating members 55 (i.e., filament) may be moved from a first position to a second position by depressing two actuator buttons 261 connected to two springs 210. (*Id.*)

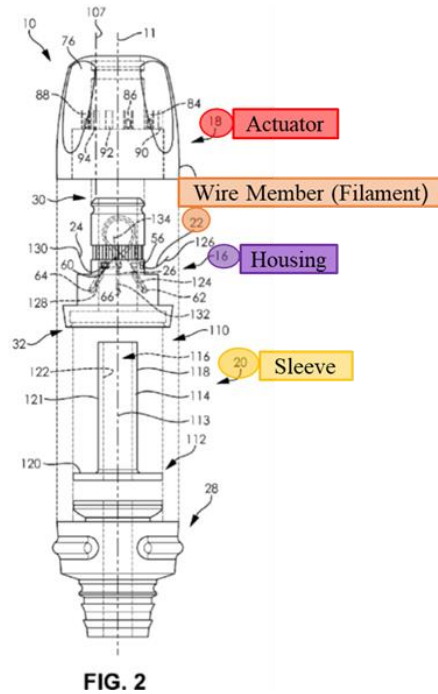
First Position – Actuator Buttons Undepressed



If the Board finds that Schaffer’s actuating members 55 are not a “filament,” Schaffer combined with Hartley or Eller renders the challenged claims obvious. (Ex. 1003, ¶¶58-60.) Hartley and Eller disclose hemostasis valves having a filament that loops around and constricts the lumen of a collapsible tubular sidewall to seal a valve. Hartley’s “filament” is a “string”:



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



(Ex. 1007, 5:1-5, Fig. 2.) Even under PO’s overly narrow construction of “filament,” Hartley’s string and Eller’s wire member are a “filament.” As demonstrated below, a POSITA would have found it obvious to substitute Hartley’s or Eller’s filaments for Schaffer’s actuating members.

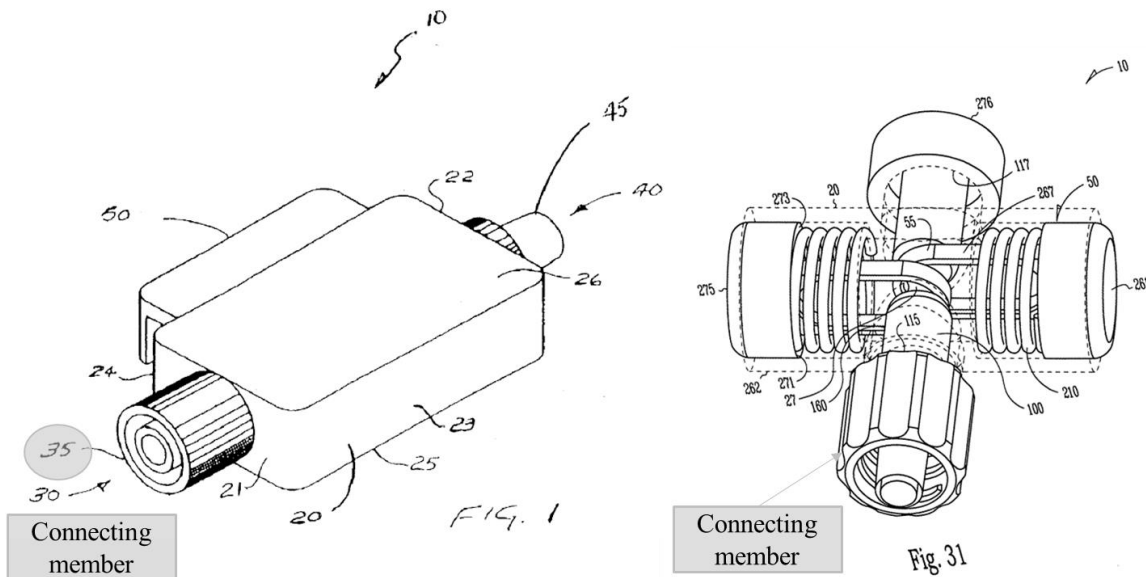
#### A. Claim 1

Schaffer anticipates claim 1 or renders it obvious alone or combined with Hartley *or* Eller. (Ex. 1003, ¶¶61-119.)

##### 1. Preamble

The preamble recites an “aspiration catheter.” The term “aspiration” is not limiting. (*Supra* §IV.B.) Schaffer discloses or renders obvious a “catheter” having the described hemostasis valve. (Ex. 1003, ¶¶62-65.)

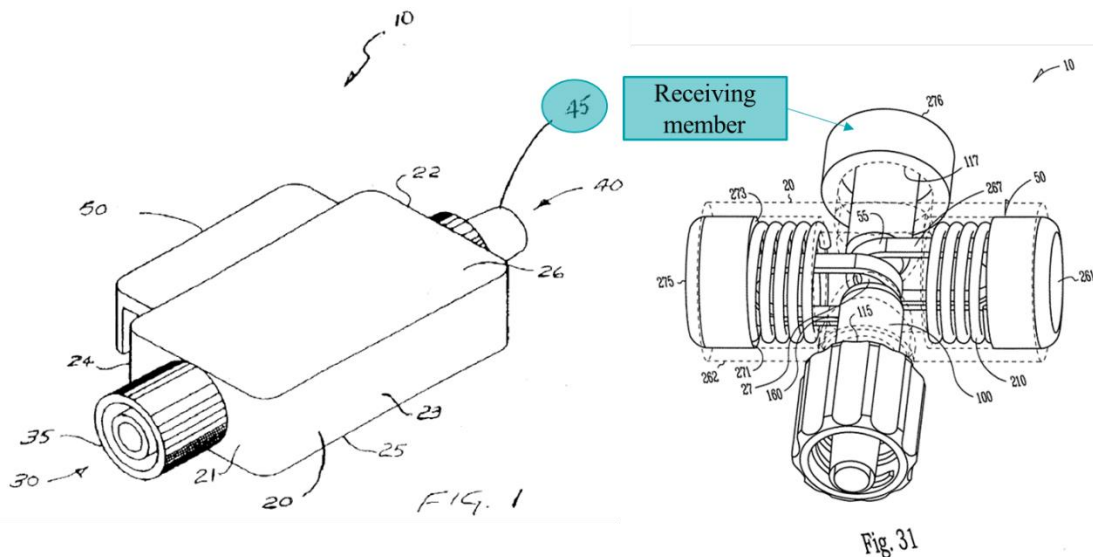
Schaffer states, “This application relates to **catheters**, in particular to a composite fluid-stasis valve for use with **catheters**.” (Ex. 1005, [0002] (emphases added) *see also id.*, [0003] (“Fluid stasis mechanisms are commonly used to prevent loss of fluids from the insertion site of a catheter ....”).) To attach a catheter, Schaffer’s valve includes a “connecting member 35”:



(*Id.*, [0047], Figs. 1, 31.) The connecting member 35 is “sized and configured to attach in fluid communication to a fluid delivery supply **or a body passage such as a blood vessel**.” (*Id.* (emphasis added).) A POSITA would have understood that the connecting member 35 attaches to a body passage via the catheter. (Ex. 1003, ¶164; *see also* Ex. 1006, [0031], Fig. 1 (describing valve “mounted onto catheter body”); Ex. 1007, 16:65-17:4, Fig. 7 (describing valve connector for “releasably attaching another component (e.g., medical device, tubular member) to the connector”).)

“The connecting member 35 is a common male thread ‘Luer’ type fitting or a common ‘slit-fit’ [sic]<sup>2</sup> tube connector or the like.” (Ex. 1005, [0047].) A POSITA would have known that Luer and slip fittings were commonly used to attach hemostasis valves to catheters. (Ex. 1003, ¶65; *see also* Ex. 1007, 16:65-17:4, Fig. 7 (describing type of slip fit connection); Ex. 1014, 4:5-10 (“hemostasis valve 10 is shown to be attached to the end of a catheter 12 by means of a luer lock connector 14 of conventional design”); Ex. 1015, 3:16-17 (similar).) Based on these collective descriptions, a POSITA would have understood Schaffer to disclose attaching a catheter to the hemostasis valve. (Ex. 1003, ¶65.)

If the preamble *were* limiting, Schaffer renders obvious an “aspiration catheter” having the described hemostasis valve. (*Id.*, ¶¶67-70.) Schaffer’s valve includes a “receiving member 45”:



<sup>2</sup> The connector is a “slip-fit” connector. (Ex. 1003, ¶65.)

(Ex. 1005, [0047], Figs. 1, 31.) “The receiving member 45 is, in one option, configured to connect to a fluid or gas delivery system or device such as a **syringe**, intravenous system or the like.” (*Id.*, [0049] (emphasis added).) POSITAs would have understood that a syringe may act as the aspiration source for an aspiration catheter. (*See, e.g.*, Ex. 1011, [0060], [0111], [0123], [0125]; Ex. 1003, ¶67.) Thus, Schaffer’s valve is configured for use with an aspiration catheter. (Ex. 1003, ¶68.) Further, aspiration catheters were a common type of catheter used with hemostasis valves in September 2017 with known benefits, and therefore, POSITAs would have been motivated to use Schaffer’s system (e.g., valve, catheter and syringe) as an aspiration catheter. (*Id.*, ¶¶69-70.) A POSITA would have reasonably expected success based on the many references disclosing the effectiveness of aspiration catheters. (*Id.*)

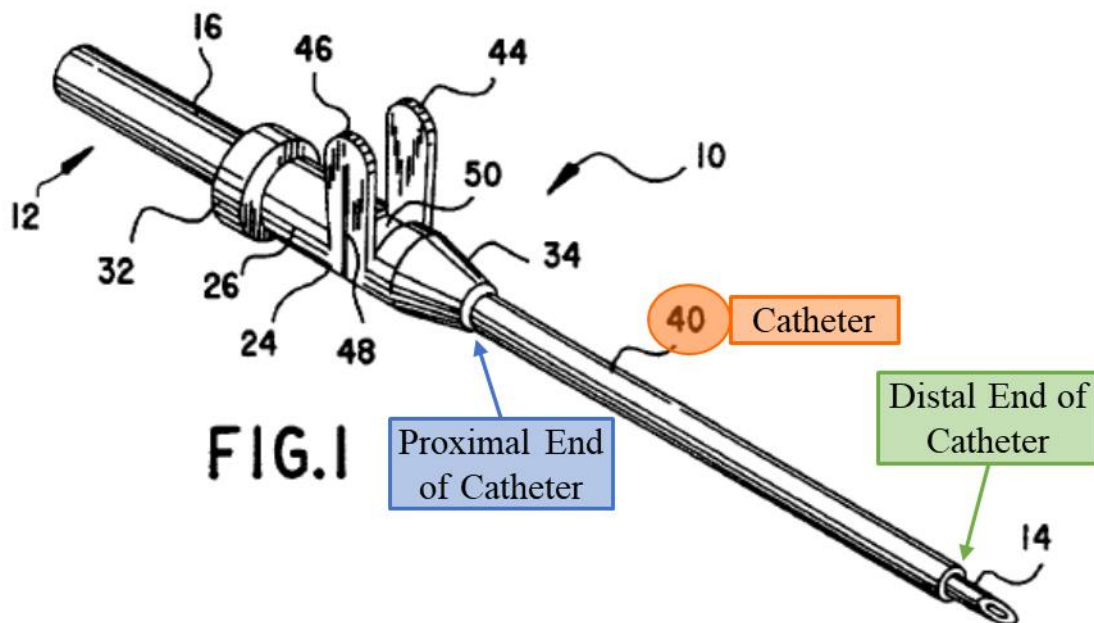
In Grounds 5-7, Petitioner expressly combines Schaffer with Garrison’s aspiration catheters to further demonstrate the obviousness of the challenged claims. *Infra* §VII.

## **2. Tubular Body**

Claim 1 next recites “an elongate, flexible tubular body, having a proximal end, a distal end and a central lumen.” Schaffer discloses this limitation. (Ex. 1003, ¶¶71-76.)

Schaffer's hemostasis valve includes a seal module 100 defining a central lumen 193 and further discloses that "a range of instruments [can be] used within the seal module," such as "a **catheter**, guidewire, needle, or fiber," and that "a guidewire and **catheter** may be placed into the same lumen 193 for extension into a body passage." (Ex. 1005, [0056], [0074] (emphases added); *see also id.*, [0047] ("The second end-wall 22 of the housing 20 is sized and configured to receive an inserted instrument, catheter or guide wire through a receiving member 45.").) POSITAs would have understood that catheters have an "elongate, flexible tubular body, having a proximal end, a distal end and a central lumen." (Ex. 1003, ¶73; Ex. 1013, 306 (defining "catheter" as "a tubular, flexible, surgical instrument that is inserted into a cavity of the body to withdraw or introduce fluid").)

For example, Schaffer incorporates by reference U.S. Patent No. 5,429,616 ("Schaffer '616"). (Ex. 1005, [0002].) Schaffer '616 discloses "catheters for venous or arterial cannulation ...." (Ex. 1009, 1:6-9.) These catheters include features common to all catheters, including an elongate, tubular body, a proximal end, a distal end, and a central lumen (which receives needle 14):



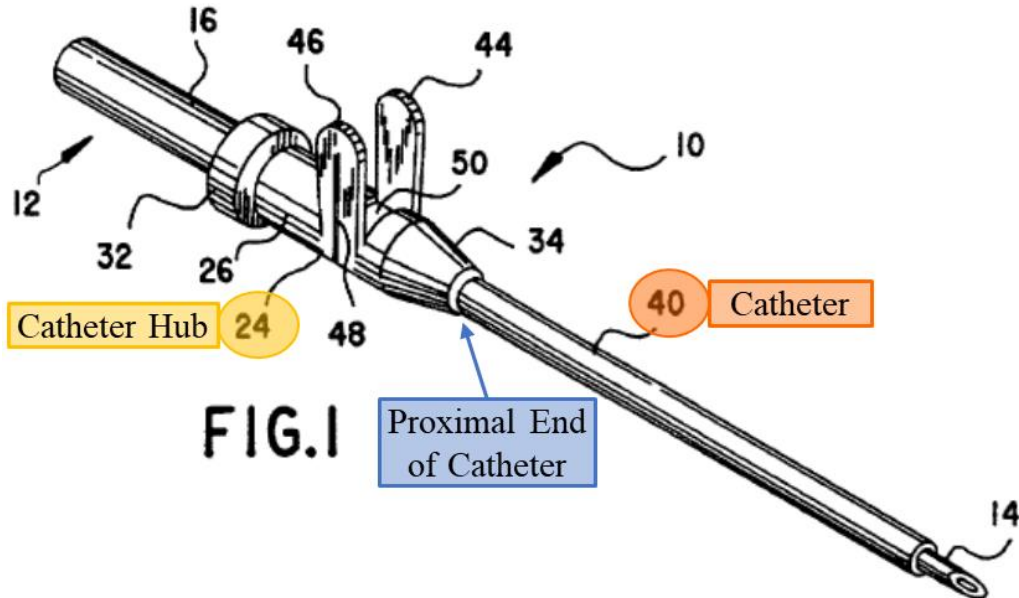
(*Id.*, 4:52-56, Fig. 1; Ex. 1003, ¶74.) Schaffer '616 discloses that the catheter is “advanced into the lumen of the vessel” during use. (Ex. 1009, 5:5-12.) POSITAs would have understood that the catheter would have a flexible body to enable the catheter to conform to the vessel and avoid damaging the patient’s tissue during insertion. (Ex. 1003, ¶¶74-75.) Thus, Schaffer '616 further confirms that the “catheters” in Schaffer would have an elongate, flexible tubular body, having a proximal end, a distal end and a central lumen. (*Id.*)

### 3. Hemostasis Valve

Claim 1 next recites “a hemostasis valve on the proximal end of the catheter.” Schaffer discloses this limitation or renders the limitation obvious. (Ex. 1003, ¶¶77-81.)

Schaffer discloses hemostasis valves for use with catheters. (Ex. 1005, [0002], [0046], [0055]; *supra* §VI.A.1.) As explained above, Schaffer’s valve includes a “connecting member 35” for attaching the hemostasis valve to a catheter. (*Id.*, [0047]; *supra* §VI.A.1.) Because the catheter is inserted into a “body passage such as a blood vessel,” the hemostasis valve must be positioned at the catheter’s proximal end because the rest of the catheter is in the patient. (Ex. 1005, [0047]; Ex. 1003, ¶¶78-79; *see also* Ex. 1006, [0031], Fig. 1 (valve mounted to catheter’s proximal end); Ex. 1007, 16:65-17:4, Fig. 7 (same).)

Moreover, Schaffer ’616 discloses a catheter having a “catheter hub 24” at the proximal end of the catheter 40:



(Ex. 1009, 4:20-56, Fig. 1.) Schaffer ’616’s “catheter hub” includes a collapsible valve 50 that prevents blood or fluid from leaking out of the catheter. (*Id.*, 4:20-49, 5:5-24.) The catheter hub, including the valve, is attached to the catheter’s proximal

end. (See *id.*, 4:34-35 (“A catheter 40 extends axially outward from distal end 34.”).) Thus, Schaffer ’616 further discloses positioning a hemostasis valve on the proximal end of a catheter.

If the Board finds Schaffer does not disclose this limitation, Schaffer renders the limitation obvious. Schaffer ’616 discloses a valve positioned on the catheter’s proximal end. The positioning of a hemostasis valve on the proximal end of a catheter was the conventional location for a hemostasis valve well before September 2017. (Ex. 1003, ¶80; Ex. 1011, Figs. 1-2; Ex. 1014, Fig. 1.) The purpose of a hemostasis valve is to prevent blood flow out the catheter’s proximal end, and to permit the introduction of other devices through the catheter’s proximal end. (*Id.*) Because the catheter body is in the patient, the hemostasis valve must be attached to the catheter’s proximal end. (*Id.*) Thus, this claim limitation merely combines prior art elements (hemostasis valve and catheter) according to known methods to yield predictable results. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007).

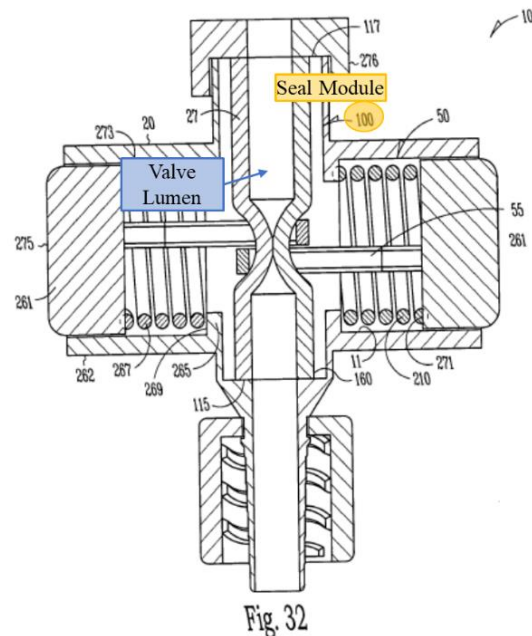
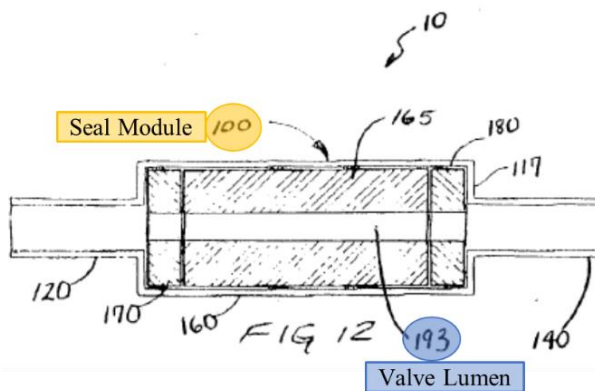
POSITAs would have been motivated to attach Schaffer’s hemostasis valve to the proximal end of the catheter to prevent blood from flowing out of the catheter and because that was the conventional location for a hemostasis valve. (Ex. 1003, ¶¶80-81.) POSITAs would have reasonably expected success in adding Schaffer’s valve to the catheter’s proximal end because, for example, Schaffer ’616 discloses

how to make such a combination. (*Id.*) Thus, POSITAs would have found it obvious to position Schaffer’s hemostasis valve on the proximal end of a catheter. (*Id.*)

#### 4. Collapsible Tubular Sidewall

Claim 1 next recites “a collapsible tubular sidewall defining a valve lumen in communication with the central lumen.” Schaffer discloses this limitation. (Ex. 1003, ¶¶82-85.)

Schaffer’s hemostasis valve includes a “seal module 100” that comprises “a flexible, elongate tubular structure 101.” (Ex. 1005, [0049], [0051], [0054].) The seal module can be “at least partially collapse[ed] ... by a compressive force.” (*Id.*, [0077].) The elongate tubular structure 101 defines a valve lumen 193:



(*Id.*, [0058], Fig. 12, 32.)<sup>3</sup>

Schaffer discloses that “a range of instruments [can be] used within the seal module,” such as “a catheter, guidewire, needle, or fiber,” and that “a guidewire and catheter may be placed into the same lumen 193 for extension into a body passage.” (Ex. 1005, [0056], [0074].) As explained above, the catheter placed into Schaffer’s lumen 193 would define a “central lumen.” (*Supra* §VI.A.2.) Therefore, Schaffer’s seal module 100 is “a collapsible tubular sidewall defining a valve lumen in communication with the central lumen.” (Ex. 1003, ¶¶83-85.)

## **5. Constricting Mechanism**

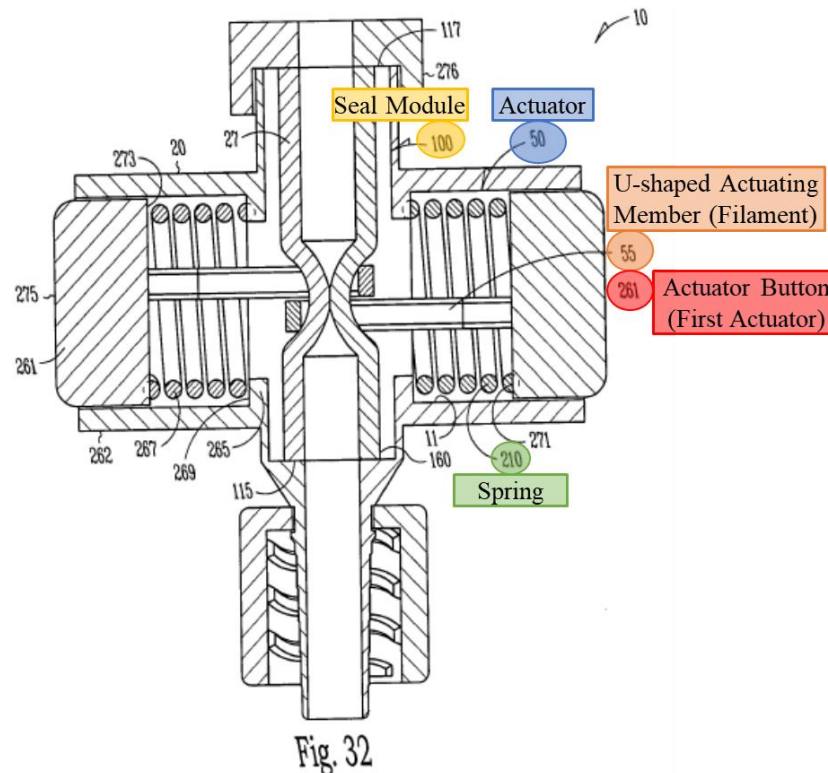
Claim 1 next recites “a constricting mechanism having at least a first actuator, a first filament formed into a loop around the collapsible tubular sidewall, the filament having at least a first end portion extending away from the loop and connected to the first actuator, and a first spring configured to move the first actuator in a direction that pulls the first end portion such that a diameter of the valve lumen decreases in response to reducing a diameter of the loop.” Schaffer discloses these limitations or renders them obvious combined with Hartley *or* Eller. (Ex. 1003, ¶¶86-123.)

---

<sup>3</sup> While Figure 12 illustrates a seal module 100 comprised of three seal members 160, 170, and 180, Schaffer discloses that “seal module 100 is formed of one or more seal members.” (Ex. 1005, [0075], Figs. 32, 34.)

**a. First Actuator**

Schaffer discloses a “first actuator.” (Ex. 1003, ¶¶87-89.) Schaffer’s valve has “two circular actuators 50” on opposite sides of the housing that are “movable from a first position to a second position”:

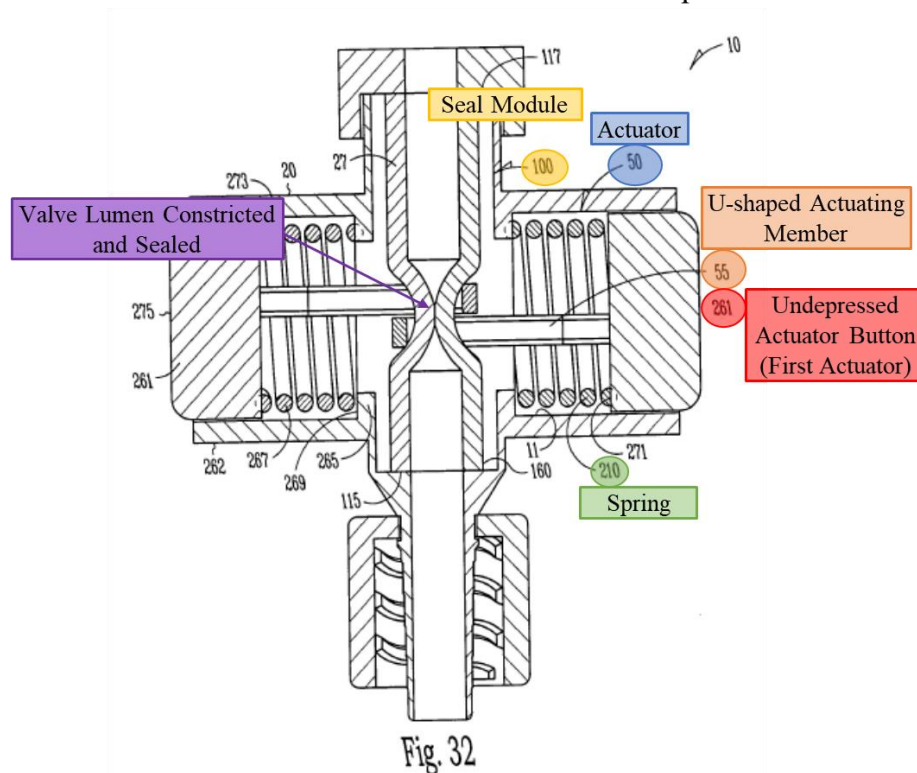


(Ex. 1005, [0075]-[0076], Figs. 31-32.) Each actuator 50 includes “an actuator button 261” and “spring 210.” (*Id.*)

Schaffer’s actuator buttons are coupled to “an actuating member 55 which, in one option, is U-shaped.” (*Id.*, [0076].) As explained below, the actuator buttons are coupled to the first and second ends of the U-shaped actuating members 55, which are the claimed “filament.” (*Infra* §VI.A.5.b.)

Schaffer discloses that in a first position, shown in Figure 32, the actuating members are “at least partially circumferentially disposed about the portion 108 of the seal module 100 depressing and at least partially collapsing a portion 108 of the containment structure 160 by a compressive force 67 (e.g. by a spring 210)”:

First Position – Actuator Buttons Undepressed

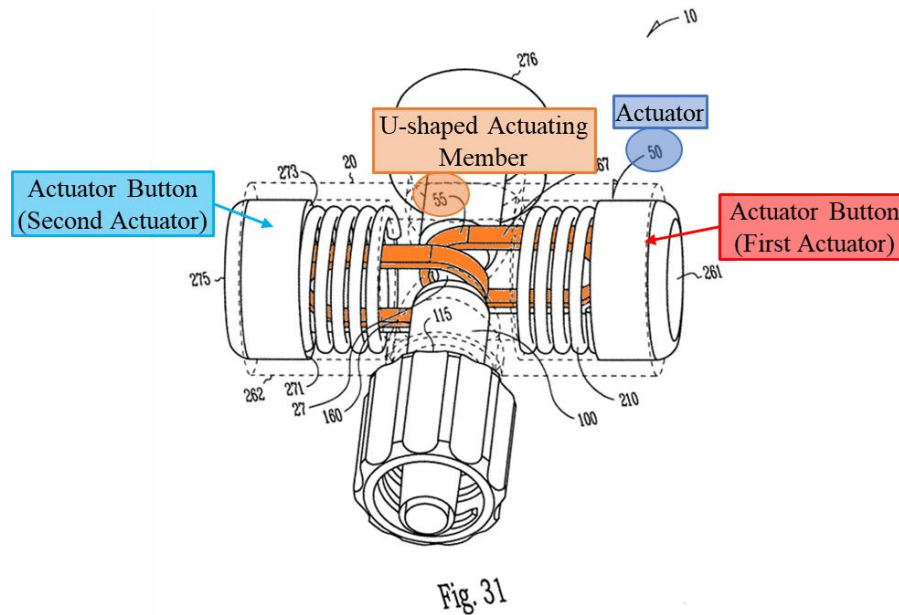


(*Id.*, [0077], Fig. 32.) Thus, either of Schaffer’s actuator buttons are a “first actuator.” (Ex. 1003, ¶¶87-89.)

**b. Filament**

**i. Schaffer**

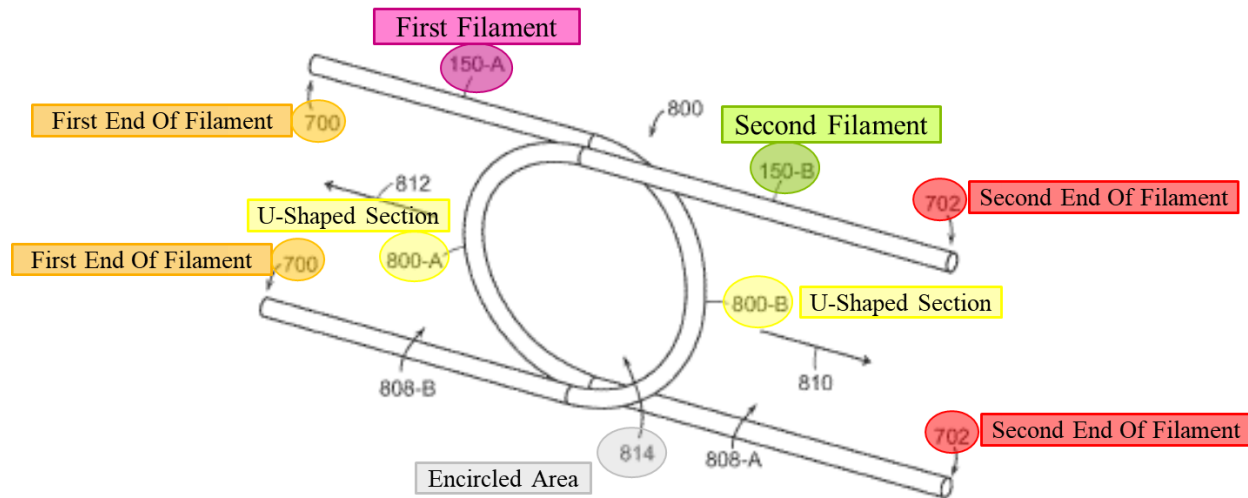
Schaffer discloses a “filament.” (Ex. 1003, ¶¶90-95.) Schaffer’s valve includes two U-shaped actuating members 55 coupled to the actuator buttons:



(Ex. 1005, [0076], Fig. 31.) Schaffer’s U-shaped actuating members are a “filament.” (*Supra* §IV; Ex. 1003, ¶¶90-91.)

Schaffer’s actuating members are formed from aluminum or plastic, and resemble a ribbon, flat wire, sheet, or tape. (Ex. 1005, [0081], Figs. 31-34; Ex. 1003, ¶91.) As discussed above, the ’012 patent states that a filament can be made from a polymer, which includes Schaffer’s plastic, or a metal, which includes Schaffer’s aluminum. (*Supra* §IV.) Likewise, the ’012 patent states that a filament may be a ribbon, flat wire, sheet, or tape, which includes Schaffer’s actuating members. (*Id.*; Ex. 1003, ¶91.) In related proceedings, PO argued that Schaffer’s actuating members are “rigid.” *Imperative Care*, IPR2024-01157, Paper 5 at 28. PO’s arguments are inconsistent with Schaffer. (Ex. 1003, ¶¶89-91.)

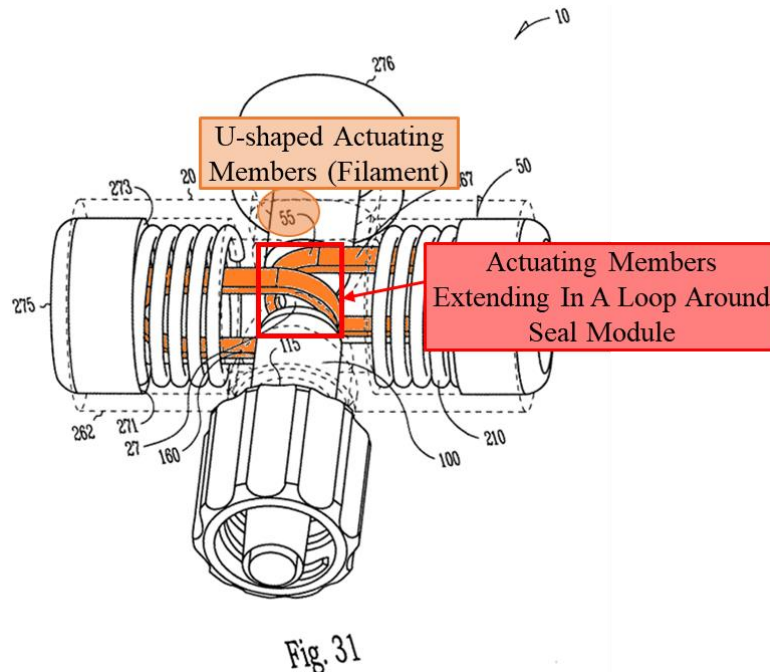
That Schaffer depicts two actuating members is of no moment here. The '012 patent discloses that the “*the filament 150* can comprise multiple filaments,” including filaments (150-A and 150-B) forming two U-shaped sections:



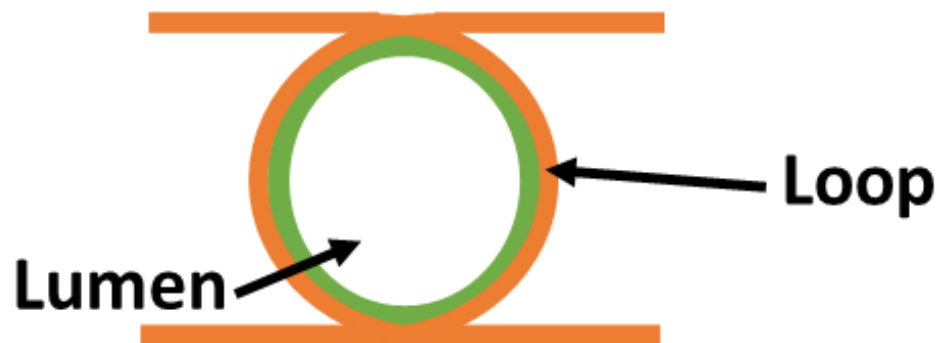
(Ex. 1001, 12:61-13:16, Fig. 8 (emphasis added).) Accordingly, Schaffer’s U-shaped actuating members collectively constitute the “first filament” claimed in the ’012 patent. (Ex. 1003, ¶92); *see also Sandisk Corp. v. Kingston Tech. Co., Inc.*, 695 F.3d 1348, 1360 (Fed. Cir. 2012) (explaining that “the later use of ‘the’ ... to refer back to an earlier claim term does not limit that claim term to the singular”); *Biagro W. Sales, Inc. v. Grow More, Inc.*, 423 F.3d 1296, 1304 (Fed. Cir. 2005) (“The phrase ‘at least one’ in patent claims typically is construed to mean ‘one or more.’”).

Schaffer’s actuating members are “at least partially circumferentially [sic] disposed about a portion of the seal module 100.” (Ex. 1005, [0076].) Schaffer’s

Figure 31 shows the actuating members collectively loop around the seal module 100:

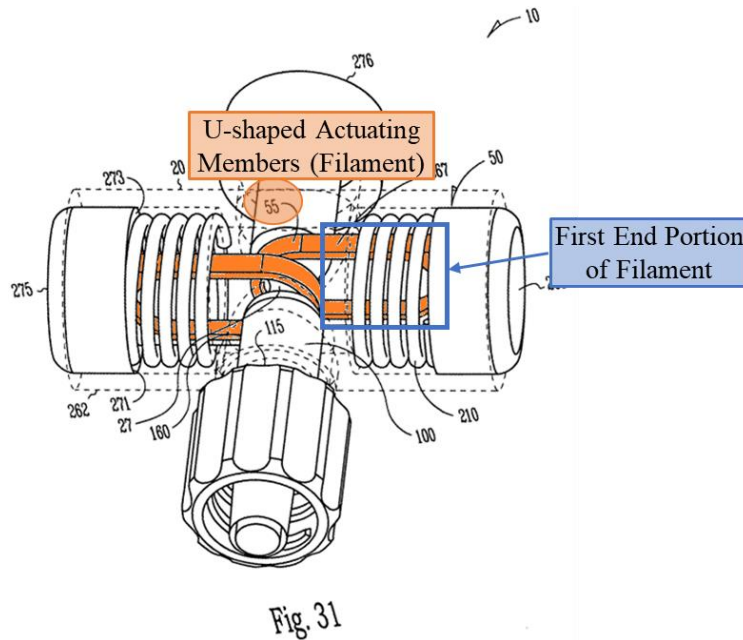


(*Id.*, Fig. 31; Ex. 1003, ¶¶93-94.) The below demonstrative further illustrates the loop created by the U-shaped members (orange) around the seal module (green):

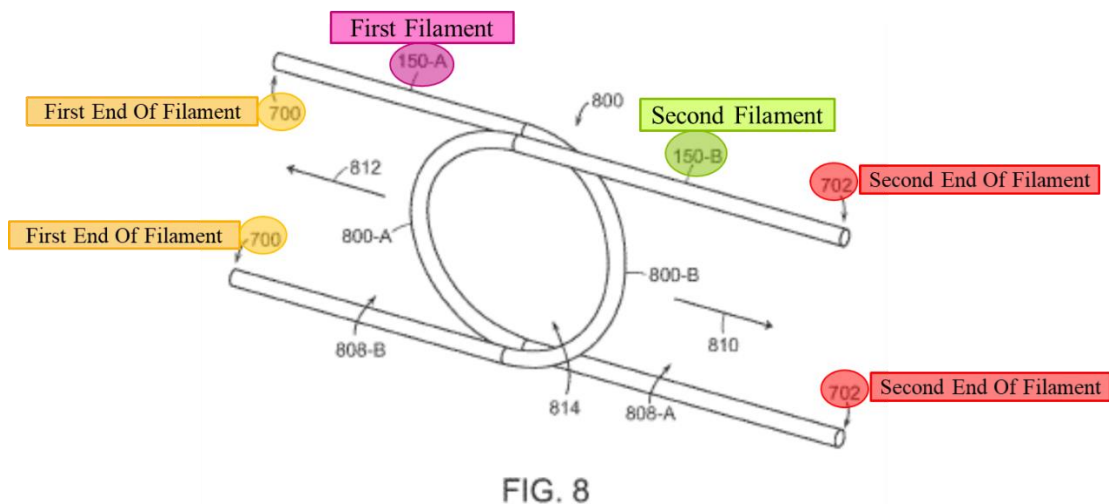


(Ex. 1003, ¶¶93-94.)

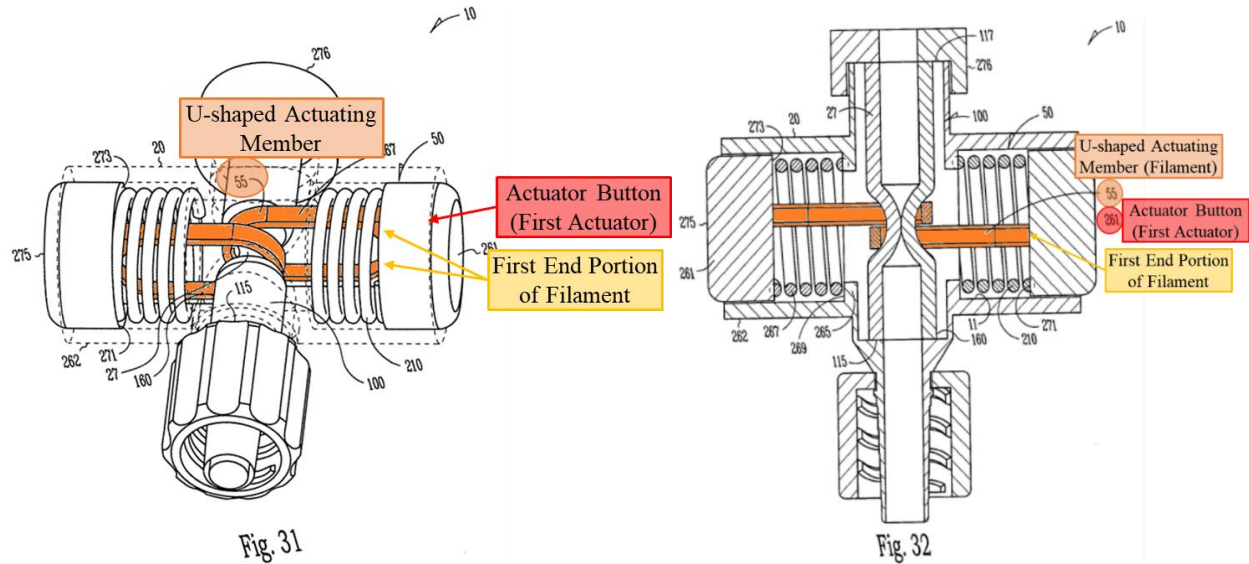
The portion of the actuating member 55 that extends away from the seal module 100 is a “first end portion” of the filament “extending away from the loop”:



(Ex. 1005, Fig. 31; Ex. 1003, ¶95.) The '012 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*”:



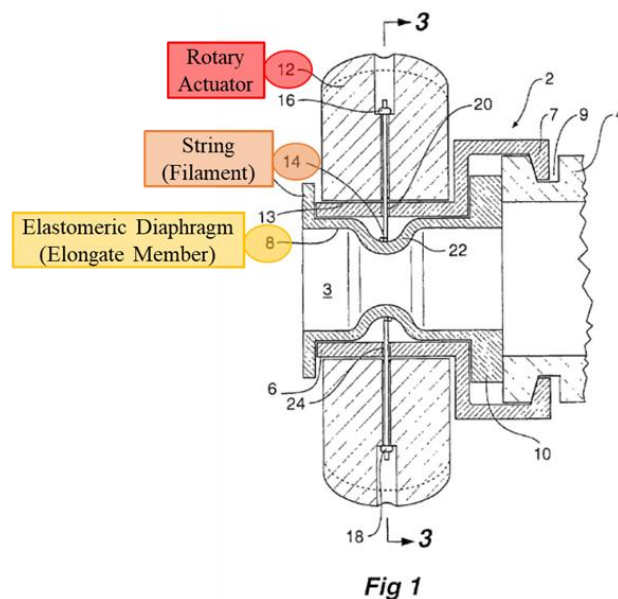
(Ex. 1001, 12:64-67, Fig. 8 (emphases added).) Thus, the first end portion of Schaffer’s U-shaped actuating member extends away from the loop and is connected to the first actuator as disclosed and claimed in the '012 patent:



(Ex. 1005, [0076], Figs. 31-32; Ex. 1003, ¶¶94-95.)

ii. Hartley

Hartley also discloses a “filament,” even if the Board adopts PO’s narrower construction. (Ex. 1003, ¶¶96-108.) Hartley describes a hemostasis valve having a cylindrical housing that holds a “cylindrical elastomeric diaphragm,” and a rotary actuator mounted to the housing:



(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, ¶96.)

Hartley’s string is secured to the rotary actuator at a first end via a knot 16 and “then passes through an aperture 20 in the cylindrical housing 6 and then is wound preferably twice around the cylindrical diaphragm 8 ... and then passes through a further aperture 24 in the cylindrical housing before being fixed by knot 18 again in the rotary actuator”:

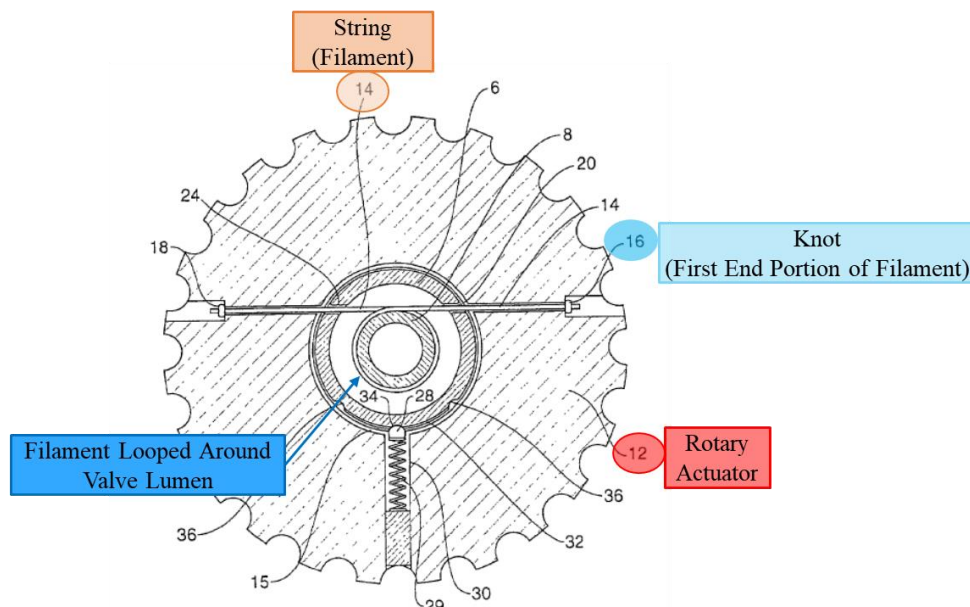


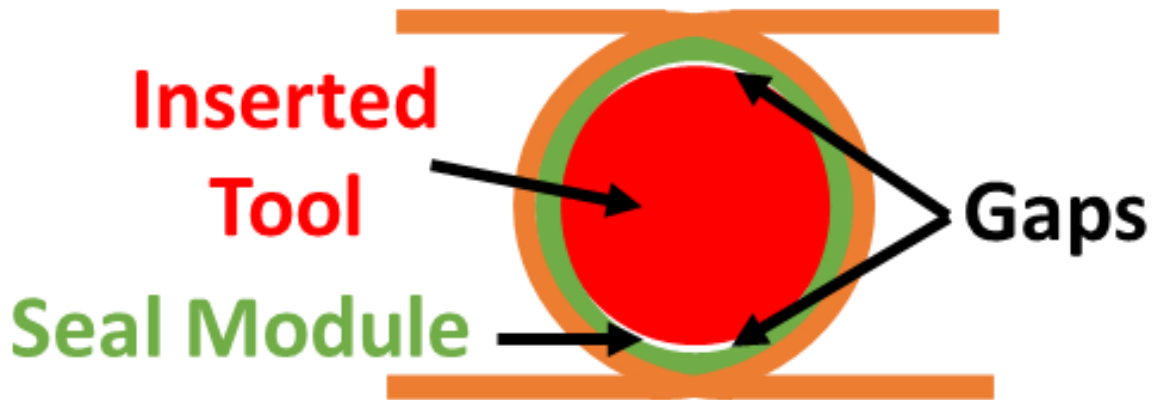
**Fig 3**

(Ex. 1006, [0031], Fig. 3.) Thus, Hartley’s string is “formed into a loop around the collapsible tubular sidewall.” (Ex. 1003, ¶97.) Additionally, Hartley’s string has “a first end portion extending away from the loop and connected to the first actuator.” (*Id.*) 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.)

POSITAs would have found it obvious to substitute Hartley’s string for Schaffer’s actuating members. (Ex. 1003, ¶¶98-108.) The combination of Hartley’s string and Schaffer’s valve would have merely entailed substitution of one known element (Hartley’s string) for another (Schaffer’s actuating members) to yield the predictable result of constricting Schaffer’s valve to form a seal. *KSR*, 550 U.S. at 416.

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, ¶99.) POSITAs would have recognized that Hartley’s string may seal more effectively across a wider range of diameters and shapes for the inserted devices than Schaffer’s U-shaped actuating members. (Ex. 1003, ¶100.) Depending on the diameter of the inserted device, Schaffer’s U-shaped actuating members may form small gaps between the valve’s lumen and the tool’s outer surface:



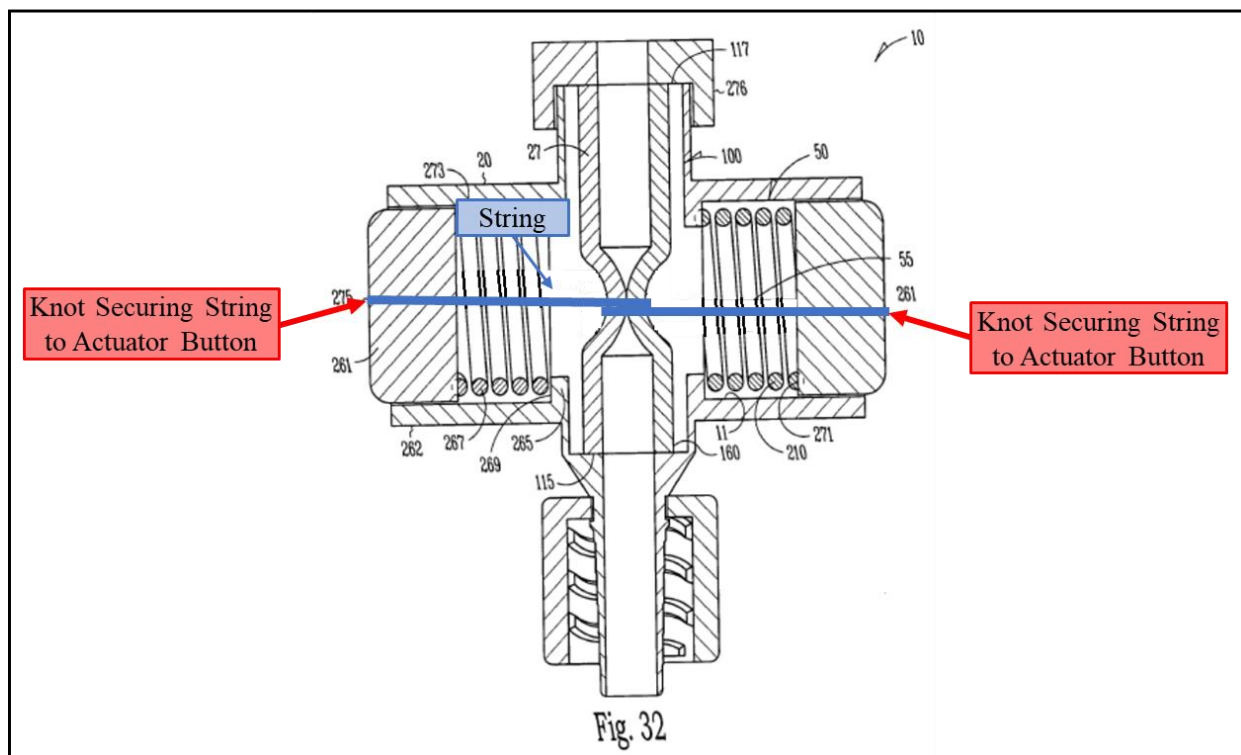
(*Id.*) Hartley’s string would not suffer from this potential issue because the string encircles the central lumen and precisely conforms to the diameter of the inserted devices. (*Id.*) In related proceedings, PO argued that Schaffer’s valve would not create gaps. *Imperative Care*, IPR2024-01157, Paper 5 at 28-29. However, the portions of Schaffer cited by PO do not support its argument. (Ex. 1003, ¶100.)

POSITAs also had a finite number of materials to select from to constrict a tubular member in a hemostasis valve in 2017. (Ex. 1003, ¶102.) Hartley and Schaffer disclose two such materials: Hartley’s string and Schaffer’s actuating members formed from metal or plastic. (*Id.*) Eller discloses a third option: one or more 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 had a reasonable expectation of success in substituting Hartley’s string for Schaffer’s U-shaped actuating members. (Ex. 1003, ¶¶103-108.) Hartley teaches a simple method of attaching the string to the rotary actuator – a knot

at each end of the string. (Ex. 1006, [0031]; Ex. 1003, ¶104.) POSITAs would have reasonably expected that similar knots could be used to secure the ends of Hartley's string to Schaffer's actuator buttons. (Ex. 1003, ¶104.) For example, small holes could be made in each of Schaffer's actuator buttons, and each end of the string could be threaded through the hole and knotted on the other side. (*Id.*) This simple modification would have been within a POSITA's skills. (*Id.*) In this arrangement, the first end of the string would be secured to the first actuator button, the string would loop at least once around Schaffer's seal module, and the second end of the string would be secured to the second actuator button:

### Demonstrative Illustration Schaffer + Hartley's String



(*Id.*)<sup>4</sup>

Also, POSITAs would have recognized that Hartley's string and Schaffer's U-shaped actuating members function in similar ways and, therefore, no other modifications to Schaffer's valve would be necessary. (*Id.*, ¶105.) Hartley collapses the valve lumen by pulling the ends of the string in opposite directions. (Ex. 1006, [0031].) Schaffer also collapses the valve lumen by pulling the U-shaped actuating members in opposite directions. (Ex. 1005, [0077].) Thus, 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 in the first position, thereby causing the string to constrict Schaffer's seal module. (*Id.*; Ex. 1006, [0031]; Ex. 1003, ¶106.)

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 loop Hartley's string around Schaffer's seal module. (Ex. 1003, ¶103.) POSITAs would have reasonably expected success in using this configuration because Hartley discloses the configuration forms an effective seal. (*Id.*)

---

<sup>4</sup> This image is a demonstrative prepared by Petitioner. All modifications to the figure have been made by Petitioner.

A POSITA would have also reasonably expected that pressing Schaffer's buttons inwardly (i.e., second position) would release the tension on the string, causing the string to loosen around the seal module and allowing the lumen to at least partially open. (See Ex. 1005, [0077]; Ex. 1006, [0034]; Ex. 1003, ¶¶106-107.) Schaffer's seal module is formed 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].) A POSITA would have reasonably expected Schaffer's seal module to have the resilience to return to its open configuration when the tension on the string is released such that no compressive force is applied to the seal. (Ex. 1003, ¶107.) 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.*, ¶108.) For example, Schaffer discloses various materials for the seal module, including "modified vinyl, silicone, polyurethane or a combination thereof." (Ex. 1005, [0081].) Similarly, Eller discloses various materials for its sleeves, including "NuSil MED-4755, NuSil MED-4765, and NuSil MED-4014." (Ex. 1007, 36:27-60.)

Thus, Schaffer combined with Hartley renders claim 1 obvious, even if the Board adopts PO's construction of "filament."

**iii. Eller**

Eller also discloses a “filament,” even if the Board adopts PO’s overly narrow construction of “filament.” (Ex. 1003, ¶¶109-121.) Eller discloses hemostasis valves that include “a housing 16, an actuator 18, a sleeve 20, [and] a first wire member 22”:

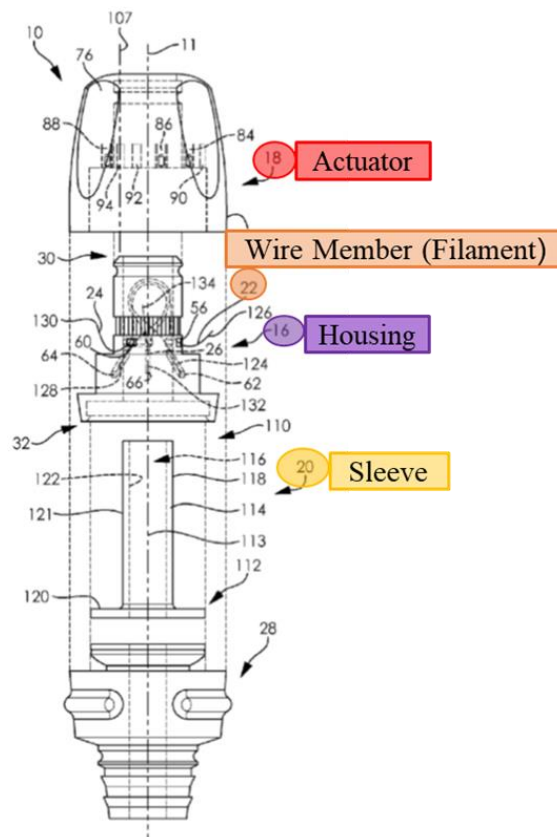


**FIG. 2**

(Ex. 1007, 5:1-5, 16:7-19, 21:37-22:31, 23:50-25:9, Fig. 2<sup>5</sup>.) Eller’s wire member is a filament. (Ex. 1003, ¶110.) The wire member “can be formed of any suitable material and using any suitable manufacturing technique, and skilled artisans will be

<sup>5</sup> Eller’s Figure 2 shows an exploded view of the device. (Ex. 1007, 2:46-47.)

able to select a suitable material and technique to form a wire member according to a particular embodiment based on various considerations including the material(s) that form the sleeve of an embodiment.” (Ex. 1007, 15:41- 47.) Eller further discloses that the wire member can have various compositions (e.g., braided materials, twisted materials), be formed from various materials (e.g., metals, polymers), and have different shapes (e.g., round, rectangular). (*Id.*, 15:47-16:6.) Thus, the wire member is a “filament” at least because the wire member is made of at least one or more threads, lines, cords, rope, ribbon, flat wire, sheet, or tape. (Ex. 1003, ¶110; *supra* §IV.)

The wire member has a first end 124 attached to the housing 16 and a second end 126 attached to the actuator 18. (Ex. 1007, 12:52-58.) The wire member loops around the outer surface of the sleeve 20:

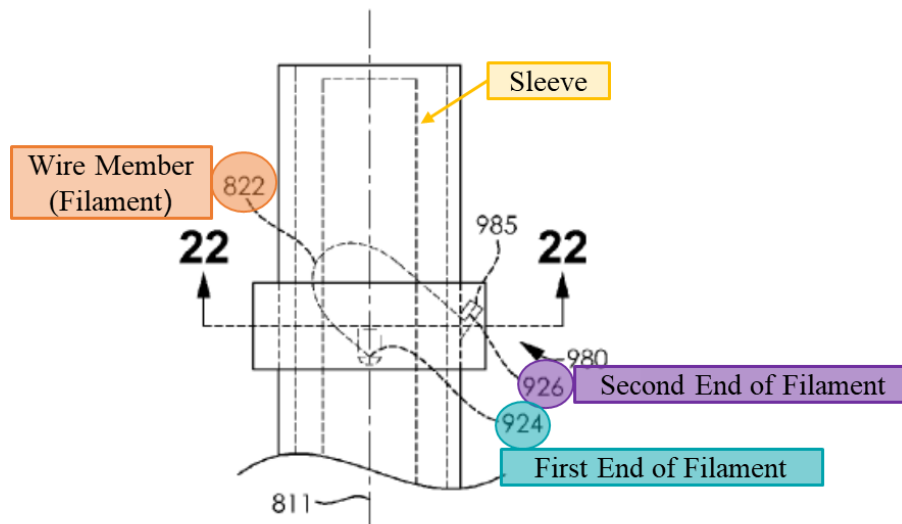


**FIG. 21**

(*Id.*, 12:58-64, 24:50-57, Fig. 21.)

Eller discloses embodiments where “the wire member can be positioned such that it extends at least one full revolution around the outer surface of the sleeve.” (Ex. 1007, 22:18-24.) In this configuration, Eller’s wire member is “formed into a loop around the collapsible tubular sidewall.” (Ex. 1003, ¶113.) When replacing Schaffer’s actuating members with Eller’s wire member, POSITAs would have been motivated to loop Eller’s wire at least one full revolution around Schaffer’s seal module to ensure the wire formed a constrictive seal. (*Id.*) POSITAs would have reasonably expected success because Eller encourages looping the wire one revolution around the sleeve and discloses that such a configuration forms a seal. (*Id.*)

Eller’s wire member is “movable between a first configuration and a second configuration.” (Ex. 1007, 15:21-25.) In the first configuration, the wire member is relaxed, and fluid is permitted to flow through the sleeve. (*Id.*, 15:21-40, 17:38-43.) In the second configuration, rotation of the actuator places 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.) Eller further discloses that “when one or more medical devices are passed through the passageway 116 defined by the sleeve 20, the material that forms the sleeve 20 contacts a portion of one or more of the medical devices to close the passageway 116 such that fluid is prevented from passing through the passageway 116.” (*Id.*, 18:3-8.)

A POSITA would have found it obvious to substitute Eller's wire member for Schaffer's actuating members. (Ex. 1003, ¶¶114-121.) The combination of Eller's wire member and Schaffer's valve would have merely entailed substitution of one known element (Eller's wire member) for another (Schaffer's actuating members) to yield the predictable results of constricting the lumen of 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 passed through the valve would have further motivated POSITAs to substitute Eller's wire member for Schaffer's actuating members. (Ex. 1007, 15:21-40, 17:38-43, 18:3-8; Ex. 1003, ¶114.) As discussed for the Schaffer-Hartley ground, POSITAs would have recognized that Eller's wire may seal more effectively across more device diameters than Schaffer's U-shaped actuating members because the wire encircles the seal module and precisely conforms to the inserted devices. (*Supra* §VI.A.3.b.ii; Ex. 1003, ¶115.)

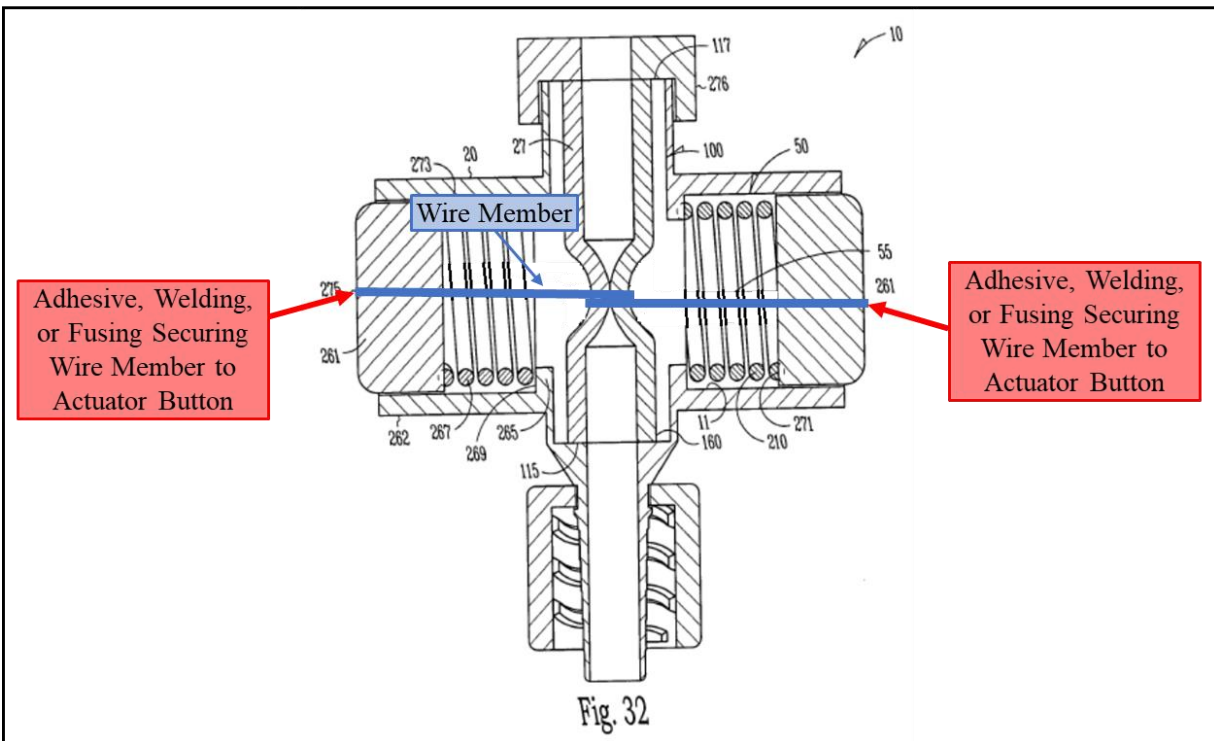
As also discussed in the Schaffer-Hartley ground, POSITAs had a finite number of materials to select from to constrict the lumen of a hemostasis valve. (*Supra* §VI.A.5.b.ii; Ex. 1003, ¶117.) A POSITA would have found it obvious to select from these finite, predictable options, including Eller's wire, and would have had a reasonable expectation of success in implementing them. (*Id.*)

A POSITA would have had a reasonable expectation of success in substituting Eller's wire member for Schaffer's actuating members for several reasons. (Ex. 1003, ¶¶118-120.) 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 further identifies several means for securing its wire member to an actuator, including "using adhesives, welding, fusing, providing a friction fit between the wire member and the ... actuator." (*Id.*, 14:43-49.) POSITAs would have reasonably expected success in securing Eller's wire member to Schaffer's actuator buttons using one or more of these simple methods. (Ex. 1003, ¶118.) For example, the first end of the wire member would be adhered or welded to the first actuator button, looped at least once around Schaffer's seal module, and the second end of the wire member would be adhered or welded to the second actuator button <sup>6</sup>:

---

<sup>6</sup> This image is a demonstrative prepared by Petitioner. All modifications to the figure have been made by Petitioner.

### Demonstrative Illustration Schaffer + Eller's Wire Member



(*Id.*)

Second, Eller discloses 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” and that “[s]killed artisans will be able to select a suitable actuator to include on a selective fluid barrier valve device according to a particular embodiment based on various considerations, including the number of wire members included in the selective fluid barrier valve device and/or the structural arrangement of the housing.” (Ex. 1007, 8:27–39.) Eller discloses that suitable actuators include “rotatable actuators, linear actuators, slidable actuators,

pivotal actuators, levers, and any other actuator considered suitable for a particular embodiment.” *Id.*, 8:39–44 (emphasis added). 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, ¶119.)

Third, Eller’s wire member and Schaffer’s U-shaped actuating members function similarly to close the valves. (Ex. 1003, ¶120.) Both Schaffer and Eller create a seal by moving an actuator from a first position to a second position to constrict the seal module/sleeve. (Ex. 1005, [0077]; Ex. 1007, 15:21-40, 17:47-18:3.) In both devices, the actuators pull the wire/actuating members in opposite directions to constrict/compress the valve’s central lumen. (Ex. 1005, [0077], Ex. 1007, 15:21-40, 17:47-18:3; Ex. 1003, ¶120.)

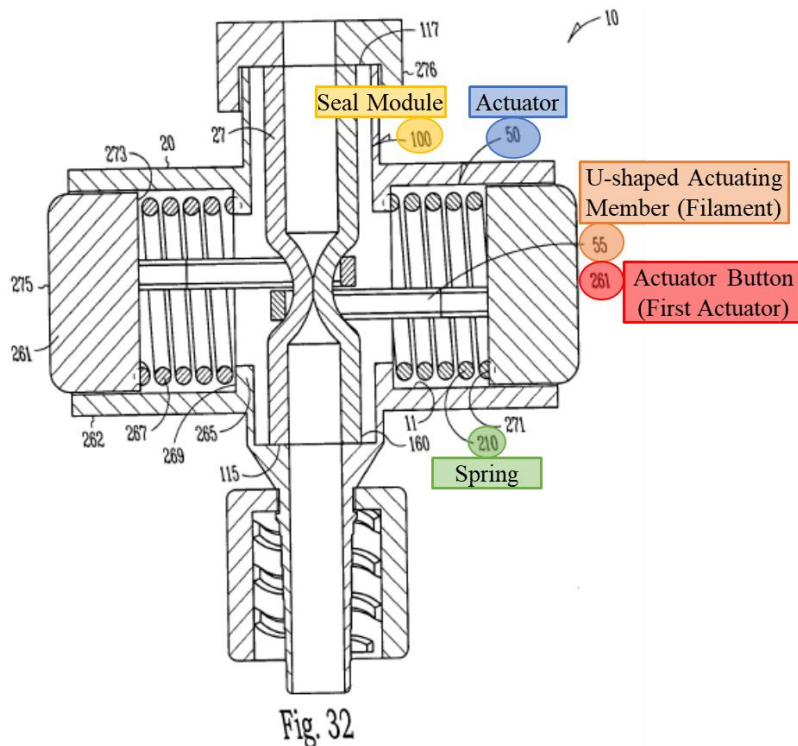
POSITAs would have recognized that Eller’s wire member would function like Schaffer’s U-shaped actuating members. (Ex. 1003, ¶121.) In the first position, the springs coupled to Schaffer’s actuator buttons would pull the ends of the wire member in opposite directions, thereby causing the wire member to constrict the lumen of Schaffer’s seal module. (See Ex. 1005, [0077]; Ex. 1007, 15:21-40, 17:47-18:3; Ex. 1003, ¶121.) 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 allowing the lumen to at least partially open. (See Ex. 1005, [0077]; Ex. 1007, 15:21-40, 17:47-18:3; Ex. 1003, ¶121.) Schaffer discloses that the

seal module is formed 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].) Therefore, 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 lumen.” (*Id.*; Ex. 1003, ¶121.) Further, if the resiliency of Schaffer’s lumen required adjustment to function with Eller’s wire, a POSITA would have possessed the knowledge to select a material with proper resiliency. (*Supra* §VI.A.5.b.ii.)

Thus, Schaffer combined with Eller renders claim 1 obvious, even if the Board adopts PO’s overly narrow construction of “filament.”

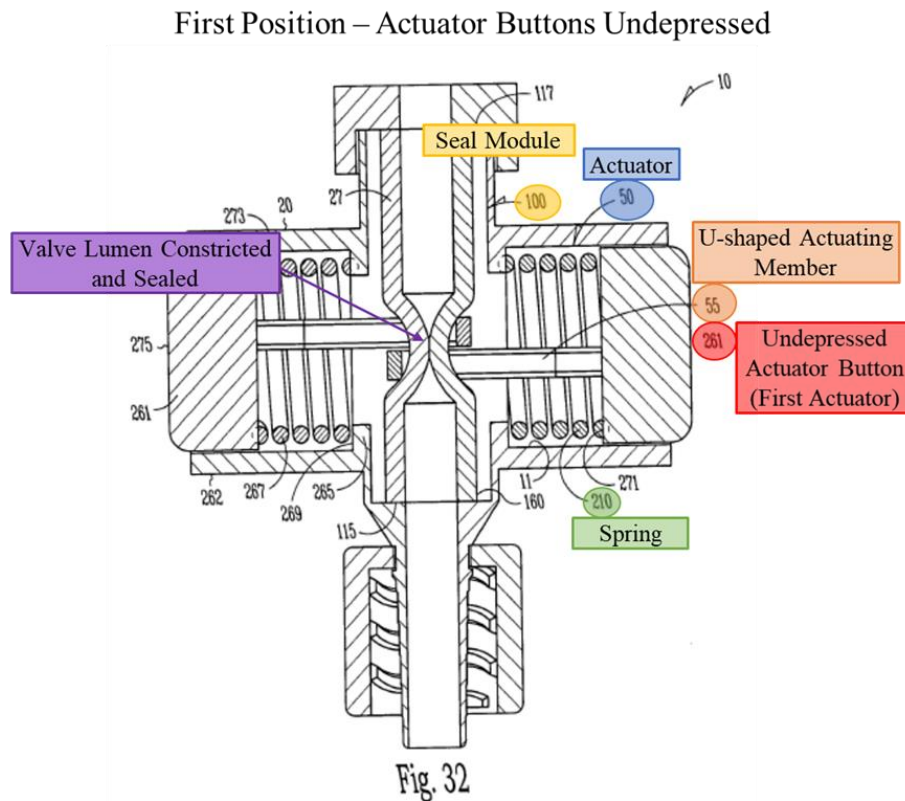
**c. First Spring**

Schaffer discloses a “first spring.” (Ex. 1003, ¶¶122-125.) 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.*) Schaffer discloses that in the first position, shown in Figure 32, the actuating members are “at least partially circumferentially disposed about the portion 108 of the seal module 100 depressing and at least partially collapsing a portion 108 of the containment structure 160 by a compressive force 67 (e.g. by a spring 210)”:



(*Id.*, [0077], Fig. 32.) As shown in Figure 32, the valve lumen is completely sealed in the first position. (*Id.*; see also *id.*, [0008] (disclosing Schaffer’s valve “blocks the flow of gas or fluid completely and immediately with or without an instrument in place within the gas/fluid path”); Ex. 1003, ¶124.)

Schaffer’s resilient member is “a first spring configured to move the first actuator in a direction that pulls the first end portion such that a diameter of the valve lumen decreases in response to reducing a diameter of the loop.” (Ex. 1003, ¶¶125.) Schaffer’s spring biases Schaffer’s actuator button toward the first (closed) position by pulling the first end portion of the actuating member (filament) away from the seal module 100. (Ex. 1005, [0077]; Ex. 1003, ¶125.) This causes the actuating

members attached to the buttons to circumferentially constrict around and collapse the seal module, preventing the flow of fluid through the valve. (Ex. 1005, [0077]; Ex. 1003, ¶125.) The loop formed by the actuating members decreases in diameter as the first end portion of the actuating member is pulled by the spring. (Ex. 1005, [0077], Figs. 31-34; Ex. 1003, ¶125.)

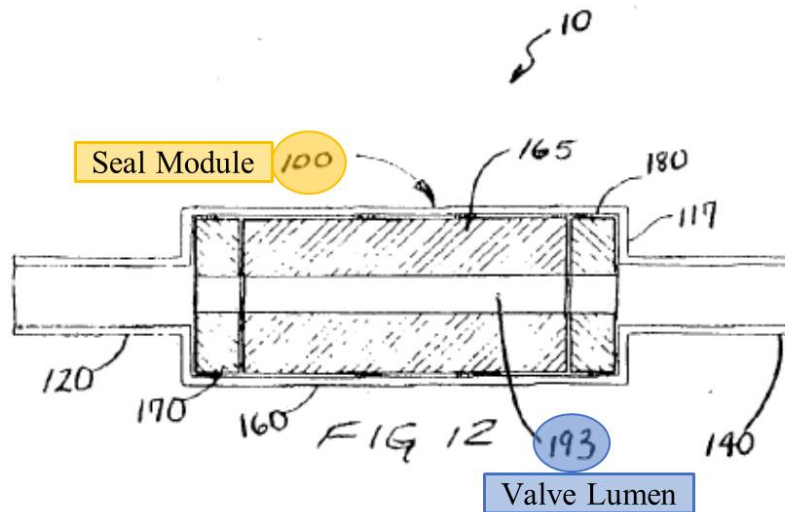
**B. Claim 2**

Claim 2 depends from claim 1 and recites additional limitations for the collapsible tubular sidewall, the constricting mechanism, and the filament. Schaffer anticipates claim 2 or renders claim 2 obvious alone or in view of Hartley *or* Eller. (Ex. 1003, ¶126-139.)

**1. Tubular Member**

Claim 2 recites that “the collapsible tubular sidewall comprises a tubular member defining the valve lumen configured to slidably receive the elongate, flexible tubular body.” Schaffer discloses this limitation. (Ex. 1003, ¶¶127-128.)

Schaffer’s hemostasis valve includes a “seal module 100” that comprises “a flexible, elongate tubular structure 101.” (Ex. 1005, [0049], [0051], [0054].) The elongate tubular structure 101 defines a lumen 193 and is a collapsible tubular sidewall:

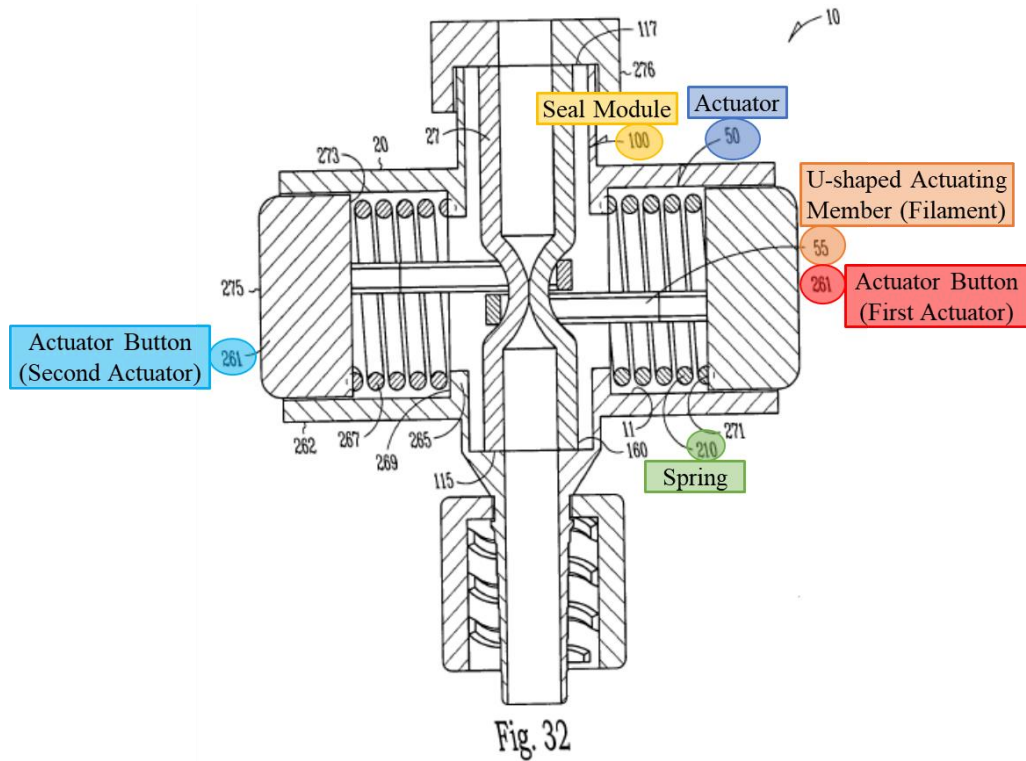


(*Id.*, [0058], Fig. 12.) Schaffer discloses that “a range of instruments [can be] used within the seal module,” such as “a catheter, guidewire, needle, or fiber,” and that “a guidewire and catheter may be placed into the same lumen 193 for extension into a body passage.” (*Id.*, [0056], [0074].) The catheter placed into Schaffer’s lumen 193 is the claimed “elongate, flexible tubular body.” (*Supra* §VI.A.2.) Accordingly, Schaffer discloses this limitation. (Ex. 1003, ¶¶127-128.)

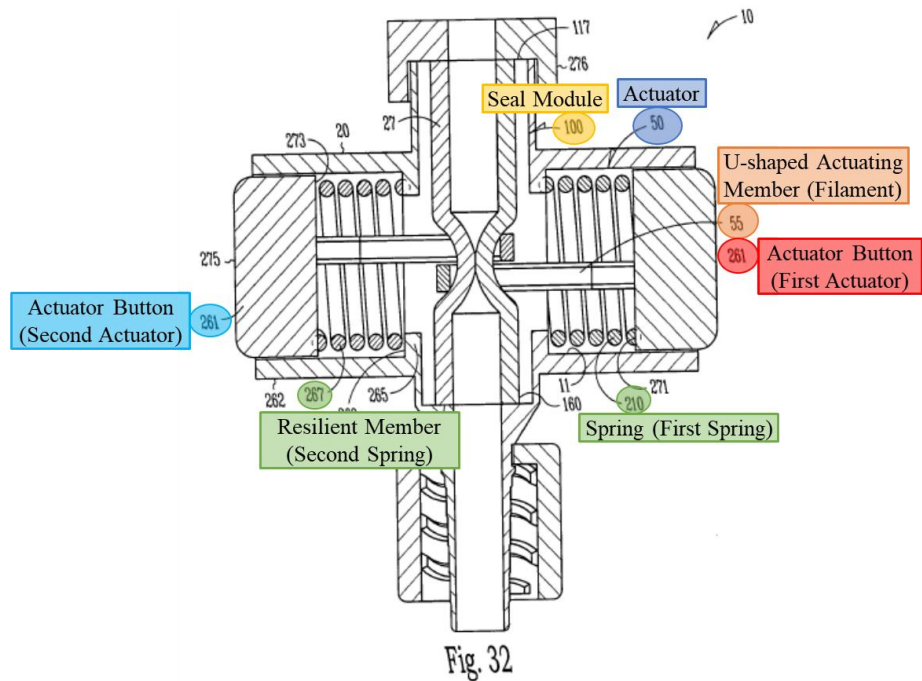
## 2. Constricting Mechanism

Claim 2 next recites that “the constricting mechanism further comprises a second actuator and a second spring coupled to the second actuator.” Schaffer discloses these limitations. (Ex. 1003, ¶¶129-131.)

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].) Each actuator 50 includes “an actuator button 261”:



(*Id.*, [0076], Figs. 32.) Schaffer’s valve also includes “two resilient members 267 (e.g., spring 210) disposed within the actuating member 55”:



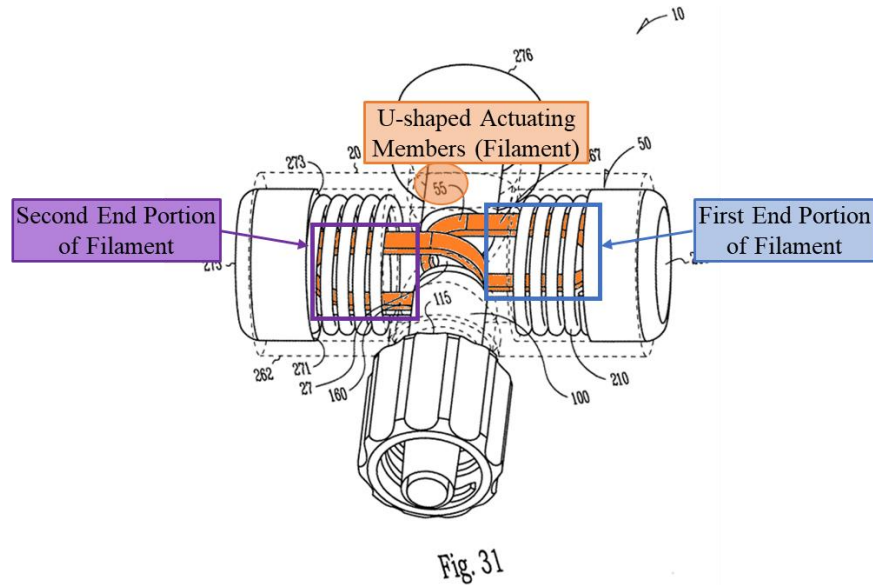
(Ex. 1005, [0076], Fig. 32.) “[T]he resilient members 267 each abut the proximal end 273 of an actuator button 261.” (*Id.*, [0076].) Accordingly, Schaffer discloses a second spring coupled to a second actuator. (Ex. 1003, ¶¶129-131.)

### **3. Filament**

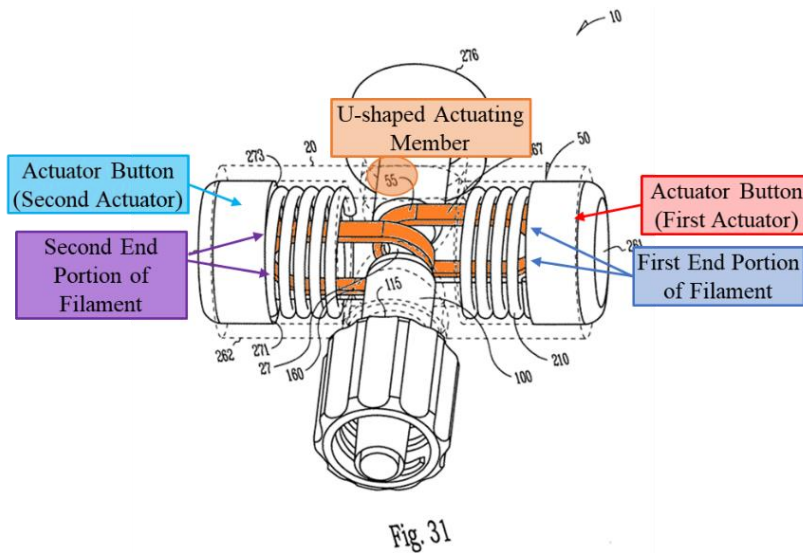
Claim 2 finally recites that “the filament further comprises a second end portion extending away from the loop in a different direction than the first end portion and connected to the second actuator, and wherein the first actuator and the second actuator are moveable between (a) a first position wherein the filament circumferentially constricts the valve lumen to create a seal about the elongate, flexible tubular body and (b) a second position wherein the filament is moved to open the valve lumen at least partially.” Schaffer discloses these limitations or renders them obvious in view of Hartley *or* Eller. (Ex. 1003, ¶¶132-139.)

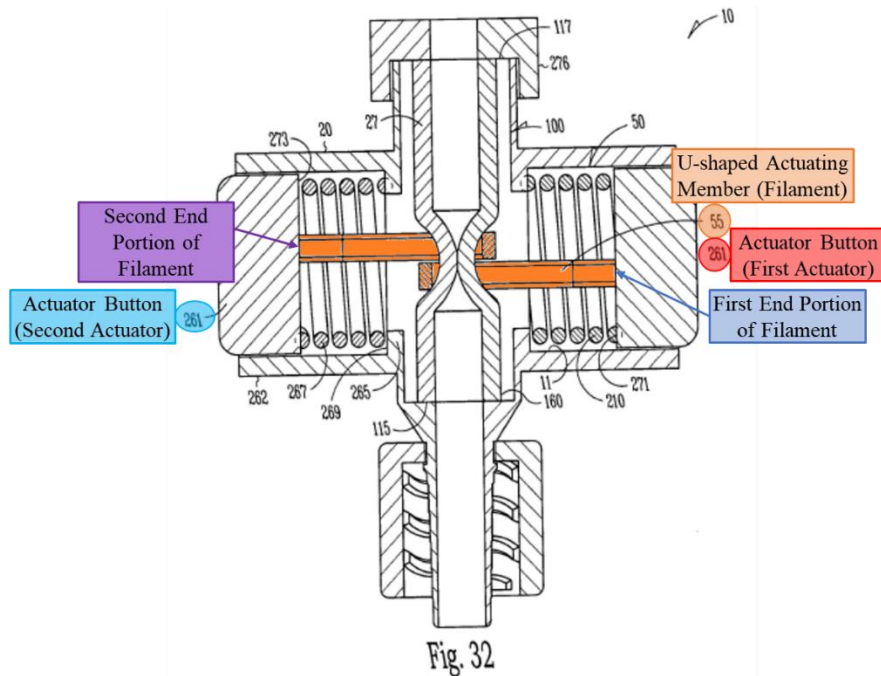
#### **a. Schaffer**

Schaffer’s actuator buttons are coupled to “an actuating member 55 which, in one option, is U-shaped.” (Ex. 1005, [0076].) As explained above, the U-shaped actuating members are the claimed “filament.” (*Supra* §VI.A.5.b.i.) Schaffer’s U-shaped actuating members have a first end portion that extends away from the seal module 100 in a first direction and a second end portion that extends away from the seal module 100 in an opposite direction, just as described in the ’012 patent:



(Ex. 1005, Fig. 31; Ex. 1003, ¶133.) The second end portion extends away from the loop formed by the actuating members and is connected to the second actuating button (second actuator):

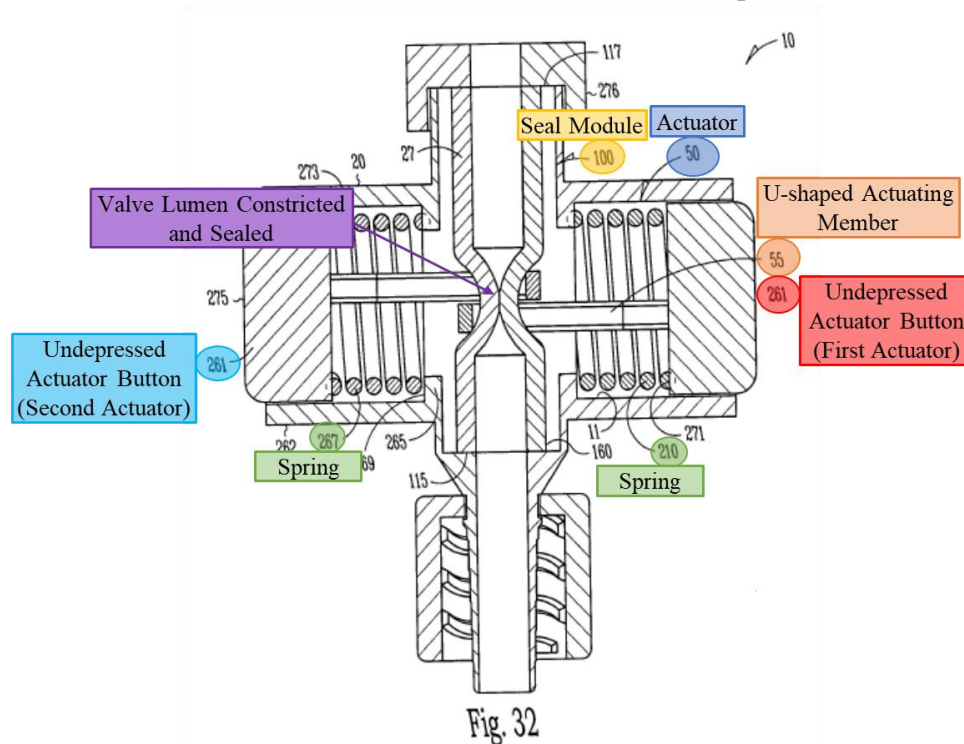




(*Id.*, [0075]-[0076], Figs. 31-32.)

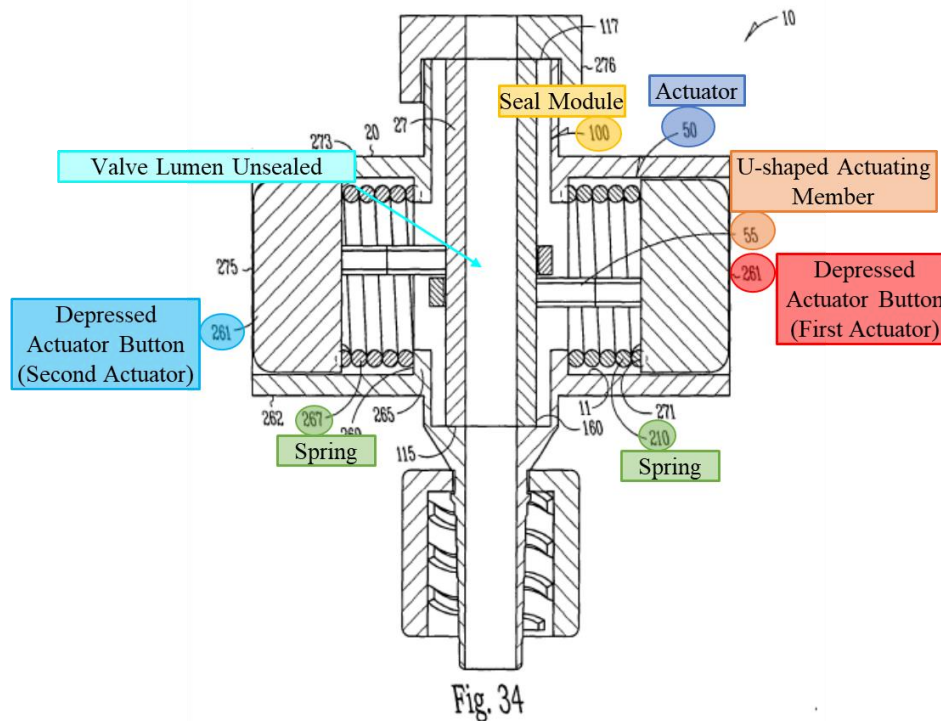
Schaffer's actuator buttons are movable between a first position wherein the lumen is constricted to create a seal around the tubular body and a second position wherein the lumen is at least partially open. (Ex. 1003, ¶133.) Schaffer discloses that in a first position, shown in Figure 32, the actuating members are "at least partially circumferentially disposed about the portion 108 of the seal module 100 depressing and at least partially collapsing a portion 108 of the containment structure 160 by a compressive force 67 (e.g. by a spring 210)":

### First Position – Actuator Buttons Undepressed



(Ex. 1005, [0077], Fig. 32.) As shown in Figure 32, the valve lumen is completely sealed in the first position. (*Id.*; *see also id.*, [0008] (Schaffer’s valve “blocks the flow of gas or fluid completely and immediately with or without an instrument in place within the gas/fluid path”)); Ex. 1003, ¶133.) In a second position, shown in Figure 34, the actuator buttons are depressed, compressing the springs and allowing the actuator members to “disengage opposing outer walls 27 of the seal module 100 allowing the portion 108 of the containment structure 160 to retract to an uncollapsed configuration where gasses and fluids can pass therethrough”:

Second Position – Actuator Buttons Depressed



(Ex. 1005, [0077], Fig. 34.)

Schaffer 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].) Schaffer also discloses that “a range of instruments [can be] used within the seal module,” such as “a catheter, guidewire, needle, or fiber,” and that “a guidewire and catheter may be placed into the same lumen 193 for extension into a body passage.” (*Id.*, [0056], [0074].) Accordingly, when Schaffer’s valve is in the first, sealed position, the U-shaped actuating members “constrict[] the valve lumen to create a seal about the elongate, flexible tubular body” of a catheter inserted through the valve. (Ex. 1003, ¶134.)

**b. Hartley**

Hartley's string is secured to the rotary actuator with two knots on either side of the valve:

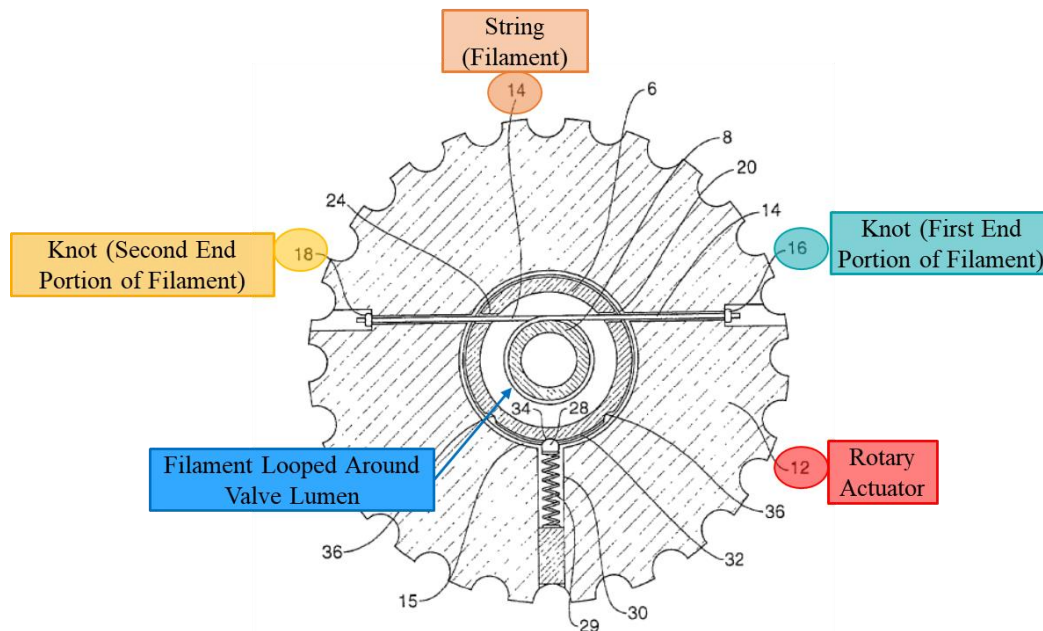


**Fig 3**

(Ex. 1006, [0031], Fig. 3.) As illustrated above, Hartley's string has a first end portion that extends away from the valve lumen in a first direction and a second end portion that extends away from the valve lumen in an opposite direction. (*Id.*; Ex. 1003, ¶136.)

When replacing Schaffer's U-shaped actuating members with Hartley's string, each of the first and second ends of Hartley's string would be secured to one of Schaffer's actuator buttons. (*Supra* §VI.A.5.b.ii; Ex. 1003, ¶137.) The first and second ends of Hartley's string would therefore extend in opposite directions from Schaffer's seal module 100. (Ex. 1003, ¶137.) Schaffer's actuator buttons would

be movable between a first position wherein Hartley's string constricts the valve lumen to create a seal around the tubular body and a second position wherein the lumen is at least partially open for the reasons discussed for Schaffer above. (*Supra* §VI.B.3.a.) Accordingly, Schaffer in combination with Hartley renders claim 2 obvious. (Ex. 1003, ¶137.)

c. **Eller**

Eller's wire member has a first end 124 attached to the housing 16 and a second end 126 attached to the actuator 18. (Ex. 1007, 12:52-58.) As illustrated below, Eller's wire member extends from its first end, around the outer surface of the sleeve 20, to its second end in a direction that differs from the direction of the first end:

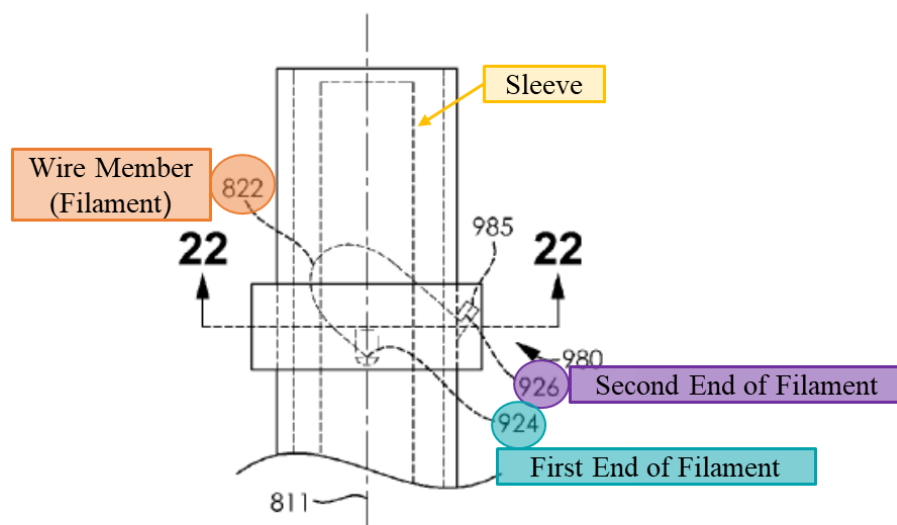


**FIG. 21**

(*Id.*, 12:58-64, 24:50-57, Fig. 21.)

When replacing Schaffer's actuating members with Eller's wire member, each of the first and second ends of Eller's wire member would be secured to one of Schaffer's actuator buttons. (*Supra* §VI.A.5.b.iii; Ex. 1003, ¶139.) The first and second ends of Eller's wire member would therefore extend in opposite directions from Schaffer's seal module 100. (Ex. 1003, ¶139.) Schaffer's actuator buttons would be movable between a first position wherein Eller's wire member constricts the valve lumen to create a seal around the tubular body and a second position wherein the lumen is at least partially open for the same reasons discussed for Schaffer above. (*Supra* §VI.B.3.a.) Accordingly, Schaffer in combination with Eller renders claim 2 obvious. (Ex. 1003, ¶139.)

**C. Claim 3**

Claim 3 recites the “aspiration catheter of claim 2 wherein the tubular member is pliable.” Schaffer anticipates claim 3 or renders claim 3 obvious alone or in combination with Hartley **or** Eller. (Ex. 1003, ¶¶140-141.)

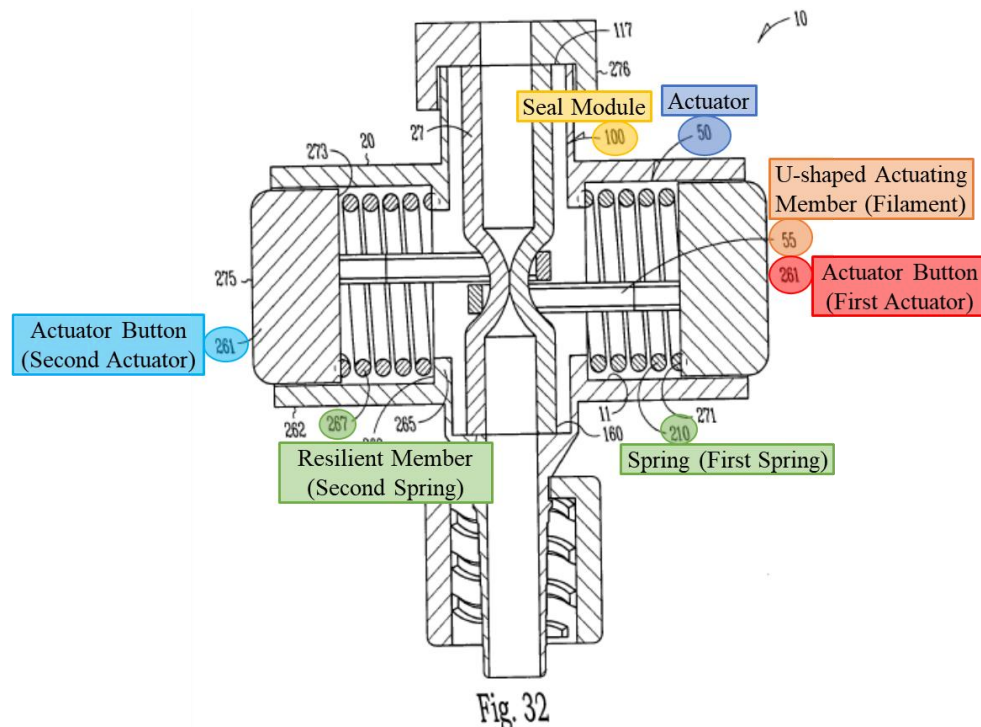
Schaffer's seal module (i.e., tubular member) “includes a flexible, elongate tubular structure 101 having an outer wall 27 which includes a material 166 that is highly elastic, deformable, compliant and yet virtually non-compressible.” (Ex. 1005, [0054].) Thus, Schaffer's tubular member is pliable. (Ex. 1003, ¶141.)

**D. Claim 4**

Claim 4 recites the “aspiration catheter of claim 2 wherein the first actuator comprises a first button and the second actuator comprises a second button, wherein the first button and the second button are undepressed in the first position, and wherein the first button and the second button are depressed in the second position.”

Schaffer anticipates claim 4 or renders claim 4 obvious alone or in combination with Hartley *or* Eller. (Ex. 1003, ¶¶142-143.)

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



(Ex. 1005, [0075]-[0076], Figs. 31-32.) Schaffer’s actuator buttons are undepressed when the valve is in the first (closed) position and depressed when the valve is in the second (open) position. (*Id.*, [0077]; Ex. 1003, ¶143.)

**E. Claim 5**

Claim 5 recites the “aspiration catheter of claim 2 wherein, when the first actuator and the second actuator are in the first position, the valve lumen of the tubular member is configured to remain constricted and sealed when a pressure differential exists between (a) a first volume outside the valve lumen and adjacent to a first end of the tubular member and (b) a second volume outside the central lumen and adjacent to a second end of the tubular member.” Schaffer anticipates claim 5 or renders claim 5 obvious alone or in combination with Hartley *or* Eller. (Ex. 1003, ¶¶144-158.)

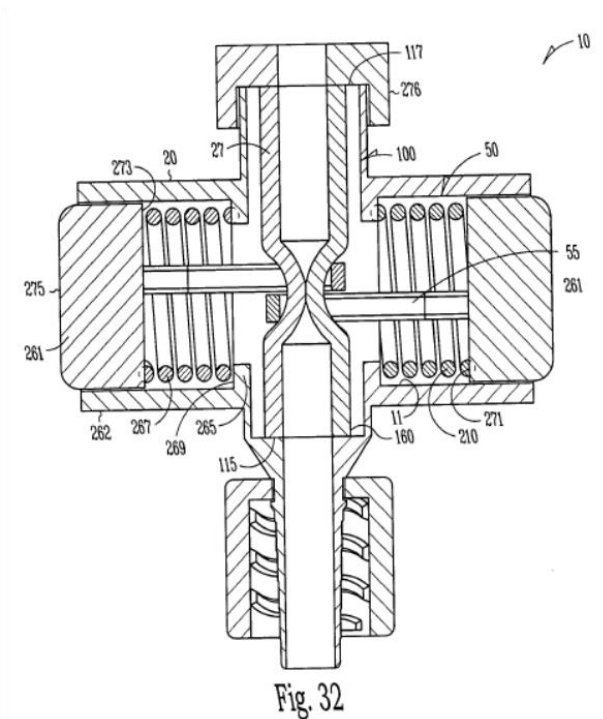
**1. Schaffer**

Schaffer’s hemostasis 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].) Schaffer’s valve is sealed when the first and second actuators (i.e., buttons) are in the first position (i.e., undepressed). (*Supra* §VI.A.5.a.)

Schaffer’s valve is “for use with catheters” inserted into the patient’s vasculature. (Ex. 1005, [0002]; Ex. 1009, Abstract, 1:1-9.) When a catheter is inserted into the patient’s vasculature, the pressure within the catheter matches the

blood pressure. (Ex. 1003, ¶145.) Conversely, the pressure outside the patient is the air pressure, which is less than the blood pressure. (*Id.*) This pressure difference between the blood and air is one reason blood spurts out of wounds. (*Id.*)

**Second End Subject to Air Pressure**



**First End Subject to Blood Pressure**

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

All hemostasis valves, including Schaffer’s valve, are designed to remain closed against the pressure differential between the blood pressure and the air pressure. (Ex. 1003, ¶¶145-148.) If Schaffer’s valve did not remain closed, blood would leak out of the catheter and the valve would not be a “hemostasis” valve (i.e., a valve that stops blood loss). (*Id.*) Schaffer’s valve blocks “the flow of gas or fluid” during medical procedures and, therefore, it remains closed when a pressure

differential exists between the two ends of the valve. (Ex. 1005, Abstract, [0008], [0077]; Ex. 1003, ¶¶146-148.)

Accordingly, when Schaffer's actuator buttons are in the first, undepressed position, the central lumen of Schaffer's seal module remains constricted and sealed, even when a pressure differential exists between the first and second ends of the tubular member. (Ex. 1005, [0008], [0077]; Ex. 1003, ¶¶146-148.)

Moreover, if Schaffer's valve did not maintain its seal when a pressure differential exists, POSITAs would have found it obvious to make adjustments to the valve to maintain the seal, including adjusting Schaffer's spring strength to apply additional force, adjusting the resilience and compressibility of the seal module that forms the valve's lumen, and/or adjusting the shape, flexibility, and/or dimensions of the actuating members to more closely conform to the shape of the seal module and any tool(s) inserted therethrough. (Ex. 1003, ¶149; *see also* Ex. 1007, 15:41-60 (recognizing POSITAs possessed the knowledge to adjust materials and configurations of actuating members).) POSITAs would have been motivated to adjust Schaffer's hemostasis valve to prevent blood leaks because that is the valve's purpose. (Ex. 1003, ¶149.)

POSITAs would have reasonably expected success in adjusting the spring strength to exert more tension on the filament by, for example, changing the spring material or adjusting the springs coils. (*Id.*) Springs are simple, predictable

mechanical devices that would have been well understood by POSITAs. (*Id.*) Additionally, POSITAs would have reasonably expected success in selecting an alternative material for the seal module given the long list of suitable materials. (*Supra* §VI.A.5.b.ii.) POSITAs would have also reasonably expected success in adjusting the shape or orientation of Schaffer’s actuating members to increase their compliance and improve the seal around the seal module. (Ex. 1003, ¶150.)

## 2. **Hartley**

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

For the reasons discussed for Schaffer above, Hartley’s string is designed to constrict and seal the lumen of a hemostasis valve where a pressure differential (e.g., blood pressure versus air pressure) exists across the valve. (*Supra* §VI.E.1; Ex. 1003, ¶¶151-153.) POSITAs would have reasonably expected Hartley’s string to constrict and seal Schaffer’s seal module when Schaffer’s actuator buttons are in the

first, undepressed position, even when a pressure differential exists between the proximal and distal ends of the lumen because that is the purpose of the string. (*Id.*, ¶152.)

Moreover, if Schaffer's valve and Hartley's string did not seal the lumen when a pressure differential exists, a POSITA would have found it obvious to make one or more adjustments to the valve, including adjusting Schaffer's spring strength, adjusting the resilience of Schaffer's lumen, and/or adjusting Hartley's string to improve the sealing of the valve for the reasons provided for Schaffer. (*Supra* §VI.E.1; Ex. 1003, ¶153.)

### **3. Eller**

Eller discloses a hemostasis valve for preventing the flow of fluid through the central sleeve when the actuator is in the closed position. In the closed position, the wire member constricts the sleeve to create a seal. (Ex. 1007, Abstract, 12:14-17, 15:21-40, 17:47-18:8, Figs. 10A-10C.) Eller further discloses tests performed on different sleeves “included in a selective fluid barrier valve device that was constructed to be similar to the embodiment illustrated in” Figures 1-10C. (*Id.*, 36:46-53.) The valves were “attached to a gravity flow rig and pressurized for 30 seconds per test at a pressure of 2.9 PSI +/- 0.1 PSI (e.g., systolic pressure)” and were measured for fluid leak “in the second configuration with no device disposed

through the sleeve passageway and with the devices described in the table disposed through the sleeve passageway.” (*Id.*, 36:53-60.) The results are below:

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

(*Id.*, 36:26-44.)

Several of the valves demonstrated no leaks despite the pressure difference across the valve, including when no device was inserted through the valve. (*Id.*, 36:64-37:3.) Eller’s results confirm that Eller’s wire member is suitable for constricting and sealing the lumen of a hemostasis valve, even when a pressure differential exists between the proximal and distal ends of the lumen. (Ex. 1003, ¶156.)

Given Eller’s and Schaffer’s disclosures discussed above, POSITAs would have reasonably expected Eller’s wire member to constrict and seal Schaffer’s seal module when Schaffer’s actuator buttons are in the first, undepressed position, even

when a pressure differential exists between the proximal and distal ends of the lumen. (*Id.*, ¶157; *supra* §VI.E.1.)

Moreover, if Schaffer’s valve and Eller’s wire member did not maintain a seal when a pressure differential exists, a POSITA would have found it obvious to make or more adjustments, including adjusting Schaffer’s spring strength to apply additional force to seal the valve, adjusting the resilience of Schaffer’s lumen, and/or adjusting Eller’s wire member to improve the sealing of the valve for the reasons provide in the Schaffer ground. (*Supra* §VI.E.1; Ex. 1003, ¶158.)

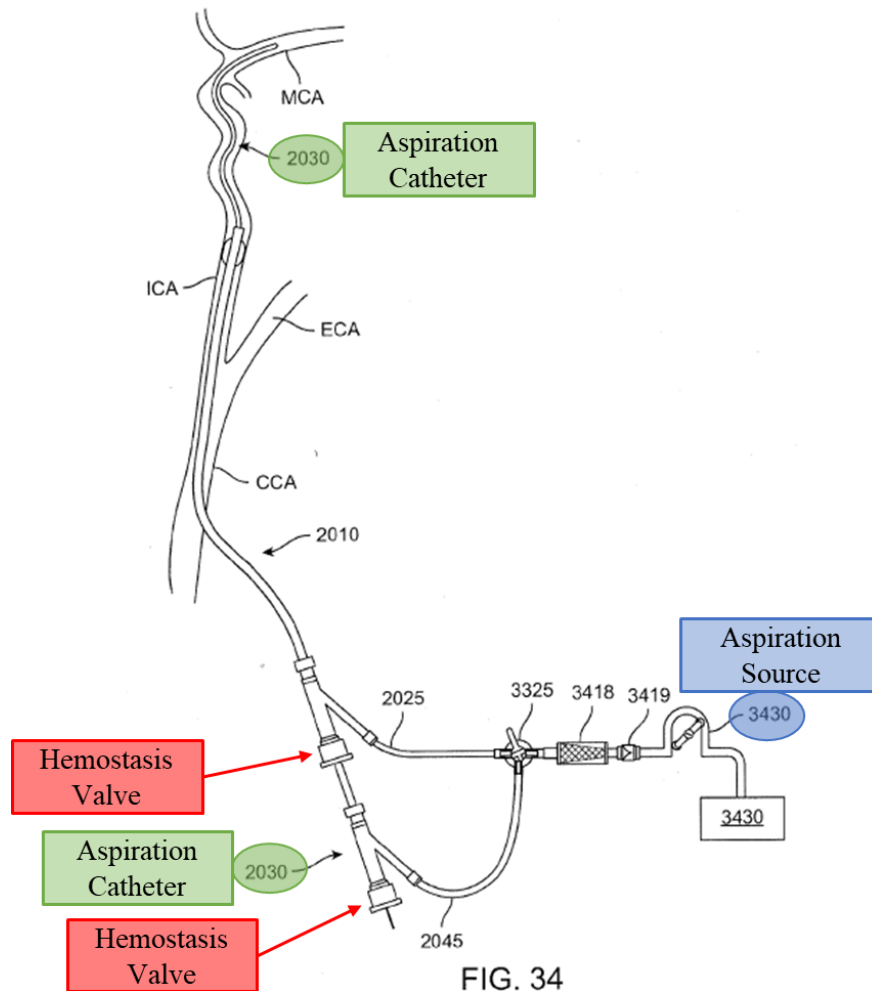
**F. Claim 6**

Claim 6 recites the “aspiration catheter of claim 2 wherein, when the first actuator and the second actuator are in the first position, the valve lumen of the tubular member is configured to remain constricted and sealed when vacuum pressure is applied to a volume outside the valve lumen and adjacent to either a first end or a second end of the tubular member.” Schaffer anticipates claim 6 or renders claim 6 obvious alone or in combination with Hartley *or* Eller. (Ex. 1003, ¶¶159-164.)

Schaffer, Hartley, and Eller disclose hemostasis valves that create a seal to prevent blood leaks during intravascular procedures. (*Supra* §VI.E.) Schaffer further discloses that its valve is configured to connect to “a fluid or gas delivery system or device such as a syringe, intravenous system or the like.” (Ex. 1005,

[0049].) POSITAs in September 2017 would have understood that syringes could be used to generate negative pressure for aspiration. (*See e.g.*, Ex. 1011, [0071] (“The flow line 905 may also be connected to an aspiration source such as a pump or syringe.”); *supra* §VI.A.1; Ex. 1003, ¶160.)

Schaffer further discloses that its valve prevents leakage across “a range of instruments,” such as “a catheter, guidewire, needle, or fiber.” (Ex. 1005, [0056].) Aspiration catheters were commonly used with hemostasis valves prior to September 2017 to apply vacuum pressure through the catheter, often using syringes. (Ex. 1003, ¶161.) For example, Garrison discloses an aspiration catheter 2030 having a proximal hub 2065 that may include a “separate hemostasis valve ... attached to proximal hub, to allow introduction of devices such as a microcatheter, guide wire, or thrombectomy device while preventing or minimizing blood loss during the procedure. Alternately, the hemostasis valve may be integral to the catheter proximal adaptor”:



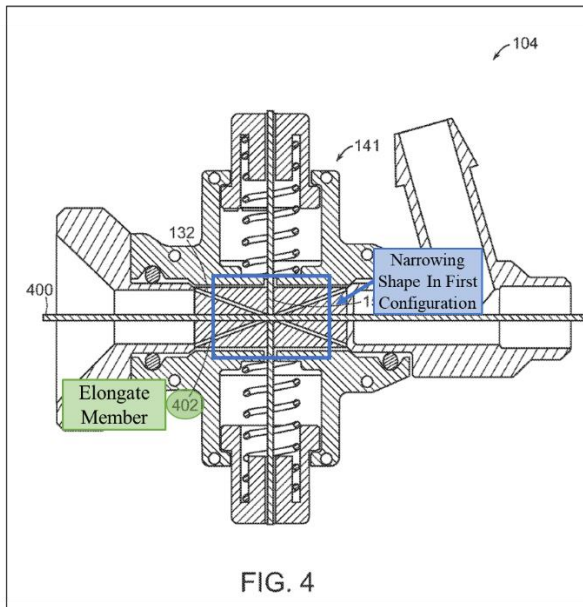
(Ex. 1011, [0098]; *see also id.*, [0130]-[0132], Fig. 34.)

Given the common practice of using hemostasis valves with suction sources in September 2017 (such as Schaffer’s syringe) and Schaffer’s disclosures discussed in claim 5, POSITAs would have understood that when Schaffer’s actuator buttons remain in the first, undepressed position, the central lumen of the tubular member would remain constricted and sealed, even when a vacuum pressure is applied to a volume outside of the valve’s lumen and adjacent to the end of the tubular member. (Ex. 1003, ¶162; Ex. 1005, [0008], [0077]; *supra* §VI.E.) The lumen on Schaffer’s

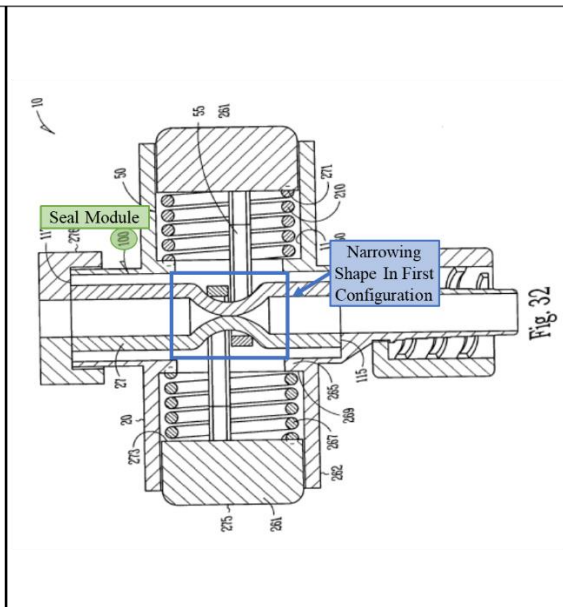
valve is held in the closed position by the springs/buttons pulling on the U-shaped actuating members. A POSITA would not have expected the vacuum pressure applied through a catheter inserted into a patient to be strong enough to overwhelm this spring force. (Ex. 1003, ¶162.) Further, the force from the vacuum pressure would be perpendicular to the actuating members and, therefore, would not force the actuating members apart. (*Id.*)

Moreover, the only disclosure in the '012 patent regarding the valve's ability to seal under vacuum pressure is the statement that: "due to the narrowing shape of the elongate member 132 when the constricting mechanism 141 is in the first configuration, a vacuum applied to the portions of the delivery device 100 distal to the axis 152 draws the elongate member 132 towards the first configuration and can, in some embodiments, increase the strength, robustness, and/or strength of the seal of the valve 104." (Ex. 1001, 10:57-63.) Schaffer's elongate member (seal module 100) also has a "narrowing shape" when the actuator buttons are in the first, undepressed configuration:

'012 Patent



Schaffer



(*Id.*, Fig. 4 (left); Ex. 1005, [0077], Fig. 32 (right).) Because Schaffer discloses the same structure that the '012 patent claims to enable sealing under vacuum pressure, PO cannot argue that Schaffer's valve is not "configured to remain constricted and sealed when vacuum pressure is applied to a volume outside the lumen and adjacent to either a first end or a second end of the tubular member."

In addition, given the disclosures of Schaffer, Hartley, and Eller discussed in claim 5, a POSITA would have reasonably expected that Hartley's string or Eller's wire member would maintain the lumen of Schaffer's tubular member in a constricted and sealed state when Schaffer's actuator buttons are in the first, undepressed position, even when a vacuum pressure is applied to a volume outside of the valve's lumen. (Ex. 1003, ¶164; Ex. 1005, [0008], [0077]; Ex. 1006, [0003], [0006]; Ex. 1007, 27:44-50, 36:46-37:3; *supra* §VI.E.) Like Schaffer, Hartley's

string and Eller's wire member are pulled perpendicular to the direction of suction. (Ex. 1003, ¶164.) A POSITA would not have expected the vacuum pressure to exert a force on the string/wire member and springs that would open the valve. (*Id.*)

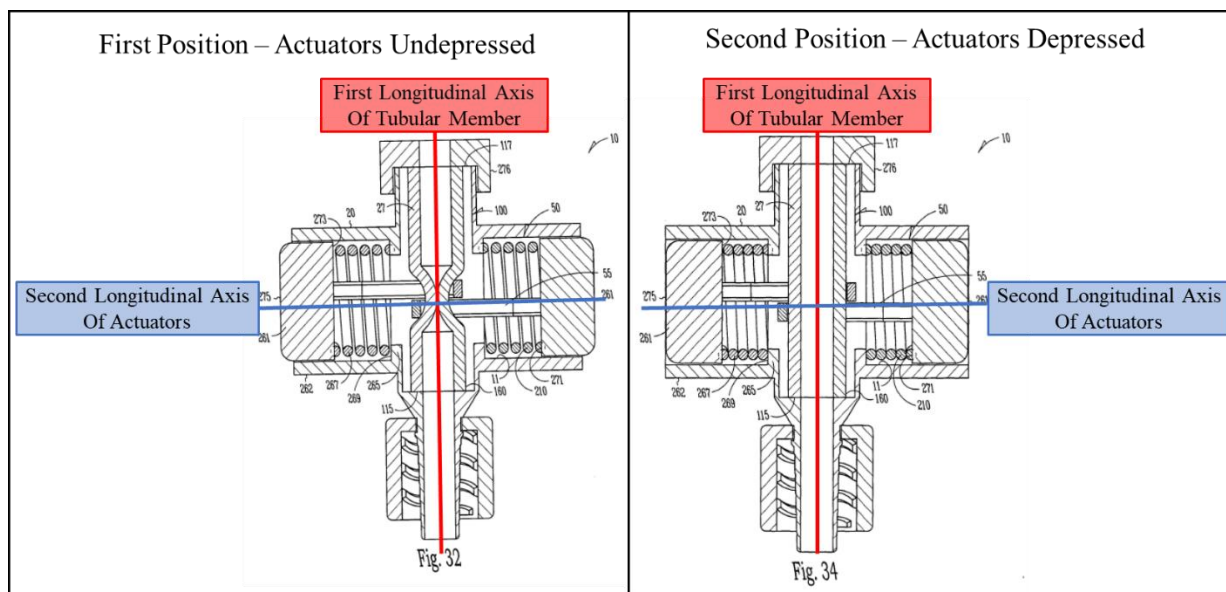
Moreover, if Schaffer's valve would not maintain its seal under vacuum pressure (either alone or with Hartley's or Eller's filament), a POSITA would have found it obvious to make one or more adjustments to the valve, including adjusting Schaffer's spring strength to apply additional force to the valve, adjusting the resilience and compressibility of the seal module that forms the valve's lumen, and/or adjusting the shape, flexibility, and/or dimensions of the U-shaped actuating members to more closely conform to the shape of the seal module and any tool(s) inserted through the valve. (Ex. 1003, ¶165.) POSITAs would have been motivated to do so because the purpose of Schaffer's hemostasis valve is to prevent leaks when a catheter is inserted into a patient, including aspiration catheters. (*Id.*) POSITAs would have reasonably expected success in making these adjustments for the reasons explained above for claim 5. (*Supra* §VI.E.)

**G. Claim 7**

Claim 7 recites the "aspiration catheter of claim 2 wherein the valve lumen of the tubular member extends a long [sic] a first longitudinal axis, wherein the first actuator and the second actuator are movable between the first and second positions along a second longitudinal axis, and wherein the first longitudinal axis is orthogonal

to the second longitudinal axis.” Schaffer anticipates claim 7 or renders claim 7 obvious alone or in combination with Hartley *or* Eller. (Ex. 1003, ¶¶166-167.)

Schaffer’s actuator buttons (i.e., first and second actuators) are movable between a first and second position along a longitudinal axis that is orthogonal to the longitudinal axis of the tubular member:



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

## H. Claim 8

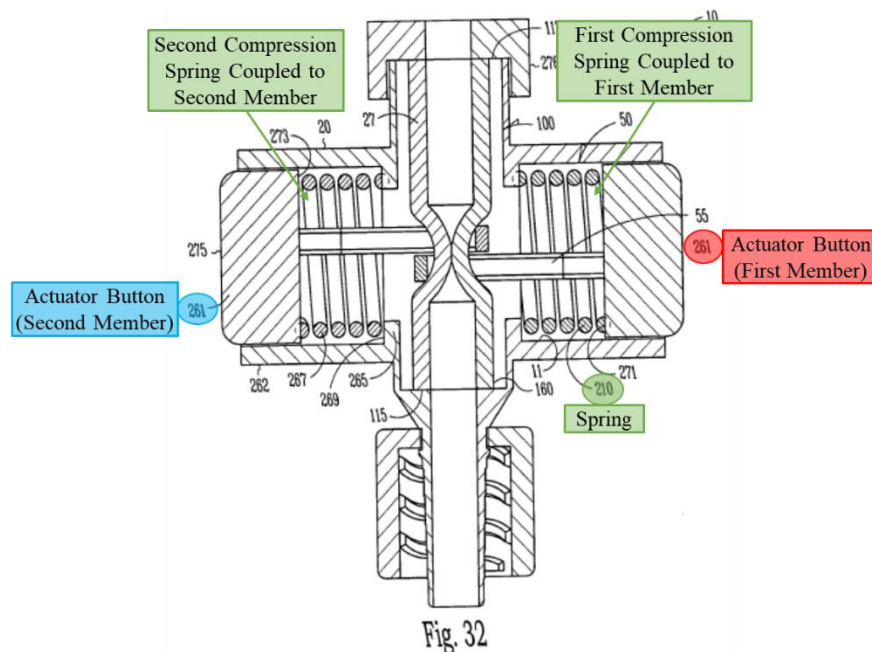
Claim 8 recites the “aspiration catheter of claim 2 wherein the first spring comprises a first compression spring coupled to the first member and the second spring comprises a second compression spring coupled to the second member.”<sup>7</sup>

---

<sup>7</sup> The terms “first member” and “second member” recited in claim 8 lack antecedent basis. For this Petition, Petitioner interprets the “first member” and “second member” to correspond with the “first actuator” and “second actuator” recited in claims 1 and 2.

Schaffer anticipates claim 8 or renders claim 8 obvious alone or in combination with Hartley **or** Eller. (Ex. 1003, ¶¶168-169.)

Schaffer’s valve includes two compression springs (resilient members), and “the distal end 271 of the resilient members 267 each abut the proximal end 273 of an actuator button 261”:



(Ex. 1005, [0076], Figs. 31-34; Ex. 1003, ¶169.)

## **I. Claim 9**

Claim 9 recites the “aspiration catheter of claim 2 wherein, in the first position, the first actuator and the second actuator pull the filament to circumferentially constrict the collapsible tubular member such that the valve lumen is constricted and sealed.” Schaffer anticipates claim 9 or renders claim 9 obvious alone or in view of Hartley **or** Eller. (Ex. 1003, ¶¶170-171.)

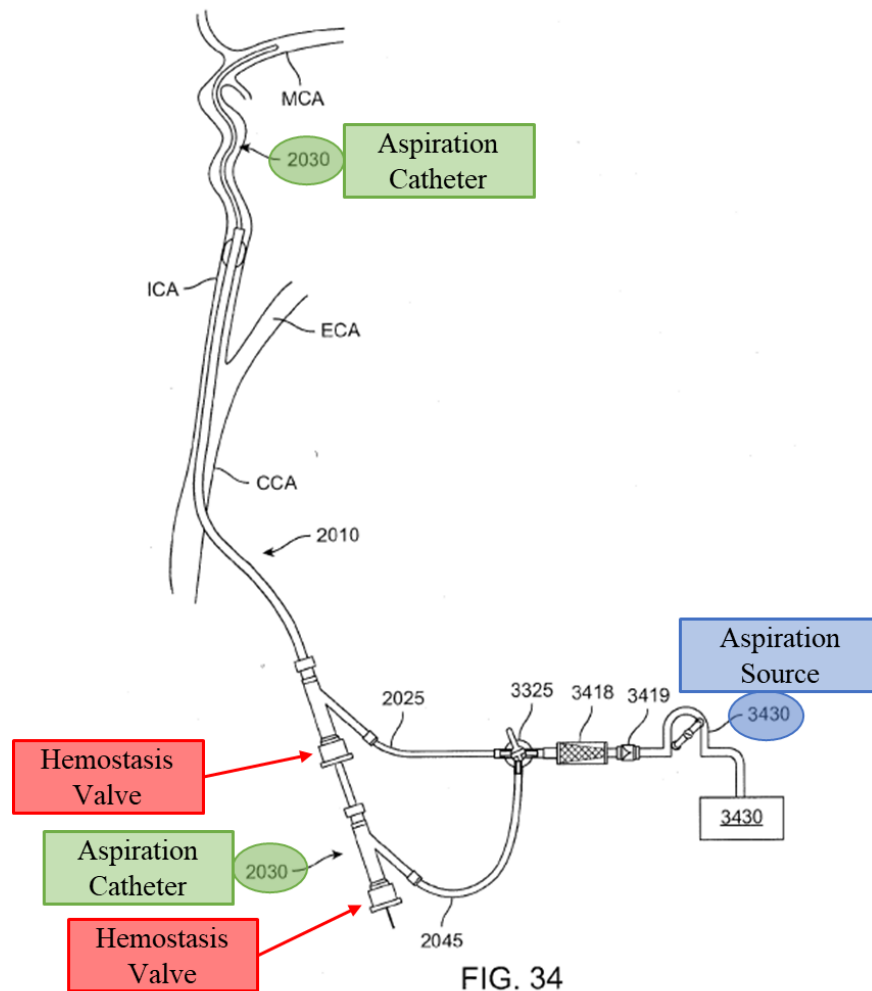
When Schaffer's actuator buttons are in the first, undepressed, position, the springs coupled to Schaffer's actuator buttons pull the U-shaped actuating members to constrict the seal module 100. (Ex. 1005, [0076]-[0077]; Ex. 1003, ¶171; *supra* §VI.A.5.c.) If Schaffer's U-shaped actuating members were replaced with Hartley's string or Eller's wire member, Schaffer's actuator buttons would similarly pull the string/wire member to circumferentially constrict the seal module 100. (Ex. 1003, ¶171.)

**VII. GROUNDS 5-7: CLAIMS 1-9 OBVIOUS OVER SCHAFFER COMBINED WITH GARRISON AND OPTIONALLY HARTLEY OR ELLER**

As explained above, the term “aspiration” recited in the preamble is not limiting. (*Supra* §IV.B.) However, even if the preamble were limiting, the combination of hemostasis valves (e.g., Schaffer) with aspiration catheters (e.g., Garrison) was well known and would have been obvious to a POSITA by September 2017. (Ex. 1003, ¶172.)

Garrison discloses a system “to provide aspiration and passive flow reversal for the purpose of facilitating removal of the occlusion as well as minimizing distal emboli.” (Ex. 1006, [0007].) Garrison's system includes an aspiration catheter 2030 having a proximal hub 2065 that may include a “separate hemostasis valve ... attached to proximal hub, to allow introduction of devices such as a microcatheter, guide wire, or thrombectomy device while preventing or minimizing blood loss

during the procedure. Alternately, the hemostasis valve may be integral to the catheter proximal adaptor”:



(Ex. 1011, [0098]; *see also id.*, [0130]-[0132], Fig. 34.)

As explained below, a POSITA would have been motivated, and found it obvious, to use Schaffer’s hemostasis valve as the proximal hemostasis valve in Garrison’s aspiration system. (Ex. 1003, ¶173.) Consequently, a POSITA would

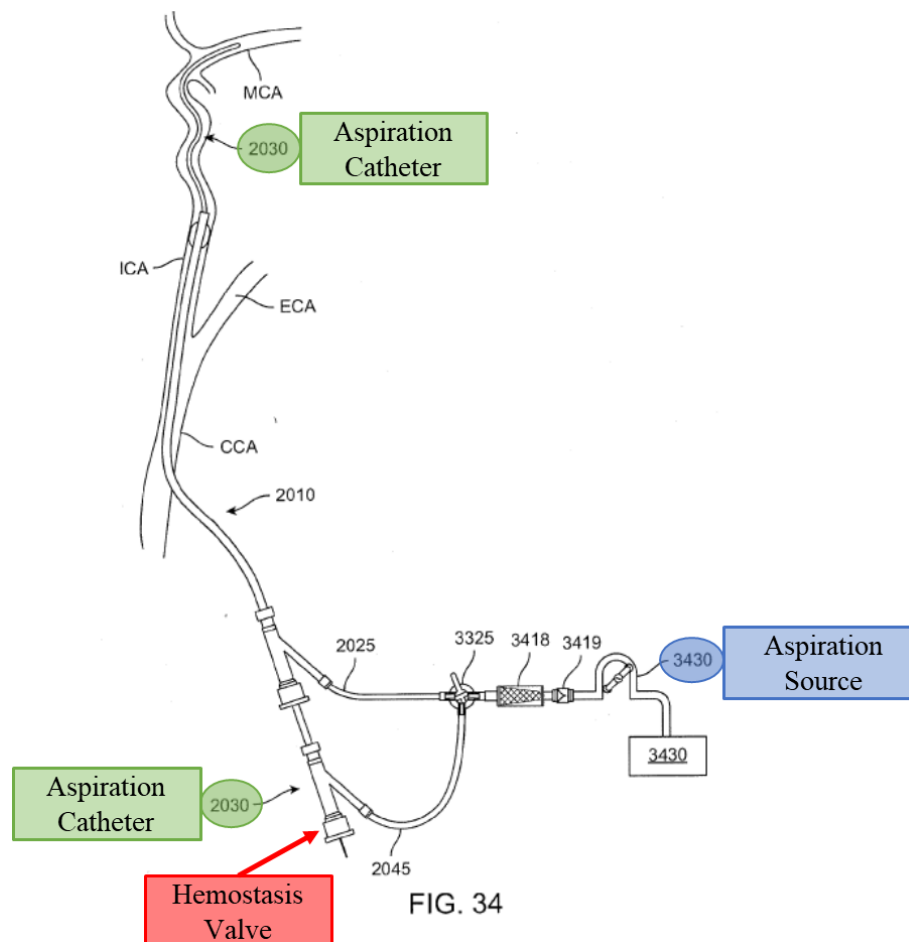
have found claims 1-9 obvious over Schaffer in combination Garrison and optionally Hartley **or** Eller. (*Id.*)

**A. Claim 1**

Schaffer in combination with Garrison and optionally Hartley **or** Eller renders claim 1 obvious. (Ex. 1003, ¶¶174-199.)

**1. Preamble**

Garrison discloses an aspiration system including an aspiration catheter [green], an aspiration source (e.g., aspiration pump) [blue], and at least one hemostasis valve [red]:



(Ex. 1011, Fig. 34, [0048], [0098], [0131]-[0134] (describing Figure 34 and related figures); Ex. 1003, ¶¶175-177.) Garrison explains that “the catheter 2030 may be connected to sources of passive or active aspiration via flow line[] ... 2045.” (Ex. 1011, [0130].) Garrison’s catheter 2030 is therefore an “aspiration catheter.” (Ex. 1003, ¶¶176-177.); *In re Gleave*, 560 F.3d 1331, 1334 (Fed. Cir. 2009) (holding that a prior art “reference need not satisfy an *ipsissimis verbis* test” to be anticipatory under § 102(b)); *Ex Parte Klop*, Appeal 2019-006763, 2020 WL 2473929, at \*4 (P.T.A.B. May 7, 2020) (“[I]t does not matter what [the prior art] calls the asserted structure. What matters is whether that structure constitutes [the limitation] within the meaning of the claim.”).

## **2. Tubular Body**

Garrison discloses “an elongate, flexible tubular body, having a proximal end, a distal end and a central lumen.” (Ex. 1003, ¶¶178-182.) Garrison’s catheter 2030 may “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.” (Ex. 1011, [0054].) Garrison expressly discloses that a “second, smaller diameter catheter may be inserted through the first catheter ....” (*Id.*) Garrison’s catheter 2030 and the second, smaller catheter both satisfy this limitation. (Ex. 1003, ¶¶179-180.)

One example of a “smaller diameter catheter” described in Garrison is “a tapered co-axial inner member 2652 ... sized and shaped to be inserted through the internal lumen of the catheter”:

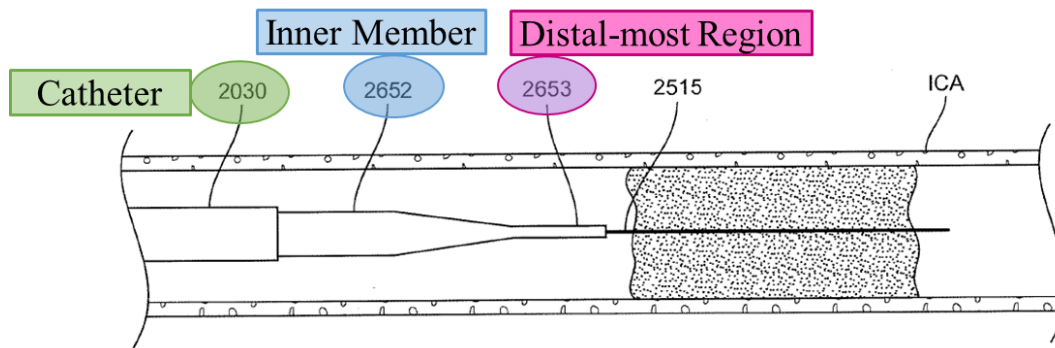


FIG. 25B

(Ex. 1011, [0112], FIG. 25B.) The inner member 2652 extends from a proximal end (not shown in FIG. 25B) to a distal end with a “distal-most region 2653 that extends distally past the tapered portion.” (*Id.*, [0113].) The inner member has “an internal lumen” through which “a guidewire 2515 or microcatheter” can “extend.” (*Id.*, [0112].) Garrison discloses that “[t]he material of the dilator (inner member 2652) is flexible enough and the taper is long enough to create a smooth transition between the flexibility of the guide wire and the catheter” which helps “facilitate advancement of the catheter through the curved anatomy and into the target cerebral vasculature.” (*Id.*, [0114].) Accordingly, Garrison’s inner member 2652 is “an elongate, flexible tubular body, having a proximal end, a distal end and a central lumen.” (Ex. 1003, ¶181.)

Another disclosed example of a “smaller diameter catheter” inserted through the catheter 2030 is “an anchor device which is configured to be easily navigable through the vasculature to a location distal to the cerebral occlusion.” (Ex. 1011, [0115].) “[T]he anchor is a microcatheter 2505 with a distal balloon 2510”:

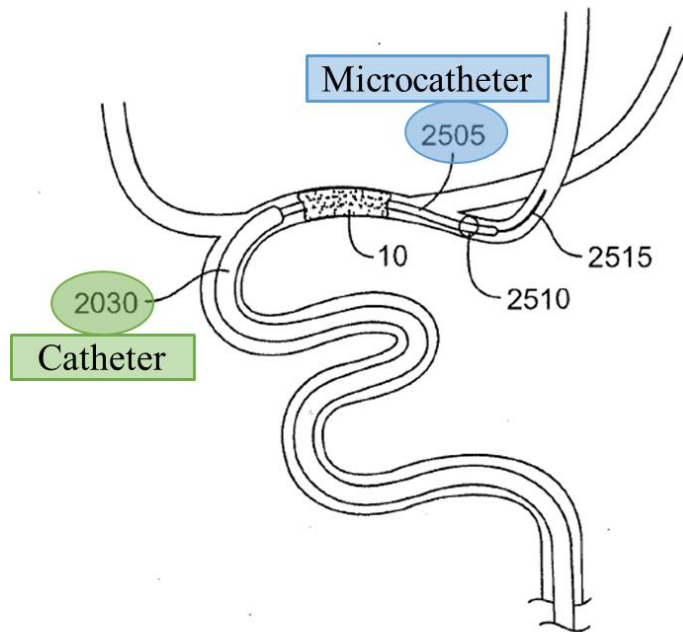


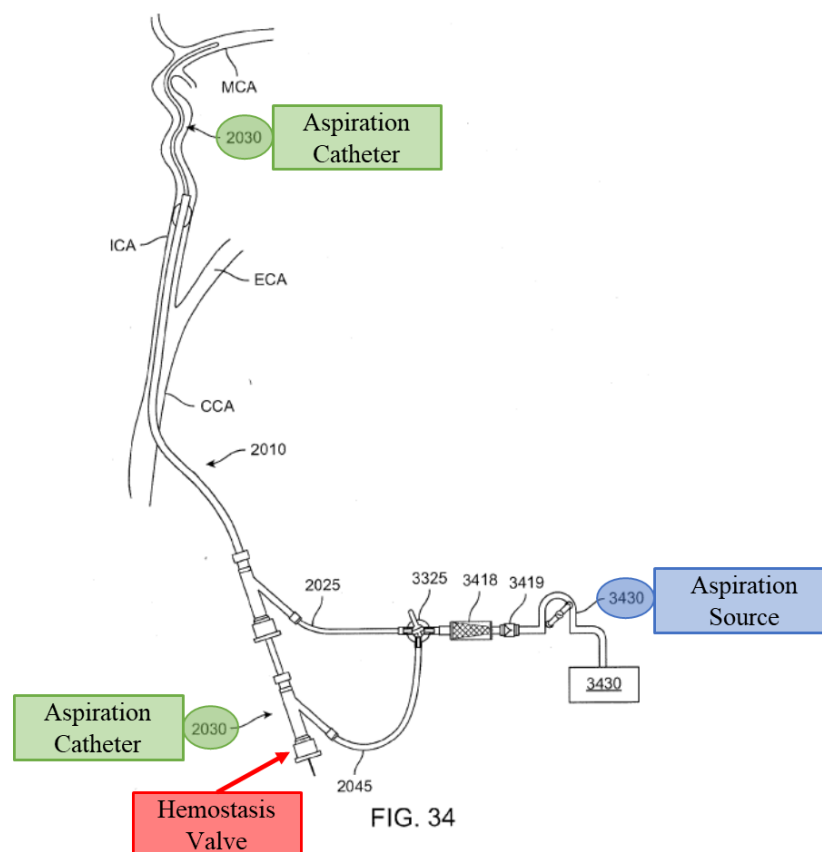
FIG. 26

(*Id.*, Fig. 26.) “The microcatheter 2505 is placed over a guidewire 2515 to a site distal of the target treatment area, for example a thrombus 10.” (*Id.*, [0115].) Accordingly, the microcatheter 2505 has a central lumen and as shown above, has a flexible, elongate, tubular body with a proximal and distal end. (Ex. 1003, ¶182.) Garrison’s microcatheter 2505 is therefore “an elongate, flexible tubular body, having a proximal end, a distal end and a central lumen.” (*Id.*)

### 3. Hemostasis Valve

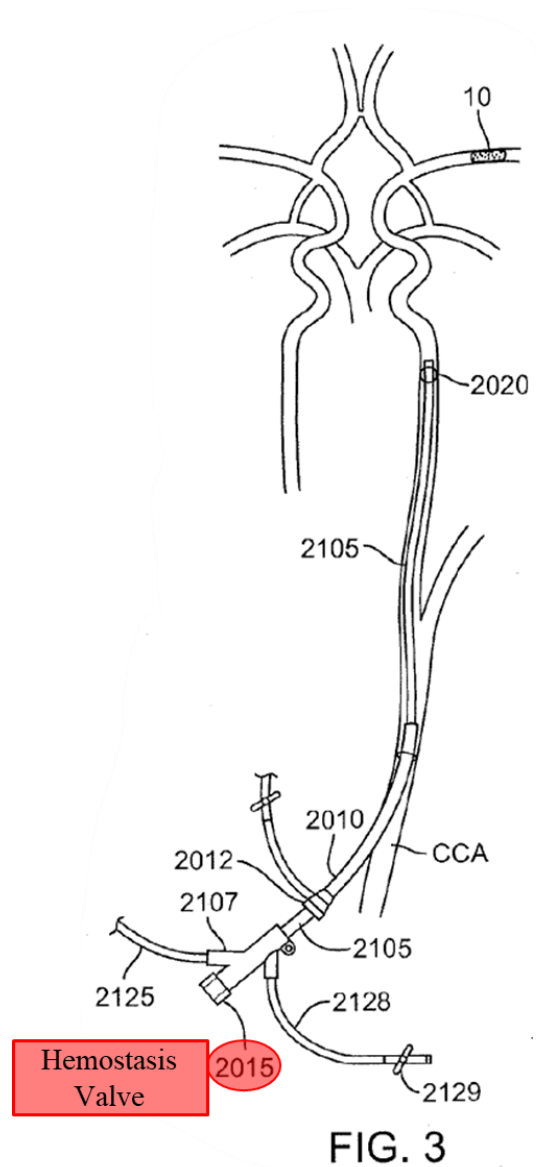
Garrison discloses “a hemostasis valve on the proximal end of the catheter.”  
(Ex. 1003, ¶¶183-198.)

Garrison discloses that the catheter 2030 (i.e., aspiration catheter) has a “proximal hub 2065” and explains that “a separate hemostasis valve may be attached to proximal hub 2065, to allow introduction of devices such as a microcatheter, guide wire, or thrombectomy device while preventing or minimizing blood loss during the procedure”:



(Ex. 1011, [0098], Fig. 34.) Figure 34 does not expressly label the proximal adaptor and hemostasis valve, but other, related figures do. For example, Figure 3 identifies

a “proximal adaptor having a proximal port 2015 **with a hemostasis valve** to allow introduction of devices while preventing or minimizing blood loss during the procedure”:



(*Id.*, [0053] (emphasis added); *see also id.*, [0050]-[0053], [0059], [0062], Figs. 1-3, 6 (describing hemostasis valve 2012 in arterial access device).) A POSITA would

have understood that catheter 2030's hemostasis valve in Figure 34 is located at the end of the proximal adaptor as in Figure 3. (Ex. 1003, ¶¶184-188.)

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 catheters (including catheter 2030) for several reasons. (Ex. 1003, ¶¶189-197.) First, Garrison discloses that the hemostasis valves used with its system "can be a static seal-type passive valve, or an adjustable-opening valve such as a Tuohy-Borst valve 227 or rotating hemostasis valve (RHV) (see FIG. 6)." (Ex. 1011, [0062], [0065], [0098].) Schaffer discloses an adjustable-opening hemostasis valve and, therefore, a POSITA would have been motivated to combine, and reasonably expected success in combining, Schaffer's valve with Garrison. (Ex. 1003, ¶190.)

Second, Schaffer discloses that its hemostasis valve is "for use with catheters" and provides "a durable stasis valve that blocks the flow of gas or fluid completely and immediately with or without an instrument in place within the gas/fluid path." (Ex. 1005, [0002], [0008].) Accordingly, POSITAs would have recognized that Schaffer's valve would perform the stated function of the "hemostasis valve" in Garrison's system—to "allow for the introduction of devices ... while preventing or minimizing blood loss via the internal lumen during the procedure." (Ex. 1011, [0098]; Ex. 1003, ¶191.)

Third, POSITAs would have recognized that Schaffer’s hemostasis valve could simplify operation of Garrison’s system. (Ex. 1003, ¶192.) For example, Schaffer’s springs would bias the valve toward the closed position, eliminating the need for the operator to manually seal the valve prior to or during the procedure as was the case with some prior-art rotating valves. (*Id.*) Thus, Schaffer’s valve could simplify the procedure in some cases. (*Id.*)

Fourth, the combination of Schaffer’s valve with Garrison’s aspiration catheters would merely entail the combination of known elements (Schaffer’s valve and catheter 2030) according to known methods (attaching the valve to a proximal hub on the catheter or forming it integrally with the hub) to yield the predictable result of preventing or minimizing blood loss through the catheter. *See KSR*, 550 U.S. at 416; (Ex. 1003, ¶193.)

Fifth, POSITA’s in August 2017 had a finite number of predictable hemostasis valves to choose, including an “adjustable-opening valve” like Schaffer’s valve, or “a passive seal hemostasis valve.” (Ex. 1003, ¶194.) A POSITA would have found it obvious to try any of these hemostasis valves in combination with Garrison’s catheter 2030. (*Id.*); *KSR*, 550 U.S. at 417. Moreover, the known valves, including Schaffer’s adjustable-opening hemostasis valve, were simple mechanical structures that operate in a predictable way. (Ex. 1003, ¶194.) For this additional

reason, POSITAs would have reasonably expected success in combining any of the known valves with Garrison. (*Id.*)

Moreover, Schaffer discloses that its hemostasis valve is “for use with catheters.” (Ex. 1005, [0002].) Schaffer also discloses that the seal module 100 is “proximally connected to the connecting member 35,” and that the “connecting member 35 [is] sized and configured to attach in fluid communication to a fluid delivery supply or a body passage such as a blood vessel.” (*Id.*, [0047], [0049].) Schaffer further discloses that “a range of instruments [can be] used within the seal module,” such as “a catheter, guidewire, needle, or fiber,” and that “a guidewire and catheter may be placed into the same lumen 193 for extension into a body passage.” (*Id.*, [0056], [0074].) Accordingly, a POSITA would have reasonably expected that Schaffer’s hemostasis valve would allow other devices to pass through the valve and into Garrison’s catheter 2030. (Ex. 1003, ¶¶195-196.)

When Schaffer’s valve, either alone or combined with Hartley or Eller, is used as the hemostasis valve on Garrison’s catheter 2030, each of the “tubular bod[ies]” disclosed in Garrison would pass through the lumen of Schaffer’s valve. (*Supra* §VII.A.2; Ex. 1003, ¶197; Ex. 1011, [0054], [0090], [0100], [0112]-[0115]], Figs. 1-3, 26.) Thus, the “central lumen” defined by each of the tubular bodies would be coaxially within Schaffer’s valve lumen, and Schaffer’s valve lumen would therefore be “in communication with the central lumen.” (Ex. 1003, ¶197.)

**4. Remaining Claim 1 Limitations**

Schaffer alone or in combination with Hartley or Eller disclose or render obvious the remaining limitations of Claim 1 for the reasons provide in Grounds 1-4. (*Supra* §§VI.A.4-5.) Thus, Schaffer combined with Garrison and optionally Hartley **or** Eller renders claim 1 obvious.

**B. Claims 2-9**

Schaffer discloses the limitations of claims 2-9 or renders those limitations obvious alone or in combination with Hartley **or** Eller, for the reasons explained in Grounds 1-4. (*Supra* §VI.B-I.) Accordingly, Schaffer combined with Garrison and optionally Hartley **or** Eller renders claims 2-9 obvious. (Ex. 1003, ¶200.)

**VIII. SECONDARY CONSIDERATIONS**

Petitioner is not aware of any evidence of secondary considerations. (Ex. 1003, ¶¶201-203.) If PO identifies evidence of secondary considerations, Petitioner respectfully requests an opportunity to respond.

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

Schaffer, which forms the basis for all grounds herein, was not submitted during prosecution of the '012 patent. For this reason, the Board should not exercise its discretion to deny institution under 35 U.S.C. §325(d).

Hartley, Eller, and Garrison were listed during prosecution of the '012 patent. In the Notice of Allowance, the examiner stated that Hartley disclosed every

limitation of allowed claim 1 except the spring limitation. (Ex. 1002, 85.) The examiner did not address the combination of Hartley with Schaffer proposed herein. Further, the examiner did not substantively address Eller or Garrison during prosecution, much less address the combinations of Eller and/or Garrison with Schaffer proposed herein. Accordingly, the Board should not deny institution based on the submission of Hartley, Eller, and Garrison because, as shown above, the references render the challenged claims unpatentable. *See e.g., Comcast Cable Commc'ns LLC v. Promptu Sys. Corp.*, IPR2018-00342, Paper 13 (PTAB July 19, 2018) (declining to deny institution under §325(d) because prior art was not applied).

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

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

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

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

PO recently filed suit alleging that Petitioner's Symphony system infringes the '012 patent, as well as U.S. Patent Nos. 12,016,580; 11,974,910; 11,969,333; 11,554,005; 11,744,691; 11,844,921; 11,697,011; and 11,865,291. *Inari Medical, Inc. v. Imperative Care, Inc.*, No. 24-cv-3117 (N.D. Cal., filed May 22, 2024) (the "Litigation"). The court has not set a case schedule or a trial date in the Litigation. Petitioner has also filed a related IPR challenging claims of U.S. Patent No. 11,697,011, which is related to the '012 Patent and shares the same specification.

*Imperative Care, Inc. v. Inari Medical, Inc.*, IPR2024-01157, Paper 1, Petition (P.T.A.B. July 8, 2024). Petitioner has also filed an IPR challenging claims of U.S. Patent No. 11,744,691, which has been asserted in the district court litigation. *Imperative Care, Inc. v. Inari Medical, Inc.*, IPR2024-01257, Paper 1, Petition (P.T.A.B. Aug. 12, 2024).

**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.

| <b>Lead Counsel</b>                                                                                                                                                                                                                                                                                       | <b>Back-up Counsel</b>                                                                                                                                                                                                                                                                                                        |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Joshua J. Stowell (Reg. No. 64,096)<br>Joshua.Stowell@knobbe.com<br>BoxImperative012@knobbe.com<br><br>Knobbe, Martens, Olson, & Bear, LLP<br><u>Postal and Hand-Delivery Address:</u><br>2040 Main St., 14 <sup>th</sup> Floor<br>Irvine, CA 92614<br>Telephone: 949-760-0404<br>Facsimile: 949-760-9502 | Joseph R. Re (Reg. No. 31,291)<br>Joe.Re@knobbe.com<br>Brian C. Barnes (Reg. No. 75,805)<br>Brian.Barnes@knobbe.com<br><br>Knobbe, Martens, Olson, & Bear, LLP<br><u>Postal and Hand-Delivery Address:</u><br>2040 Main St., 14 <sup>th</sup> Floor<br>Irvine, CA 92614<br>Telephone: 949-760-0404<br>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 BoxImperative012@knobbe.com.

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

Petitioner certifies that the '012 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**

Petitioner has established a reasonable likelihood that at least one of the challenged claims of the '012 patent is unpatentable. Accordingly, Petitioner requests that the Board institute this IPR to reconsider the patentability of the '012 patent.

Dated: November 8, 2024

By: /Joshua J. Stowell/

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

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

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

KNOBBE MARTENS OLSON & BEAR, LLP

*Attorneys for Petitioner,  
Imperative Care, Inc.*

**CERTIFICATE OF COMPLIANCE**

Pursuant to 37 C.F.R. § 42.24(d), the undersigned certifies that this PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 11,697,012 contains 13,984 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: November 8, 2024 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. 11,697,012, PETITIONER’S POWER OF ATTORNEY, AND EXHIBITS 1001-1016**, were served by Express Mail on the Patent Owner at the correspondence address of record for the subject patent as follows:

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

A courtesy copy has been sent by email on this day to Patent Owner’s counsel of record in the Litigation as follows:

|                                                                                                                                                                                                                   |                                                                                                                                                                                       |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>Amanda Tessar<br/>Email: atessar@perkinscoie.com<br/><b>Perkins Coie LLP</b><br/>1900 Sixteenth Street<br/>Suite 1400<br/>Denver, CO 80202<br/>Telephone: 303-291-2357</p>                                     | <p>Ramsey M. Al-Salam<br/>Email: ralsalam@perkinscoie.com<br/><b>Perkins Coie LLP</b><br/>1201 Third Avenue<br/>Suite 4000<br/>Seattle, WA 98101-3099<br/>Telephone: 206-359-8000</p> |
| <p>Daniel T. Keese<br/>Email: DKeese@perkinscoie.com<br/><b>Perkins Coie LLP</b><br/>1120 NW Couch Street, 10th Floor<br/>Portland, Oregon 97209-4128<br/>Telephone: 503.757.2000<br/>Facsimile: 503.727.2222</p> | <p>Bingjie Li<br/>Email: BLi@perkinscoie.com<br/><b>Perkins Coie LLP</b><br/>3150 Porter Dr.<br/>Palo Alto, CA 94304-1212<br/>Telephone: 650.838.4754<br/>Facsimile: 650.38.4350</p>  |

Dated: November 8, 2024

By: /Joshua J. Stowell/

Joshua J. Stowell (Reg. No. 64,096)  
KNOBBE MARTENS OLSON & BEAR, LLP