

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

IMPERATIVE CARE, INC.,
Petitioner,

v.

INARI MEDICAL, INC.,
Patent Owner.

Case No. IPR2025-00156
U.S. Patent No. 11,697,012

PATENT OWNER'S PRELIMINARY RESPONSE

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EXHIBIT LIST

	Petitioner's Exhibits
Exhibit	Description
EX1001	U.S. Patent No. 11,697,012 (“the ’012 Patent”)
EX1002	’012 Patent Prosecution History Excerpts
EX1003	Expert Declaration of Troy Thornton
EX1004	Resume of Troy Thornton
EX1005	U.S. Patent Publication US 2003/0225379 A1 to Schaffer et al. (“Schaffer”)
EX1006	U.S. Patent Publication US 2003/0116731 A1 to Hartley (“Hartley”)
EX1007	U.S. Patent No. 9,980,813 B1 to Eller (“Eller”)
EX1008	Drawings Submitted During Prosecution of U.S. Patent Application No. 10/371,190
EX1009	U.S. Patent No. 5,429,616 to Schaffer (“Schaffer ’616”)
EX1010	U.S. Patent Publication US 2011/0144592 A1 to Wong et al. (“Wong”)
EX1011	U.S. Patent Publication US 2015/0173782 A1 to Garrison et al. (“Garrison”)
EX1012	U.S. Patent No. 9,216,277 B2 to Myers (“Myers”)
EX1013	Dorland’s Illustrated Medical Dictionary, 32nd ed. (2012) - Definition of “Catheter”
EX1014	U.S. Patent No. 4,723,550 to Bales et al.
EX1015	U.S. Patent No. 5,895,376 to Schwartz et al.
EX1016	U.S. Patent No. 12,109,384 B2 to Merritt et al.

	Patent Owner's Exhibits
Exhibit	Description
2001	Declaration of Paul J. Zalesky
2002	Merriam-Webster's Collegiate Dictionary (11th ed. 2014)
2003	New Oxford American Dictionary (3rd ed. 2010)
2004	U.S. Patent Application Publication No. 2018/0193043
2005	Deposition Transcript of Troy Thornton (September 30, 2024)

I. INTRODUCTION

The '012 Patent generally discloses catheter systems comprising a “garrote” hemostasis valve that “provides convenient, single-handed operation [and] allows the user to easily and quickly swap different tools being used through the valve without compromising hemostasis and therefore simplifying the procedure.” EX1001, 5:55-64. The '012 Patent's garrote valve “provides robust sealing either with or without a tool extending through the valve,” enabling minimal leakage in scenarios where a pressure differential exists across the valve, such as during vacuum aspiration procedures. *Id.* at 5:65-6:6. A person of ordinary skill in the art (“POSA”) will readily appreciate that the combination of single-handed operation and the seal integrity provided by the structure of the '012 hemostasis valve plays a vital role in patient safety and optimal medical outcomes.

Claim 1, the sole independent claim of the '012 Patent, addresses those issues, reciting, *inter alia*, a “hemostasis valve” comprising a “collapsible tubular sidewall defining a valve lumen” and “a first filament formed into a loop around the collapsible tubular sidewall” wherein “a diameter of the valve lumen decreases in response to reducing a diameter of the loop.” But none of grounds 1-7 disclose or render those limitations obvious such that Petitioner has failed to demonstrate a

reasonable likelihood that it would prevail with respect to the patentability of any of Claims 1-9 of the '012 Patent.¹

Regarding ground 1, Schaffer cannot anticipate Claim 1 because Schaffer does not disclose “a first filament formed into 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 expressly recited in Claim 1. EX2001, ¶¶58-59 & 75-83; *see also Imperative Care, Inc. v. Inari Medical Inc.*, IPR2024-01157, Paper 7 at p.16 (P.T.A.B. Jan.23, 2025) (Institution Decision in related U.S. Patent No. 11,697,011, of which the '012 Patent is a continuation, recognizing that for the loop 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).”). In contrast, Schaffer discloses two rigid U-shaped members that are not “formed into a loop” because they are instead U-shaped, let alone where the “diameter of the loop” can reduce as claimed. Indeed, the shape and dimension of Schaffer's actuating members cannot reduce or otherwise change during operation of Schaffer's valve because the

¹ Patent Owner's Preliminary Response addresses grounds 1-7 as applied to Claim 1. Claims 2-9 depend either directly or indirectly from Claim 1 and are patentable over grounds 1-7 for at least the same reasons as Claim 1.

actuating members 55 are rigid. *Id.* at ¶83. Thus, ground 1 fails because Schaffer's U-shaped actuating members are rigid, not flexible, and cannot be formed into a loop that can reduce in diameter. *Id.* at ¶¶66-83.

Regarding ground 2, Petitioner does not assert that it would have been obvious for a POSA to have modified Schaffer's actuating members to be flexible, formed into a loop, or to have a diameter that reduces during operation. Accordingly, Petitioner has failed to satisfy its burden that Schaffer alone renders Claim 1 obvious because Schaffer does not disclose those features.

Regarding grounds 3 and 4, replacing Schaffer's rigid U-shaped actuating members with a flexible string or wire as disclosed in Hartley or Eller² is **not** a simple "substitution of one known element (Hartley's string [or Eller's wire]) for another (Schaffer's actuating members)" as Petitioner asserts. Petition, pp.42, 50. Petitioner's proposed combination requires more, namely, further modifying the combination such that one end of Hartley's string or Eller's wire is attached to one of Schaffer's actuator buttons and the other end is attached to the other of Schaffer's actuator buttons. *Id.* at pp.43, 44, 51, & 52. But, none of Petitioner's three references disclose such an arrangement. Instead, (i) Schaffer's rigid U-shaped actuating

² Both Hartley and Eller were expressly considered by the Office during prosecution of the '012 Patent. EX1002, p.89.

members are each attached to a single actuator button, (ii) Hartley's string is attached to a single rotary actuator, and (ii) Eller's wire member is attached to a single rotary actuator. EX2001, ¶¶92-95 & 146-152. As such, Petitioner proposed substitution does not result in a loop that can reduce in diameter as claimed. Grounds 3 and 4 fail for that reason alone.

Grounds 3 and 4 also fail because a POSA would not have been motivated to replace Schaffer's rigid U-shaped actuating members with a flexible string or wire as disclosed in Hartley or Eller, let alone then further modify the proposed combination to eliminate one of Schaffer's U-Shaped members completely and instead form a loop as claimed. Petitioner's purported motivation to combine is that according to Petitioner, Schaffer's device creates a poor seal. *See, e.g.,* Petition, p.43. But, Petitioner's assertion ignores Schaffer's express disclosure to the contrary that Schaffer's device provides "a durable stasis valve that blocks the flow of gas or fluid ***completely*** and immediately ***with or without an instrument in place*** within the gas/fluid path." EX1005, ¶[0008] (emphasis added). In fact, both Petitioner and its expert repeatedly tout Schaffer's complete seal and rely on Schaffer's ability to form a complete seal for the purported motivation to combine Schaffer with Garrison in grounds 5-7. *See, e.g.,* EX1003, ¶¶70, 149, & 161; Petition, pp.76, 80, & 91. In other words, Petitioner's purported problem to be solved, Schaffer's poor seal, is manufactured from whole cloth.

Indeed, Schaffer's design employs a fundamentally different approach to "block the flow of gas or fluid" through a sealing member, namely rigid U-shaped actuating members that are central to Schaffer's disclosed principles of operation. EX2001, ¶¶123-136 & 157-161. Specifically, Schaffer's rigid U-shaped actuating members apply a compression force to a sealing member and at the same time allow for forcible disengagement, simple manufacturing, and durability. *Id.* Schaffer itself addresses Petitioner's purported sealing issues that Petitioner attributes to the rigid U-shaped actuating members by including an internal sealing member having "a 'selfclosing' nature in that it sticks occlusively to itself forming a nearly fluid/gas tight seal under very light compression." EX1005, ¶[0059]. Petitioner's proposed modification first requires that a POSA remove Schaffer's "sealing member" and/or choose materials for the sealing member that do not seal to create a purported sealing problem. *See, e.g.,* EX1003, ¶100. Only then, would a POSA be motivated according to Petitioner to also eliminate Schaffer's rigid U-shaped actuating members, and all accompanying advantages of those rigid U-Shaped actuating members expressly articulated in Schaffer. But, a POSA would not have modified Schaffer to create a sealing issue and then further combine Schaffer with Hartley or Eller to address that purported sealing issue, thus negating all the advantages of Schaffer's rigid U-Shaped actuating members that are fundamental to Schaffer's principle of operation.

Moreover, Petitioner's purported substitution of Hartley's flexible string or Eller's flexible wire member for Schaffer's rigid U-Shaped actuating members would in fact cause Schaffer's valve to likely be inoperable with its sticky seal module, as sticky nature would inhibit opening of the seal module as admitted by Petitioner's expert (EX1003, ¶100) if not used with Schaffer's rigid members. That is, Hartley's string or Eller's wire member would not disengage—let alone forcibly disengage—the seal module, causing the sticky seal module to remain in a closed position. EX2001, ¶¶141 & 165.

In sum, Petitioner's proposed combinations of Schaffer with Hartley or Eller are 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 the operation of Schaffer.

Regarding grounds 5-7, Petitioner's combinations of Garrison in addition to Schaffer, or Schaffer and Hartley or Eller, fail because Petitioner does not rely on Garrison for disclosing any of the missing limitations identified above. That is, Garrison does not remedy the deficiencies of Schaffer, Hartley, and Eller.

For these and the reasons set forth herein, Petitioner has failed to demonstrate a reasonable likelihood that any of Claims 1-9 are unpatentable under any of grounds 1-7. Thus, Patent Owner requests that the Petition be denied.

II. BACKGROUND

A. Overview of the '012 Patent

The '012 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. The '012 Patent addresses those drawbacks by providing a hemostasis valve with easy one-handed operation and a strong seal around a variety of different-sized instruments, both of which are important for hemostasis valves in many applications, including particularly for use with aspiration in large-bore thrombectomy systems, an embodiment of the '012 Patent. EX2001, ¶33; EX1001, 16:7-21 (incorporating, *e.g.*, U.S. Patent Application 15/498,320, which was published as US2018/0193043 (EX2004) by reference).

Specifically, the '012 Patent discloses a valve, also referred to in the '012 Patent as a garrote valve (a term coined by the inventors to describe their novel device), that can seal with or without a tool extending through the valve.³ *Id.* at 5:56-57. The design and functionality of the hemostasis valve enables medical

³ Merriam-Webster defines “garotte” to mean “an implement (such as a wire with a handle at each end) for strangulation.” EX2002, p.516.

professionals to operate the valve with one hand while maintaining a robust seal to prevent blood loss during procedures. *Id.* at 5:55-67; EX2001, ¶35. The hemostasis valve can be a component of an aspiration catheter that includes a flexible tubular sidewall. EX1001, 6:28-41; EX2001, ¶¶37-38. The design enables such ease of use while maintaining an effective and strong seal, for example, under a pressure differential caused by vacuum during aspiration thrombectomy procedures. EX1001, 2:11-13, 5:17-23, 5:55-6:6, 16:6-19; EX2001, ¶36. In particular, the design allows for quicker and more effective sealing of large-bore catheters for thrombectomy in large veins and pulmonary arteries, such as for treating deep vein thrombosis or pulmonary embolism (i.e., applications where blood loss is a particular risk). EX2001, ¶¶47-49.

To address those issues and provide the benefits of reduced blood loss and one-handed operation, the '012 Patent discloses a new type of valve, a “garrote” valve, that comprises a collapsible tubular sidewall defining a valve lumen and a constricting mechanism. EX1001, 7:11-57 & 8:5-16. The constricting mechanism includes at least one filament that is formed into a loop around a tubular sidewall and an actuator connected to an end of the filament. EX1001, 8:5-12, 13:17-29 & 22:17-25. The filament(s) 150 can have different configurations as shown in Figures 6-9 of the '012 Patent. EX2001, ¶¶43-46. For example, as shown in Figure 6, the

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

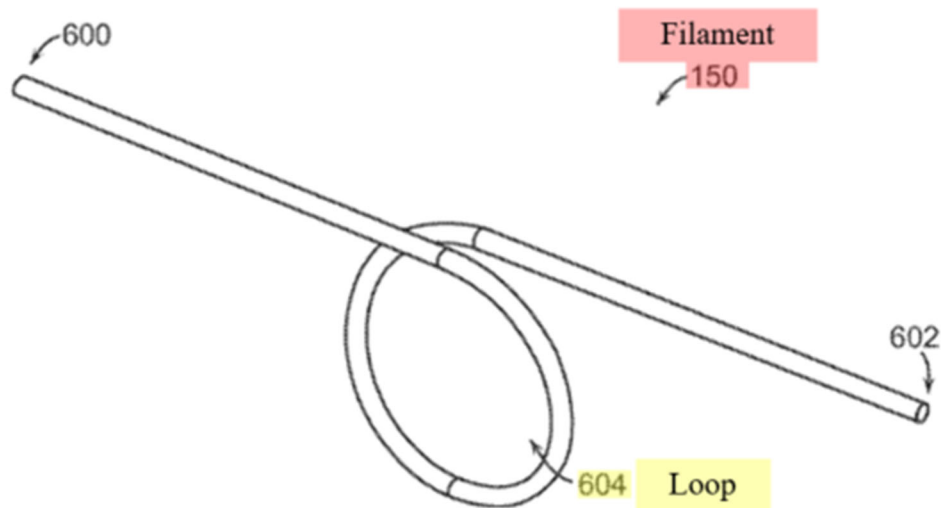
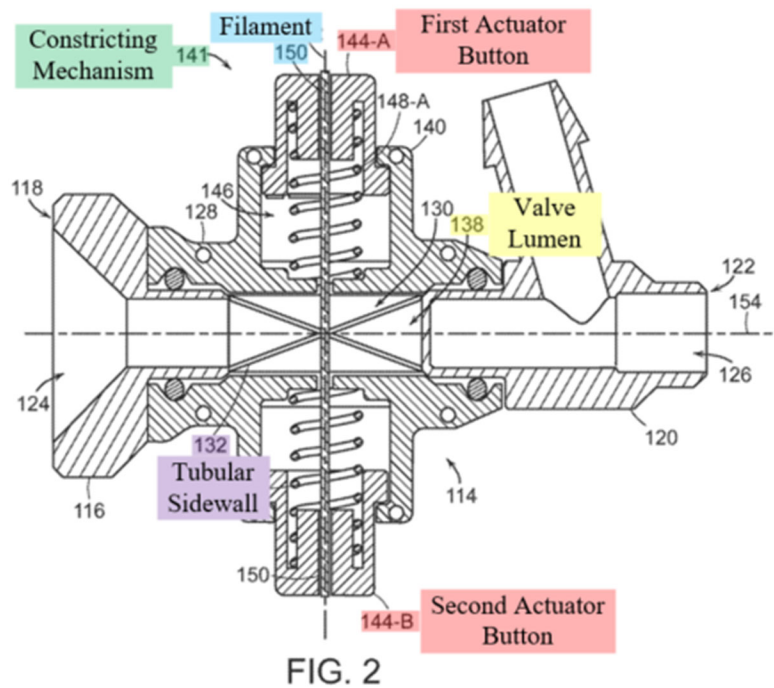


FIG. 6

EX1001, 13:17-21.

The actuator may be a manual button, enabling easy one-handed use. EX1001, 8:8-12. Specifically, the actuator 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, ¶39.

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

B. Claims

Claim 1, the only independent claim of the '012 Patent, recites:

An aspiration catheter, comprising:
an elongated, flexible tubular body, having a proximal
end, a distal end and a central lumen;
a hemostasis valve on the proximal end of the catheter, the

hemostasis valve comprising

(a) a collapsible tubular sidewall defining a valve lumen in communication with the central lumen; and

(b) a constricting mechanism having at least a first actuator, a first filament formed into a loop around the collapsible tubular sidewall, the filament having at least a first end portion extending away from the loop and connected to the first actuator, and a first spring configured to move the first actuator in a direction that pulls the first end portion such that a diameter of the valve lumen decreases in response to reducing a diameter of the loop.

A POSA would understand that the innovative hemostasis valve design of Claim 1 enhances the sealing capability of the catheter lumen compared to prior art valves, particularly around a variety of tools, while simplifying operator use. EX2001, ¶¶40 & 47-49. Specifically, the garrote or “constricting mechanism” of Claim 1 includes at least one “first filament formed into a loop around the collapsible tubular sidewall.” The “first filament” further comprises “a first end portion extending away from the loop and connected to the first actuator.” Additionally, “a first spring” biases the actuator such that “a diameter of the valve lumen decreases in response to reducing a diameter of the loop.”

C. Prosecution History

The Patent Office issued a Restriction Requirement on September 20, 2022, in the application that matured into the '012 Patent.

In response, the Patent Owner elected Species I (Figs. 1-5) and Species IB (Fig. 6). *Id.* at p.175. Figure 6 is directed to at least a filament loop rather than, for example, multiple U-shaped filaments, i.e., bights, as shown in Figures 8 and 9:

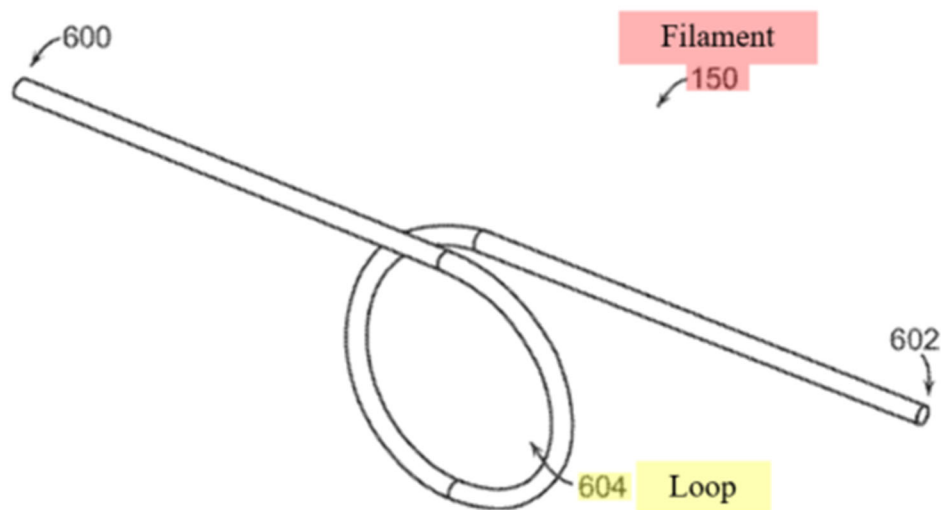


FIG. 6

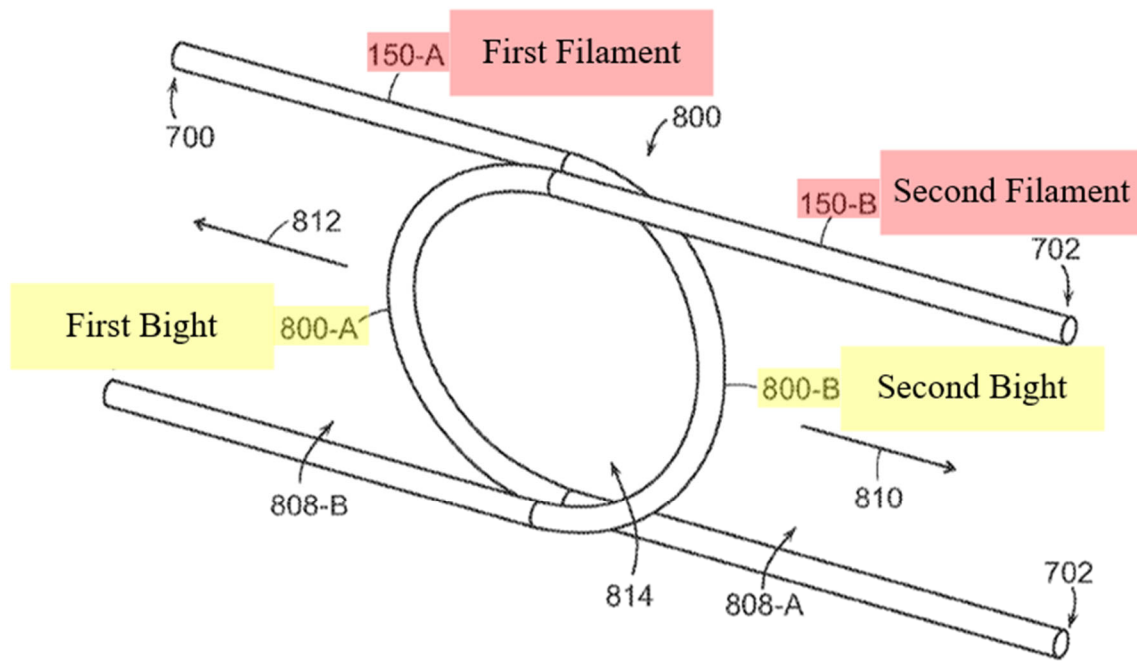


FIG. 8

EX1001, 13:17-21 & 13:30-36; EX2001, ¶¶42-46. In other words, a POSA would understand that the claimed “a first filament formed into a loop” requires a filament formed in a loop, and excludes U-shaped members, or “bights” shown in Figures 8 and 9.

Later in prosecution, the Examiner conferred with the Applicant via telephone to resolve an issue with antecedent basis in Claim 1 via an Examiner’s Amendment, before allowing the application. EX1002, p.88. In the Notice of Allowance, the Examiner referenced Hartley, Wong, and Myers and explained that Hartley fails to disclose a “first spring,” Wong fails to disclose a “constricting mechanism having a first filament formed in a loop,” and Myers fails to disclose a “first filament.” *Id.* at

pp.85-87. In addition to expressly considering Hartley, the Examiner expressly considered Eller, listing Eller as one of six references (including Hartley) in a Notice of References Cited that accompanied the Notice of Allowance. *Id.* at p.89.

D. Claim Construction

In an IPR, a claim is construed “using the same claim construction standard that would be used to construe the claim in a civil action” and “in accordance with the ordinary and customary meaning as understood by a POSITA and the prosecution history pertaining to the patent.” 37 C.F.R. § 42.100(b). In *Phillips v. AWH Corp.*, the Federal Circuit explained that “words of a claim ‘are generally given their ordinary and customary meaning’” and that “the ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application.” 415 F.3d 1303, 1312-13 (Fed. Cir. 2005) (cleaned up).

“To act as its own lexicographer a patentee must clearly set forth a definition of the disputed claim term other than its plain and ordinary meaning and must clearly express an intent to redefine the term.” *Kyocera Senco Indus. Tools Inc. v. Int’l Trade Comm’n*, 22 F.4th 1369, 1378 (Fed. Cir. 2022) (emphasis added). “We depart from the plain and ordinary meaning of claim terms based on the specification in only two instances: lexicography and disavowal.... The standards for finding

lexicography and disavowal are exacting.” *Hill-Rom Services, Inc. v. Stryker Corp.*, 755 F. 3d 1367, 1371 (Fed. Cir. 2014) (internal citations omitted).

1. Filament

Claim 1 recites “a constricting mechanism having ... a first filament formed into a loop around the collapsible tubular sidewall ... such that a diameter of the valve lumen decreases in response to reducing a diameter of the loop.” EX1001, 22:10-25. 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.”

Petitioner’s proposed construction omits the requirement that a filament is flexible, proposing that a “filament” simply means “at least ‘one or more threads, lines, cords, ropes, ribbons, flat wires, sheets, or tapes.’” Petition, p.16. A POSA will readily recognize that Petitioner’s proposed construction is incorrect and inconsistent with the structures mandated by claim language, the specification, the prosecution history, and the extrinsic evidence. EX2001, ¶¶56-62.

a) Language of the claims

The claim language itself confirms that the filament must be flexible. Claim 1 recites that “the first filament [is] formed into a loop around the collapsible tubular sidewall” and that “a diameter of the valve lumen decreases in response to reducing

a diameter of the loop.” Both of these limitations necessarily require that the filament be flexible to form a loop that can decrease in diameter to constrict.

First, a filament that is incapable of bending or curving could not be “formed into a loop” around the tubular sidewall. This inherent property of flexibility is essential to achieving the claimed loop formation. EX2001, ¶58. Second, the claim further states that “a diameter of the valve lumen decreases in response to reducing a diameter of the loop.” The filament must be flexible to be able to be drawn tighter, allowing the loop to decrease in diameter to constrict the valve lumen. *Id.* In contrast, a rigid filament, even somehow arranged in a loop-like shape, would resist any attempt to reduce in diameter, preventing the claimed decrease in the valve lumen’s diameter. *Id.* This structure requires a “filament” according to its plain and ordinary meaning: “a thin, flexible length of material formed by one or more strands of material,” allowing it to bend or deform rather than remaining rigid.

b) The specification

The specification further confirms that a “filament” must be flexible for the hemostasis valve to function as intended. In Figure 6 of the ’012 Patent, a single 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, ¶59. Likewise, Figure 7 of the '012 Patent 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, ¶59. If the filaments depicted in Figures 6 and 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 deform under tension is therefore not optional but fundamental to the proper operation of the device. Accordingly, the specification makes clear that flexibility is a necessary characteristic of the filament, consistent with the plain and ordinary meaning of the term.

While the specification provides 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 rigid components. EX2001, ¶60. A POSA would understand that flexibility is a function of both material and form. *Id.* For example, metals can be used to create a girder for a building, which is rigid, but metals can also be formed into long, narrow strands to

produce a flexible wire or cable. *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 list of example materials ignores that the form of a component often dictates its properties. *Id.*

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. That defies logic. 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 each of those configurations is consistent with the plain meaning of a filament, which must be flexible, although not everything that *includes* such a structure would be a filament (for example a brick wall including a sheet). EX2001, ¶60. 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 and results-oriented construction is not supported by the claim language, specification, prosecution history, and the plain meaning of the term in the art.

c) Prosecution History

The prosecution history further reinforces that “filament” refers to a “thin, flexible length of material formed by one or more strands of material.” This is evident from the prior art cited by the Examiner, which included a filament (Hartley’s) that was explicitly described as flexible. In the Notice of Allowance issued on November 23, 2022, the Examiner identified Hartley as disclosing “at least one filament” in item 14. EX1002, p.85. Thus, the prosecution history aligns with the plain and ordinary meaning of “filament” and reinforces that a POSA would recognize flexibility as a necessary attribute of the claimed structure. EX2001, ¶61.

d) 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 incorporates the subject matter of the ’012 Patent by reference and claims a hemostasis valve including a “filament,” Petitioner’s expert admitted that “in the ordinary meaning of filament, it has flexibility.” *Id.* at 123:1-3. In other words, Petitioner’s own expert agrees that the plain and ordinary meaning of “filament” requires flexibility. His testimony here that a “filament” need not be flexible is not credible.

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."). These definitions comport with the plain and ordinary meaning of filament to a POSA. EX2001, ¶62. And Patent Owner's expert further agrees that the term filament as used in the '011 Patent means a "thin, flexible length of material formed by one or more strands of material." EX2005, 123:1-3.

Accordingly, the term "filament" should be construed to mean "a thin, flexible length of material formed by one or more strands of material."

e) Related IPR Proceedings

In an Institution Decision concerning U.S. Patent No. 11,697,011, which the '012 Patent is a continuation of, the Board declined to construe the term "filament" according to the constructions of either Petitioner or Patent Owner suggested here. *Imperative Care, Inc. v. Inari Medical Inc.*, IPR2024-01157, Paper 7 pp.12-18 (P.T.A.B. Jan.23, 2025). In that decision, 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 requires “a first filament formed into a loop” wherein “a diameter of the valve lumen decreases in response to reducing a diameter of the loop.” As such, Claim 1 requires that the filament be flexible regardless of the construction of the term “filament.”

2. Aspiration in the Preamble

Petitioner proposes that “aspiration” in the preamble of Claim 1 is not limiting. Petition, pp.18-20. This claim construction issue is not germane to Patent Owner’s arguments here. Patent Owner reserves the right to contest whether “aspiration” is limiting in this proceeding and in connection with other proceedings relating to the ’012 Patent and other related patents.

E. Person of Ordinary Skill in the Art

For the purposes of this preliminary response, Patent Owner has applied Petitioner’s definition of a POSA. That is, “[a] POSITA in September 2017 would have had an undergraduate degree in mechanical engineering or a related engineering discipline and 2-4 years of product design or engineering experience.” Petition, p.15. Patent Owner reserves the right to contest this definition here or in the context of other proceedings relating to this and other related patents.

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 the required “first filament,” the “first filament formed into a loop around the collapsible tubular sidewall,” and that the “diameter of the valve lumen decreases in response to reducing a diameter of the loop,” as recited in Claim 1.

A. Schaffer does not disclose a “first filament.”

As set forth above, the term “filament,” as recited in Claim 1 of the '012 Patent, means “a thin, flexible length of material formed by one or more strands of material.” In contrast, Schaffer discloses rigid U-shaped members. Accordingly, Schaffer does not anticipate Claim 1.

Schaffer's U-shaped actuating members are rigid, not flexible. EX2001, ¶¶66-74. For example, Schaffer discloses that the actuating members 55 are “made from machining pre-existing amounts of metals and/or plastics.” EX1005, ¶¶[0081]-[0082].

Petitioner implicitly admits that Schaffer's U-shaped members are rigid, asserting that Schaffer's U-shaped actuating members 55 would purportedly form

gaps and a poor seal as the supposed motivation to modify Schaffer. Petition, pp.40-46. Schaffer's disclosure also supports that its actuating members are rigid. Schaffer explains that its U-shaped actuating members "forcibly disengage," which requires a rigid member, when it says: "[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 where gases and fluids can pass therethrough.” EX1005, ¶[0077]. The actuating members would need to be rigid to “forcibly disengage” opposing outer walls of the seal module. EX2001, ¶68. In contrast, a “filament” cannot “forcibly disengage” because it is flexible and would merely deform when the actuator button is pressed and tension on the filament is reduced. *Id.*

Schaffer further discloses that its seal module 100 (which the actuating members 55 contact and collapse) is made of an “extremely soft and compliant and intrinsically ‘sticky’” material. EX1005, ¶[0059]. A POSA would understand the forcible disengagement provided by the rigid actuating members 55 of Schaffer helps ensure proper disengagement of the actuating members 55 from the seal module. EX2001, ¶¶68-69. For example, flexible actuating members 55 would not disengage the soft and sticky seal module 100 at all when the actuator buttons 261 are depressed. *Id.* at ¶69. Instead, the seal module 100 would stick to and retain the

actuating members 55 in the closed position—rendering Schaffer's valve inoperable by inhibiting or even preventing movement of the seal module 100 to the open position. *Id.* Notably, Petitioner's own expert acknowledges that such sticking could hinder the valve's ability to reopen. EX1003, ¶100 (a “seal module made of the ‘sticky’ or ‘gelatinous’ materials would not easily return to its uncollapsed configuration.”).

Additionally, Schaffer's disclosed method of assembly relies on the rigidity of its U-shaped actuating members. EX2001, ¶¶72-73. The method of assembly disclosed in Schaffer uses two rigid U-shaped members to form an area through which a seal module can be inserted, as follows: “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. In contrast, a filament's flexibility would result in the members collapsing and not forming an opening to insert the seal module through. EX2001, ¶¶72-73.

Finally, the method of manufacturing U-shaped members used in Schaffer supports that they are rigid. Schaffer discloses that “[t]he actuating member 55 ... is machined from aluminum.” EX1005, ¶[0082]. A POSA will recognize that machining aluminum would result in a rigid member. EX2001, ¶71.

Petitioner has therefore failed to demonstrate a reasonable likelihood that Schaffer anticipates Claim 1 for the reason alone that Schaffer's U-shaped actuating members are not flexible.

B. Schaffer does not disclose the “first filament formed into a loop around the collapsible tubular sidewall” wherein the “diameter of the valve lumen decreases in response to reducing a diameter of the loop.”

Whether or not the term “filament” itself requires flexibility, Claim 1 is limited to a filament that is flexible reciting, *inter alia*, “a first filament formed into a loop around the collapsible tubular sidewall” wherein “a diameter of the valve lumen decreases 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. In contrast, as explained above, Schaffer's rigid U-Shaped 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]; EX2001, ¶¶75-83. As such, Schaffer cannot anticipate Claim 1.

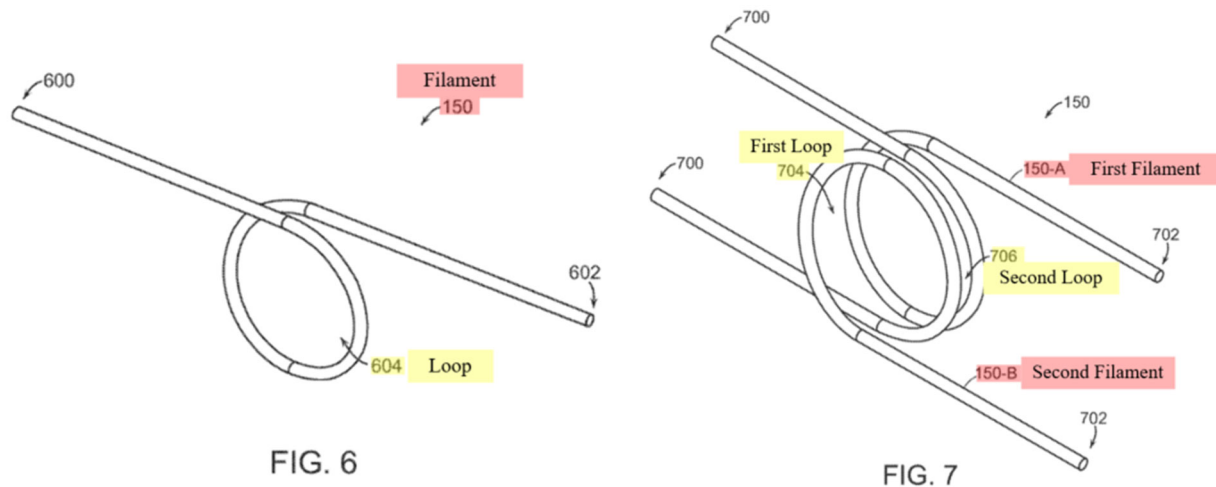
Petitioner does not allege that a single one of either of Schaffer's U-shaped actuating members 55 is “formed into a loop” but instead alleges that “Schaffer's U-shaped actuating members collectively constitute the ‘first filament’ claimed in the '012 patent” and that “the actuating members *collectively* loop around the seal module 100.” Petition, pp.37-38 (emphasis added). Schaffer's U-shaped actuating

members cannot together be construed as the claimed “first filament”—Claim 1 requires a single “first filament” by itself “formed into 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). Here, Schaffer's two U-shaped actuating members do not together suffice as “a first filament” because neither is “formed into a loop.”

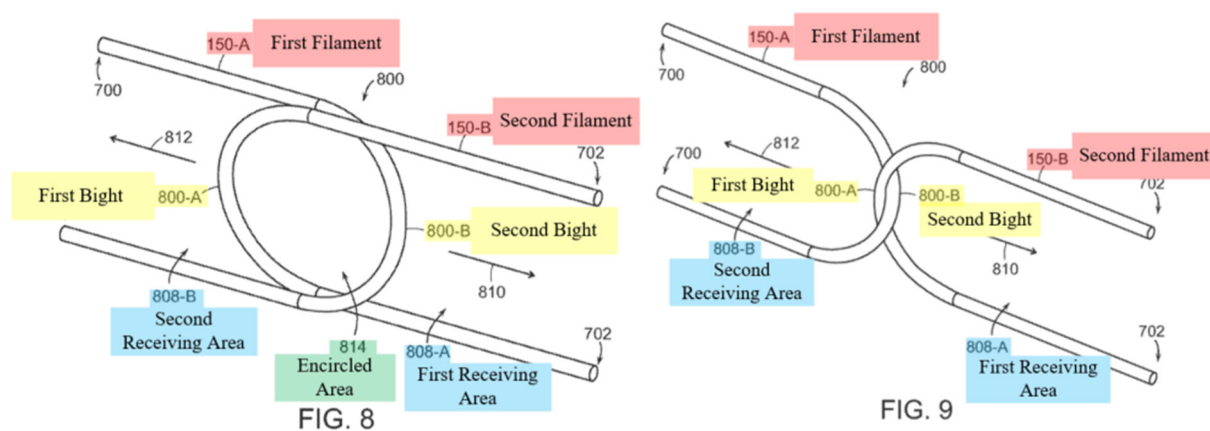
Second, the specification and prosecution history of the '012 Patent support that Claim 1 requires a single filament that is “formed into a loop.” While the '012 Patent discloses multiple different filament arrangements with respect to Figures 6-9, the term “loop” is used exclusively for the Figures 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, ¶76.

In contrast, Figures 8 and 9 of the '012 Patent illustrate two positions of a different arrangement in which two filaments form U-shaped bights rather than loop:



EX1001, 13:30-51; EX2001, ¶77. The '012 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 of the filaments, 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, ¶77.

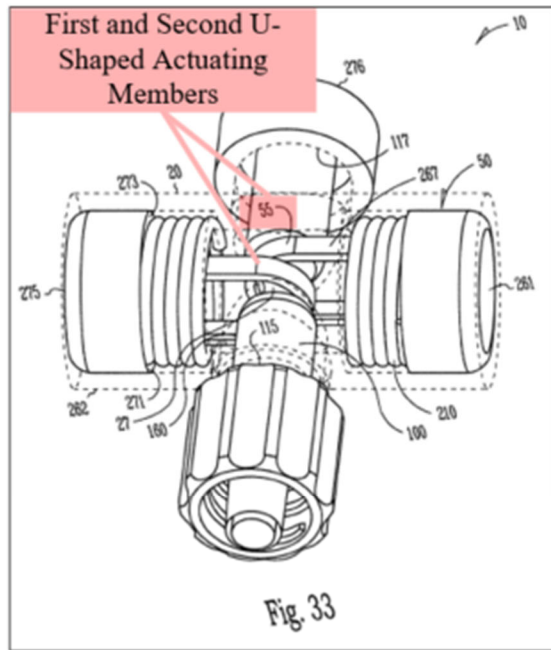
Accordingly, when the '012 Patent uses the term “loop,” the term refers to a loop, and not multiple U-shaped filaments that overlap as shown in Figures 8 and 9. EX2001, ¶78.

The prosecution history of the '012 Patent further supports this understanding. In response to a Restriction Requirement, the Applicant elected the filament loop embodiments. EX1002, pp.171-176. By electing this embodiment, the Applicant made clear that the “first filament” of Claim 1 comprises a filament “formed into a loop,” as exemplified in Figure 6 rather than, for example, an arrangement of multiple filaments forming U-shaped bights as shown in Figures 8 and 9.⁴

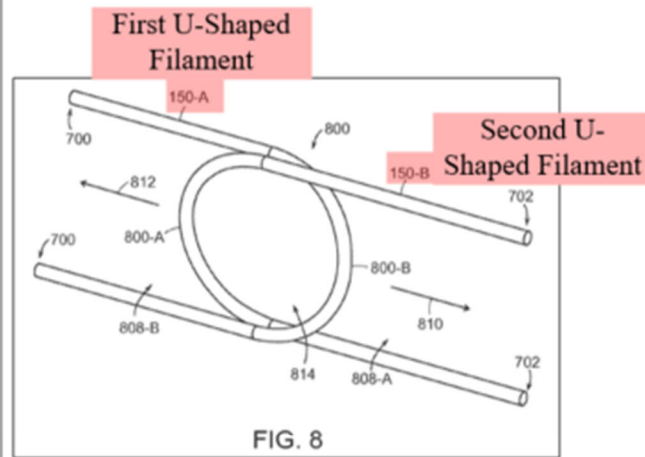
Petitioner's reliance on Figure 8 of the '012 Patent to argue that Schaffer's U-shaped actuating members 55 could together comprise the “first filament” therefore fails. Petition, p.37. The arrangement of Schaffer's U-shaped actuating members 55

⁴ Election of the filament of Figure 6 necessarily includes election of the embodiment of Figure 7 because Figure 7 includes, *inter alia*, the filament of Figure 6. In contrast, Figures 8 and 9 do not include a “loop” as explained herein and, in fact, are the same embodiment. EX2001, ¶52.

is similar to the U-shaped embodiment shown in Figures 8 and 9 of the '012 Patent and relied on by Petitioner, as illustrated in the comparison below:



Schaffer's Valve 10 Opened



'012 Patent Figure 8

EX2001, ¶80. But, as set forth above, the specification of the '012 Patent distinguishes the illustrated filament bights from the filament loops in Figure 6 and 7. And, Petitioner's reliance on Figures 8 and 9 of the '012 Patent to support its interpretation of Schaffer is further contradicted by the Applicant's election of loop embodiments—rather than Figures 8 and 9—in Response to a Restriction Requirement during prosecution of the '012 Patent. Claim 1 requires at least a single filament that is “formed into a loop,” and neither of Schaffer's actuating members

are so arranged.⁵ Petitioner has therefore failed to demonstrate a reasonable likelihood that Schaffer anticipates Claim 1 for the reason alone that 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 "a diameter of the valve lumen decreases 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, ¶83. Accordingly, Schaffer cannot disclose a "reducing a diameter of the loop." *Id.*

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) (finding that asserted claims are not rendered obvious in view of the cited prior art because

⁵ Claim 1's generic recitation of a "valve comprising . . . a first filament formed into a loop" requires at least a single filament formed into a loop, an example of which is shown in Figure 6, but does not exclude additional filaments whether or not those additional filaments are also formed into a loop as shown in, for example, Figure 7.

they do not supply the missing element for purposes of obviousness analysis and Petitioner did not argue that the cited art taught this element).

As set forth in §III above, Schaffer does not disclose the “first filament formed into a loop around the collapsible tubular sidewall” or the “diameter of the valve lumen decreases in response to reducing a diameter of the loop,” as recited in Claim 1. Petitioner does not allege that it would have been obvious for a POSA to have modified Schaffer alone to arrive at those limitations of Claim 1. Rather, Petitioner alleges that it would have been obvious to have modified Schaffer to arrive at other limitation of Claim 1, such as the “aspiration catheter” recited in the preamble and a “hemostasis valve on the proximal end of the catheter.” Petition, pp.24-27 & 29-32. Accordingly, because Schaffer does not disclose all the limitations of Claim 1 set forth in §III above, and because Petitioner does not contend that Schaffer alone renders such limitations obvious, ground 2 necessarily fails.

V. CLAIM 1 IS NOT OBVIOUS OVER THE COMBINATION OF SCHAFFER AND HARTLEY (GROUND 3) OR THE COMBINATION OF SCHAFFER AND ELLER (GROUND 4)

Whether “combining disclosures from multiple references, combining multiple embodiments from a single reference, or selecting from large lists of elements in a single reference, there must be a motivation to make the combination and a reasonable expectation that such a combination would be successful, otherwise a skilled artisan would not arrive at the claimed combination.” *In re Stephan Co.*,

868 F.3d 1342, n.1 (Fed. Cir. 2017) (reversing and vacating PTAB finding of obviousness). As the Federal Circuit explained *In re Kahn*, the rationale underlying the motivation-suggestion-teaching test serves as a safeguard against the improper use of hindsight in an obviousness analysis. 441 F.3d 977, 986 (Fed. Cir. 2006).

Moreover, when there is good reason ***not*** to modify or combine references, courts find that the required motivation is missing. *E.g.*, *Medtronic, Inc. v. Teleflex Innovs. S.à.r.l.*, 69 F.4th 1341, 1348 (Fed. Cir. 2023) (affirming PTAB finding of no motivation to combine when modifying reference would render device inoperable to achieve its purpose); *Trivascular, Inc. v. Samuels*, 812 F.3d 1056, 1068 (Fed. Cir. 2016) (upholding finding of nonobviousness where “substitution would destroy the basic objective of” a key feature of the reference being modified).

Here, contrary to Petitioner's assertion, replacing Schaffer's rigid U-shaped actuating members with a flexible string or wire as disclosed in Hartley or Eller is not a simple “substitution of one known element (Hartley's string [or Eller's wire]) for another (Schaffer's actuating members).” Petition, pp.42, 50. Petitioner's proposed combination requires one end of Hartley's string or Eller's wire member 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. *Id.* at pp.43, 44, 51, & 52. But, neither Schaffer, Hartley, nor Eller disclose such an arrangement: (i) Schaffer's U-shaped actuating members are each attached to a single one of the actuator buttons, (ii)

Hartley's string has both ends attached to the same rotary actuator, and (iii) Eller's wire member has one end attached to the housing and the other to a single actuator. EX2001, ¶¶92-95 & 146-152. Therefore, Petitioner's arrangement including a string or wire member having both ends attached to two separate actuators is not disclosed by Petitioner's references and was not a "known element." Such a substitution is also not "simple" because a POSA would understand that controlling a string or wire with two independently movable actuators—rather than one actuator as taught by Schaffer, Hartley, and Eller—would increase the complexity and variability of Schaffer's valve and make the valve more difficult to manufacture. *Id.* at ¶¶95 & 152. Grounds 3 and 4 fail for that reason alone.

Regardless, a POSA would not have been motivated to substitute Hartley's string or Eller's wire member for Schaffer's U-shaped actuating members because Petitioner's purported motivation that Schaffer's valve does not form a complete seal is manufactured from whole cloth. Under a proper reading of Schaffer, Hartley, and Eller:

1. Schaffer's seal module 100 "blocks the flow of gas or fluid completely" as expressly disclosed by Schaffer and *admitted by Petitioner*. See §V.B.1.
2. Schaffer discloses a "sticky," "gelatinous," and "selfclosing" material for the seal module to form a complete seal around a variety of profile shapes and diameters of the lumen, around small instruments, around large

- instruments, in the absence of instruments, and even around irregularly shaped instruments. *See* §V.B.1-2.
3. Petitioner and its expert admit that a POSA could simply adjust Schaffer's spring strength or adjust the properties of the seal module to address sealing issues, if any, in Schaffer. *See* §V.B.4.
 4. None of Schaffer, Hartley or Eller disclose "a first filament" connected at opposite ends to two actuators as proposed in Petitioner's combination. *See* §V.A.
 5. Substituting Hartley's string or Eller's wire member for Schaffer's U-shaped actuating members would fundamentally change Schaffer's principles of operation. *See* §V.B.3.
 6. Hartley's string or Eller's wire member would not provide a better seal than Schaffer's U-shaped members and seal module. *See* §V.B.1.

EX2001, ¶¶140 & 164. A POSA would thus not have substituted Hartley's string or Eller's wire and further modified the structure to connect the string or wire to two separate actuators, as Petitioner contends. Indeed, Petitioner's proposed combinations are 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 the operation of Schaffer.

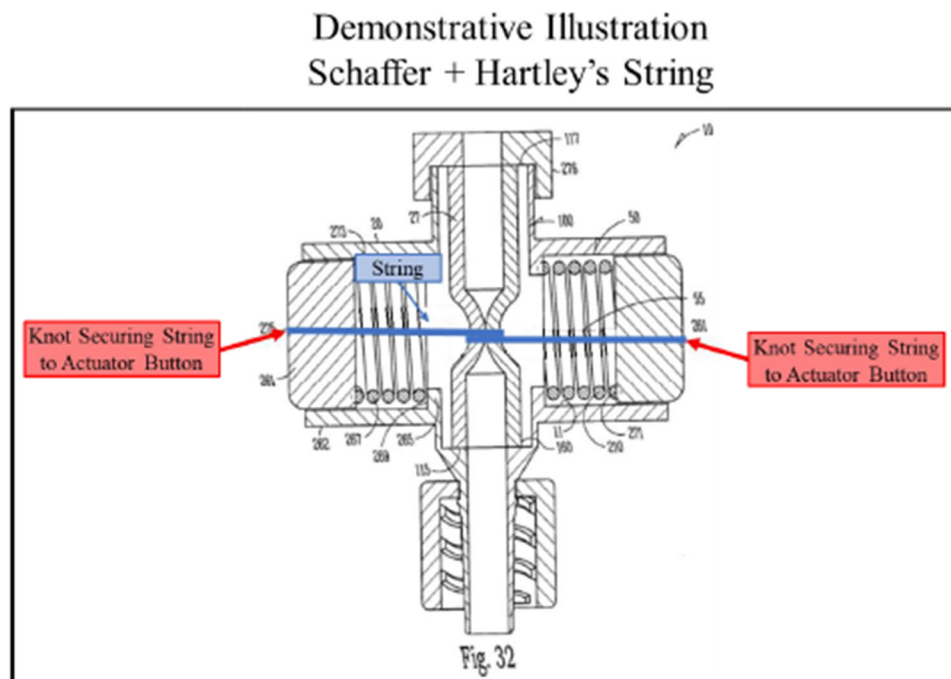
Moreover, a POSA would have realized that the sticky nature of the seal module disclosed in detail by Schaffer could inhibit opening of the seal module as admitted by Mr. Thornton (EX1003, ¶100) if not used with Schaffer's rigid members. Hartley's string or Eller's wire member would not disengage—let alone forcibly disengage—the seal module, causing the sticky seal module to remain in a closed position. EX2001, ¶¶141 & 165. Petitioner's proposed combinations create a valve that operates in complete contrast to Schaffer's stated purposes, and create such a stark departure from the principles of operation of Schaffer's valve that a POSA would not have been motivated to arrive at Petitioner's purported combination. *Id.*

A. Petitioner's Proposed Substitution of Harley's String or Eller's Wire Member for Schaffer's U-Shaped Actuating Members Is Not a Simple Substitution.

Petitioner's proposed combination is not a simple substitution of Hartley's flexible string or Eller's flexible wire for Schaffer's rigid U-shaped actuating members. Instead, under Petitioner's proposed combination, a POSA would need to not only *replace* Schaffer's rigid U-Shaped actuating members with a flexible wire or string, but would also have to *modify* Schaffer to eliminate one of those rigid U-shaped actuating members and instead connect a single flexible member to two different opposed actuators, a configuration not found in any of Schaffer, Hartley, or Eller, or any other reference cited in the Petition. EX2001, ¶¶92-95 & 146-152.

Accordingly, a POSA would not have found it obvious to have modified Schaffer in the manner Petitioner proposes.

Petitioner contends that in its proposed combination of Schaffer and Hartley “the first end of the string would be secured to the first actuator button, the string would loop at least once around Schaffer’s seal module, and the second end of the string would be secured to the second actuator button.” Petition, p.44. Petitioner provides the following demonstrative illustration of the proposed substitution:



Id. Similarly, Petitioner contends that in its proposed combination of Schaffer and Eller “the first end of the wire member would be adhered or welded to the first actuator button, looped at least once around Schaffer’s seal module, and the second

end of the wire member would be adhered or welded to the second actuator button.”

Id. at pp.51-52.

Petitioner's arrangement therefore requires attaching opposite ends of Hartley's string or Eller's wire member to different ones of the actuator buttons 261 of Schaffer. EX2001, ¶¶92 & 146. But such an arrangement is not disclosed by any of Schaffer, Hartley, or Eller. Petitioner does not explain why this additional modification of the references would be obvious, despite it not being taught in any of the references.

1. Schaffer

Schaffer discloses two U-shaped actuating members 55 each having their respective ends coupled to separate ones of actuator buttons 261:

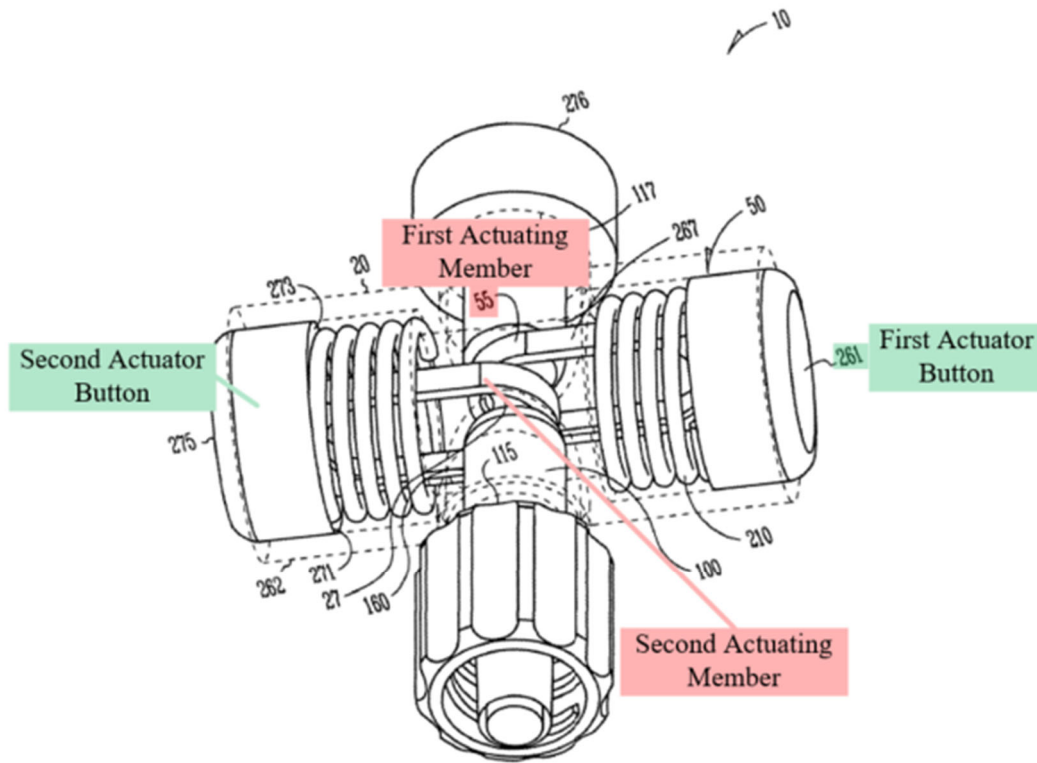


Fig. 31

EX2001, ¶93. Each of the two U-shaped actuating members 55 is attached to and controlled by a single one of the actuator buttons 261. *Id.* While Petitioner proposes a purported simple substitution of Hartley's string or Eller's wire member for Schaffer's U-shaped actuating members, Petitioner's proposed combination not only substitutes a flexible member for Schaffer's rigid U-Shaped members, but also redesigns Schaffer to eliminate one rigid U-shaped member completely and instead attach a single flexible member to two actuators, an arrangement not found in any of the three references. EX2001, ¶¶93 & 147.

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:

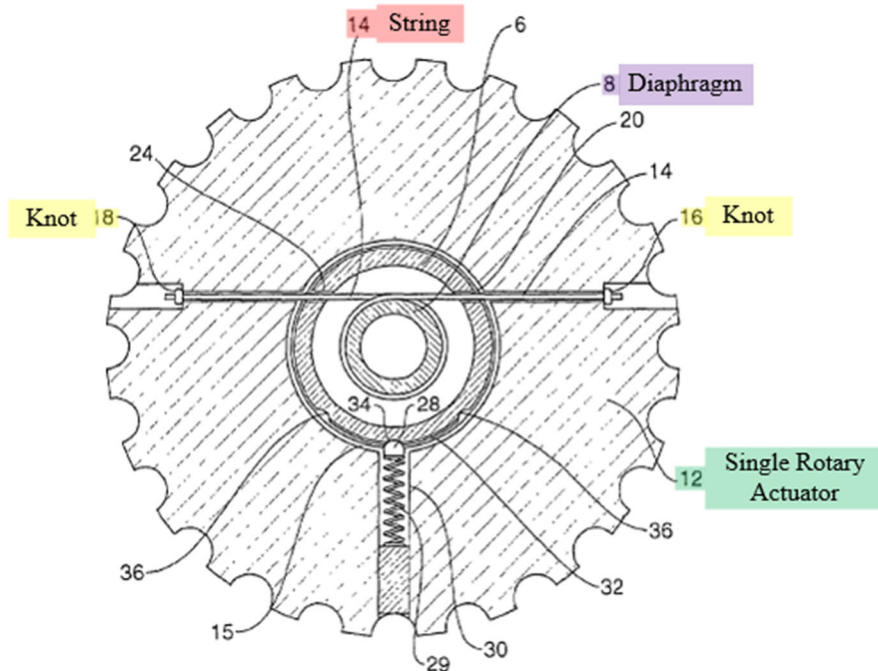


Fig 3

EX1006, ¶[0031]; EX2001, ¶94. The rotary actuator 12 is a single integral piece such that the knots 16 and 18 are not attached to separate actuator buttons, as required in Petitioner's purported combination. EX2001, ¶94. Movement of the single rotary actuator 12 controls movement of both ends of the string 14. *Id.* In contrast, in Petitioner's proposed combination the string 14 would be controlled by Schaffer's *two* independent U-shaped actuating members 55 rather than by a single actuator as taught by Hartley. *Id.*

Accordingly, a string or actuating member having two ends coupled to independent actuators is not disclosed in either Schaffer or Hartley. EX2001, ¶95.

3. Eller

Similarly, 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 the actuator 818”:

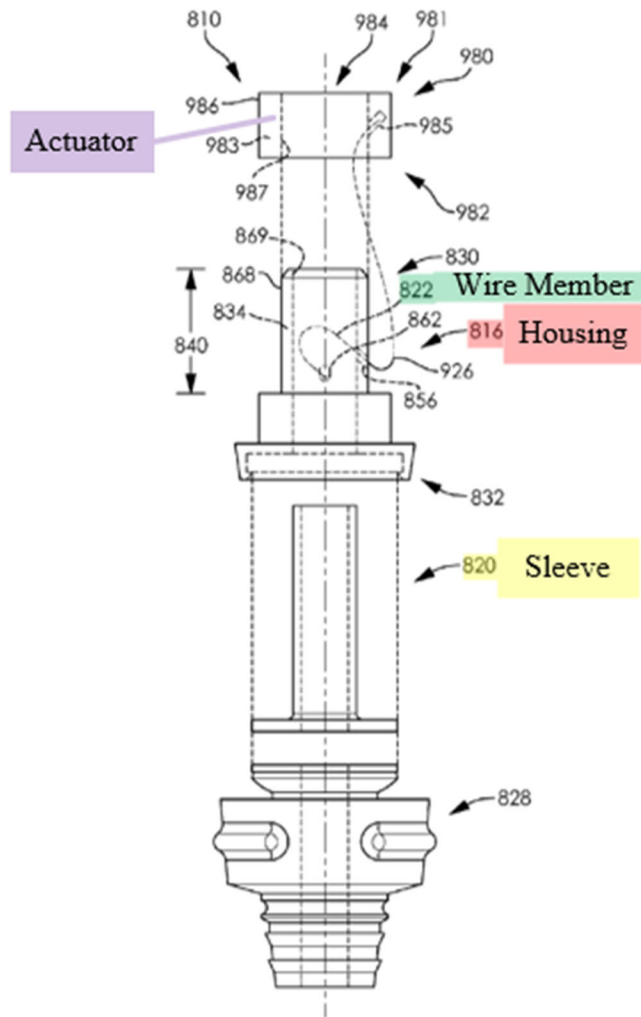


FIG. 20

EX1007, 23:50-62 & 24:50-52. Movement of the single rotary actuator 818 pulls the second end 926 of the wire member 822 to tension the wire member 822 and compress the sleeve 820. *Id.* at 24:58-25:2; EX2001, ¶149. Eller discloses other embodiments with multiple wire members each having a first end attached to a housing and a second end attached to a single rotary actuator. EX1001, FIGS.1-10C, 5:2-6, 12:21-14:27, 15:21-40, & 17:38-18:8; EX2001, ¶148. In each of these embodiments, the wire members have a first end coupled to a housing of the selective

fluid barrier device and a second end coupled to an actuator of the selective fluid barrier device. EX2001, ¶151. Movement (e.g., rotation) of the single actuator pulls only the second end of the wire member while the first end remains stationary to tension the wire member. *Id.*

Again, Eller's wire member is attached to a single actuator rather than separate actuator buttons as shown in Petitioner's purported combination. *Id.* Movement of the single actuator controls movement of the wire member. *Id.* In contrast, in Petitioner's proposed combination the wire member would be controlled by Schaffer's *two* actuators rather than by a single actuator as taught by Eller. *Id.*

Accordingly, a wire member or actuating member having two ends coupled to independent actuators is not disclosed in either Schaffer or Eller. EX2001, ¶152.

4. Petitioner's proposed combination departs from the disclosure and intended purpose of Hartley, Schaffer, and Eller.

Petitioner's proposed combination of Schaffer and Hartley or Eller departs from the intended purpose and express disclosure of both Schaffer and Hartley in which a single U-shaped actuating member 55 or string 14, respectively, are controlled by a single actuator. EX2001, ¶95. Likewise, Petitioner's proposed combination of Schaffer and Eller also departs from the intended purpose and express disclosure of Eller in which a single wire member is controlled by a single actuator. *Id.* at ¶152. For example, a POSA would understand that controlling a

string, wire member, or actuating member with independently movable actuators would increase the complexity and variability of the valve and make the valve more difficult to manufacture. *Id.* at ¶¶95 & 152. In sum, neither Schaffer, Hartley, nor Eller disclose any element (U-shaped actuating member, string, or wire member) attached to separate, individually-controlled actuator buttons as in Petitioner's proposed combination. *Id.*

B. A POSA Would Not Have Been Motivated to Substitute Hartley's String or Eller's Wire Member for Schaffer's U-Shaped Members

1. Petitioner's stated motivation to combine Schaffer with Hartley or Eller is contradicted by Schaffer and the statements of Petitioner and Its Expert.

Petitioner's asserted motivation to substitute Hartley's string or Eller's wire member for Schaffer's U-shaped actuating members is based only on its expert's statements that a POSA would have recognized that Hartley's string or Eller's wire "may seal more effectively across a wider range of diameters and shapes for the inserted devices than Schaffer's U-shaped actuating members" and that "[d]epending on the diameter of the inserted device, Schaffer's U-shaped actuating members may form small gaps between the valve's lumen and the tool's outer surface." Petition, pp.42 & 50. But Petitioner and its expert, Mr. Thornton, repeatedly admit that Schaffer's valve forms a complete seal—even when various instruments are inserted therethrough. EX2001, ¶¶117-122. Accepting this is true,

as it is, then this should be dispositive: there can be no motivation to solve a non-existent problem.

Mr. Thornton testifies that a POSA would expect Schaffer's valve to prevent leaks and seal around an instrument inserted therethrough, such as an aspiration catheter, when discussing the relevance of Garrison to Claim 1:

Further, Schaffer's hemostasis valve is a part of a system that is inserted into the patient's vasculature, and the hemostasis valve helps prevent blood and air leaks in the device by **"block[ing] the flow of gas or fluid completely and immediately with or without an instrument in place within the gas/fluid path."** Ex. 1005 (Schaffer) at [0002], [0008]; see also Ex. 1009 (Schaffer '616) at Abstract, 1:1-9 (disclosing catheter systems for insertion into a blood vessel). Schaffer also discloses that its hemostasis valve can prevent leaks even when "a range of instruments," such as "a catheter, guidewire, needle, or fiber," are inserted through the valve. Ex. 1005 at [0056]. Thus, **a person of ordinary skill in the art would have reasonably expected that Schaffer's hemostasis valve could be used to prevent leaks around an aspiration catheter inserted through the valve.**

EX1003, ¶70 (emphasis added). Accordingly, Mr. Thornton first acknowledges that Schaffer discloses that its valve completely seals with or without an instrument in place and then explains that a POSA would have expected that Schaffer's valve could be used to prevent leaks around an instrument (e.g., aspiration catheter)

inserted through the valve as the basis for combination with Garrison. EX2001, ¶118.

Yet at the same time in direct contrast to Schaffer's express disclosure, Mr. Thornton manufactures a purported motivation to modify Schaffer asserting that a POSA would understand that Schaffer's valve would form gaps and would not seal completely. *See, e.g.*, EX1003, ¶100. But if a POSA would have reasonably expected Schaffer's valve to prevent leaks around an instrument inserted through the valve as admitted by Mr. Thornton, a POSA would not have understood that small gaps (i.e., leak paths) would form in Schaffer's valve as Petitioner alleges as its only motivation to substitute Hartley's string or Eller's wire member for Schaffer's U-shaped actuating members. EX2001, ¶118. Accordingly, because a POSA would understand Schaffer's valve to effectively prevent leaks, as Mr. Thornton admits, a POSA would not have been motivated to modify Schaffer in view of Hartley or Eller to avoid the formation of gaps (i.e., leaks) and effect a better seal. *Id.*

Petitioner likewise admits that Schaffer "discloses that its valve prevents leakage across 'a range of instruments,' such as 'a catheter, guidewire, needle, or fiber'." Petition, pp.76 & 80; *see also* EX1003, ¶¶149 & 161. Again, if a POSA would have understood Schaffer's valve to prevent leaks around an instrument inserted through the valve, a POSA would not have been motivated to modify

Schaffer in any way to avoid the formation of gaps and effect a better seal. EX2001, ¶119.

Similarly, when describing how Schaffer seals about the elongate, flexible tubular body recited in Claim 2, Petitioner states:

Schaffer discloses that its valve “**blocks the flow of gas or fluid completely and immediately with or without an instrument in place within the gas/fluid path.**” (Ex. 1005, [0008].) Schaffer also discloses that “a range of instruments [can be] used within the seal module,” such as “a catheter, guidewire, needle, or fiber,” and that “a guidewire and catheter may be placed into the same lumen 193 for extension into a body passage.” (*Id.*, [0056], [0074].) Accordingly, **when Schaffer’s valve is in the first, sealed position, the U-shaped actuating members “constrict[] the valve lumen to create a seal about the elongate, flexible tubular body” of a catheter inserted through the valve.** (Ex. 1003, ¶ 134.)

Petition, p.64 (emphasis added). Like Mr. Thornton’s testimony, these statements conflict with Petitioner’s manufactured motivation to combine. If Schaffer’s valve forms a seal when instruments are inserted through the valve, a POSA would not have been motivated to modify Schaffer for the reasons Petitioner relies on. EX2001, ¶120.

Indeed, Schaffer’s valve does form a complete seal with or without instruments inserted therethrough. Specifically, Schaffer discloses that its rigid U-

shaped members 55 *do not* result in gaps due to the inclusion of sealing member 165. EX1005, ¶[0059]; EX2001, ¶¶96-101. Schaffer discloses that the valve creates a “nearly fluid/gas tight seal under very light compression,” a functionality achieved through the use of materials that “can be compared to a gelatinous substance.” EX1005, ¶[0059]. Schaffer discloses that this compliant material ensures a robust seal, even in the presence of rigid components, as it is designed to “be easily compressed upon itself or upon an inserted instrument,” due to its sticky nature and “selfclosing” properties. *Id.* Indeed, the “seal member 165 is so compliant that it forms a seal around [multiple instruments 260 [inserted therethrough] even if the instruments 260 are irregularly shaped.” *Id.* at ¶[0068].

The absence of gaps due to Schaffer's gelatinous seal member 165 is further shown in Schaffer's Figures 16-19, reproduced below:

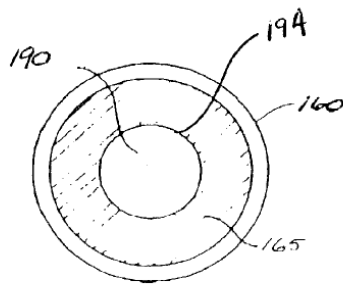


FIG. 16

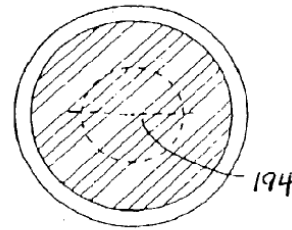


FIG. 17

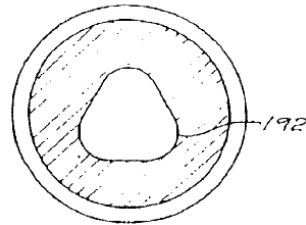


FIG. 18

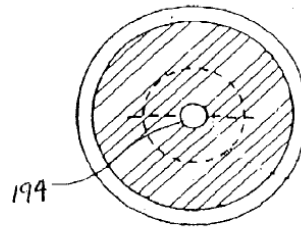


FIG. 19

EX2001, ¶¶99-101 (citing EX1005, ¶[0060]). No gaps are formed when the seal module 100 seals around a large circular lumen 194 (Figure 16), when the seal module 100 is in a sealed state with the lumen 194 completely closed (Figure 17; e.g., without an instrument inserted through the lumen 194), when the seal module 100 seals around an irregularly shaped lumen (Figure 18), or when the seal module 100 seals around a small circular lumen 194 (Figure 19). EX2001, ¶101.

Indeed, Petitioner's own expert recognizes Schaffer's disclosure of a sealing member that "exhibits a 'selfclosing' nature in that it sticks occlusively to itself forming a nearly fluid/gas tight seal [**under very light compression.**]" EX1005,

¶[0059] (emphasized text omitted in EX1003). *See* EX1003, ¶100. Despite that express disclosure and to manufacture the purported defect in Schaffer necessary for motivation to modify Schaffer, Petitioner's expert testifies that a POSA would either choose materials for the sealing member that would not seal or would omit the sealing member altogether. *Id.* According to Petitioner's expert, only after a POSA redesigned Schaffer's sealing member so that it does not seal, would a POSA then need to redesign Schaffer rigid U-shaped actuating members to remedy Schaffer's purported sealing problem. *Id.*

Petitioner was aware of Schaffer's sealing member in a related IPR, *Imperative Care, Inc. v. Inari Medical Inc.*, IPR2024-01157, Paper 5 at pp.28-29 (P.T.A.B. Oct. 29, 2024), and thus had an opportunity to address Schaffer's sealing member here, but instead simply alleges without explanation that "the portions of Schaffer cited by PO [in that IPR] do not support its argument. (EX1003, ¶100.)" Petition, p.43. Petitioner's attorney's conclusion cannot demonstrate a reasonable likelihood that Claim 1 is unpatentable here.

Thus, a POSA would not have been motivated to substitute Hartley's string or Eller's wire member for Schaffer's U-shaped members to prevent Petitioner's purported gaps because Schaffer makes clear that its seal module and actuating members form a complete (i.e., gapless) seal. EX2001, ¶¶96-109. Accordingly, Petitioner fails to provide any motivation to modify Schaffer as claimed.

2. 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 modification/combination would alter the principle of operation or would 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 necessary to “forcibly disengage” those members and for Schaffer's disclosed method of manufacture. EX1005, ¶¶[0080]-[0082]. As such, a POSA would not have been motivated to modify Schaffer as Petitioner suggests.

a) Substituting Hartley's string or Eller's wire member for Schaffer's U-shaped actuating members would prevent forcible disengagement.

Contrary to Petitioner's assertions, a POSA would not replace Schaffer's rigid U-shaped actuating members 55 with Hartley's string or Eller's wire member

because such a modification would eliminate Schaffer's principle of operation: forcible disengagement. EX2001, ¶¶134-136 & 160-161. Schaffer discloses that when actuator buttons 261 are depressed to open its valve, the U-shaped members "forcibly disengage," allowing the flow of gases and fluids. EX1005, ¶[0080]. Schaffer describes the mechanics once the button is depressed by explaining that "such movement allows each engaging 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." *Id.*

In Petitioner's proffered substitutions of Hartley's string or Eller's wire member for Schaffer's U-shaped actuating members, Hartley's string "would loop at least once around the lumen of Schaffer's seal module" or Eller's wire member would be "looped at least once around Schaffer's seal module." Petition, pp.44 & 51. Petitioner further explains that the seal module 100 would expand against Hartley's string or Eller's wire member to open when tension is released on the string or wire member. *Id.* at pp.46 & 53. In this arrangement, Hartley's string or Eller's wire member would never disengage—let alone forcibly disengage—Schaffer's seal module 100. EX2001, ¶¶135 & 160. Therefore, this modification would change the principle of operation of Schaffer. *Id.* Additionally, as conceded by Mr. Thornton (EX1003, ¶100), the seal module would stick to and retain Hartley's string or Eller's

wire member in the closed position—rendering Schaffer's valve inoperable by inhibiting or even preventing movement of the seal module 100 from the collapsed closed position to the uncollapsed open position. EX2001, ¶¶136 & 161.

b) Substituting Hartley's string or Eller's wire member for Schaffer's U-shaped actuating members would compromise its ease of manufacturing and durability.

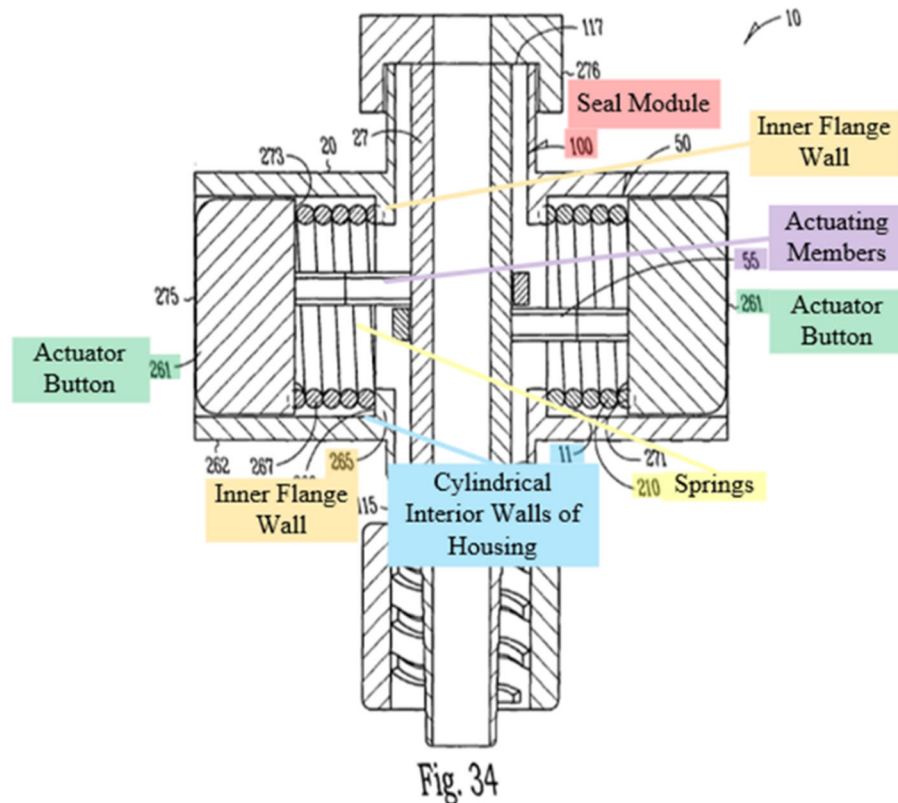
Substituting Hartley's string for Schaffer's U-shaped actuating members would introduce assembly difficulties and undermine the durability of Schaffer's valve. EX2001, ¶¶123-133 & 157-159. Schaffer's rigid U-shaped actuating members 55 are purposefully designed to be rigid and attached to only a single actuator. *Id.* at ¶¶123 & 157. That design choice provides a simple method(s) of assembly and manufacturing, and it effectively addresses Schaffer's recognized need for "a durable stasis valve that blocks the flow of gas or fluid completely and immediately with or without an instrument in place within the gas/fluid path." EX1005, ¶[0008].

First, Schaffer discloses a method of manufacture of its valve that relies upon its U-shaped actuating members being rigid and attached to only a single actuator. EX2001, ¶125. Specifically, Schaffer discloses that its U-shaped members are advantageously machined, and that the valve is assembled by inserting the seal module "through the housing 20 and between each actuator 50" after those positions of the valve are already assembled, as follows:

[I]nserting the actuator button 261 and resilient member 267 (e.g., spring 210) into one side of the housing 20. The actuator button 261 and resilient member 267 (e.g., spring 210) are inserted into an opposing side of the housing 20. 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. Each actuator button is released and the cap 276 secured to the housing 20, for example, with an adhesive. Further, the connecting member 35 is snapped onto the housing.

EX1005, ¶[0083]. The components used in this assembly can be seen in annotated Figure 34, below, showing that in the depressed position, the rigid U-shaped actuating members are forcibly pushed open (similar to forcible disengagement) to provide a gap through which the seal module can be inserted during assembly.

EX2001, ¶125.



A POSA would understand that Hartley's string or Eller's wire member substituted for Schaffer's U-shaped member would not only complicate this manufacturing process but also introduce practical challenges that could render the assembly inefficient and unreliable compared to Schaffer's straightforward design employing rigid actuating members attached to a single actuator. *Id.* at ¶¶126-131. In Petitioner's proposed combination of Schaffer and Hartley (not taught by either) "the first end of the string would be secured to the first actuator button, the string would loop at least once around Schaffer's seal module, and the second end of the string would be secured to the second actuator button" and, likewise, in Petitioner's proposed combination of Schaffer and Eller (likewise not taught by either) "the first

end of the wire member would be adhered or welded to the first actuator button, looped at least once around Schaffer's seal module, and the second end of the wire member would be adhered or welded to the second actuator button." Petition, pp.44 & 51.

In Petitioner's combination the string or wire member must be tethered to both of Schaffer's actuator buttons. But, to achieve this arrangement, the string or wire member would need to be either (1) secured to the actuator buttons 261 before the actuator buttons 261 are inserted into the cylindrical openings in the housing 20 or (2) secured to the actuator buttons 261 after the actuator buttons 261 are inserted into the cylindrical openings. EX2001, ¶¶126, 158. However, the first method of assembly in which Hartley's string or Eller's wire member is secured to the actuator buttons 261 before their assembly into the valve would not be possible because the tethered actuator buttons 261 could not be inserted through the respective cylindrical openings on either side of the housing 20 while also positioning Hartley's string as alleged by Petitioner. *Id.* at ¶¶127 & 158. Likewise, a POSA would understand the second method of assembly in which Hartley's string is secured to the actuator buttons 261 after their assembly into the valve to be unduly difficult, because the housing 20 and the actuator buttons 261 would block access to the interior of the housing 20 and inhibit or even prevent the positioning of Hartley's string or Eller's wire member in Petitioner's combination. *Id.* at ¶¶128 & 158.

Even if the first or second method of assembly was somehow workable, Schaffer teaches that the “[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]. The thin, flexible string of Hartley would be not tensioned (e.g., loose) when the actuator buttons 261 are compressed in Petitioner’s proposed combination such that it would not provide a uniform opening like Schaffer’s rigid U-shaped actuating members 55 to permit positioning of the seal module 100 therethrough. EX2001, ¶¶129 & 158.

Therefore, a POSA would recognize that the substitution of Hartley’s string or Eller’s wire member for Schaffer’s U-shaped actuating members is contrary to Schaffer’s disclosed method of assembly. Petitioner’s assertion of a reasonable expectation of success for its proposed modifications does not address Schaffer’s express method of assembly relying upon rigid actuating members attached to separate actuator buttons or that a POSA would have a reasonable expectation of success assembling a valve with the proposed modification.

Regarding manufacturing, Schaffer discloses that its U-shaped members can be advantageously quickly and efficiently manufactured by means of machining (by controlled removal of material to form the desired shape) or by injection molding the same rigid materials as follows:

The stasis valve 10, in one option, is made from machining pre-existing amounts of metals and/or plastics. For example, [t]he actuating member 55 and the actuating button 261 is machined from aluminum. In another example, the actuating member 55 and the actuating button 261 are machined from plastic where the housing 20, in one option, is machined from ABS plastic. In another example, the housing 20, actuator button 261, the connecting member 35 and a cap 276 are injection molded utilizing the various material outlined above.

EX1005, ¶[0082]; EX2001, ¶132.

Schaffer's standard machining methods to manufacture its rigid U-shaped members would not work well with filaments. EX2001, ¶132. Filaments deform when subjected to force during the machining process, which makes it exceedingly challenging—if not unfeasible—to achieve the precise dimensions and structural integrity required for effective valve operation. *Id.* A POSA would recognize that Hartley's string or Eller's wire member are ill-suited for Schaffer's straightforward manufacturing and assembly techniques. *Id.*

With respect to durability, Schaffer's construction enables the valve to endure operational demands and maintain its performance and structural integrity over time. EX2001, ¶¶133 & 159. 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.* The introduction of Hartley's string or Eller's wire member 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.*

For these reasons, a POSA would neither find it obvious nor be motivated to substitute Hartley's string or Eller's wire member for Schaffer's U-shaped actuating members, as doing so would change Schaffer's principle of operation, assembly method, and reduce durability.

3. Even assuming Petitioner's stated motivations to form a better seal and avoid the formation of gaps, Petitioner does not explain why a POSA would not use any of the alternatives to substituting that it admits would work to improve Schaffer's seal.

Even assuming that a POSA would understand Schaffer's valve to form gaps (it would not), a POSA would not have been motivated to substitute Hartley's string or Eller's wire member for Schaffer's U-shaped actuating members as claimed rather than make simple modifications to Schaffer's valve that Petitioner admits would address any sealing issues. EX2001, ¶¶137 & 162. For example, when addressing Schaffer's alleged anticipation of dependent Claim 5, Petitioner asserts that a POSA would have recognized multiple straightforward ways to enhance or maintain the valve's seal with a reasonable expectation of success. EX2001, ¶137. The Petition recites that:

[I]f Schaffer's valve did not maintain its seal when a pressure differential exists, POSITAs would have found it obvious to make

adjustments to the valve to maintain the seal, including **adjusting Schaffer's spring strength to apply additional force, adjusting the resilience and compressibility of the seal module that forms the valve's lumen** POSITAs would have been motivated to adjust Schaffer's hemostasis valve to prevent blood leaks because that is the valve's purpose. (Ex. 1003, ¶ 149.)

POSITAs would have reasonably expected success in adjusting the spring strength to exert more tension on the filament by, for example, changing the spring material or adjusting the springs coils. (*Id.*) Springs are simple, predictable mechanical devices that would have been well understood by POSITAs. (*Id.*) Additionally, **POSITAs would have reasonably expected success in selecting an alternative material for the seal module given the long list of suitable materials.** (*Supra* §VI.A.5.b.ii.)

Petition. pp.71-72 (emphasis added).

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. EX2001, ¶¶138 & 162. A POSA would have also understood that such adjustments employ Schaffer's stated principles of operation including two rigid actuating members each attached to a single actuator button, simple manufacturability, durability, forcible disengagement, and the like. *Id.*

Petitioner provides no reason why a POSA would contradict these principles of operation by substituting Hartley's string or Eller's wire member for Schaffer's

U-shaped members. Indeed, substituting Hartley's string or Eller's wire member for Schaffer's U-shaped members would render Schaffer's valve inoperable for its intended purposes as explained above. *Id* at ¶¶139 & 162. A POSA would instead make any of the simple modifications Petitioner asserts would work to complete the seal and prevent blood leaks through the valve. *Id*. That is, the simple modifications that Petitioner admits a POSA would understand as viable alternatives to complete Schaffer's seal would not require a complete redesign of Schaffer's valve that departs from its stated principles of operation. *Id*.

VI. CLAIM 1 IS NOT OBVIOUS OVER THE COMBINATIONS OF SCHAFFER, HARTLEY, AND ELLER WITH GARRISON (GROUNDS 5-7)

Petitioner relies on Garrison for allegedly disclosing the term “aspiration” in the preamble of Claim 1, the “tubular body” of Claim 1, and the “hemostasis valve of” Claim 1. Petition, pp.83-94. However, Petitioner does not rely on Garrison for disclosing any of the hemostasis valve structural limitations of Claim 1 discussed above (e.g., the “constricting mechanism having ... a first filament formed into a loop around the collapsible tubular sidewall ... such that a diameter of the valve lumen decreases in response to reducing a diameter of the loop”). For at least these reasons, Garrison does not remedy the deficiencies in Schaffer, Hartley, and Eller, and Petitioner does not contend that Garrison does.

VII. DEPENDENT CLAIMS 2-9 ARE NOT ANTICIPATED BY SCHAFFER OR OBVIOUS OVER SCHAFFER ALONE OR IN COMBINATION WITH HARTLEY, ELLER, AND/OR GARRISON

Claims 2-9 depend from Claim 1 and thus include all the limitations from Claim 1. Accordingly, those claims are also not anticipated by Schaffer (ground 1), rendered obvious by Schaffer alone (ground 2), or rendered obvious by Schaffer in combination with Hartley, Eller, and/or Garrison (grounds 3-7).

VIII. THERE IS NO GOOD CAUSE FOR A PRE-INSTITUTION REPLY

In view of the deficiencies in the Petition discussed above, Petitioner might seek to file a pre-institution reply. But there would be no good cause for a pre-institution reply. All of Patent Owner's arguments above address the merits of the Petition, and Petitioner could have—and should have—addressed these issues in the Petition itself. *See, e.g., Ontel Prods. Corp. v. Guy A. Shaked Invs. Ltd.*, IPR2020-01703, Paper 10 p.2 (Feb. 4, 2021) (denying reply for “subjects that Petitioner should have developed in its Petition”).

IX. 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: February 25, 2025

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

CERTIFICATE OF COMPLIANCE

Pursuant to 37 C.F.R. § 42.24(d), I, Joseph Hamilton, certify that **PATENT OWNER'S PRELIMINARY RESPONSE** contains 11,890 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: February 25, 2025

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

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), I certify that on February 25, 2025, a copy of **PATENT OWNER'S PRELIMINARY RESPONSE** was served upon the below-listed counsel by electronic mail:

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