

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
U.S. Patent No. 11,554,005

PATENT OWNER'S RESPONSE

TABLE OF CONTENTS

I.	INTRODUCTION	1
II.	BACKGROUND	4
A.	Overview of the ’005 Patent.....	4
B.	Prosecution History	12
C.	Asserted Art.....	13
1.	Garrison.....	13
2.	Schaffer	13
3.	Hartley.....	20
4.	Eller	21
D.	Claim Construction	23
1.	Claim language.	25
2.	The specification.	26
3.	Extrinsic evidence.....	30
4.	A POSA would understand the degree of flexibility required by the “filament” in the context of a hemostasis valve.....	32
E.	Person of Ordinary Skill in the Art	32
III.	CLAIMS 1 AND 10 ARE NOT OBVIOUS OVER THE COMBINATION OF GARRISON AND SCHAFFER (GROUND 1)	33
A.	Neither Garrison nor Schaffer Disclose the “housing” with “a flow path extending through the housing” and “on-off control in the flow path.”	33
B.	Neither Garrison nor Schaffer Disclose the “Filament” of Claims 1 and 10.....	40
C.	Neither Garrison nor Schaffer Disclose the Properties of the Filament Required by Claims 1 and 10.	42
1.	Garrison and Schaffer do not disclose a filament that “circumferentially constricts the lumen.”	42
2.	Garrison and Schaffer do not disclose a “filament” formed in a loop that reduces in diameter.	45
D.	It Would Not Have Been Obvious to Have Modified Schaffer to Include the Filament Recited in Claims 1 or 10.....	49

IV. CLAIMS 1 AND 10 ARE NOT OBVIOUS OVER THE COMBINATION OF GARRISON, SCHAFFER, AND HARTLEY (GROUND 2) OR ELLER (GROUND 3)	50
A. A POSA Would Not Have Been Motivated to modify Schaffer’s U-Shaped Members.	52
1. Petitioner’s stated motivation to combine Schaffer with Hartley/Eller does not exist.	52
2. Petitioner’s alleged defect in Schaffer would only exist after first modifying Schaffer to create an inferior valve—but even this would fail to motivate a POSA to substitute Hartley’s string or Eller’s wire. 57	
B. Petitioner’s Proposed Modification to Include Hartley’s String/Eller’s Wire Is Not a Simple Substitution.....	61
1. An actuating member including two ends attached to and controlled by different actuators was not “known” in the art.	62
2. Schaffer discloses comparably more plausible substitutions/modifications to address any purported sealing issues..	68
3. Petitioner’s proposed substitution would not seal.	70
C. The Solutions for Constricting a Tubular Member in a Hemostasis Valve Were Not Finite, Identifiable, or Known.....	71
D. Petitioner’s Proposed Modifications Would Change Schaffer’s Principles of Operation.....	73
E. A POSA would not have used Schaffer’s allegedly ineffective valve in Garrison, then further modify that ineffective valve rather than use the hemostasis valve disclosed by Garrison.	76
V. CLAIMS 1 AND 10 ARE NOT OBVIOUS OVER THE COMBINATION OF GARRISON, HARTLEY, AND ELLER (GROUND 4)	77
A. Garrison, Hartley, and Eller Do Not Disclose the “Filament” Having Two Ends Extending in Different Directions and Coupled to Different Members of an Actuator of Claim 1.....	78
B. Petitioner’s Proposed Modification Would Change Hartley’s Principle of Operation and Render Its Detent System Inoperable for Its Intended Purpose.....	79

C.	It Would Not Have Been Obvious to Have Modified Garrison to Include Hartley's Valve, Then Further Modify Hartley's Valve in View of Eller Rather Than Use Garrison's Hemostasis Valve.	82
VI.	DEPENDENT CLAIMS 2-9 AND 11-15 ARE NOT OBVIOUS OVER ANY COMBINATION OF GARRISON, SCHAFFER, HARTLEY, AND ELLER	83
VII.	CONCLUSION	84

TABLE OF AUTHORITIES

	Page(s)
CASES	
<i>Abbott Labs. v. Sandoz, Inc.</i> , 544 F.3d 1341 (Fed. Cir. 2008)	72
<i>Adidas AG v. Nike, Inc.</i> , 963 F.3d 1355 (Fed. Cir. 2020)	73
<i>Aruba Networks, Inc. v. Xr Commc 'ns LLC</i> , No. IPR2018-00701, 2018 WL 4090629 (P.T.A.B. Aug. 27, 2018).....	56
<i>Aug. Tech. Corp. v. Camtek, Ltd.</i> , 655 F.3d 1278 (Fed. Cir. 2011)	33
<i>Axonics, Inc. v. Medtronic, Inc.</i> , 73 F.4th 950 (Fed. Cir. 2023)	52
<i>Hill-Rom Services, Inc. v. Stryker Corp.</i> , 755 F. 3d 1367 (Fed. Cir. 2014)	23
<i>Imperative Care, Inc. v. Inari Medical Inc.</i> , IPR2024-01157, Paper 7 (P.T.A.B. Jan. 23, 2025)	32, 79, 81, 83
<i>In re Schweickert</i> , 676 F. App'x 988 (Fed. Cir. 2017)	56
<i>In re Varma</i> , 816 F.3d 1352 (Fed. Cir. 2016)	46
<i>Innogenetics, N.V. v. Abbott Labs.</i> , 512 F.3d 1363 (Fed. Cir. 2008)	52
<i>Intel Corp. v. Qualcomm Inc.</i> , 21 F.4th 784 (Fed. Cir. 2021)	60, 62, 70
<i>Kingston Tech. Co., Inc. v. Polaris Innovations Ltd.</i> , No. IPR2016-01623, 2018 WL 851884 (P.T.A.B. Feb. 9, 2018).....	72

<i>KSR Int’l Co. v. Teleflex Inc.</i> , 550 U.S. 398 (2007).....	61, 71
<i>Kyocera Senco Indus. Tools Inc. v. Int’l Trade Comm’n</i> , 22 F.4th 1369 (Fed. Cir. 2022)	passim
<i>Philip Morris Products S. A. v. RAI Strategic Holdings, Inc.</i> , IPR2020-01602, 2022 WL 1022576 (P.T.A.B. Mar. 30, 2022).....	58
<i>Philip Morris Prods. S.A. v. RAI Strategic Holdings, Inc.</i> , No. 2022-1846, 2023 WL 5970786 (Fed. Cir. Sept. 14, 2023).....	59, 60, 61, 68
<i>Plas-Pak Indus. V. Sulzer MixPak AG</i> , 600 Fed.App’x. 755 (Fed. Cir. 2015)	73
<i>R.J. Reynolds Vapor Co. v. Fontem Holdings I B.V.</i> , IPR2016-01268, Paper 63 (P.T.A.B. Dec. 19, 2017)	68
<i>Rolls–Royce, PLC v. United Techs. Corp.</i> , 603 F.3d 1325 (Fed. Cir. 2010)	72
<i>Salazar v. AT&T Mobility, LLC</i> , 64 F.4th 1311 (Fed. Cir. 2023)	46
STATUTES	
35 U.S.C. § 102	passim
OTHER AUTHORITIES	
37 C.F.R. § 42.100	23

EXHIBIT LIST

	Petitioner's Exhibits
Exhibit	Description
1001	U.S. Patent No. 11,697,005 (“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 US 2003/0116731 A1 to Hartley (“Hartley”)
1007	U.S. Patent No. 9,980,813 B1 to Eller (“Eller”)
1008	Drawings Submitted During Prosecution of U.S. Patent Application No. 10/371,190 dated June 18, 2003
1009	U.S. Patent No. 5,429,616 to Schaffer (“Schaffer ’616”)
1010	U.S. Patent Publication US 2011/0144592 A1 to Wong et al. (“Wong”)
1011	U.S. Patent Publication US 2015/0173782 A1 to Garrison et al. (“Garrison”)
1012	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”)

	Petitioner's Exhibits
Exhibit	Description
1018	U.S. Patent No. 7,775,501 B2 to Kees ("Kees")
1019	U.S. Patent Publication No. 2016/0220741 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.

	Patent Owner's Exhibits
Exhibit	Description
2001	Declaration of Paul J. Zalesky
2002	Merriam-Webster's Collegiate Dictionary (11th ed. 2014)
2003	New Oxford American Dictionary (3rd ed. 2010)
2004	Drawings Submitted During Prosecution of U.S. Patent Application No. 16/117,519
2005	Deposition Transcript of Troy Thornton (September 30, 2024)
2006	First Amended Complaint for Patent Infringement in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 4:24-cv-03117-YGR (N.D. Cal.), Dkt. 20
2007	Docket Report in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 5:24-cv-03117-EKL (N.D. Cal.)

	Patent Owner's Exhibits
Exhibit	Description
2008	Imperative Care Inc.'s Notice of Motion and Motion to Stay Pending <i>Inter Partes</i> Review in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 5:24-cv-03117-EKL (N.D. Cal.), Dkt. 100
2009	Order Granting Joint Stipulated Request for Order Changing Briefing Schedule in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 5:24-cv-03117-EKL (N.D. Cal.), Dkt. 104
2010	Motion For Preliminary Injunction in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 5:24-cv-03117-EKL (N.D. Cal.), Dkt. 24
2011	Opposition to Motion for a Preliminary Injunction in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 5:24-cv-03117-EKL (N.D. Cal.), Dkt. 36
2012	Corrected Opposition to Motion for a Preliminary Injunction in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 5:24-cv-03117-EKL (N.D. Cal.), Dkt. 40
2013	Complaint for Patent Infringement in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 5:24-cv-03117-EKL (N.D. Cal.), Dkt. 1
2014	Clerk's Notice Resetting Motion Hearing and Setting PI Tutorial in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 5:24-cv-03117-EKL (N.D. Cal.), Dkt. 87
2015	Clerk's Notice Resetting Motions Hearing in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 5:24-cv-03117-EKL (N.D. Cal.), Dkt. 92
2016	Case Management and Scheduling Order in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 5:24-cv-03117-EKL (N.D. Cal.), Dkt. 54
2017	Stipulated Protective Order in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 5:24-cv-03117-EKL (N.D. Cal.), Dkt. 76
2018	Joint Letter Brief Concerning Plaintiff's Motion to Compel Production of Materials Relating to Defendant's Blood Return System in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 5:24-cv-03117-EKL (N.D. Cal.), Dkt. 94
2019	Order Re Inari Medical's Motion to Compel Production of Materials in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 5:24-cv-03117-EKL (N.D. Cal.), Dkt. 105

	Patent Owner's Exhibits
Exhibit	Description
2020	Imperative Care, Inc.'s Preliminary Invalidity Contentions and Document Production Accompanying Invalidity Contentions Pursuant to Patent Local Rules 3-3 and 3-4 (omitting accompanying claim charts)
2021	Imperative Care, Inc.'s Preliminary Invalidity Contentions and Document Production Regarding U.S. Patent Nos. 12,109,384 and 12,156,669 Pursuant to Patent Local Rules 3-3 and 3-4 (omitting accompanying claim charts)
2022	Second Amended Complaint for Patent Infringement in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 5:24-cv-03117-EKL (N.D. Cal.), Dkt. 68
2023	Declaration of Joseph P. Hamilton (April 28, 2025)
2024	Inari's Reply in Support of Motion for Preliminary Injunction in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 5:24-cv-03117-EKL (N.D. Cal.), Dkt. 46
2025	Inari's Notice of Motion and Motion for Leave to File Third Amended Complaint in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 5:24-cv-03117-EKL (N.D. Cal.), Dkt. 88
2026	Supplemental Declaration of Paul J. Zalesky
2027	Institution Decision of <i>Inter Partes</i> Review for U.S. Patent No. 11,697,012 (Paper 6) in <i>Imperative Care, Inc. V. Inari Medical, Inc.</i> , IPR2025-00156 (P.T.A.B. Apr. 22, 2025)
2028	Deposition Transcript of Troy Thornton (March 19, 2025)
2029	Deposition Transcript of Troy Thornton (June 25, 2025)
2030	U.S. Patent No. 7,682,380 to Thornton ("Thornton")
2031	Deposition Transcript of Troy Thornton (August 15, 2025)

I. INTRODUCTION

The '005 Patent is directed to improved vacuum aspiration systems for removing clot material from a blood vessel. The '005 Patent discloses that such vacuum aspiration systems can include a “garrote” hemostasis valve coupled to an aspiration catheter that provides (i) a robust seal to prevent blood loss during an aspiration thrombectomy procedure, (ii) convenient, single-handed operation, and (iii) the ability to swap different tools easily and quickly through the valve. EX1001, 5:47-54; EX1017, ¶¶[0032], [0033]; EX2026, ¶42.

Ground 1 (Garrison and Schaffer) fails for several reasons. First, Garrison and Schaffer do not render obvious Claims 1 or 10 because Garrison fails to disclose a “housing, a flow path extending through the housing, [and] an on-off control in the flow path” as claimed. As explained below, Claims 1 and 10 require that the on-off control be “in” the flow path that extends through the housing and distinguish claim features that are simply fluidically coupled to the flow path. Petitioner does not assert that Garrison discloses an “on-off control in the flow path” that is “extending through the housing” and instead points to a valve that is spaced apart and separate from the alleged housing. Ground 1, and thus grounds 2-4, fail for that reason alone.

Second, Schaffer does not disclose a “filament” at all, let alone one that “circumferentially constricts” as recited in claim 1 or that is formed into a “loop” and “reducing the diameter of the loop” as recited in Claim 10. First, the '005 Patent

confirms that the term “filament” should be accorded its plain and ordinary meaning, namely, “a thin, flexible length of material formed by one or more strands of material.” In contrast, Schaffer discloses a different way of sealing and unsealing a valve where rigid side-by-side U-shaped actuating members compress an internal sealing member that is so compliant that it forms a complete seal around instruments inserted through the valve—including multiple and irregularly-shaped instruments. EX2026, ¶¶137-141, 169. Second, Shaffer's rigid members are side-by-side so they do not form a loop, cannot reduce in diameter, and cannot circumferentially constrict. Schaffer discloses that an advantage of its design employing rigid actuating members allows the actuating members to “forcibly disengage” that sealing member to allow the highly compliant material to expand and open the valve. *Id.* at ¶¶181-183. The rigid actuating members also make Schaffer's valve more durable and easier to manufacture. *Id.* at ¶¶169-180.

Grounds 2 and 3 (Garrison, Schaffer, and Hartley or Eller) fail because a POSA would not have been motivated to replace Schaffer's rigid side-by-side U-shaped actuating members with a flexible string or wire as disclosed in Hartley or Eller, let alone then further modify the proposed combination by first eliminating one of Schaffer's U-shaped members completely and instead attaching a string or wire member between Schaffer's two actuating members. Petitioner's purported motivation to combine requires that a POSA first remove the features of Schaffer

that Petitioner itself asserts form a complete seal, namely Schaffer's sealing member that is "so complaint that it forms a seal around the instruments 260 even if the instruments 260 are irregularly shaped" by conforming to the shape of the instruments. EX1005, ¶[0068]; *see, e.g.*, EX1003, ¶124. But, a POSA would not intentionally create a sealing issue in Schaffer, so that they would then redesign Schaffer to Petitioner's liking in an effort to address that self-inflicted flaw. Indeed, Petitioner's expert admitted at deposition in an IPR for related U.S. Patent No. 11,697,011 ("the related '011 IPR") that if Schaffer forms a complete seal, there would be no need to modify Schaffer's U-shaped actuating members. EX2028, 116:18-117:2. In sum, Petitioner's proposed combinations of Garrison and Schaffer with Hartley or Eller employ impermissible hindsight—requiring a POSA to manufacture a non-existent problem with Schaffer (poor sealing), then modify Schaffer in view of that non-existent problem in a manner that fundamentally changes Schaffer's principle of operation.

Grounds 2-3 also fail because Petitioner's "simple substitution" rationale for obviousness does not involve the substitution of a "known element." None of Petitioner's references disclose a single actuating member (U-shaped member, string, or wire) having two ends coupled to and controlled by different actuators. Instead, each of Petitioner's references includes one or more actuating members each controlled alone by a single actuator. EX2026, ¶¶159-166.

Grounds 2-3 further fail because Petitioner apparently relies on an “obvious to try” rationale but does not demonstrate that there were a finite number identifiable and known solutions for constricting a tubular member in a hemostasis valve. Petitioner's expert admitted during deposition: “I don't know how many options could be used to compress [a] tube.” EX2029, 107:12-13.

Ground 4 (Garrison, Hartley, and Eller) fails because inserting Eller's spring into Hartley's valve as Petitioner proposes would render Hartley's valve inoperable for its intended purposes of providing tactile feedback and maintaining a diameter of the valve lumen. EX2026, ¶¶198-201. Ground 4 also fails for Claims 1 and 11, and the claims that depend therefrom, because neither Hartley nor Eller disclose a filament having a “first end extending ... in one direction” and coupled to a “first member” of an actuator and a “second end extending ... in another direction” and coupled to a “second member” of the actuator. Instead, both Hartley and Eller disclose attaching a string or wire to a single unitary actuator. EX2026, ¶¶194-197.

For these and the other reasons set forth below, Petitioner has failed to demonstrate that any of Claims 1-15 are unpatentable under any of grounds 1-4.

II. BACKGROUND

A. Overview of the '005 Patent

The '005 Patent is directed to improved vacuum aspiration systems for removing clot material from a blood vessel of a human patient. EX1001, 4:10-12.

The systems are well-suited for treating venous thromboembolism (“VTE”), a disease caused by blood clot formation in the veins that is, unfortunately, a leading cause of both death and disease worldwide. *Id.* at 1:39-61; EX2026, ¶¶32, 33. Pulmonary embolism (“PE”) and deep vein thrombosis (“DVT”) are common and dangerous types of VTE. *Id.*

The '005 Patent discloses vacuum aspiration systems for rapidly aspirating clot material from a patient's blood vessel that offer significant benefits over conventional treatments. *Id.* 4:10-12; EX2026, ¶35. For example, the '005 Patent describes various vacuum aspiration systems that pre-charge or store vacuum in one or more chambers or canisters before applying the vacuum to an aspiration catheter positioned near clot material (e.g., PE/DVT) in a patient's blood vessel to rapidly generate large suction forces (and corresponding fluid flow velocities) needed to effectively aspirate and remove the clot material. EX1001, 4:27-43; EX2026, ¶35. The generated suction forces/flow velocities are greater than conventional systems, more effectively removing clot material—even clot material that is strongly lodged/attached within the blood vessel (e.g., chronic clots) and/or very large clots. EX1001, 10:22-26; EX2026, ¶35.

The '005 Patent's claims recite a vacuum aspiration system including, *inter alia*:

- a housing;

- a flow path extending through a housing;
- an on-off control in the flow path;
- a first catheter in fluid communication with the flow path and a connector configured to place a source of aspiration in communication with the flow path;
- a clot cannister fluidly coupled to the flow path; and
- a hemostasis valve in the housing.

EX1001, Claims 1, 10.

The hemostasis valve includes buttons that can be actuated (e.g., depressed) to open the valve. EX1001, 5:47-49; EX2026, ¶38. The hemostasis valve is configured to receive a second catheter as shown in Figure 11 of the '005 Patent:

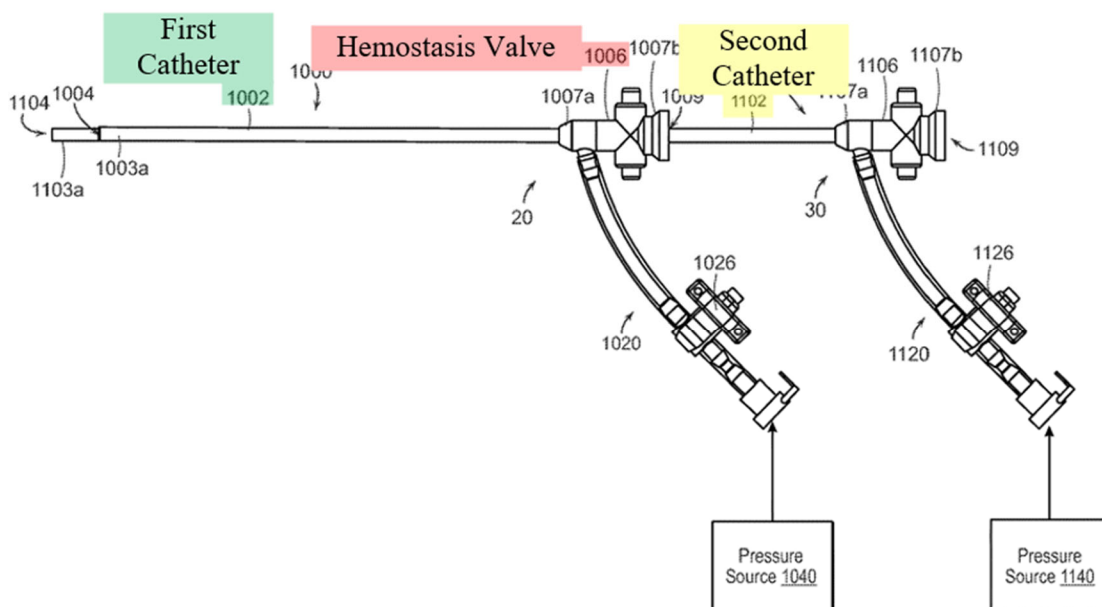


FIG. 11

EX2026, ¶38.

The hemostasis valve “can be a valve of the type disclosed in U.S. patent application Ser. No. 16/117,519, filed Aug. 30, 2018, and titled ‘HEMOSTASIS VALVES AND METHODS OF USE,’ which is incorporated herein by reference in its entirety.” EX1001, 5:49-54. Accordingly, the ’005 Patent specifically incorporates by reference the hemostasis valves described in U.S. Patent Application No. 16/117,519 (“the ’519 Application”; EX1017).

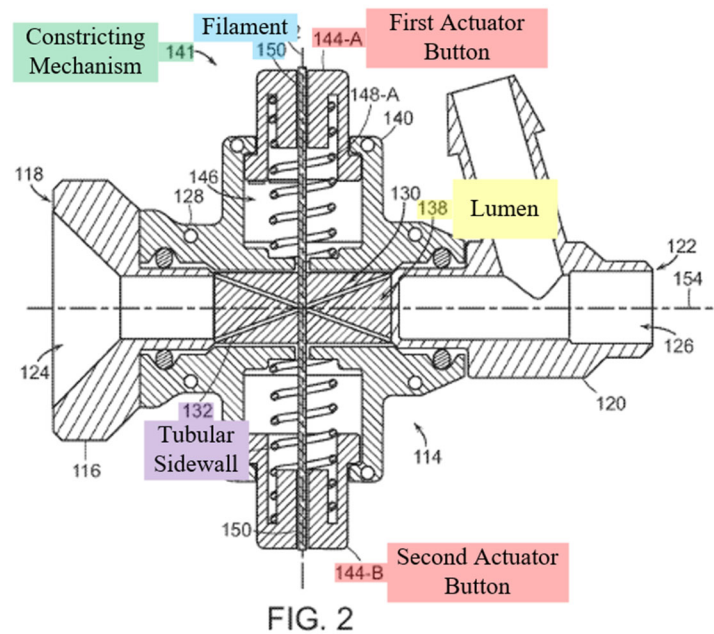
The ’005 Patent, via its incorporation of the ’519 Application,¹ explains that while “traditional hemostasis valves are greatly beneficial for intravascular access, they have some drawbacks. For example, some valves may not seal adequately for all interventional applications or tools, and/or the operation of some valves may be complicated for operator use.” EX1017, ¶[0005]. The ’005 Patent addresses those drawbacks by providing a hemostasis valve with easy one-handed operation and a strong seal around a variety of different-sized instruments, both of which are particularly important for hemostasis valves used in the vacuum aspiration systems claimed in ’005 Patent.

¹ Reference is made herein to the disclosure of the ’005 Patent with citations to the incorporated disclosure of the ’519 Application (EX1017) where appropriate.

The design and functionality of the hemostasis valve enables medical professionals to easily operate the valve with one hand while maintaining a robust seal to prevent blood loss during vacuum aspiration thrombectomy procedures. EX1017, ¶¶[0033]; EX2026, ¶42. In particular, the design allows for quicker and more effective sealing of large-bore catheters for thrombectomy in large veins and pulmonary arteries, such as for treating DVT or PE (i.e., applications where blood loss is a particular risk) described in the '005 Patent. EX2026, ¶¶57-59.

The '005 Patent's new type of "garrote"² valve can include a tubular sidewall/member defining a lumen, and a constricting mechanism. EX1017, ¶¶[0039]-[0043]; EX2026, ¶¶44-45. The constricting mechanism can collapse and seal the tubular sidewall via constriction with a filament that can extend at least partially around the tubular member. EX1017, ¶[0043]; EX2026, ¶45. Specifically, the constricting mechanism can comprise an actuator (e.g., one or more buttons), and the filament can be coupled to the actuator such that the filament selectively constricts, collapses, and/or seals the lumen of the tubular sidewall based on the movement and/or position of the actuator:

² Merriam-Webster defines "garotte" to mean "an implement (as a wire with a handle at each end) for strangulation." EX2002, p.516.



EX1017, ¶¶[0044], [0048]³; EX2026, ¶45.

The filament(s) 150 can have different configurations as shown in Figures 6-9. EX2026, ¶¶49-52. For example, as shown in Figure 6, the filament can be configured to form a single loop that extends around the tubular sidewall:

³ The drawings of the '519 Application reproduced herein are from the replacement drawings (EX2004) submitted during prosecution for clarity.

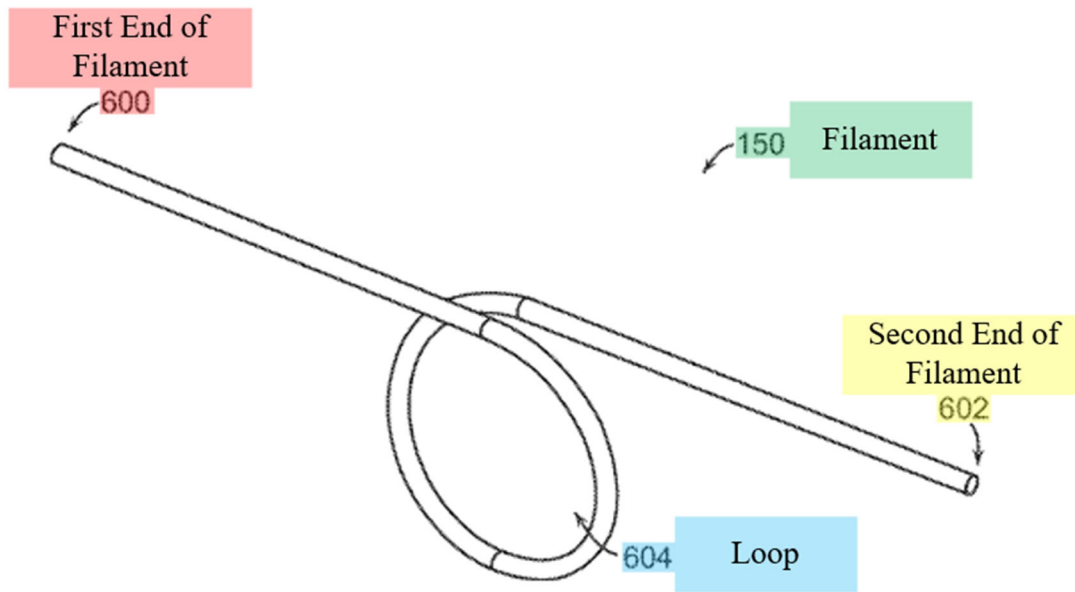


FIG. 6

EX1017, ¶[0064]; EX2026, ¶49. As shown in Figure 7, the filament can comprise a first filament and a second filament with each of the single filaments forming a respective first loop and second loop:

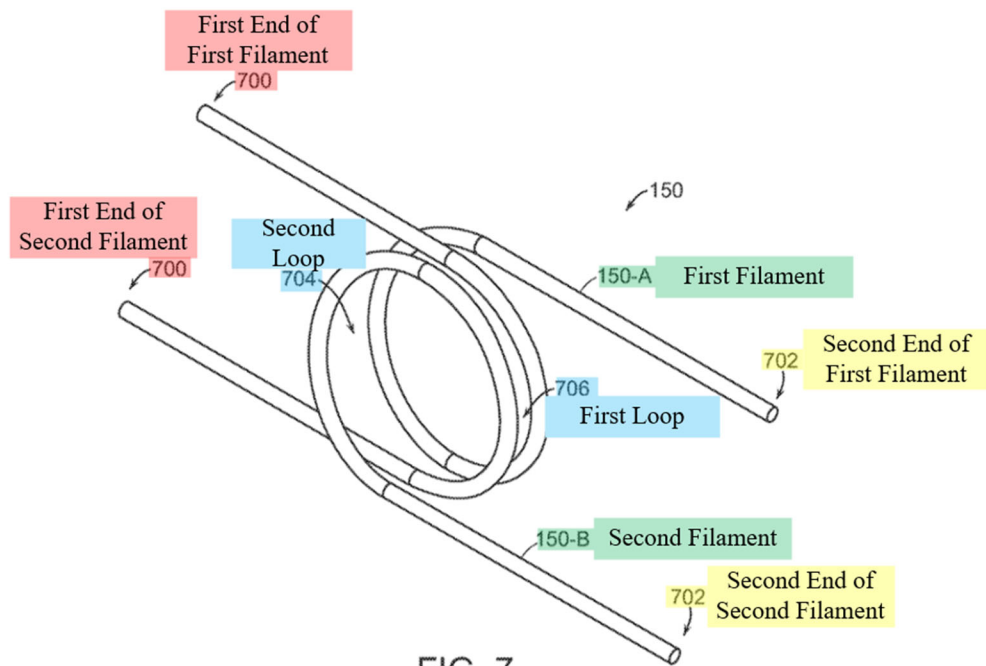


FIG. 7

EX1017, ¶[0065], EX2026, ¶49. For the filament loop embodiments shown in Figures 6-7, the constricting mechanism reduces a diameter of the loop (Figure 6) or the first and second loops (Figure 7). EX1017, ¶[0066]; EX2026, ¶50.

In Figures 8-9, first and second filaments are first and second bights:

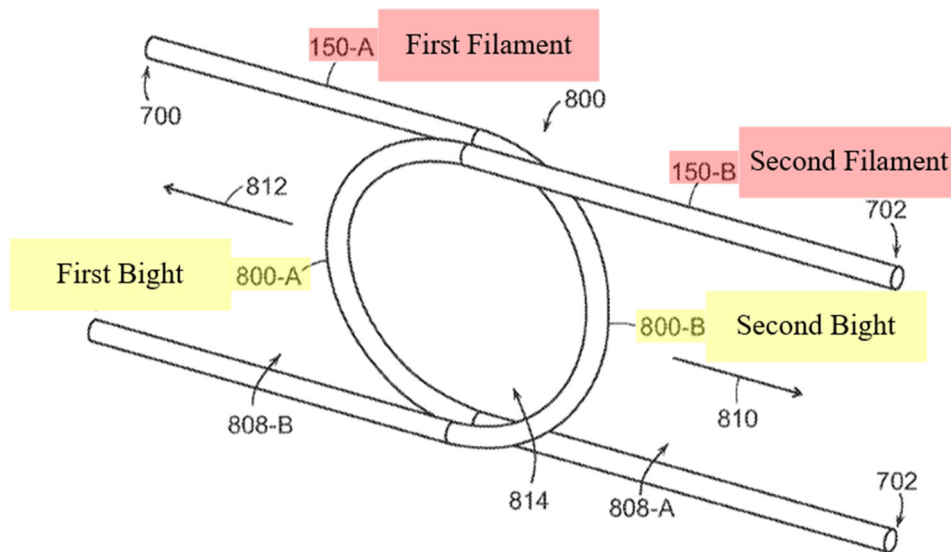


FIG. 8

EX1017, ¶¶[0067]-[0068], EX2026, ¶¶51, 52. In this embodiment, movement of the constricting mechanism 141 loosens the filaments such that the bights slacken to allow the tubular sidewall to expand and unseal the lumen. EX1017, ¶[0069], EX2026, ¶52. The '005 Patent discloses two different embodiments of “semicircular bights”: bights that interlock (as illustrated in Figures 8-9) and bights that do not interlock (no corresponding figures). EX1017, ¶[0067]; EX2026, ¶52.

Referencing Figures 7-9, the '005 Patent further explains that “[i]n embodiments in which the filament 150 comprises multiple filaments, each of the multiple filaments can have a first end 700 and a second end 702.” EX1017, ¶[0065].

B. Prosecution History

The Patent Office initially rejected original claim 1 under 35 U.S.C. § 102 over Garrison '741 (EX1019). EX1002, pp.211-212. Garrison '741 discloses several

systems similar to those of Garrison (EX1011) and both inventors of Garrison '741 are listed inventors of Garrison. The Patent Office found dependent claims 2-10 allowable but for depending on rejected claim 1, and allowed original claims 11-16. *Id.* at p.212.

Patent Owner responded by canceling claim 1 and rewriting original claim 2 in independent form incorporating the features of canceled claim 1. *Id.* at pp.191-199. The Patent Office subsequently allowed claims 2-16. *Id.* at pp.168-175.

In the Notice of Allowance, the Examiner referenced Hartley (EX1006) relied upon by Petitioner here, and explained that Hartley fails to disclose a “first spring” or “biasing system.” EX1002, pp.173-174. The Examiner also considered Garrison (EX1011) in an Information Disclosure Statement (*id.* at pp.183, 200) and Eller (EX1007) in an Information Disclosure Statement (*id.* at pp.39, 258, 300).

C. Asserted Art

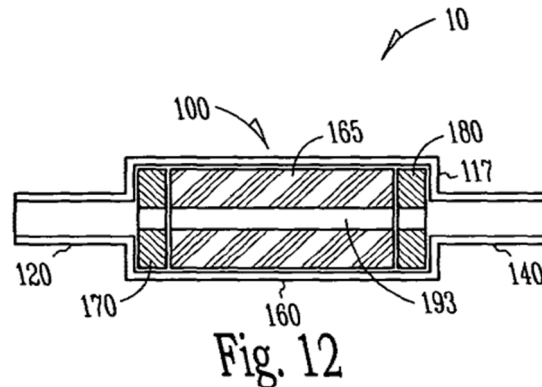
1. Garrison

Garrison discloses intravenous systems for transcarotid access of the cerebral arterial vasculature and treatment of cerebral occlusions. EX1011, ¶ [0002].

2. Schaffer

Schaffer discloses a hemostasis valve that employs a different method of sealing from the '005 Patent. To effectuate sealing, Schaffer discloses a plurality of

sealing members internal to a seal module 100, shown as seal members 165, 170, and 180 in Figure 12 reproduced below.



Schaffer's sealing members are central to Schaffer's method of forming a seal and sealing member 165 is included in every illustrated embodiment. EX2026, ¶68. Specifically, Schaffer discloses that "[t]he third central seal member 165 is sized and configured to maintain an open lumen 193 when no compressive force 67 is applied." EX1005, ¶[0054]. To effectuate a seal, actuating members 55 are "forcibly pushed against the central portion of the seal module 100, [and] the compressive force 67 of the actuating member 55 against the outer wall 27 of the containment structure 160 inwardly depresses or collapses the third central seal member 165." *Id.* at ¶[0055]. The internal seal member 165 "includes a material 166 that is highly elastic, deformable, compliant and yet virtually non-compressible." *Id.* at ¶[0054]. And, that "highly compliant third central seal member 165 seals around a variety of profile shapes 192 and diameters 194 of the lumen 193 when at least one side of compressive force 67 is exerted upon the central region 195 with respect to the

central portion 110 of the containment structure 160.” *Id.* at ¶[0060]. In other words, Schaffer employs actuating members 55 that apply an external compressive force 67 to a seal module 100 without conforming to the outer surface of the seal module, and the highly-compliant internal seal member 165 conforms to various shapes and sizes as the actuating members 55 compress it to seal a lumen as illustrated throughout Schaffer. See, for example Figures 16-19, reproduced below.

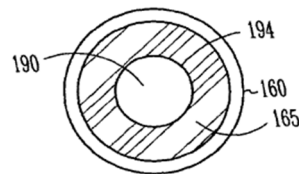


Fig. 16

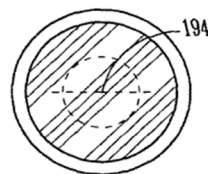


Fig. 17

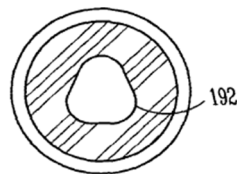


Fig. 18

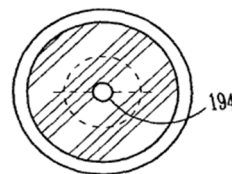


Fig. 19

Every illustrated embodiment in Schaffer operates in that manner with the highly compliant seal member 165. See for example, Figure 4, showing seal member 165:

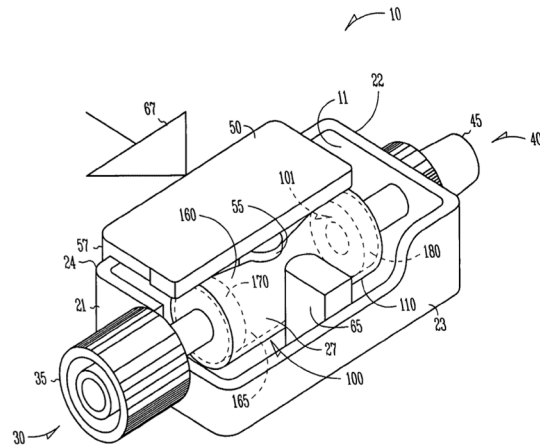
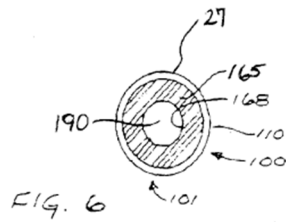
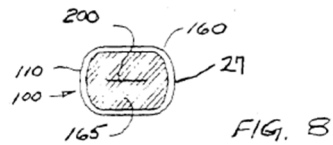
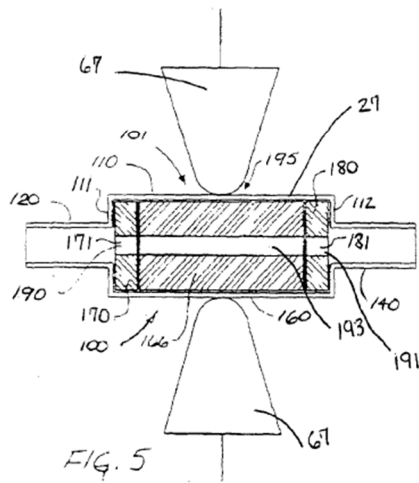
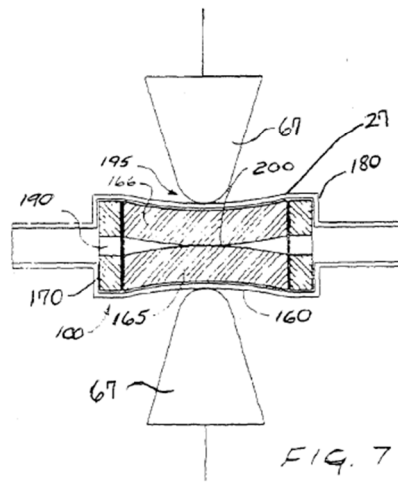


Fig. 4

Figures 6-8, showing seal member 165:



Figures 9A-10B, showing seal member 165:

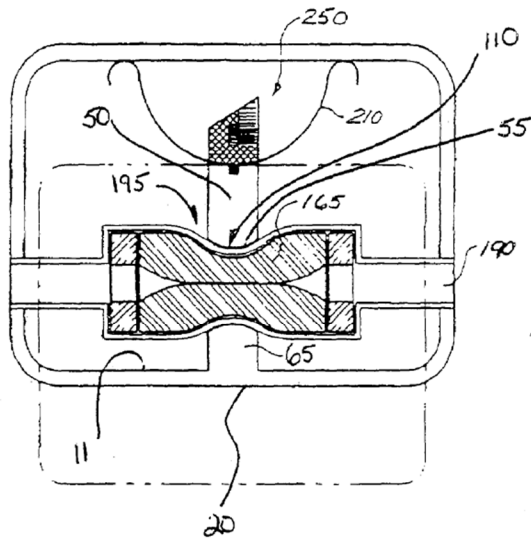


FIG. 10A

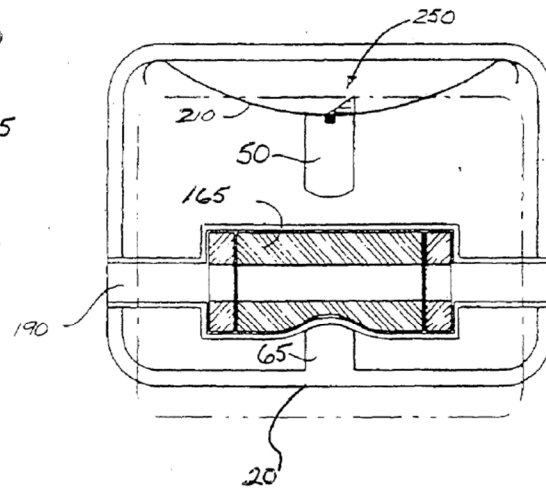


FIG. 9A

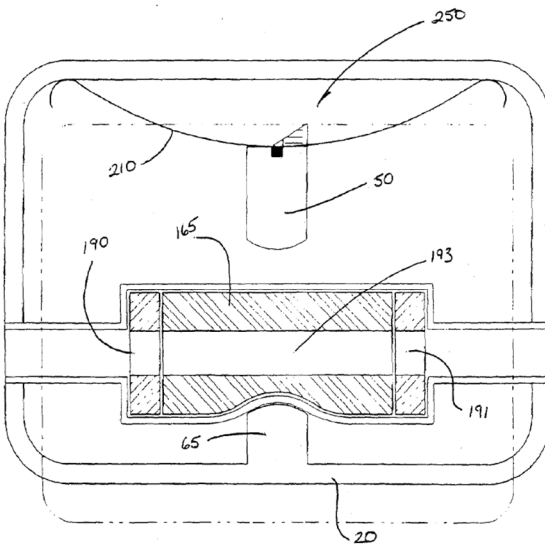


FIG. 9B

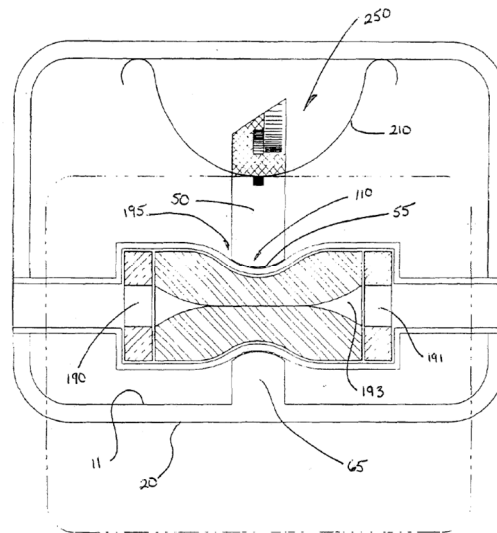
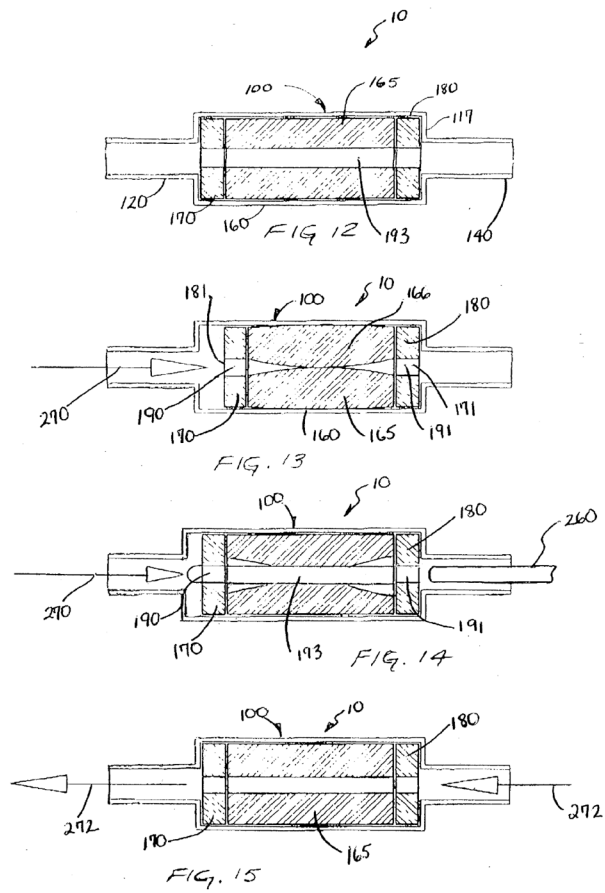


FIG. 10B

Figures 12-15, showing seal member 165:



Figures 23-26, showing seal member 165:

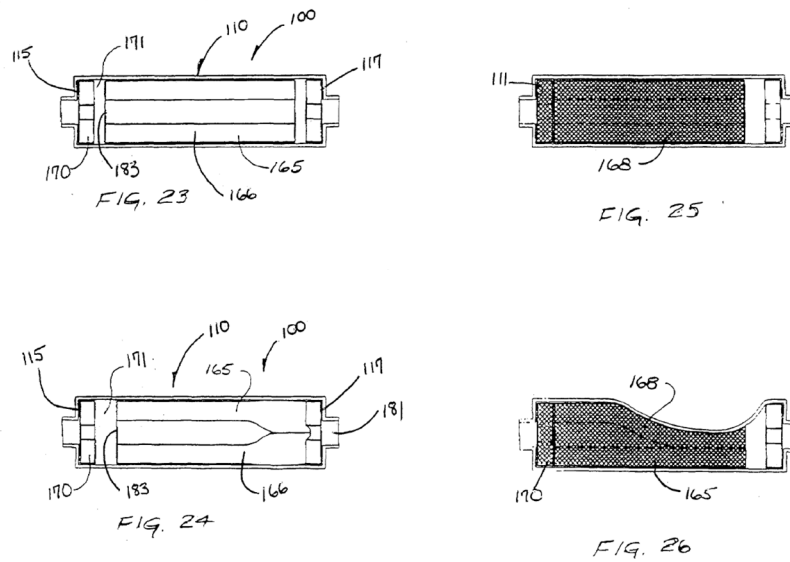


Figure 27, showing seal member 165:

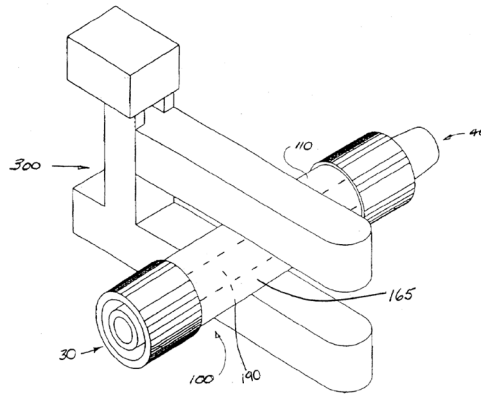


FIG. 27

Figures 28-29, showing seal member 165:

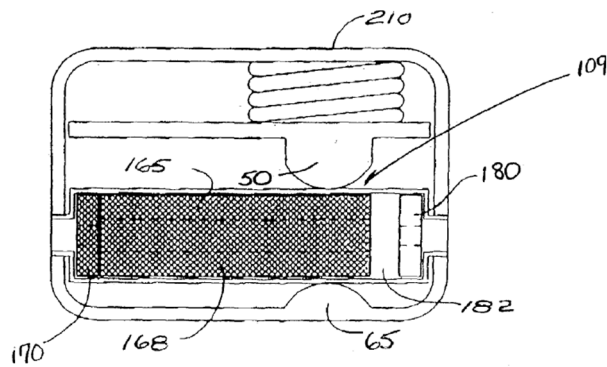


FIG. 28

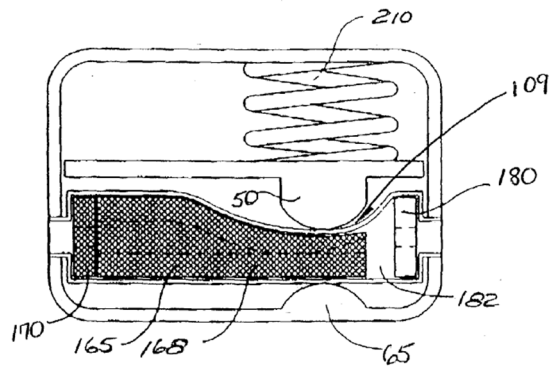
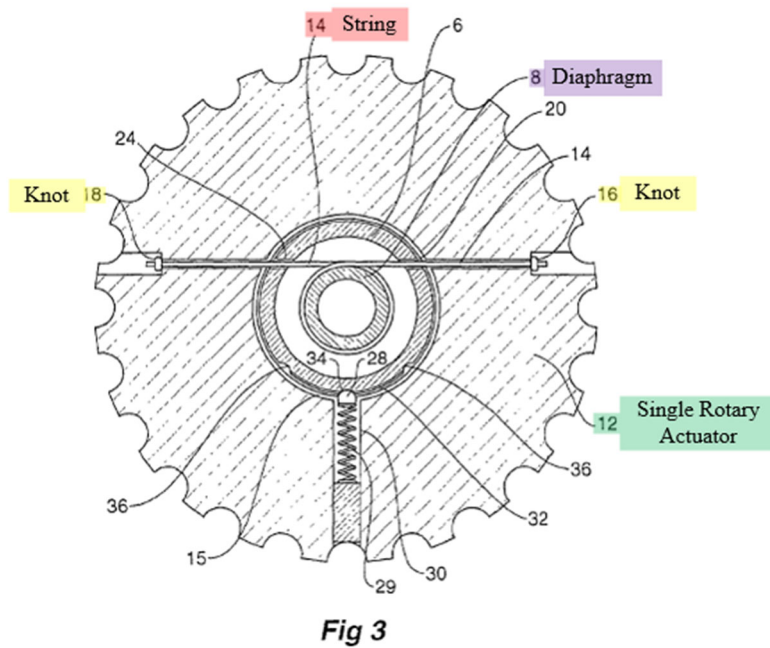


FIG. 29

And, for the primary embodiment relied upon by Petitioner shown in Figures 30-34, Schaffer references only seal member 165 (EX1005, ¶¶[0075], [0077]) and discloses that “[t]he seal module 100 is formed of one or more seal members, as discussed above.” *Id.* at ¶[0075]. Schaffer further discloses that the seal member 165 is made from the same materials as the other embodiments. *Id.* at ¶[0081]. Like all other embodiments, Schaffer further discloses how the seal member 165 operates in the embodiment of Figures 30-34. *Id.* at ¶[0077]. Thus, the actuating members 55 collapse the seal member 165 to seal, and forcibly disengage the seal member 165 to allow it to retract and open.

3. Hartley

Hartley discloses an access valve having a string 14 extending around a cylindrical elastomeric diaphragm 8 and attached by knots 16 and 18 to a single rotary actuator 12:



EX1006, ¶[0031]; EX2026, ¶¶72, 161.

4. Eller

Eller discloses a selective fluid barrier device 810 including a housing 816, a single actuator 818, a sleeve 820, and a wire member 822 having “a first end 924 attached to the housing 816 ... and a second end 926 attached to the actuator 818”:

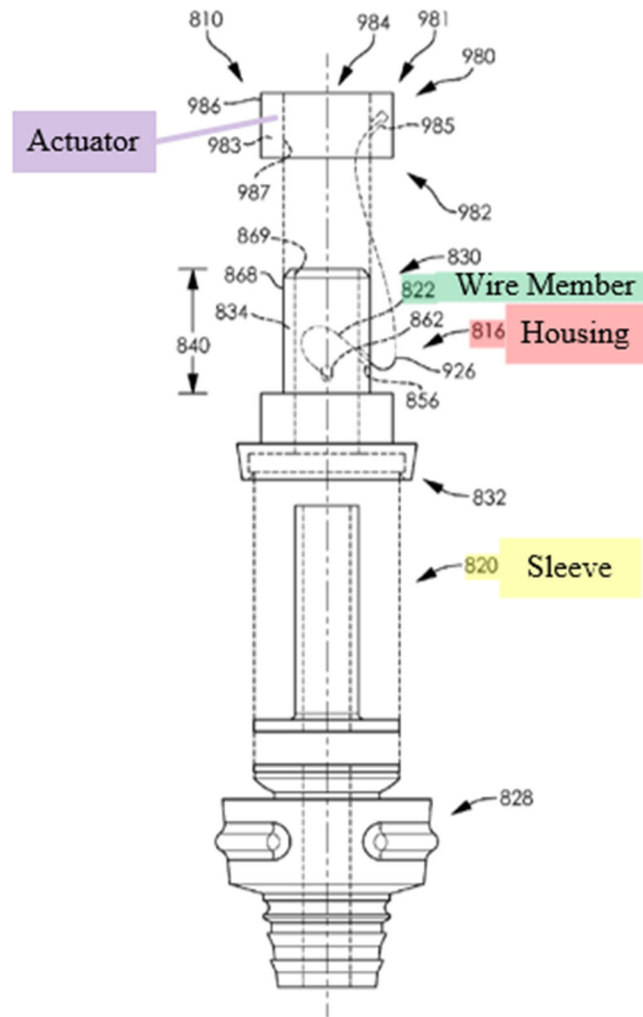


FIG. 20

EX1007, 23:50-62, 24:50-52. Eller discloses other embodiments with multiple wire members each having a first end attached to a housing and a second end attached to a single actuator. EX2026, ¶¶73, 162-165. In each of these embodiments, the wire members have a first end coupled to a housing and a second end coupled to an actuator. *Id.* Movement of the actuator pulls only the second end of the wire member

while the first end remains stationary such that the single integral actuator controls movement of the wire member. *Id.*

D. Claim Construction

In an IPR, a claim is construed “using the same claim construction standard that would be used to construe the claim in a civil action” and “in accordance with the ordinary and customary meaning as understood by a POSITA and the prosecution history pertaining to the patent.” 37 C.F.R. § 42.100(b). In *Phillips v. AWH Corp.*, the Federal Circuit explained that “words of a claim ‘are generally given their ordinary and customary meaning’” and that “the ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application.” 415 F.3d 1303, 1312-13 (Fed. Cir. 2005) (cleaned up). “To act as its own lexicographer a patentee must clearly set forth a definition of the disputed claim term other than its plain and ordinary meaning and must clearly express an intent to redefine the term.” *Kyocera Senco Indus. Tools Inc. v. Int’l Trade Comm’n*, 22 F.4th 1369, 1378 (Fed. Cir. 2022) (emphasis added). “We depart from the plain and ordinary meaning of claim terms based on the specification in only two instances: lexicography and disavowal....The standards for finding lexicography and disavowal are exacting.” *Hill-Rom Services, Inc. v. Stryker Corp.*, 755 F. 3d 1367, 1371 (Fed. Cir. 2014) (internal citations omitted).

Claim 1 recites “a constricting mechanism including a filament.” EX1001, 35:63-36:10. Claim 10 recites “a filament formed in a loop around the collapsible tubular sidewall ... such that a diameter of the lumen decreases in response to reducing a diameter of the loop.” *Id.* at 37:6-13. A POSA would understand that the term “filament” recited in Claims 1 and 10 should be accorded its plain and ordinary meaning, “a thin, flexible length of material formed by one or more strands of material.”

Petitioner agrees that the plain and ordinary meaning of filament includes flexibility. At deposition in related litigation, Petitioner's expert testified that the plain and ordinary meaning of “filament” includes that it is flexible. EX2005, 116:25 118:13, 122:17-21; 123:1-15, 125:17-25. Petitioner's expert testified that “in the ordinary meaning of filament, it has flexibility.” *Id.* at 123:1-3. In other words, Petitioner's expert agrees that the plain and ordinary meaning of “filament” requires flexibility.

Despite this, Petitioner proposes a claim construction for “filament” that *omits* the flexibility requirement, defining a filament as “one or more threads, lines, cords, ropes, ribbons, flat wires, sheets, or tapes.” Petition, p.17. Thus, to prevail with its proposed construction, Petitioner must meet the high burden of showing that the '005 Patent clearly and unambiguously redefined the term “filament” to omit any

requirement of “flexibility.” *Kyocera Senco Indus. Tools Inc.* 22 F.4th at 1378. For the reasons explained below, Petitioner has failed to do so.

1. Claim language.

The claim language confirms that the “filament” must be flexible. Claim 1 recites that the filament “circumferentially constricts the lumen to create a seal.” A POSA would understand that, for the filament to “circumferentially constrict,” it must be thin and flexible in accordance with Patent Owner’s proposed construction for filament. EX2026, ¶77. Indeed, Petitioner’s own expert admits as much. In asserting that the limitation “circumferentially constricts” is obvious over Schaffer, Petitioner’s expert explains that “the actuating members could be formed from a thin, flexible sheet or flat ribbon of metal or plastic so that they have the flexibility to conform to the outer surface of the cylindrical seal module.” EX1003, ¶86. Petitioner’s expert then asserts that “[a]ctuating members with this type of structure and flexibility would circumferentially constrict the lumen of Schaffer’s seal module when pulled in opposite directions by the actuator buttons.” *Id.* In other words, Petitioner’s expert asserts that for Schaffer’s actuating members to “circumferentially constrict,” the actuating members must be thin and flexible to conform to the outer surface of Schaffer’s seal module. Thus, the express recitation in Claim 1 that “the filament circumferentially constricts the lumen to create a seal”

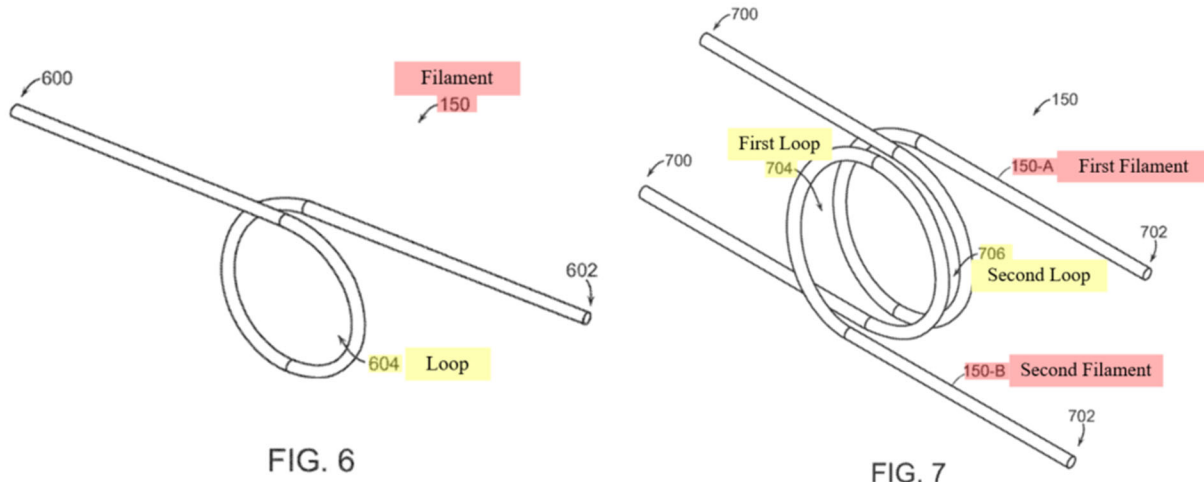
supports that the term filament should be according its plain and ordinary meaning, “a thin, flexible length of material formed by one or more strands of material.”

Claim 10 also requires flexibility. For example, Claim 10 recites that “the filament [is] formed in a loop around the tubular sidewall” and that a “diameter of the lumen decreases in response to reducing a diameter of the loop.” These limitations necessitate that the filament be flexible for the loop to decrease in diameter. EX2026, ¶78. In contrast, a rigid “filament” formed in a loop cannot reduce in diameter. *Id. See also* Institution Decision, p.17 (“when a claim requires ‘a filament formed into a loop’ as recited in claim 10...we conclude that flexibility is required.”). Thus the claims support that “filament” means “a thin, flexible length of material formed by one or more strands of material.”

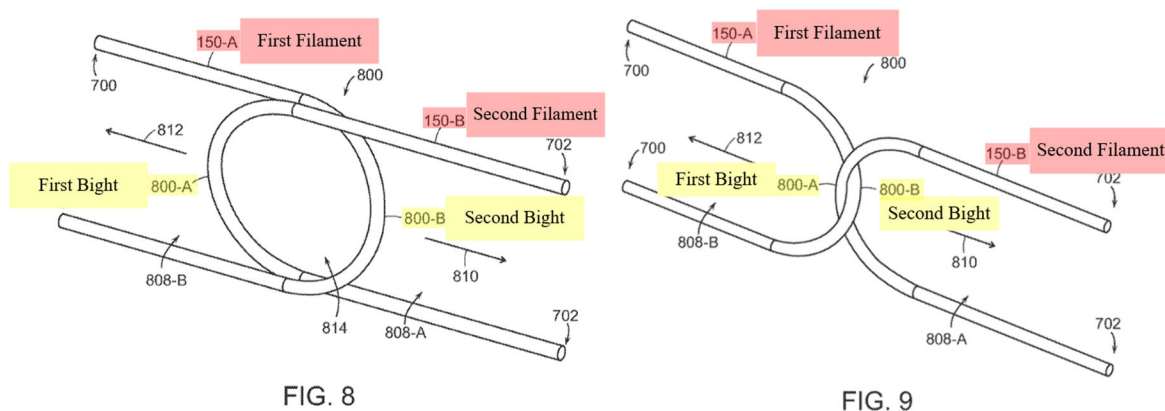
2. The specification.

The specification further confirms that a “filament” must be flexible. Contrary to Petitioner's position, the examples of filaments in the '005 Patent do not redefine the term “filament” to depart from its plain and ordinary meaning. As set forth above in §II.A, the '005 Patent provides examples of two general forms of filaments. First, the '005 Patent discloses filaments formed into loops that reduce in diameter to constrict a lumen as shown in Figures 6 and 7. EX1017, ¶[0066] (referring to Figures 6-7, shown below, and reciting that “a diameter or size of the loop 604, or of the

loops 704, 706 can decrease when the constricting mechanism 141 is moved from the second configuration to the first configuration.”).



Second, referring to Figures 8-9 shown below, the '005 Patent discloses that “[i]n some embodiments, the filament 150 can be configured to form a bight 800, which bight 800 can be a single bight or multiple bights.” *Id.* at ¶[0067].



The Institution Decision explained that “when a claim requires ‘a filament formed into a loop’ as recited in claim 10...we conclude that flexibility is required.” Institution Decision, p.17; EX2026, ¶80. But the Board questioned whether the bight

embodiments require a flexible filament. Institution Decision, p.16. They do. First, a bight by definition is formed from slack and therefore must be flexible. EX2002, p.120 (“bight”: a “slack part or loop in a rope”); EX2026, ¶81. Second, if the two interlocking U-shaped bights in Figures 8-9 were inflexible, they would need to be rotated in opposite directions as they are pulled from the position of Figure 8 to arrive at the position shown in Figure 9. EX2026, ¶81. The ’005 Patent includes no such disclosure. So, the bight embodiments shown in Figures 8-9 do not support that a filament can be inflexible. *Id.* And, even if in theory, a similar arrangement to the bight embodiment with two side-by side, non-interlocking bights could work with rigid members, that example also works with flexible members. Institution Decision, pp.16-17. That all of the disclosed bight embodiments function with flexible filaments and that one embodiment could function differently is not a clear and unambiguous redefining of the term filament from its plain and ordinary meaning. *Kyocera Senco*, 22 F.4th at 1378. Forming slack is necessary for both the loop and bight embodiments disclosed in the ’005 Patent. EX2026, ¶79.

While the ’005 Patent provides example materials for the filament, including “a polymer, a synthetic, and/or a metal” (EX1017, ¶[0047]), that the filament can be made from materials that can be flexible or can be formed into rigid components does not redefine the term “filament” from its plain and ordinary meaning to instead include rigid components. EX2026, ¶82. Petitioner’s expert agrees that material

alone does not dictate flexibility/rigidity, and that all the materials/forms disclosed in the '005 Patent are consistent with the plain and ordinary meaning of the term “filament.” EX2028, 125:2-126:4, 131:16-132:12 (“The relative flexibility or the relative stiffness or rigidity is not clear from those three materials without knowing much more information.”).

Petitioner also contends that the proper construction for “filament” is “at least ‘one or more threads, lines, cords, ropes, ribbons, flat wires, sheets, or tapes’” regardless of whether or not those configurations are flexible. Petition, p.17; EX1003, ¶54. A POSA would understand that those forms are commonly considered flexible. Though some of those forms can also be configured to be rigid does not redefine the term filament to include rigid members. EX2026, ¶75.

There is no lexicographical definition in the specification, much less a clear and unambiguous one, that would support Petitioner's departure from the plain meaning of the term “filament” as that term is consistently used in the specification and claims.⁴

⁴ Petitioner's passing reference to claim 1 of a patent that is not related by priority to the '005 Patent does not clearly and unambiguously redefine the term “filament” here. Petition, p.19. Regardless, Petitioner omits that that claim 1 further recites

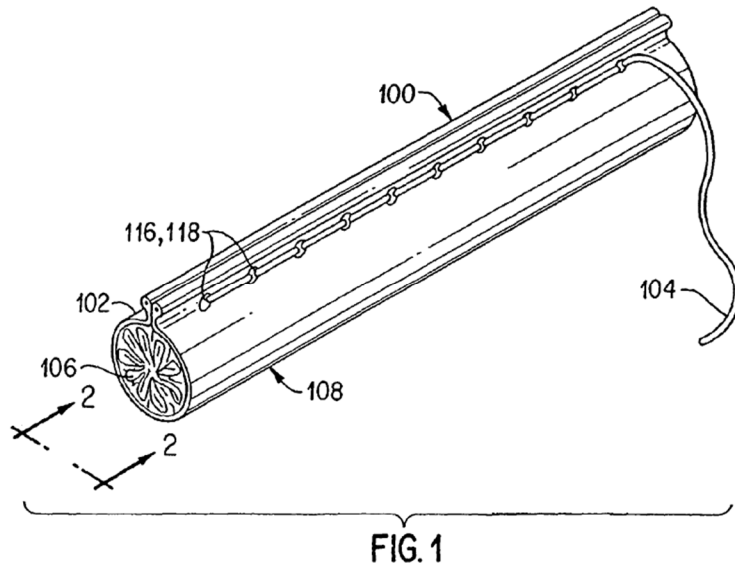
3. Extrinsic evidence.

At deposition in related litigation, Petitioner's expert testified that the plain and ordinary meaning of "filament" includes that it is flexible. EX2005, 116:25-118:13, 122:17-21; 123:1-15, 125:17-25. Specifically, when questioned about the meaning of the term "filament" in U.S. Patent No. 11,744,691, which is related to the '005 Patent and claims a hemostasis valve including a "filament," Petitioner's expert testified that "in the ordinary meaning of filament, it has flexibility." *Id.* at 123:1-3.

Merriam-Webster's Collegiate Dictionary defines a filament as "a single thread or a thin flexible threadlike object, process, or appendage." EX2002, p.467. *See also* New Oxford American Dictionary, EX2003, p.644 (filament: "a slender threadlike object or fiber."). That definition confirm the plain and ordinary meaning of filament. EX2026, ¶85.

first/second "filament[s]" forming "loop[s]" and "decreasing a dimension of the [] loop[s]" and "increase the dimension of the [] loop[s]." EX1016, claim 1. As such, reciting "is flexible" does not change the meaning of "filament" to include rigid members. Just like for "reducing a diameter of the loop" in claim 10 here, a filament must be flexible to increase or decrease in dimension. EX2006, ¶78.

Petitioner's expert has also equated the term "filament" in his own patent to a "thread-like element." EX2028, 199:10-200:20. U.S. Patent No. 7,682,380 (EX2030, hereafter "Thornton") references Figure 1 and recites that "the coupling member 104 is shown as a filament or thread-like element." EX2030, 8:7-9, 53.



Thornton further discloses that its "filament or thread-like element" can be made from various polymers or metal and yet still be thin and flexible as follows:

The thread-like coupling member (104) may also comprise ePTFE. Sutures of polyethers such as polyethylene terephthalate (DACRON® or MYLAR®) or polyaramids such as KEVLAR® or metal wire comprising nitinol, stainless steel or gold may also be used for the coupling member (104).

Id. at 9:18-22. Accordingly, Petitioner's own expert's use of the term "filament" and the material from which the filament can be made supports Patent Owner's proposed construction.

4. A POSA would understand the degree of flexibility required by the "filament" in the context of a hemostasis valve.

A POSA would understand how "thin and flexible" the "filament" is in the context of the '005 Patent claims. In the Institution Decision in the related proceeding (*Imperative Care, Inc. v. Inari Medical Inc.*, IPR2024-01157), the Board questioned how flexible a structure would need to be to qualify as a "filament" as claimed. Paper 7 at p.15 (P.T.A.B. Jan. 23, 2025). While flexibility exists along a spectrum in different contexts, a POSA would readily understand the flexibility required for the claimed filament in the context of a filament to constrict a hemostasis valve as claimed. EX2026, ¶86; EX2029, 38:22-39:7. In particular, the filament must be sufficiently flexible so that it can reduce in diameter when formed in a loop, or circumferentially constrict. *Id.*

E. Person of Ordinary Skill in the Art

For the purposes of this response, Patent Owner has applied Petitioner's definition of a POSA: 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" (Petition, p.17) as, even under this definition, grounds

1-4 fail. Nevertheless, Patent Owner disagrees with this definition and reserves the right to contest this definition here or in the context of other proceedings relating to this and other related patents.

III. CLAIMS 1 AND 10 ARE NOT OBVIOUS OVER THE COMBINATION OF GARRISON AND SCHAFER (GROUND 1)

A claim is not obvious if a limitation of the claim is missing in the cited art. *See Aug. Tech. Corp. v. Camtek, Ltd.*, 655 F.3d 1278, 1290 (Fed. Cir. 2011) (finding that asserted claims are not rendered obvious in view of the cited prior art because they do not supply the missing element for purposes of obviousness analysis).

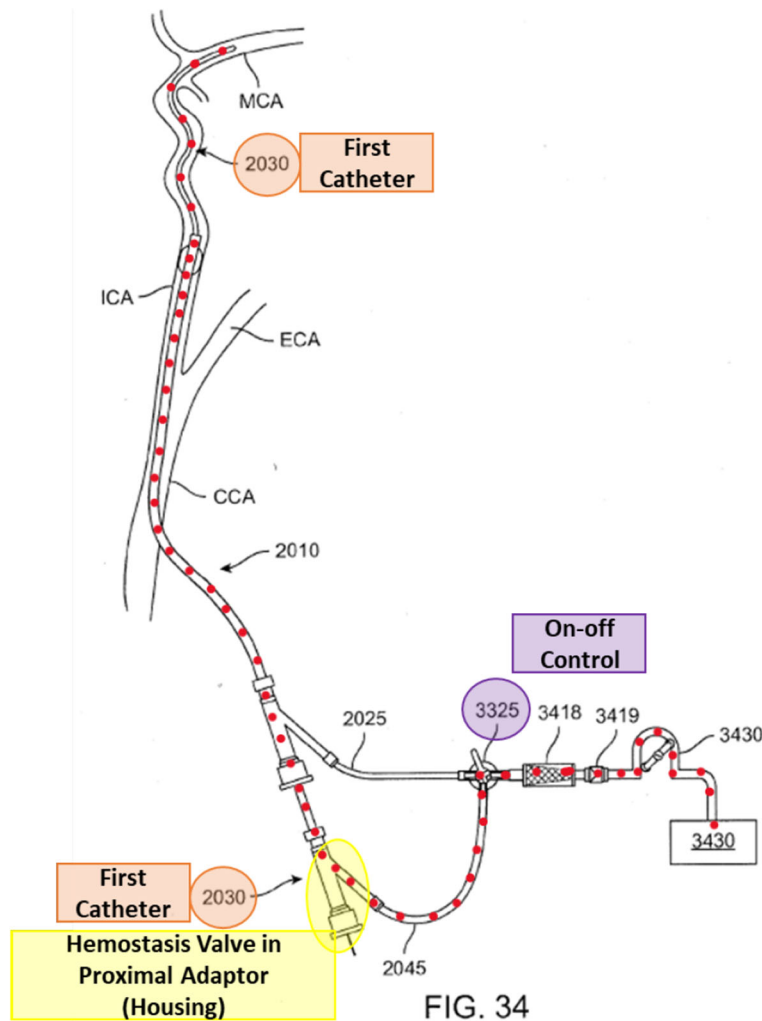
Here, Garrison and Schaffer fail to disclose the claimed (1) “housing” having a “flow path extending through the housing” and “on-off control in the flow path,” or (2) “filament,” much less a filament that “circumferentially constricts the lumen to create a seal,” as recited in Claim 1, or a “filament formed in a loop” that can “reduc[e] a diameter of the loop,” as recited in Claim 10.

A. Neither Garrison nor Schaffer Disclose the “housing” with “a flow path extending through the housing” and “on-off control in the flow path.”

Claims 1 and 10 each recite, *inter alia*, “[a] vacuum aspiration system, comprising: a housing; a flow path extending through the housing; an on-off control in the flow path; [and] a hemostasis valve in the housing....” As such, claims 1 and 10 each require a “housing” with several features, namely, “a flow path extending

through the housing,” “an on-off control in the flow path,” and “a hemostasis valve in the housing.” Because the antecedent basis for “flow path” in “an on-off control in the flow path” is “a flow path extending through the housing,” the limitation “an on-off control in the flow path” requires “an on-off control in the flow path extending through the housing.”

Petitioner does not assert that Garrison discloses “an on-off control in the flow path” “[extending] through the housing” and instead asserts first that Garrison discloses a “housing” and “a hemostasis valve in the housing” and then alleges that valve 3325 is the claimed “on-off control” as shown in Petitioner’s annotation to Garrison’s Figure 34, below.



Petition, pp.22-25.

But, valve 3325 is not in the “flow path extending through the housing” as claimed. EX2026, ¶¶91-93. At best for Petitioner, Garrison’s valve 3325 is fluidically coupled to a “flow path extending though the housing” via a flow line 2045, not “in the flow path.” *Id.* at ¶92.

In fact, both Claims 1 and 10 make clear that the recited “on-off control in the flow path” requires more than fluidly coupling to the “flow path *extending through*

the housing.” Specifically, both claims Claim 1 and 10 distinguish “in the flow path” and “fluidly coupled to the flow path,” reciting both an “on-off control *in* the flow path” and “a clot cannister *fluidly coupled to* the flow path.” In other words, when the claims require an item be “fluidly coupled” it recites “fluidly coupled.” In contrast to “fluidly coupled,” Claims 1 and 10 require the “on-off switch *in* the flow path.” *Id.* at ¶93. Moreover, Claims 1 and 10 further distinguish (by using different language) “extending through” with “extending from” “extending away from” and “extending around” making clear that the “flow path extending through the housing” refers to a flow path in the housing.

Similarly, the '005 Patent distinguishes embodiments with tubing that “fluidly couples” items from embodiments that omit tubing such that the items are in a housing. *Id.* at ¶93. The '005 Patent discloses an aspiration assembly 10 in Figure 1, reproduced below:

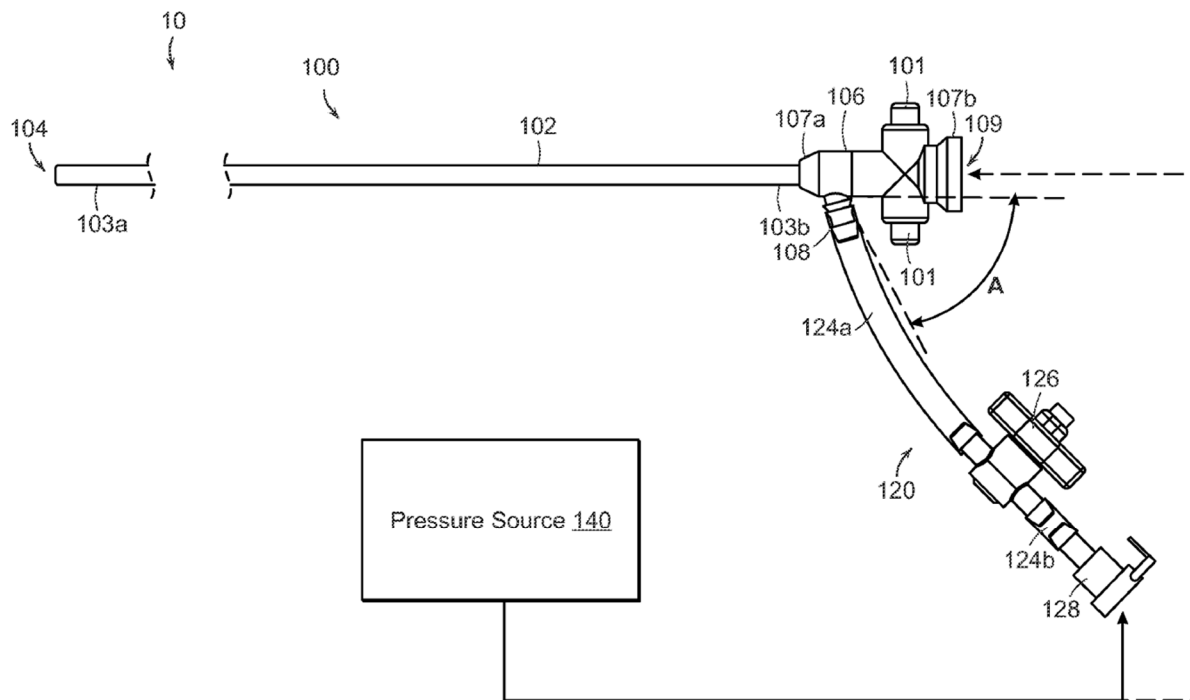


FIG. 1

EX1001, FIG. 1. The '005 Patent explains that “assembly 10 includes a catheter subsystem 100, a tubing subsystem 120, and a pressure source 140” (EX1001, 5:18-21) where the “tubing subsystem 120 fluidly couples the catheter subsystem to the pressure source” (EX1001, 5:66-67). The valve 106 can be a hemostasis valve (EX1001, 5:49-54), and the fluid control device 126 can be an on-off control that can “regulate the flow of fluid ... from the lumen 104 of the catheter 102 to the pressure 20 source 140 (EX1001, 6:18-20). The '005 Patent further explains that as shown in Figure 1, first tubing section 124a “fluidly couples” the hemostasis valve 106 to the fluid control device 126 and the second tubing section 124b “fluidly couples” the fluid control device 126 to a connector 128. EX1001, 6:6-11. The '005

Patent then discloses that “the tubing subsystem 120 can have more or fewer tubing sections, connectors, and/or fluid control devices, and can have other suitable configurations. In some embodiments, one or more of the components can be permanently connected and/or integrally formed.” EX1001, 6:45-49. Similarly, the ’519 application, incorporated by reference by the ’005 Patent as disclosing a hemostasis valve, discloses a hemostasis valve having a housing 128, that “can define an interior channel 130” and that “can be a one-piece housing 128 or a multi-piece housing 128.” EX1017, ¶¶[0038], [0039]. So, just like as recited in Claims 1 and 10, the ’005 Patent distinguishes between an “on-off control” or other item that is “in the flow path” from one that is fluidly coupled to the flow path via tubing. EX2026, ¶93. Claims 1 and 10 expressly require the former. *Id.*

Petitioner argues that the prosecution history supports its position regarding housing. Petition, p.23. But the prosecution history confirms the opposite. During prosecution, the Examiner asserted that “valve 242” of a different Garrison reference (EX1019) discloses the claimed “on-off control in the flow path.” EX1002, 211. As shown in EX1019, Figure 5, valve 242 is not separated from the hemostasis valve 234 via tubing and is thus in the flow path extending through the housing.

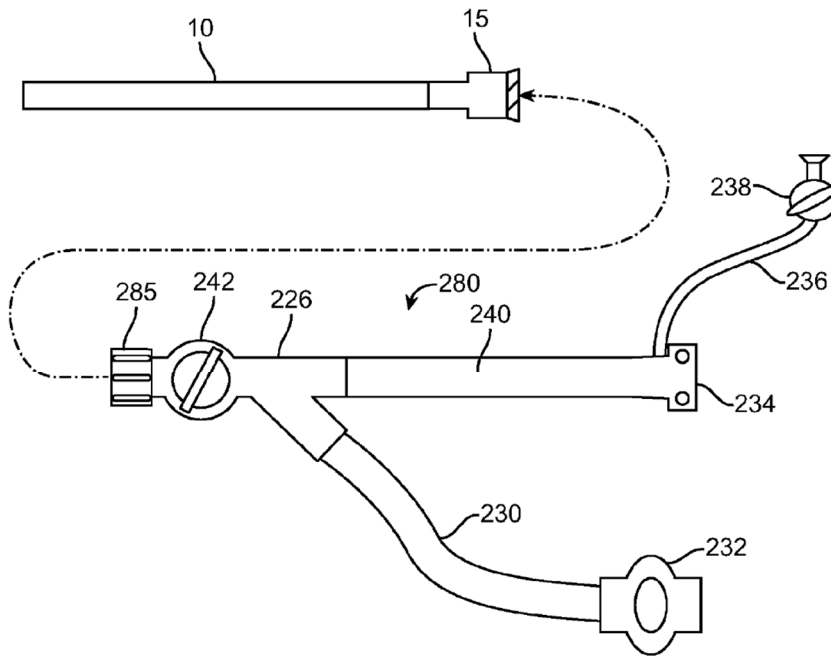


FIG. 5

Notably, in contrast to valve 242, while relying on other portions of EX1019's Figures 1 and 11, the Examiner did not identify EX1019's valve 232, stopcock 238, or valve 292 as disclosing the claimed "on-off switch in the flow line path," each of which is shown fluidly coupled to, but not *in*, the hemostasis valve via an aspiration line 230 or flush line 236 as shown in Figure 5 above and in Figures 1 and 11 reproduced below:

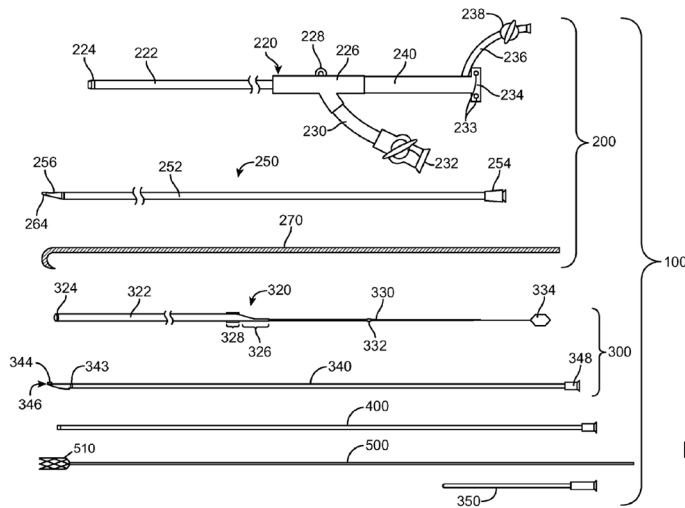


FIG. 1

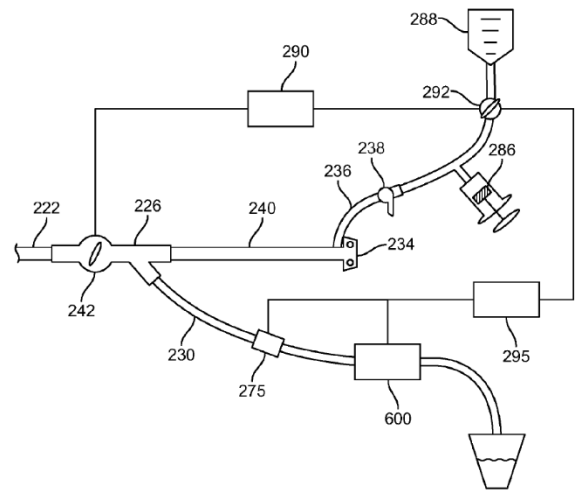


FIG. 11

Accordingly, Garrison's valve 3325 is not an "on-off control in the flow path" "extending through the housing" as recited in Claims 1 and 10. Petitioner has failed to meet its burden to demonstrate unpatentability of either claim for that reason alone.

B. Neither Garrison nor Schaffer Disclose the "Filament" of Claims 1 and 10.

As set forth above in §II.D, the term "filament" in Claims 1 and 10 of the '005 Patent means "a thin, **flexible** length of material formed by one or more strands of material." Petitioner does not allege that Garrison discloses a "filament" for the hemostasis valve and instead relies on Schaffer's U-shaped actuating members 55 for disclosing the "filament." Petition, p.44. But the U-shaped actuating members are rigid, not flexible. EX2026, ¶¶94-105. In the related '0156 IPR, addressing Patent No. 11,697,012, the Board agreed, noting in the Institution Decision that "a skilled artisan would more likely understand the U-shaped actuating members

described in Schaffer as being substantially 'rigid.'" p.32. And as the Board recognized here, Petitioner admits as much by asserting that Schaffer's U-shaped actuating members would purportedly form gaps and a poor seal as the supposed motivation to modify Schaffer in view of Hartley and Eller. Petition, pp.51-60; Institution Decision, p.30 ("We agree with Patent Owner that Petitioner admits that Schaffer's U-shaped actuating members are substantially rigid."). Accordingly, Schaffer does not disclose the filament of Claims 1 or 10 when the term filament is properly construed because Schaffer does not disclose "a thin, flexible length of material." Ground 1 necessarily fails for this reason alone.

Schaffer's disclosure also supports that its actuating members are rigid. Schaffer explains that its U-shaped actuating members "forcibly disengage," which requires a rigid member. EX1005, ¶[0077]. The actuating members must be rigid to "forcibly disengage" opposing outer walls of the seal module—a "filament" cannot "forcibly disengage" because it is flexible and would merely loosen/slacken, not "forcibly disengage." EX2026, ¶98.

Additionally, Schaffer's disclosed method of assembly relies on the rigidity of its U-shaped actuating members. *Id.* at ¶¶102-103. Schaffer uses two rigid U-shaped members to form an area through which a seal module can be inserted. EX1005, ¶[0083]. Because Schaffer's U-shaped actuating members are rigid, an opening is formed for the seal module to be inserted through. EX2026, ¶102. In

contrast, a filament's flexibility would not form an opening to insert the seal module. *Id.* at ¶103.

Finally, Schaffer's method of manufacturing U-shaped actuating members supports that they are rigid: "[t]he actuating member 55... is machined from aluminum." EX1005, ¶[0082]. A POSA will recognize that machining thin and flexible components is impractical given that the flexible component would deform upon the application of force during the machining process. EX2026, ¶101.

Petitioner has therefore failed to demonstrate a reasonable likelihood that the combination of Garrison and Schaffer renders Claims 1 or 10 obvious.

C. Neither Garrison nor Schaffer Disclose the Properties of the Filament Required by Claims 1 and 10.

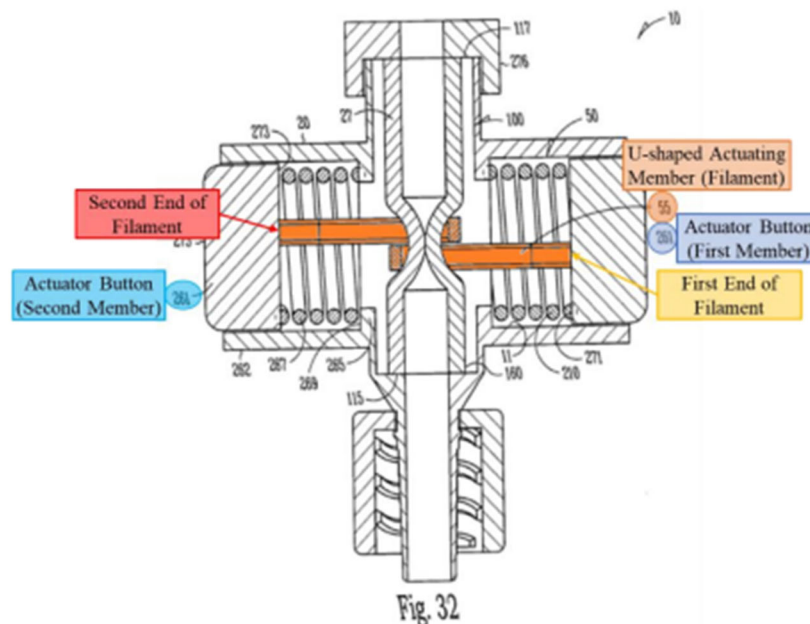
Whether or not the term "filament" requires flexibility, Schaffer does not disclose the additional features of the "filament" recited in Claims 1 and 10, as set forth below.

1. Garrison and Schaffer do not disclose a filament that "circumferentially constricts the lumen."

Claim 1 requires, in part, that "the filament circumferentially constricts the lumen to create a seal." As set forth above, the Petitioner relies upon Schaffer to disclose a filament that "circumferentially constricts." Petition, pp.41-42. But Schaffer discloses side-by side actuating members that apply a compressive force in two opposing directions. EX2026, ¶108. The side-by-side members do not form a

circumference or constrict the lumen around its circumference. *Id.* See also, EX2028, 133:11-21.

Schaffer discloses side-by-side (i.e., parallel) U-shaped members that do not interlock or overlap and thus cannot form an encircled area, as shown in Petitioner's own annotated Figure 32 from Schaffer:



Petition, p.31. Because Schaffer’s side-by-side members do not “define an encircled area” they cannot “circumferentially constrict.” EX2026, ¶108.

That the '005 Patent also discloses non-interlocking bights is of no import. As explained above in §II.A, the '005 Patent discloses two different embodiments of “semicircular bights”: bights that interlock (as illustrated in Figures 8-9 reproduced below) and bights that do not interlock (no corresponding figures). EX1017, ¶[0067].

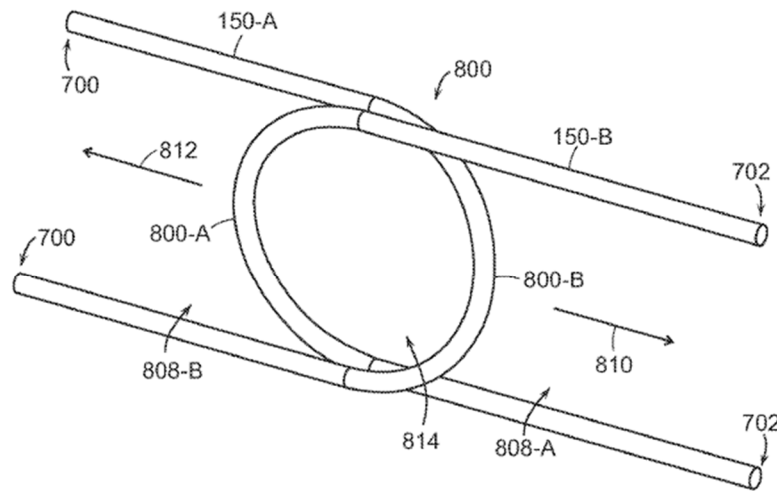


FIG. 8

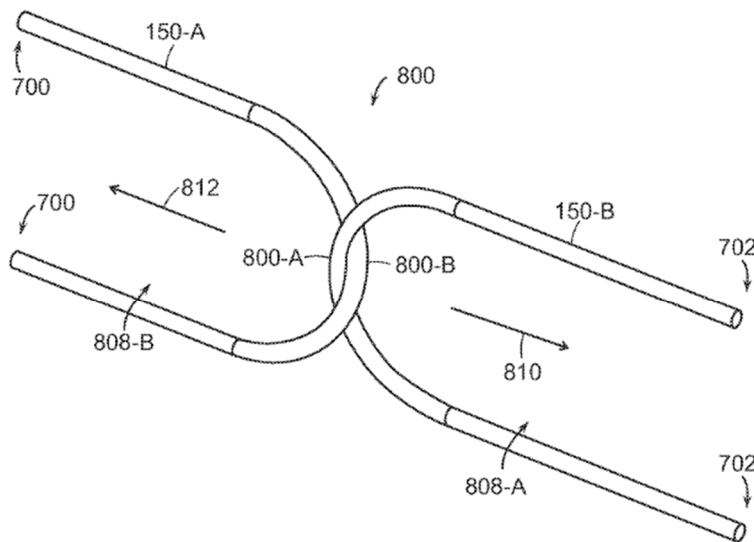


FIG. 9

The '005 Patent explains that the interlocking embodiment illustrated in Figures 8-9 can “circumferentially constrict” because the bights are flexible filaments that overlap as follows: “the first and second receiving areas 808-A, 808-B overlap and define an encircled area 814, also referred to herein as a constricting area 814.” *Id.* at ¶[0069] (emphasis added). The '005 Patent further explains that for

embodiments including an “encircled area,” like the interlocking bights, “the arcuate line of pressure **may be a singular substantially circular line or zone** that encircles the elongate member at least once.” *Id.* at ¶[0070] (emphasis added). The '005 Patent discloses that the filaments circumferentially constrict in “some embodiments,” not all embodiments. *Id.* at ¶[0069]. And, the '005 Patent further contrasts different “zones of pressure” for constriction, explaining that as opposed to an embodiment that “encircles,” and thus circumferentially constricts, in “some embodiments, the arcuate line or zone of pressure may form two opposing arcs.” *Id.* at ¶[0070].

Accordingly, Schaffer's side-by-side U-shaped members do not “circumferentially constrict” as claimed. Ground 1 fails for this reason alone.

2. Garrison and Schaffer do not disclose a “filament” formed in a loop that reduces in diameter.

Claim 10 recites a “filament formed in a loop around the tubular sidewall,” wherein “a diameter of the lumen [of the tubular sidewall] decreases in response to reducing a diameter of the loop.” As explained above, Schaffer's side-by-side actuating members are U-shaped and rigid, and thus do not disclose the claimed “loop” or a reduction in diameter of that loop as recited in Claim 10. EX1005, ¶[0076]; EX2026, ¶¶117-126.

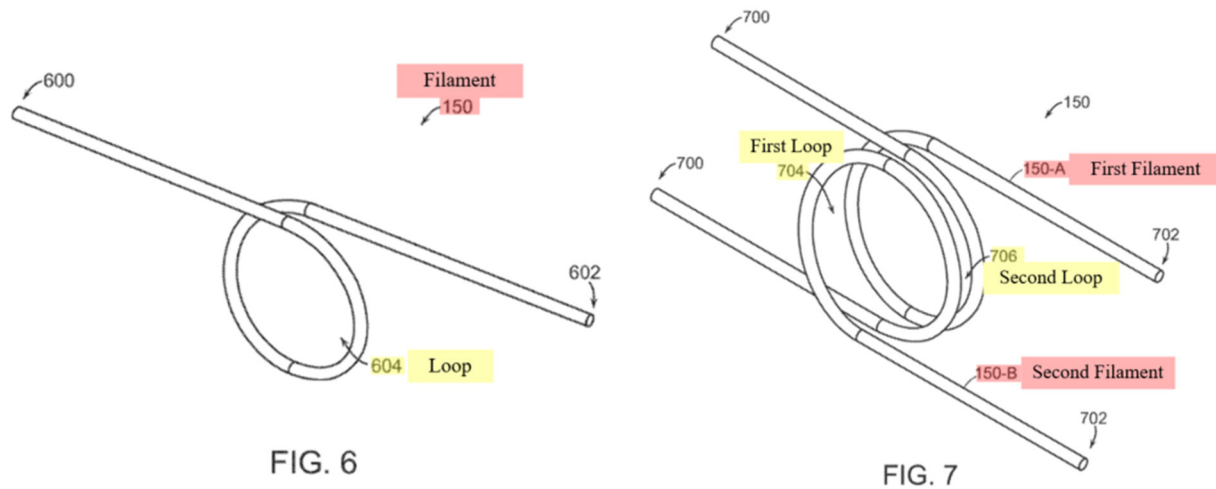
Petitioner does not allege that either of Schaffer's U-shaped actuating members alone is “formed in a loop” but instead alleges that Schaffer's U-shaped

actuating members “collectively constitute the ‘filament’” and “collectively loop around” Schaffer’s seal module. Petition, pp.45, 62-63, 82. However, Schaffer’s U-shaped actuating members cannot together be a loop because they are side-by-side and thus do not encircle any portion of the lumen.

First, Petitioner’s position is incorrect as a matter of law. The Federal Circuit has held that while “claim language that introduces a claim element using an indefinite article and further defines the element with subsequently recited functionality ... may allow for more than a single instance of the claim element, it may nonetheless require that a single instance of the element be capable of performing all the recited functionality.” *Salazar v. AT&T Mobility, LLC*, 64 F.4th 1311, 1317 (Fed. Cir. 2023) (affirming district court claim construction that claim reciting “a microprocessor” performing several functions requires a single microprocessor that performs all the recited functions). That is, “[f]or a dog owner to have ‘a dog that rolls over and fetches sticks,’ it does not suffice that he have two dogs, each able to perform just one of the tasks.” *In re Varma*, 816 F.3d 1352, 1362-64 (Fed. Cir. 2016). Schaffer’s two U-shaped actuating members do not together suffice as “a first filament” because neither is “formed into a loop.”

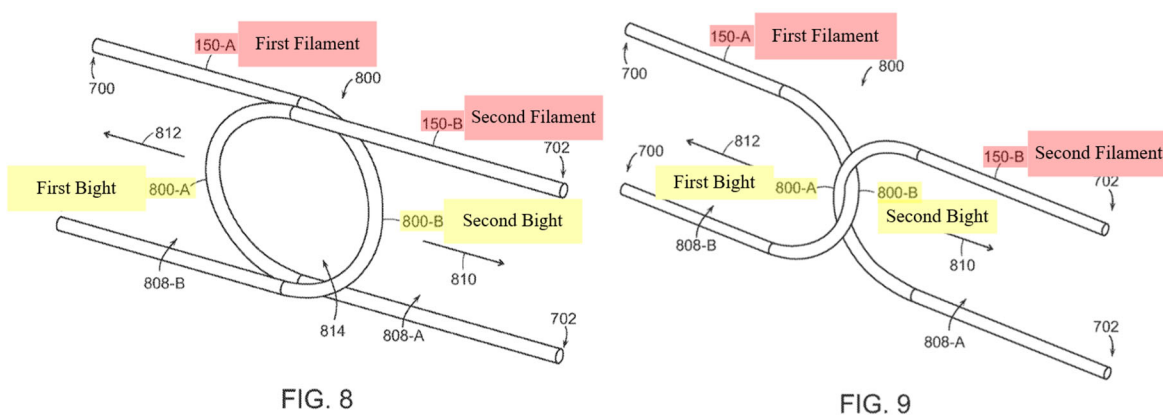
Second, the ’005 Patent demonstrates that Claim 10 requires at least one single filament “formed in a loop.” While the ’005 Patent discloses multiple different filament arrangements in Figures 6-9, the term “loop” is used exclusively for the

embodiments of Figures 6-7, which depict embodiments with one filament formed in a loop and two filaments each separately formed in a loop:



EX1017, ¶¶[0064]-[0066]; EX2026, ¶118.

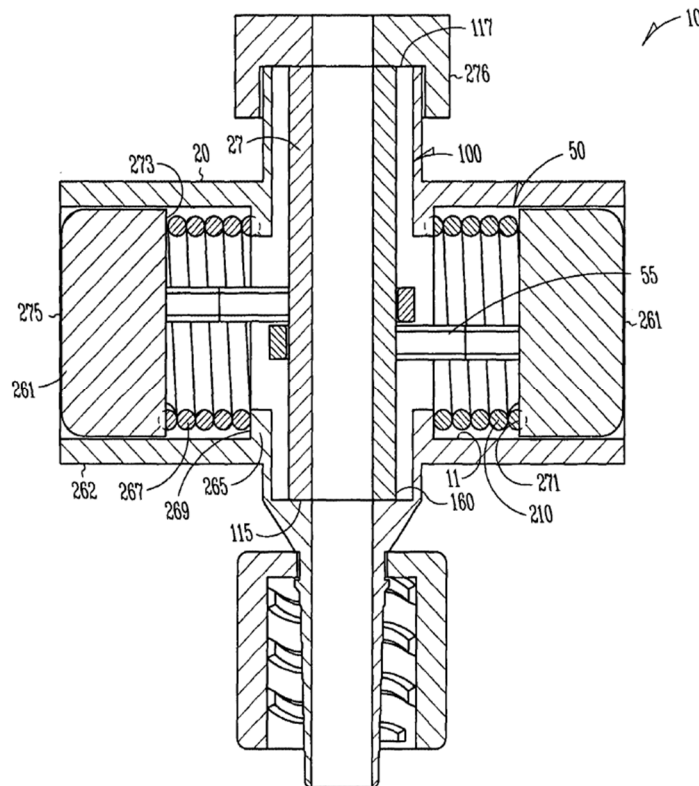
In contrast, Figures 8-9 illustrate a different arrangement with two filaments each forming a U-shaped bight:



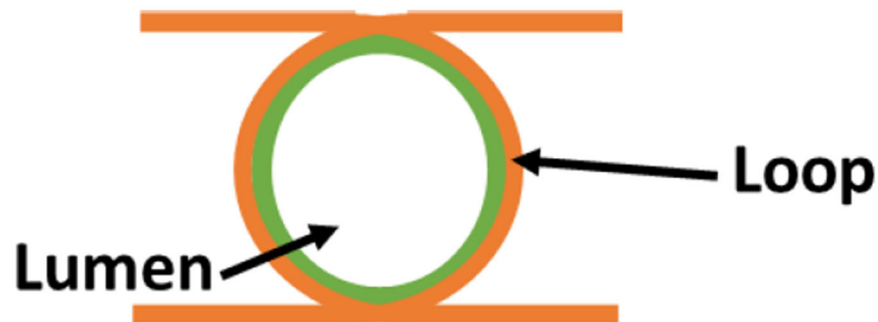
EX1017, ¶¶[0067]-[0069]; EX2026, ¶119. The '005 Patent explains that “a ‘bight’ refers to *a U-shaped section* between the two ends of the filament.” EX1017, ¶[0067] (emphasis added). Accordingly, when the '005 Patent uses the term “loop,”

the term does not refer to multiple U-shaped filaments as shown in Figures 8-9.
EX2026, ¶120.

Even if Schaffer's U-shaped members 55 are considered together, those members still do not form a "loop" because they are side-by-side, not overlapping:



EX1008, FIG. 34. Petitioner's "demonstrative graphic" is misleading:



Petition, p.63. Petitioner's expert admitted at deposition that the view provided in this "demonstrative graphic" is **not** a cross-section view—so the purported loop in this graphic does not exist. EX2029, 95:2-8.

Petitioner has therefore failed to demonstrate that Garrison and Schaffer render obvious Claim 1 because neither of Schaffer's U-shaped actuating members are "formed in a loop."

Schaffer also does not disclose "a diameter of the lumen decreases in response to reducing a diameter of the loop." The shape/dimension of each of Schaffer's rigid U-shaped actuating members is fixed such that the actuating members do not reduce in dimension or otherwise change during operation. EX2026, ¶125. Accordingly, Schaffer cannot disclose "reducing a diameter of the loop." *Id.*

Therefore, Schaffer does not disclose those limitations of Claim 10, regardless of the construction of "filament."

D. It Would Not Have Been Obvious to Have Modified Schaffer to Include the Filament Recited in Claims 1 or 10.

As set forth in §§III.B-C above, neither Garrison nor Schaffer disclose the "filament" or its specific configuration recited in Claims 1 and 10. With respect to ground 1, Petitioner does not allege that it would have been obvious for a POSA to have modified Garrison or Schaffer to arrive at those limitations of Claim 1. Rather, Petitioner simply alleges that "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.” Petition, pp.48-49. As explained herein, Petitioner’s purported motivation requires that a POSA first remove Schaffer’s internal seal member that seals by conforming to various shapes to then be motivated to replace Schaffer’s rigid actuating members with a filament that conforms as it constricts. But, POSA would not be motivated to do so as explained below. EX2026, ¶130. Nevertheless, because Garrison and Schaffer do not disclose all the limitations of Claims 1 and 10 set forth in §§III.A-C., and because Petitioner does not contend that Garrison or Schaffer renders such limitations obvious, ground 1 necessarily fails.

IV. CLAIMS 1 AND 10 ARE NOT OBVIOUS OVER THE COMBINATION OF GARRISON, SCHAFFER, AND HARTLEY (GROUND 2) OR ELLER (GROUND 3)

First, as set forth above in §III.A., Garrison and Schaffer do not disclose the claimed “on-off control in the flow path” “extending through the housing.” Petitioner does not allege that Hartley or Eller disclose this feature, nor do they. For this reason alone, Grounds 2 and 3 fail.

Second, a POSA would not have been motivated to replace Schaffer’s U-shaped actuating members with Hartley’s string or Eller’s wire, and *then further replace* Garrison’s valve with the modified Schaffer/Hartley/ Eller valve. Petitioner’s proposed modification and combinations are hindsight—requiring a POSA to first

manufacture a non-existent problem with Schaffer (gaps/poor sealing) by omitting Schaffer's third seal member, then modify Schaffer to remedy that non-existent problem in a manner that fundamentally changes Schaffer's principle of operation.

Moreover, Petitioner's proposed substitution is not a simple substitution of one known element for another because none of Petitioner's references disclose a single member (e.g., U-shaped member, string, or wire) coupled to and controlled by two actuators as in Petitioner's only proposed combination. Petitioner and its expert also admit that there are several comparably more plausible substitutions/modifications to seal Schaffer's valve, including those expressly disclosed in Schaffer. And, those modifications would not fundamentally change Schaffer's mode of operation. In contrast, a flexible string/wire would diminish the predictable sealing of Schaffer's valve.

Likewise, Petitioner's expert admits there were an unknown—not a finite and identified—number of options for constricting a tubular member in a hemostasis valve in 2017, contradicting Petitioner's reliance on an apparent “obvious-to-try” rationale.

Further yet, Garrison's readily-available and easy-to-use rotatable/passive hemostasis valves sufficiently “allow introduction of devices ... while preventing or minimizing blood loss during the procedure” (EX1011, ¶[0098]) such that a POSA

would not have been motivated to substitute Schaffer's ineffectively-sealing valve into Garrison and then further modify Schaffer's valve in view of Hartley or Eller.

A. A POSA Would Not Have Been Motivated to modify Schaffer's U-Shaped Members.

1. Petitioner's stated motivation to combine Schaffer with Hartley/Eller does not exist.

To demonstrate obviousness, Petitioner must provide a reason why a POSA would have been motivated to modify/combine the prior art to achieve the claimed invention. *Innogenetics, N.V. v. Abbott Labs.*, 512 F.3d 1363, 1374 (Fed. Cir. 2008); *see also Axonics, Inc. v. Medtronic, Inc.*, 73 F.4th 950, 957 (Fed. Cir. 2023) ("When an obviousness challenge asserts a combination of identified prior art, the motivation-to-combine portion of the inquiry is 'whether a 'skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention.'"). Petitioner's asserted motivation to modify Schaffer's actuating members would not have motivated a POSA because Schaffer's valve already solves the purported goal motivating the modification—sealing without gaps. Thus, Petitioner has not met its burden of showing that a "skilled artisan would have been motivated to combine the teachings" of Schaffer and Hartley/Eller.

Petitioner claims that a POSA would have recognized that "[d]epending on the inserted tool, Schaffer's actuating members may form small gaps between the valve's seal module and the tool's outer surface," and that a flexible member such

as Hartley's string/Eller's wire "may seal more effectively across a wider range of tool diameters and shapes than Schaffer's U-shaped actuating members." Petition, p.51. But, every illustrated embodiment of Schaffer discloses a valve that seals across a wide range of instruments without gaps—indeed, that is the purpose of Schaffer. EX2026, ¶¶134-139. More specifically, every illustrated embodiment of Schaffer includes the third seal member 165 that seals without gaps across a wide range of tool/device diameters and shapes. *Id.* at ¶¶ 68, 137-139.

First, as explained in § II.D.2, each of Schaffer's embodiments—including the embodiment shown in FIGS. 30-34 relied upon by Petitioner—includes the seal member 165. *See also* EX2026, ¶¶71, 137, 142, 151. And, at deposition, Petitioner's expert agreed that the seal member 165 is included in every illustrated embodiment in Schaffer: Schaffer Embodiment: Figures 1-4 (EX2029, 69:12-70:3), Schaffer Embodiment: Figures 5-19 (*id.* at 70:5-71:23), Schaffer Embodiment: Figures 20-22 (*id.* at 71:24-72:19), Schaffer Embodiment: Figures 23-26 (*id.* at 72:20-73:2), Schaffer Embodiment: Figure 27 (*id.* at 73:3-5), Schaffer Embodiment: Figures 28 and 29 (*id.* at 73:6-9), and Schaffer Embodiment: Figures 30-34 (*id.* at 73:13-77:3).

Mr. Thornton's admission that Figures 30-34 include the seal member 165 is contrary to his declaration that "Schaffer makes clear that the valves in Figures 31-34 do not require the third portion." EX1003, ¶124. But, Schaffer recites that "one or more seal members" are included and then illustrates and discloses only the third

seal member 165 as effectuating the seal. EX1005, ¶[0077]. Petitioner's assertion that the embodiment of Figures 31-34 does not require the very seal member that Schaffer expressly recites forms the seal, only to turn around and argue that a POSA would then be motivated to redesign Schaffer's valve because it forms a poor seal, is nonsensical.

Schaffer discloses that the third seal member 165 seals completely without gaps across a wide range of tool/device diameters and shapes. EX2026, ¶¶134-139. For example, Figures 16-19 of Schaffer show no gaps forming when the seal member 165 seals around a large circular lumen (Figure 16), a completely closed lumen without an instrument (Figure 17), an irregularly shaped lumen (Figure 18), and a small circular lumen (Figure 19):

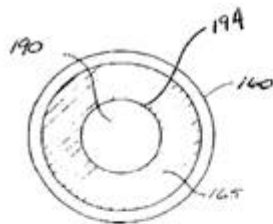


FIG. 16

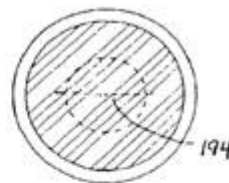


FIG. 17

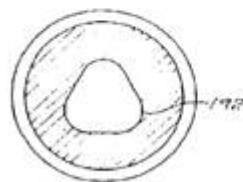


FIG. 18

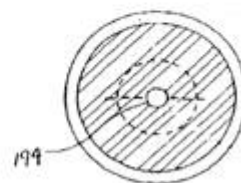


FIG. 19

EX2026, ¶138 (citing EX1005, ¶[0060]). The seal member 165 seals completely in all those scenarios by being highly compliant to conform to different shapes. *Id.* at ¶139; EX1005, ¶[0060] (“the highly compliant third central seal member 165 seals around a variety of profile shapes 192 and diameters 194 of the lumen”), ¶[0068] (The “material 166 of the third central seal member 165 is so compliant that it forms a seal around the [multiple] instruments 260 even if the instruments 260 are irregularly shaped.”).

Petitioner's expert asserts that “[n]othing in Schaffer suggests that the third valve portion must be made with a ‘sticky’ or ‘gelatinous’ substance.” EX1003, ¶124. In the Institution Decision, the Board similarly found Schaffer's “sticky” and “gelatinous” properties to be optional. Institution Decision, p.39. But Schaffer's Figures 30-34 (and every embodiment of Schaffer) do require the highly-compliant seal member 165 to effect sealing under compression, whether or not it is “sticky” and “gelatinous.” EX2026, ¶143. A POSA would further understand that Schaffer's seal member 165 seals regardless of whether it is “sticky” or “self-closing. *Id.* at ¶140. Moreover, for the embodiment of Figures 30-34, Schaffer discloses the same materials for the third seal member as in the previous embodiments. *Compare* EX1005, ¶[0059] with ¶[0081]; EX2026, ¶ 138.

Even Petitioner and its expert acknowledge that “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.” Petition, p.36; EX1003, ¶63. Moreover, Petitioner states: “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) ... Schaffer’s valve blocks ‘the flow of gas or fluid’ during medical procedures and, therefore, it remains closed.” Petition, pp.68; EX1003 ¶¶163-165. Accordingly, Petitioner acknowledges that Schaffer’s valve completely seals and that, if it did not, it would not be a “hemostasis valve.”

Grounds 3-4 fail for this reason alone: “[a] motivation to combine the teachings of references cannot be based on the alleged existence of a problem that does not exist...” *Aruba Networks, Inc. v. Xr Commc’ns LLC*, No. IPR2018-00701, 2018 WL 4090629 at *4 (P.T.A.B. Aug. 27, 2018), citing *In re Schweickert*, 676 F. App’x 988, 995-996 (Fed. Cir. 2017). Here, Petitioner’s expert admitted at deposition in the related ’011 IPR that if Schaffer forms a complete seal, there would be no need to modify Schaffer’s actuating members:

QUESTION: So if [Schaffer’s] U-shaped members formed a complete seal around multiple tools, there would be no reason to include Ellers’ wire member or Hartley’s string in Shafer; isn’t that correct?

MR. THORNTON: If it worked perfectly for all the range of tools, then there probably wouldn't be a need to make adjustments and move to a string-type member.

EX2028, 116:18-117:2. Dr. Zalesky agrees. EX2026, ¶140.

Schaffer's valve seals for the range of tools by virtue of the compliant seal member 165 such that POSA would not have been motivated to modify Schaffer to incorporate Hartley's string or Eller's wire.

2. Petitioner's alleged defect in Schaffer would only exist after first modifying Schaffer to create an inferior valve—but even this would fail to motivate a POSA to substitute Hartley's string or Eller's wire.

To arrive at Petitioner's stated motivation—the presence of gaps—a POSA would need **remove** or **omit** the third seal member 165 to create the purported gaps. Only then, according to Petitioner, would a POSA need to look elsewhere to solve that self-inflicted defect. But:

- (1) a POSA would not have removed the seal member 165 from Schaffer's valve;
- (2) Even if a POSA did, Petitioner has not demonstrated that a POSA would have been motivated to solve their manufactured problem by adding Hartley's string/Eller's wire; and
- (3) Petitioner's proposed modification based on Hartley/Eller is not suitable because it would not seal, unlike Schaffer's actual disclosure.

First, Petitioner provides no reason why a POSA would have removed or omitted the compliant seal member 165 from Schaffer's valve to create an inferior valve: not one reason. A POSA would not have because doing so would not achieve Schaffer's stated purposes of creating a "complete seal against leakage in the presence of a wide range of instruments or in the presence of multiple instruments." EX1005, ¶¶[0006], [0008]; EX2026, ¶144.

Second, even if a POSA were to remove the seal member 165 (they would not), a POSA still would not have been motivated to include Hartley's string/Eller's wire in Petitioner's proposed arrangement. In *Philip Morris Products S. A. v. RAI Strategic Holdings, Inc.*, the Board found Petitioner had failed to establish that a POSA would have been motivated to modify a primary reference Hon based on a secondary reference Whittemore when Hon itself taught modifications that would have addressed the alleged motivation. IPR2020-01602, 2022 WL 1022576 at *11-12 (P.T.A.B. Mar. 30, 2022). Specifically, the Board disagreed with Petitioner's proposed modification to simplify Hon by entirely removing Hon's atomizer and replacing it with Whittemore's wick and heater because "Hon itself described ways to simplify its design," and Petitioner did "not show persuasively that [the modification] would have simplified the device **as compared with the modifications Hon expressly teaches.**" *Id.* at *12 (emphasis added). The Federal Circuit affirmed explaining that "the proposed combination was based on a

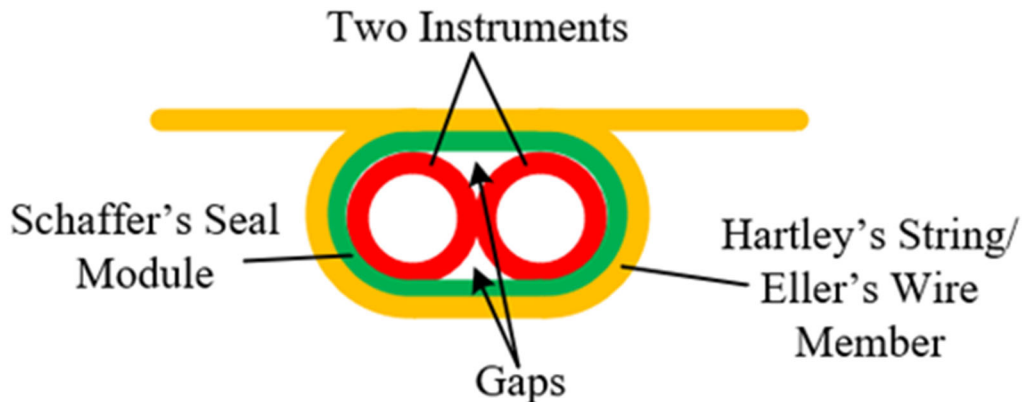
purported simplification of Hon **beyond what Hon itself teaches.**” *Philip Morris Prods. S.A. v. RAI Strategic Holdings, Inc.*, No. 2022-1846, 2023 WL 5970786 at *2 (Fed. Cir. Sept. 14, 2023).

Likewise here, Petitioner's motivation for modifying Schaffer requires modifying Schaffer beyond what Schaffer itself teaches. Schaffer teaches comparably simple modifications for solving the purported defect of Schaffer if, for some unexplained reason, a POSA omitted Schaffer's sealing member 165. EX2026, ¶¶184-186. First, a POSA would simply include the sealing member: problem solved with no further modification and without changing Schaffer's principle of operation or express methods of manufacture.

Moreover, Petitioner and its expert admit that Schaffer's valve could be improved—if needed—by adjusting properties of the seal module (which is just another way of saying to include the sealing member 165, or something like it), the spring strength of Schaffer's springs, and the like, as explained in detail in §IV.B.2; EX2026, ¶¶184-186.

Third, even if Schaffer were modified to remove the seal member 165, Petitioner's proposed combination would not solve the problem (gaps) when sealing around multiple/irregularly-shaped instruments—for which Schaffer is specifically designed to seal. EX2026, ¶146. For example, if two circular instruments were inserted side-by-side through Schaffer's seal module, Hartley's string/Eller's wire

in Petitioner's combination (which requires removing the seal member) might not seal the space (e.g., gaps/divots) between the instruments as shown below:



Id. So as further described below in §IV.B.3, Petitioner's proposed combination is **not** a "suitable option" for addressing the purported gaps and instead would create gaps not found in Schaffer. *Intel Corp. v. Qualcomm Inc.*, 21 F.4th 784, 800 (Fed. Cir. 2021). In contrast, Schaffer's seal member 165 **would** seal around multiple instruments by filling in the gaps and thus would be a "suitable option." *Intel*, 21 F.4th at 800; EX1005, ¶[0068]. A POSA would simply utilize Schaffer's disclosed design.

Petitioner has not met its burden of showing that a POSA would have been motivated to substitute Hartley's string/ Eller's wire member for Schaffer's U-shaped members to prevent Petitioner's purported gaps.

B. Petitioner's Proposed Modification to Include Hartley's String/Eller's Wire Is Not a Simple Substitution

Petitioner also advances a “simple substitution” rationale for modifying Schaffer's U-shaped members. Petition, pp.42, 50; *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007). But, a single actuating member (U-shaped member, string, or wire) having two ends coupled to and controlled by different actuators was not “known” from any of Petitioner's references. Moreover, a POSA would not have been motivated to substitute Hartley's string/Eller's wire member for Schaffer's U-shaped members because they would understand there are comparably more plausible substitutions—admitted by Petitioner—that would not depart from Schaffer's principles of operation including forcible disengagement, ease of manufacturing, and durability. *Philip Morris Prods. S.A. v. RAI Strategic Holdings, Inc.*, No. 2022-1846, 2023 WL 5970786, at *1 (Fed. Cir. Sept. 14, 2023) (“we view the Board in that case as agreeing with the patent owner's expert testimony that a more plausible ‘simple substitution,’ compared to the petitioner's proposed substitution, would be to replace Hon's entire atomizer...). Petitioner's proposed combinations would also not lead to the predictable result of sealing Schaffer's valve because Petitioner's proposed combination is not suitable for sealing around multiple/irregularly-shaped instruments—express purposes of Schaffer's valve.

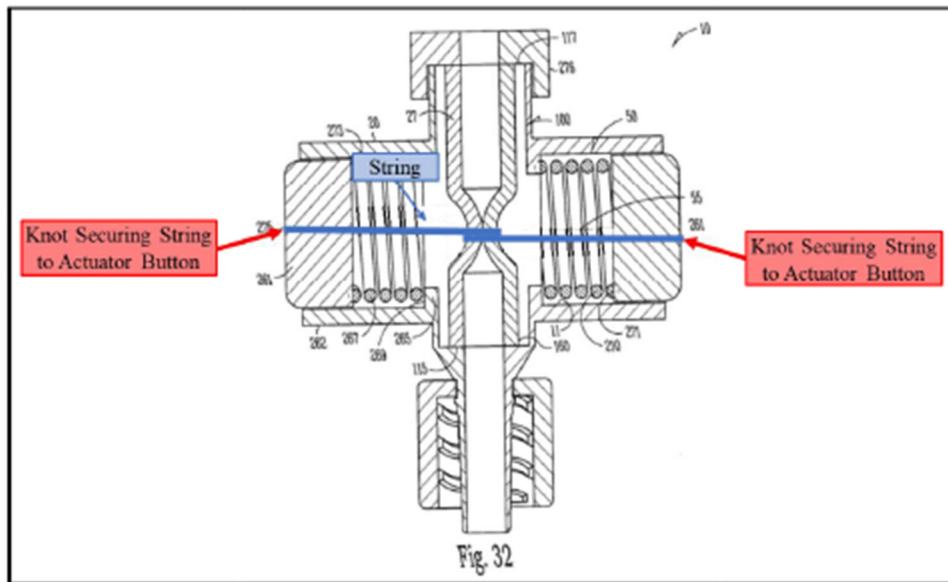
Intel Corp. v. Qualcomm Inc., 21 F.4th 784, 800 (Fed. Cir. 2021) (“It’s not necessary to show that a combination is ‘the best option, only that it be a *suitable* option.’”).

1. An actuating member including two ends attached to and controlled by different actuators was not “known” in the art.

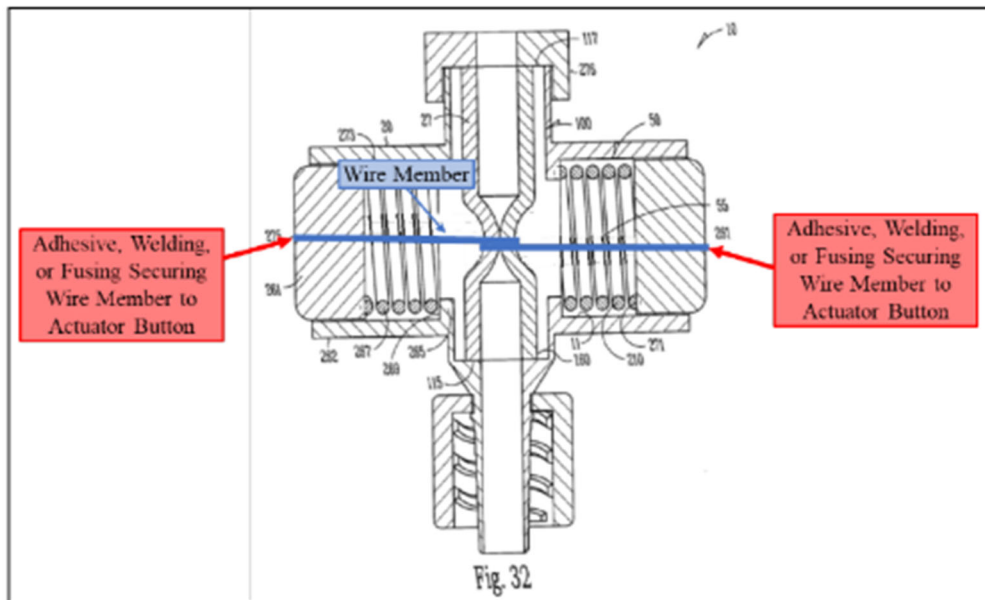
Petitioner’s proposed combination would not “have merely entailed substitution of one known element (Hartley’s string [or Eller’s wire member]) for another (Schaffer’s actuating members).” Petition, pp.50-51, 57. Instead, Petitioner’s proposed combination requires one end of Hartley’s string or Eller’s wire to be attached to one of Schaffer’s actuator buttons and the other end to be attached to the other of Schaffer’s actuator buttons. In that way, each of Schaffer’s actuator buttons independently control movement of one end of the string/wire, as shown in Petitioner’s demonstrative illustrations⁵:

⁵ Petitioner’s sole proposed combination of Schaffer and Hartley/Eller includes two actuators and one string/wire. Patent Owner accordingly addresses this combination.

Demonstrative Illustration
Schaffer + Hartley's String



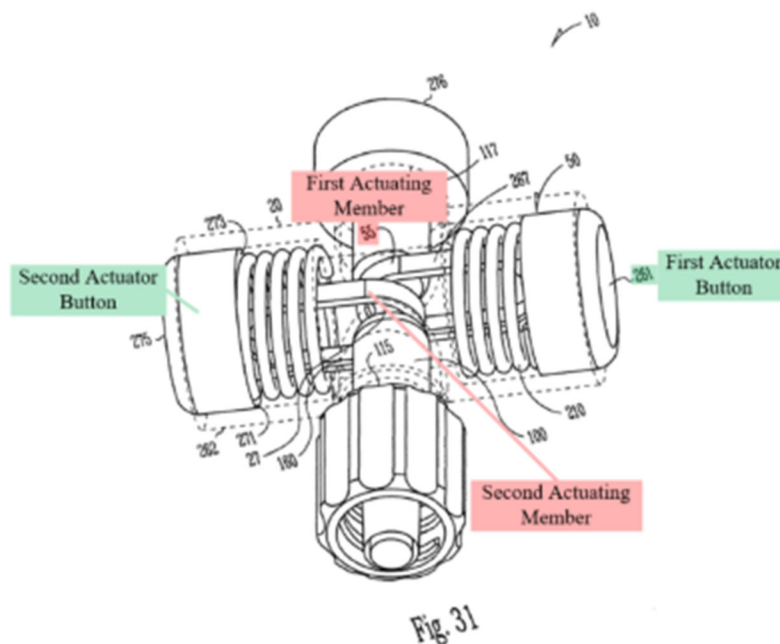
Demonstrative Illustration
Schaffer + Eller's Wire Member



Id. at pp.53, 58. But, as Petitioner's expert admitted at deposition, Schaffer, Hartley, and Eller do not disclose such an arrangement. Petitioner cites no reference

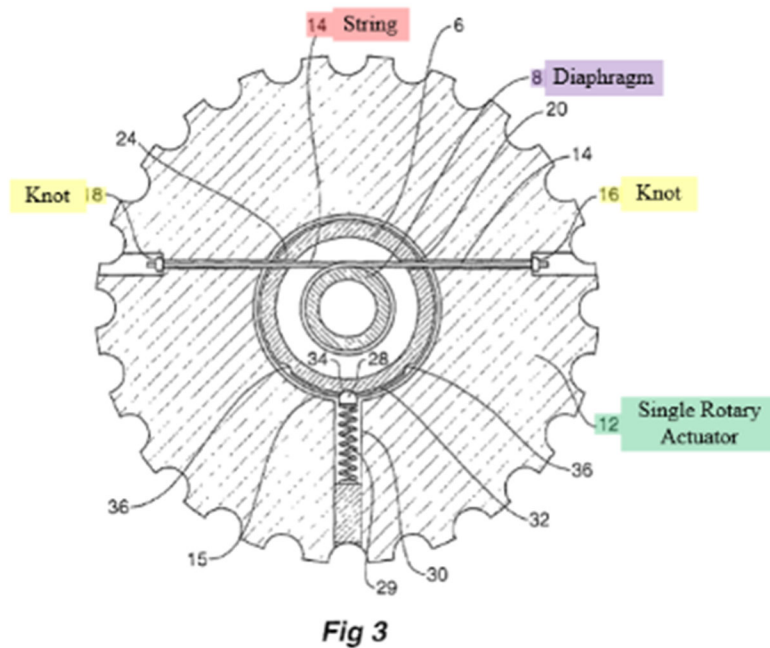
disclosing a single string/wire attached to and controlled by two independently movable actuators.

Both ends of each of Schaffer's U-shaped rigid actuating members 55 are attached to just one of the actuator buttons 261 such that movement of each of the actuator buttons controls movement of only one, not both, of the U-shaped actuating members:



EX2026, ¶160; EX2029, 57:7-22; EX2026, ¶160.

Hartley discloses an access valve having a string 14 extending around a cylindrical elastomeric diaphragm 8 and attached by knots 16/18 to a single rotary actuator 12:



EX1006, ¶[0031]; EX2026, ¶161. The rotary actuator 12 is a single piece such that both ends of the string are attached to and controlled by the same actuator. EX2026, ¶161. Neither end of the string can move without the exact same and equal movement of the other end of the string 14. *Id.*; EX2029, 77:12-22.

Eller discloses a selective fluid barrier device 810 including a housing 816, an actuator 818, a sleeve 820, and a wire member 822 having “a first end 924 attached to the housing 816 ... and a second end 926 attached to [a single] actuator 818”:

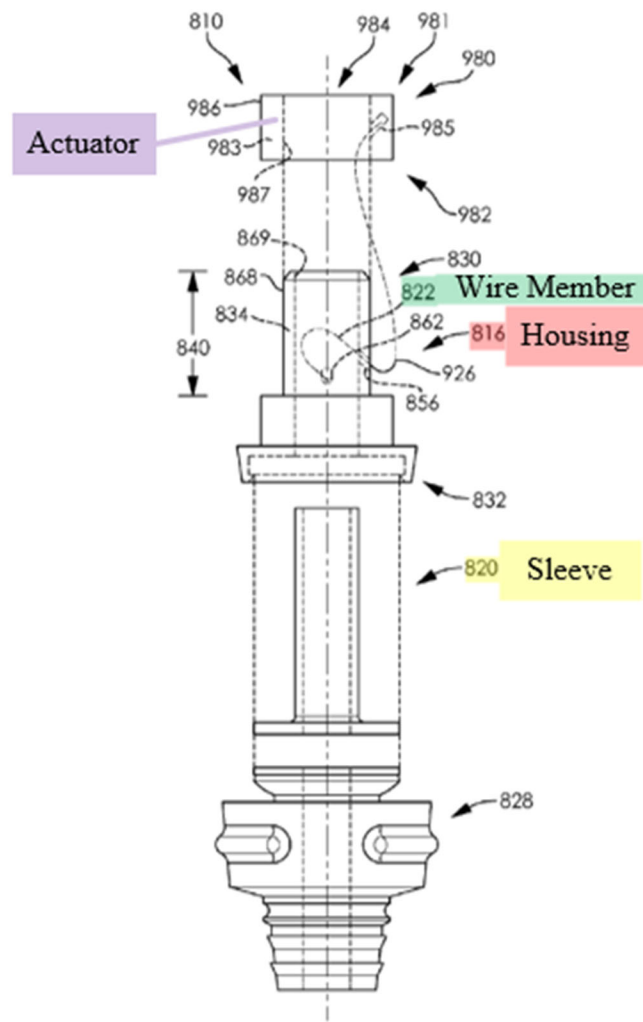


FIG. 20

EX1007, 23:50-62, 24:50-52. Eller discloses other embodiments with multiple wire members each having the same arrangement. EX2026, ¶¶162-164. In those embodiments, the wires have a first end coupled to a housing and a second end coupled to a single actuator. *Id.* at ¶165. Movement of the actuator pulls only the second end while the first end remains stationary such that wire moves predictably and a precise amount. *Id.*; EX2029, 80:11-19.

Accordingly, Petitioner's references disclose a single actuator that controls movement of a single actuating member. Petitioner's arrangement including a string/wire having two ends attached to two separate independently movable actuators is not disclosed by any of Petitioner's references and was thus not a "known element." EX2026, ¶167.

So under Petitioner's proposed combination, a POSA would need to not only *eliminate* Schaffer's rigid U-Shaped actuating members and replace them with a single flexible wire/string, but would also have to modify Schaffer to connect that single wire/string to *two different opposed actuators*—again, a configuration not found in any of Petitioner's references. EX2026, ¶¶159-167. Petitioner does not explain why this additional modification would be obvious, let alone why a POSA would make this additional modification. As such, Petitioner has failed to show that the claimed arrangement existed in the prior art, let alone provide a reason to modify the references to include that arrangement.

In sum, Schaffer, Hartley, and Eller do not disclose any element (U-shaped actuating member, string, or wire) attached to separate, individually-controlled buttons as in Petitioner's proposed combination, nor is there motivation to modify the references as Petitioner proposes. Grounds 2-3 fail for that reason alone.

2. Schaffer discloses comparably more plausible substitutions/modifications to address any purported sealing issues.

Petitioner's motivation to substitute Hartley's string/Eller's wire for Schaffer's U-shaped members is based on its expert's testimony that the combinations would "seal more effectively" and avoid the formation of "small gaps." Petition, pp.51, 57. As set forth in §IV.A. above, a POSA would not have been motivated to do so because Schaffer includes the highly-compliant seal member 165 which seals completely around a wide range of and multiple instruments and would not depart from Schaffer's principles of operation including forcible disengagement, ease of manufacturing, and durability. *R.J. Reynolds Vapor Co. v. Fontem Holdings I B.V.*, IPR2016-01268, Paper 63, pp.17-18 (P.T.A.B. Dec. 19, 2017) (finding Petitioner's proposed simple substitution nonobvious because there was a comparably more plausible substitution to simply replace the primary reference's entire atomizer with the secondary reference's atomizer); *see also Philip Morris Prods.*, 2023 WL 5970786, at *1 (Fed. Cir. Sept. 14, 2023) ("we view the Board in that case as agreeing with the patent owner's expert testimony that a more plausible 'simple substitution,' compared to the petitioner's proposed substitution, would be to replace Hon's entire atomizer").

Here, Petitioner and its expert provide several other modifications that are considerably more plausible than the wholesale change to Schaffer's valve that

would result in eliminating the two U-shaped members and replacing them with the single string/wire of Hartley/Eller. For example, when addressing Schaffer's alleged disclosure of Claim 5, Petitioner asserts that a POSA would have recognized multiple straightforward ways to enhance or maintain Schaffer's seal with a reasonable expectation of success, but that is a reason why a POSA would not make the wholesale changes that Petitioner proposes. *See* Petition, p.69. During deposition, Mr. Thornton confirmed that these simple adjustments would work, whether or not there was a pressure differential across the valve. EX2029, 121:21-122:12. Dr. Zalesky agrees. EX2026, ¶185. And, this would not require the wholesale hindsight changes that Petitioner proposes.

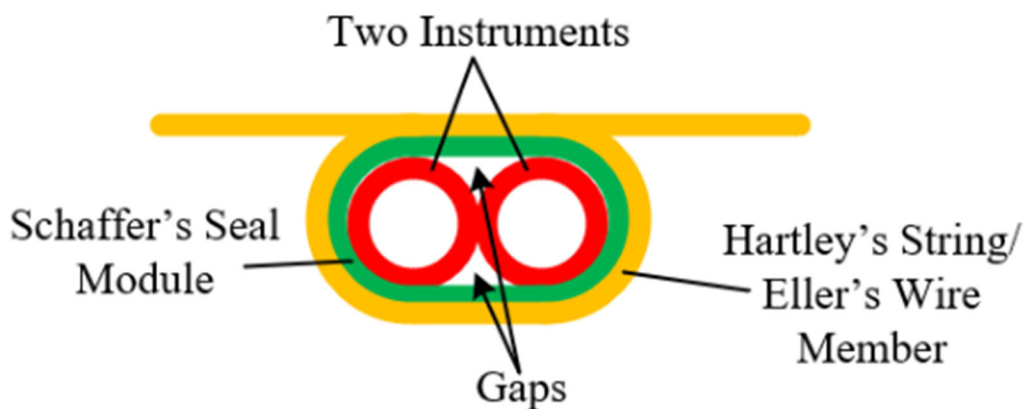
For example, Mr. Thornton confirmed that adjusting the spring strength would allow Schaffer's valve to be manufactured in the same manner it discloses. EX2029, 123:13-19. Dr. Zalesky agrees. EX2026, ¶185. And Petitioner provides no reason why a POSA would not have made the comparably simple "change" to use the specific properties of the seal member 165 disclosed in Schaffer if there was somehow a sealing issue (there is not), and that would also maintain Schaffer's principles of operations. EX2026, ¶¶185-186; EX1005, ¶[0059]; EX2026, ¶185.

Accordingly, Petitioner and its expert provide a number of comparably simple modifications found expressly in Schaffer's own disclosure, that a POSA would know would work to fix any sealing issues in Schaffer, but provide no reason why a

POSA would not make those simple modifications rather than their more complicated hindsight-based modifications that contradict Schaffer's principles of operation as explained below in §IV.D. EX2026, ¶¶184-186.

3. Petitioner's proposed substitution would not seal.

Petitioner's proposed combination would seal less effectively around multiple and/or irregularly-shaped instruments—scenarios for which Schaffer's valve is designed to form a complete seal as explained above in §IV.B.2:



EX2026, ¶146. It is therefore not a predictable result that Petitioner's proposed simple substitution would seal Schaffer's valve in the manner it is intended to, as it is not suitable for sealing around multiple instruments and irregularly-shaped instruments. *Intel Corp. v. Qualcomm Inc.*, 21 F.4th 784, 800 (Fed. Cir. 2021).

Likewise, Mr. Thornton testified that if flexible strings were used in the embodiment of Figures 8 and 9, he would be unable to know how the filaments would act. EX2029, 44:21-45:11. Accordingly, Mr. Thornton acknowledges that

using a flexible filament rather than rigid actuating members (like Schaffer's) can lead to positional variability that is not predictable without knowing more (e.g., "building prototype devices"). Dr. Zalesky agrees. EX2026, ¶103. That unpredictability is exacerbated by Petitioner's proposed modification because Hartley and Eller—the only references that disclose a flexible member—precisely control movement of that flexible member with a single actuator such that the flexible string/wire moves an equal amount upon actuation. EX2026, ¶¶161-165. In Petitioner's combination, the movement of the string/wire member would not be precisely controlled because either of Schaffer's buttons could be depressed independently to move the string/wire unpredictably. *Id.* at ¶167.

C. The Solutions for Constricting a Tubular Member in a Hemostasis Valve Were Not Finite, Identifiable, or Known

Petitioner advances what appears to be an "obvious to try" rationale for substituting Hartley's string/Eller's wire for Schaffer's U-shaped members. Petition, pp.43, 50; *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007) (discussing "obvious to try," and stating "[w]hen there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp."). To reach a determination that the claimed invention would have been obvious to try, "the possible approaches and selection to solve the problem

must be ‘known and finite.’” *Rolls–Royce, PLC v. United Techs. Corp.*, 603 F.3d 1325, 1339 (Fed. Cir. 2010) (citing *Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341, 1351 (Fed. Cir. 2008)). “The important question is whether the invention is an ‘identified, predictable solution’ and an ‘anticipated success.’” *Id.* (citing *Abbott Labs.*, 544 F.3d at 1352). “Thus, it is not enough for there to be a finite number of solutions, the options and solutions must have been identified and known.” *Kingston Tech. Co., Inc. v. Polaris Innovations Ltd.*, No. IPR2016-01623, 2018 WL 851884, at *5 (P.T.A.B. Feb. 9, 2018).

Here, Petitioner has failed to demonstrate that the options for “constricting a tubular member in a hemostasis valve” were finite, identified and known. Petitioner proposes only three options: “Hartley and Schaffer disclose two such materials: Hartley’s string and Schaffer’s actuating members formed from metal or plastic ... Eller discloses a third option: one or more wire members.” *Id.*; EX1003, ¶102. But at deposition, Petitioner’s expert admitted that there were many more ways to constrict a tubular member in a hemostasis valve including those disclosed in Schaffer ’616 (EX2027, 105:24-106:4, 106:12-14), Wong (*Id.* at 106:15-19), Kees (*Id.* at 108:14-20, 110:7-19), Myers (*Id.* at 111:9-23), his previous work on a hemostatic-type clamp prototype (*Id.* at 106:20-24), and more (*Id.* at 112:5-114:24).

In fact, Mr. Thornton admitted that he did not know how many options exist: “I don’t know how many options could be used to compress [a] tube.” EX2027,

107:3-13. Petitioner's "obvious to try" argument fails for this reason alone—the options and solutions for compressing a tubular member in a hemostasis valve were not known, finite, or identified.

D. Petitioner's Proposed Modifications Would Change Schaffer's Principles of Operation.

There is no motivation to modify a reference or combine prior art references where the modification/combination would alter the principle of operation or render the prior art inoperable for its intended purpose. *See Adidas AG v. Nike, Inc.*, 963 F.3d 1355, 1358-59 (Fed. Cir. 2020) (affirming lack of motivation to combine references where the proposed modification would "require the alteration of the principle of operation of [the primary reference] or would render [the primary reference] inoperable for its intended purpose."); *Plas-Pak Indus. V. Sulzer MixPak AG*, 600 Fed.App'x. 755, 758 (Fed. Cir. 2015) (rejecting obviousness findings where the necessary alterations to a first reference would fundamentally change its "principle of operation").

Schaffer's express purpose is to provide a device that seals yet provides a balance of "closing force, opening force, friction, compression and durability" so as not to damage or allow the insertion of delicate instruments and catheters and to allow a user to manipulate and advance those tools while compression is applied and the valve is sealed. EX1005, ¶[0007]; EX2026, ¶183; EX2031, 60:20-61:15.

Schaffer's rigid compression members and highly compliant internal seal member accomplish that purpose by, e.g., sealing "under very light compression." EX1005, ¶[0059]; EX2026, ¶183. Petitioner's proposed combination ignores that express purpose and fundamentally changes how Schaffer seals. A POSA would not make such a modification contrary to Schaffer's express disclosure, particularly where the modification does not improve, and could impair, the seal "in the presence of a wide range of instruments or in the presence of multiple instruments." EX1005, ¶[0006]; EX2026, ¶183.

Moreover, a POSA would understand that Schaffer's rigid U-shaped actuating members are necessary to "forcibly disengage" when unsealing, necessary for Schaffer's disclosed method of manufacture, and necessary to provide Schaffer's various benefits including reliability, durability, and an ability to seal under light compression. EX1005, ¶¶[0080]-[0082]. As such, a POSA would not have been motivated to modify Schaffer based on Eller/Hartley as Petitioner suggests. EX2026, ¶¶181-183.

Forcible disengagement is an important principle of Schaffer's valve design because it is part of Schaffer's solution for "balanc[ing] between closing force, opening force, friction, compression and durability." EX1005, ¶[0007]; EX2026, ¶183. Specifically, forcible disengagement makes it easy to open the valve and yet have strong closing forces. EX2026, ¶182. As explained above, Hartley's string or

Eller's wire would wrap around Schaffer's seal module in Petitioner's combination, and the seal module would expand against the string/wire to open when tension is released thereon. Petition, pp.53-54, 58-60. In this arrangement, Hartley's string/Eller's wire would never disengage—let alone forcibly disengage—Schaffer's seal module. EX2026, ¶182.

Moreover, Schaffer's U-shaped actuating members 55 are purposefully designed to be rigid and attached to a single actuator. EX2026, ¶169. That design choice provides simple methods of assembly and manufacturing, and effectively addresses Schaffer's recognized need for "a durable stasis valve" that can seal "under very light compression." EX1005, ¶¶ [0008], [0059]. Petitioner's proposed substitutions would introduce assembly difficulties and undermine the durability of Schaffer's valve. EX2026, ¶¶169-180. And, Schaffer's rigid members enables the valve to endure operational demands and maintain its performance and structural integrity over time. EX2026, ¶180.

In the Institution Decision, the Board stated that the "[manufacturing] methods cited by Patent Owner appear to relate to examples or optional techniques in Schaffer for making the valve." Institution Decision, p.43. Even if those methods are "optional," they are the only techniques disclosed. A POSA would not make the proposed wholesale changes to Schaffer that require abandoning the only manufacturing methods disclosed in Schaffer, particularly where other simple

modifications, including those disclosed in Schaffer, could be made that are consistent with Schaffer's disclosed methods of manufacture and operation.

E. A POSA would not have used Schaffer's allegedly ineffective valve in Garrison, then further modify that ineffective valve rather than use the hemostasis valve disclosed by Garrison.

As explained above, Petitioner's stated motivations to modify Schaffer in view of Hartley or Eller is based on a POSA's alleged understanding that Schaffer's valve forms gaps and thus does not seal effectively. Petition pp.51, 57. However, if this were true—it is not—a POSA would not have been motivated to substitute Schaffer's valve for Garrison's hemostasis valve and then further modify Schaffer's valve (in a manner antithetical the intended purpose and function of Schaffer's valve) in view of Hartley or Eller rather than utilize the conventional hemostasis valves that Garrison discloses “allow introduction of devices such as a microcatheter ... while preventing or minimizing blood loss during the procedure.” EX1011, ¶[0098]; EX2026, ¶187.

In particular, Petitioner relies on Garrison's disclosure of a hemostasis valve “such as a Tuohy-Borst or rotating hemostasis valve (RHV)” or “a passive seal hemostasis valve” to “allow introduction of devices such as a microcatheter, guide wire, or thrombectomy device while preventing or minimizing blood loss during the procedure.” EX1011, ¶[0098].

A POSA would understand the rotatable/passive hemostasis valves disclosed by Garrison to be easy-to-use, readily-available from many manufacturers, and—based on the disclosure of Garrison—sufficient to allow for the introduction of devices while “preventing or minimizing blood loss.” *Id.*; EX2026, ¶189. Assuming that a POSA would understand Schaffer's valve to seal ineffectively as alleged by Petitioner, a POSA would not have been motivated to substitute Schaffer's ineffective valve for Garrison's hemostasis valve, and then completely redesign Schaffer's valve to substitute Hartley's string or Eller's wire member to fix the ineffective valve. *Id.* Rather, a POSA would simply have used Garrison's rotatable/passive hemostasis valve that is expressly disclosed as effective for preventing blood loss. *Id.*

V. CLAIMS 1 AND 10 ARE NOT OBVIOUS OVER THE COMBINATION OF GARRISON, HARTLEY, AND ELLER (GROUND 4)

First, as set forth above in §III.A., Garrison does not disclose the claimed “on-off control in the flow path” “extending through the housing.” Petitioner does not allege that Hartley or Eller disclose this limitation. For this reason alone, Ground 4 fails.

Second, none of Garrison, Hartley, or Eller disclose a filament having “a first end” coupled to a first member of an actuator and a “second end” coupled to a second member of the actuator, as recited in Claim 1. EX2026, ¶¶194-197. The Board

agrees. Institution Decision, p.45. Ground 4 fails with respect to Claim 1 for this reason alone.

Further, Petitioner concedes that Hartley fails to disclose a “biasing system” or a “first spring” as recited in Claims 1 and 10, respectively, and alleges that it would have been obvious to include a biasing system/spring based on Eller. Petition, pp.93-97, 106. But a POSA would not have been motivated to modify Hartley in view of Eller as Petitioner proposes because doing so would be contrary to the purpose of Hartley. EX2026, ¶¶198-207. Ground 4 fails with respect to Claims 1 and 10 for this reason too.

A. Garrison, Hartley, and Eller Do Not Disclose the “Filament” Having Two Ends Extending in Different Directions and Coupled to Different Members of an Actuator of Claim 1.

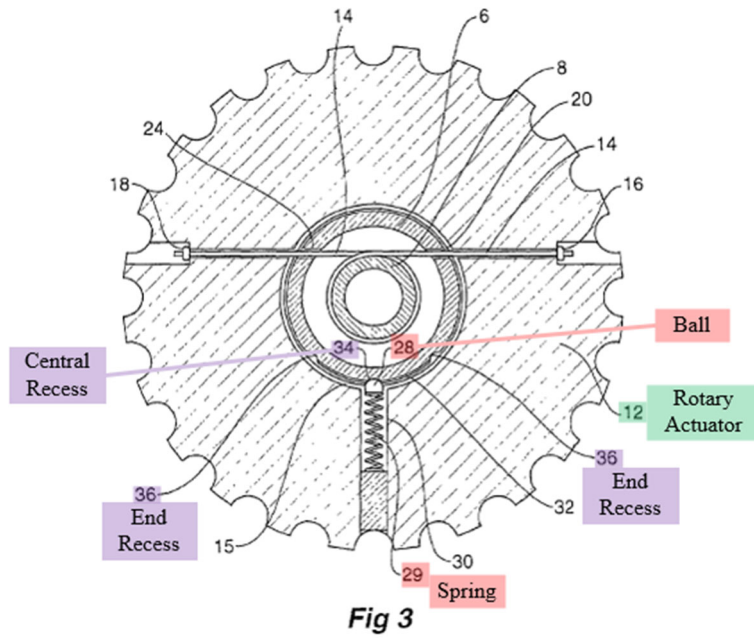
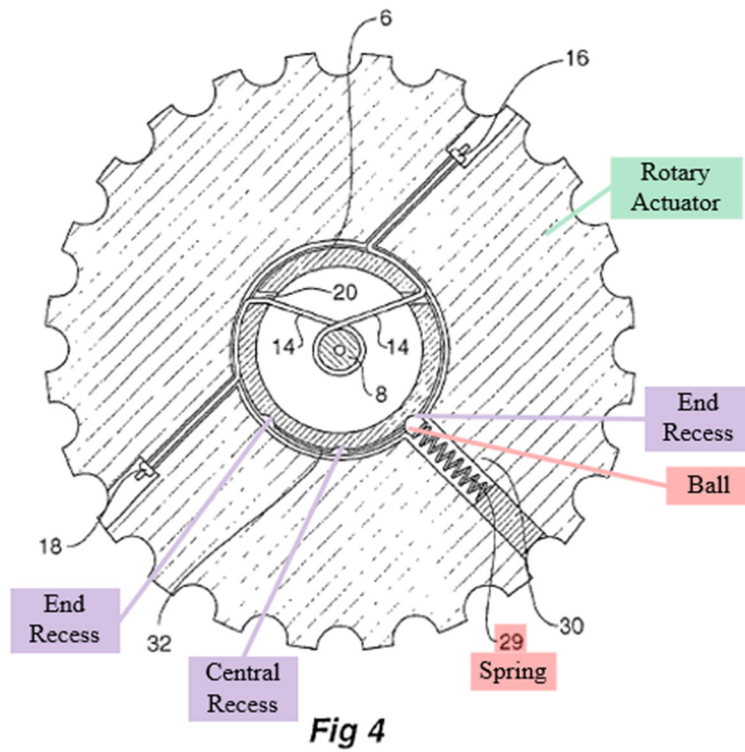
Garrison, Hartley, and Eller fail to disclose the filament of Claim 1 having “a first end extending ... in one direction and a second end extending ... in another direction” and an “actuator compris[ing] a first member coupled to the first end of the filament and a second member coupled to the second end of the filament.” Instead, both Hartley and Eller disclose a single actuator: (i) Hartley discloses a single string 14 having both ends coupled to the single rotary actuator 12 and (ii) Eller discloses a wire member having a first end attached to the actuator and a second end attached to the housing. EX2026, ¶¶194-197.

Indeed, in the related proceeding (*Imperative Care, Inc. v. Inari Medical Inc.*, IPR2024-01157), the Board disagreed with similar arguments raised by Petitioner, stating “[w]e agree with Patent Owner that Petitioner has not established that the modification of Hartley in view of Eller includes an actuator with a ‘first member’ and a ‘second member’ as claimed ... [t]he alleged ‘first member’ and ‘second member’ cited by Petitioner ... are simply portions of a single, unitary rotary actuator in Hartley.” Paper 7, p.42. The Board continued to agree with Patent Owner here, for similar reasons. Institution Decision, pp.45-46. Ground 4 fails for this reason.

B. Petitioner's Proposed Modification Would Change Hartley's Principle of Operation and Render Its Detent System Inoperable for Its Intended Purpose.

A POSA also would not have been motivated to modify Hartley to include Eller's spring as alleged by Petitioner, because that modification would eliminate the object of Hartley's invention. EX2026, ¶¶198-207. Specifically, the sole object of the invention in Hartley is to “provide an access valve which can be controlled to vary the size of the aperture through the valve and be flexible so that a seal may be formed against an instrument...inserted through the access valve.” EX1006, ¶[0004]. Hartley achieves that objective through a “detent arrangement” that includes a ball 28 biased by a spring 29 (both positioned in an aperture 30 in the

rotary actuator 12) to engage a central recess 34 and end recesses 36 of the housing
6:



Id.; EX2026, ¶199.

The ball and detent system ***retains*** the rotary actuator on the cylindrical housing in a selected position (EX1006, ¶¶[0015], ¶[0018]) and provides tactical feedback as the rotary actuator is rotated (*id.* at ¶¶[0018], [0033]). EX2026, ¶¶199-200. Accordingly, the three detents provide three different locking positions that correspond to three different opening sizes for the lumen, although Hartley further discloses that additional detents may be provided to allow for additional locked/retained lumen sizes. EX1006, ¶[0033]; EX2026, ¶¶199-200.

A POSA would understand that modifying Hartley to include Eller's spring "to bias the actuator [of Hartley] toward the closed position" as proposed by Petitioner (Petition, pp.96-97) would render Hartley's ball and detent system inoperable. EX2026, ¶201. To bias to the closed position, Eller's torsion spring would override the ball and detent system and eliminate Hartley's ability to selectively maintain various opening sizes for the lumen—acting to always seal the valve. *Id.* Specifically, for example, Hartley's valve could not be maintained in the open position shown in Figure 3 above in which the ball 28 engages the central recess 34 to maintain the valve in an open position. *Id.* The Board agrees that "adding a torsion spring to bias Hartley's valve to a closed position would seem to override the disclosed ball and detent system." Institution Decision, p.5.

Further, the pressure exerted by the torsion spring could create significant resistance against any instruments being advanced through Hartley's valve, especially in cases where softer instruments are used. EX2026, ¶205. Accordingly, a POSA would understand that Hartley's detent system, which allows for various lumen sizes to be maintained and instruments to be easily advanced, is necessary to Hartley's principle of operation and that modifying Hartley to include a spring would render that feature inoperable. *Id.* at ¶¶198-207. Petitioner fails to address Hartley's detent system and does not assert that a POSA would remove or change that system, let alone provide motivation for such a modification.

Accordingly, a POSA would not have been motivated to modify Hartley in view of Eller, and then substitute the modified valve into Garrison, because Petitioner's proposed modification would change the principle of operation of Hartley's detent system and eliminate the objective of Hartley's invention.

C. It Would Not Have Been Obvious to Have Modified Garrison to Include Hartley's Valve, Then Further Modify Hartley's Valve in View of Eller Rather Than Use Garrison's Hemostasis Valve.

As explained above, a POSA would understand the rotatable/passive hemostasis valves disclosed by Garrison to be easy-to-use, readily-available, and effective for allowing the introduction of devices while "preventing or minimizing blood loss." EX1011, ¶[0098]; EX2026, ¶208. A POSA would further understand Garrison's rotatable (e.g., Tuohy-Borst) valves to operate similarly to Hartley's

valve in that they can be selectively rotated to maintain various size openings of the valve, and Garrison's passive (e.g., cross-slit) valves to operate similarly to Eller's valve in that they return to a sealed position absent insertion of an instrument therethrough. *Id.*

Even if a POSA would have understood biasing to a sealed position to be the most important consideration for Garrison's valve—they would not have—Petitioner provides no explanation for why a POSA would not have simply used Garrison's passive hemostasis valve instead of substituting Hartley's valve and then further modifying the combination of Garrison and Hartley based on Eller to provide a self-closing structure in a manner that destroys the functionality of Hartley's ball and detent. *Id.* at ¶209. And, a POSA would not have in such a scenario—they would have simply used Garrison's passive valve. *Id.*

VI. DEPENDENT CLAIMS 2-9 AND 11-15 ARE NOT OBVIOUS OVER ANY COMBINATION OF GARRISON, SCHAFFER, HARTLEY, AND ELLER

Claims 2-9 depend from Claim 1 and thus include all the limitations of Claim 1. Claims 11-15 depend from Claim 10 and thus include all the limitations from Claim 10. Accordingly, those claims are also not rendered obvious by any of the combinations of Garrison, Schaffer, Hartley, and Eller (grounds 1-4).

These dependent claims are also not obvious over any of the combinations of Garrison, Schaffer, Hartley, and Eller for additional reasons. For example, Claim 11,

which depends from Claim 10, recites “a second member movably coupled to the support.” As set forth above in §IV.B., none of Garrison, Schaffer, Hartley, and Eller disclose a moveable second member in combination with the other features of Claim 10. As another example, Claim 12, which depends from Claim 10 via intervening dependent Claim 11, recites that “the filament further comprises a second end portion extending away from the loop to the second member.” As set forth in §IV.B., none of Garrison, Schaffer, Hartley, or Eller disclose a filament connected to different actuating members at different ends. As yet another example, Claim 13, which depends from Claim 10 via intervening dependent Claims 11 and 12, recites that the “first end portion [of the filament], the loop, and the second end portion [of the filament] are one continuous filament.” As set forth in §IV.B., none of Garrison, Schaffer, Hartley, or Eller disclose a “continuous filament” coupled at opposite end portions to opposite, movable members. Claims 14 and 15 depend from Claim 10 via intervening Claims 11 and 12, and therefore are not rendered obvious by any of the combinations of Garrison, Schaffer, Hartley, and Eller for these reasons as well.

VII. CONCLUSION

For all the above reasons, Petitioner has not met its burden of establishing a reasonable likelihood of success in showing that at least one claim is unpatentable as obvious over the cited art. Patent Owner respectfully requests that the Board deny institution.

Respectfully submitted,

Dated: September 10, 2025

By: / Joseph P. Hamilton /
Joseph Hamilton
Reg. No. 51,770
Lead Counsel for Patent Owner

CERTIFICATE OF COMPLIANCE

Pursuant to 37 C.F.R. § 42.24(d), I, Joseph Hamilton, certify that **PATENT OWNER'S PRELIMINARY RESPONSE** contains 13,930 words, excluding those portions identified in 37 C.F.R. § 42.24(a), as measured by the word-processing system used to prepare this paper.

Dated: September 10, 2025

By: / Joseph P. Hamilton /
Joseph Hamilton
Reg. No. 51,770

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), I certify that on September 10, 2025, a copy of **PATENT OWNER'S PRELIMINARY RESPONSE, and EXHIBITS 2026-2031** was served upon the below-listed counsel by electronic mail:

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