

Filed: December 13, 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: BoxImperative005@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. IPR2025-00289
Patent No. 11,554,005

**PETITION FOR *INTER PARTES* REVIEW OF
U.S. PATENT NO. 11,554,005**

TABLE OF CONTENTS

	Page No.
I. INTRODUCTION	1
II. THE '005 PATENT	9
A. Overview	9
B. Prosecution History	14
C. Earliest Possible Priority Date.....	16
III. LEVEL OF ORDINARY SKILL	17
IV. CLAIM CONSTRUCTION	17
V. STATEMENT OF RELIEF REQUESTED	19
A. IPR Grounds	19
B. The Asserted References Are Prior Art	20
C. The Asserted References Are Analogous Art	20
VI. GROUNDS 1-3: GARRISON COMBINED WITH SCHAFER AND OPTIONALLY HARTLEY OR ELLER	21
A. Independent Claim 1	21
1. Preamble.....	21
2. Housing	22
3. Flow Path	23
4. On-off Control.....	24
5. First Catheter	26
6. Connector	27

TABLE OF CONTENTS (*cont'd*)

	Page No.
7. Clot Cannister	30
8. Hemostasis Valve.....	34
a. Tubular Member	38
b. Constricting Mechanism.....	39
i. Actuator	40
ii. Filament.....	43
c. Biasing System	60
B. Claim 2	61
C. Claim 3	62
1. Schaffer	62
2. Hartley.....	63
3. Eller	64
D. Claim 4	65
E. Claim 5	67
1. Schaffer	67
2. Hartley.....	69
3. Eller	70
F. Claim 6	71
G. Claim 7	75
H. Claim 8	76

TABLE OF CONTENTS

(*cont'd*)

	Page No.
I. Claim 9	77
J. Independent Claim 10	78
1. Hemostasis Valve.....	78
a. Support.....	78
b. Actuator	79
c. Tubular Sidewall.....	80
d. Filament	82
e. First Spring	82
K. Claim 11	85
L. Claim 12	85
M. Claim 13	85
1. Schaffer-Hartley	86
2. Schaffer-Eller	86
N. Claim 14	87
O. Claim 15	88
VII. GROUND 4: GARRISON COMBINED WITH HARTLEY AND ELLER	88
A. Independent Claim 1	88
1. Preamble and Limitations 2-7	88
2. Hemostasis Valve.....	88

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

	Page No.
a. Tubular Member	90
b. Constricting Mechanism.....	90
i. Actuator	91
ii. Filament.....	92
c. Biasing System	93
B. Claim 2	97
C. Claim 3	97
D. Claim 5	98
E. Claim 6	99
F. Claim 9	101
G. Independent Claim 10	102
1. Preamble and Limitations 2-7	102
2. Hemostasis Valve.....	102
a. Support.....	102
b. Actuator	103
c. Tubular Sidewall.....	105
d. Filament	106
e. First Spring	106
H. Claim 11	106
I. Claim 12	106

TABLE OF CONTENTS
(cont'd)

	Page No.
J. Claim 13	106
K. Claim 14	106
L. Claim 15	107
VIII. SECONDARY CONSIDERATIONS	107
IX. THE BOARD SHOULD NOT DENY INSTITUTION UNDER §§314(a) OR 325(d).....	107
X. MANDATORY NOTICES, GROUNDS FOR STANDING, AND FEE PAYMENT	109
A. Real Parties-In-Interest (37 C.F.R. §42.8(b)(1))	109
B. Related Matters (37 C.F.R. §42.8(b)(2)).....	109
C. Lead and Backup Counsel (37 C.F.R. §42.8(b)(3))	110
D. Service Information (37 C.F.R. §42.8(b)(4))	110
E. Grounds for Standing (37 C.F.R. §42.104).....	110
F. Payment of Fees (37 C.F.R. §42.15(a))	110
XI. CONCLUSION.....	111

TABLE OF AUTHORITIES

Page No(s).

<i>Biagro W. Sales, Inc. v. Grow More, Inc.</i> , 423 F.3d 1296 (Fed. Cir. 2005)	45
<i>Comcast Cable Commc'ns LLC v. Promptu Sys. Corp.</i> , IPR2018-00342 (P.T.A.B. July 19, 2018)	108
<i>In re Gleave</i> , 560 F.3d 1331 (Fed. Cir. 2009)	41
<i>Imperative Care, Inc. v. Inari Med., Inc.</i> , IPR2024-01157 (P.T.A.B. July 8, 2024)	19, 44, 51, 109
<i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2024-01257 (P.T.A.B. Aug. 12, 2024)	109
<i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-00156 (P.T.A.B. Nov. 8, 2024)	109
<i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , No. 24-cv-3117 (N.D. Cal., filed May 22, 2024)	107, 108, 109, 110
<i>Ex Parte Klop</i> , Appeal 2019-006763, 2020 WL 2473929 (P.T.A.B. May 7, 2020)	41
<i>KSR Int'l Co. v. Teleflex Inc.</i> , 550 U.S. 398 (2007)	<i>passim</i>
<i>In re Nilssen</i> , 851 F.2d 1401 (Fed. Cir. 1988)	21
<i>Phillips v. AWH Corp.</i> , 415 F.3d 1303 (Fed. Cir. 2005)	17
<i>Sandisk Corp. v. Kingston Tech. Co., Inc.</i> , 695 F.3d 1348 (Fed. Cir. 2012)	45

TABLE OF AUTHORITIES (*cont'd*)

Page No(s).

<i>Unwired Planet, LLC v. Google Inc.</i> , 841 F.3d 995 (Fed. Cir. 2016)	20
<i>Vitronics Corp. v. Conceptiontronic, Inc.</i> , 90 F.3d 1576 (Fed. Cir. 1996)	17

OTHER AUTHORITIES

35 U.S.C. §102	20
35 U.S.C. §103	20
35 U.S.C. §§314	107, 108
35 U.S.C. §325	109
37 C.F.R. §1.11	6
37 C.F.R. §42.8	109, 110
37 C.F.R. §42.15	110
37 C.F.R. §42.100	17
37 C.F.R. §42.104	110

LIST OF EXHIBITS

Exhibit No.	Description
1001	U.S. Patent No. 11,554,005 (“the ’005 patent”)
1002	Excerpts from the prosecution history of the ’005 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 No. 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 No. 2015/0173782 A1 to Garrison et al. (“Garrison”)
1012	RESERVED
1013	RESERVED
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.
1017	U.S. Patent Application No. 16/117,519 (the “’519 application”)

Exhibit No.	Description
1018	U.S. Patent No. 7,775,501 B2 to Kees (“Kees”)
1019	U.S. Patent Publication No. 2016/022041 A1 to Garrison et al. (“Garrison ’741”)
1020	U.S. Patent No. 6,776,770 B2 to Treretola
1021	U.S. Patent Publication No. 2010/0042118 A1 to Garrison et al.
1022	U.S. Patent No. 5,938,645 to Gordon (“Gordon”)
1023	U.S. Patent Publication No. 2014/0296868 A1 to Garrison et al.
1024	WIPO Publication No. WO 2006/124307 A2 to Goff et al.

Petitioner Imperative Care, Inc. (“Petitioner”) requests *inter partes* review (“IPR”) of claims 1-15 (“the challenged claims”) of U.S. Patent No. 11,554,005 (“the ’005 patent,” Ex.1001), which is assigned to Inari Medical, Inc. (“Patent Owner” or “PO”).

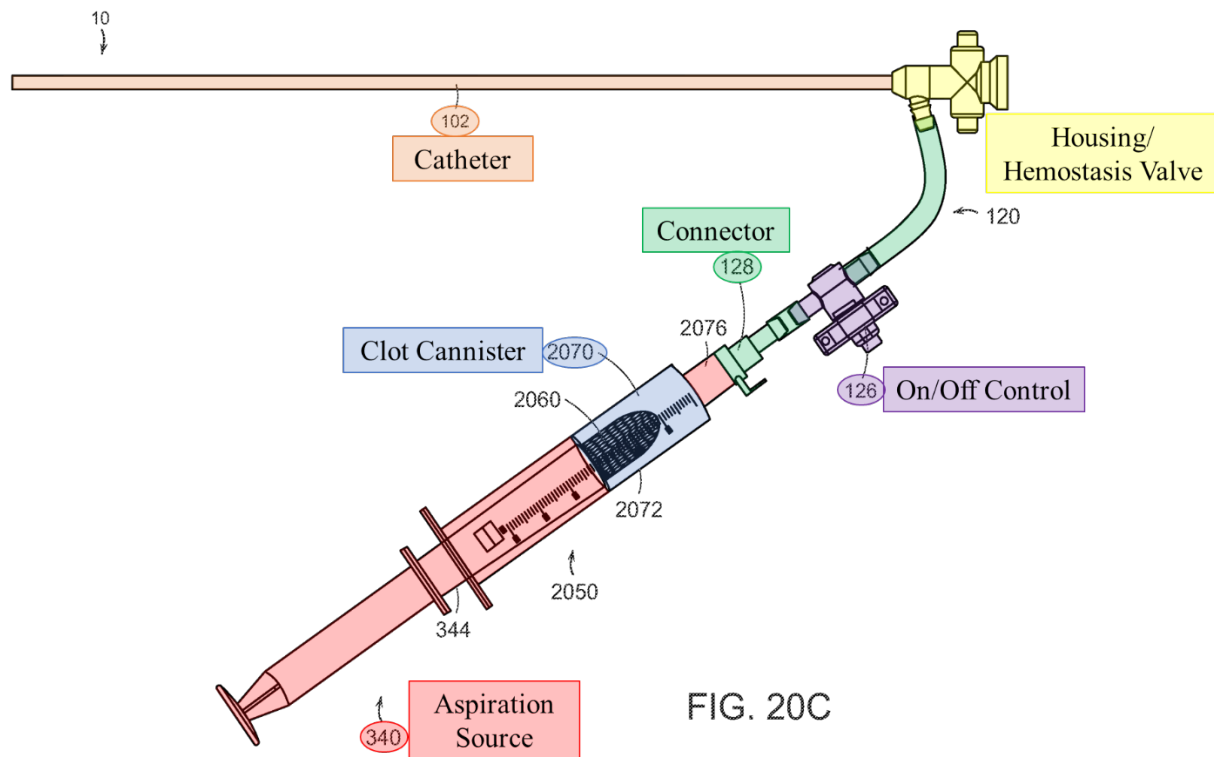
I. INTRODUCTION

The accumulation of unwanted material, such as blood clots, in a patient’s vasculature can cause serious conditions, including stroke and death. Over the last several decades, medical device companies have developed devices to remove such undesirable material from the vasculature, including catheter-based systems that aspirate (i.e., suction) the material from the blood vessel.

The ’005 patent claims such an aspiration system. However, the patent provides little description regarding what is new and nonobvious about the claimed system. The patent generically states, “there exists a need for improved systems and methods for embolic extraction” and argues that prior art systems were “highly complex,” “cause trauma to the treatment vessel,” and “may not completely capture and/or collect all of the clot material.” (Ex. 1001, 2:26-39.) However, the ’005 patent does not explain how the claimed system addresses these alleged shortcomings.

Instead, the claims merely list conventional aspiration components, including a catheter, an aspiration source, a connector placing the aspiration source in

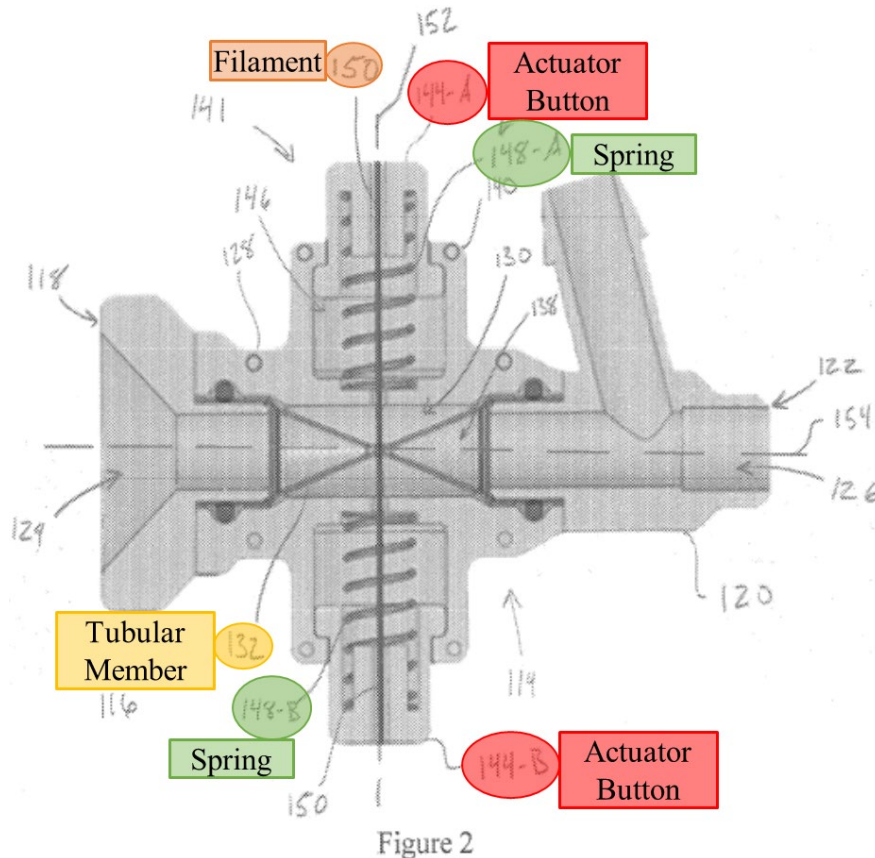
communication with a flow path through the device, an on-off control, and a clot cannister:



(*Id.*, Fig. 20C.) As demonstrated below, aspiration catheters having these conventional components were known and used before August 2018, the earliest claimed priority date of the '005 patent.

The challenged claims also require a specific hemostasis valve having a “tubular member” that can “slidably receive a second catheter,” “a constricting mechanism including a filament” that extends “around at least a portion of the tubular member,” “an actuator coupled to the filament,” and a “biasing system.” Importantly, the '005 patent specification does not describe or illustrate a hemostasis valve having these components. Any written description for the claimed valve must

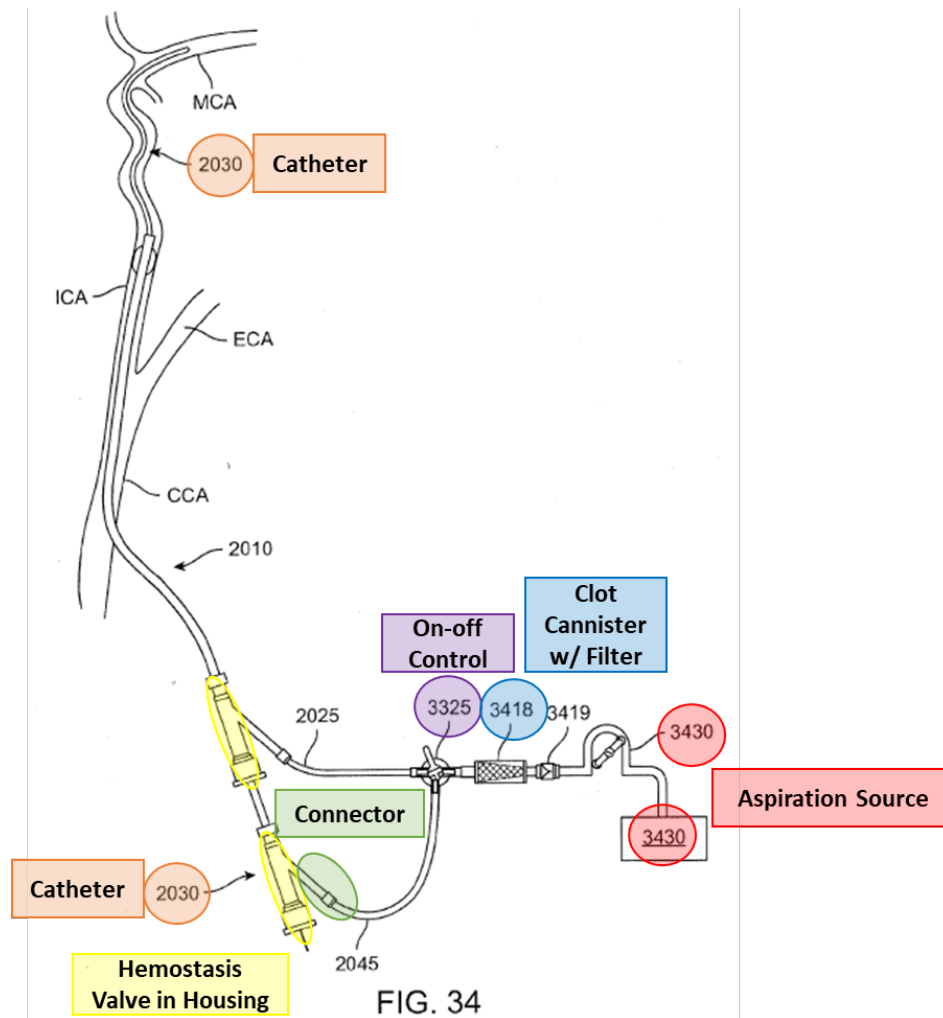
come from another patent application (the '519 application) purportedly incorporated by reference. (*Id.*, 5:49-54.)



(Ex. 1017, Fig. 2.) However, even if PO successfully incorporated the valve disclosure, tightening a loop around a collapsible tube in a valve to create a seal was well known in August 2018. Further, biasing the valve to the constricted configuration was also known and predictably used because the biasing system automatically closed the valve, minimized blood loss, and avoided excessive manual manipulation of the valve.

Garrison, a prior art patent application published in June 2015, describes an aspiration system for removing unwanted material from a patient's vasculature. As

illustrated below, Garrison’s aspiration system includes the components claimed in the ’005 patent, including a catheter [orange], aspiration source [red], connector [green] placing the aspiration source in communication with a flow path, on/off control [purple], and clot cannister [blue]:

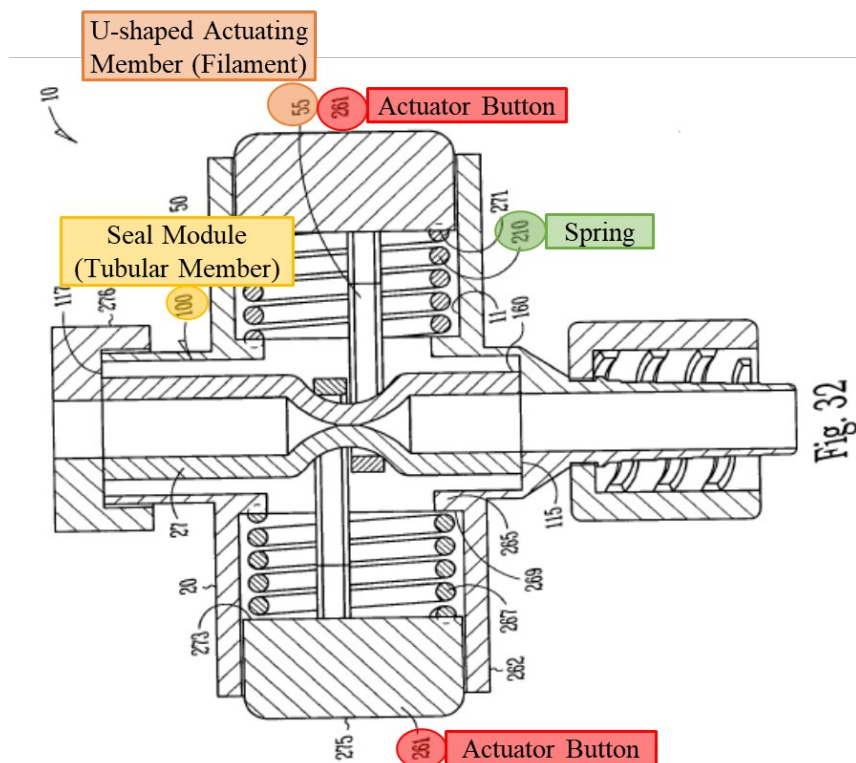


(Ex. 1011, Fig. 34.)

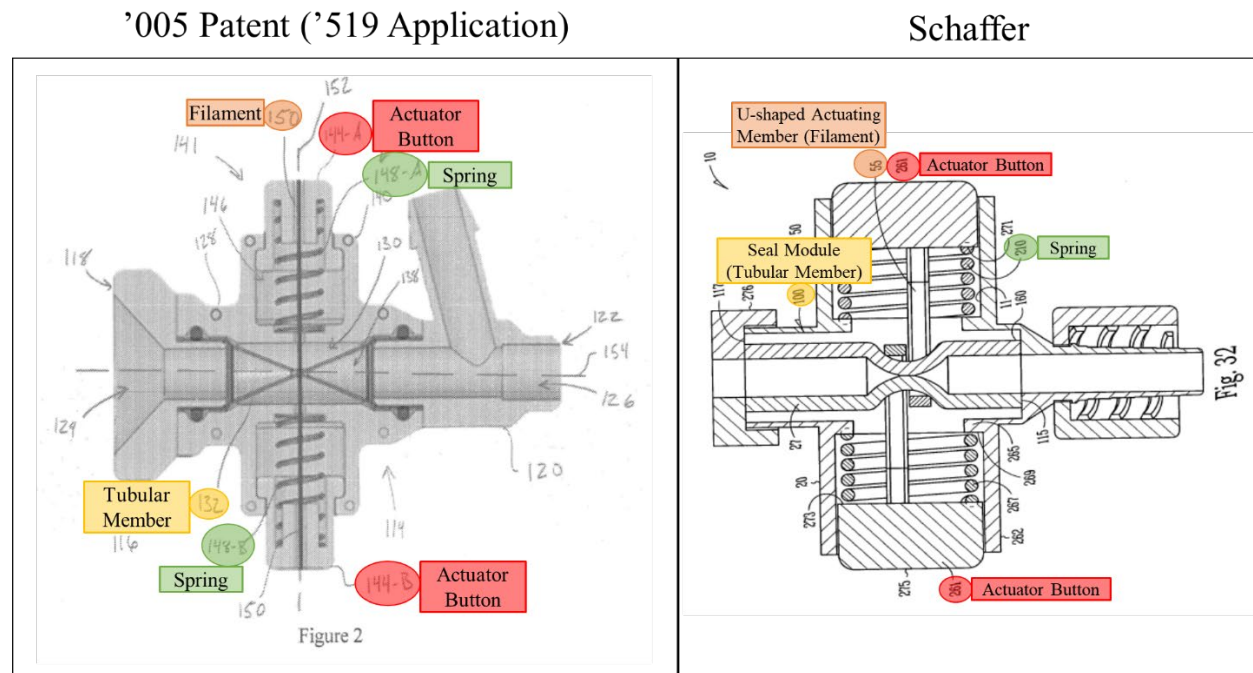
Garrison’s aspiration system can also include various hemostasis valves including, “an adjustable-opening valve” and a “rotating hemostasis valve.” (*Id.*, [0062].) Garrison explains that the hemostasis valves “allow for the introduction of

devices therein while preventing or minimizing blood loss via the internal lumen during the procedure.” (*Id.*) Garrison presumes a person of ordinary skill in the art (“POSITA”) would have been familiar with the available hemostasis valves and, therefore, does not describe their structures. However, other prior art references do.

For example, **Schaffer**, a patent application published in 2003, describes an adjustable-opening hemostasis valve for use during minimally invasive intravascular procedures. (Ex. 1005, [0002], [0008].) Schaffer was *not* before the Examiner during prosecution of the ’005 patent. Like the claimed valves, Schaffer’s valve includes a tubular member that can slidably receive a second catheter, a constricting mechanism including a filament, an actuator coupled to the filament, and a biasing system (e.g., spring):



(*Id.*, Fig. 32.)¹ As illustrated below, Schaffer's valve has the same components, in the same arrangement, as the valve claimed in the '005 patent (and described in the '519 application):

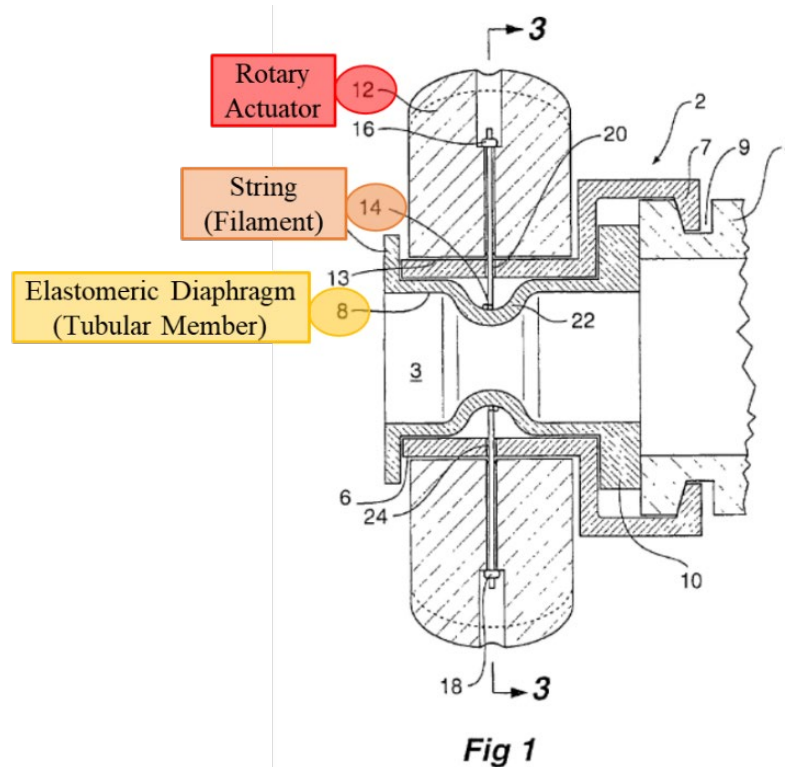


A POSITA would have found it obvious to combine Garrison's aspiration system with Schaffer's hemostasis valve for the reasons presented in this Petition.

Additionally, **Hartley**, a patent application published in 2003, describes a rotating hemostasis valve for use with catheters to prevent blood loss. (Ex. 1006, [0002]-[0003].) Hartley's valve also includes a tubular member that can slidably

¹ Petitioner uses the versions of Schaffer's drawings submitted during prosecution on June 18, 2003 (Ex. 1008) because they are clearer. The drawings became publicly available when Schaffer published on December 4, 2003. 37 C.F.R. §1.11.

receive a second catheter, a constricting mechanism including a filament, and an actuator coupled to the filament:



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

During prosecution of the '005 patent, the Examiner found that Hartley disclosed every hemostasis-valve limitation in the challenged claims except a movable actuator coupled to a spring. (Ex. 1002, 214-215.) However, as shown above, Schaffer discloses movable actuator buttons coupled to springs and satisfies this limitation. If Schaffer does not disclose a “filament,” Schaffer combined with Hartley does.

Likewise, **Eller**, a patent published in 2015, describes a rotating hemostasis valve having a filament that constricts a tubular member upon rotation of an actuator:

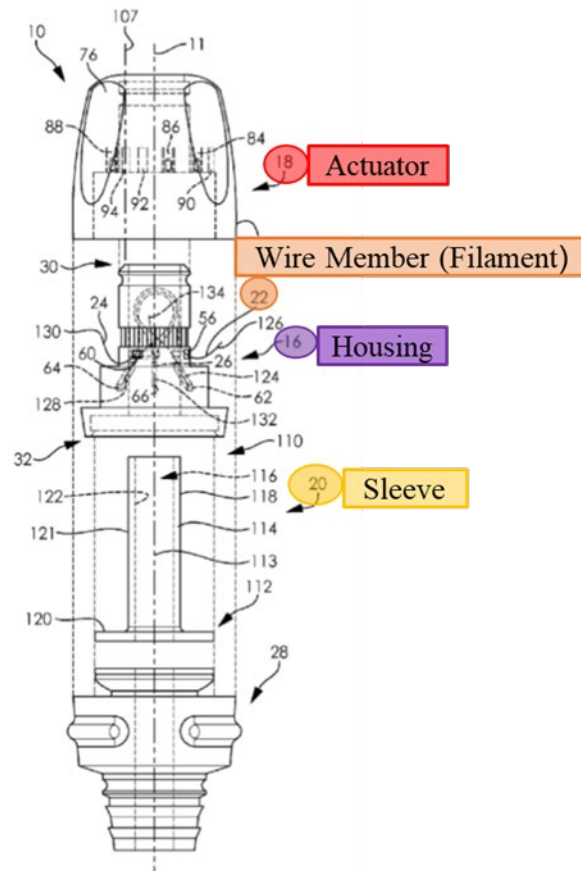


FIG. 2

(Ex. 1007, 5:1-12, Fig. 2.) Eller's valve also includes an optional biasing system, such as a torsion spring, that biases the valve toward the sealed state. (*Id.*, 19:22-30.) As explained herein, a POSITA would have found it obvious to combine Eller's torsion spring with Hartley's rotatable hemostasis valve and, therefore the combination of Garrison with Hartley and Eller also renders the challenged claims obvious. Eller's publication was listed in an Invention Disclosure Statement ("IDS") during prosecution but was not discussed or applied by the Examiner. Thus, the Examiner never addressed the combination of Eller's torsion spring with Hartley's valve.

As demonstrated herein, the challenged claims merely combine known aspiration systems and hemostasis valves according to their known functions to yield predictable results. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007). Petitioner has demonstrated a reasonable likelihood that at least one claim of the ’005 patent is unpatentable. Accordingly, Petitioner requests that the Board institute this IPR to reconsider the patentability of the ’005 patent.

II. THE ’005 PATENT

A. Overview

The ’005 patent describes an aspiration system for intravascular treatment of clot material. (Ex. 1001, 4:10-4:26.) The aspiration system includes a catheter 102 “comprising an elongated shaft defining a lumen 104,” and a “valve 106” with a “lumen 109 extending therethrough.” (*Id.*, 5:18-5:43.) The valve “is configured to maintain hemostasis during a clot removal procedure by preventing fluid flow in the proximal direction through the valve 106” when other components are inserted, such as “interventional devices” or “other aspiration catheters.” (*Id.*)

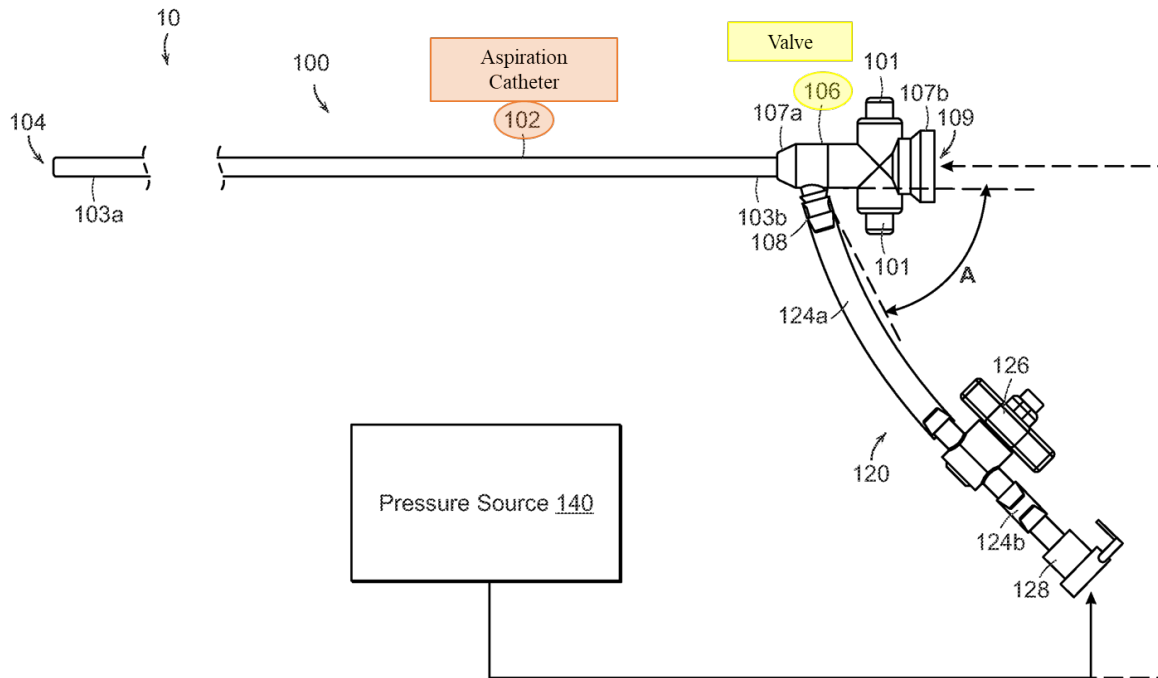


FIG. 1

The tubing subsystem “fluidly couples the catheter subsystem 100 to the pressure source 140.” (*Id.*, 5:66-67.) The tubing subsystem can include “one or more tubing sections 124,” at least one “fluid control device 126” such a stopcock, and at least one “connector 128 for fluidly coupling the tubing subsystem 120 to the pressure source 140 and/or other suitable components.” (*Id.*, 5:66-6:6.)

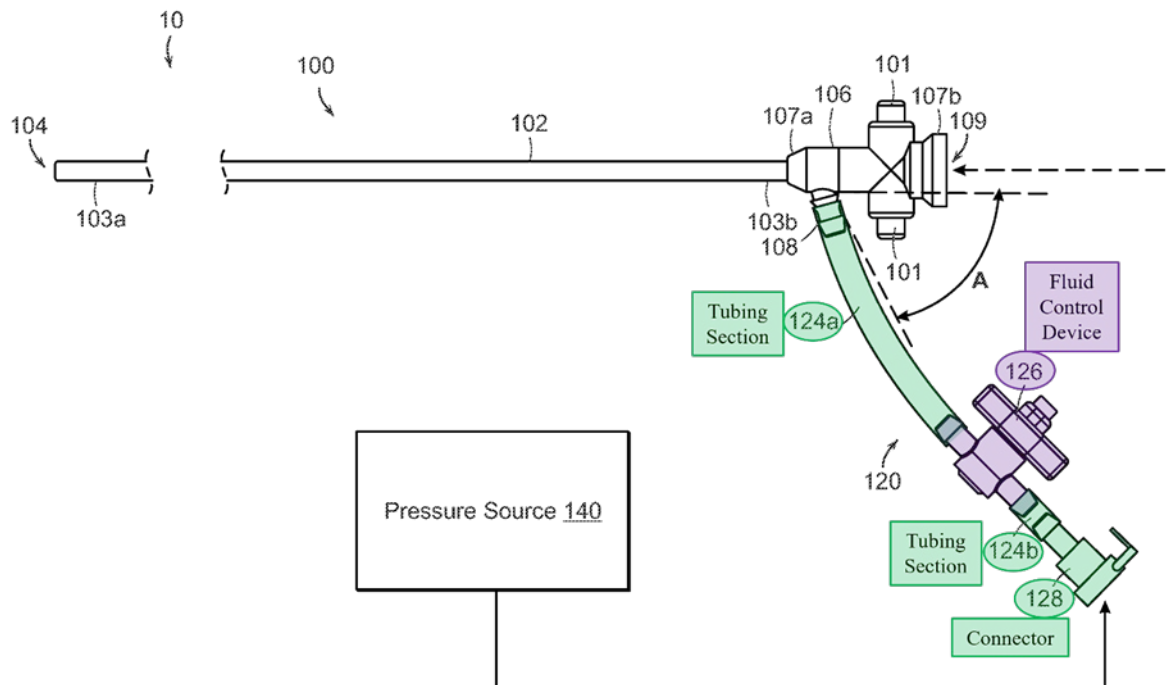
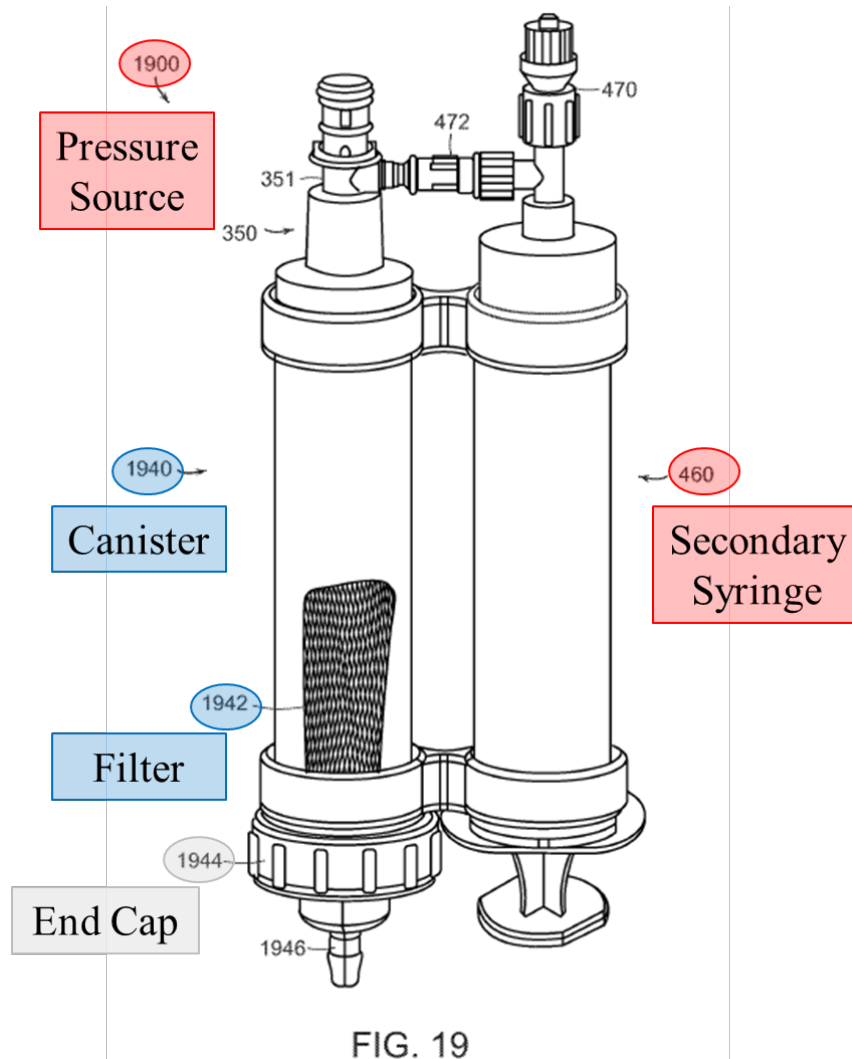


FIG. 1

The '005 patent also describes embodiments and modifications of the aspiration system. For example, the patent describes embodiments having a “pressure source 1900” with a “secondary syringe 460” and a “canister 1940.” (*Id.*, 31:9-19, Fig. 19.) The “canister 1940 further includes a filter 1942.” (*Id.*, 31:28-29.)

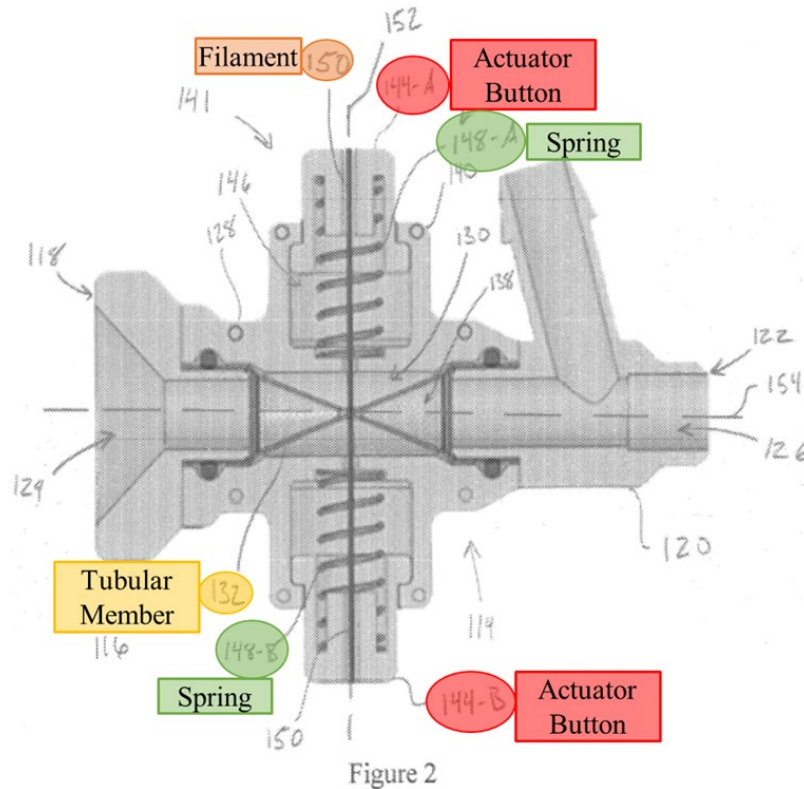


(*Id.*, Fig. 19.)

The '005 patent does not describe the structure of any hemostasis valve. However, the '005 patent purports to incorporate by reference “U.S. patent application Ser. No. 16/117,519” (the “’519 application” (Ex. 1017)). (*Id.*, 5:49-53.)² The '519 application describes a valve having an “elongate member 132” that

² Petitioner reserves its right to challenge written description and the incorporation by reference in future proceedings.

extends through the valve. (Ex. 1017, [0039].) 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.*, [0039], 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.*, [0042-0043], 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.*) 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.*, [0048].)

The valve also includes a “bias feature,” such as a spring, that biases the actuator toward the open or closed configuration. (*Id.*, [0045].) In Figure 2 (above), the springs bias the valve toward the closed configuration. (*Id.*) 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.*, [0050], Fig. 3.)

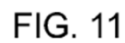
B. Prosecution History

The Examiner issued a single Office Action rejecting original claim 1 as anticipated by U.S. 2016/0220741 (“Garrison ’741,” Ex. 1019).³ (Ex. 1002, 209-217.) Original claim 1 resembled final claim 1 but excluded the hemostasis-valve limitations reciting the “tubular member,” “constricting mechanism,” and “biasing system.” (*Compare* Ex. 1002, 406 *with* Ex. 1001, claim 1.) The Examiner found that Garrison ’741 disclosed a vacuum aspiration system (100) having a hemostasis valve (234) in a housing (220), a connector (240) for connecting to a source of aspiration, and first (320) and second (400) catheters:

³ Garrison (relied on herein) and Garrison ’741 both describe aspiration systems but have different specifications.



(*Id.*, 211-212; Ex. 1019, Fig. 1.) The Examiner also found that Garrison '741 disclosed an on-off control (242) and clot cannister:



(Ex. 1002, 211-212; Ex. 1019, Fig. 11.)

The Examiner found original claims 2 and 11 allowable because they included the additional hemostasis-valve limitations (e.g., “constricting mechanism”) now in final claims 1 and 10. (Ex. 1002, 212-215.) The Examiner determined the closest prior art of record was Wong (Ex. 1010), Kees (Ex. 1018), and Hartley (Ex. 1006). *Id.* The Examiner found that Hartley disclosed all the hemostasis-valve limitations except an “actuator having a first member movable coupled to the support and the first spring configured to move the first member.” (*Id.*) The Examiner also found that Wong and Kees did not disclose a “filament.” (*Id.*) Further, the Examiner concluded that while “Hartley discloses a filament, a person skilled in the art would recognize that it would [sic] improper to add the filament of Hartley to either device of Wong or Kees for this would conflict with the operation of the devices.” (*Id.*) The Examiner did not further explain this position.

PO did not dispute the Examiner’s findings. Rather, PO cancelled rejected claim 1 and rewrote claim 2 (final claim 1) in independent form to include the hemostasis-valve limitations. (*Id.*, 191-199.)

C. Earliest Possible Priority Date

The ’005 patent claims priority to two provisional applications 62/718,248 and 62/718,269, filed August 13, 2018, which is the earliest possible priority date for the ’005 patent. (Ex. 1001.) Petitioner applies this earliest priority date in this

Petition; however, Petitioner reserves its right to challenge the priority date in subsequent proceedings.

III. LEVEL OF ORDINARY SKILL

A POSITA in August 2018 would have had an undergraduate degree in mechanical engineering or a related engineering discipline and 2-4 years of catheter design 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); *see Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005). However, “the specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess [and i]n such cases, the inventor's lexicography governs.” *Id.* at 1316.

The challenged claims require a hemostasis valve having a “filament.” A POSITA would have understood the term “filament” to mean at least “one or more threads, lines, cords, ropes, ribbons, flat wires, sheets, or tapes” based on the intrinsic record. (Ex. 1003, ¶¶54-60.)

Claim construction generally begins with the claim language. *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). Here, however, the

claims provide little information regarding the “filament.” For example, claim 1 describes the “filament” as having “a first portion extending around at least a portion of the tubular member” and ends that extend in different directions, wherein the filament is moveable between a first and second position. Claim 10 includes similar limitations. This claim language does not provide a POSITA with guidance on the “filament” structure.

Further, the '005 patent does not describe a hemostasis valve having a filament. In fact, the word “filament” does not appear in the '005 patent outside the challenged claims. If this limitation has support, it must be incorporated by reference from the '519 application. The '519 application identifies examples of “filaments” that expand the meaning of “filament” beyond the plain and ordinary meaning. The '519 application states, “the filament 150 can comprise one or several threads, lines, cords, rope, ribbon, flat wire, sheet, or tape.” (Ex. 1017, [0047].) 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.*) 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.*) Additionally, the specification

explains that “the filament 150 can comprise multiple filaments, and specifically, as shown in Figures 7 through 9, the filament 150 can comprise a first filament 150-A and a second filament 150-B.” (*Id.*, [0065].)

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 ’519 application does not describe the “filament” as “thin” or “flexible.” Further, PO’s definition would exclude specific “filaments” identified in the ’519 application, 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, ¶60.)

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

V. STATEMENT OF RELIEF REQUESTED

A. IPR Grounds

Petitioner asserts the following grounds of unpatentability:

Ground	Reference(s)	35 U.S.C.	Challenged Claims
1	Garrison + Schaffer	§103	1-12, 14-15
2	Garrison + Schaffer + Hartley	§103	1-15
3	Garrison + Schaffer + Eller	§103	1-15
4	Garrison + Hartley + Eller	§103	1-3, 5-6, 9-15

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 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 '005 patent, e.g., devices for aspirating unwanted material from a patient including hemostasis valves. (Ex. 1003, ¶26; *see also* Ex. 1002, 211-215.) The references are also pertinent to the problem

the inventor was focused on, e.g., removing unwanted material from a patient’s blood vessel and sealing the catheter with a hemostasis valve during such procedures. (Ex. 1003, ¶26; *see also* Ex. 1001, 2:38-39.) 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 1-3: GARRISON COMBINED WITH SCHAFFER AND
OPTIONALLY HARTLEY OR ELLER**

A. Independent Claim 1

Claim 1 is rendered obvious by Garrison combined with Schaffer and optionally Hartley or Eller. (Ex. 1003, ¶¶67-147.)

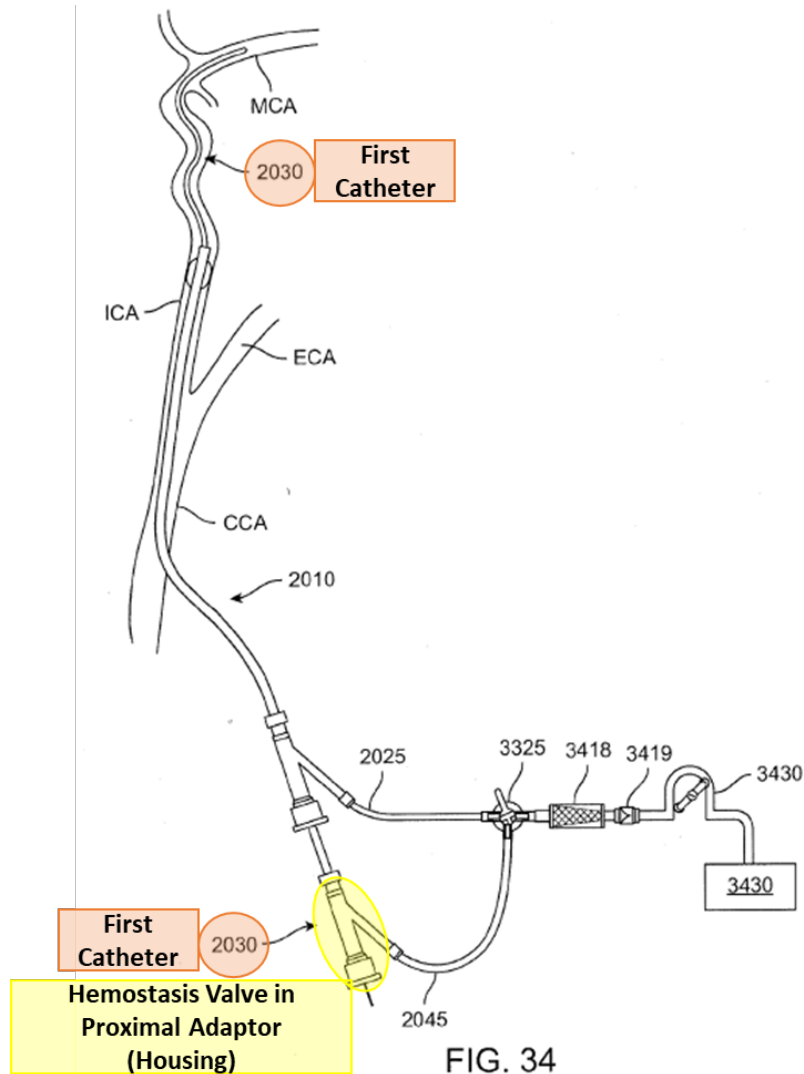
1. Preamble

The preamble recites a “vacuum aspiration system.” If the preamble is limiting, Garrison discloses this limitation. (*Id.*, ¶¶68-69.) Garrison discloses a vacuum aspiration system “to provide aspiration ... for the purpose of facilitating removal of the occlusion as well as minimizing distal emboli.” (Ex. 1011, [0007]; *see also id.*, [0029] (“FIGS. 32-35 showing examples of systems for treating an artery with active aspiration”); [0048] (similar).) Garrison’s aspiration source (e.g., aspiration pump or syringe) creates a vacuum that aspirates (i.e., suctions) blood clots from the patient’s vessel. (Ex. 1003, ¶69.) Thus, Garrison’s system is a “vacuum aspiration system.” (*Id.*)

2. Housing

Claim 1 recites “a housing” and “a hemostasis valve in the housing.” Garrison discloses these limitations. (Ex. 1003, ¶¶70-76.)

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

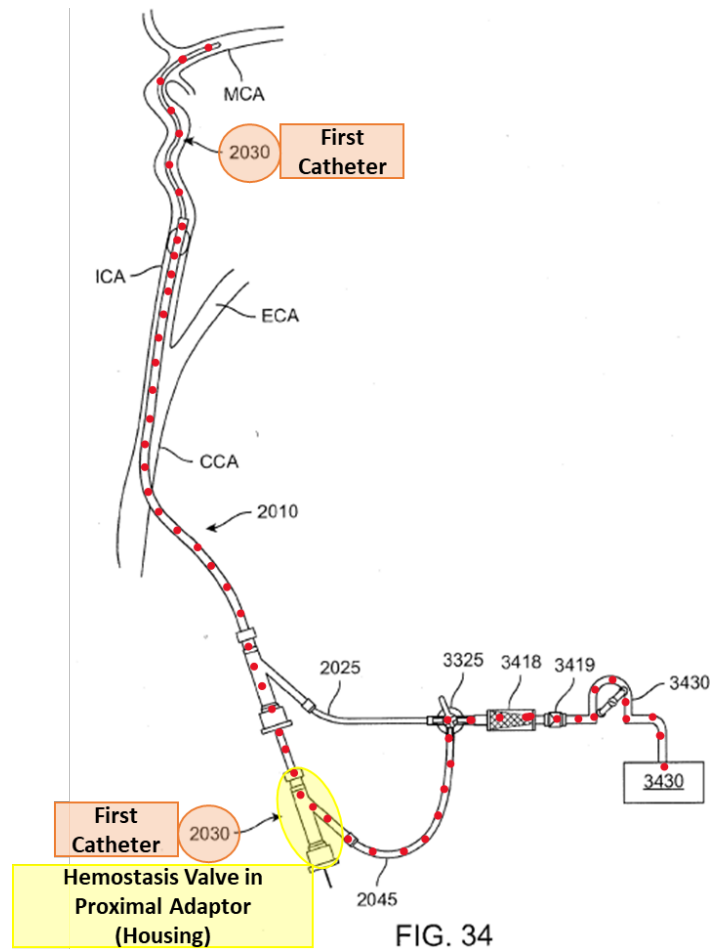


(Ex. 1011, [0098], Fig. 34.) Thus, the proximal hub/adaptor, inclusive of any attached or integral valve, is a “housing.” (Ex. 1003, ¶71.) This understanding is consistent with the prosecution history, where the Examiner found that a similar hub/adaptor in Garrison ’714 satisfied the housing limitation. (Ex. 1002, 211-212.)

3. Flow Path

Claim 1 recites a “flow path extending through the housing.” Garrison discloses this limitation. (Ex. 1003, ¶¶77-78.)

Garrison discloses that “the catheter 2030 may be connected to sources of passive or active aspiration via flow lines ... 2045 (Fig. 1) on the devices.” (Ex. 1011, [0130]; *see also id.*, [0059] (describing flow path).) The flow line 2045 permits fluid to flow from the catheter 2030 through the system to the aspiration source/cannister. (*Id.*, [0133].) Thus, a “flow path” extends through the housing, as illustrated by the dashed red line below:

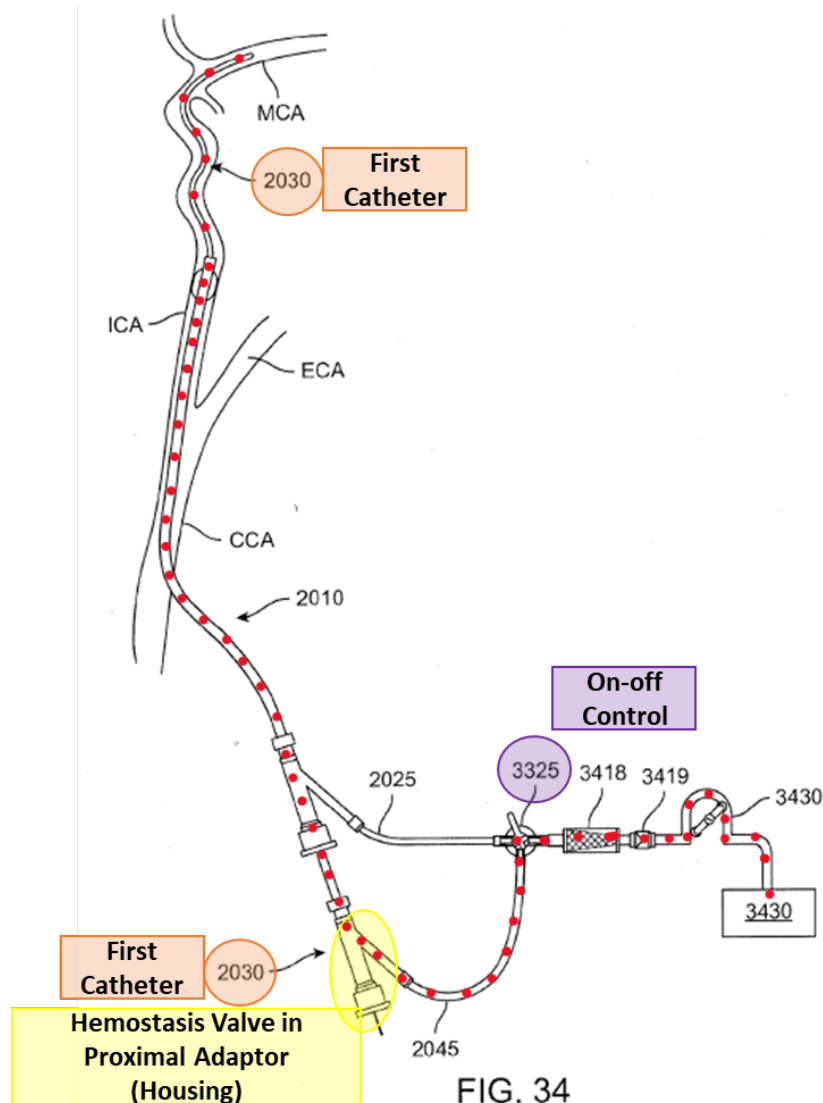


(*Id.*, [0059], Fig. 34; *see also id.*, (“The flow line 2025 has an internal lumen that communicates with an internal lumen of the arterial access device 2010 for shunting blood from the arterial access device.”); Ex. 1003, ¶78.)

4. On-off Control

Claim 1 recites “an on-off control in the flow path.” Garrison discloses this limitation. (Ex. 1003, ¶¶79-80.)

Garrison’s vacuum aspiration system includes a “valve 3325” in the flow path:



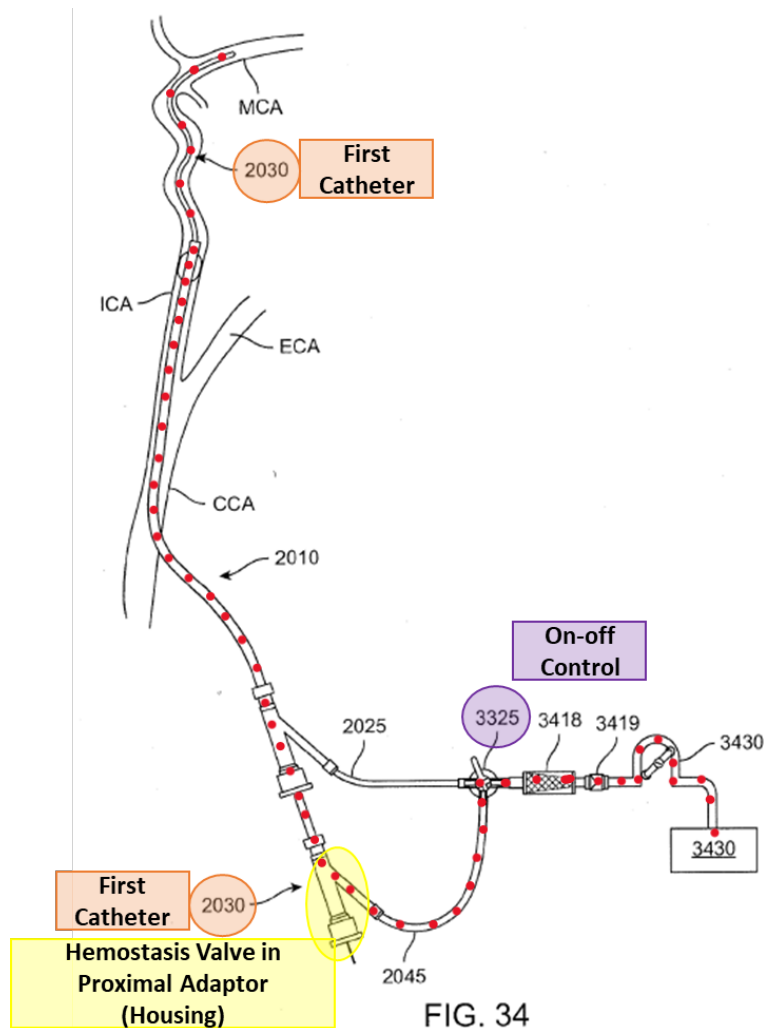
(Ex. 1011, [0132], Fig. 34.) The “valve 3325 controls which device is connected to the aspiration source 3430.” (*Id.*) “The valve may be a 3-way or 4-way stopcock” and “enable one device, the other device, both devices, or neither device to be connected to the aspiration source at any given time.” (*Id.*) Thus, the valve 3325 is an on-off control. (Ex. 1003, ¶80.)

5. First Catheter

Claim 1 recites “a first catheter in fluid communication with the flow path.”

Garrison discloses this limitation. (Ex. 1003, ¶¶81-82.)

Garrison discloses a “catheter 2030 [that] may be connected to sources of passive or active aspiration via flow lines ... 2045 (Fig. 1) on the devices.” (Ex. 1011, [0130].) The flow line 2045 permits fluid to flow from the catheter 2030 through the system to the aspiration source/cannister. (*Id.*, [0133].) Thus, catheter 2030 (i.e., first catheter) is in fluid communication with the “flow path,” as illustrated by the dashed red line:



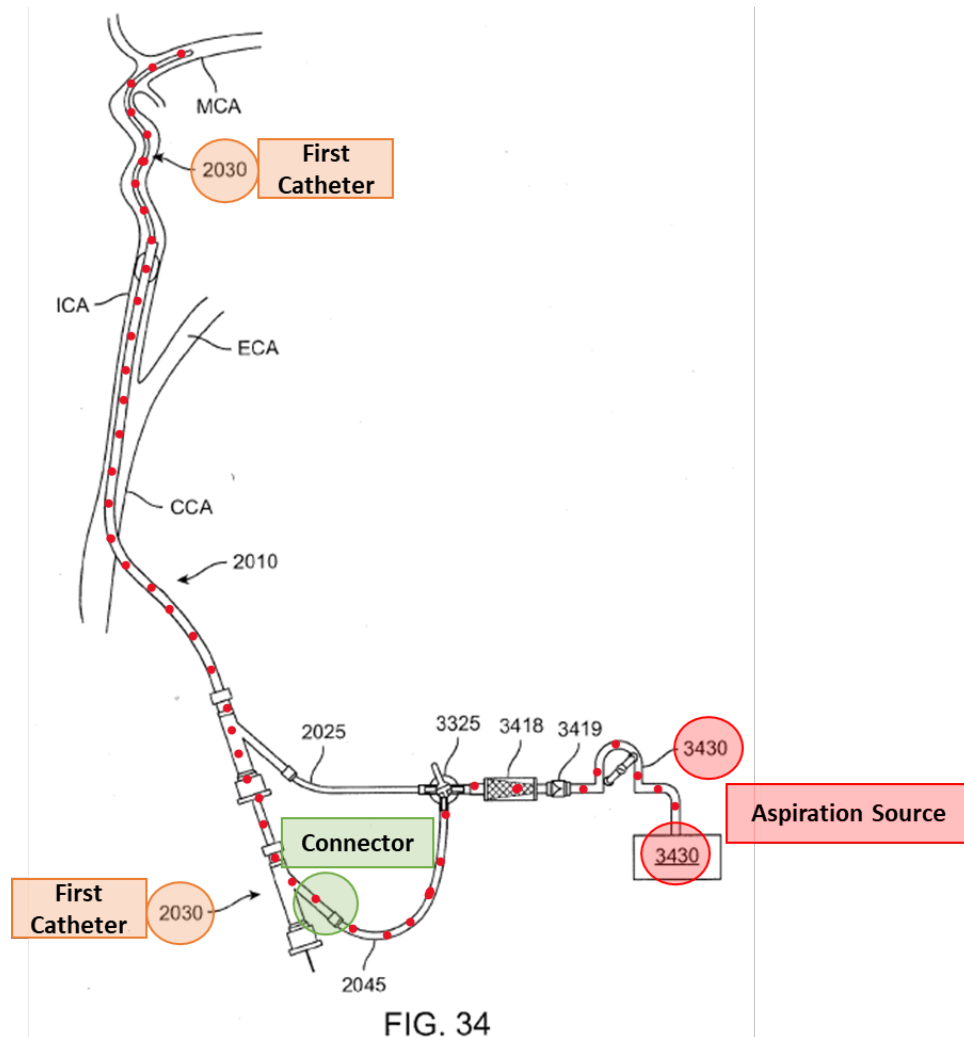
(*Id.*, [0059], Fig. 34; Ex. 1003, ¶82.)

6. Connector

Claim 1 recites “a connector configured to place a source of aspiration in communication with the flow path.” Garrison discloses this limitation in multiple ways. (Ex. 1003, ¶¶83-87.)

First, Garrison’s “catheter 2030 may be connected to sources of passive or active aspiration via flow line[] ... 2045.” (Ex. 1011, [0130].) As shown below, the

flow line 2045 is connected to the catheter 2030 through the Y-arm of the hub/adaptor:



(*Id.*, Fig. 34.) The Y-arm is a connector that places the aspiration source 3430 in communication with the flow path. In fact, Garrison refers to similar Y-arms as a “connector”:

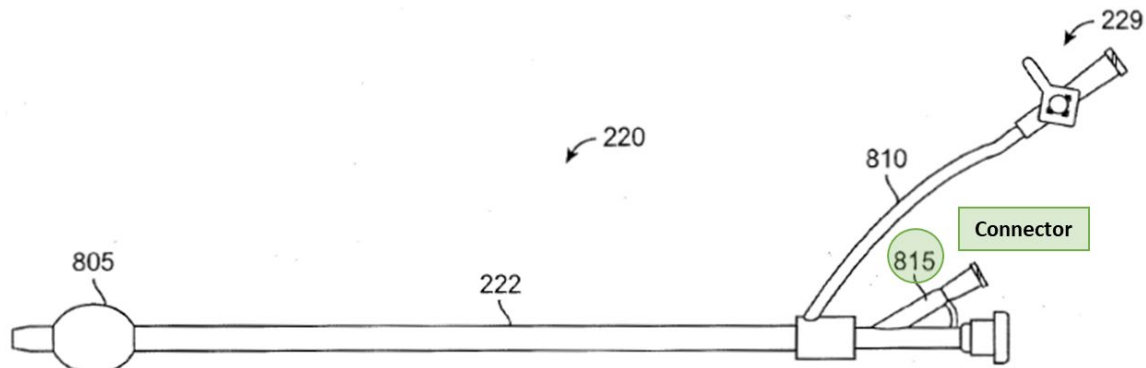


FIG. 9

(Ex. 1011, [0067], Fig. 9.)

Second, Garrison's flow line 2045 is a connector configured to place the aspiration source 3430 in communication with the flow path. (Ex. 1003, ¶85.) As shown above, the flow line connects the pressure source to the catheter and permits fluid to flow between them. (*Id.*)

Third, Garrison explains that several components are optionally connected to the flow line 2045, including the aspiration source 3430, the filter 3418, and/or the check valve 3419. (Ex. 1011, [0131]-[0132], Figs. 33-34.) A POSITA would have understood a connector is required to join the component to the flow line. (Ex. 1003, ¶86.) In August 2018, several standard connectors were common in the field to connect flow lines to medical components, including Luer connectors and slip-fit connectors. (*Id.*; *see also* Ex. 1005 [0047] (describing Luer and slip-fit connectors); Ex. 1007, 16:65-17:4, Fig. 7 (describing type of slip fit connector); Ex. 1011, [0062], [0065], Fig. 11 (illustrating stopcock with standard female connector); Ex. 1020,

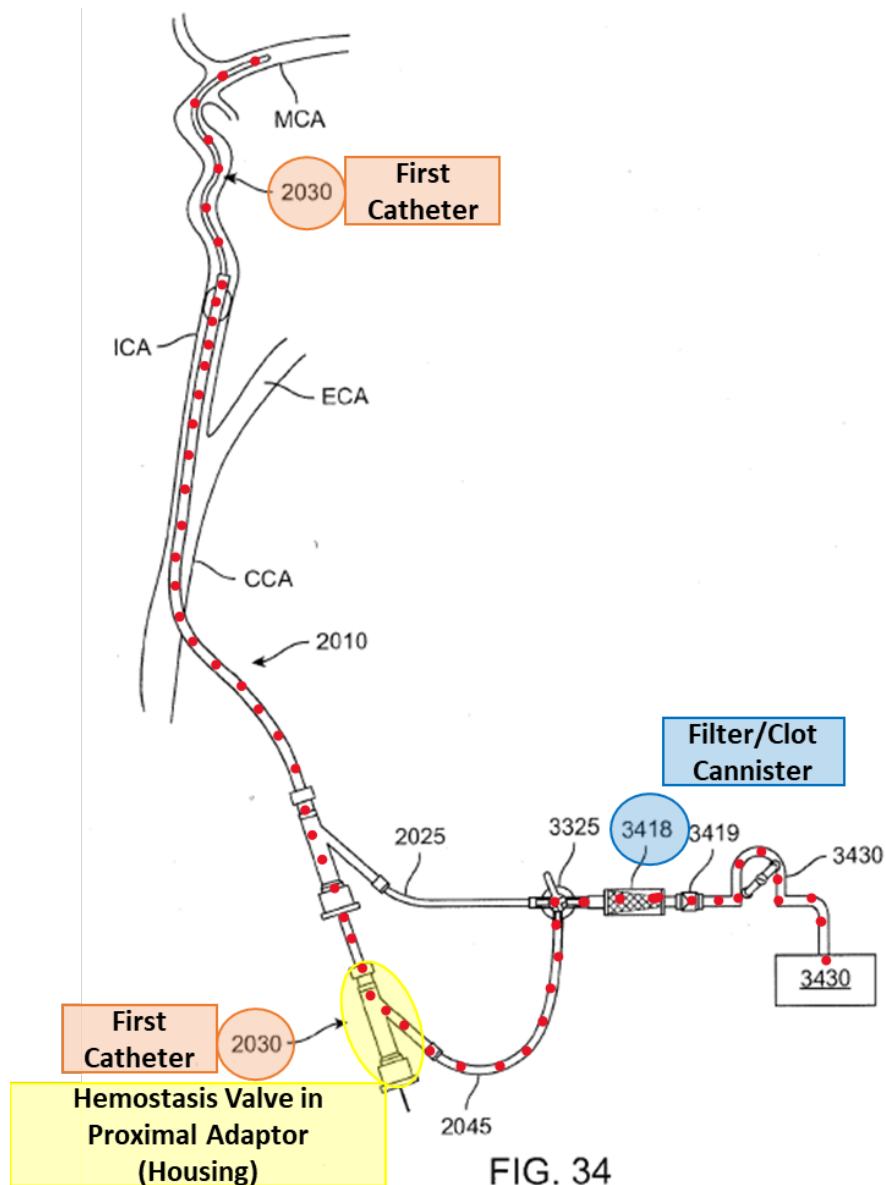
4:29-40 (describing Luer-type connectors); Ex. 1001, 7:54-58 (describing a “standard luer connector”), 33:32 (describing a “standard Luer or large bore connector”).)

For example, Garrison explains that proximal hub 2065, described above, includes “a female Luer configuration for attachment of a syringe during prep and attachment of other components.” (Ex. 1011, [0098].) Garrison also incorporates by reference patents and publications that describe attaching catheter components using “a conventional luer fitting” or improvements to such fittings. (Ex. 1021, [0130]; *see also* Ex. 1022, 8:45, 8:63 (describing an “auxiliary Luer port”); Ex. 1023, [0056]-[0059] (describing improvements to the “standardized ... locking Luer taper design”). Thus, the connectors between Garrison’s components and flow line 2045 place the aspiration source in communication with the flow path. (Ex. 1003, ¶87.)

7. Clot Cannister

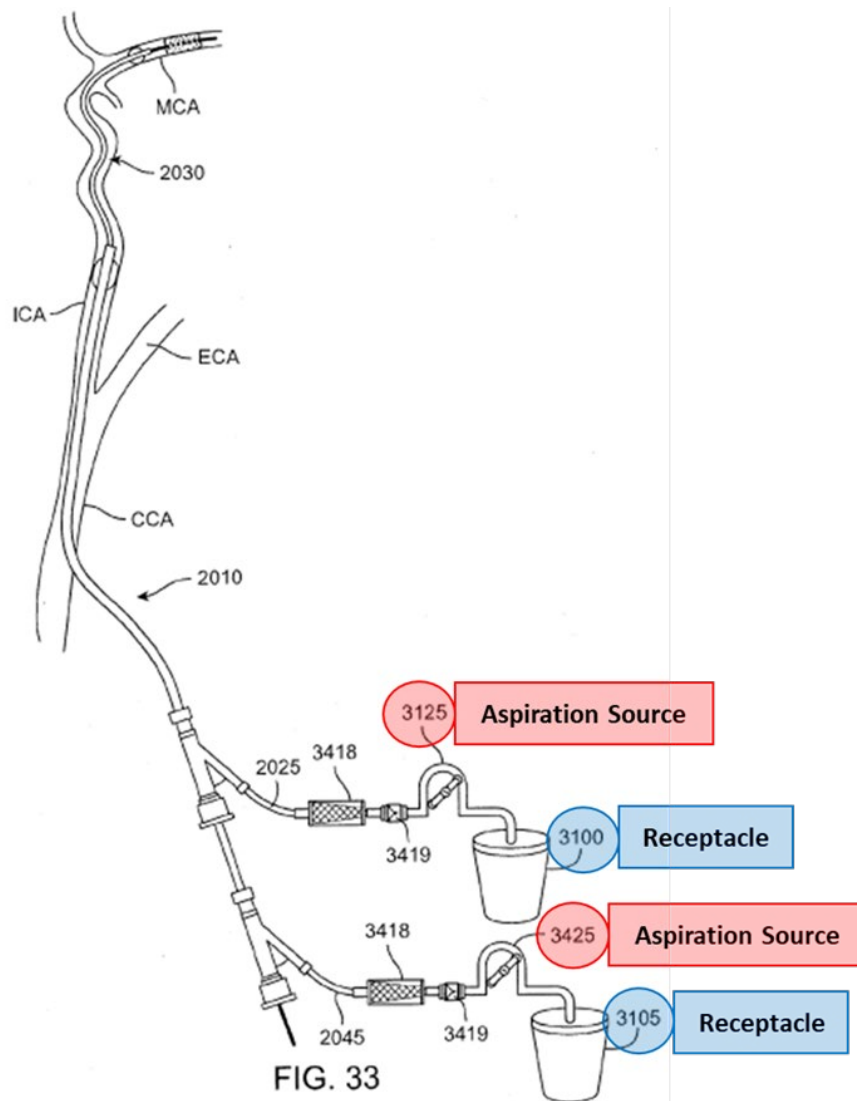
Claim 1 recites “a clot cannister fluidly coupled to the flow path.” Garrison discloses this limitation in two ways. (Ex. 1003, ¶¶88-90.)

First, Garrison discloses that a “filter 3418 ... may also be coupled with flow line 2045”:

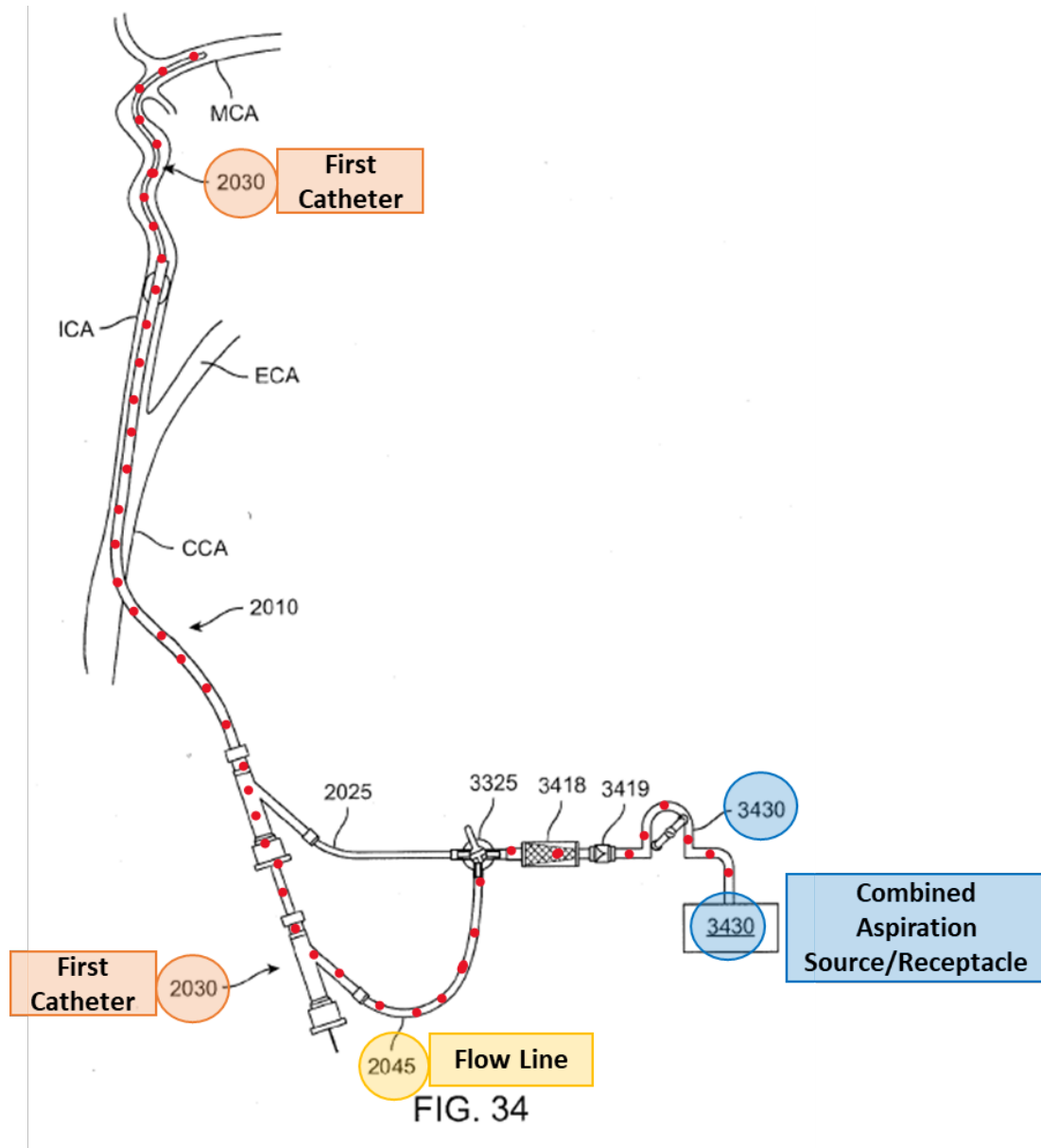


(Ex. 1011, [0131], Fig. 34.) The filter container captures clot material and separates it from the aspirated blood. (*See id.* at [0142] (“If desired, the blood could be filtered and subsequently returned to the patient.”); Ex. 1003, ¶89.) Similar filters were commonly used with prior-art aspiration systems to separate clot material from the aspirated blood. (*See* Ex. 1024, [0025], Fig. 2; Ex. 1003, ¶89.) Thus, Garrison’s filter 3418 is a “clot cannister fluidly coupled to the flow path.”

Second, Garrison discloses that the aspiration system may include receptacle(s) 3100/3105 to receive the aspirated blood and clot material. (Ex. 1011, [0131], Fig. 33.)



The receptacle 3100/3105 and source of aspiration “may be separate,” as in Figure 33, or “may be combined into a single device such as a syringe,” as in Figure 34. (*Id.*)

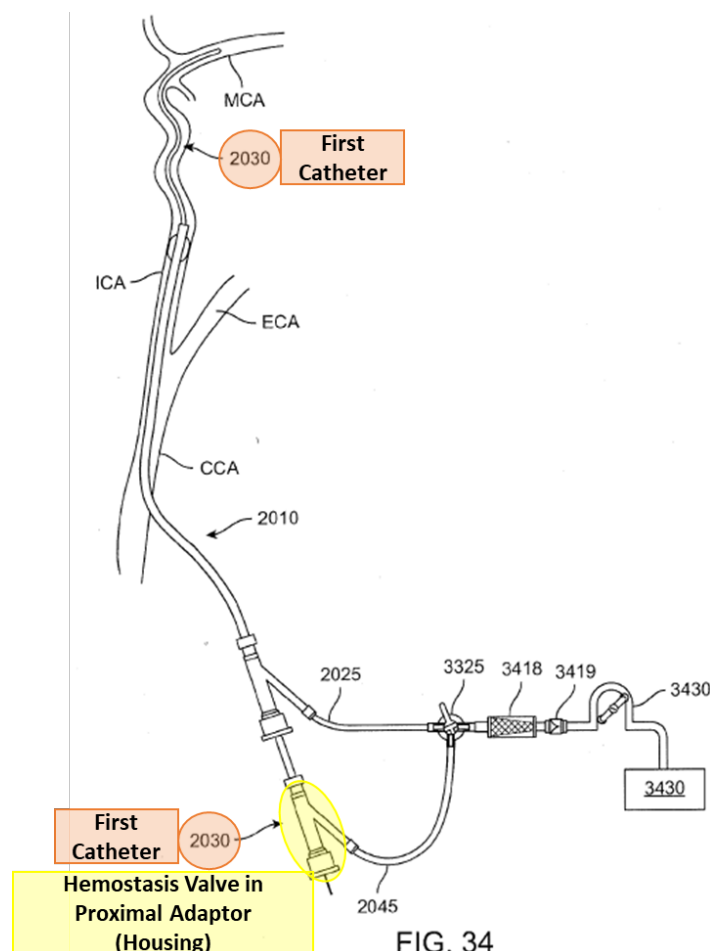


Any clot material that passes through the filter will flow to the receptacle. (Ex. 1003, ¶90.) Thus, the receptacle is also a “clot cannister fluidly coupled to the flow path.” (*Id.*)

8. Hemostasis Valve

Claim 1 recites “a hemostasis valve in the housing configured to receive a second catheter and direct the second catheter through the first catheter.” Claim 1 then recites several hemostasis valve features, including a “tubular member,” “constricting mechanism,” and “biasing system.” Garrison combined with Schaeffer and optionally Hartley or Eller renders these hemostasis-valve limitations obvious. (*Id.*, ¶¶91-147.)

As explained above, Garrison’s catheter 2030 (i.e., first catheter) includes a housing containing a hemostasis valve:



(Ex. 1011, [0098], Fig. 34 (emphasis added); *supra* §VI.A.2.) Garrison’s hemostasis valve allows “*introduction of devices such as a microcatheter*, guide wire, or thrombectomy device while preventing or minimizing blood loss during the procedure.” (Ex. 1011, [0098] (emphasis added).) Garrison further discloses that a “second, smaller diameter catheter may be inserted through the first catheter” (*Id.*) Thus, Garrison’s hemostasis valve in the housing is configured to receive a second catheter and direct the second catheter through the first catheter. (Ex. 1003, ¶92.)

Garrison also explains that catheter 2030 can include different types of hemostasis valves, including, for example, “an adjustable-opening valve such as a Tuohy-Borst or rotating hemostasis valve (RHV).” (Ex. 1011, [0098].) However, Garrison does not expressly describe the structure of the hemostasis valves, instead presuming that POSITAs would have been familiar with such valves.

Schaffer discloses an adjustable-opening “fluid stasis valve” for use with catheters to prevent the flow of blood through the valve during medical procedures. (Ex. 1005, [0002], [0046], [0055].) A POSITA would have been motivated, and found it obvious, to use Schaffer’s valve (with or without Hartley’s or Eller’s filaments) as the hemostasis valve on Garrison’s catheters for several reasons. (Ex. 1003, ¶¶94-101.)

First, Garrison teaches that the hemostasis valves used with its system “can be ... an adjustable-opening valve.” (Ex. 1011, [0062], [0065], [0098].) Schaffer discloses an adjustable-opening valve and, therefore, a POSITA would have been motivated to combine, and reasonably expected success in combining, Schaffer’s valve with Garrison. (Ex. 1003, ¶95.)

Second, Schaffer discloses that its hemostasis valve is “for use with catheters” and “blocks the flow of gas or fluid completely and immediately with or without an instrument in place within the gas/fluid path.” (Ex. 1005, [0002], [0008], [0047], [0049].) Schaffer further discloses that a range of instruments can be used within the valve, such as “a catheter, guidewire, needle, or fiber.” (*Id.*, [0056], [0074].) Thus, Schaffer’s valve performs the stated function of Garrison’s “hemostasis valve” — to “allow introduction of devices ... while preventing or minimizing blood loss during the procedure.” (Ex. 1011, [0098].) For this added reason, a POSITA would have been motivated to combine, and reasonably expected success in combining, Schaffer’s valve with Garrison. (Ex. 1003, ¶96.)

Third, POSITAs would have recognized that Schaffer’s hemostasis valve could simplify operation of Garrison’s system. (Ex. 1003, ¶97.) For example, Schaffer’s springs bias the valve toward the closed position, eliminating the need to manually seal the valve during procedures as occurred with some prior-art valves. (*Id.*; *infra* §VI.A.8.c.)

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 catheter’s proximal hub or forming it integrally with the hub) to yield the predictable result of minimizing blood loss through the catheter. *See KSR*, 550 U.S. at 416; (Ex. 1003, ¶98.)

Fifth, POSITA’s in August 2018 had a finite number of predictable hemostasis valves to choose, including an “adjustable-opening valve” or RHV. (Ex. 1003, ¶99.) A POSITA would have found it obvious to try any of these hemostasis valves with Garrison’s catheter 2030. (*Id.*); *KSR*, 550 U.S. at 417. The known valves, like Schaffer’s adjustable-opening hemostasis valve, were simple mechanical structures that operate in a predictable way. (Ex. 1003, ¶99.) For this additional reason, POSITAs would have reasonably expected success in combining Schaffer’s valve with Garrison. (*Id.*)

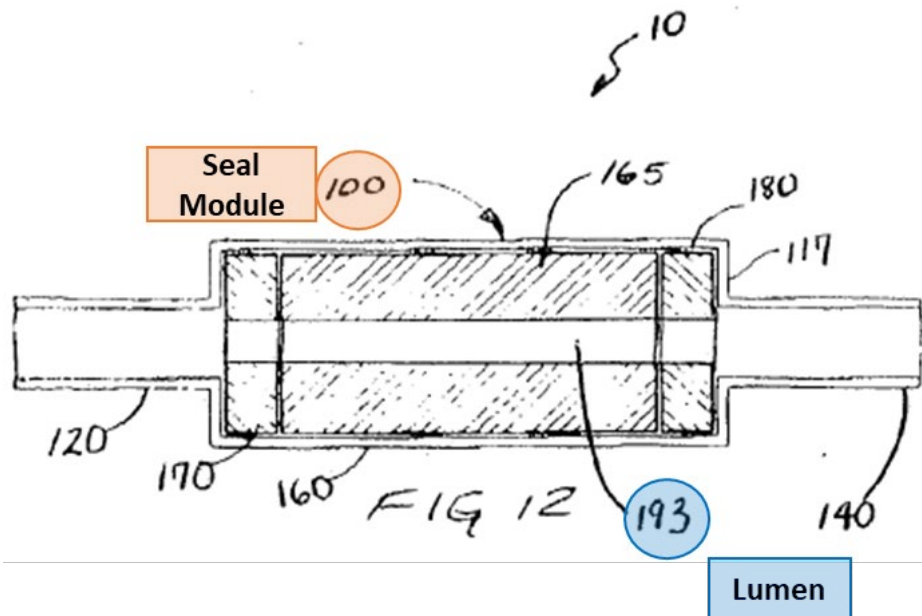
As explained below, Schaeffer discloses or renders obvious, both alone and combined with Hartley or Eller, the hemostasis valve recited in claim 1. (*Id.*, ¶¶102-147.)

a. Tubular Member

Claim 1 recites “wherein the hemostasis valve comprises: a tubular member defining a lumen configured to slidably receive the second catheter.” Schaffer discloses this limitation. (*Id.*, ¶¶103-105.)

Schaffer's hemostasis valve includes a "seal module 100" that comprises "a flexible, elongate tubular structure 101." (Ex. 1005, [0049], [0051], [0054], [0075].)

The seal module 100 defines a lumen 193:



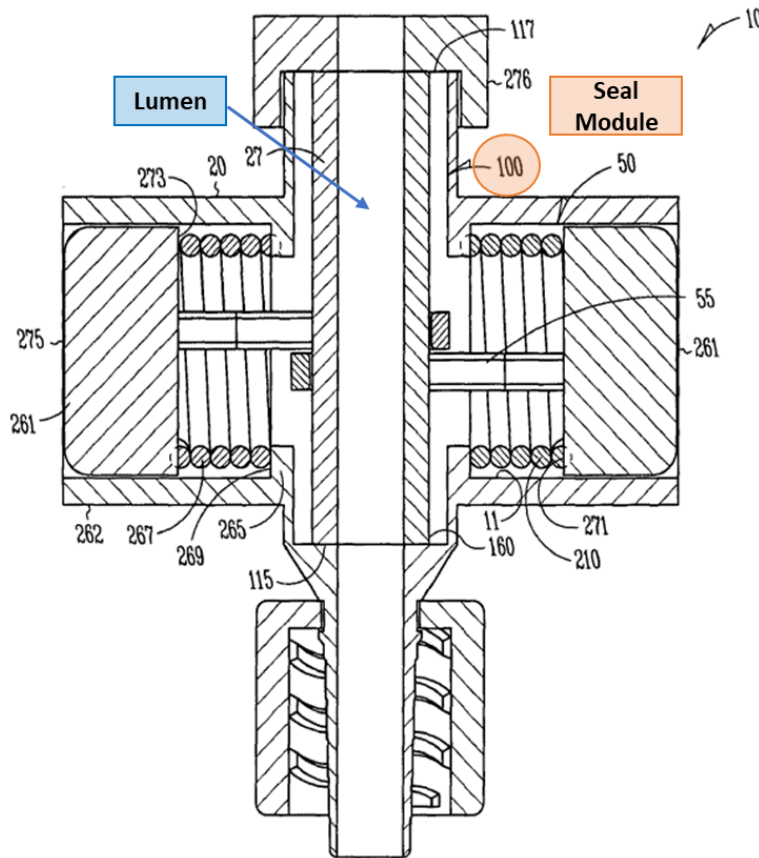


Fig. 34

(*Id.*, [0058], Figs. 12, 34.) Schaffer discloses that “a range of instruments [can be] used within the seal module,” such as “a catheter, guidewire, needle, or fiber.” (*Id.*, [0056].) Thus, Schaffer’s seal module 100 is “a tubular member defining a lumen configured to slidably receive the second catheter.” (Ex. 1003, ¶105.)

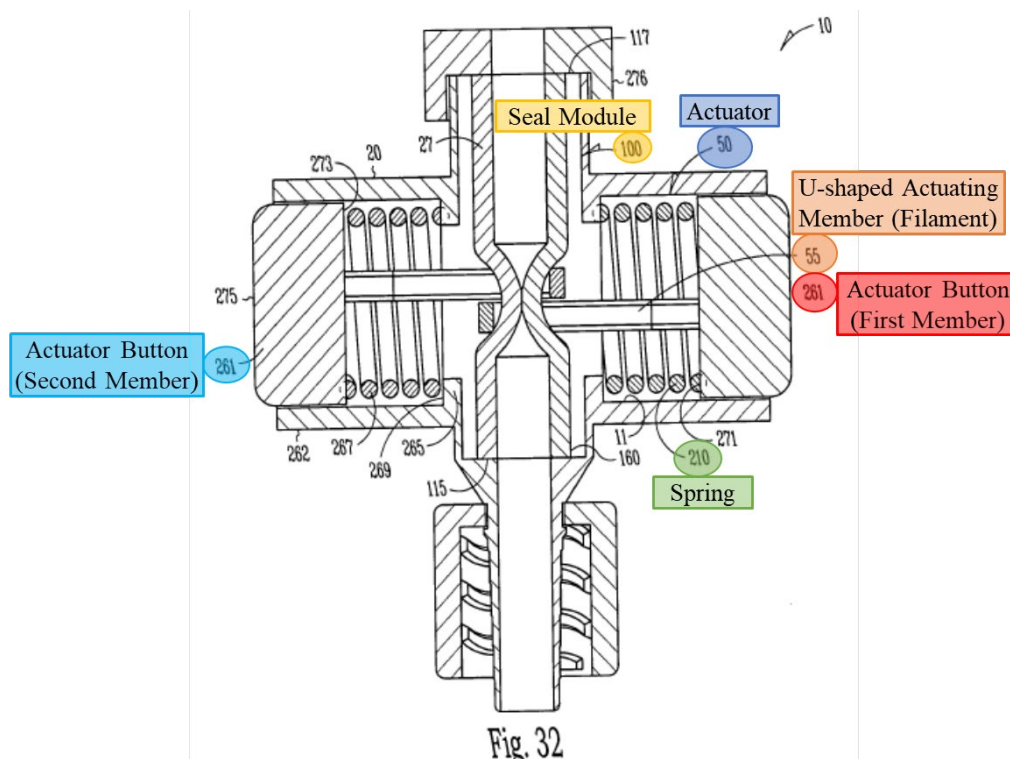
b. Constricting Mechanism

Clam 1 recites that the hemostasis valve comprises “a constricting mechanism including a filament and an actuator coupled to the filament, the filament comprising a first portion extending around at least a portion of the tubular member and a second portion having a first end extending from the first portion in one direction and a

second end extending from the first portion in another direction, and the actuator comprises a first member coupled to the first end of the filament and a second member coupled to the second end of the filament, wherein the first member and the second member of the actuator are moveable between (a) a first position wherein the filament circumferentially constricts the lumen to create a seal and (b) a second position wherein the filament is moved to at least partially open the lumen.” Schaffer discloses the claimed constricting mechanism or renders it obvious in combination with Hartley or Eller. (*Id.*, ¶¶106-144.)

i. Actuator

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



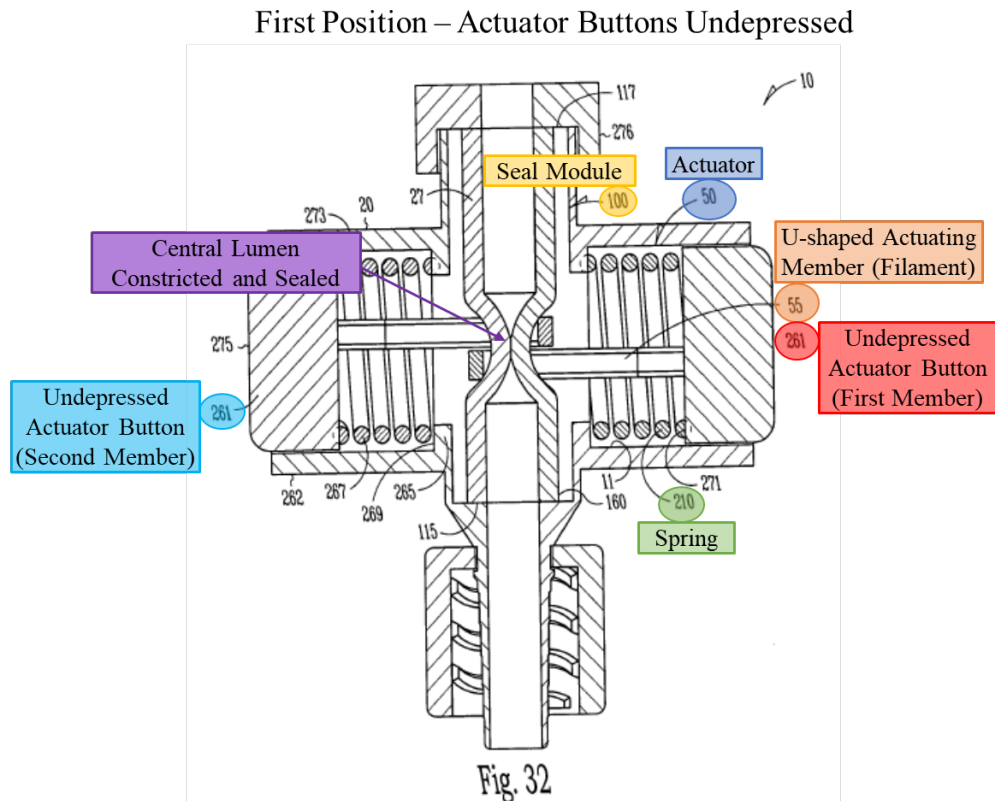
(Ex. 1005, [0075]-[0076], Figs. 31-32.) Each actuator 50 includes “an actuator button 261” attached to a “spring 210.” (*Id.*)

While Schaffer describes the hemostasis valve in Figures 31-34 as having “two circular actuators 50,” the ’519 application describes the same structure (i.e., two buttons) as a single “actuator.” (*Id.*; Ex. 1017, [0043]-[0045].) Because Schaffer’s actuators 50 have the same components and function in the same way as the actuator allegedly incorporated into the ’005 patent, Schaffer’s collective actuators 50 form an “actuator” within the meaning of the ’005 patent. (Ex. 1003, ¶108); *In re Gleave*, 560 F.3d 1331, 1334 (Fed. Cir. 2009) (prior art “reference need not satisfy an *ipsissimis verbis* test” to be anticipatory); *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.”).)

Schaffer’s actuator buttons are each coupled to “an actuating member 55 which, in one option, is U-shaped.” (Ex. 1005, [0076].) As explained below, the actuator buttons are coupled to the first and second ends of the U-shaped actuating members, which are the claimed “filament.” (*Infra* §§VI.A.8.b.ii.)

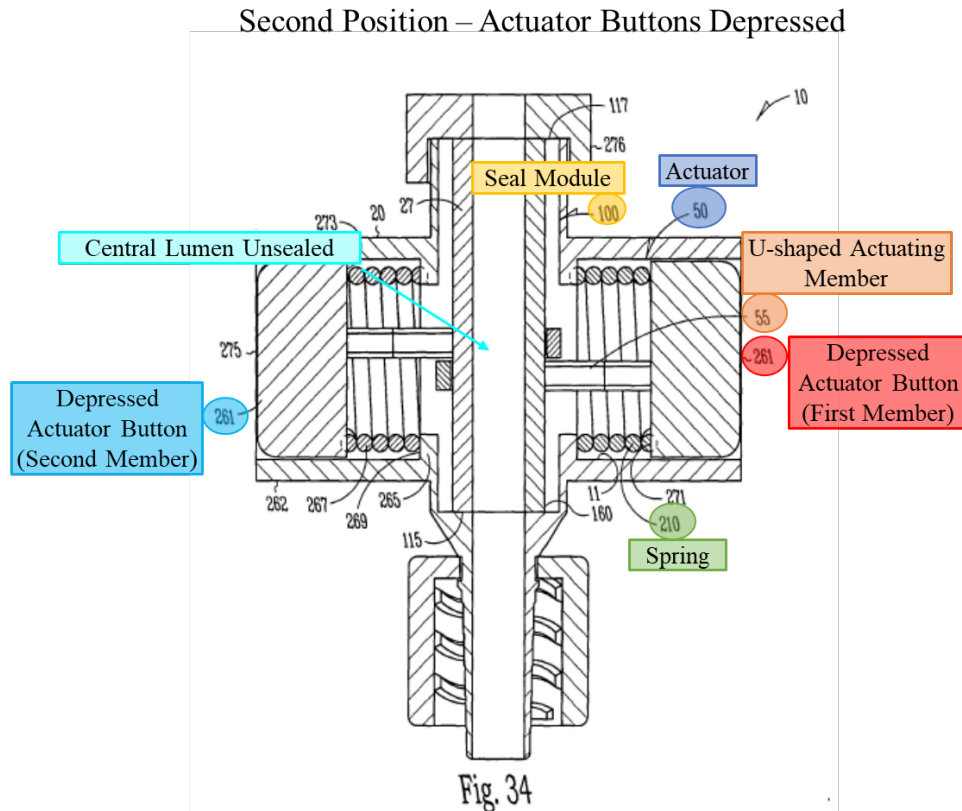
The actuator buttons are movable between a first position wherein the lumen is circumferentially constricted to create a seal and a second position wherein the lumen is at least partially open. (Ex. 1003, ¶111.) Schaffer discloses that in a first

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)”:



(Ex. 1005, [0077], Fig. 32.) As shown above, the central lumen is constricted and sealed in this 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, ¶111.) In a second position, shown in Figure 34, the actuator buttons are pressed inwardly, compressing the springs and

allowing the actuating members to disengage from the seal module 100 so the module can return to its uncollapsed configuration and fluid can pass therethrough:

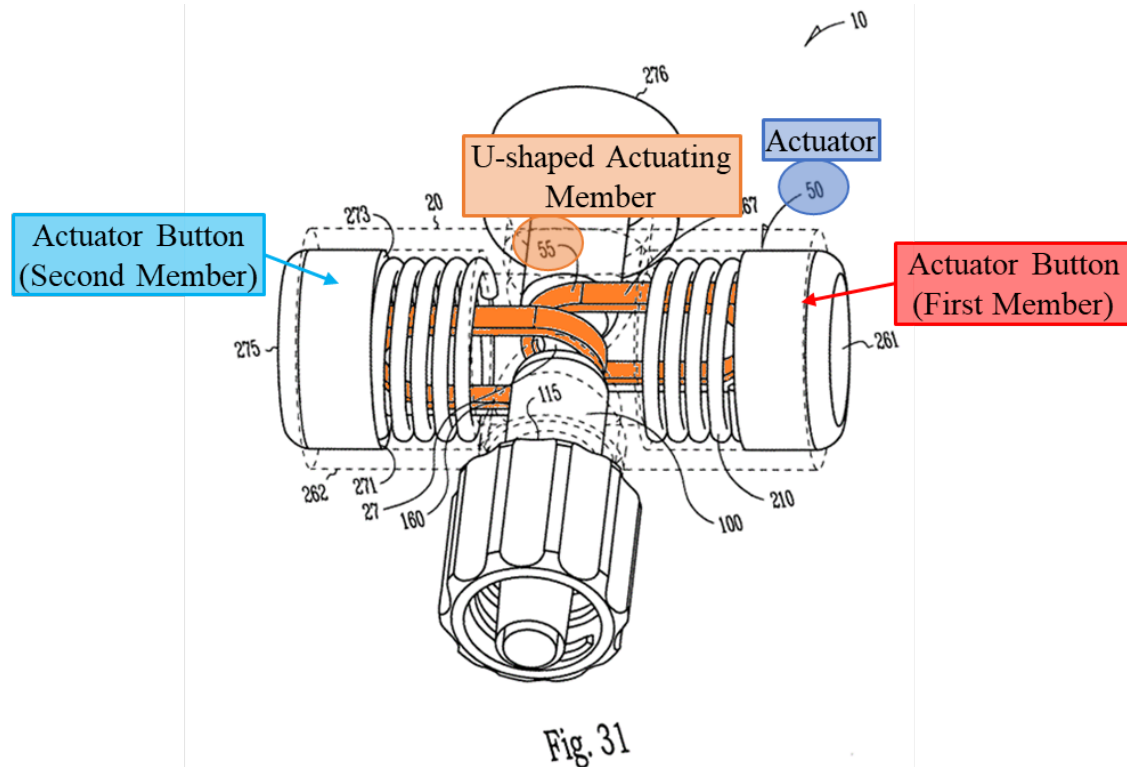


(Ex. 1005, [0077], Fig. 34.) Schaffer’s actuator buttons are therefore a “first member” and “second member” as claimed in the ’005 patent. (Ex. 1003, ¶¶109-111.)

ii. Filament

(a) Schaffer

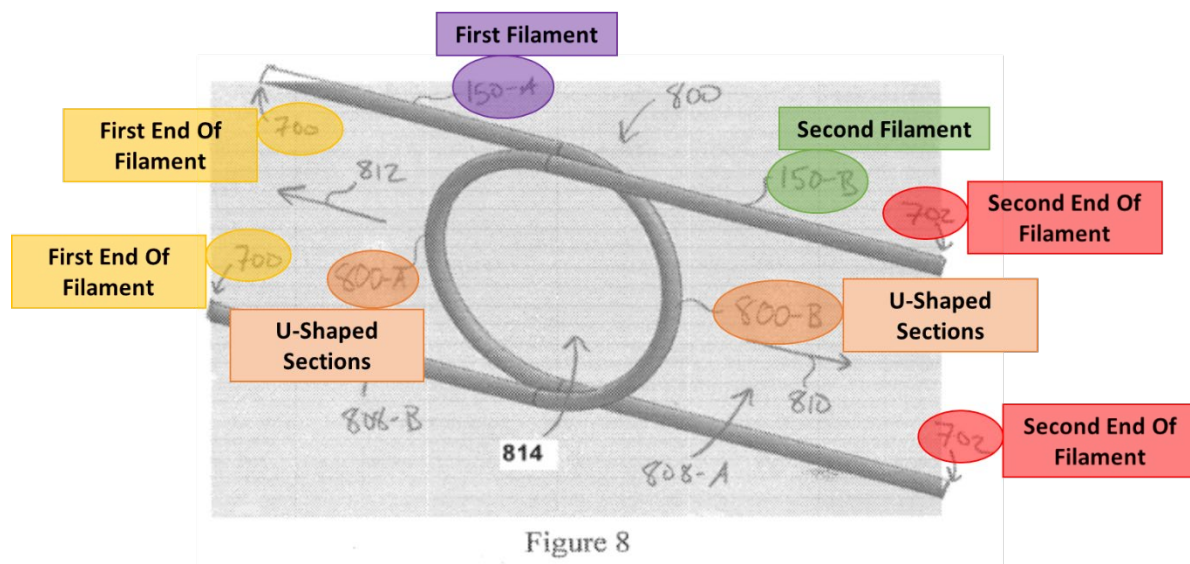
Schaffer’s valve includes two actuating members, which may be U-shaped, coupled to the actuator buttons:



(Ex. 1005, [0076], Fig. 31.) Schaffer’s actuating members are a “filament” as claimed in the ’005 patent. (*Supra* §IV; Ex. 1003, ¶112.)

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, ¶113.) The ’519 application states that the filament can be made from a polymer, which includes Schaffer’s plastic, or a metal, which includes Schaffer’s aluminum. (*Supra* §IV.) Likewise, the ’519 application states that a filament may be a ribbon, flat wire, sheet, or tape, which includes Schaffer’s U-shaped actuating members. (*Id.*) 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, ¶113.)

That Schaffer uses two separate actuating members is of no moment here. The '519 application discloses that the “the filament 150 can comprise multiple filaments,” including filaments forming two U-shapes:



(Ex. 1017, [0065], Fig. 8 (emphasis added).) Accordingly, Schaffer’s U-shaped actuating members collectively constitute the “filament” claimed in the ’005 patent. (Ex. 1003, ¶114); *see also Sandisk Corp. v. Kingston Tech. Co., Inc.*, 695 F.3d 1348, 1360 (Fed. Cir. 2012) (“the later use of ‘the’ ... to refer back to an earlier claim term does not limit that claim term to the singular”); *Biagro W. Sales, Inc. v. Grow More, Inc.*, 423 F.3d 1296, 1304 (Fed. Cir. 2005).

Schaffer’s actuating members are “at least partially circumferentially [sic] disposed about the portion of the seal module 100.” (Ex. 1005, [0076].) This portion of the actuating members is a “first portion [of the filament] extending around at least a portion of the tubular member”:

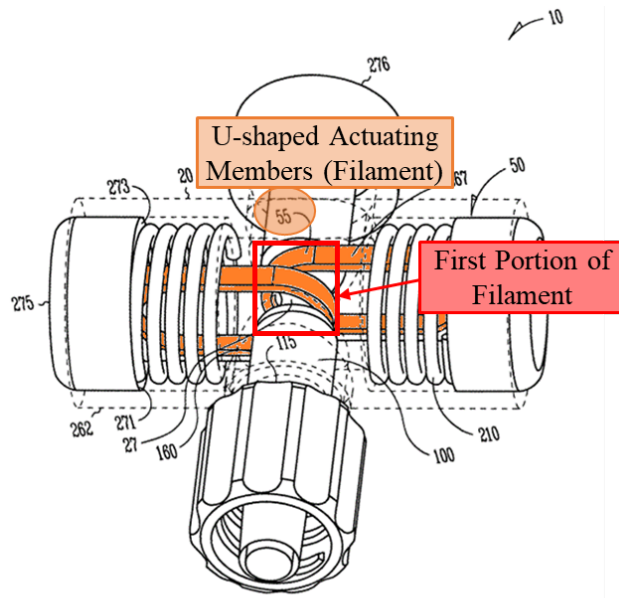


Fig. 31

(*Id.*, [0076], Fig. 31; Ex. 1003, ¶115.) The portions of the actuating members that extend in opposite directions from the seal module 100 are a “second portion” of the filament:

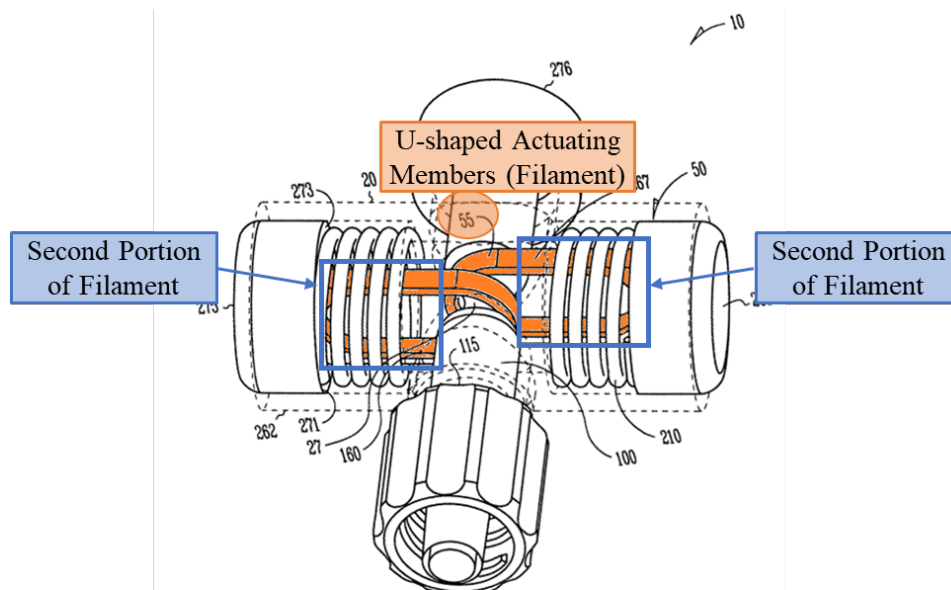
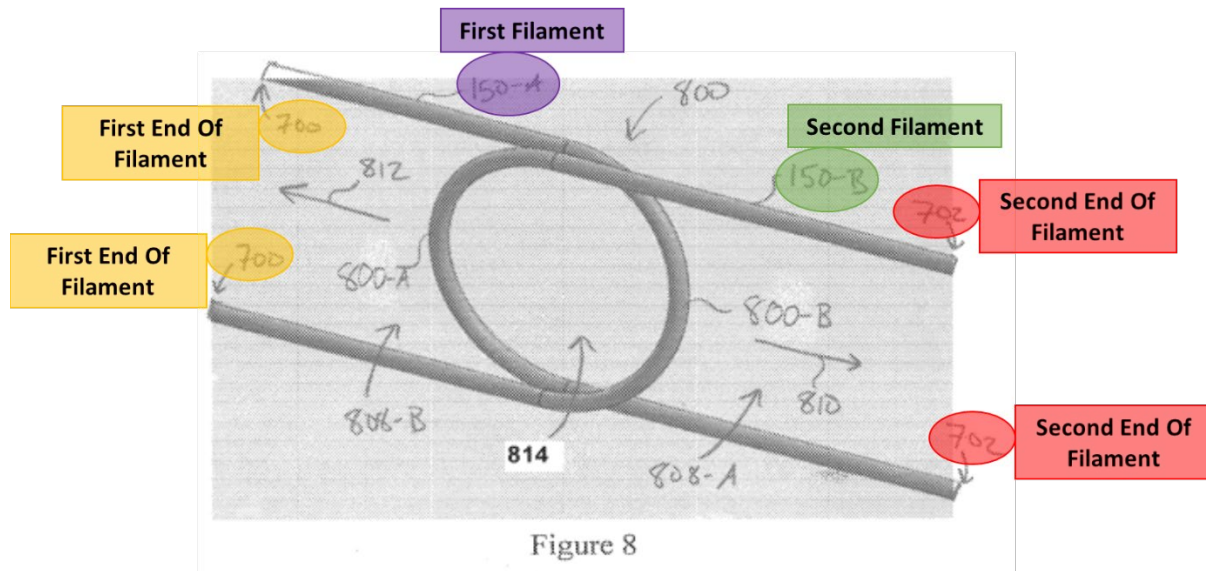


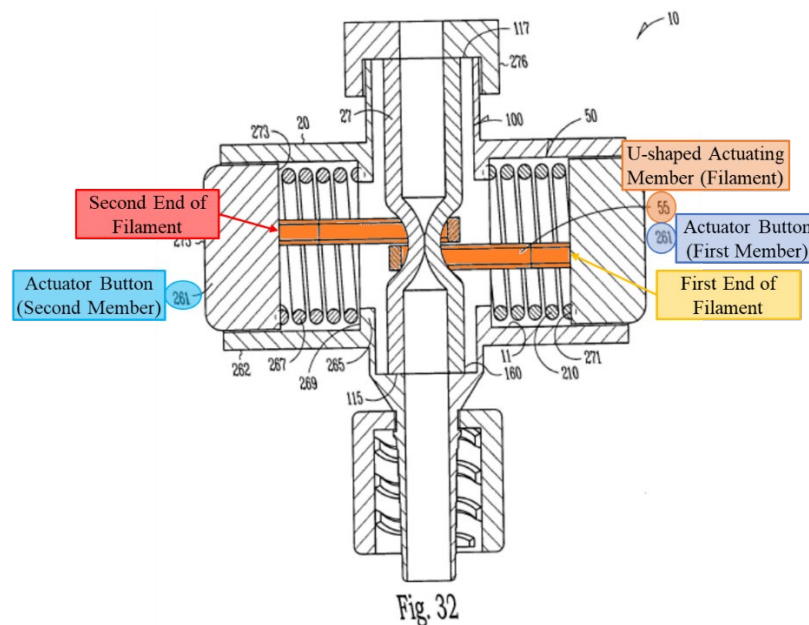
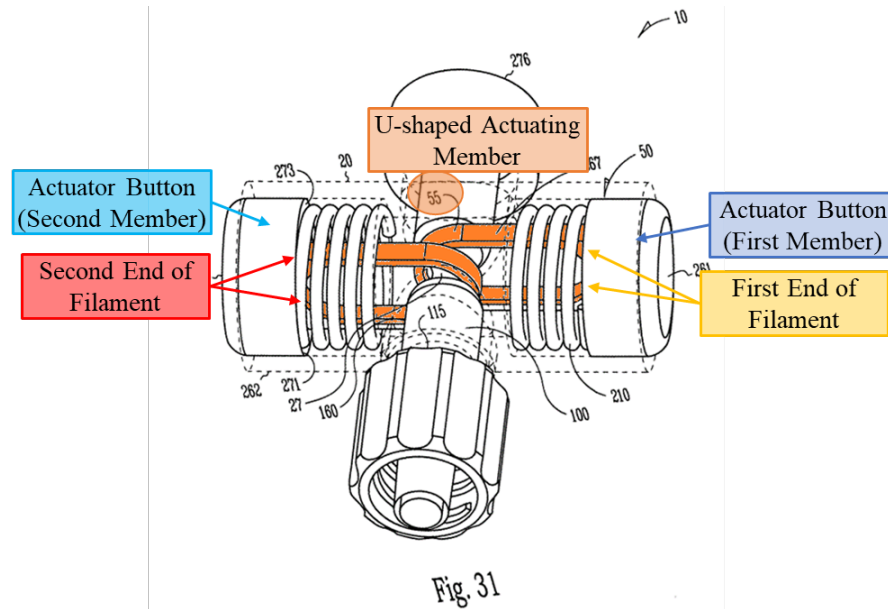
Fig. 31

(Ex. 1005, Fig. 31; Ex. 1003, ¶115.)

The '519 application 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. 1017, [0065], Fig. 8 (emphasis added).) Consistent with this disclosure, the second portion of Schaffer’s U-shaped actuating members includes a “first end” coupled to the first actuator button (first member) and a “second end” coupled to the second actuator button (second member):



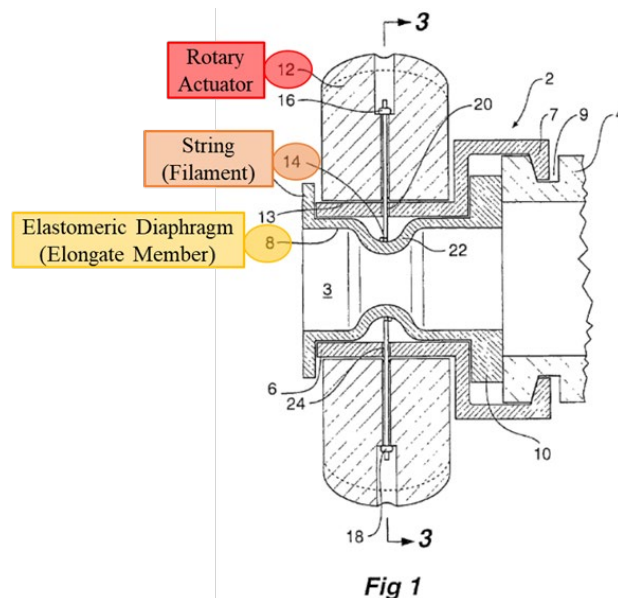
(Ex. 1005, [0076], Figs. 31-32; Ex. 1003, ¶116.)

Even if the Board concludes that Schaffer’s U-shaped actuating members do not “circumferentially constrict[] the lumen [of Schaffer’s valve] to create a seal” as claimed in the ’005 patent, a POSITA would have found it obvious to modify the U-

shaped actuating members to closely conform to the seal module to circumferentially constrict the lumen. (Ex. 1003, ¶118.)

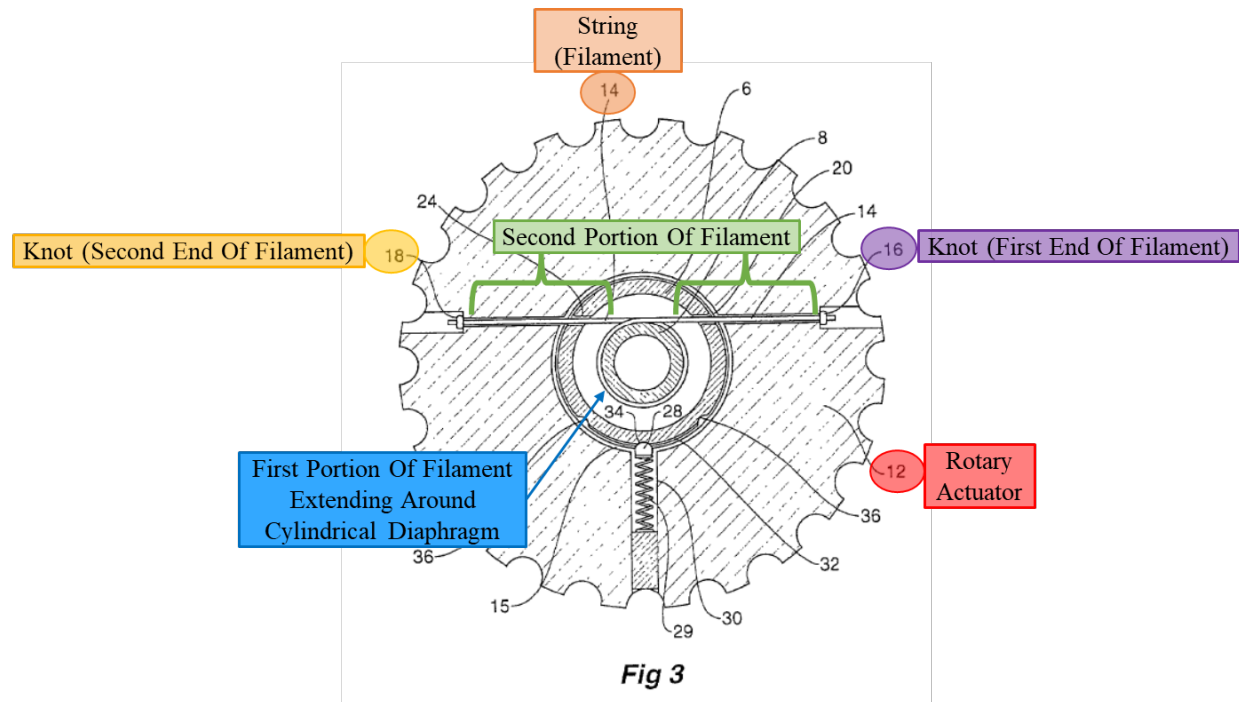
(b) Hartley

Hartley also discloses a filament, even if the Board adopts PO’s narrower construction of “filament.” (Ex. 1003, ¶¶119-132.) 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 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, ¶119.)

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



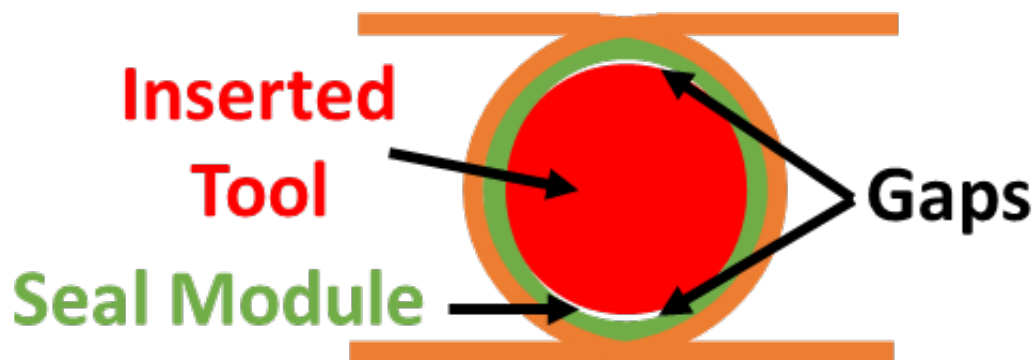
(Ex. 1006, [0031], Fig. 3.) Thus, Hartley’s string has the first and second portions recited in the claim. (*Id.*; Ex. 1003, ¶¶120-121.)

Hartley discloses that “[r]otation of the rotary actuator 12 with respect to the cylindrical housing 6 will cause the string 14 to be pulled in both directions at once and hence the cylindrical diaphragm 8 to be constricted.” (Ex. 1006, [0031], [0034], Fig. 4.) Hartley further discloses the valve “will close over a range of diameters of devices passed through the valve or can close completely down to be self sealing.” (*Id.*, [0037].)

POSITAs would have found it obvious to substitute Hartley’s string for Schaffer’s actuating members in Schaffer’s valve. (Ex. 1003, ¶¶123-132.) The combination of Hartley’s string and Schaffer’s valve would have merely entailed

substitution of one known element (Hartley’s string) for another (Schaffer’s actuating members) to yield the predictable result of sealing Schaffer’s valve. *KSR*, 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, ¶123.) POSITAs would have recognized that Hartley’s string may seal more effectively across a wider range of tool diameters and shapes than Schaffer’s U-shaped actuating members. (Ex. 1003, ¶124.) Depending on the inserted tool, Schaffer’s actuating members may form small gaps between the valve’s seal module and the tool’s outer surface:



(*Id.*) Hartley’s string would not suffer from this potential issue because the string more precisely conforms to the tool diameters. (*Id.*) In related proceedings, PO argued that Schaffer’s valve would not create gaps. *Imperative Care*, IPR2024-

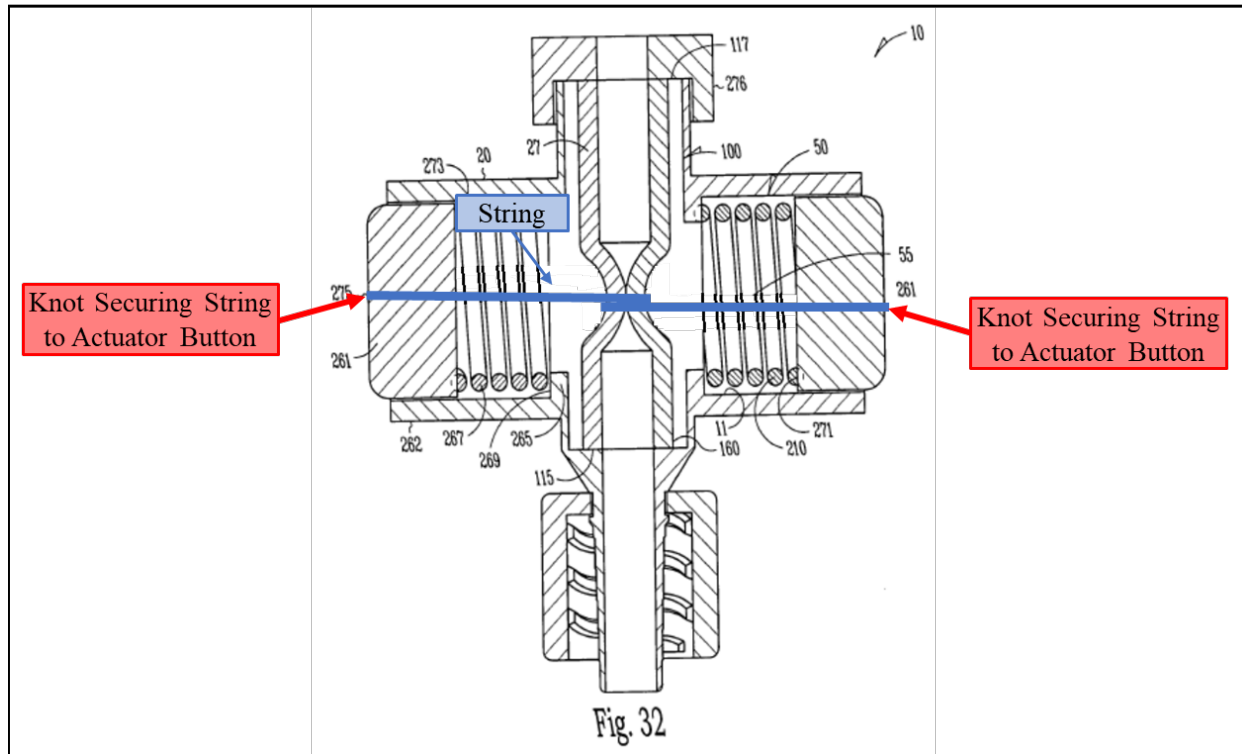
01157, Paper 5 at 28-29. However, the portions of Schaffer cited by PO do not support its argument. (Ex. 1003, ¶124.)

POSITAs also had a finite number of materials to select from to constrict a tubular member in a hemostasis valve in 2018. (*Id.*, ¶126.) Hartley and Schaffer disclose two such materials: Hartley’s string and Schaffer’s actuating members. (*Id.*) Eller discloses a third option: wire members. A POSITA would have found it obvious to select from these finite, predictable options and, as discussed below, would have had a reasonable expectation of success in implementing them. (*Id.*); *KSR*, 550 U.S. at 421.

POSITAs would have had a reasonable expectation of success in substituting Hartley’s string for Schaffer’s actuating members. (Ex. 1003, ¶¶128-132.) Hartley teaches using simple knots to attach the string to the rotary actuator. (Ex. 1006, [0031].) POSITAs would have reasonably expected that similar knots would secure Hartley’s string to Schaffer’s actuator buttons. (Ex. 1003, ¶128.) For example, each end of Hartley’s string could be threaded through small holes in Schaffer’s buttons and knotted on the other side. (*Id.*) This simple modification would have been within a POSITA’s skills:

Demonstrative Illustration

Schaffer + Hartley's String


$$(Id.)^4$$

Also, POSITAs would have recognized that Hartley's string and Schaffer's actuating members function in similar ways and, therefore, no other modifications to Schaffer's valve would be necessary. (*Id.*, ¶129.) Both valves collapse the valve lumen by pulling the ends of the actuating members/string in opposite directions. (Ex. 1005, [0077]; Ex. 1006, [0031].) Thus, if Hartley's string were incorporated into Schaffer's valve, a POSITA would have reasonably expected Schaffer's springs

⁴ This image is a demonstrative prepared by Petitioner.

to pull the ends of the string in opposite directions to constrict Schaffer's seal module. (*Id.*; Ex. 1003, ¶129.)

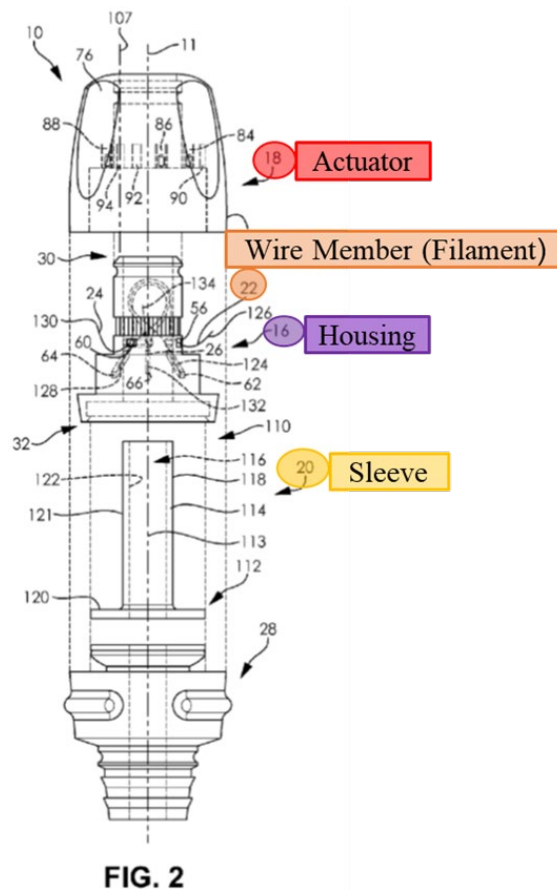
Likewise, POSITAs would have also reasonably expected that pressing Schaffer's buttons inwardly (i.e., second position) would release the tension on the string, allowing the lumen to open. (*See* Ex. 1005, [0077]; Ex. 1006, [0034]; Ex. 1003, ¶131.) Schaffer's seal module is formed from a "highly deformable, 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].) Thus, Schaffer's seal module has the resilience to open when the tension on the string is released. (Ex. 1003, ¶131.) 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.*, ¶132.) Schaffer discloses various materials for the seal module, including "modified vinyl, silicone, polyurethane or a combination thereof." (Ex. 1005, [0081]; *see also* Ex. 1007, 36:27-60 (disclosing materials for seal modules).)

Further, Hartley discloses that looping the string around the central lumen forms an effective seal. (Ex. 1006, [0031], [0037].) Thus, when replacing Schaffer's actuating members with Hartley's string, POSITAs would have been motivated to similarly loop Hartley's string around Schaffer's seal module. (Ex. 1003, ¶127.) POSITAs would have reasonably expected success in using this configuration

because Hartley teaches the configuration forms an effective seal. (*Id.*) Thus, Schaffer combined with Hartley renders claim 1 obvious.

(c) Eller

Eller also discloses a “filament.” (Ex. 1003, ¶133.) Eller discloses hemostasis valves that include “a housing 16, an actuator 18, a sleeve 20, [and] a first wire member 22”:

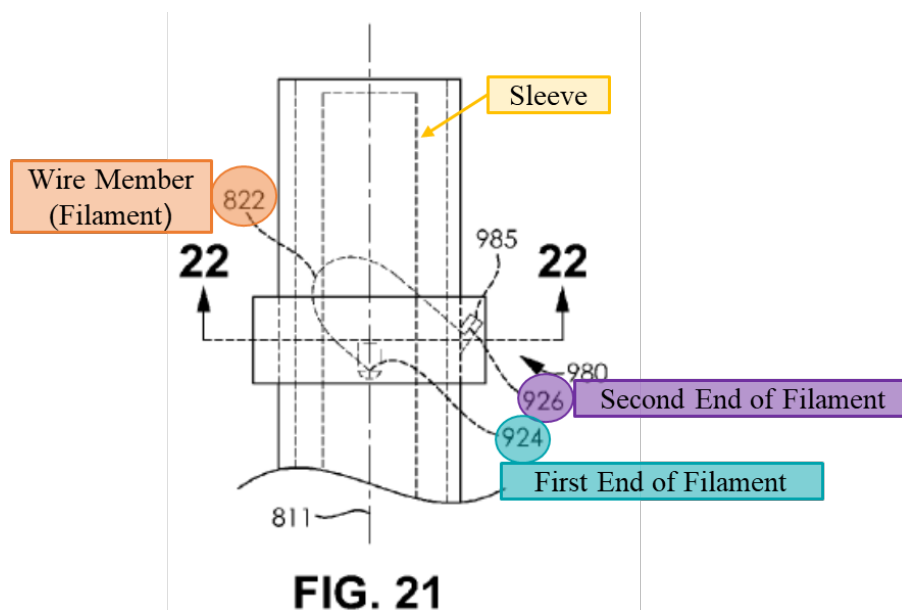


(Ex. 1007, 5:1-5, 16:7-19, 21:37-22:31, 23:50-25:9, Fig. 2⁵.) Eller's wire member is a filament. (Ex. 1003, ¶133.) Eller's wire member can have various compositions

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

(e.g., “braided materials,” “twisted materials”), be formed from various materials (e.g., “metals,” “polymers,” “polyester,” “nylon,” “flexible materials”), and have different shapes (e.g., “round,” “rectangular”). (Ex. 1007, 15:41-16:6.) Thus, the wire member is a “filament” at least because the wire member is made of at least one or more threads, lines, cords, rope, ribbon, flat wire, sheet, or tape. (Ex. 1003, ¶134; *supra* §IV.)

The wire member loops around the sleeve and has a first end 124 attached to the housing 16 and a second end 126 attached to the actuator 18:



(Ex. 1007, 12:52-64, 24:50-57, Fig. 21.) Eller’s wire member is “moveable between a first configuration and a second configuration.” (*Id.*, 15:21-25.) In the first configuration, the wire member is in a relaxed state and fluid is permitted to flow through the sleeve. (*Id.*, 15:21-40, 17:38-43.) In the second configuration, rotational force from the actuator places the wire member in a tensioned state, causing the wire

member to constrict the sleeve and prevent fluid from passing therethrough. (*Id.* 15:21-40, 17:62–67, 18:3-8.)

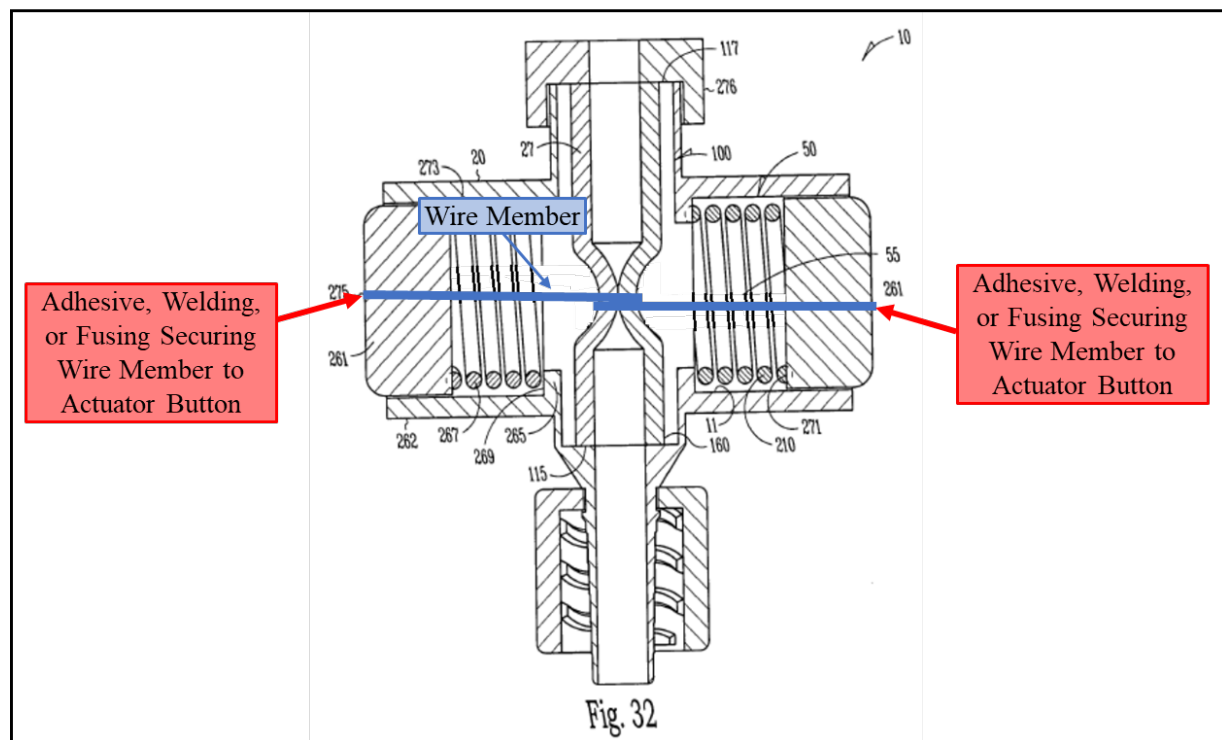
A POSITA would have found it obvious to substitute Eller’s wire member for Schaffer’s actuating members in Schaffer’s valve. (Ex. 1003, ¶¶137-144.) The combination of Eller’s wire member and Schaffer’s valve would have entailed merely substituting one known element (Eller’s wire member) for another (Schaffer’s actuating members) to yield the predictable results of constricting Schaffer’s valve. *See KSR*, 550 U.S. at 416.

Eller’s disclosure that the wire member can form a seal around one or more medical devices would have further motivated POSITAs to substitute Eller’s wire member for Shaffer’s actuating members. (Ex. 1007, 15:21-40, 17:38-43, 18:3-8; Ex. 1003, ¶137.) POSITAs would have recognized that Eller’s wire may seal more effectively across more device diameters than Schaffer’s actuating members. (*Supra* §VI.A.8.b.ii.b; Ex. 1003, ¶138.)

POSITAs also had a finite number of materials to select from to constrict the lumen of a hemostasis valve. (*Supra* §VI.A.8.b.ii.b; Ex. 1003, ¶140.) 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 reasonably expected success in substituting Eller's wire member for Schaffer's actuating members for several reasons. (Ex. 1003, ¶¶141-144.) 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 "adhesives, welding, fusing." (*Id.*, 14:43-49.) POSITAs would have reasonably expected success in securing Eller's wire member to Schaffer's actuator buttons using these simple methods. (Ex. 1003, ¶141.)

Demonstrative Illustration Schaffer + Eller's Wire Member



(*Id.*)⁶

Second, Eller teaches that its wire member may be used with “any suitable actuator capable of moving the selective fluid barrier valve device between a first configuration and a second configuration.” (Ex. 1007, 8:27–39.) Eller teaches that suitable actuators include “rotatable actuators, linear actuators, slidable actuators, pivotable actuators, levers, and any other actuator considered suitable for a particular embodiment.” (*Id.*, 8:39–44.) Given this disclosure, POSITAs would have reasonably expected Eller’s wire member to work with Schaffer’s buttons, which are linear and/or slidable actuators. (Ex. 1003, ¶142.)

Third, Eller’s wire member and Schaffer’s actuating members function similarly to close the valves. (*Id.*, ¶143.) Both references disclose actuators that pull the wire/actuating members in opposite directions to constrict the valve’s lumen. (Ex. 1005, [0077], Ex. 1007, 15:21-40, 17:47-18:3; Ex. 1003, ¶143.) POSITAs would have recognized that Eller’s wire member would function the same way in Schaffer’s valve. (Ex. 1003, ¶143.) In the first position, the springs coupled to Schaffer’s actuator buttons would pull the ends of the wire member in opposite directions, thereby causing the wire member to constrict the seal module. (*See* Ex. 1005, [0077]; Ex. 1007, 15:21-40, 17:47-18:3; Ex. 1003, ¶144.) When Schaffer’s actuator buttons are pressed inwardly, the tension on the wire member would be

⁶ This image is a demonstrative prepared by Petitioner.

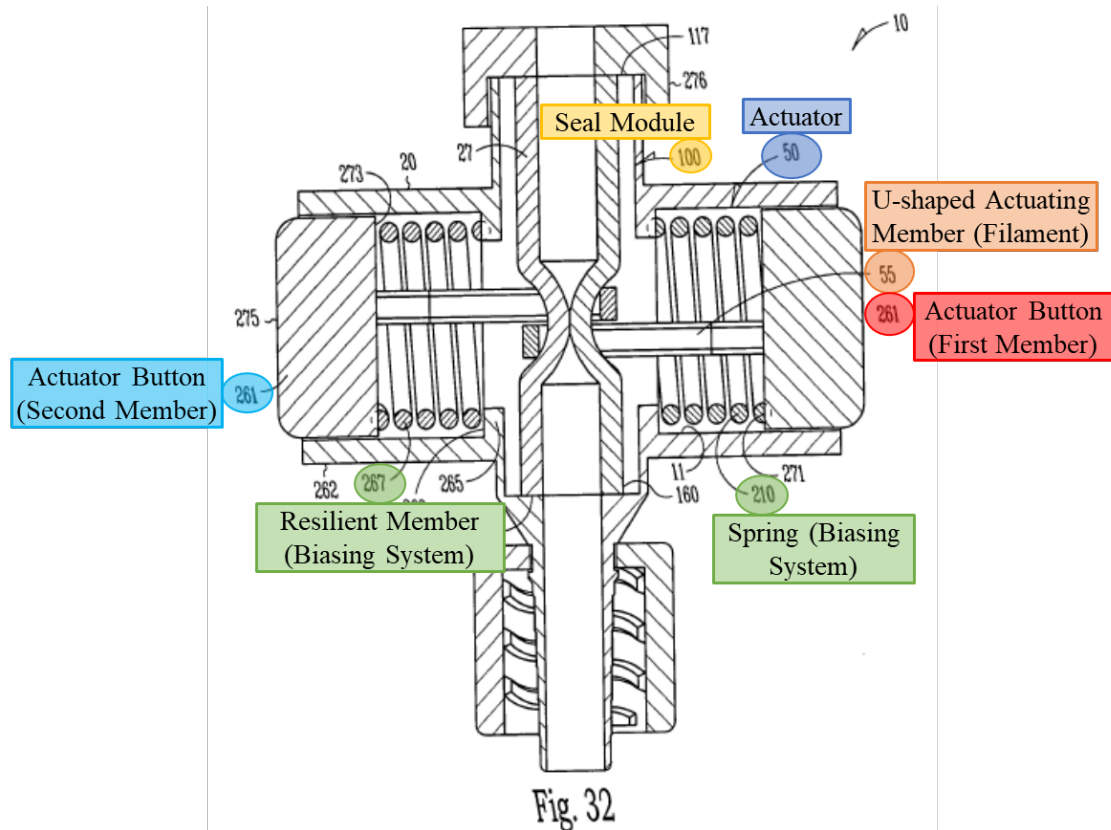
relaxed, causing the wire member to loosen around the seal module. (*See* Ex. 1005, [0077]; Ex. 1007, 15:21-40, 17:47-18:3; Ex. 1003, ¶144.) As explained above, a POSITA would have expected Schaffer’s seal module to have the resilience to return to its open configuration when “no compressive force [] is applied” to the lumen.” (*Supra* §VI.A.8.b.ii.b; Ex. 1003, ¶144.) Further, if Schaffer’s lumen required adjustment to function with Eller’s wire, a POSITA would have possessed the knowledge to make the necessary adjustments. (*Id.*)

Thus, Schaffer combined with Eller renders claim 1 obvious.

c. Biasing System

Claim 1 finally recites that the hemostasis valve comprises “a biasing system configured to bias the first member and the second member to the first position.” Schaffer discloses this limitation. (Ex. 1003, ¶¶145-147.)

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



(Ex. 1005, [0076], Fig. 32.) Schaffer’s resilient members bias Schaffer’s actuator buttons (first and second members) toward the first (i.e., closed) position. (Ex. 1005, [0077]; Ex. 1003, ¶147.) Therefore, Schaffer’s resilient members/springs meet this limitation. (Ex. 1003, ¶¶146-147.)

B. Claim 2

Claim 2 recites the “vacuum aspiration system of claim 1 wherein the tubular member is pliable.” Garrison combined with Schaffer and optionally Hartley or Eller renders claim 2 obvious. (Ex. 1003, ¶¶148-149.)

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

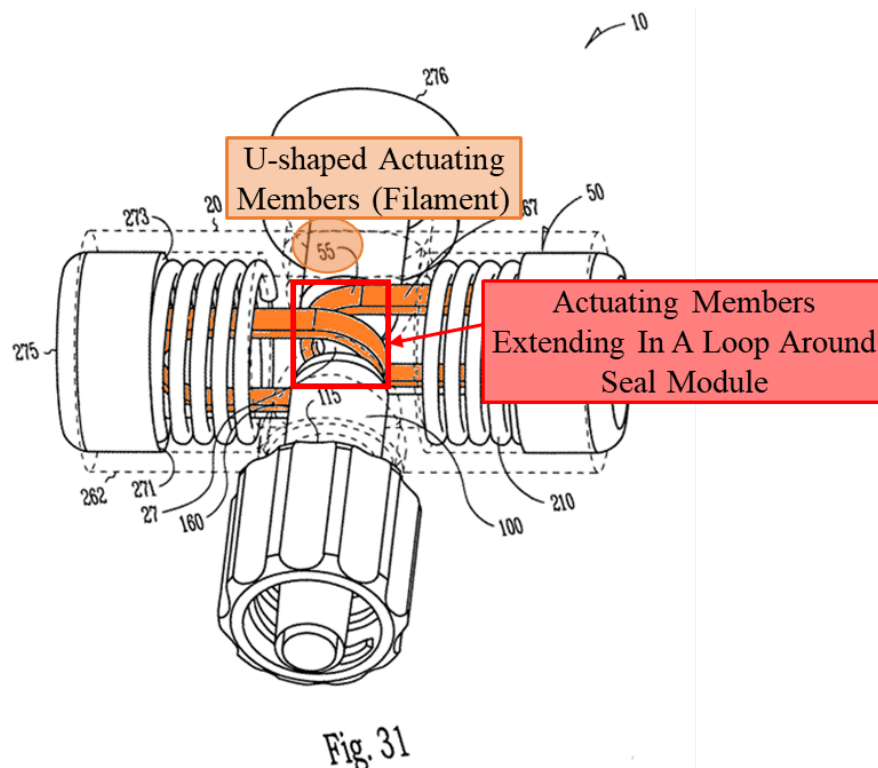
highly elastic, deformable, compliant and yet virtually non-compressible.” (Ex. 1005, [0054].) Thus, Schaffer’s tubular member is pliable. (Ex. 1003, ¶149.)

C. Claim 3

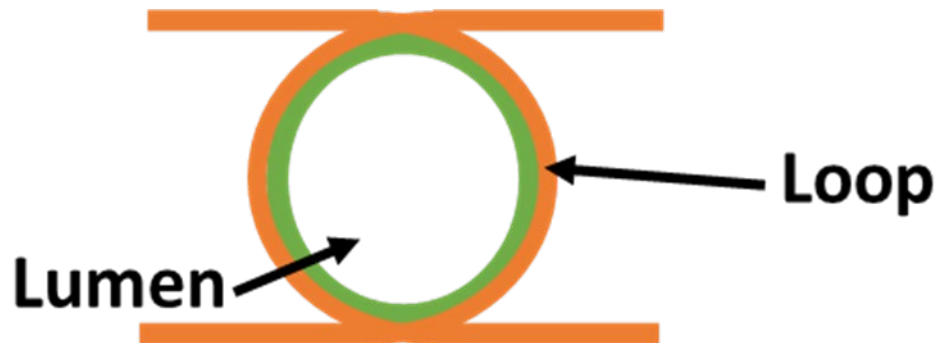
Claim 3 recites the “vacuum aspiration system of claim 1 wherein the first portion of the filament extends in a loop completely around the tubular member.” Garrison combined with Schaffer and optionally Hartley or Eller renders claim 3 obvious. (Ex. 1003, ¶¶150-158.)

1. Schaffer

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



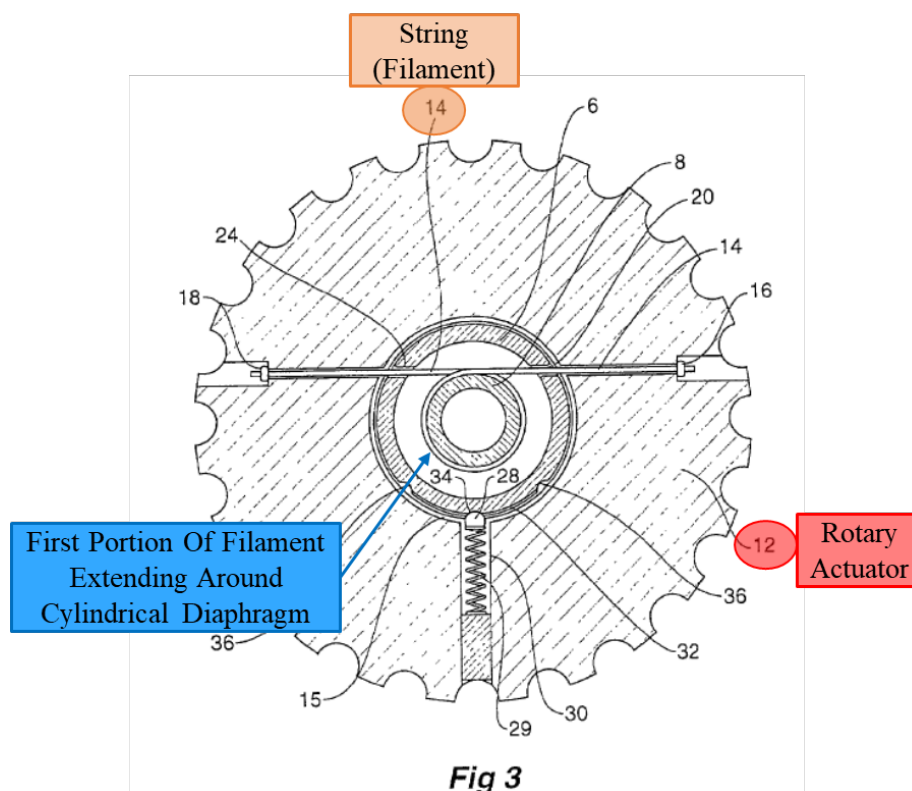
(Ex. 1005, [0076], Fig. 31; Ex. 1003, ¶151.) The below demonstrative illustrates the loop formed by the U-shaped members:



(Ex. 1003, ¶151.)

2. Hartley

Hartley's string "is wound preferably twice around the cylindrical diaphragm":

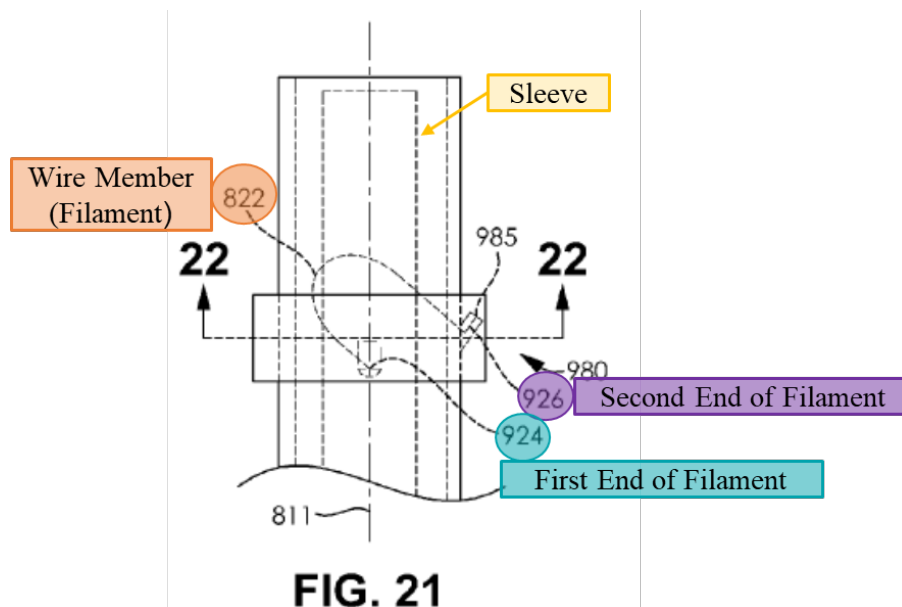


(Ex. 1006, [0031], Fig. 3.) Hartley’s string therefore includes a first portion that “extends in a loop completely around the tubular member.” (*Id.*; Ex. 1003, ¶153.)

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, ¶154.) POSITAs would have reasonably expected success because Hartley teaches the configuration forms an effective seal. (*Id.*, ¶¶154-155.)

3. Eller

Eller explicitly states, “the wire member can be positioned such that it extends at least one full revolution around the outer surface of the sleeve”:



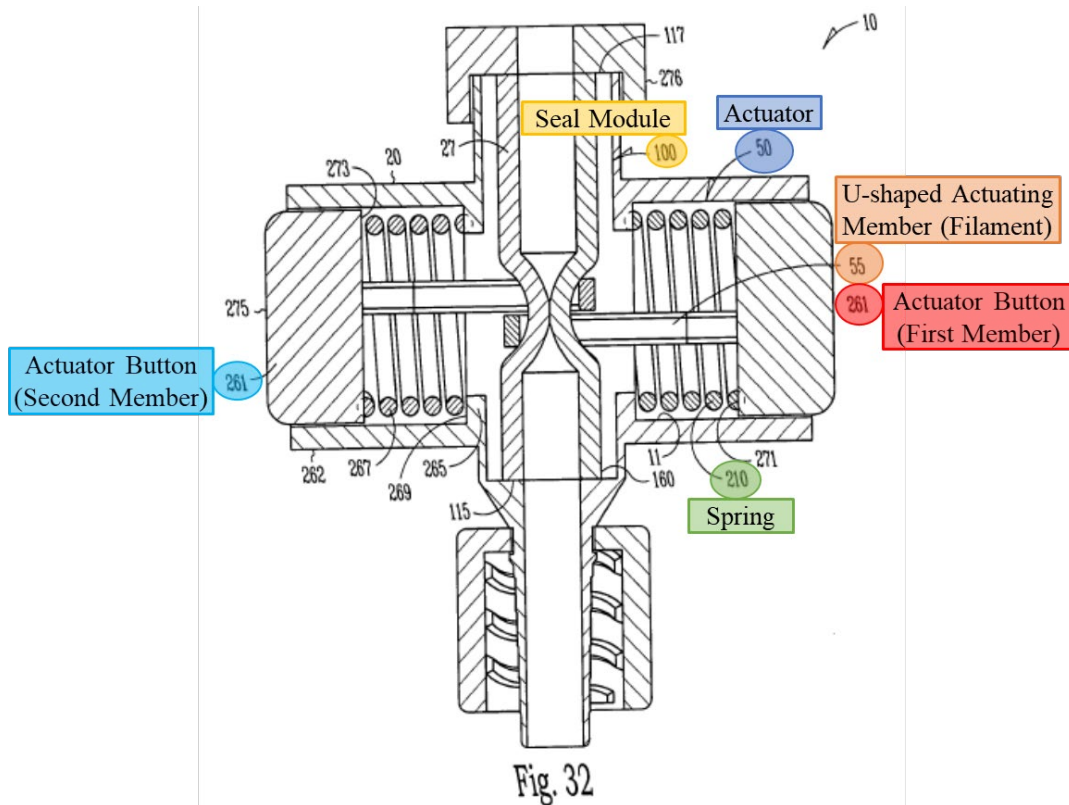
(Ex. 1007, 22:18-24; *see also id.*, 12:52-64, 24:50-57, Fig. 21.)

Thus, the wire member forms a loop completely around the tubular member. (Ex. 1003, ¶156.) When replacing Schaffer’s actuating members with Eller’s wire member, POSITAs would have been motivated to loop Eller’s wire at least one revolution around Schaffer’s seal module to ensure the wire formed a constrictive seal. (*Id.*, ¶157.) POSITAs would have reasonably expected success because Eller encourages looping the wire one revolution around the sleeve and discloses that such a configuration is effective. (*Id.*, ¶¶157-158.)

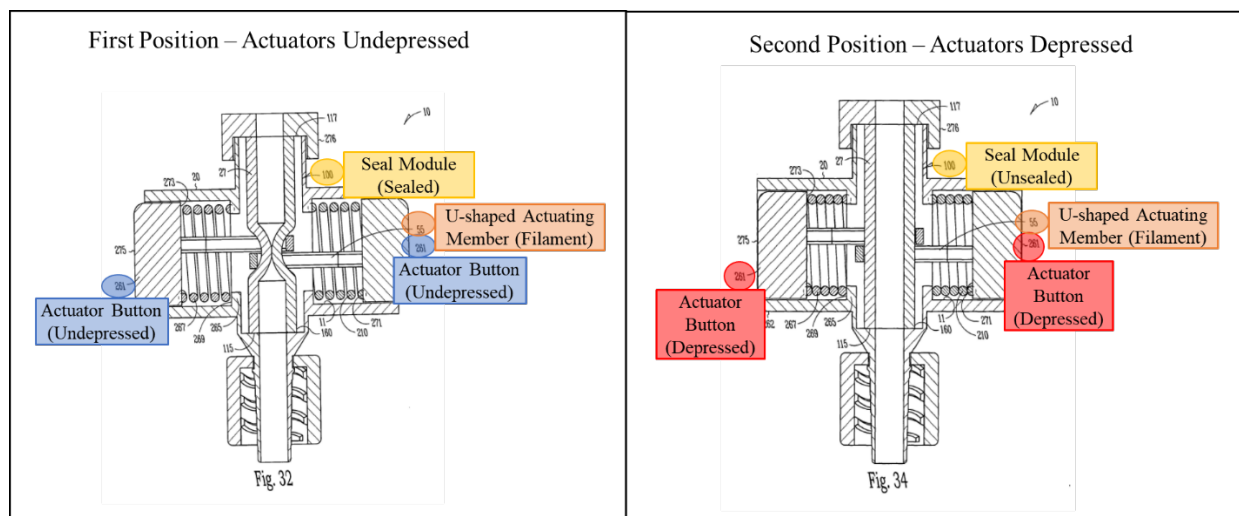
D. Claim 4

Claim 4 recites the “vacuum aspiration system of claim 1 wherein the first member of the actuator comprises a first button and the second member of the 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.” Garrison combined with Schaffer and optionally Hartley or Eller renders claim 4 obvious. (Ex. 1003, ¶¶159-160.)

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



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



(*Id.*, [0077], Figs. 32, 34; Ex. 1003, ¶160.)

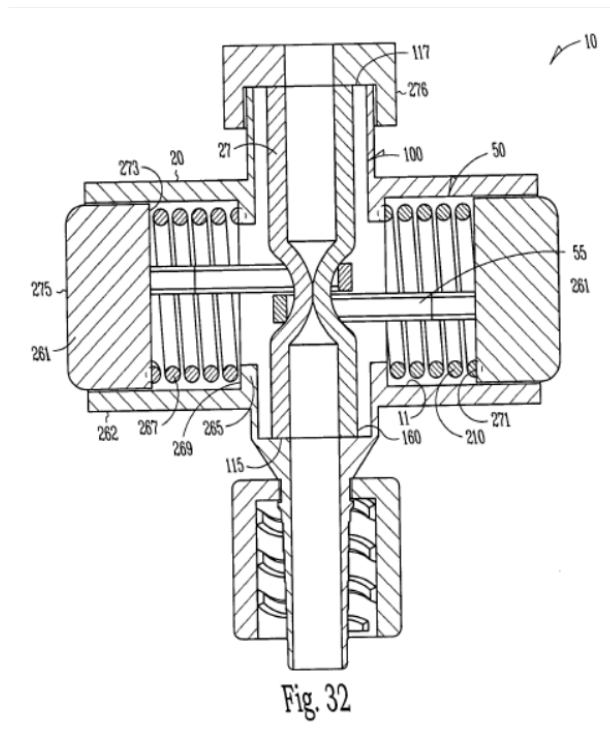
E. Claim 5

Claim 5 recites the “vacuum aspiration system of claim 1 wherein, when the first member and the second member of the actuator are in the first position, the lumen of the tubular member is configured to remain constricted and sealed when a pressure differential exists between (a) a first volume outside the lumen and adjacent to a first end of the tubular member and (b) a second volume outside the central lumen and adjacent to a second end of the tubular member.” Garrison combined with Schaffer and optionally Hartley or Eller renders claim 5 obvious. (Ex. 1003, ¶¶161-175.)

1. Schaffer

Schaffer’s valve is sealed when the first and second members (i.e., buttons) are in the first position (i.e., undepressed). (Ex. 1005, [0008]; *Supra* §VI.A.8.b.i.) Schaffer’s valve is “for use with catheters” inserted into the patient’s vasculature. (Ex. 1005, [0002].) When a catheter is inserted into the patient’s vasculature, the pressure within the catheter matches the blood pressure. (Ex. 1003, ¶162.) 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, ¶162.) 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.*, ¶163) 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 seal module (i.e., tubular member). (Ex. 1005, Abstract, [0008], [0077]; Ex. 1003, ¶¶164-165.)

Moreover, if Schaffer’s valve did not maintain its seal when a pressure differential exists, POSITAs would have been motivated to make adjustments to the valve to maintain the seal, including adjusting Schaffer’s spring strength to apply additional force, adjusting the resilience and compressibility of the seal module that forms the valve’s lumen, and/or adjusting the shape, flexibility, and/or dimensions of the actuating members to more closely conform to the shape of the seal module and any tool(s) inserted therethrough. (Ex. 1003, ¶¶166-167; *see also* Ex. 1007, 15:41-60 (identifying different filament materials); Ex. 1005, [0081] (identifying different seal module materials).) POSITAs would have been motivated to adjust Schaffer’s hemostasis valve to prevent blood leaks because that is the valve’s purpose. (Ex. 1003, ¶¶166-167.) POSITAs would have reasonably expected success in making such adjustments. (*Id.*)

2. Hartley

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

closes around an instrument, for instance a catheter, passed through the valve.” (*Id.*, [0006].)

A POSITA would have recognized that Hartley’s string constricts and seals the lumen of the hemostasis valve where a pressure differential exists across the valve for the same reasons as Schaffer’s valve. (*Supra* §VI.E.1; Ex. 1003, ¶168.) 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 Hartley’s string. (*Id.*, ¶169.)

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 so that it did. (*Supra* §VI.E.1; Ex. 1003, ¶170.)

3. Eller

Eller’s hemostasis valve prevents fluid flow through the sleeve when the actuator is in the closed position (Ex. 1007, Abstract, 12:14-17, 15:21-40, 17:47-18:8, Figs. 10A-10C.) Eller further discloses tests performed on valves having different sleeves that show no leaks despite a pressure difference across the valve. (*Id.*, 36:25-37:27.) Eller’s results confirm that Eller’s wire member is suitable for constricting and sealing a hemostasis valve lumen , even when a pressure differential exists between the proximal and distal ends of the valve. (Ex. 1003, ¶¶171-172.)

POSITAs would have reasonably expected Eller’s wire member to behave in the same way to seal Schaffer’s seal module when Schaffer’s actuator buttons are in the first, undepressed position, even when a pressure differential exists between the proximal and distal ends of the lumen. (*Id.*, ¶174; *supra* §§VI.E.1-2.)

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 to the valve as described in the Schaffer ground. (*Supra* §§VI.E.1-2; Ex. 1003, ¶175.)

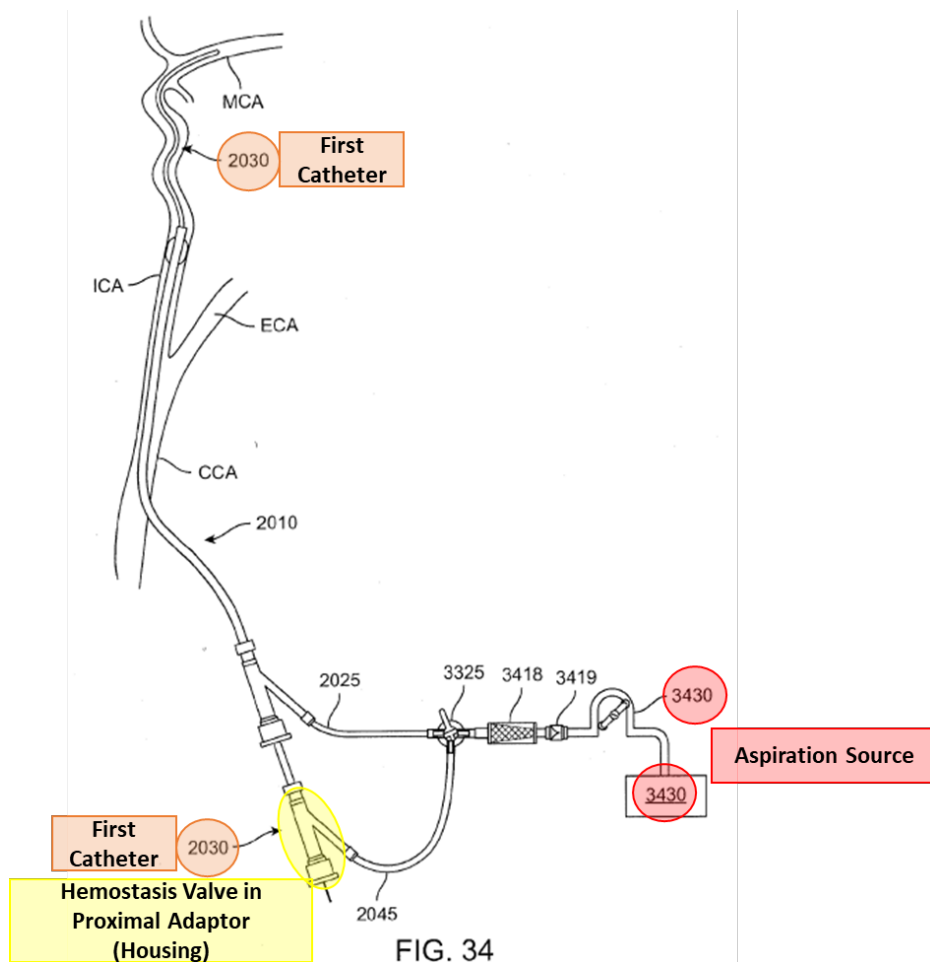
F. Claim 6

Claim 6 recites the “vacuum aspiration system of claim 1 wherein, when the first member and the second member of the actuator are in the first position, the lumen of the tubular member is configured to remain constricted and sealed when vacuum pressure is applied to a volume outside the lumen and adjacent to either a first end or a second end of the tubular member.” Garrison combined with Schaffer and optionally Hartley or Eller renders claim 6 obvious. (Ex. 1003, ¶¶176-182.)

Schaffer’s 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 August 2018 would have understood that syringes were used to generate negative pressure for aspiration. (*See e.g.*, Ex. 1011, [0071] (“The flow line 905

may also be connected to an aspiration source such as a pump or syringe.”); *supra* §VI.A.1; Ex. 1003, ¶177.)

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 August 2018 to apply vacuum pressure through the catheter. (Ex. 1003, ¶178.) As shown below, Garrison discloses an aspiration catheter 2030 having a hemostasis valve:

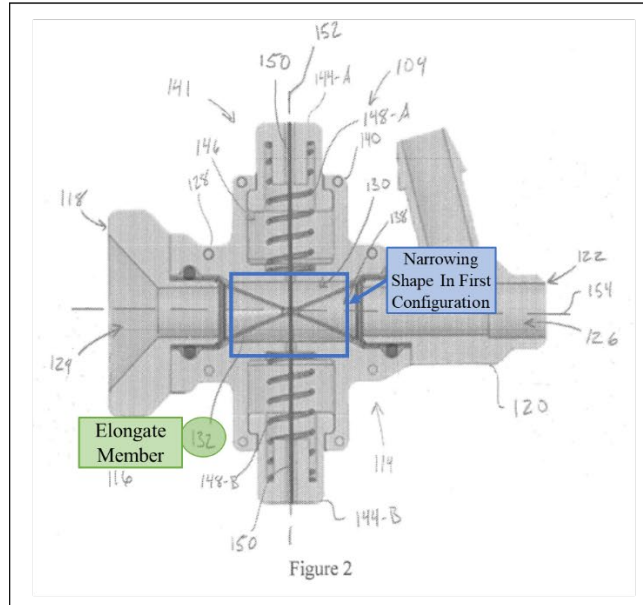


(Ex. 1011, [0098]; *supra* §VI.A.2.)

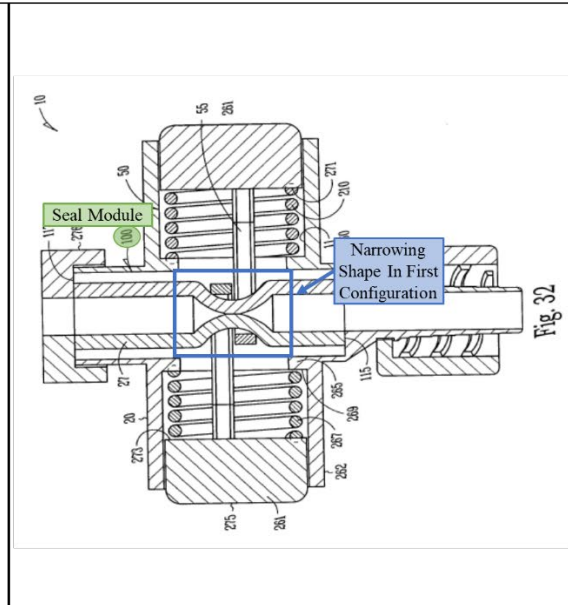
Given the common practice of using hemostasis valves with aspiration sources in August 2018 (such as Schaffer’s syringe) and Schaffer’s disclosures discussed in claim 5, POSITAs would have understood that when Schaffer’s actuator buttons remain in the first, undepressed position, the central lumen of 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, ¶179; Ex. 1005, [0008], [0077]; *supra* §VI.E.) The lumen on Schaffer’s valve is held in the closed position by the springs/buttons pulling on the actuating members. A POSITA would not have expected the vacuum pressure applied through a catheter inserted into a patient to be strong enough to overwhelm this spring force. (Ex. 1003, ¶179.) 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 ’519 application allegedly incorporated into the ’005 patent regarding sealing under vacuum pressure attributes the ability to maintain a seal to the narrowing shape of the valve. (Ex. 1017, [0055].) Schaffer’s elongate member (seal module 100) also has a “narrowing shape” when the actuator buttons are in the first position:

'519 Application



Schaffer



(*Id.*, Fig. 2 (left); Ex. 1005, [0077], Fig. 32 (right).) Because Schaffer discloses the same structure that the '519 application claims to enable sealing under vacuum pressure, PO cannot argue that fails to disclose this limitation.

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 constrict and seal Schaffer's tubular member when Schaffer's actuator buttons are in the first position, even when a vacuum pressure is applied to a volume outside of the valve's lumen. (Ex. 1003, ¶181; 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, ¶181.) A POSITA would not have expected the

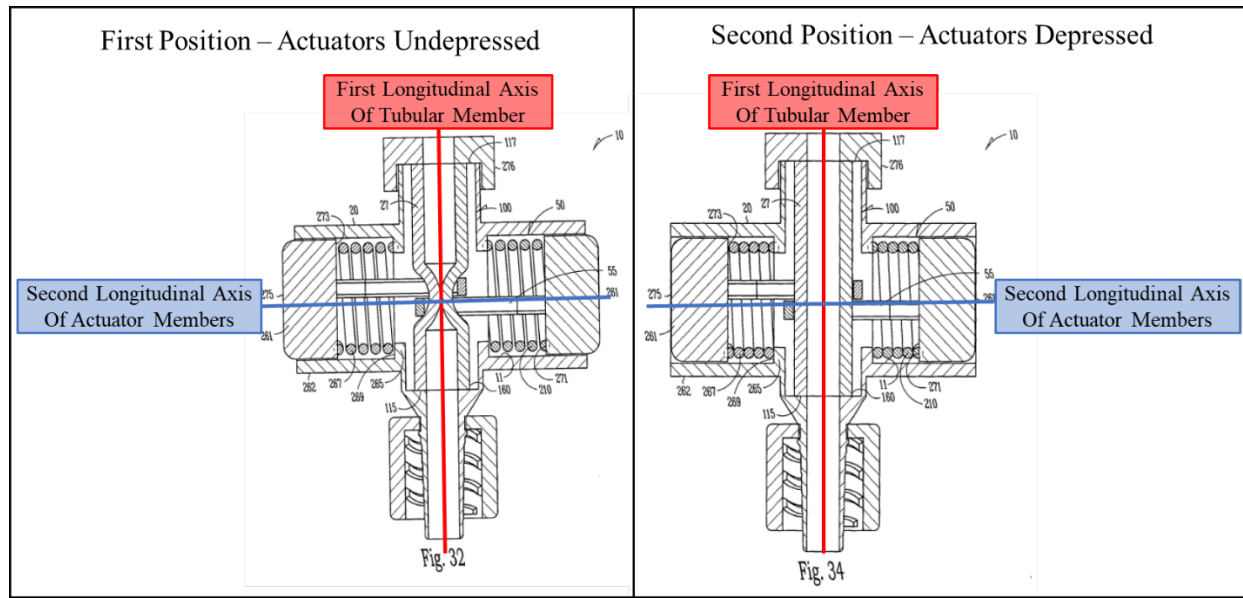
vacuum to exert a force on the string/wire member and springs that would open the valve. (*Id.*)

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 to ensure a seal. (*Supra* §VI.E; Ex. 1003, ¶182.) POSITAs would have been motivated to do so because the purpose of Schaffer's valve is to prevent leaks when a catheter is inserted into a patient, including aspiration catheters. (*Id.*) POSITAs would have reasonably expected success in making these adjustments for the reasons explained in claim 5. (*Id.*)

G. Claim 7

Claim 7 recites the “vacuum aspiration system of claim 1 wherein the lumen of the tubular member extends a long [sic] a first longitudinal axis, wherein the first member and the second member of the 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.” Garrison combined with Schaffer and optionally Hartley or Eller renders claim 7 obvious. (Ex. 1003, ¶¶183-184.)

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

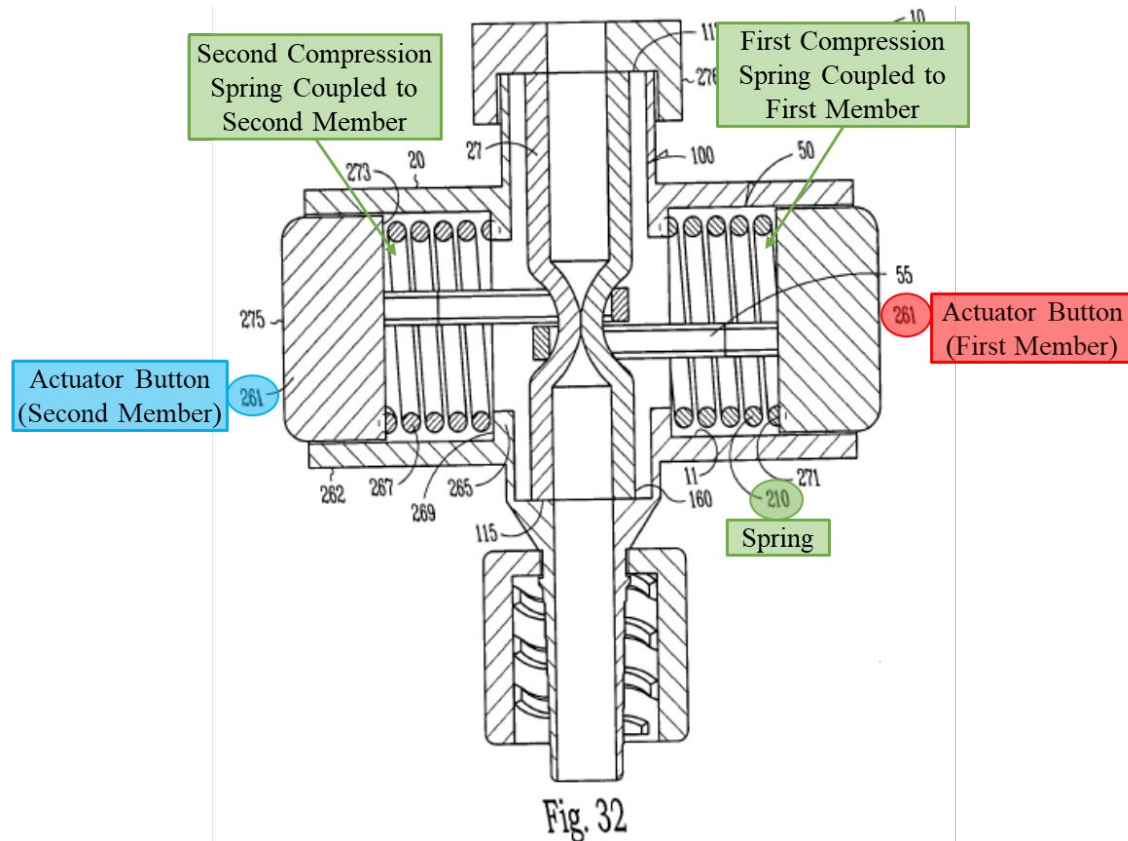


(Ex. 1005, [0077], Figs. 31-34; Ex. 1003, ¶184.)

H. Claim 8

Claim 8 recites the “vacuum aspiration system of claim 1 wherein the biasing system comprises a first compression spring coupled to the first member and a second compression spring coupled to the second member.” Garrison combined with Schaffer and optionally Hartley or Eller renders claim 8 obvious. (Ex. 1003, ¶¶185-186.)

Schaffer’s biasing system includes two compression springs that are coupled to the proximal end 273 of each actuator button 261:



(Ex. 1005, [0076], Figs. 31-34; Ex. 1003, ¶186.)

I. Claim 9

Claim 9 recites the “vacuum aspiration system of claim 1 wherein, in the first position, the first member and the second member of the actuator pull the filament to circumferentially constrict the tubular member such that the lumen is constricted and sealed.” Garrison combined with Schaffer and optionally Hartley or Eller renders claim 9 obvious. (Ex. 1003, ¶¶187-188.)

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, ¶188.) If

Schaffer's 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, ¶188.)

J. Independent Claim 10

Claim 10 is rendered obvious by Garrison combined with Schaffer and optionally Hartley or Eller. (Ex. 1003, ¶¶189-202.) The only differences between claims 1 and 10 are with respect to the hemostasis-valve limitations. Garrison discloses the limitations relating to the aspiration system for the reasons provided in claim 1. (*Supra* §§VI.A.1-7.)

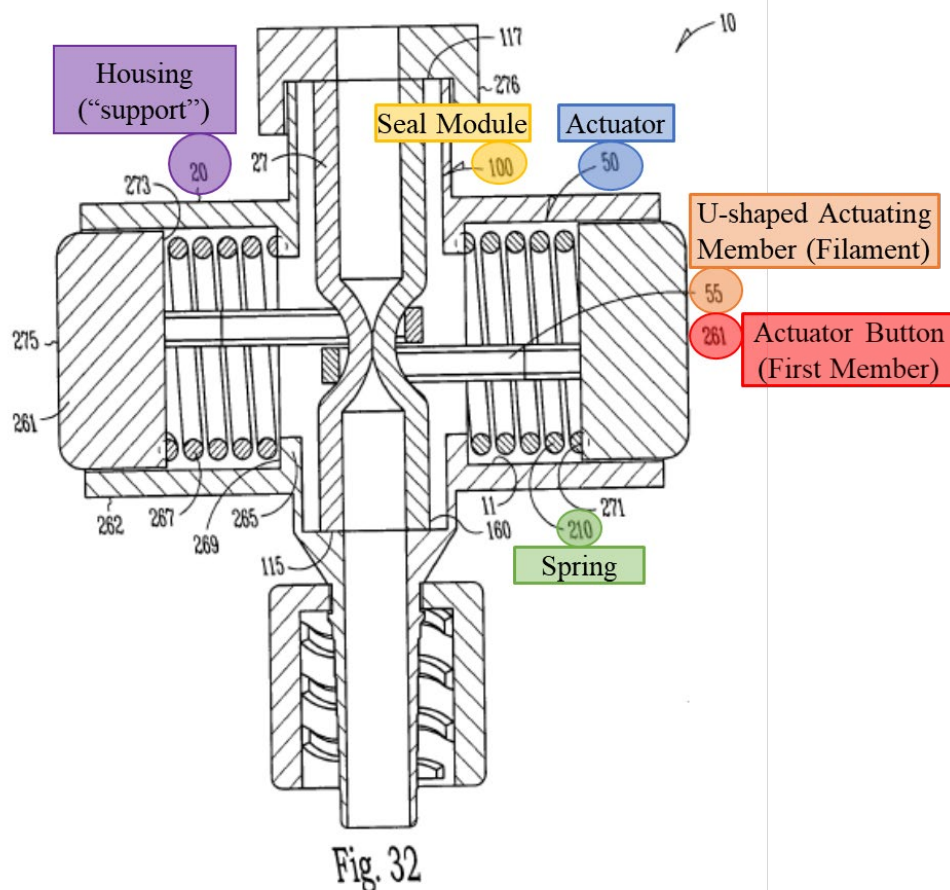
1. Hemostasis Valve

Petitioner address the new hemostasis-valve limitations below and incorporates its discussion from claim 1 for the duplicated limitations and the motivation to combine Garrison with Schaeffer and optionally Hartley or Eller. (Ex. 1003, ¶¶190-202.)

a. Support

Claim 10 recites that the hemostasis valve comprises “a support.” Schaffer discloses this limitation. (Ex. 1003, ¶¶191-192.)

Schaffer's hemostasis valve includes a housing 20:

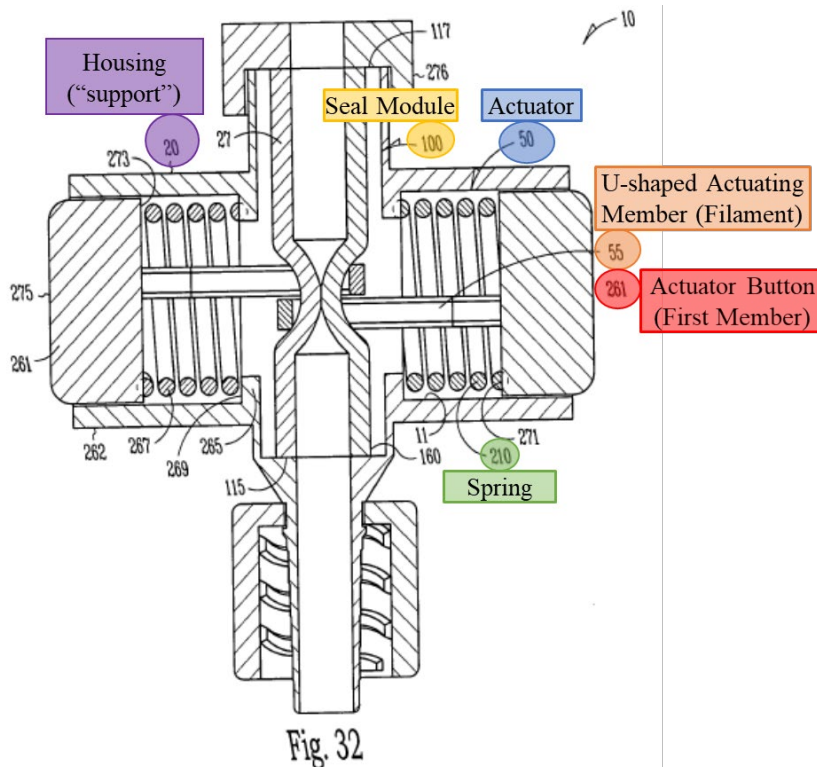


(Ex. 1005, [0076], Fig. 32.) “[T]he housing 20 is sized and configured to hold and control a composite seal module 100, a portion of an actuator 50, and an actuating member 55.” (*Id.*, [0046].) The housing 20 therefore supports the other components and is a “support.” (Ex. 1003, ¶192.)

b. Actuator

Claim 10 recites that the hemostasis valve comprises “an actuator having a [sic] least a first member movably coupled to the support.” Schaffer discloses this limitation. (Ex. 1003, ¶¶193-194.)

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



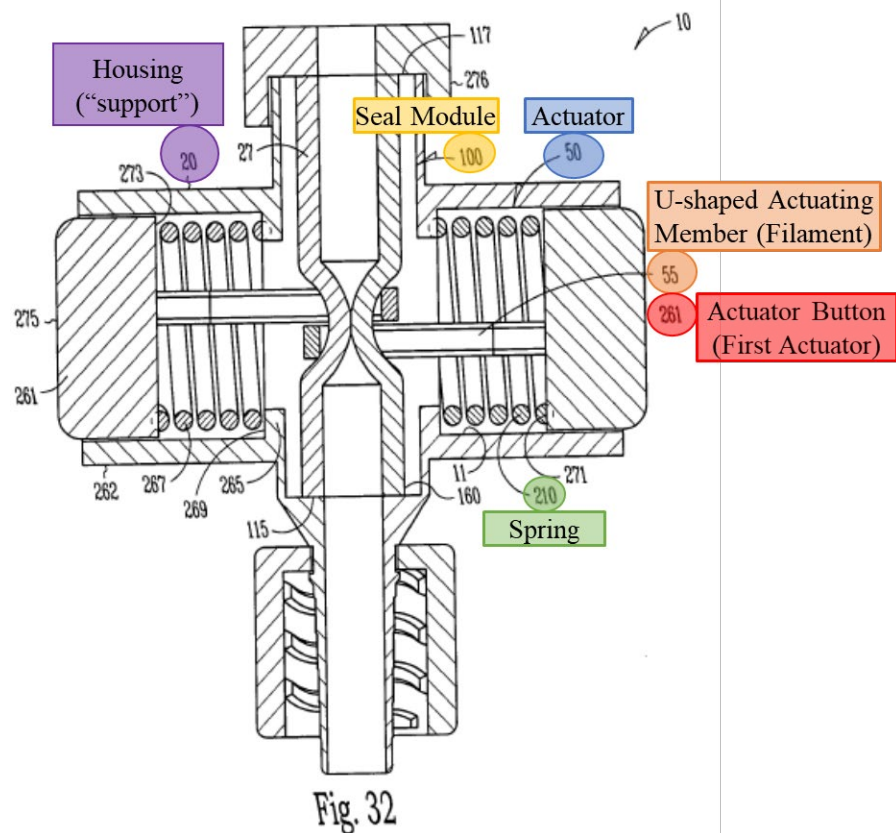
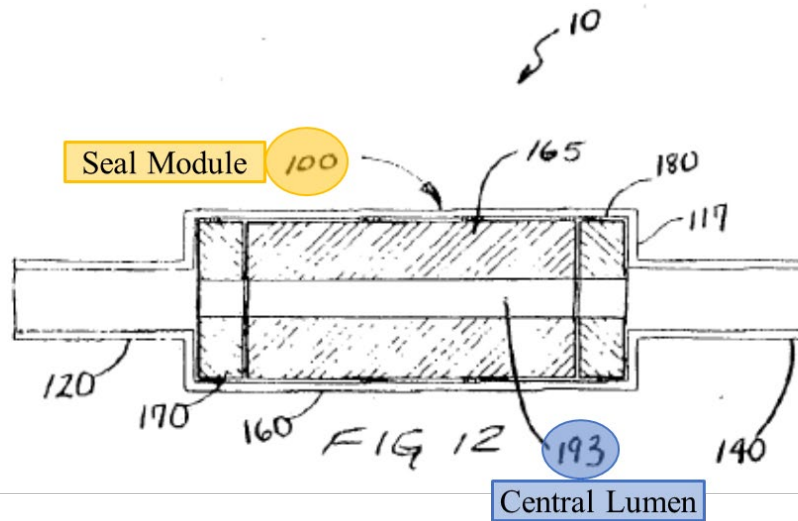
(*Id.*, [0076], Fig. 32.) Thus, Schaeffer's actuator button (first member) is movably coupled the housing (support). (Ex. 1003, ¶194.)

c. Tubular Sidewall

Claim 10 recites that the hemostasis valve comprises “a collapsible tubular sidewall defining a lumen carried by the support.” Schaffer discloses this limitation. (Ex. 1003, ¶¶195-197.)

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

[0077].) The seal module 100 defines a lumen 193:



(*Id.*, [0058], [0075], Figs. 12, 32.) As shown above, the seal module is carried by the housing 20 (i.e., support). (*Id.*) Thus, Schaeffer’s seal module satisfies this limitation. (Ex. 1003, ¶¶196-197.)

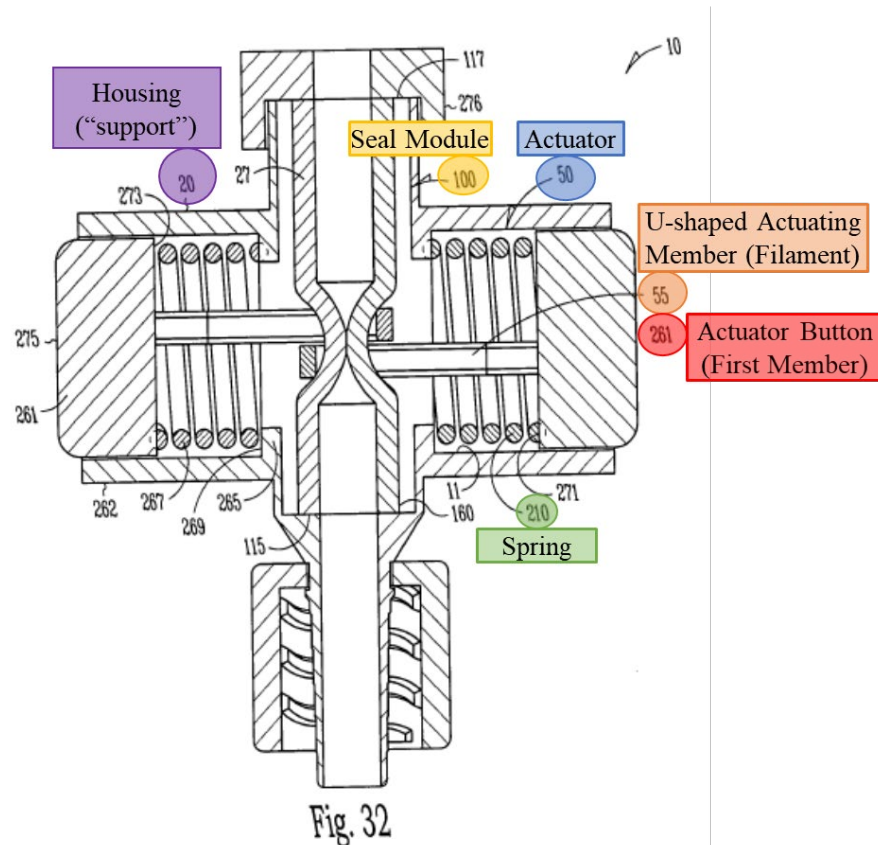
d. Filament

Claim 10 recites that the hemostasis valve comprises “a filament formed in a loop around the tubular sidewall, the filament having at least a first end portion extending away from the loop to the first member.” Schaffer discloses this limitation or renders it obvious with Hartley or Eller for the reasons explained in claims 1 and 3. (*Supra* §§VI.A.8.b.ii; VI.C.)

e. First Spring

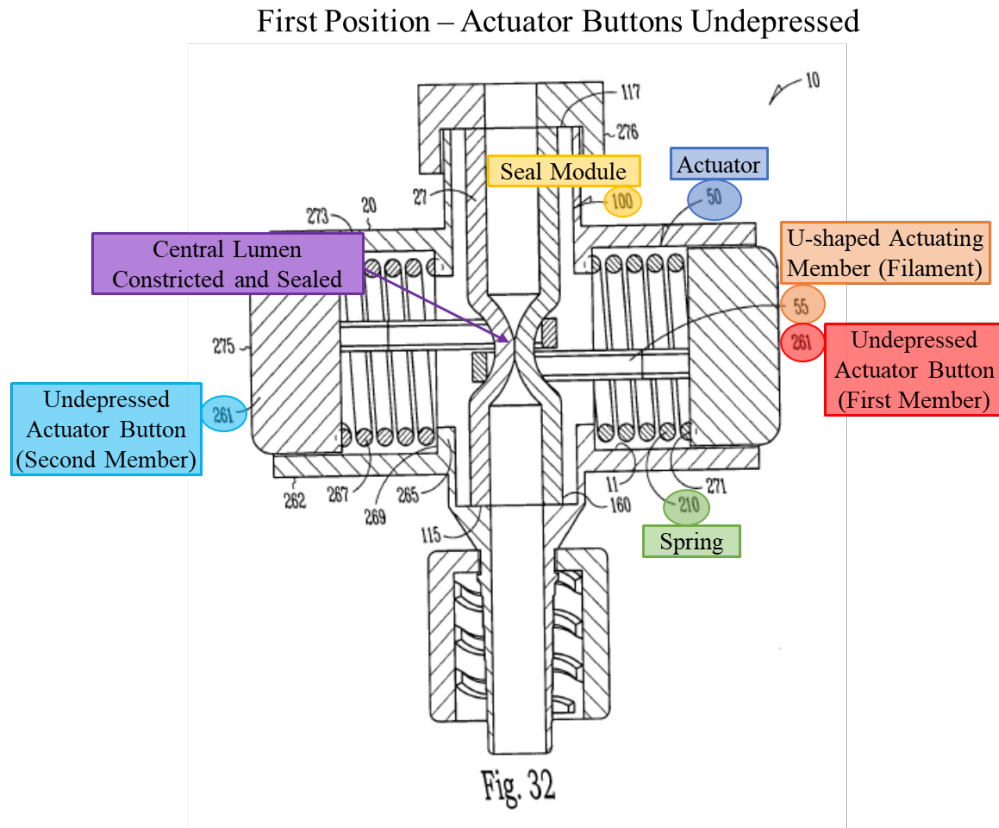
Claim 10 finally recites that the hemostasis valve comprises “a first spring configured to move the first member in a direction that pulls the first end portion such that a diameter of the lumen decreases in response to reducing a diameter of the loop.” Schaffer discloses this limitation. (Ex. 1003, ¶¶199-202.)

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



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

Schaffer's actuator buttons are "movable from a first position to a second position." (*Id.*) In Schaffer's first position, shown in Figure 32, the spring exerts a force on the buttons and pulls the first end portion of the actuating member (filament) to constrict the valve lumen:



(*Id.*, [0008], [0077], Fig. 32; *see also* VI.A.8.b.ii.a; Ex. 1003, ¶201.)

The force created by the springs causes the actuating members to circumferentially constrict around and collapse the seal module, preventing the flow of fluid through the valve. (Ex. 1005, [0077]; Ex. 1003, ¶202.) The loop formed by the actuating members decreases in diameter as the first end portion of the actuating member is pulled by the buttons/spring. (Ex. 1005, [0077], Figs. 31-34; Ex. 1003, ¶202.) Schaffer's spring would have the same effect on the loop formed by Hartley's string or Eller's wire member if either were substituted for Schaffer's actuating members. (Ex. 1003, ¶202.)

K. Claim 11

Claim 11 recites the “vacuum aspiration system of claim 10, further comprising a second member movably coupled to the support.”

Schaffer discloses the second member (i.e., actuator button) recited in claim 11 for the reasons explained in claims 1 and 10. (*Supra* §§VI.A.8.b.i; VI.J.1.b.) Therefore, Garrison combined with Schaffer and optionally Hartley or Eller renders claim 11 obvious. (Ex. 1003, ¶203.)

L. Claim 12

Claim 12 recites the “vacuum aspiration system of claim 11 wherein the filament further comprises a second end portion extending away from the loop to the second member.” Schaffer discloses the “second end portion” in claim 12 or renders it obvious in combination with Hartley and Eller for the reasons explained for claim 1. (*Supra* §VI.A.8.B.ii.) Therefore, Garrison combined with Schaffer and optionally Hartley or Eller renders claim 12 obvious. (Ex. 1003, ¶204.)

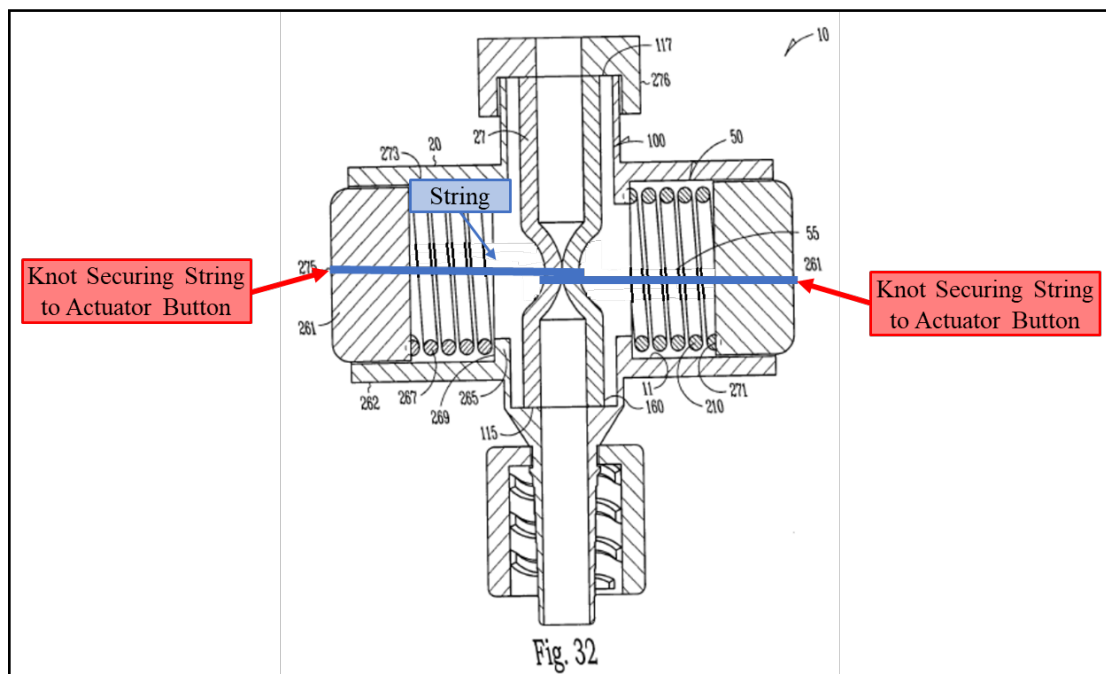
M. Claim 13

Claim 13 recites the “vacuum aspiration system of claim 12 first end portion, the loop, and the second end portion are one continuous filament.” Garrison in combination with Schaffer and Hartley or Eller renders claim 13 obvious. (Ex. 1003, ¶¶205-207.)

1. Schaffer-Hartley

Hartley discloses a continuous string (i.e., filament) that forms a loop around the outer surface of the valve lumen. (*Supra* §VI.A.8.b.ii.b.) As explained in claims 1 and 3, POSITAs would have been motivated to, and reasonably expected success in, looping Hartley’s string around Schaffer’s seal module:

Demonstrative Illustration Schaffer + Hartley’s String



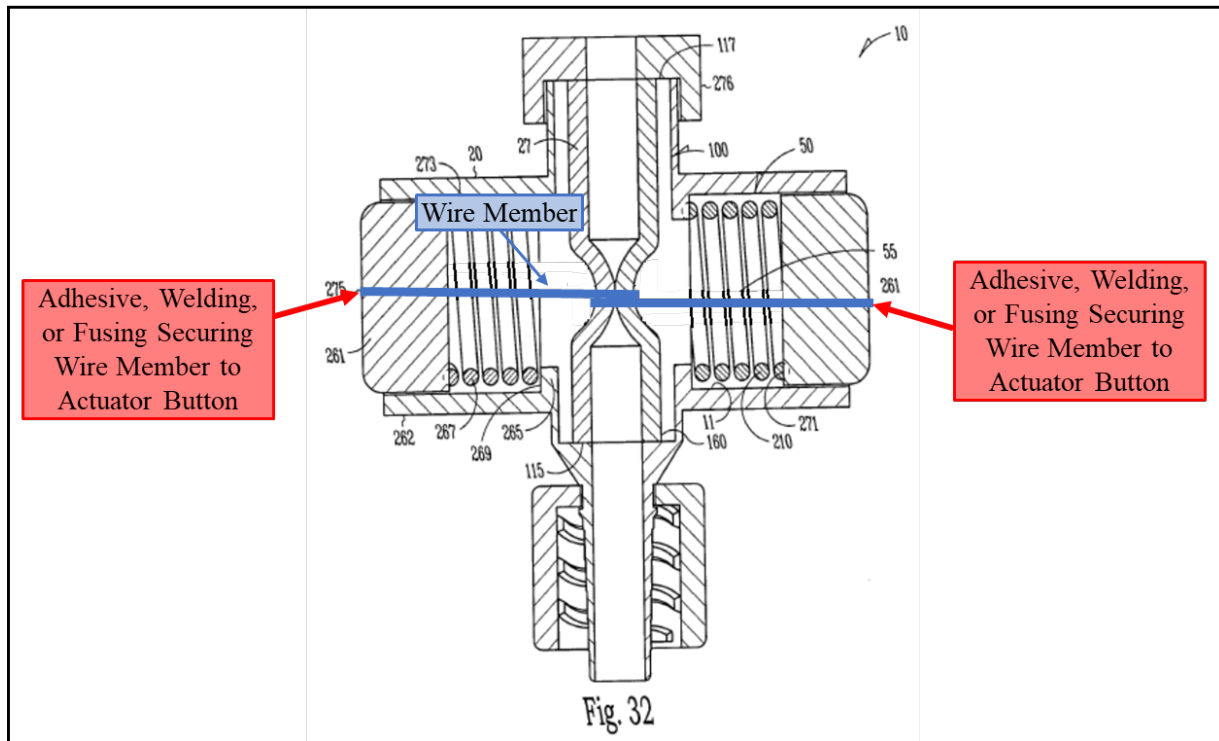
(*Supra* §§VI.A.8.b.ii.b; VI.C.2.) In this configuration, the loop, the first end portion, and the second end portion of the string are a continuous filament. (Ex. 1003, ¶207.)

2. Schaffer-Eller

Eller discloses a continuous wire member (i.e., filament) that can form a loop around the outer surface of the valve lumen. (*Supra* §VI.C.3.) As explained in

claims 1 and 3, POSITAs would have been motivated to, and reasonably expected success in, looping Eller’s wire member around Schaffer’s seal module:

Demonstrative Illustration Schaffer + Eller’s Wire Member



(*Supra* §§VI.A.8.b.ii.c; VI.C.3.) In this configuration, the loop, the first end portion, and the second end portion of the member are a continuous filament. (Ex. 1003, ¶208.)

N. **Claim 14**

Claim 14 recites the “vacuum aspiration system of claim 12 wherein first member and the second member are biased in a direction that places the first end portion and the second end portion under sufficient tension to reduce the diameter

of the lumen and provide a seal around a device extending through the lumen.” Schaffer discloses the limitations recited in claim 14 for the reasons explained for claim 1. (*Supra* §VI.A.8.c.) Therefore, Garrison combined with Schaffer and optionally Hartley or Eller renders claim 14 obvious. (Ex. 1003, ¶208.)

O. Claim 15

Claim 15 recites the “vacuum aspiration system of claim 12 wherein the first member and the second member are biased in a direction that places the first end portion and the second end portion under sufficient tension to close the lumen.” Schaffer discloses the limitations recited in claim 15 for the reasons explained for claim 1. (*Supra* §VI.A.8.c.) Therefore, Garrison combined with Schaffer and optionally Hartley or Eller renders claim 15 obvious. (Ex. 1003, ¶209.)

VII. GROUND 4: GARRISON COMBINED WITH HARTLEY AND ELLER

A. Independent Claim 1

Claim 1 is rendered obvious by Garrison combined with Hartley and Eller. (Ex. 1003, ¶¶215-243.)

1. Preamble and Limitations 2-7

Garrison discloses the preamble (if limiting) and the catheter limitations for the reasons provided in Grounds 1-3. (*Supra* §§VI.A.1-7.)

2. Hemostasis Valve

Garrison combined with Hartley and Eller renders the hemostasis-valve limitations obvious. (Ex. 1003, ¶¶217-243.)

Garrison’s catheter 2030 (i.e., first catheter) includes a hemostasis valve in a housing. (Ex. 1011, [0098]; *supra* §§VI.A.2, VI.A.8.) Garrison explains that different types of hemostasis valves can be combined with the catheter. (*Id.*)

Hartley discloses a rotating hemostasis valve. (Ex. 1006, [0004].) A POSITA would have been motivated, and found it obvious, to combine Hartley’s hemostasis valve with Garrison’s system for several reasons. (Ex. 1003, ¶¶219-225.)

First, Garrison expressly suggests combining its aspiration system with a “rotating hemostasis valve.” (Ex. 1011, [0062], [0098].) Hartley discloses a rotating hemostasis valve and, therefore, a POSITA would have been motivated to combine, and reasonably expected success in combining, Hartley’s valve with Garrison. (Ex. 1003, ¶220.)

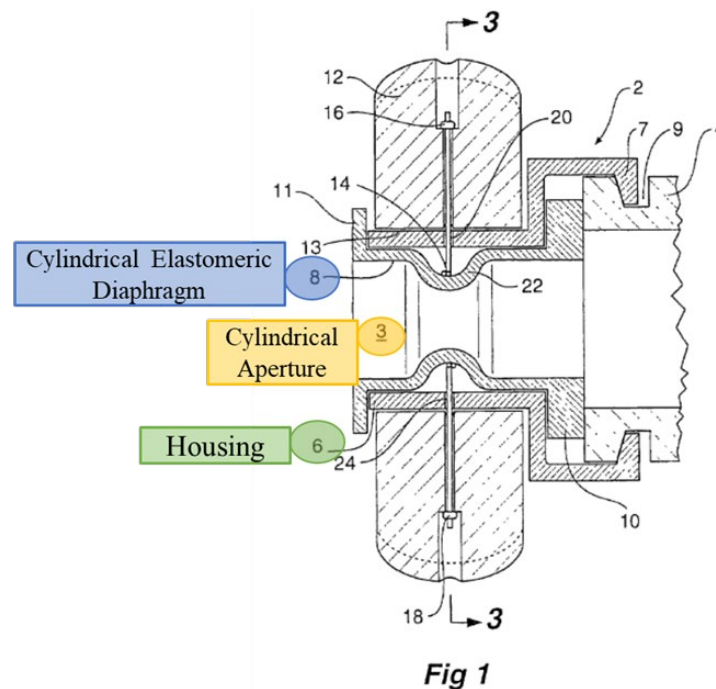
Second, combining Hartley’s valve with Garrison’s catheter 2030 would have merely entailed the combination of known elements (Hartley’s hemostasis valve and Garrison’s catheter 2030) according to known methods (attaching the valve to a proximal portion of the adaptor/hub or forming it integrally with the adaptor/hub) to yield the predictable result of reducing leakage through the valve. *KSR*, 550 U.S. at 416; (Ex. 1011, [0062], [0098], Ex. 1003, ¶221.)

Third, POSITA’s in August 2018 had a finite number of predictable hemostasis valves to choose and would have found it obvious to use any of these valves with Garrison’s system. (Ex. 1003, ¶222.)

As explained below, Hartley combined with Eller renders the additional hemostasis-valve limitations in claim 1 obvious. (*Id.*, ¶¶226-243.)

a. Tubular Member

Hartley’s valve includes a “cylindrical housing 6 into which is received a cylindrical elastomeric diaphragm 8 ... [that] defines a cylindrical aperture 3 therethrough”:



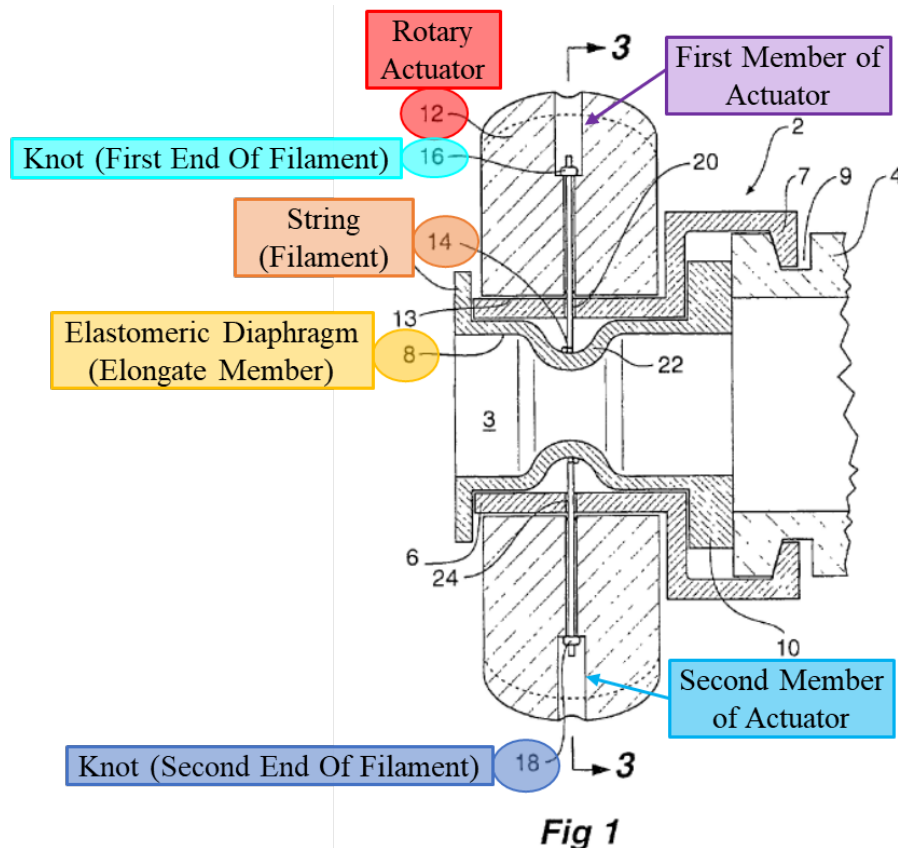
(Ex. 1011, [0031], Fig. 1.) Hartley’s cylindrical diaphragm can close “around an instrument, for instance a catheter, passed through the valve.” (*Id.*, [0006].) Accordingly, Hartley’s elastomeric diaphragm satisfies this limitation. (Ex. 1003, ¶227.)

b. Constricting Mechanism

Hartley discloses the “constricting mechanism” in claim 1. (*Id.*, ¶¶228-235.)

i. Actuator

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



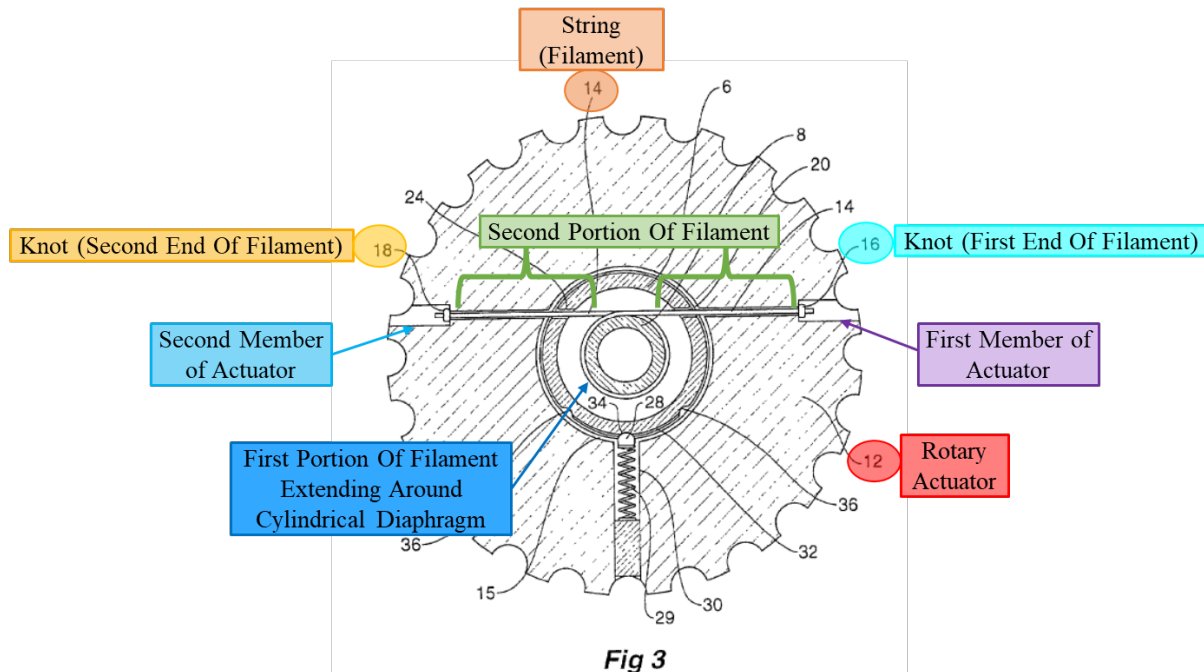
(Ex. 1006, [0031], Fig. 1.)

The actuator portions secured to the first and second ends of the string 14 are the first and second members claimed in the '005 patent. (Ex. 1003, ¶229.) As discussed below, Hartley's first and second members are coupled to the first and second ends of the string 14 (i.e., filament). (*Infra* §VII.A.2.b.ii.) The first and second members are also “moveable between (a) a first position wherein the filament circumferentially constricts the lumen to create a seal and (b) a second position

wherein the filament is moved to at least partially open the lumen.” (Ex. 1003, ¶231.) For example, Hartley discloses that “[r]otation of the rotary actuator 12 with respect to the cylindrical housing 6 will cause the string 14 to be pulled in both directions at once and hence the cylindrical diaphragm 8 to be constricted.” (Ex. 1006, [0031], [0034], Fig. 4.) Hartley further discloses that “[r]otation of the rotary actuator back to the central position ... will cause the sutures to loosen again so that the resilient cylindrical diaphragm will retain its original shape as shown in FIGS. 1 and 3.” (*Id.*) Thus, Hartley discloses the actuator in claim 1. (Ex. 1003, ¶¶228-231.)

ii. Filament

Hartley’s valve includes a filament (e.g., string) having “a first portion extending around at least a portion of the tubular member” and “a second portion having a first end extending from the first portion in one direction and a second end extending from the first portion in another direction” for the reasons provided in Grounds 1-3 (*Supra* §VI.A.8.b.ii.b; Ex. 1003, ¶¶232-234.)



(Ex. 1006, [0031], Fig. 3.)

c. Biasing System

Hartley combined with Eller renders obvious the claimed “biasing system.”

(Ex. 1003, ¶¶236-243.)

Eller's hemostasis valve includes "a housing 16, an actuator 18, a sleeve 20, [and] a first wire member 22":

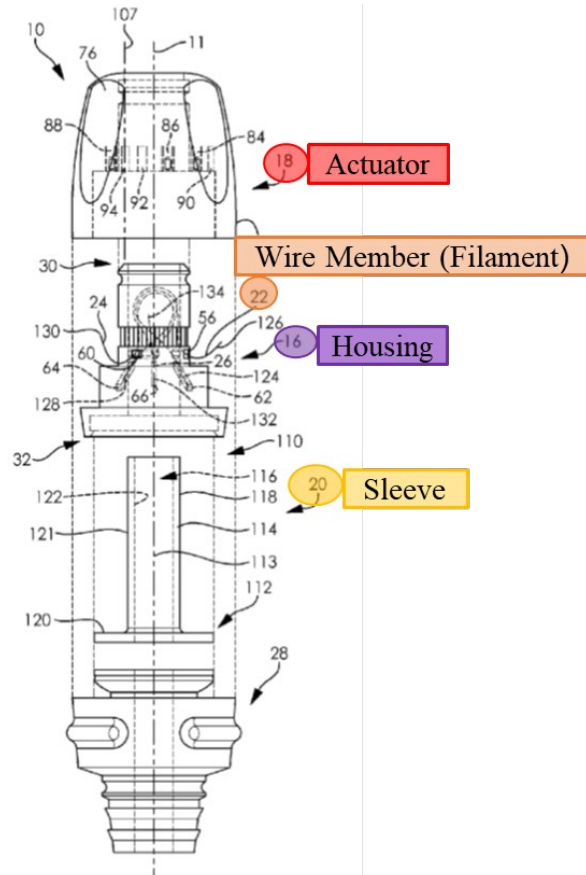


FIG. 2

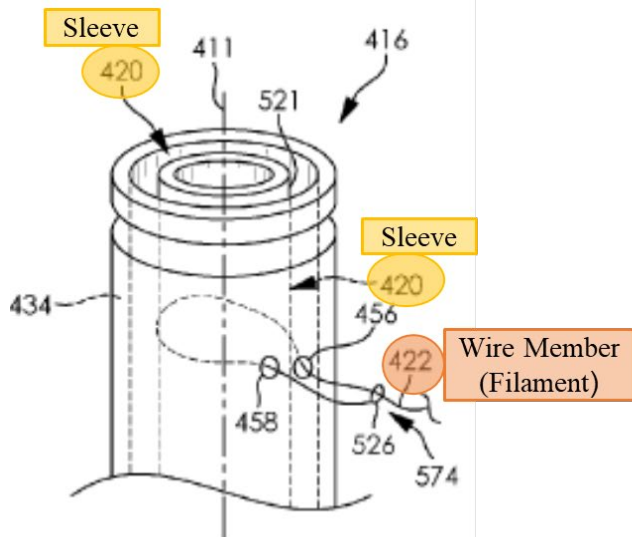


FIG. 16

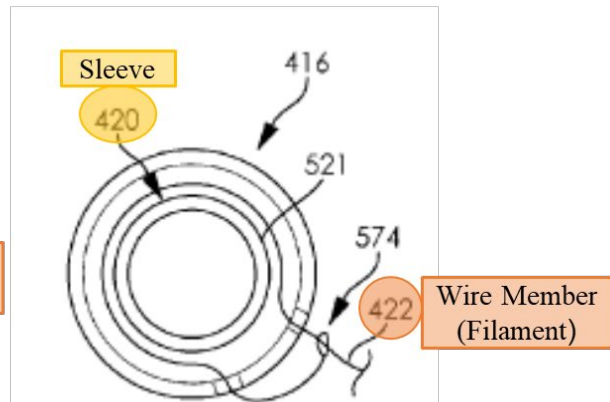


FIG. 17

(Ex. 1007, 5:1-5, Figs. 2, 16-17.) Eller’s valve has two configurations. “In the first configuration, the passageway 116 defined by the sleeve 20 is open such that fluid can pass through the passageway. In the second configuration, the passageway 116 defined by the sleeve 20 is closed such that fluid is prevented from passing through the passageway 116.” (*Id.*, 12:13-18.) Eller discloses that the valve “can be biased to the second configuration.” (*Id.*, 19:22-30.) As an example, Eller teaches “a torsion spring can be positioned between the housing and the actuator and can be attached to the housing and the actuator such that when no outside forces are applied to the selective fluid barrier valve device, the spring positions the actuator in the second position.” (*Id.*)

POSITAs would have been motivated to combine Eller’s biasing system (e.g., torsion spring) with Hartley’s valve for several reasons. (Ex. 1003, ¶238.) First, the biasing system would ensure that Hartley’s valve seals quickly and minimizes blood loss when a catheter is removed through the valve. (*Id.*) Further, the biasing system would ensure that the physician could not inadvertently leave the valve open after removing a device. (*Id.*)

Second, the biasing system can simplify Hartley’s valve. (*Id.*, ¶239.) For example, the biasing system eliminates the need for the operator to manually seal the valve prior to or during the procedure. (*Id.*) Eliminating this step could make the procedure simpler for the physician. (*Id.*)

Third, adding the biasing system to Hartley’s valve would merely entail the combination of known elements (Hartley’s valve and Eller’s torsion spring) according to known methods (positioning a torsion spring between the valve housing and actuator) to yield the predictable result of reducing leaks. *See KSR*, 550 U.S. at 416; (Ex. 1003, ¶240.)

POSITAs would have reasonably expected success in combining Eller’s torsion spring with Hartley’s valve because Hartley and Eller are from the same field of endeavor and share the same objective of providing seals around devices inserted through the valve during intravascular procedures. (Ex. 1006, [0004]; Ex. 1007, Abstract, 12:15-18, 15:21-40, 17:47-18:8; Ex. 1003, ¶241.) Additionally, the valves in Hartley and Eller share many features, including: a housing, a rotational actuator mounted to the housing, a tubular sleeve/diaphragm extending through the actuator, and a constricting string/wire extending around the sleeve/diaphragm. (*See, e.g.*, Ex. 1006, [0031], Figs. 1-3; Ex. 1007, 5:1-12, Figs. 1-10; Ex. 1003, ¶242.) Eller also teaches positioning a torsion spring “between the housing and the actuator.” (Ex. 1007, 19:26-30.) The positioning of a torsion spring between two components that rotate with respect to each other was conventional in August 2018 and would have been within a POSITA’s skill. (Ex. 1003, ¶243.) Consequently, POSITAs would have reasonably expected that a similar arrangement could be successfully used to

attach a torsion spring to Hartley’s housing and rotary actuator to bias the actuator toward the closed position. (*Id.*)

B. Claim 2

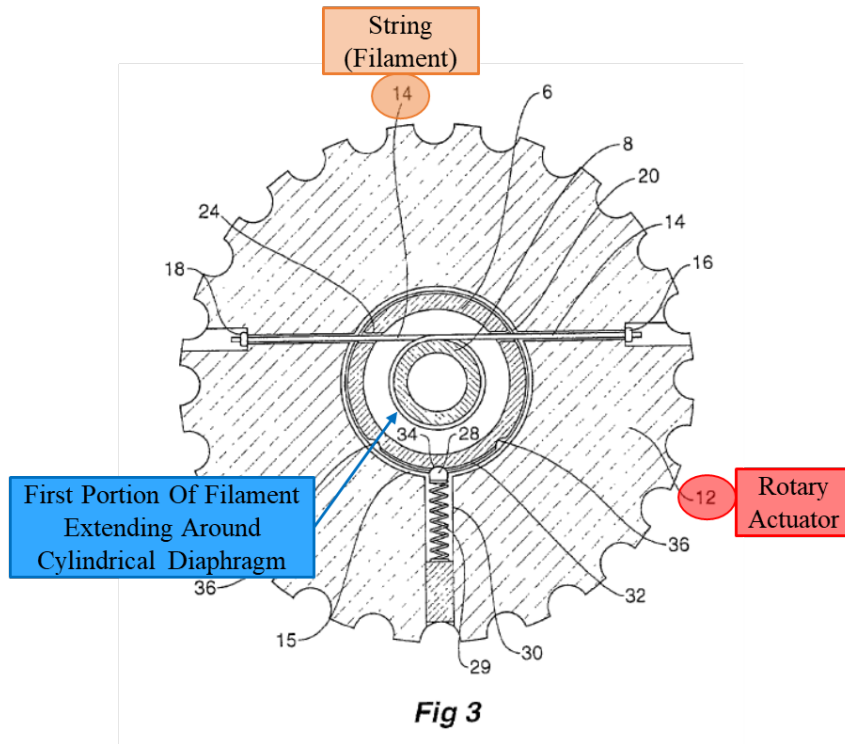
Garrison combined with Hartley and Eller renders claim 2 obvious. (Ex. 1003, ¶¶244-245.)

Hartley’s cylindrical diaphragm (i.e., tubular member) “may be constructed from a [sic] elastomeric material such as silicone rubber” and can be constricted by the string. (Ex. 1006, [0016].) Thus, the cylindrical diaphragm is pliable. (Ex. 1003, ¶245.)

C. Claim 3

Garrison combined with Hartley and Eller renders claim 3 obvious. (Ex. 1003, ¶¶246-247.)

Hartley discloses that its string “is wound preferably twice around the cylindrical diaphragm”:



(Ex. 1006, [0031], Fig. 3.) Hartley’s string therefore includes a first portion that “extends in a loop completely around the tubular member.” (*Id.*; Ex. 1003, ¶247.)

D. Claim 5

Garrison combined with Hartley and Eller renders claim 5 obvious. (Ex. 1003, ¶¶248-251.)

Hartley’s valve “can be controlled to vary the size of the aperture through the valve and be flexible so that a seal may be formed against an instrument or other object inserted through the access valve.” (Ex. 1006, [0004].) Hartley further teaches that “[d]epending on how much the flexible member is pulled radially and/or tangentially the cylindrical diaphragm can be completely constricted to prevent fluid

flow through the valve or can be constricted to the extent that it closes around an instrument, for instance a catheter, passed through the valve.” (*Id.*, [0006].)

As explained in Grounds 1-3, a pressure differential exists between the proximal and distal ends of a catheter inserted into a patient’s vasculature. (*Supra* §VI.E.) The purpose of Hartley’s valve is to maintain a seal when devices are inserted through the valve into the patient’s vasculature. (Ex. 1003, ¶250.) Thus, POSITAs would have reasonably expected that Hartley’s valve would maintain the lumen of the cylindrical diaphragm in a constricted, sealed state when the actuator is in the first, closed position, even when a pressure differential exists between the proximal and distal ends of the lumen. (*Id.*, ¶¶250-251.)

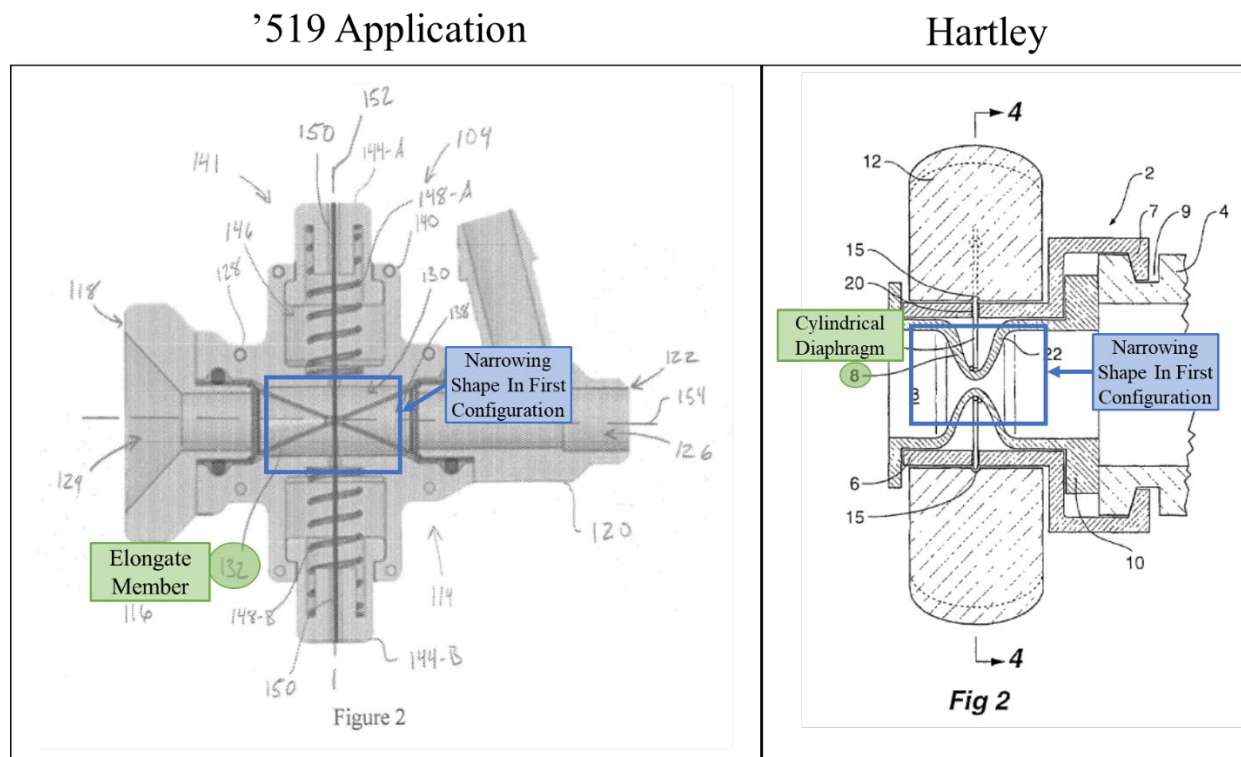
E. Claim 6

Garrison combined with Hartley and Eller renders claim 6 obvious. (Ex. 1003, ¶252-256.)

As explained in Grounds 1-3, POSITAs commonly used hemostasis valves with suction devices, such as aspiration catheters, in August 2018 to create a seal during intravascular procedures. (*Supra*, §VI.F.) Given this common practice and Hartley’s disclosures discussed for claim 5, POSITAs would have understood that Hartley’s valve would maintain the lumen of the cylindrical diaphragm in a constricted, sealed state when the actuator is in the first, closed position, even when

a vacuum pressure is applied to a volume outside of the valve's lumen. (Ex. 1003, ¶¶253-254; Ex. 1006, [0003], [0006].)

Moreover, Hartley discloses that its elongate member (cylindrical diaphragm 8) has a “narrowing shape” when the actuator is in in the first (i.e., closed) configuration:



(*Id.*, Fig. 2 (left); Ex. 1006, [0031], Fig. 2⁷ (right).) Accordingly, because Hartley discloses the same structure allegedly incorporated in the '005 patent for sealing the valve in the presence of vacuum pressure, PO cannot argue that Hartley's valve is

⁷Figure 2 of Hartley depicts the valve in a “partially constricted position.” (Ex. 1006, [0026].) The cylindrical diaphragm would have an even narrower shape when fully constricted. (Ex. 1003, ¶255.)

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.” (*Supra* §VI.F; Ex. 1003, ¶255.)

Moreover, to the extent Hartley’s valve did not maintain its seal under vacuum pressure, a POSITA would have found it obvious to adjust the torsion spring strength to apply additional force to seal the valve, adjust the resilience and compressibility of the cylindrical diaphragm that forms the valve’s lumen, and/or adjust the shape, flexibility, and/or dimensions of the string. (Ex. 1003, ¶256.) POSITAs would have been motivated to do so because the purpose of Hartley’s hemostasis valve is to prevent leaks through the valve. (*Id.*) POSITAs would have had a reasonable expectation of success in making such adjustments for the reasons discussed in Grounds 1-3. (*Supra* §VI.F.)

F. Claim 9

Garrison combined with Hartley and Eller renders claim 9 obvious. (Ex. 1003, ¶¶257-258.)

Hartley discloses that “[r]otation of the rotary actuator 12 with respect to the cylindrical housing 6 will cause the string 14 to be pulled in both directions at once and hence the cylindrical diaphragm 8 to be constricted.” (Ex. 1006, [0031].) Hartley therefore discloses the limitations of claim 9. (Ex. 1003, ¶258.)

G. Independent Claim 10

1. Preamble and Limitations 2-7

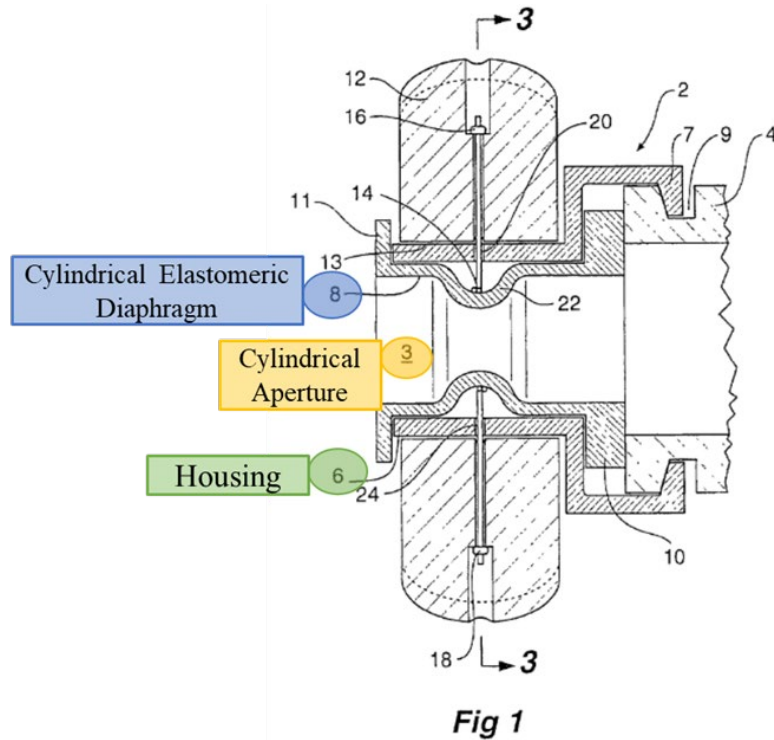
Garrison discloses the preamble (if limiting) and the catheter limitations for the reasons provided in Grounds 1-3. (*Supra* §§VI.A.1-7.)

2. Hemostasis Valve

A POSITA would have been motivated to combine Hartley’s valve with Garrison’s aspiration system with a reasonable expectation of success for the reasons explained for claim 1. (*Supra* §VII.A.2.) As explained below, Hartley and Eller render the additional hemostasis-valve limitations in claim 10 obvious. (Ex. 1003, ¶¶261-265.)

a. Support

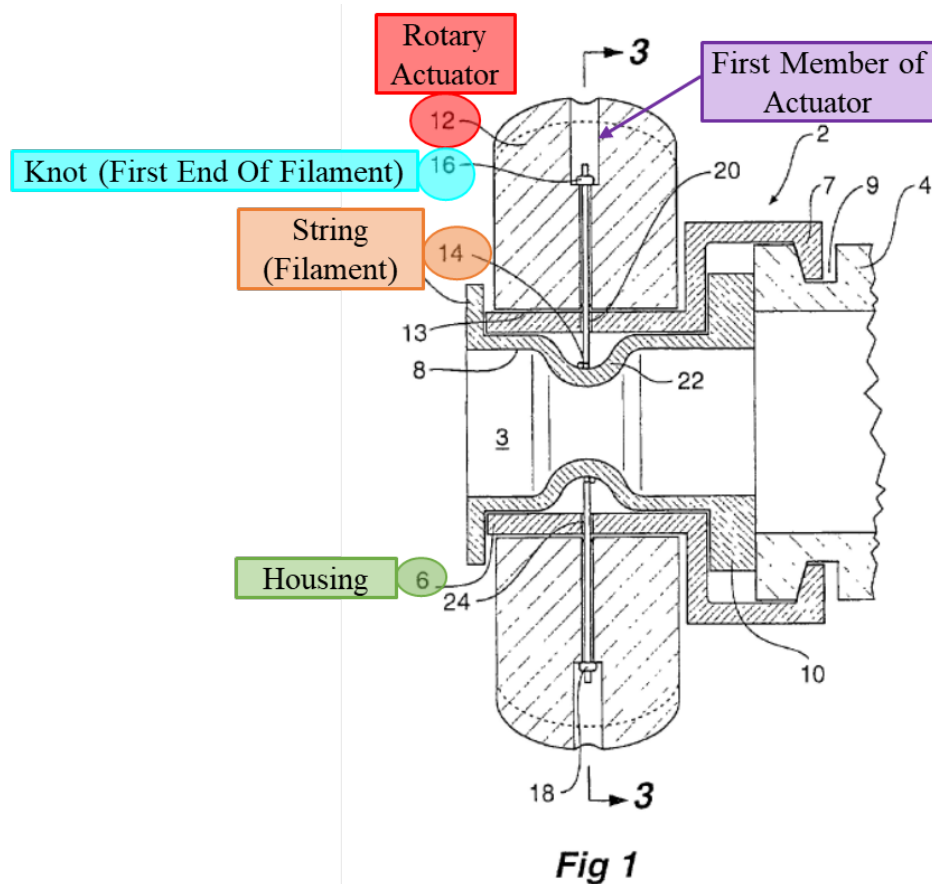
Hartley’s valve includes a “cylindrical housing 6 into which is received a cylindrical elastomeric diaphragm 8 ... [that] defines a cylindrical aperture 3 therethrough”:



(Ex. 1006, [0031], Fig. 1.) Hartley also discloses that the “rotary actuator 12 is mounted onto the cylindrical housing 6.” (*Id.*) Hartley’s housing 6 therefore supports the other components of the valve and is a “support” as claimed in the ’005 patent. (Ex. 1003, ¶261.)

b. Actuator

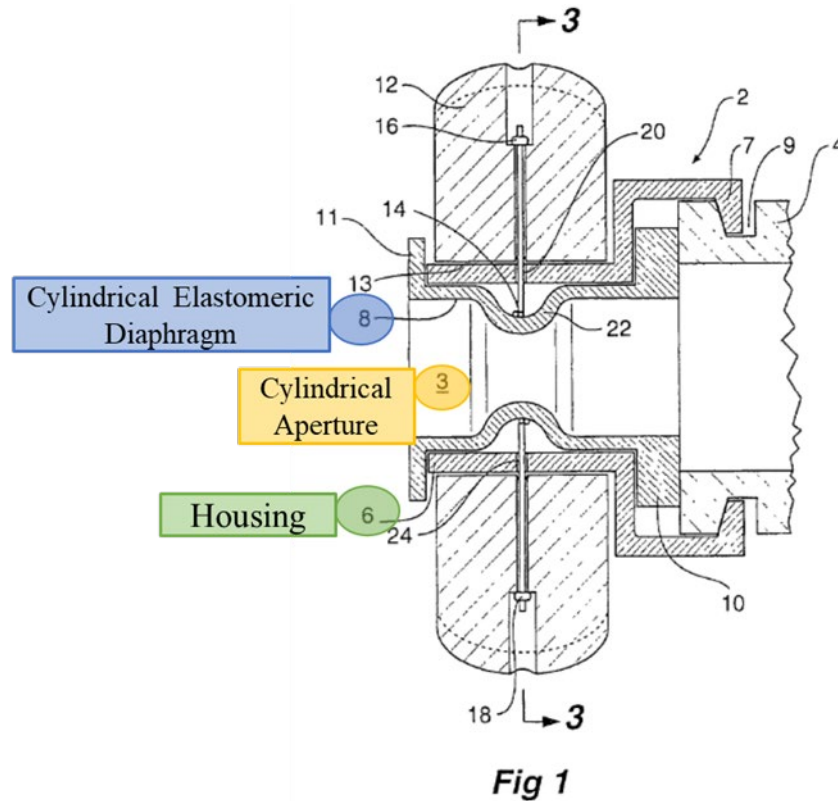
Hartley’s valve includes a “rotary actuator 12 [that] is mounted onto the cylindrical housing 6”:



(Ex. 1006, [0031], Fig. 1.) Hartley’s actuator has a “first member” where the first end of the string is secured to the actuator. (*Id.*; *supra* §VII.A.2.b.i.) 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].) The first member of Hartley’s actuator is therefore “movably coupled to the support.” (Ex. 1003, ¶263.)

c. Tubular Sidewall

Hartley's valve includes a "cylindrical housing 6 into which is received a cylindrical elastomeric diaphragm 8 ... [that] defines a cylindrical aperture 3 therethrough":



(Ex. 1006, [0031], Fig. 1.) Hartley’s “cylindrical diaphragm can be completely constricted to prevent fluid flow through the valve.” (*Id.*, [0006].) Accordingly, Hartley’s elastomeric diaphragm is “a collapsible tubular sidewall defining a lumen carried by the support.” (Ex. 1003, ¶265.)

d. Filament

Hartley discloses this limitation for the reasons explained in claims 1 and 3.
(*Supra* §§VII.A.8.b.ii, VII.C.)

e. First Spring

Hartley combined with Eller's biasing system (e.g., torsion spring) renders this limitation obvious for the reasons explained in claim 1. (*Supra* §VII.A.2.c.)

H. Claim 11

Hartley discloses the limitations recited in claim 11 for the reasons explained in claim 1. (*Supra* §VII.A.2.b.i.) Therefore, Garrison combined with Hartley and Eller renders claim 11 obvious. (Ex. 1003, ¶268.)

I. Claim 12

Hartley discloses the limitations recited in claim 12 for the reasons explained in claim 1. (*Supra* §§VII.A.2.b.ii.) Therefore, Garrison combined with Hartley and Eller renders claim 12 obvious. (Ex. 1003, ¶269.)

J. Claim 13

Hartley discloses a continuous string (i.e., filament) that forms a loop around the outer surface of the valve lumen. (*Supra* §VI.M.1; Ex. 1003, ¶271.)

K. Claim 14

Hartley combined with Eller renders the limitations in claim 14 obvious for the reasons explained in claim 1. (*Supra* §VII.A.2.c.) Therefore, Garrison in combination with Hartley and Eller renders claim 14 obvious. (Ex. 1003, ¶272.)

L. Claim 15

Hartley combined with Eller renders the limitations in claim 15 obvious for the reasons explained in claim 1. (*Supra* §§VII.A.2.c.) Therefore, Garrison combined with Hartley and Eller renders claim 15 obvious. (Ex. 1003, ¶273.)

VIII. SECONDARY CONSIDERATIONS

Petitioner is not aware of any evidence of secondary considerations. (Ex. 1003, ¶¶274-276.) If PO identifies evidence of secondary considerations, Petitioner respectfully requests an opportunity to respond.

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

The Director has explained, “the PTAB will not discretionarily deny institution of an IPR or PGR in view of parallel district court litigation where a petitioner stipulates not to pursue in a parallel district court proceeding the same grounds as in the petition or any grounds that could have reasonably been raised in the petition.” *Interim Procedure for Discretionary Denials in AIA Post-Grant Proceedings with Parallel District Court Litigation* at 7 (June 21, 2022). Although the case is in its early stages, Petitioner offers the following stipulation:

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

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

Additionally, denial of institution under 325(d) would also be unwarranted because Schaffer, which forms the basis for Grounds 1-3 herein, was not of-record during prosecution of the '005 patent.

Further, while Garrison and Eller's publication (but not Eller) were listed on IDS's during prosecution along with hundreds of other references, the references were not discussed. (Ex. 1002, 200, 283-311.) Additionally, in the only Office Action, the Examiner determined that Hartley disclosed every limitation of the hemostasis valve recited in pending claims 2 and 11 except "the actuator having a first member movable [sic] coupled to the support and the first spring configured to move the first member." (*Id.*, 214-215.) As explained above, POSITAs would have found it obvious to combine Hartley's valve with Eller's biasing system, rendering most of the challenged claims unpatentable. (*Supra* §VII.) The Examiner therefore materially erred in allowing the challenged claims over Garrison, Hartley, and Eller (as well as Schaffer). The Examiner never addressed the combination of these references; nor were the grounds presented in this Petition presented to the Patent Office. Accordingly, the Board should not deny institution based on the citation of Garrison, Hartley, and Eller's publication during prosecution. *See e.g., Comcast Cable Commc'ns LLC v. Promptu Sys. Corp.*, IPR2018-00342, Paper 13 (P.T.A.B.

July 19, 2018) (declining to deny institution under §325(d) because prior art was not applied).

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

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

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

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

PO recently filed suit alleging that Petitioner’s Symphony system infringes the ’005 patent, as well as U.S. Patent Nos. 11,974,910; 11,969,333; 11,744,691; 11,844,921; 11,697,011; 11,697,012; 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 schedule or a trial date in the litigation.

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

Lead Counsel	Back-up Counsel
Joshua J. Stowell (Reg. No. 64,096) 2JYS@knobbe.com BoxImperative005@knobbe.com Knobbe, Martens, Olson, & Bear, LLP <u>Postal and Hand-Delivery Address:</u> 2040 Main St., 14 th Floor Irvine, CA 92614 Telephone: 949-760-0404 Facsimile: 949-760-9502	Joseph R. Re (Reg. No. 31,291) 2jrr@knobbe.com Brian C. Barnes (Reg. No. 75,805) 2BCB@knobbe.com Knobbe, Martens, Olson, & Bear, LLP <u>Postal and Hand-Delivery Address:</u> 2040 Main St., 14 th Floor Irvine, CA 92614 Telephone: 949-760-0404 Facsimile: 949-760-9502

D. Service Information (37 C.F.R. §42.8(b)(4))

Please direct all correspondence to lead counsel and back-up counsel at the addresses shown above. Petitioner also consents to electronic service by email to BoxImperative005@knobbe.com.

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

Petitioner certifies that the '005 patent is available for IPR and that Petitioner is not barred or estopped from requesting IPR on the identified grounds. This Petition is being filed within one year of service of the Complaint in the Litigation.

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

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

XI. CONCLUSION

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

Dated: December 13, 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 ,554 ,005** contains 13,993 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: December 13, 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 SERVICE

The undersigned hereby certifies that on the date below a copy of this **PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 11,554,005 AND EXHIBITS 1001-1024**, 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:

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

Dated: December 13, 2024 By: /Joshua J. Stowell/
Joshua J. Stowell (Reg. No. 64,096)
KNOBBE MARTENS OLSON & BEAR, LLP