

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

IMPERATIVE CARE, INC.,
Petitioner,

v.

INARI MEDICAL, INC.,
Patent Owner.

Case No. IPR2025-00989
U.S. Patent No. 11,865,291

PATENT OWNER'S PRELIMINARY RESPONSE

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EXHIBIT LIST

	Petitioner’s Exhibits
Exhibit	Description
1001	U.S. Patent No. 11,865,291 (“the ’291 patent”)
1002	Prosecution History of the ’291 Patent
1003	Expert Declaration of Troy Thornton
1004	Resume of Troy Thornton
1005	U.S. Patent Publication US 2003/0225379 A1 to Schaffer et al. (“Schaffer”)
1006	U.S. Patent Publication US 2003/0116731 A1 to Hartley (“Hartley”)
1007	U.S. Patent No. 9,980,813 B1 to Eller (“Eller”)
1008	Certified File History of U.S. Patent Application 10/371,190 (Schaffer File History)
1009	U.S. Patent No. 5,429,616 to Schaffer (“Schaffer ’616”)
1010	RESERVED
1011	U.S. Patent Publication US 2015/0173782 A1 to Garrison et al. (“Garrison”)
1012	U.S. Patent No. 11,697,011 (“the ’011 patent”)
1013	Inari’s Supplemental Infringement Contentions (without claim charts) from <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , No. 24-cv-3117 (N.D. Cal.) (served February 7, 2025).
1014	New Oxford American Dictionary, 3rd ed. (2010) – definitions of “diameter,” “filament,” and “loop”
1015	RESERVED
1016	U.S. Patent No. 12,109,384 B2 to Merritt et al.

	Petitioner's Exhibits
Exhibit	Description
1017	Decision Granting Institution of <i>Inter Partes</i> Review for U.S. Patent No. 11,697,011 (Paper 7) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2024-01157 (P.T.A.B. Jan. 23, 2025)
1018	PCT Patent Publication WO 2018/019829 A1 to Brady et al.
1019	Inari's Notice of Motion and Motion for Leave to File Third Amended Complaint (Dkt. #88) in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 24-cv-03117-EKL (N.D. Cal.) (filed March 5, 2025)
1020	U.S. Patent No. 6,776,770 B2 to Trerotola
1021	Case Management & Scheduling Order (Dkt. #54) in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 24-cv-03117-EKL (N.D. Cal.) (issued December 19, 2024)
1022	U.S. Patent No. 11,697,012 B2 ("the '012 patent")
1023	Decision Granting Institution of <i>Inter Partes</i> Review for U.S. Patent No. 11,697,012 (Paper 6) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-00156 (P.T.A.B. Apr. 22, 2025)
1024	Imperative Care's Opposition to Inari's Motion for Leave to File Third Amended Complaint (Dkt. #98) in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 24-cv-03117-EKL (N.D. Cal.) (filed March 26, 2025)
1025	Imperative Care's Notice of Motion and Motion to Stay Pending <i>Inter Partes</i> Review (Dkt. #100) in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 24-cv-03117-EKL (N.D. Cal.) (filed April 2, 2025)
1026	Patent Owner's Exhibit 2002 filed in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-00289 (P.T.A.B.)
1027	Claim Construction Excerpt Report of Troy Thornton in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 24-cv-03117-EKL (N.D. Cal.)

	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	U.S. Patent Application Publication No. 2018/0193043
2005	Deposition Transcript of Troy Thornton (September 30, 2024)
2006	Deposition Transcript of Troy Thornton (March 19, 2025)
2007	Deposition Transcript of Troy Thornton (June 25, 2025)
2008	U.S. Patent No. 7,682,380 to Thornton ("Thornton")

I. INTRODUCTION

Patent Owner requests that the Board deny institution because Petitioner has failed to demonstrate that any one of Claims 1-8 and 12-19 of the '291 Patent are unpatentable.¹ Independent Claims 1 and 18 of the '291 Patent each recite, *inter alia*, a “hemostasis valve” comprising a “collapsible tubular sidewall defining a lumen” and “a filament formed in a loop around the tubular sidewall” where the lumen is constricted “in response to reducing a diameter of the loop.” As explained herein, the terms “filament” and that the filament must be “formed in a loop” and constrict by “reducing a diameter of the loop” require that the filament be flexible.

In contrast, Petitioner's primary reference for Grounds 1-4, Schaffer, adopts a fundamentally different approach to sealing a lumen and thus operates in a manner that neither discloses nor renders obvious those limitations. Instead of a filament that is “formed in a loop” and constricts by “reducing a diameter of the loop,” Schaffer discloses applying compression with rigid, side-by-side U-shaped actuating members that are not formed into a loop and cannot reduce in diameter. Instead, Schaffer's fundamentally different approach relies on those rigid U-shaped members to compress a highly-compliant seal member 165 inside the lumen that internally conforms to the shape of the lumen or any instruments inserted through the lumen

¹ The Petition does not challenge the patentability of Claims 9-11 or 20.

as the seal member is compressed to form a seal. Indeed, every illustrated embodiment of Schaffer includes the seal member 165 to effectuate a seal. EX2007, 69:7–77:3.

Schaffer's fundamentally different principle of operation addresses a particular challenge in the field of hemostasis valves. As Schaffer explains, the “problems are complex” and require a “balance between closing force, opening force, friction, compression and durability.” EX1005, ¶[0007]. Schaffer further explains that “[i]f a valve is inordinately tight ... it may not allow the insertion of soft, flexible instrumentation” or can damage “delicate” catheters. *Id.* To achieve that balance, Schaffer discloses a valve employing rigid nonconforming actuating members which allow for precise regulation of compression to reliably open or close the valve in a controlled manner. And then to effectuate a seal, Schaffer employs an internal “highly compliant third central seal member 165 [that] seals around a variety of profile shapes 192 and diameters 194 of the lumen 193”—including both around multiple instruments and irregularly shaped instruments—as the rigid actuating members apply an external compressive force. EX1005, ¶[0060]; EX2001, ¶¶108-110. The internal seal member can form a complete seal “under very light compression.” EX1005, ¶[0059]. Schaffer further discloses additional advantages of its design, such as improved durability and simplified manufacturing, attributable to the use of rigid, nonconforming actuating members. EX2001, ¶¶138-149.

Ground 1 (anticipation by Schaffer) fails because Petitioner does not demonstrate that Schaffer discloses “a filament formed in a loop” or where a “diameter of the loop” is capable of “reducing.” First, a POSA would recognize that the claimed filament must be flexible to form a loop capable of reducing in diameter as recited in Claim 1. EX2001, ¶¶65-66, 86-93; *see also* Institution Decision in an IPR for related U.S. Patent No. 11,697,012 (“the related ’012 IPR”), EX1023, p.17 (“[i]f the filament used to form this ‘loop’ was not flexible to some degree, we do not see how the hemostasis valve would function as intended.”). Schaffer’s side-by-side, rigid U-shaped members are neither flexible nor “formed in a loop.” Indeed, two side-by-side members cannot form a loop, and the shape and dimension of Schaffer’s rigid actuating members cannot reduce or otherwise change during operation because they are rigid. EX2001, ¶¶78-93. Thus, Ground 1 fails.

Grounds 2-4 (obviousness over Schaffer alone, or with 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 string or wire as disclosed in Hartley and Eller, respectively. Petitioner’s purported motivation to combine ignores that Schaffer’s valve forms a complete seal (as Petitioner admits) via the seal member 165 that is “so compliant that it forms a seal around ... instruments 260 even if the instruments 260 are irregularly shaped” by conforming to their shape. EX1005, ¶[0068]. Instead, Petitioner’s purported motivation to combine relies on its expert’s

testimony that Schaffer's valve would form a poor seal with gaps despite Schaffer's disclosure otherwise. Petition, p.51. As such, a POSA would not have redesigned Schaffer to introduce a non-existent problem (gaps) particularly where the proposed modification is contrary to Schaffer's fundamental principle of operation, namely, using nonconforming compression members with an internal highly-compliant seal member and all its associated benefits. 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. EX2006, 116:18-117:2. In sum, Petitioner's proposed modifications to Schaffer either alone or in combination 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 3-4 further fail because, as Petitioner and its expert admit, there are other simpler modifications based on Schaffer's disclosure that would remedy sealing issues, if any, that are consistent with and would not change Schaffer's principles of operation including those expressly disclosed in Schaffer. EX2001, ¶¶153-155. Additionally, Petitioner's proposed substitution is not suitable because it would not predictably seal Schaffer's valve in the presence of multiple instruments

or irregularly shaped instruments—scenarios for which Schaffer is intended to seal completely. *Id.* at ¶113; EX1005, ¶¶[0006], [0008], [0068]. Finally, Petitioner's apparent "obvious to try" rationale does not establish 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 in the related '012 IPR: "I don't know how many options could be used to compress a tube." EX2007, 107:12-13.

Grounds 5-7 (obviousness over Garrison and Schaffer, or over Garrison, Schaffer, and either of Hartley or Eller) fail for the same reasons as Grounds 1-4, namely, Petitioner does not rely on Garrison for disclosing or rendering obvious any of the missing limitations identified above that are also recited in Claim 18. Instead, Petitioner relies on Garrison for other limitations. As such, Garrison does not remedy the deficiencies of Schaffer, Hartley, and Eller as explained herein.

For those and the reasons set forth herein, Petitioner has failed to demonstrate a reasonable likelihood that any of Claims 1-8 and 12-19 are unpatentable under any of Grounds 1-7.

II. BACKGROUND

A. Overview of the '291 Patent

The '291 Patent 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.” EX1001, 1:51-55. So, to address those drawbacks, the '291 Patent discloses a hemostasis valve, “referred to as a garrote valve,” that “can seal with or without a tool extending through the valve.” EX1001, 5:56-58.² This hemostasis valve enables medical professionals to easily operate the valve while maintaining a robust seal to prevent blood loss during procedures, such as aspiration thrombectomy procedures with large bore catheters in large vessels for treating deep vein thrombosis or pulmonary embolism, in which ease of use and a robust seal are particularly important. EX2001, ¶¶34-36; EX1001, 1:64-2:14, 5:17-23, 5:58-6:6, 16:7-31.

So, the '291 Patent's “garrote” valve includes a collapsible tubular sidewall defining a valve lumen and a constricting mechanism. EX1001, 7:11-57, 8:5-16. The constricting mechanism includes a filament that is formed into a loop around a tubular sidewall and an actuator element connected to an end of the filament for tensioning the filament to (1) tighten and constrict in one position to seal the valve and (2) loosen in another position to allow the valve to at least partially open and unseal. *Id.* at 8:5-12, 13:17-29. The filament(s) can have different configurations as shown in Figures 6-9 of the '291 Patent. EX2001, ¶¶41-47. For example, as shown

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

in Figure 6, a filament 150 can be configured to form a single loop 604 that extends around the tubular sidewall:

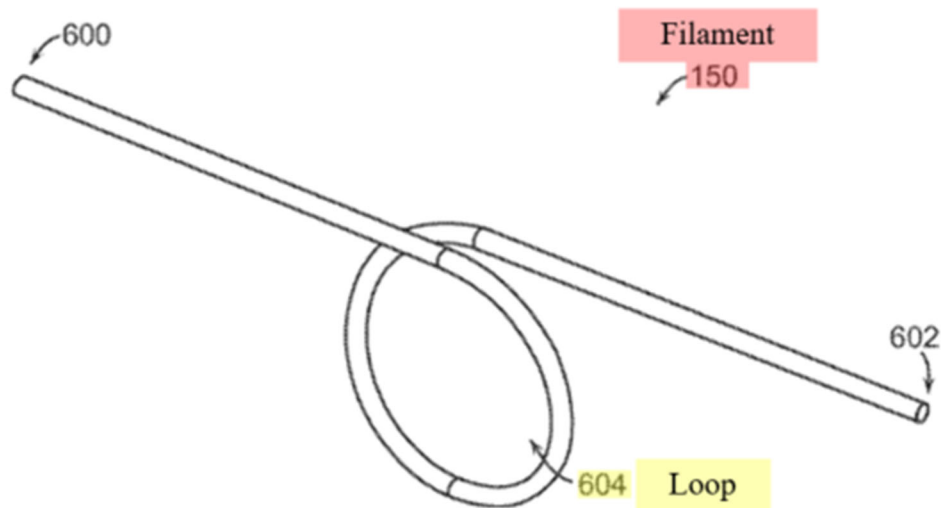
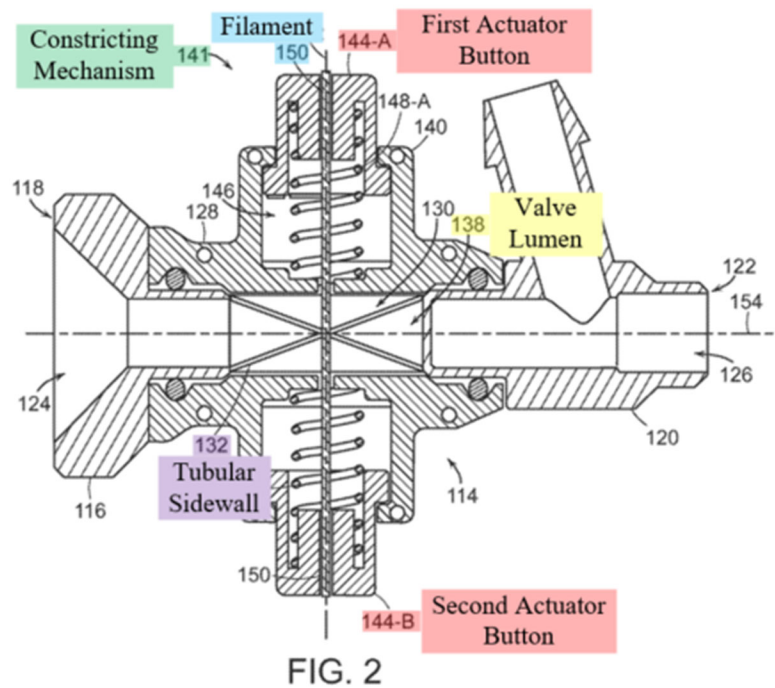


FIG. 6

EX1001, 13:17-21. Figure 7 depicts two filaments each formed into a loop (704 and 706).

The actuator may be a manual button, enabling easy one-handed use. EX1001, 8:23-32. Specifically, the actuator element(s) pulls the filament to decrease a diameter of the loop, thereby collapsing and sealing the tubular sidewall:



Id. at 8:12-16, 13:17-29; EX2001, ¶40.

The actuator can be biased towards a sealed position. EX1001, 8:38-40; EX2001, ¶41. In the first configuration, depicted in Figure 2 above, the tubular sidewall is collapsed or sealed, with the buttons in an undepressed position. EX1001, 8:40-46; EX2001, ¶41. Springs bias the buttons towards this first configuration. EX1001, 8:46-67; EX2001, ¶41.

B. Claims

Claim 1 is directed to an innovative hemostasis valve including garrote mechanisms that enhance the sealing capability compared to prior art valves while simplifying operator use. EX2001, ¶¶34-37.

Specifically, Claim 1 includes a “filament formed in a loop around the tubular sidewall” that “define[s] a lumen.” The “filament” further comprises “a first end portion extending away from the loop to the first member.” Additionally, “a spring” biases the actuator such that “a diameter of the lumen” decreases “in response to reducing a diameter of the loop.”

Claim 2 depends from Claim 1 and further requires “a second member movably coupled to the support.” Claim 3 depends from Claim 2 and recites, *inter alia*, “the filament further comprises a second end portion extending away from the loop to the second member.” Claim 4, in turn, depends from Claim 3 and recites, *inter alia*, “the end portion, the loop, and the second end portion are one continuous filament.” Finally, Claim 18 is directed to an aspiration catheter system that incorporates the hemostasis valve disclosed in Claim 1.

C. Prosecution History

In the Notice of Allowance, the Examiner referenced Hartley and explained that “[a]lthough Har[t]ley discloses a spring 29; however, the spring 29 does not perform a function required in the claimed invention, i.e. the spring configured to move the first member in a direction that pulls the first end portion away from the tubular sidewall, reducing a diameter of the lumen in response to reducing a diameter of the loop.” EX1002 at pp.393-394. In addition to expressly considering Hartley,

the Examiner also considered Eller, listing Eller as one of eight references in a Notice of References Cited that accompanied the Notice of Allowance. *Id.* at p.396.

D. Asserted Art

1. Schaffer

Schaffer discloses a hemostasis valve that employs a different method of sealing from the '291 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.

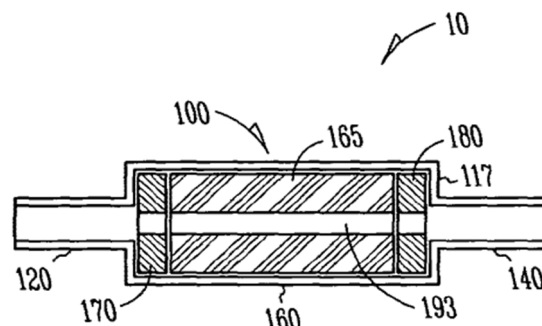


Fig. 12

Schaffer's sealing members are central to Schaffer's method of forming a seal and sealing member 165 is included in every illustrated embodiment. EX2001, ¶55. 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.

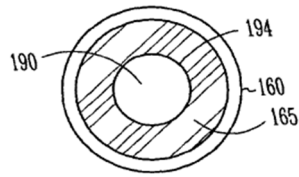


Fig. 16

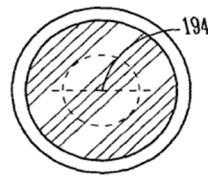


Fig. 17

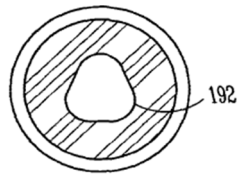


Fig. 18

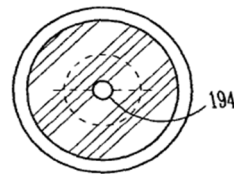


Fig. 19

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

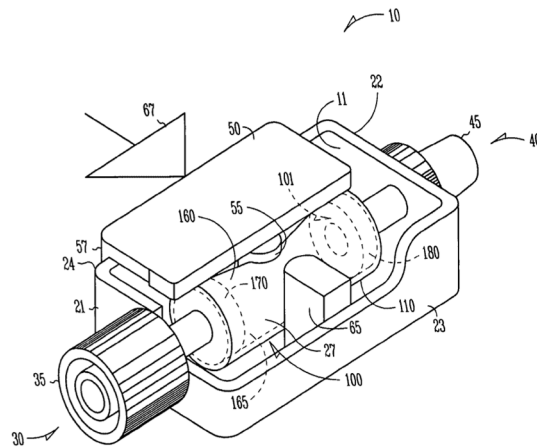
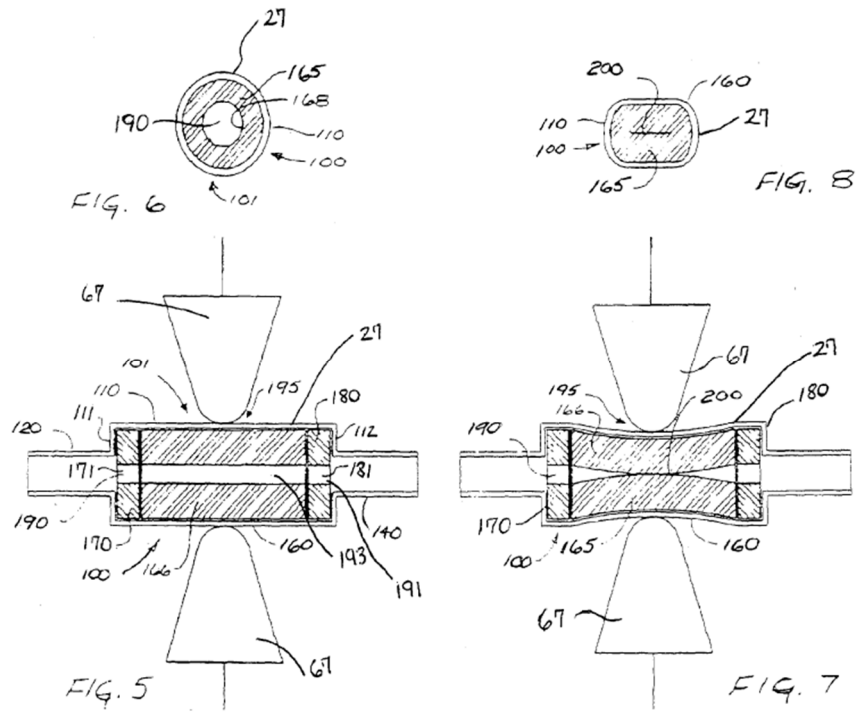
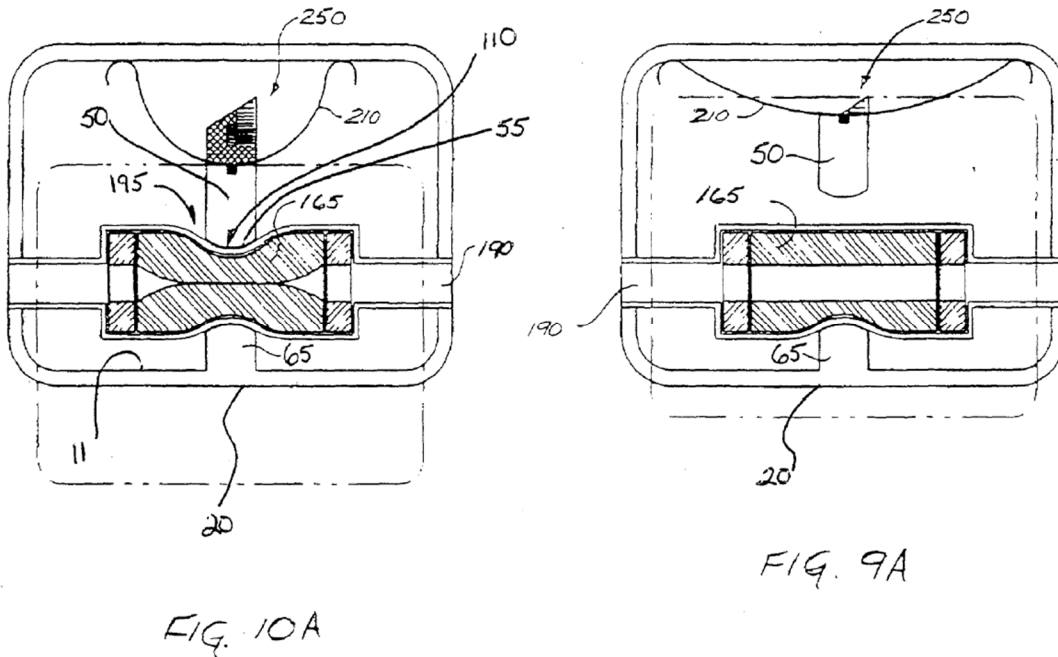


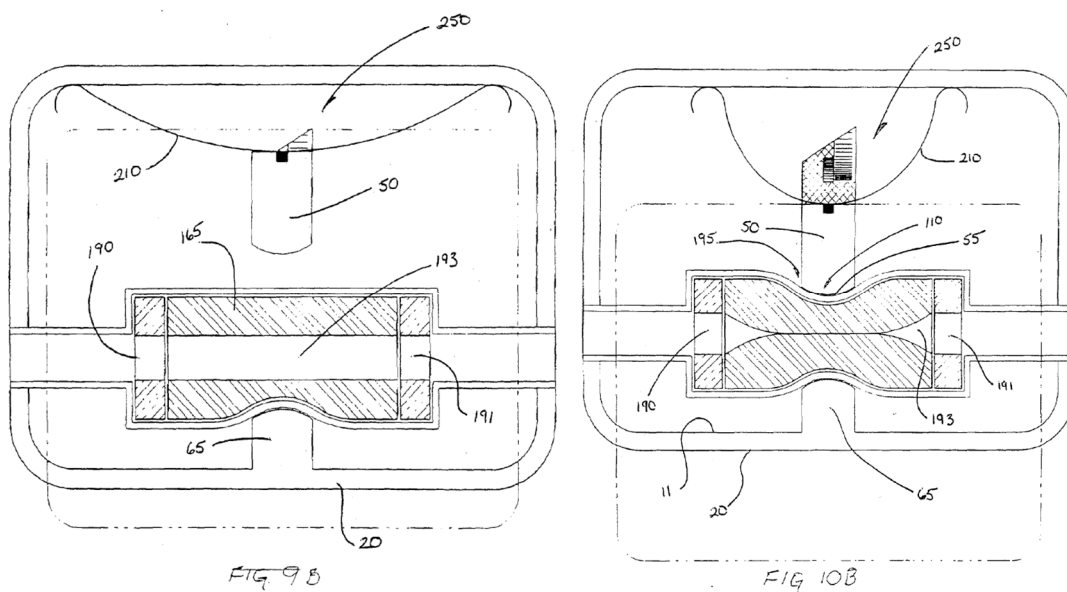
Fig. 4

Figures 6-8 showing seal member 165:

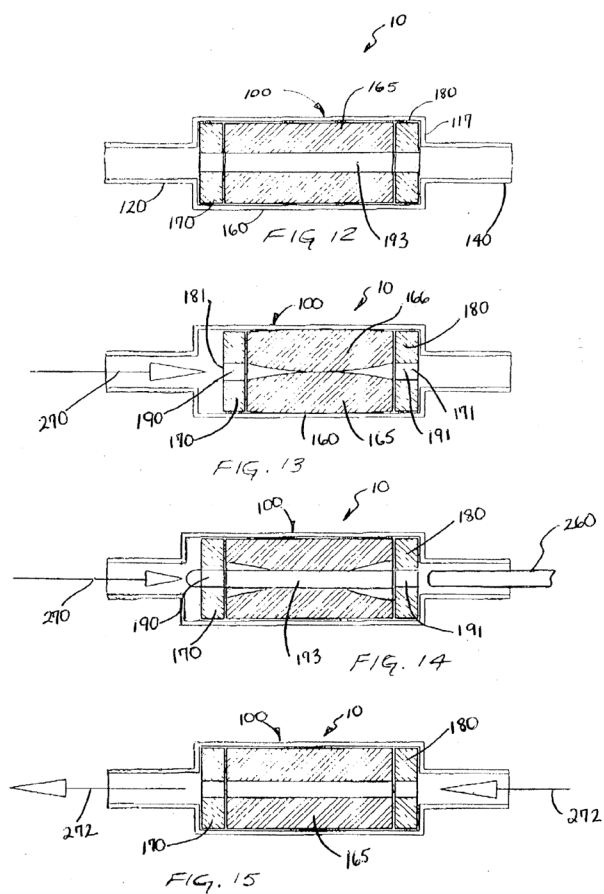


Figures 9A-10B showing seal member 165:





Figures 12-15: showing seal member 165:



Figures 23-26, showing seal member 165:

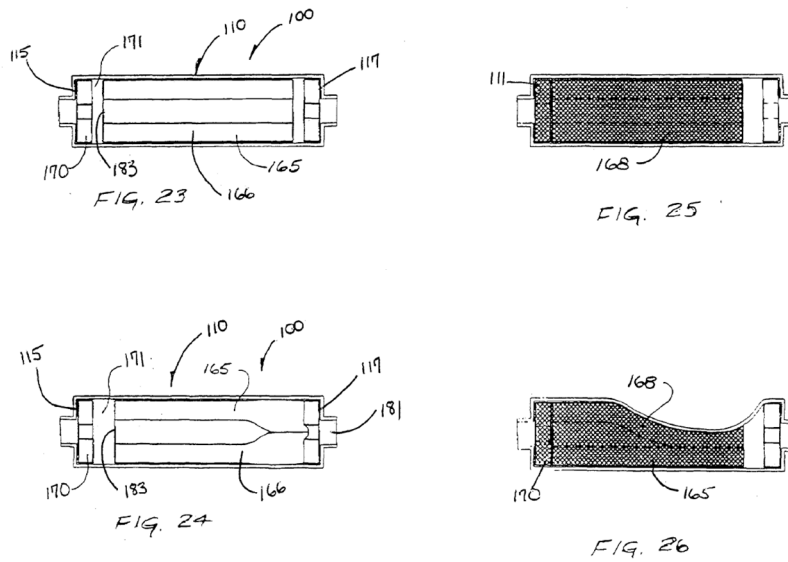
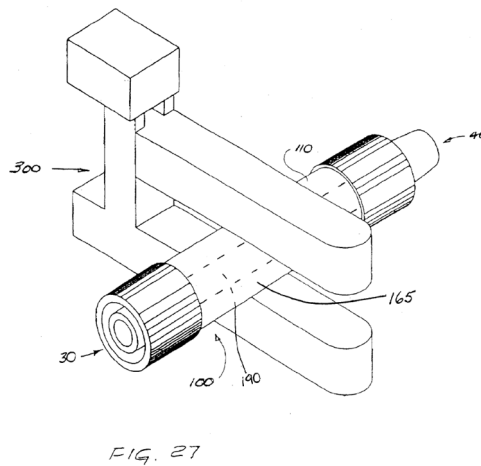


Figure 27, showing seal member 165:



Figures 28-29, showing seal member 165:

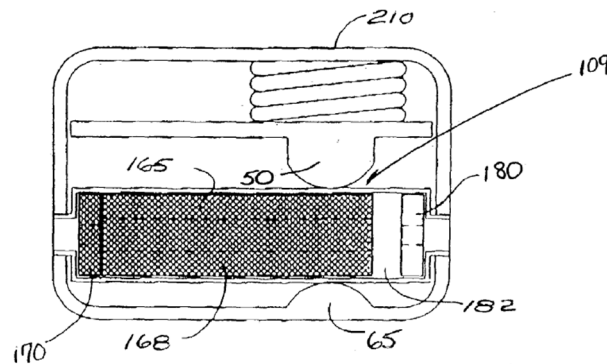


FIG. 28

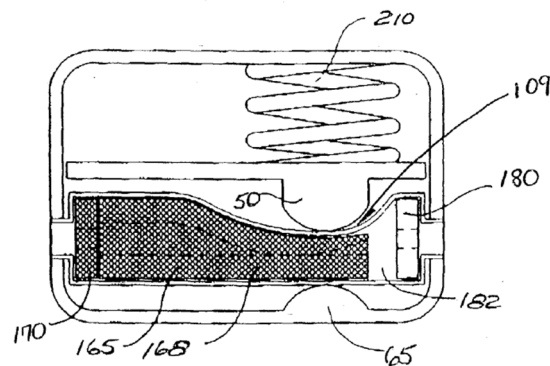


FIG. 29

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:

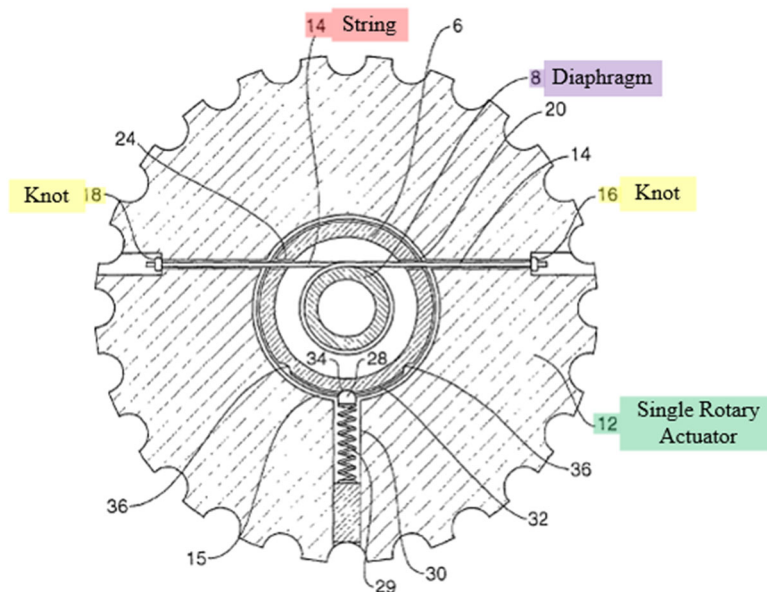
The lumen 193 of the third seal member 165 is at least partially collapsed by the compressive force 67 [and actuator] movement allows

each engaged actuating member 55 to forcibly disengage opposing outer walls 27 of the seal module 100 allowing the portion 108 of the containment structure 160 to retract to an uncollapsed configuration where gases and fluids can pass therethrough. As the actuator 50 is disposed away from the portion 108 of the seal module 100, the lumen 193 of the third seal member 165 is able to retract in an unsealed configuration.

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.

2. Hartley

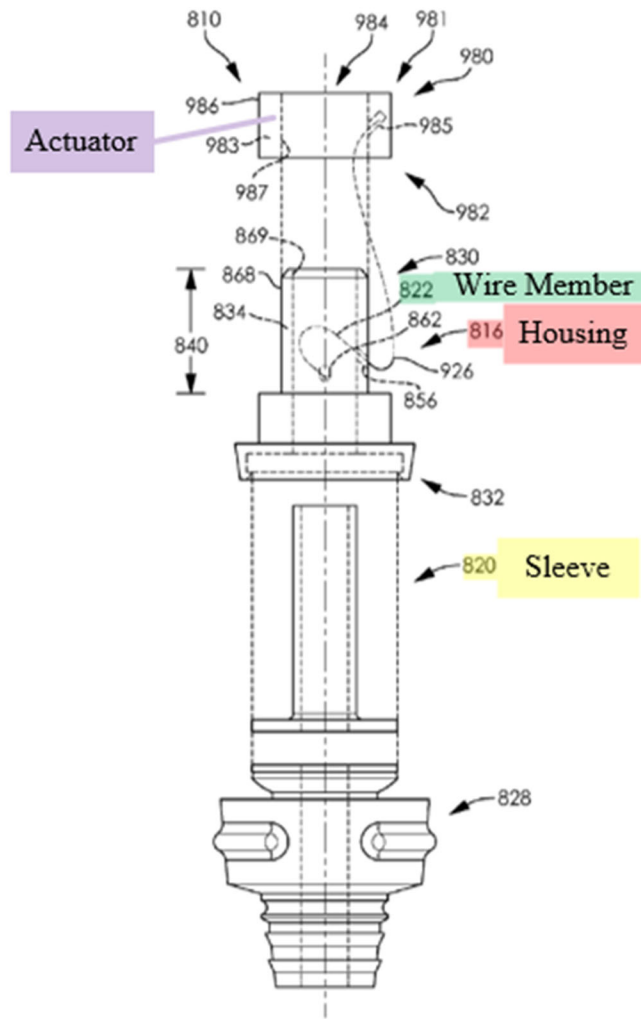
Hartley discloses an access valve having a string 14 extending around a cylindrical elastomeric diaphragm 8 and attached by knots 16 and 18 to a single rotary actuator 12:



EX1006, ¶[0031]; EX2001, ¶¶59, 130. A POSA would understand the rotary actuator 12 to be a single integral piece such that the knots 16 and 18 are attached to the **same** rotary actuator 12. *Id.* That single rotary actuator 12 controls movement of both ends of the string 14. *Id.*

3. 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”:



EX1007, 23:50-62, 24:50-52. Eller discloses other embodiments with multiple wire members attached to a single actuator. EX2001, ¶¶60, 131-134. 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 actuator controls movement of the wire member. *Id.*

4. Garrison

Garrison discloses various systems of devices for accessing the cerebral arterial vasculature. EX1011, ¶50.

E. Claim Construction

In an IPR, a claim is construed “in accordance with the ordinary and customary meaning as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent.” 37 C.F.R. § 42.100(b). “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).

1. Filament

Claim 1 recites “[a] hemostasis valve, comprising ... a filament formed in a loop around the tubular sidewall” and “reducing a diameter of the lumen in response to reducing a diameter of the loop.” A POSA would understand that the term filament as recited in Claim 1 should be accorded its plain and ordinary meaning: “a thin, flexible length of material formed by one or more strands of material.” EX2001, ¶63.

Petitioner’s proposed construction omits the requirement that a filament is flexible, proposing that a filament means “at least ‘one or more threads, lines, cords, ropes, ribbons, flat wires, sheets, or tapes.’” Petition, p.16. A POSA will readily

recognize, however, that Petitioner's proposed construction is incorrect and inconsistent with the structures mandated by the claim language itself, the specification, and the extrinsic evidence. EX2001, ¶¶63-71.

a) Language of the claims

The claim language itself confirms that the filament must be flexible. Claim 1 recites that "a filament [is] formed in a loop around the tubular sidewall" and that "a diameter of the lumen [is reduced] in response to reducing a diameter of the loop." These limitations necessarily require that the filament be flexible to form a loop around the tubular sidewall that can decrease in diameter to constrict.

First, a filament that is incapable of bending or curving could not be "formed in a loop around the tubular sidewall." This inherent property of flexibility is essential to achieving the claimed loop formation. EX2001, ¶65. Second, Claims 1 and 18 further recite: "reducing a diameter of the lumen in response to reducing a diameter of the loop." As such, the claims make clear that both the diameter of the lumen inside the loop and the loop itself must decrease in diameter. Petitioner's arguments that rigid members that do not change in dimension can reduce in diameter is directly contradicted by that claim language. Indeed, the Board recognized in the related '012 IPR, "the claimed filament requires flexibility to form a loop that decreases in diameter when the ends (or end) of the filament are pulled." EX1023, p.32.

Petitioner's arguments regarding Claim 4 are not relevant to the meaning of the term filament. Even if Claim 1 covered the “bight” embodiment of Figures 8 and 9, that embodiment also confirms that the term filament requires flexibility. EX2001, ¶67. 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”); EX2001, ¶67. Second, if the two interlocking U-shaped bights in Figures 8 and 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. *Id.* The '291 Patent includes no such disclosure. So, the bight embodiments shown in Figures 8 and 9 must be flexible and 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. *Id.* 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 '291 Patent. EX2001, ¶67.

Similarly, Petitioner's citation to the language of claim 1 of U.S. Patent No. 12,109,384 (“the '384 Patent”) is misplaced. In *Kraft Foods, Inc. v. Int'l Trading Co.*, the Federal Circuit explained that “claim differentiation only creates a

presumption that each claim in a patent has a different scope; it is ‘not a hard and fast rule of construction[.]’” and rejected Kraft’s argument that the “protecting back panel” recited in claim 2 need not be relatively rigid because, unlike claim 1, claim 2 does not recite a back panel comprising “a flat relatively stiff planar sheet[.]” 203 F.3d 1362, 1368 (Fed. Cir. 2000) (citing *Comark Communications, Inc. v. Harris Corp.*, 156 F.3d 1182, 1186 (Fed. Cir. 1998)). The court further explained: “[t]hat the patentee chose several words in drafting a particular limitation of one claim, but fewer (though similar) words in drafting the corresponding limitation in another, does not mandate different interpretations of the two limitations, since defining a state of affairs with multiple terms should help, rather than hinder, understanding.” *Id.* (cleaned up). Here, the recitation of “flexible” in claim 1 of the ’384 Patent does not imply that a “filament” forming a loop that reduces in diameter in that same claim could be anything other than flexible. Rather, the claim itself requires a first and second filament to be “extending in a [first/second] loop around the tubular member” and “decreasing a dimension of the [first/second] loop” which necessitates flexibility, as a rigid or inflexible member could not be configured into a loop or reduce in diameter. So, claim 1’s use of multiple terms should help, rather than hinder, understanding of the term. Accordingly, claim 1 in the ’384 Patent does not clearly and ambiguously change the plain meaning of the term filament to include a rigid component.

Thus, the claim language confirms that the term filament means “a thin, flexible length of material formed by one or more strands of material.”

b) The specification

Like the claims, the specification further confirms that the term “filament” requires flexibility for the hemostasis valve to function as intended. In Figure 6 of the '291 Patent, a filament 150 forms a loop around a collapsible tubular sidewall. EX1001, 13:18-21. The specification further states that “each of the first end 600 and the second end 602 can be coupled to different buttons 144” of the actuator. *Id.* at 12:54-56. When these button(s) are actuated, they exert opposing forces on the respective filament ends, causing the loop's diameter to decrease and constrict the elongated member. EX2001, ¶66; EX1001, 13:11-16. Likewise, Figure 7 illustrates two filaments each formed into a loop that must also be sufficiently flexible to reduce in diameter. *Id.*; EX1001, 13:22-29.

For the constriction mechanism to work as described in the specification, the filament must be flexible. EX2001, ¶¶67-69. If the filaments depicted in Figures 6-7 were not flexible, the application of force to its ends would not change the loop's diameter. *Id.* In that scenario, the elongated member 132 could not be compressed, and no seal would form. *Id.* The filament's ability to reduce in diameter under tension is therefore not optional but fundamental to the operation of the device. *See also* EX1023, p.17 (“If the filament used to form this ‘loop’ was not flexible to some

degree, we do not see how the hemostasis valve would function as intended.”). Accordingly, the specification makes clear that flexibility is a necessary characteristic of the filament, consistent with the plain and ordinary meaning of the term.

Petitioner's reliance on the specification's description of the filaments in Figures 6-7 and 8-9 as “behaving the same way” misinterprets how those filaments “behave.” Both require that the filament is flexible. As explained above, for the bight embodiments shown in Figures 8 and 9, movement between the positions shown in Figures 8 and 9 could not occur if the bights were not flexible without rotating their orientation, which is not disclosed in the '291 patent. EX2001, ¶67.

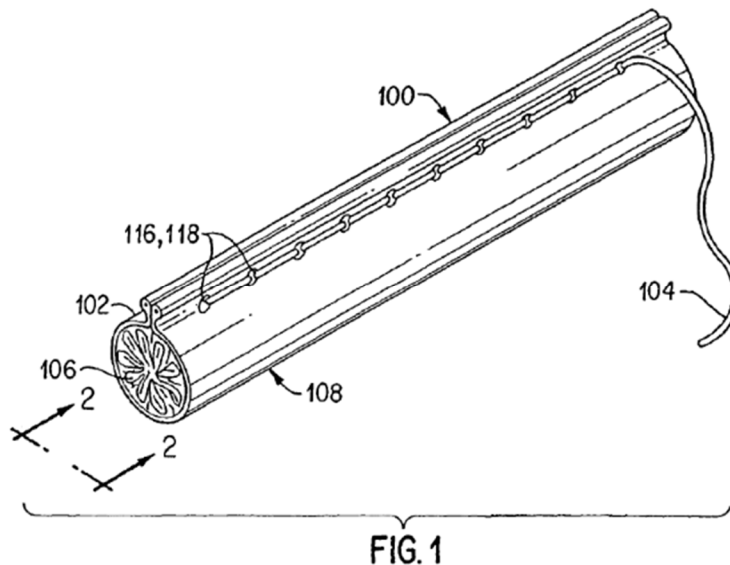
Moreover, while the specification provides nonlimiting example materials for the filament, including “a polymer, a synthetic, and/or a metal” (EX1001, 9:14-15), that the filament can be made from materials that can be flexible or can be formed into rigid components does **not** redefine the term “filament” from its plain and ordinary meaning to include rigid components. EX2001, ¶68. A POSA would understand that flexibility is a function of both material and form. *Id.* For example, metals are a broad category of material that can be used to create a rigid member, but metals can also be formed into long, narrow strands to produce a flexible wire or cable, e.g., steel or aluminum wire. *Id.* Similarly, polymers can be rigid or formed into flexible strands or lines that could serve as a filament. *Id.* The material chosen

to form the filament does not redefine the ordinary and customary meaning of the term “filament.” *Id.* Petitioner's reliance solely on a non-limiting list of example materials ignores that the form of a component often dictates its properties. *Id.* Even Petitioner's expert agrees that material alone does not dictate flexibility/rigidity, and that all the materials/forms disclosed in the '291 Patent are consistent with the plain and ordinary meaning of the term “filament.” EX2006, 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.16; EX1003, ¶48. But, virtually any structure can include at least one or more of these examples, and Petitioner asserts that a filament is any structure that includes “at least one or more” of the recited list of structures. But not everything that *includes* such a structure would be a filament (for example a brick wall with a sheet attached to display a projected movie or a bedsheet on a bed). EX2001, ¶78. 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. Petitioner's improperly broad construction is not supported by the claim language, specification, prosecution history, and the plain meaning of the term in the art.

c) 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 US Patent 11,744,691, which 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. Moreover, Petitioner’s expert has also equated the term “filament” in his own patent to a “thread-like element.” EX2008, 199:10-200:20. U.S. Patent No. 7,682,380 (EX2008, hereafter “Thornton”) references Figure 1 and recites that “the coupling member 103 is shown as a filament or thread-like element.” EX2008, 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 expert's use of the term "filament" and the material from which the filament can be made confirms that the plain and ordinary meaning of "filament" requires flexibility.

Furthermore, Merriam-Webster's Collegiate Dictionary defines a filament as "a single thread or a thin flexible threadlike object, process, or appendage." EX2002 at 467. *See also* New Oxford American Dictionary, EX2003 at 644 (3rd Ed. 2010) (filament: "a slender threadlike object or fiber."). Those definitions comport with the plain and ordinary meaning of filament. EX2008, ¶73.

d) Related IPR Proceedings

In an Institution Decision in the related '011 IPR, the Board declined to construe the term "filament" according to the constructions of either Petitioner or Patent Owner suggested here. EX1017, pp.12-18. There, the Board recognized that "filaments having at least some degree of flexibility are encompassed by the claims" noting that in the embodiment of Figure 6 a "flexible filament is required (i.e., a filament that is sufficiently flexible that it can decrease the size/diameter of the loop to constrict and seal the valve)." *Id.* at p.16. However, the Board found it "not evident

at this preliminary stage that [the embodiment of Figures 8 and 9] using **'bights'** requires that the filament be 'flexible' in the manner urged by Patent Owner." *Id.* at p.17. Here, Claim 1 expressly recites a "loop" and thus not a "bight." And as explained above the interlocking bight embodiment of Figures 8 and 9 require that the filament is flexible.

In addition, the Board's Institution Decision in the related '012 IPR further supports this position. The Board specifically confirmed that claims reciting a "filament formed in a loop" and "reducing a diameter of the loop" inherently require the filament to be flexible, stating that "if the filament used to form this 'loop' was not flexible to some degree, we do not see how the hemostasis valve would function as intended." EX1023, p.17. Thus, as correctly recognized by the Board in the '012 IPR, when claims recite a "loop," the filament forming that loop must be flexible and cannot be rigid.

Accordingly, there is no "irreconcilable inconsistency" between the Board's preliminary position in the related '011 IPR, the related '012 IPR, and the Patent Owner's claim construction in the present matter. EX1023, pp.17-18. Indeed, Claim 1 requires that the filament be flexible regardless of the construction of the term "filament."

e) A POSA would understand the degree of flexibility of the “filament.”

A POSA would understand the degree of “thin and flexible” required by the filament in the context of the '291 Patent claims. EX2001, ¶71. In the Institution Decision in the related '011 IPR, the Board questioned how flexible a structure would need to be to qualify as a “filament” as claimed. EX1017, p.15. While rigidity and flexibility exist along a spectrum, a POSA would readily understand the flexibility required for the claimed filament in the context of a filament to constrict a hemostasis valve as described in the '291 Patent—the filament must be sufficiently flexible so that it can loosen and reduce in diameter when formed in a loop as shown in Figures 6-7. EX2001, ¶71. That is, a POSA would understand that in the context of the '291 Patent's hemostasis valves, the filament must be flexible to the degree necessary so that it can be formed into a loop that can reduce in diameter as expressly recited in the claims. *Id.*

And, Petitioner's expert agrees that a POSA could determine the level of flexibility required:

QUESTION: So that level of flexibility, in this context of a hemostasis valve for an aspiration catheter, one skilled in the art would be able to determine what that level of flexibility is, wouldn't they?

MR. THORNTON: “I think a person skilled in the art would be able to engineer the right balance of material properties for the filament, the

compression tube, or tubular sidewall, the springs, et cetera, in order to make the design work well.

EX2007, 38:22-39:7.

In other words, a POSA could easily determine how flexible the filament needs be for the hemostasis valve to function as claimed.

F. Person of Ordinary Skill in the Art

A POSA in September 2017 would have had an undergraduate degree in mechanical engineering or a related engineering discipline and 2-4 years of product design or engineering experience designing medical devices in the field of the '291 Patent. A person with less education but more relevant practical experience, or more relevant education but less practical experience, may also meet this standard. EX2001, ¶73.

While Petitioner's proposed definition of a POSA includes a similar level of education, Petitioner's definition omits any requirement of experience in designing medical devices generally, let alone in the field of the '291 Patent. Petition, p.15. In fact, Petitioner's expert testified during the related '011 IPR that a POSA would need no experience designing hemostasis valves, and no experience designing medical devices at all. EX2006, 180:5-25. But, experience in the field of the invention is a critical component of the skills a POSA would need. Indeed, Petitioner's expert contradictorily explained that the starting point to design or select a hemostasis valve

is an understanding of the requirements of the particular medical procedure for which the valve will be used:

QUESTION: So then is it fair to say, in selecting a hemostasis valve for use with a procedure, to determine the design requirements for the hemostasis valve, you would need to understand the needs of the procedure?

MR. THORNTON: Needs from the physician, the needs of the procedure, the needs of the patient.

EX2006, 24:5-21.

Petitioner's arguments and reliance upon a declaration from an incomplete perspective having no understanding of the design considerations including medical procedures and tools used therewith should be afforded little or no weight. A POSA, under Petitioner's definition, would have no understanding of why Schaffer is designed to seal via nonconforming actuating members that apply compression to an internal conforming seal member and would have given no weight to the advantages of such a configuration or why a POSA would not have modified Schaffer to arrive at the claimed invention, *e.g.*, that Schaffer's internal seal member provides a seal with precise control of compression force for easy manipulation of, and to prevent damage to, delicate tools inserted therethrough. EX1005, ¶¶[0006]-[0007]; EX2001, ¶56.

III. CLAIM 1 IS NOT ANTICIPATED BY SCHAFFER (GROUND 1)

Anticipation requires that “each and every element of the claimed invention” must be disclosed either explicitly or inherently and the “elements must be arranged or combined in the same way as in the claim” in a single reference. *In re Gleave*, 560 F.3d 1331, 1334 (Fed. Cir. 2009).

Here, Schaffer fails to disclose any filament, much less “a filament formed in a loop around the tubular sidewall,” and “reducing a diameter of the lumen in response to reducing a diameter of the loop,” as recited in Claim 1.

A. Schaffer does not disclose a “filament.”

As set forth above, the term “filament,” as recited in Claim 1, means “a thin, flexible length of material formed by one or more strands of material” to a POSA. In contrast, Schaffer discloses rigid U-shaped members. EX2001, ¶¶78-85; EX1023, p.32.

Petitioner's attempt to equate the filament of the '291 Patent with Schaffer's actuating members—stating that “the '291 patent discloses that filaments may be made from a polymer, which includes Schaffer's plastic actuating members, or a metal, which includes Schaffer's metal or aluminum actuating members”—is incorrect. Petition, pp.40-41. That Schaffer's actuating members may be formed from materials disclosed in the '291 Patent does not mean they are a “filament.” *See, for example*, EX1023, p.32; EX2001, ¶¶68, 82. Thus, the material composition alone

does not establish that Schaffer's actuating members meet the "filament" limitation as required by the '291 Patent.

Petitioner's argument that "Schaffer does not mention rigidity and does not identify any dimensions or physical properties that would lead a POSITA to believe that the actuating members must be rigid" (Petition, pp.41-42) is contradicted by Petitioner's own implicit admission that Schaffer's U-shaped members are, in fact, rigid. Specifically, Petitioner asserts that Schaffer's U-shaped actuating members 55 would purportedly form gaps and a poor seal, using this as the supposed motivation to modify Schaffer. Petition, p.51. Furthermore, merely suggesting that "Schaffer's actuating members would have some flexibility" does not establish that such flexibility would be sufficient to meet the level understood by a POSA as necessary for a "filament formed in a loop," or the loop reducing in diameter as recited in Claim 1. As explained above in §E(1)(e), a POSA would readily recognize the degree of flexibility required for a filament as claimed, which is not met by Schaffer's actuating members.

Furthermore, Schaffer's own disclosure confirms that its actuating members are rigid. Schaffer describes its U-shaped actuating members as being able to "forcibly disengage," a function that inherently requires rigidity. Specifically, Schaffer states: "[i]n the second position ... each actuator button 261 is depressed[,]," which "allows each engaged actuating member 55 to forcibly disengage opposing

outer walls 27 of the seal module 100 allowing the portion 108 of the containment structure 160 to retract to an uncollapsed configuration” EX1005, ¶[0077]. This mechanism depends on the actuating members being rigid enough to push against and disengage the outer walls of the seal module. In contrast, a “filament,” by its nature, is flexible and would simply deform rather than forcibly disengage when the actuator button is pressed and tension is reduced (EX2001, ¶81). Therefore, Petitioner’s suggestion that “Schaffer’s actuating members would work if they were flexible” is incorrect and unsupported by Schaffer’s own disclosure.

Schaffer’s disclosed method of assembly also relies on the rigidity of Schaffer’s U-shaped actuating members. EX2001, ¶¶83-84. Schaffer uses two rigid U-shaped members to form an area through which a seal module can be inserted: “Each actuator button 261 is completely compressed and held while the seal module 100 is inserted through the housing 20 and between each actuator 50.” EX1005, ¶[0083]. Because Schaffer’s U-shaped actuating members are rigid, an opening is formed for the seal module to fit through when it is inserted through that opening. If the U-shaped members were flexible, they would collapse and not form an opening to insert the seal module through. EX2001, ¶¶83-84. Thus, Schaffer’s assembly method underscores that its actuating members cannot be flexible like a filament, but must be rigid to function as described.

Finally, a POSA would not manufacture Schaffer's actuating members using techniques that result in flexibility, contrary to Petitioner's suggestion. Petition, p.42; EX2001, ¶69. As discussed above, the U-shaped actuating members of Schaffer must be rigid to perform essential functions such as forcibly disengaging the seal module's outer walls. Consequently, even if alternative manufacturing methods could produce more flexible actuating members, a POSA would recognize that such flexibility is contrary to Schaffer's intended operation. *Id.* Instead, a POSA would follow Schaffer's disclosure and utilize a machining process to ensure the U-shaped actuating members possess the necessary rigidity. *Id.*

Accordingly, like the Board recognized in the Institution Decision in the related '012 IPR, Schaffer does not anticipate Claim 1 at least because Schaffer does not disclose a flexible filament. EX1023, p.32 ("We are doubtful that Petitioner can prevail on its anticipation challenge ... [because] the claimed filament requires flexibility ... [and] a skilled artisan would more likely understand [Schaffer's] U-shaped actuation members...as being substantially 'rigid.'").

B. Schaffer does not disclose “a filament formed in a loop around the tubular sidewall” and “reducing a diameter of the lumen in response to reducing a diameter of the loop.”

Whether or not the term “filament” itself requires flexibility, Claim 1 requires a filament that is flexible reciting, *inter alia*, “a filament formed in a loop around the tubular sidewall” wherein “a diameter of the lumen [is reduced] in response to

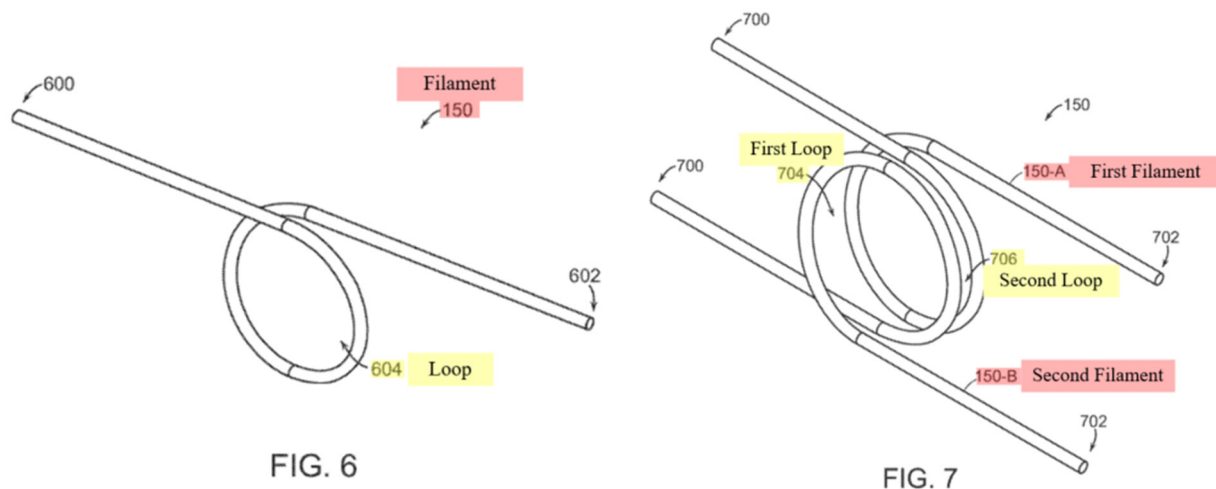
reducing a diameter of the loop.” The claimed filament cannot be formed into a loop or reduce in diameter unless it is flexible. EX2001, ¶71. As explained above, Schaffer's rigid actuating members are U-shaped and designed to retain that shape during operation and as such do not disclose the claimed loop or a reduction in diameter of that loop. EX1005, ¶[0076]; EX1008, ¶¶89-97.

Moreover, Petitioner does not allege that a single one of either of Schaffer's U-shaped actuating members 55 is “formed in a loop” but instead alleges that “Schaffer's U-shaped actuating members collectively constitute the ‘filament formed in a loop around the tubular sidewall’” Petition, p.45. Schaffer's U-shaped actuating members cannot together be construed as the claimed “filament”—because Claim 1 requires a single filament by itself “formed in a loop.”

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

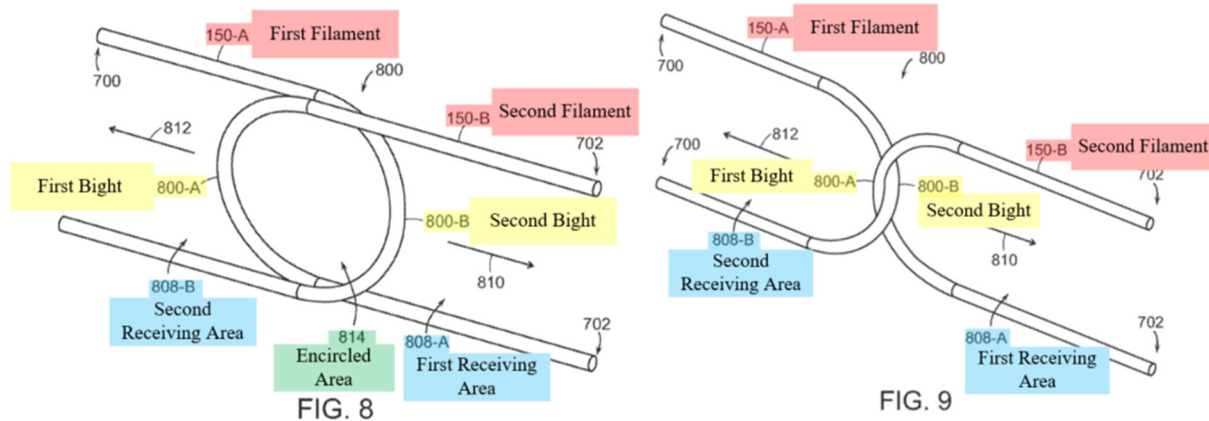
to have ‘a dog that rolls over and fetches sticks,’ it does not suffice that he have two dogs, each able to perform just one of the tasks.” *In re Varma*, 816 F.3d 1352, 1362-64 (Fed. Cir. 2016). Schaffer’s two U-shaped actuating members do not together suffice as a filament and certainly even the combination of the two u-shaped members are not “formed in a loop.”

Second, the specification of the ’291 Patent supports that Claim 1 requires a single filament that is “formed in a loop.” While the ’291 Patent discloses multiple different filament arrangements with respect to Figures 6-9, the term loop is used exclusively for the Figures 6 and 7 embodiments, which respectively depict a one-filament arrangement having the filament formed into a loop and a two-filament arrangement having two single filaments that each separately form a loop:



EX1001, 13:18-25; EX2001, ¶87.

In contrast, Figures 8 and 9 of the '291 Patent illustrate two positions of a different arrangement in which two filaments form U-shaped bights rather than loop:

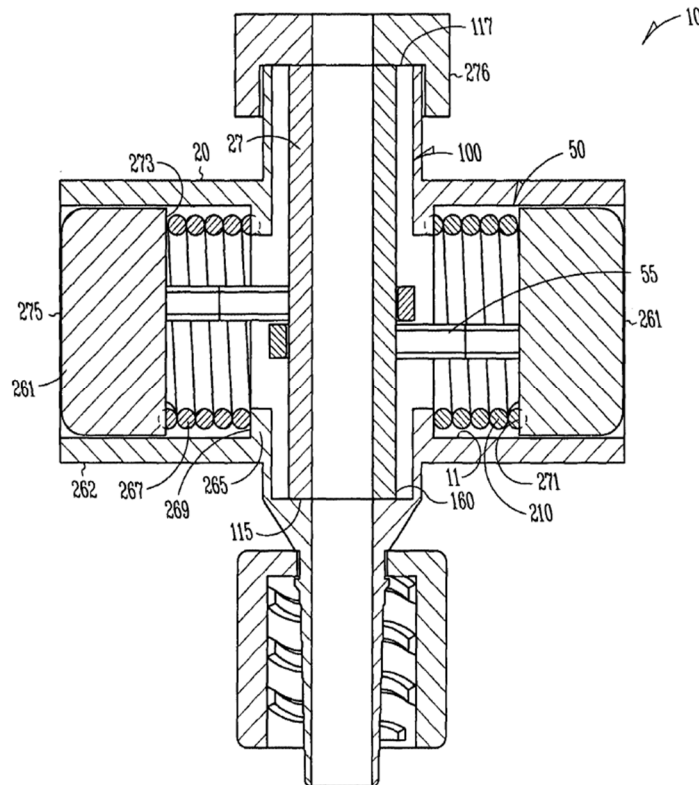


EX1001, 13:30-51; EX2001, ¶88.

The '291 Patent specifies that “a ‘bight’ refers to *a U-shaped section* between the two ends of the filament.” EX1001, 13:32-33 (emphasis added). In this arrangement, the filaments each define a partially enclosed receiving area 808-A, 808-B, and together the first and second receiving areas 808-A and 808-B overlap to define an encircled area 814. EX1001, 13:47-61; EX2001, ¶88. Accordingly, when the '291 Patent uses the term “loop,” the term refers to a loop, and not multiple U-shaped filaments that overlap as shown in Figures 8 and 9. EX2001, ¶89.

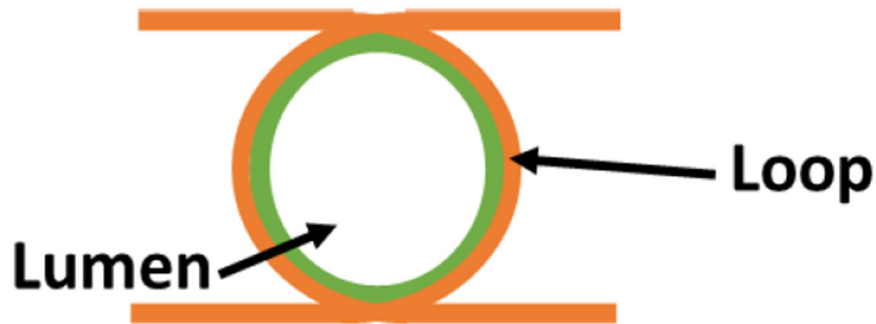
Thus, Petitioner's reliance on Figure 8 of the '291 Patent to argue that Schaffer's U-shaped actuating members 55 collectively comprise the “first filament” fails. Petition, p.37. As set forth above, the specification of the '291 Patent distinguishes the filament bights from the filament loops in Figure 6-7.

Further yet, even if Schaffer’s U-shaped members 55 were collectively considered “a filament”, which they are not, these members still do not form a loop because they are side-by-side, not overlapping:



EX1008, FIG. 34; EX2001, ¶90.

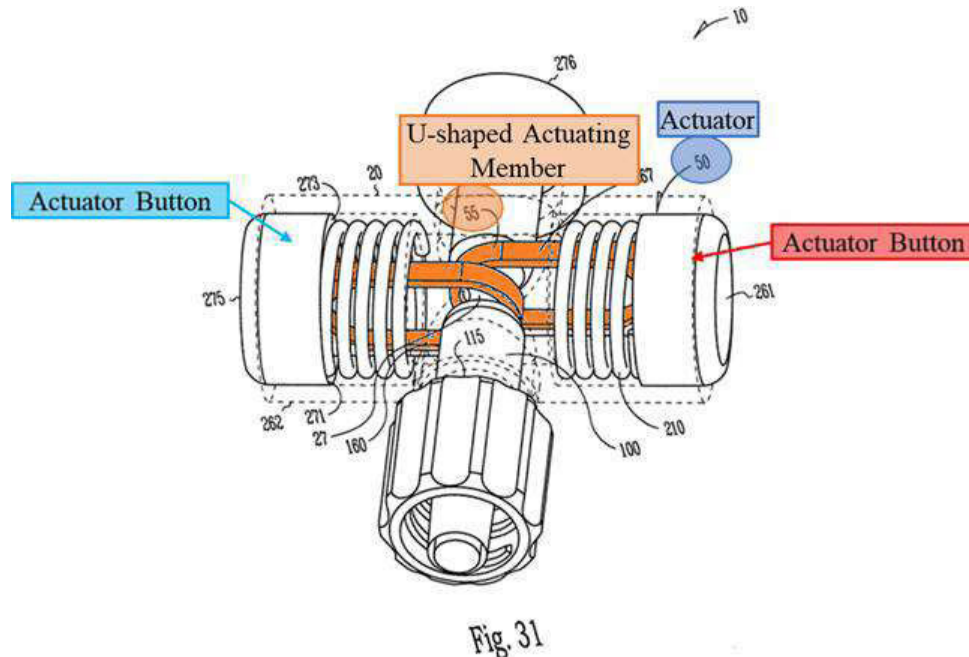
Petitioner’s “demonstrative graphic” that purportedly illustrates “the loop formed by the U-shaped actuating members” is misleading and incorrect:



EX1003, ¶92, Petition, p.46. Indeed, Petitioner's expert admitted at deposition in the related '012 IPR that the view provided in this demonstrative graphic is **not** a cross-section view—so the purported loop in this graphic does not exist. EX2007, 95:2-8.

Moreover, the '291 Patent discloses two different embodiments of bights: bights that interlock (as illustrated in Figures 8-9) and bights that do not interlock (no corresponding figures). EX1001, 13:36-42. To the extent the Board determines that the interlocking bight embodiment shown in Figures 8 and 9 collectively form a loop despite the '291 using different terminology, “bights” to describe those embodiments, does not mean that Schaffer's side-by side U-shaped members are formed into a loop as claimed. The '291 Patent explains that the interlocking embodiment illustrated in Figures 8-9 define an encircled area because they 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 13:56-61 (emphasis added). In contrast, Schaffer discloses side-by-side (i.e.,

parallel) U-shaped members that do not interlock or overlap and thus cannot form an encircled area, let alone a loop, as shown Figure 31 from Schaffer:



Petition, p.46; EX2001, ¶¶86, 90.

Because Claim 1 requires a filament that is “formed in a loop,” Schaffer cannot anticipate Claim 1.

That the '291 Patent also discloses an alternative embodiment of non-interlocking bights that do not form an encircled area is of no import—the claims require a loop. Therefore, Petitioner has failed to demonstrate that Schaffer anticipates Claim 1 because neither of Schaffer's U-shaped actuating members are “formed in a loop” regardless of the construction of “filament.”

Schaffer also cannot anticipate Claim 1 because Schaffer does not disclose “reducing a diameter of the lumen in response to reducing a diameter of the loop.”

The shape and dimension of each of Schaffer's actuating members 55 is fixed because the actuating members are rigid and therefore cannot reduce or otherwise change during operation of Schaffer's valve 10. EX2001, ¶93. Accordingly, Schaffer cannot disclose "reducing a diameter of the loop." *Id.* As explained above the claims require "reducing the diameter of the loop" and that it is the filament that is "formed in a loop." Even if Schaffer's side-by-side rigid U-shaped members are collectively considered a loop, simply decreasing the space withing those members is insufficient. The claims require that the "diameter of the loop" formed from the filament itself must reduce in diameter.

IV. CLAIM 1 IS NOT OBVIOUS OVER SCHAFFER (GROUND 2)

A claim is not obvious if an element of the claim is missing in the cited art. *See Aug. Tech. Corp. v. Camtek, Ltd.*, 655 F.3d 1278, 1290 (Fed. Cir. 2011). As set forth in §III, Schaffer does not disclose a "filament," "a filament formed in a loop around the tubular sidewall," or "reducing a diameter of the lumen in response to reducing a diameter of the loop," as recited in Claim 1. Petitioner alleges that "a POSITA would have found it obvious to make Schaffer's actuating members more flexible," even if the Board determines that Schaffer's actuating members are rigid. Petition, p.28. However, as explained in detail in §V below, a POSA would not have found it obvious to make Schaffer's actuating members flexible. EX2001, ¶96. Doing so would result in less effective sealing around multiple and/or irregularly

shaped instruments, would prevent forcible disengagement—an important principle of Schaffer's valve design—and would not only complicate manufacturing, but also render Schaffer's method of assembly inefficient and unreliable. Accordingly, because Schaffer does not disclose all the limitations of Claim 1, and a POSA would not modify Schaffer as claimed, Ground 2 fails.

V. CLAIM 1 IS NOT OBVIOUS OVER THE COMBINATION OF SCHAFFER AND HARTLEY/ELLER (GROUNDS 3-4)

A POSA would not have been motivated to replace Schaffer's U-shaped actuating members with Hartley's string or Eller's wire, much less create a loop as the claims require. Petitioner's proposed modification/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 actuating 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 that would work to seal Schaffer's valve, including those expressly disclosed in Schaffer. Those substitutions would not

fundamentally change Schaffer's mode of operation. By contrast, a flexible string/wire would diminish the predictable sealing of Schaffer's valve. Likewise, Petitioner's expert admits there were an unknown—not 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. Moreover, Petitioner's proposed combination would not work to seal around multiple instruments, one of Schaffer's express purposes.

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 motivation—complete 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. *Axonics*, 73 F.4th at 957.

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 or 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 includes the third seal member 165 that seals without gaps across a wide range of instruments—indeed, that is the purpose of Schaffer. EX2001, ¶¶101-109.

As explained in § II.D.1, each of Schaffer’s embodiments—including the embodiment shown in FIGS. 30-34 relied upon by Petitioner—includes the seal member 165. *See also* EX2001, ¶¶58, 109. And, at deposition in the related ’012 IPR, Petitioner’s expert agreed that the seal member 165 is included in every illustrated embodiment in Schaffer: Schaffer Embodiment: Figures 1-4 (EX2007, 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).

Notably, 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, ¶108. 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 with respect to that embodiment. 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.

Indeed, Schaffer discloses that the third seal member 165 seals completely without gaps across a wide range of tool/device diameters and shapes. EX2001, ¶¶104-109. 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):

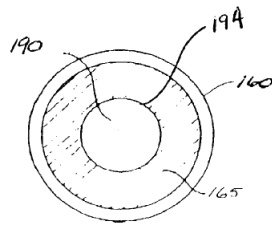


FIG. 16

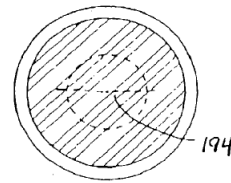


FIG. 17

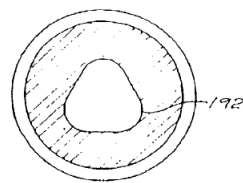


FIG. 18

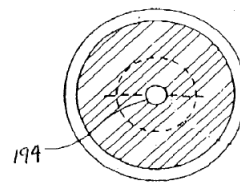


FIG. 19

EX2001, ¶¶105-108 (citing EX1005, ¶[0060]). The seal member 165 seals completely in all those scenarios by being highly compliant to conform to different shapes. *Id.* at ¶109; 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, ¶108. In the Institution Decision in the related ’012 IPR, the Board similarly found Schaffer’s “sticky” and “gelatinous” properties to be optional. EX1023, p.41. 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." EX2001, ¶110.

And, a POSA would further understand that Schaffer's seal member 165 seals regardless of whether it is "sticky" or "self-closing. *Id.* A POSA would have understood that Schaffer's valves are designed to do just that—seal completely—including in any embodiments without a "sticky" or "self-closing" characteristics (via the seal member 165). EX2001, ¶110.

Taken together, every embodiment in Schaffer includes the seal member 165, and the seal member—regardless of its specific material construction—forms a complete seal around various instruments or no instruments. Thus, Schaffer does not form gaps. 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).

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.

EX2006, 116:18-117:2. Dr. Zalesky agrees. EX2001, ¶107.

That is the case here—Schaffer's valve seals for the range of tools by virtue of the compliant seal member 165. According to even Petitioner's expert, in that instance a 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 then a POSA would not be motivated to substitute Hartley's string or Eller's wire.

As set forth above, the highly-compliant seal member 165 of Schaffer provides a complete (non-gapless) seal across a wide range of instruments. Thus, to arrive at Petitioner's stated motivation—the presence of gaps—a POSA would need to 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.

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]; EX2001, ¶111. For that reason alone, Petitioner's arguments fail.

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

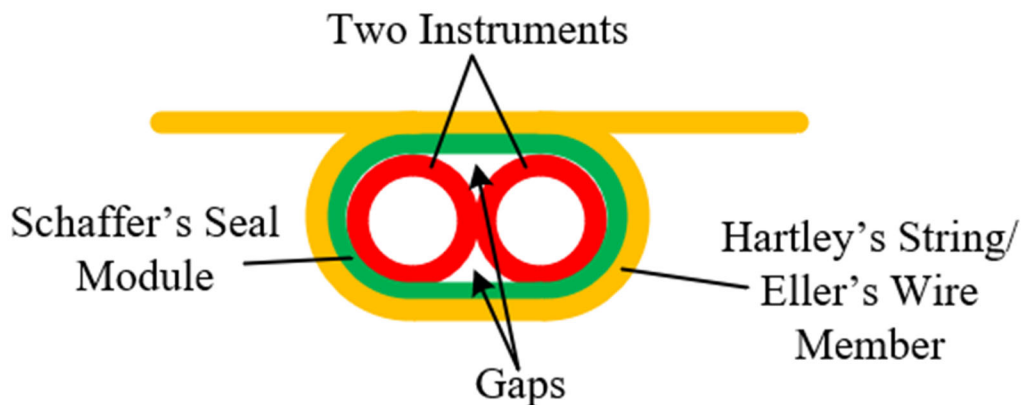
have addressed the alleged motivation. IPR2020-01602, 2022 WL 1022576 at *11-12 (P.T.A.B. Mar. 30, 2022). Specifically, the Board disagreed with Petitioner's proposed modification to simplify Hon by entirely removing Hon's atomizer and replacing it with Whittemore's wick and heater because "Hon itself 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. 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 itself teaches comparably simple modifications for solving the purported defect of Schaffer if, for some unexplained reason, a POSA omitted Schaffer's sealing member 165. EX2001, ¶¶153-155. First, a POSA would simply include the sealing member: problem solved with no further modification to Schaffer or need to change Schaffer's principle of operation or express methods of manufacture or durability.

Moreover, Petitioner and its expert admit that Schaffer's valve could be improved—if needed—by simply 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 §V.B.2; EX2001, ¶¶153-155. Petitioner has provided no reason why a POSA would first have been motivated to remove/omit the seal member 165 and then subsequently look elsewhere to solve the problem it manufactured rather than follow Schaffer's disclosure itself that could solve the issue.

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—scenarios for which Schaffer's valve is specifically designed to form a seal as explained above. EX2001, ¶113. 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. In other words, and as described below in § V.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 disclosed design with the seal member 165 would seal around multiple instruments by filling in the gaps shown due to its highly-compliant nature, and thus would be a "suitable option." *Intel*, 21 F.4th at 800; EX1005, ¶[0068]. A POSA would simply utilize Schaffer's disclosed designs.

Thus, 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

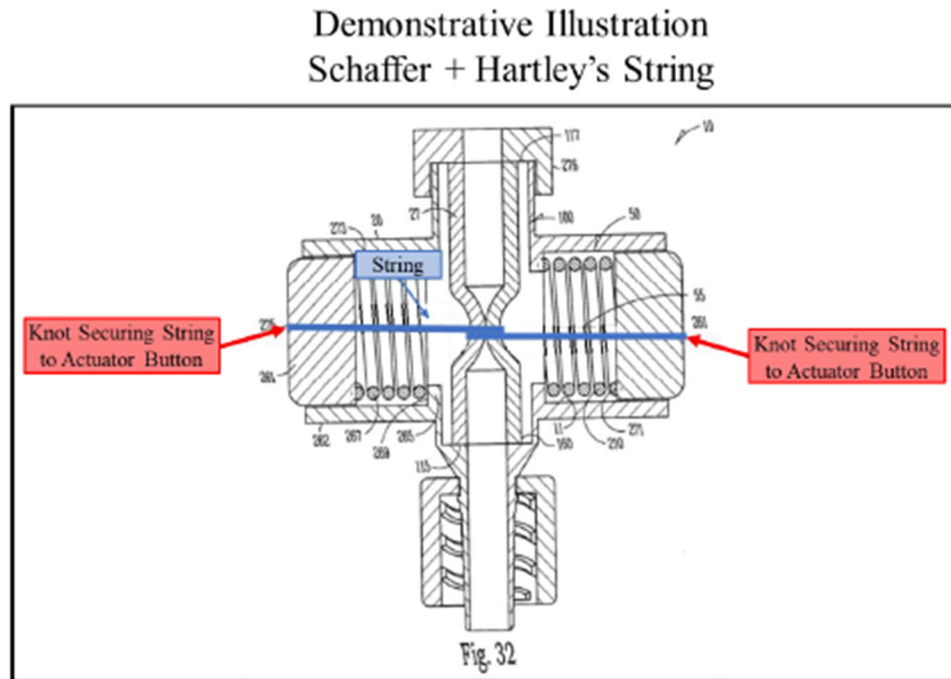
Petitioner advances a "simple substitution" rationale for modifying Schaffer's U-shaped members. Petition, pp.50-51, 58; *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007). But, a single actuating member (U-shaped member, string, or wire) having two ends coupled to and controlled by different 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 and 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.

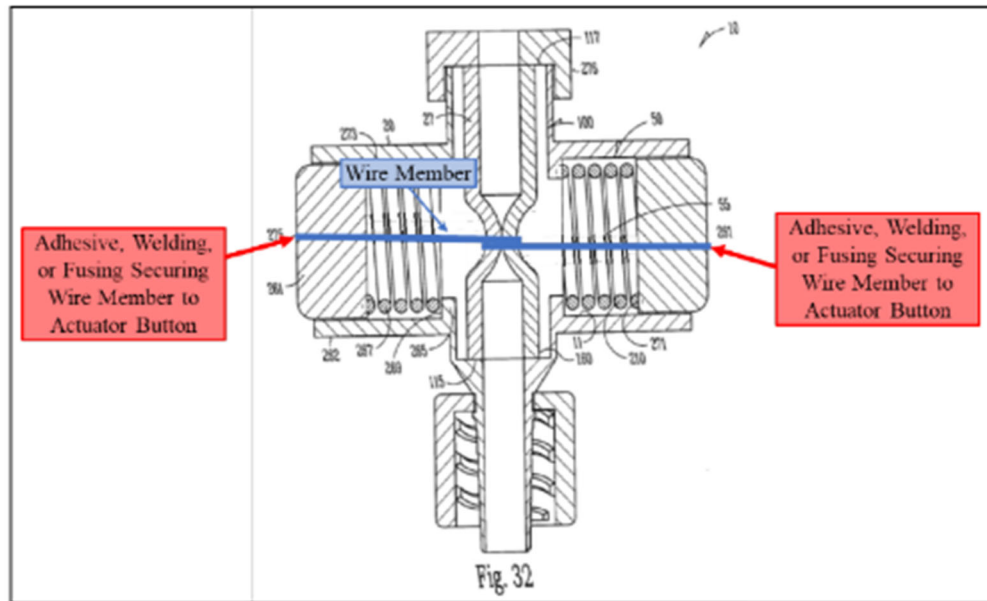
Petitioner's proposed combination would not "have merely entailed substitution of one known element (Hartley's string [or Eller's wire member]) for another (Schaffer's actuating members)." Petition, pp.51, 58. Instead, Petitioner's proposed combination requires one end of Hartley's string or Eller's 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.³ 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 illustrations:



³ Petitioner's sole proposed combination of Schaffer and Hartley/Eller includes two actuators and one string/wire. And, as discussed below in §VII, dependent Claim 2 further requires the second actuator.

Demonstrative Illustration
Schaffer + Eller's Wire Member



Id. at pp.53, 60. But, as Petitioner's expert admitted at deposition, neither Schaffer, Hartley, nor Eller disclose such an arrangement. And, Petitioner cites no reference disclosing a single string or wire attached to and controlled by two independently movable actuators.

Each of Schaffer's U-shaped rigid actuating members 55 are attached to 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:

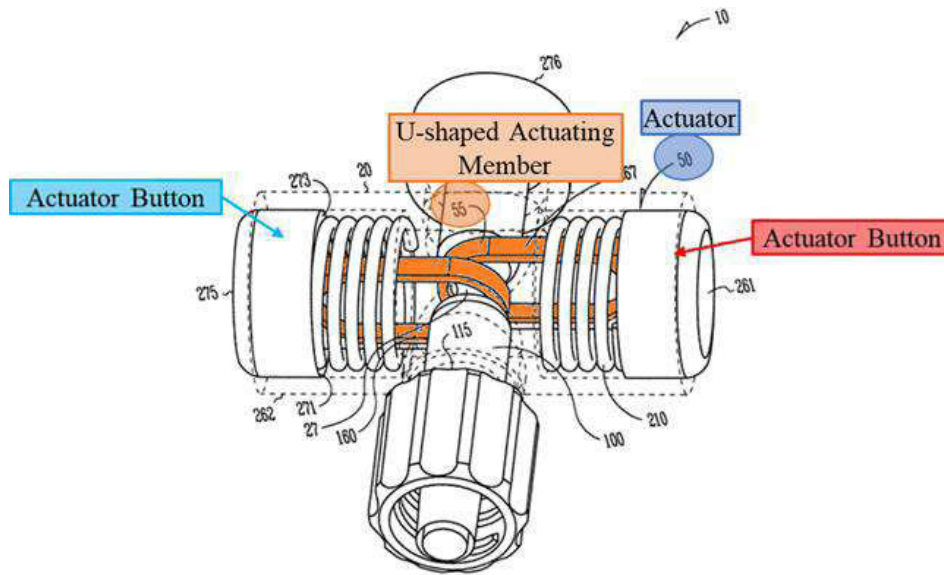
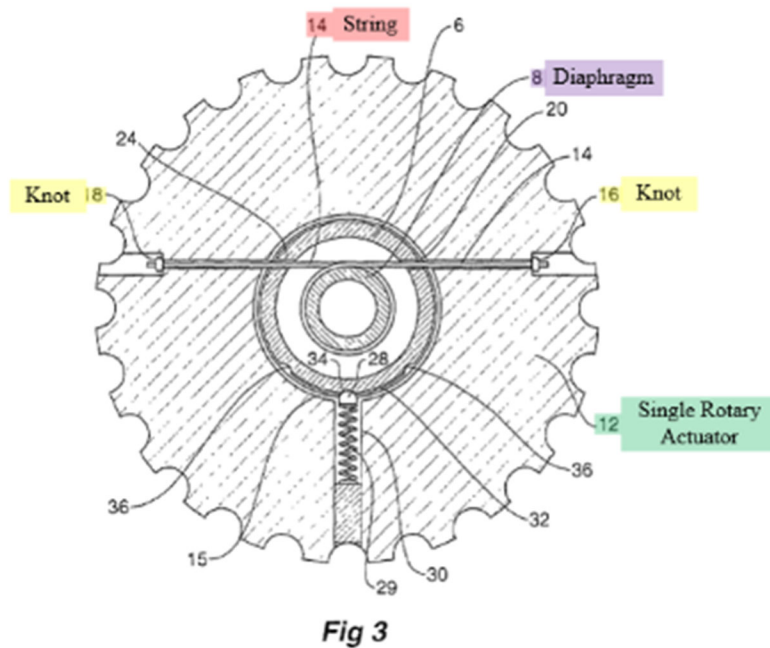


Fig. 31

EX1003, ¶94; EX2001, ¶134. During deposition in the related '012 IPR, Petitioner's expert agreed. EX2007, 57:7-22. Such a configuration is required because Schaffer's rigid actuating members could not function if they were attached to two separate independently-operable buttons because they would immovably tether the buttons together. EX2001, ¶136.

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]; EX2001, ¶130. The rotary actuator 12 is a single piece such that both ends of the string are attached to and controlled by the same actuator. EX2001, ¶130. Neither end of the string can move without the exact same and equal movement of the other end of the string 14. *Id.* Again, Petitioner's expert agrees. *See* EX2007, 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”:

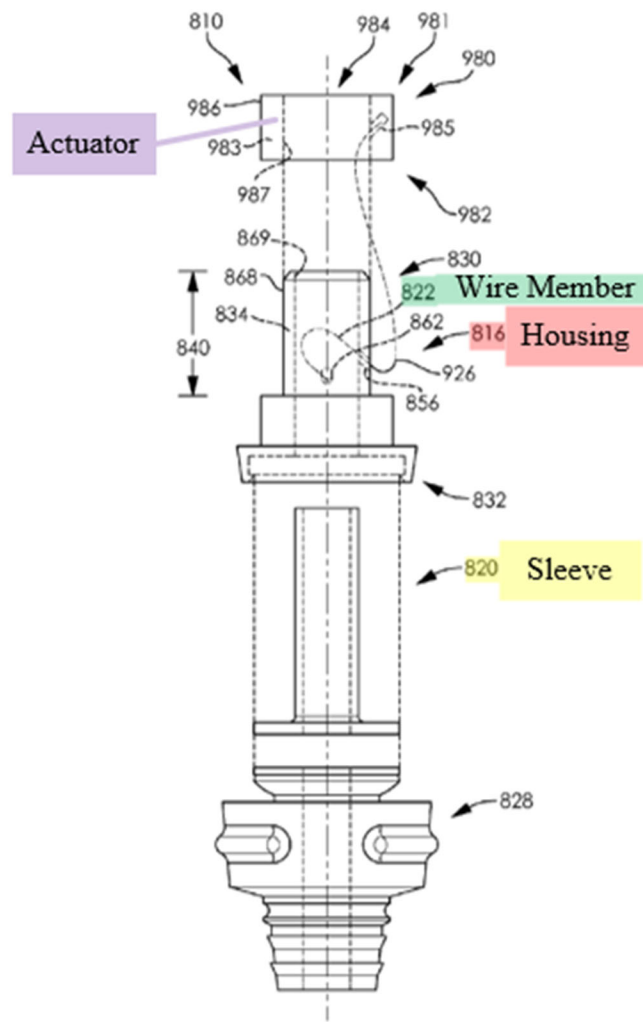


FIG. 20

EX1007, 23:50-62, 24:50-52. Eller discloses other embodiments with multiple wire members each having the same arrangement. EX2001, ¶¶131-134. In those embodiments, the wires are coupled to a single actuator. *Id.* at ¶134. 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.* Again, Petitioner's expert agrees. *See* EX2007, 80:11-19.

Accordingly, both experts agree that Petitioner's references disclose a single actuator that controls movement of a single actuating member (U-shaped member/string/wire). 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." EX2001, ¶136.

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. EX2001, ¶¶135-136. 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. Even if the arrangement existed generally that would not provide a motivation to combine Schaffer with Hartley and/or Eller. *See Virtek Vision Int'l v. Assembly Guidance Sys.*, 97 F.4th 882, 887 (Fed. Cir. 2024) (reversing PTAB finding of obviousness because the "mere fact that these possible arrangements existed in the prior art does not provide a reason that a skilled artisan would have substituted" one for the other.)

In sum, neither Schaffer, Hartley, nor Eller 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 3-4 fail for that reason alone.

2. A POSA would understand that 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 only on its expert's testimony that the combinations would "seal more effectively" and avoid the formation of "small gaps." Petition, pp.51, 58. As set forth in §V.A. above, a POSA would not have been so motivated because Schaffer includes the highly-compliant seal member 165 which seals completely around a wide range of multiple instruments. Even assuming that Schaffer's valve somehow did not seal in some embodiments, a POSA would not have been motivated to modify Schaffer's U-shaped members because they would understand there are comparably more plausible substitutions that 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, Petitioner asserts that a POSA would have recognized multiple straightforward ways to enhance or maintain Schaffer’s seal with a reasonable expectation of success. *See* Petition, pp.54, 61. During deposition in the related ’012 IPR, Mr. Thornton confirmed that these simple adjustments would work, whether or not there was a pressure differential across the valve. EX2007, 121:21-122:12. Dr. Zalesky agrees. EX2001 ¶¶153-154.

Accordingly, a POSA would have understood that simple properties of Schaffer’s existing valve such as spring force or properties of the seal module could be adjusted to improve Schaffer’s seal. *Id.*; Petition, pp.54, 61. A POSA would have also understood that such adjustments employ Schaffer’s stated principles of operation including two nonconforming actuating members each attached to a single actuator button that compress the compliant seal member 165 to conform and seal,

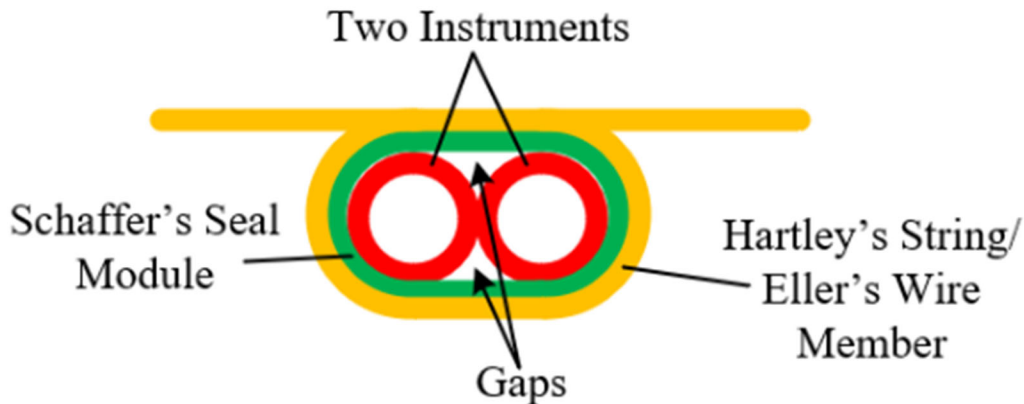
and simple manufacturability, durability, and forcible disengagement. EX2001, ¶¶154-155.

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. EX2001, ¶¶154-155.

Accordingly, Petitioner and its expert provide a number of comparably simple modifications, including those 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 §V.D. EX2001, ¶¶153-157.

3. Petitioner's proposed substitution would also not yield the predictable results of sealing Schaffer's valve.

Petitioner's proposed combination would seal less effectively and is thus not suitable for sealing around multiple and/or irregularly-shaped instruments—scenarios for which Schaffer's valve is designed to form a complete seal as explained above in §V.A.2.:



EX2001, ¶113. 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, during deposition in the related '012 IPR, 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:

QUESTION: So let's say those two sub filaments, as you refer to them, are made of a string. And you had said you're not sure where their orientation would be in an actual device; is that correct?

[Objection]

MR. THORNTON: Yes, if these were a very flexible string, and the buttons were compressed such that it's in the expanding configuration it's unlikely that they would have the shape shown here of -- with your perfectly straight lines and your perfectly partial circle on the byte area.

QUESTION: And you had said unknown, you wouldn't know what shape they would take, would you?

MR. THORNTON: Probably not without knowing the rest of the parameters and building prototype devices.

EX2007, 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—a POSA would understand the results of substituting Hartley's flexible string/ Eller's flexible wire for Schaffer's rigid actuating members to likewise be unpredictable. EX2001, ¶136. For example, the inherent floppiness/flexibility of the string/wire would render its relaxed geometry uncontrollable, resulting in non-orthogonal positioning around Schaffer's seal module. *Id.* at ¶145. That unpredictability is exacerbated by Petitioner's proposed modification/combination because Hartley and Eller—the only references that disclose a flexible member—precisely control movement of that flexible member with a single movable actuator such that the flexible string/wire moves an equal amount upon actuation. EX2001, ¶¶130, 134. In Petitioner's combination, the movement of the string/wire member would not be precisely controlled in that manner by a single actuator as either of Schaffer's buttons could be depressed independently to move the string/wire unpredictably. *Id.* at ¶136.

Petitioner's proposed combinations of Schaffer and Hartley/Eller therefore not only depart from the intended purpose and express disclosure of these references in which a single U-shaped actuating member/string/wire are controlled by a single actuator, but do not predictably seal.

In the Institution Decision in the related '012 IPR, the Board asserted that "Schaffer's two actuating members apply a constricting force to the valve's seal module when pulled by opposing spring-actuated buttons," and that "replacing those members with a single string (or wire) would provide substantially the same function." EX1023, p.39. But the function is not similar and in fact is unpredictable because that modification, not found anywhere in the prior art, allows each end of the string or wire to be manipulated independently. And, as Dr. Zalesky explains, "there are many design considerations that a POSITA would need to contemplate if they had been motivated to redesign Schaffer's valve seal module" "to accommodate Hartley's string or Eller's wire member" as arranged in Petitioner's proposed combination. EX2001, ¶137. Several of these design considerations are discussed below in §V.D.

C. Petitioner Fails to Establish that that the Solutions for Constricting a Tubular Member in a Hemostasis Valve Were Finite, Identifiable, or Known

Petitioner also 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.50, 58; *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 and solutions for “constricting a tubular member in a hemostasis valve” were finite, identified and known. Petition, p.52. Petitioner proposes only three options: “Hartley and Schaffer disclose two such methods: Hartley’s single string and Schaffer’s two U-shaped actuating members formed from metal or plastic... Eller discloses a third option: one or more wire members.” *Id.*; EX1003, ¶110. First, none of those options include

connecting a single string or wire to two independently operable actuators as required in Petitioner's proposed modification to Schaffer. As such the proposed arrangement was not known at all.

And second, at deposition in the related '012 IPR, Mr. Thornton admitted that there were more than those three ways to constrict a tubular member in a hemostasis valve including those disclosed in Schaffer '616 (EX2007, 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:

QUESTION: Do you think there's other ways that exist [to compress a tubular member in a hemostasis valve]?

[Objection]

MR. THORNTON: Could be other ways that exist.

QUESTION: How many other?

MR. THORNTON: **I don't know.**

QUESTION: So when you say, these finite predictable options, you don't know how many other finite predictable options there are; is that correct?

[Objection]

MR. THORNTON: I don't know how many options could be used to compress [a] tube.

EX2007, 107:3-13 (emphasis added). Petitioner's "obvious to try" argument fails because the options and solutions for compressing a tubular member in a hemostasis valve were not "known," "finite" or "identified" as confirmed by Petitioner's own expert.

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").

Here, a POSA would understand that Schaffer's rigid U-shaped actuating members are fundamental to Schaffer's principle or operation, of compressing a

highly compliant member using rigid actuators as explained above, and 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 and durability. EX1005, ¶¶[0080]-[0082]. As such, a POSA would not have been motivated to modify Schaffer based on Eller/Hartley as Petitioner suggests.

1. Substituting Hartley’s string/Eller’s wire for Schaffer’s actuating members would prevent forcible disengagement.

A POSA would not replace Schaffer’s rigid U-shaped actuating members with Hartley’s string/Eller’s wire because such a modification would prevent forcible disengagement, as described above in §III.A. EX2001, ¶¶150-152. 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]; EX2001, ¶152.

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.52-54, 59-61. In this arrangement, Hartley’s string/Eller’s wire would never disengage—let alone forcibly disengage—Schaffer’s seal module. EX2001, ¶151. Therefore, this modification would change the principle of operation of Schaffer. *Id.*

In the Institution Decision in the related '012 IPR, the Board stated that while Petitioner's proposed combination of Schaffer and Hartley/Eller requires a "structural change," the "valve's operation and purpose is (at least arguably) materially unchanged in the modified Schaffer valve." EX1023, p.43. Patent Owner respectfully disagrees. Even if the modified Schaffer valve has a similar operation and purpose, that does not mean the modification entails a simple substitution or that there is a motivation to make such a change, as explained above in §V.B.1-3. EX2001, ¶137. Instead, Petitioner's alleged modification is not found in the art at all and is based on impermissible hindsight stemming from the '291 Patent.

2. Substituting Hartley's string/Eller's wire for Schaffer's actuating members would compromise its ease of manufacturing and durability.

Schaffer's U-shaped actuating members 55 are purposefully designed to be rigid and attached to a single actuator. EX2001, ¶138. That design choice provides simple methods of assembly and manufacturing, and effectively addresses Schaffer's recognized need for "a durable stasis valve." EX1005, ¶[0008]. Petitioner's proposed substitutions would introduce assembly difficulties and undermine the durability of Schaffer's valve. EX2001, ¶¶138-149.

Schaffer discloses a method of manufacture that relies upon its U-shaped actuating members being rigid and attached to only a single actuator. EX2001, ¶140. Specifically, Schaffer discloses that its U-shaped members are advantageously

machined, and that the valve is then assembled by inserting the seal module “through the housing 20 and between each actuator 50” with “[e]ach actuator button 261 [] completely compressed.”

A POSA would understand that Petitioner's modification with Hartley's string/Eller's wire would not only complicate manufacturing but also render Schaffer's method of assembly inefficient and unreliable compared to Schaffer's straightforward design. *Id.* at ¶¶141-149.

Further, Schaffer teaches that “[e]ach actuator button 261 is completely compressed and held while the seal module 100 is inserted through the housing 20 and between each actuator 50.” EX1005, ¶[0083]. A flexible string or wire would loosen when the actuator buttons 261 are compressed such that neither would provide a uniform opening like Schaffer's rigid U-shaped actuating members 55 to easily permit positioning of the seal module therethrough. EX2001, ¶144. Thus, the substitution of Hartley's string/Eller's wire for Schaffer's U-shaped actuating members is contrary to Schaffer's only disclosed method of assembly. *Id.* at ¶¶146-147.

Schaffer also discloses that its U-shaped members are manufactured by means of machining (the controlled removal of material). EX1005, ¶[0082]; EX2001, ¶148. Schaffer's standard machining methods to manufacture its rigid U-shaped members would not work well with filaments. EX2001, ¶148. A string/wire would deform

when subjected to force during the machining process, making it exceedingly challenging—if not unfeasible—to manufacture the filament in that manner. *Id.* Thus, a POSA would recognize that Hartley's string/ Eller's wire are ill-suited for Schaffer's straightforward manufacturing and assembly techniques. *Id.*

Regarding durability, Schaffer's construction enables the valve to endure operational demands and maintain its performance and structural integrity over time. EX2001, ¶149. For example, the rigidity of the U-shaped members imparts the necessary strength and stability to prevent deformation or failure when the actuating members are actuated. *Id.* Substituting Hartley's string/ Eller's wire could weaken the valve's durability given the flexible nature of these components, ultimately undermining its intended function of providing a dependable and long-lasting seal mechanism. *Id.*

In the Institution Decision in the related '012 IPR, 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.” EX1023, p.46. But even if these methods are “optional,” they are the only methods disclosed. Moreover, even if a POSA could have manufactured Petitioner's proposed modification without undue experimentation, that does not mean the modification entails a simple substitution, as explained above in §V.B.1-3.

Accordingly, a POSA would neither have found it obvious nor have been motivated to substitute Hartley's string/ Eller's wire for Schaffer's U-shaped actuating members, as doing so would reduce the ease of manufacturing and durability of Schaffer's valve.

VI. CLAIM 18 IS NOT OBVIOUS OVER THE COMBINATION OF GARRISON WITH SCHAFFER, OR OVER THE COMBINATION OF GARRISON, SCHAFFER AND EITHER OF HARTLEY OR ELLER (GROUNDS 5-7)

Petitioner relies on Garrison for allegedly disclosing the "aspiration catheter" of Claim 18. Petition, pp.90-97. Petitioner does not rely on Garrison for disclosing any of the hemostasis valve structural limitations of Claim 18 discussed above (e.g., "a hemostasis valve comprising ... a filament formed in a loop around the tubular sidewall ... reducing a diameter of the lumen in response to reducing a diameter of the loop"). And, Petitioner acknowledges that "Garrison does not expressly describe the structure of the hemostasis valves." Petition, p.92. For at least that reason, Garrison does not remedy the deficiencies in Schaffer, Hartley, and Eller set forth above.

VII. DEPENDENT CLAIMS 2-8, 12-17, AND 19 ARE NOT ANTICIPATED BY SCHAFFER OR OBVIOUS OVER SCHAFFER ALONE OR IN COMBINATION WITH HARTLEY, ELLER, AND/OR GARRISON

Claims 2-8 and 12-17 ultimately depend from Claim 1 and thus include all the limitations from Claim 1. Although Claim 19 is currently written as depending from

Claim 1, this is a clear clerical error. The subject matter of Claim 19 pertains to the "aspiration catheter system," as recited in Claim 18, whereas Claim 1 is directed to a hemostasis valve. It is evident that Claim 19 was intended to depend from Claim 18, not Claim 1, and should be read accordingly. Therefore, Claim 19 includes all the limitations of Claim 18. Accordingly, those claims are also not anticipated by Schaffer (Ground 1), rendered obvious by Schaffer alone (Ground 2), rendered obvious by Schaffer in combination with Hartley or Eller (Grounds 3-4), or rendered obvious by Garrison in combination with Schaffer and Hartley or Eller (Grounds 5-7) for the reasons set forth above.

A. Claim 3

Dependent claim 3 is also patentable over Petitioner's asserted art for the additional features of this claim. For example, Claim 3 recites "the filament further comprises a second end portion extending away from the loop to the second member." As explained in §V.B.1., Petitioner cites no reference that discloses a string/wire attached to and controlled by two independently movable actuators, nor provides any reason why it would have been obvious to have modified Schaffer to have such configuration. Grounds 1-4 fail with respect to Claim 3, and Claims 4-6 that depend from Claim 3, for these additional reasons.

B. Claim 4

Dependent Claim 4 depends from Claim 3 and is also patentable over Petitioner's asserted art for the additional features of this claim. For example, Claim 4 recites, "the first end portion, the loop, and the second end portion are one continuous filament." Petitioner cites no reference that discloses "one continuous filament" that is "formed in a loop around the tubular sidewall" and is attached to and controlled by two independently movable actuators nor provides any reason why it would have been obvious to have modified Schaffer to have such configuration. Grounds 1-4 fail with respect to Claim 4 for these additional reasons.

VIII. 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 15, 2025

By: / Joseph P. Hamilton /
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CERTIFICATE OF COMPLIANCE

Pursuant to 37 C.F.R. § 42.24(d), I, Joseph Hamilton, certify that **PATENT OWNER'S PRELIMINARY RESPONSE** contains 13,864 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 15, 2025

By: / Joseph P. Hamilton /
Joseph Hamilton
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Lead Counsel for Patent Owner

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), I certify that on September 15, 2025, a copy of **PATENT OWNER'S PRELIMINARY RESPONSE and EXHIBITS 2001-2008** was served upon the below-listed counsel by electronic mail:

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