

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. IPR2025-00728
U.S. Patent No. 11,844,921

PATENT OWNER'S RESPONSE

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EXHIBIT LIST

Petitioner's Exhibits	
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1001	U.S. Patent No. 11,844,921 (“the ’921 patent”)
1002	’921 Patent Prosecution History Excerpt
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	U.S. Patent No. 3,438,607 to Williams et al.
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	Google Dictionary Definition of “String”
1015	Cambridge Dictionary Definition of “String”
1016	U.S. Patent No. 12,109,384 B2 to Merritt et al.
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)

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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 Treretola
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)

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Exhibit	Description
2001	Complaint for Patent Infringement in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 5:24-cv-03117-EKL (N.D. Cal.), Dkt. 1
2002	First Amended Complaint for Patent Infringement in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 4:24-cv-03117-YGR (N.D. Cal.), Dkt. 20
2003	Second Amended Complaint for Patent Infringement in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 5:24-cv-03117-EKL (N.D. Cal.), Dkt. 68
2004	Third Amended Complaint for Patent Infringement in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 5:24-cv-03117-EKL (N.D. Cal.), Dkt. 112
2005	Imperative Care Inc.'s Notice of Motion and Motion to Stay Pending <i>Inter Partes</i> Review in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 5:24-cv-03117-EKL (N.D. Cal.), Dkt. 100
2006	Motion For Preliminary Injunction in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 5:24-cv-03117-EKL (N.D. Cal.), Dkt. 24
2007	Opposition to Motion for a Preliminary Injunction in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 5:24-cv-03117-EKL (N.D. Cal.), Dkt. 36
2008	Corrected Opposition to Motion for a Preliminary Injunction in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 5:24-cv-03117-EKL (N.D. Cal.), Dkt. 40
2009	Stipulated Protective Order in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 5:24-cv-03117-EKL (N.D. Cal.), Dkt. 76
2010	Joint Letter Brief Concerning Plaintiff's Motion to Compel Production of Materials Relating to Defendant's Blood Return System in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 5:24-cv-03117-EKL (N.D. Cal.), Dkt. 94
2011	Order Re Inari Medical's Motion to Compel Production of Materials in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 5:24-cv-03117-EKL (N.D. Cal.), Dkt. 105

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2012	Imperative Care, Inc.'s Preliminary Invalidity Contentions and Document Production Accompanying Invalidity Contentions Pursuant to Patent Local Rules 3-3 and 3-4 (omitting accompanying claim charts) in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 5:24-cv-03117-EKL (N.D. Cal.)
2013	Imperative Care, Inc.'s Preliminary Invalidity Contentions and Document Production Regarding U.S. Patent Nos. 12,109,384 and 12,156,669 Pursuant to Patent Local Rules 3-3 and 3-4 (omitting accompanying claim charts) in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 5:24-cv-03117-EKL (N.D. Cal.)
2014	Al-Salam Letter to Truvic (September 29, 2023)
2015	Declaration of Joseph P. Hamilton (April 28, 2025)
2016	Minute Entry for Proceedings Held Before Judge Eumi K Lee in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 5:24-cv-03117-EKL (N.D. Cal.), Dkt. 110
2017	Minute Entry for Proceedings Held Before Judge Eumi K Lee in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 5:24-cv-03117-EKL (N.D. Cal.), Dkt. 111
2018	U.S. Patent Publication US 2008/0087853 A1 to Kees ("Kees")
2019	U.S. Patent Publication US 2011/0144592 A1 to Wong et al. ("Wong")
2020	Notice of Allowance Issued in U.S. Patent Application No. 16/117,519 (January 27, 2021)
2021	Inari's Reply in Support of Motion for Preliminary Injunction in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 5:24-cv-03117-EKL (N.D. Cal.), Dkt. 46
2022	Inari's Report Regarding Claim Construction Schedule and Claim Narrowing in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 5:24-cv-03117-EKL (N.D. Cal.), Dkt. 116
2023	Imperative Care, Inc.'s Proposed Schedule for Claim Construction and Narrowing Asserted Patents and Claims in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 5:24-cv-03117-EKL (N.D. Cal.). Dkt. 117

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2024	Declaration of Paul J. Zalesky
2025	Merriam-Webster's Collegiate Dictionary (11 th ed. 2014)
2026	New Oxford American Dictionary (3 rd ed. 2010)
2027	U.S. Patent Application Publication No. 2018/0193043
2028	Deposition Transcript of Troy Thornton (September 30, 2024)
2029	U.S. Patent No. 7,682,380 to Thornton ("Thornton")
2030	Deposition Transcript of Troy Thornton (March 19, 2025)
2031	Deposition Transcript of Troy Thornton (June 25, 2025)
2032	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)
2033	Supplemental Declaration of Paul J. Zalesky
2034	Deposition Transcript of Troy Thornton (November 20, 2025)
2035	Deposition Transcript of Troy Thornton (January 7, 2026)

I. INTRODUCTION

Petitioner has failed to demonstrate that any of Claims 1-7, 9-10, 15-18, or 20-24 (“the Claims”) of the ’921 Patent are unpatentable. The ’921 Patent discloses a “garrote valve” that “provides convenient, single-handed operation” that “allows the user to easily and quickly swap different tools being used through the valve without compromising hemostasis and therefore simplifying the procedure.” EX1001, 5:52-58. This “garrote valve” design includes a filament, either in the form of a loop or a bight, that is flexible so that the filament can tighten to constrict and seal a tube in the valve and loosen to permit the tube to open and unseal the valve. EX2033, ¶¶41-44, 69-72. That is, the filament is capable of conforming to the shape of the tube as it constricts to provide a robust seal and, as it expands, loosening to allow the tube’s lumen to open. *Id.* at ¶¶42, 68-69.

In accordance with that disclosure, Claim 1 recites a valve comprising, *inter alia*, an “active tensioning mechanism including an actuator coupled to [an] elongate member via a filament extending at least partially around the elongate member.” The “actuator is moveable between (a) a first position wherein the lumen is constricted and sealed and (b) a second position wherein the lumen is at least partially open.” Independent Claims 15 and 21 similarly recite, *inter alia*, a “filament coupled to [an] elongate member” and an “actuator [that] is moveable between (a) a first position ... [wherein] the lumen is constricted and sealed and (b) a second position wherein the

lumen is at least partially open.” In other words, the Claims recite a flexible “filament” that conforms to the valve’s elongate member (e.g., a tube) when acted on by an actuator that tightens the filament in a first position to constrict the tube and loosens the filament in a second position to at least partially open the tube.

Petitioner’s primary reference for grounds 1-4, Schaffer, takes a different approach. Schaffer does not disclose, in name or concept, a garrote valve. Schaffer instead discloses applying compression with *rigid* actuating members that do not conform to the shape of the tube being compressed. Instead, to form a seal using nonconforming actuating members, 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 around both multiple instruments and irregularly-shaped instruments—as the rigid actuating members apply an external compressive force. EX1005, ¶[0060]; EX2033, ¶¶120-122. So, rather than an external filament capable of conforming to the outer shape of the tube as it constricts as described and claimed in the ’921 Patent, Schaffer’s fundamentally different approach relies on the highly-compliant seal member 165 that is part of the tube that directly conforms to the shape of any instruments inserted through the tube as the seal member is compressed by the nonconforming actuating members. And, as admitted by Petitioner’s expert, every illustrated embodiment operates in that

manner, namely using internal seal member 165 to effectuate the seal. EX2031, 69:7–77:3.

That fundamentally different principle of operation found in Schaffer addresses a specific and different problem in the art. Specifically, Schaffer explains that for hemostasis valves, the “problems are complex” and require a “balance between closing force, opening force, friction, compression and durability.” EX1005, ¶[0007]. Schaffer further explains that “if 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 so that the amount of compression can be precisely controlled to open or close the valve. And then to effectuate a complete seal, the internal seal member forms a complete seal “under very light compression.” *Id.* at ¶[0059]. Schaffer further discloses that other advantages to its design including that its rigid nonconforming actuating members also provide a more durable and easier to manufacture valve. EX2033, ¶¶155-166.

Here, Ground 1 fails because Petitioner has not demonstrated that Schaffer discloses a “filament” under either party’s proposed claim construction. Under Patent Owner’s proposed construction, the term “filament” should be accorded its plain and ordinary meaning: “a thin, flexible length of material formed by one or more strands of material.” As the Board Preliminary agreed, Schaffer’s

nonconforming actuating members fail to disclose a “filament” under that plain and ordinary meaning because they are rigid. *Id.* at ¶¶94-100; Paper 13 (“Institution Decision”), pp.25-27.

Grounds 2-4 fail because a POSA would not have been motivated to modify Schaffer to replace Schaffer's nonconforming actuating members with a filament, including a flexible string or wire as disclosed in Hartley and Eller, respectively, and then further modify that combination as claimed. EX2033, ¶¶118-135. Petitioner's purported motivation to combine ignores that Schaffer's valve forms a complete seal (as Petitioner admits) via the highly-compliant seal member 165 that is “so compliant that it forms a seal around ... instruments 260 even if the instruments 260 are irregularly shaped.” EX1005, ¶[0068]. Instead, Petitioner's purported motivation to combine relies on its expert's contradictory testimony that Schaffer's valve would form gaps despite Schaffer's express disclosure otherwise. Petition, pp.36, 43. As such, a POSA would not have redesigned Schaffer to address 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. Indeed, Petitioner's expert (Mr. Thornton) 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. EX2030,

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 also fail because Petitioner's "simple substitution" rationale for obviousness does not involve the substitution of a "known element." Namely, a single actuating member (U-shaped member, string, or wire) having two ends coupled to and controlled by different actuators is not disclosed in any of Petitioner's references. Instead, each of Petitioner's references includes one or more actuating members each controlled alone by a single actuator. EX2033, ¶¶142-154. Additionally, Petitioner and its expert admit that there are comparably simpler substitutions based on Schaffer's disclosure that would fix any sealing issues, and those substitutions would not change Schaffer's principles of operation, e.g., simply including the same third seal member actually disclosed in Schaffer. *Id.* at ¶¶170-172. Finally, Petitioner's proposed substitution 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 ¶130; EX1005, ¶¶[0006], [0008], [0068].

And, more generally over the course of this and related IPRs, Petitioner's proposed "simple substitution" changes depending on the arrangement of the filament(s) in the claims at issue in each IPR. Petitioner's shifting positions for its purported "simple substitution" from one filament configuration to another, and then to another, depending on the claimed filament configuration demonstrate that in fact none are a simple substitution, but instead are motivated by impermissible hindsight using the claims at issue as a roadmap. Petitioner's impermissible hindsight fails to establish a reasonable likelihood of unpatentability.

Grounds 3-4 further fail because Petitioner's apparent "obvious to try" rationale fails to establish that there were a finite number of identifiable and known solutions for constricting a tubular member in a hemostasis valve in 2017. Petitioner's expert admitted during deposition in a related IPR for U.S. Patent No. 11,697,012 ("the related '012 IPR"): "I don't know how many options could be used to compress [a] tube." EX2031, 107:12-13.

And finally, Ground 5 fails because Petitioner's proposed modification to include Eller's torsion spring in Hartley's valve would change Hartley's principle of operation by rendering its ball-and-detent system inoperable for its purpose of retaining Hartley's rotary actuator in different positions corresponding to different valve positions (e.g., open, partially open). EX2033, ¶¶186-198.

For those and the other reasons set forth below, Petitioner has failed to demonstrate that any of the Claims are unpatentable under any of Grounds 1-5.

II. BACKGROUND

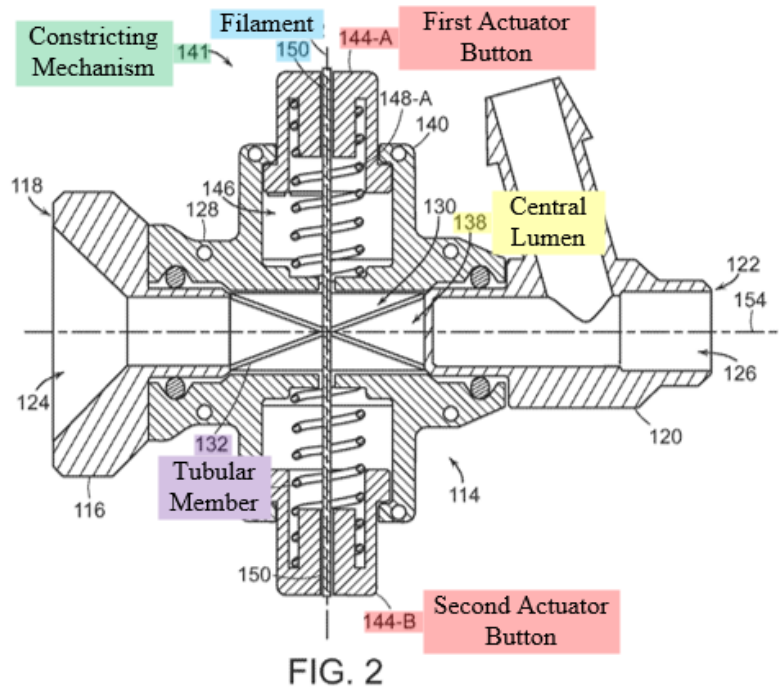
A. Overview of the '921 Patent

The '921 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, 1:45-49. So, the '921 Patent discloses a hemostasis valve, “referred to as a garrote valve,” that “can seal with or without a tool extending through the valve.” EX1001, 5:50-52.¹ 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. EX2033, ¶¶33-36; EX1001, 1:58-2:7, 5:11-16, 5:52-67, 16:1-25.

¹ Merriam-Webster defines “garrote” to mean “an implement (as a wire with a handle at each end) for strangulation.” EX2025, p.516.

To address those issues and provide those benefits, the '921 Patent's "garrote" valve includes a constricting mechanism with an actuator and at least one filament coupled to an elongate member. EX1001, 8:1-5. The actuator may be a manual button enabling easy one-handed use to seal effectively when needed. *Id.* at 8:17-26. The filament is designed to constrict the elongate member to create a seal when the actuator is engaged, to ensure effective hemostasis during medical procedures. *Id.* at 9:18-22.

The actuator can be biased to a position where the valve is sealed. *Id.* at 8:32-34. In the first configuration, depicted in FIG. 2 below, the elongated member is collapsed/sealed, with buttons in an undepressed position. *Id.* at 8:34-40. Springs bias the buttons towards the first configuration. *Id.* at 8:40-47. This design ensures the mechanism remains in a sealed state absent actuation of the actuator based on the biasing force applied by the springs. *Id.* at 8:32-34.



EX2033, ¶37.

B. Claims

The Claims of the '921 Patent are directed to the disclosed innovative “garrote” hemostasis valves that enhance the sealing capability compared to prior art valves while simplifying operator use. EX2033, ¶¶33-36.

Specifically, the garrote of Claim 1 includes an “active tensioning mechanism including an actuator coupled to [an] elongate member via a filament extending at least partially around the elongate member.” The “actuator is moveable between (a) a first position wherein the lumen is constricted and sealed and (b) a second position wherein the lumen is at least partially open.” The garrote mechanisms of Claims 15 and 21 similarly include a “filament coupled to [an] elongate member” and an

“actuator [that] is moveable between (a) a first position ... [wherein] the lumen is constricted and sealed and (b) a second position wherein the lumen is at least partially open.”

C. Prosecution History

The Examiner issued a Notice of Allowance on October 18, 2023, along with a List of References Cited by the Examiner. EX1002, pp.19-27, 29-30. The Notice of Allowance included an Examiner's Amendment amending what became Claim 21 to add a “biasing member configured to bias the actuator to the first position”. *Id.* at p.24.

The Examiner listed 16 references in the List of References Cited that they specifically analyzed before allowing the claims. *Id.* at pp.29-30. Those references appear on the face of the '921 Patent with an “*” and include Petitioner's asserted references Hartley (EX1006) and Eller (EX1007), as well as Wong (EX2019), Kees (EX2018), and Williams (EX1010)—references which, like Schaffer, include one or more rigid actuating members biased to collapse/seal a tube.

The Examiner found that the “closest prior art of record is [Hartley and Williams,] however these references do not disclose the device as claimed or described.” EX1002, p.25. The Examiner concluded that Hartley “fails to disclose a biasing member configured to bias the actuator to the first position” and Williams “fails to disclose [sic] a filament extending around the elongate member.” *Id.* at

pp.25-26. Accordingly, the claims were allowed over the same or the same type of art and combinations that Petitioner now relies on.

D. Person of Ordinary Skill in the Art (POSA)

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 '921 Patent. A person with less education but more relevant practical experience, or more relevant education but less practical experience, may also meet this standard. EX2033, ¶¶60-61.

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 '921 Patent. Petition, p.16. That experience designing medical devices is necessary as the Board preliminarily found: "Petitioner's proposed POSA definition lacks specificity" and is "too broad." Institution Decision, p.11. Indeed, Petitioner's expert seems to agree as he 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. EX2030, 24:5-21.

While the Board preliminarily found that Petitioner's expert "appear[s] to have at least the qualifications of the POSA and [is] capable of testifying about the

POSA's perspective," the declaration of Petitioner's expert is not from that perspective—but rather from the “too broad” perspective of a POSA having no experience designing medical devices. Institution Decision, pp.11-12. Petitioner's arguments and reliance upon that declaration from an incomplete perspective having no understanding of the design considerations including medical procedures and tools used therewith should be afforded little 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]; EX2033, ¶55. Instead, Petitioner's expert claims, for example, that a POSA with no medical experience could simply increase the spring strength (*see* Petition, p.55; *see also* EX1003, ¶¶128-129), contradicting that express goal of Schaffer.

E. Claim Construction: “Filament”

The claims each require a valve including a “filament.” A POSA would understand that the term “filament” should be accorded its plain and ordinary meaning: “a thin, flexible length of material formed by one or more strands of

material.” Namely, at issue here is whether the term “filament” requires flexibility. As the Board preliminarily found, it does: “a POSA would have understood the plain and ordinary meaning of filament as a flexible length of material.” Institution Decision, p.18. Even Petitioner’s expert testified in related litigation that the plain and ordinary meaning of “filament” includes flexibility. EX2028, 123:1-3 (“in the ordinary meaning of filament, it has flexibility”).

Because the plain meaning of the term filament requires flexibility, Petitioner argues here that the '921 Patent engages in lexicography and “reveal[s] a special definition” for the term “that differs from the meaning it would otherwise possess” because—according to Petitioner—the '921 Patent provides examples of “filaments” that allegedly use the term more broadly than that plain and ordinary meaning. Petition, pp.17-19. But Petitioner’s arguments do not meet the standard needed to show lexicography, which requires clear and unambiguous disclosure sufficient to depart from the plain and ordinary meaning. *Kyocera Senco Indus. Tools Inc. v. Int’l Trade Comm’n*, 22 F.4th 1369, 1378 (Fed. Cir. 2022) (“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”); *see also Hill-Rom Services, Inc. v. Stryker Corp.*, 755 F. 3d 1367, 1371 (Fed. Cir. 2014) (internal citations omitted) (“The standards for finding lexicography and disavowal are exacting.”).

1. Claim language

Petitioner concedes that the claim language provides no basis for Petitioner's proposed departure from the plain meaning of the term filament. Petition, p.19 ("the claims provide little information regarding the 'filament.'"). But, the language of Claim 1 (and 25) requiring an "active tensioning mechanism including ... a filament" supports Patent Owner's proposed construction because a POSA would understand the filament must be flexible to be actively tensioned. EX2033, ¶¶66-67.

With this design the actuator actively changes (increases/decreases) the tension in the filament when the actuator is moved between the first and second positions. *Id.* at ¶67; EX2025, p.1288 (defining the verb "tension" as to "tighten to a desired or appropriate degree") and p.13 (defining "active" as "producing or involving action or movement"). A POSA would understand the "active tensioning mechanism" to require movement/change of the tension in the filament—e.g., loosening of the filament when the actuator is moved to the second position and tightening of the filament when the actuator is moved to the first position as disclosed throughout the '921 Patent. EX2033, ¶67. If the filament were rigid/inflexible, there would be no "active tensioning." *Id.* Thus, the recitation in Claims 1 and 25 of an "active tensioning mechanism including ... a filament" supports that the term filament should be accorded its plain and ordinary meaning.

2. The specification

The '921 Patent provides examples of two general arrangements of filaments: formed into loop(s) as in Figures 6-7 and formed into bight(s) as in Figures 8-9. EX1001, 13:10-35.

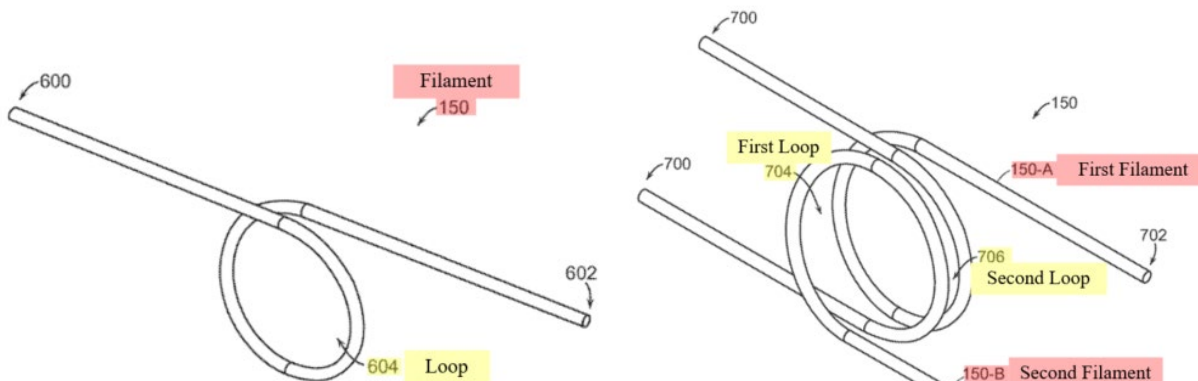


FIG. 6

FIG. 7

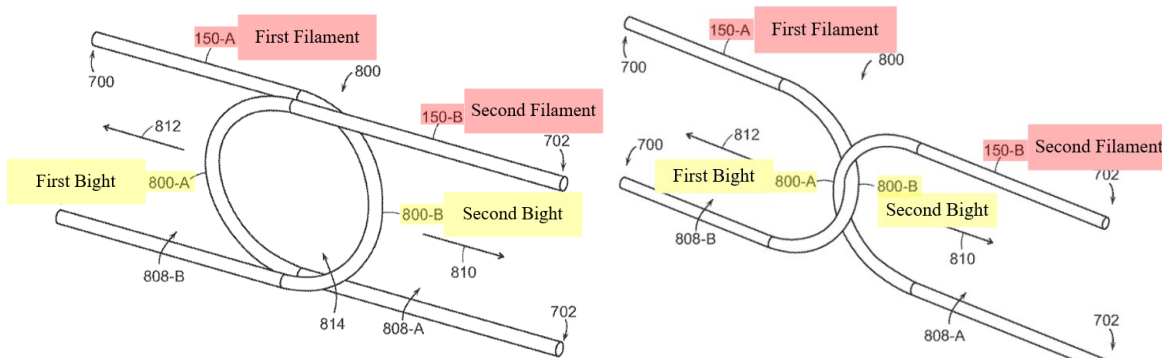


FIG. 8

FIG. 9

As the Board preliminarily found, “the '921 patent’s loop embodiments ... require a flexible structure.” Institution Decision, p.15. The Board also found that “[a]lthough flexibility of the filament in the patent’s ‘bight’ embodiments ... is not manifestly clear, there is a dearth of evidence from Petitioner—either intrinsic or

extrinsic to the patent—showing why a POSA would have understood the bights as embracing rigid structures.” *Id.*

A POSA would understand that the bight embodiments (and the loop embodiments) require flexibility based on the disclosure of the '921 Patent. For example, the '921 Patent discloses that when the buttons 144 are depressed to open the valve, “the filament 150 is *loosened*” and, likewise, when the buttons are released “the filament 150 is *tightened*.” EX1001, 9:36-37, 9:53-56 (emphasis added). That disclosure of the filament 150 applies to all embodiments of the filament including the “different embodiments and/or configurations of the filament 150” shown in Figures 6-9 including the loop and bight embodiments. EX1001, 12:37-39; EX2033, ¶68. And, a bight by definition is formed from slack and therefore must be flexible to form slack. EX2025, p.120 (“bight”: a “slack part or loop in a rope”); EX2033, ¶69.

A POSA would understand that when the tension on the filament is “loosened,” the filament slackens and relaxes as the tension is decreased therein. EX2033, ¶¶69, 72. “Loose” is defined as “not tightly drawn or stretched: *slack*” and “being *flexible*.” EX2025, p.735 (emphasis added). Conversely, when the filament is “tightened,” a POSA would understand that the slack is removed as tension in the filament increases and the filament constricts the tube. EX2033, ¶69. A POSA would further understand that this is precisely the type of “active tensioning” recited in the

Claims—the filament loosens/slackens when the actuator buttons are pressed and tightens when they are released. *Id.* Thus, the ability of the filament to flex/slacken is a necessary property of the filament—whether formed into a loop or bight. *Id.* The filament's ability to flex is not optional but necessary, consistent with the plain and ordinary meaning of “filament.”

In a petition for IPR for related U.S. Patent 11,865,291, Petitioner contested the import of the loosen/tighten language stating that “[m]any inflexible items can be loosened, such as screws and bolts.” *Imperative Care, Inc. v. Inari Medical, Inc.*, IPR2025-00728, Paper 2, p.25. While a rigid screw/bolt can be loosened or tightened relative to a substrate (e.g., a piece of wood), that rigid screw/bolt must be able to move (e.g., rotate) relative to the substrate to do so. EX2033, ¶70. In contrast to a screw/bolt that can move to be loosened tightened relative to a substrate, in each of the embodiments of the '921 Patent, the filament(s) are fixedly coupled to the actuator 142 such that they could not move relative to the actuator 142 if they were rigid, and therefore could not be loosened/tightened. *Id.* That principle is demonstrated, for example, in the loop embodiments of Figures 6-7 which require flexibility because they would not function if the filament(s) were inflexible. *Id.* at ¶71.

And, contrary to Petitioner's position, the nonlimiting list of example filaments in the '921 Patent further supports that the '921 Patent has not redefined

the term “filament” to depart from its plain and ordinary meaning. Petitioner’s purported examples of inflexible filaments are not filaments at all, but instead are simply example materials from which a filament can be made or forms that the filament can take. EX2033, ¶73. None of those materials or forms support that the ’921 Patent has departed from the plain meaning of the term filament, let alone redefined the term as Petitioner urges. Nor does Patent Owner’s proposed construction exclude specific filaments as, for example, a sheet/tape of metal/polymer would comprise one strand of material—a “monofilament” as disclosed in the ’921 Patent—and multiple such sheets/tapes could also be “twisted, woven, grouped and/or fused to form [a] filament.” EX1001, 9:10-15; EX2033, ¶74.

At deposition in the related ’011 IPR, Petitioner’s expert confirmed that every material and form of a filament in the ’921 Patent is consistent with the understanding that a filament is a “thin, flexible length of material formed by one or more strands of material.” EX2030,125:2-126:4 (“The relative flexibility or the relative stiffness or rigidity is not clear from those three materials without knowing much more information”), 131:25-132:12 (“you would need to know more details about the material and the dimensions and the construction of those materials to be able to quantify or compare relative flexibility of one element versus another”), 131:16-24 (agreeing that “one skilled in the art could construct a filament out of any of those materials, in any of those forms – threads, lines, cords, rope, ribbon, flat

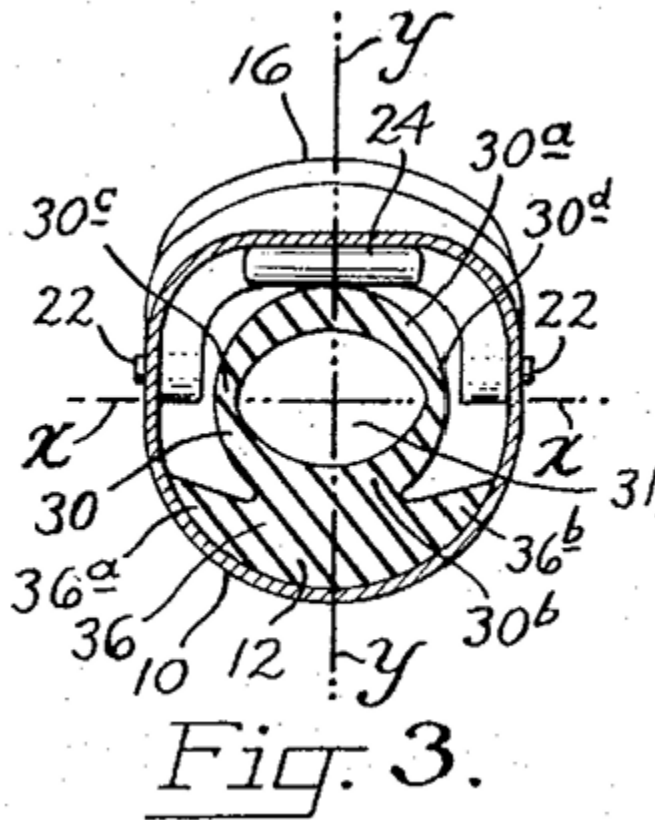
wire, sheet or tape – that would be sufficiently flexible to loop around a lumen in a hemostasis valve”). Every disclosed form of the “filament” is consistent with the plain meaning of the term filament including flexibility. EX2033, ¶73. Accordingly, such a nonlimiting list of example materials/categories of form does not redefine or broaden the term filament from its plain and ordinary meaning.

3. Prosecution history

Petitioner's proposed construction of filament to include example structures (“one or several threads, lines, cords, rope, ribbon, flat wire, sheet, or tape”) that can be rigid is overly broad and contrary to the Patent Office's repeated interpretation of “filament” during prosecution. For example, in the Notice of Allowance the Examiner found that Hartley and Williams were the “closest prior art of record,” and that Hartley discloses a “filament” whereas Williams does not. EX1002, pp.25-26. Indeed, in accordance with the plain and ordinary meaning of the term, Hartley discloses a thin and *flexible* string 14 (EX1006, ¶[0031]) while Williams discloses a *rigid* clamp 16 having a rib 24 that is biased to compress and seal a tube 12 (EX1010, 2:39-44, 2:63-65). EX2033, ¶¶76, 86. Williams' valve is substantially similar to Schaffer in which a non-flexible/rigid member compresses a tube to seal. *Id.* at ¶86.

Thus, the Examiner plainly understood that a flexible string was a “filament” while a rigid actuating structure (clamp/rib) was not. *Id.* at ¶87. But, under

Petitioner's overly-broad construction, the rib 24 of Williams is a filament because it is rigid and at least a "line," "cord," "ribbon," or the like as best seen in Figure 3:



Id.

The Patent Office also specifically analyzed additional references that are substantially similar to Schaffer having rigid actuating members that are biased to compress and seal a resilient/expandable tube including, for example, Wong (EX2019) and Kees (EX2018). EX1002, p.29; EX1001, p.5. And again, in accordance with the plain and ordinary meaning of "filament," the Patent Office did not find those references to disclose a filament. EX2033, ¶¶79-85.

Accordingly, the Patent Office understood that Hartley's string was a "filament" because it is flexible, whereas the Patent Office understood the rigid actuating structures of Wong, Kees, and Williams are not filaments contradicting Petitioner's overly-broad construction of "filament."

4. Extrinsic evidence

Merriam-Webster's Collegiate Dictionary defines a filament as "a single thread or a thin flexible threadlike object, process, or appendage." EX2025, p.467 (11th ed. 2014). *See also* New Oxford American Dictionary, EX2026, p.644 (3rd ed. 2010) (filament: "a slender threadlike object or fiber"). That definition confirms the plain and ordinary meaning of filament to a POSA: "a thin, flexible length of material formed by one or more strands of material." EX2033, ¶88.

Moreover, Petitioner's expert, in his own patent (U.S. Patent No. 7,682,380 (EX2029)), equated a "filament" to a "thread-like element" that can be made from various polymers or metal and yet still be thin and flexible. EX2029, 8:7-9, 8:53, 9:18-22. Accordingly, Petitioner's own expert's use of the term "filament," at least when he was explaining his own alleged invention, supports Patent Owner's proposed construction.

Finally, the recitation in related U.S. Patent No. 12,109,384 (EX1016) that the "first filament is flexible" does not change the construction of filament to include rigid materials. EX2033, ¶89. As the Board preliminarily found, that claim requires

the filament to be flexible regardless of the inclusion of the word “flexible.” *Id.*; Institution Decision, pp.17-18.

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

A POSA would understand the degree of flexibility required by the “filament” in the context of the '921 Patent claims. 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 disclosed—the filament must be sufficiently flexible so that it can loosen, reduce in diameter when formed in a loop as shown in Figures 6-7, and slacken when formed in a bight as shown in Figures 8-9. EX2033, ¶90. That is, a POSA would understand that in the context of the '921 Patent's hemostasis valves, the filament must be flexible to the degree necessary to slacken/loosen when the actuator is actuated (e.g., depressed) as disclosed throughout. *Id.* And, Petitioner's expert agrees. EX2031, 38:22-39:7 (agreeing a POSA “would be able to determine what that level of flexibility is”).

6. Conclusion

The '921 Patent does not redefine the term “filament” via a nonlimiting set of example materials. There is no such lexicography, and the specification is clear that the operation of the disclosed and claimed valves requires flexibility. As such the term filament should be accorded its plain and ordinary meaning, “a thin, flexible length of material formed by one or more strands of material.”

III. THE CLAIMS ARE NOT ANTICIPATED BY SCHAFFER (GROUND 1)

Schaffer discloses a hemostasis valve that employs a fundamentally different method of sealing from the Claims—rigid actuating members that compress a seal module without conforming to the outer surface of the seal module. Because Schaffer's actuating members do not conform to the seal module, the seal module includes 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 when ... [a] compressive force 67 is exerted” thereupon. EX1005, ¶60.

In contrast, Claim 1 of the '921 Patent requires an “*active tensioning mechanism*” including an actuator coupled to the elongate member via a “*filament*” wherein the “actuator is moveable” to “a first position wherein the lumen is constricted and sealed.” Claims 15 and 21 similarly require a “filament.” Schaffer fails to disclose such a “filament” and, accordingly, fails to anticipate Claims 1, 15, or 21 (and the claims depending therefrom).

A. Schaffer Fails to Disclose a “Filament” Under Patent Owner's Construction

As set forth above, the term “filament” recited in the Claims requires flexibility. In contrast, as the Board preliminarily found, Schaffer discloses *rigid* U-shaped actuating members—not a “filament”—and therefore does anticipate the Claims. Institution Decision, pp.25-27; EX2033, ¶¶91-100.

Petitioner implicitly admits that Schaffer's U-shaped actuating members 55 are rigid, asserting that those members would purportedly form gaps and a poor seal as the supposed motivation to modify Schaffer. Petition, p.36. And, Schaffer provides ample disclosure that its actuating members are rigid. EX2033, ¶¶95-101.

First, Schaffer explains that its U-shaped actuating members "forcibly disengage opposing outer walls 27 of the seal module 100" to allow it "to retract to an uncollapsed configuration" when "each actuator button 261 is depressed." EX1005, ¶[0077]. The actuating members need to be rigid to "forcibly disengage" the seal module. EX2033, ¶¶95-96. In contrast, if flexible, the actuating members would remain in contact with and never disengage the seal module as the seal module expands. *Id.*

Second, Schaffer's only disclosed method of manufacturing its U-shaped members indicates they are rigid. Schaffer discloses that the actuating members 55 are "made from machining pre-existing amounts of metals and/or plastics." EX1005, ¶[0082]. A POSA would have recognized that machining plastic or metal would result in a rigid member. EX2033, ¶97.

Third, Schaffer's disclosed method of assembly relies on the rigidity of its actuating members to form an area through which a seal module can be inserted: "[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]; EX2033, ¶98. Because Schaffer's actuating members are rigid, an opening is formed for the seal module to be inserted through. EX2033, ¶98. If those members were flexible, they would collapse/deform without forming an opening to insert the seal module. *Id.* at ¶99.

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

Despite the substantial disclosure that Schaffer's actuating members are rigid, Petitioner simply asserts that it "is inaccurate" that Schaffer's actuating members are rigid because "Schaffer does not describe the actuating members as 'rigid,' nor does it contain disclosure suggesting rigidity." Petition, pp.30-31. Such an assertion is incorrect based on Schaffer's disclosure discussed above.

B. Dependent Claim 3 is Further Not Anticipated by Schaffer Because Schaffer Does Not Disclose the "Filament Extend[ing] in a Loop."

Even if the Board were to find the term "filament" not to require flexibility, dependent Claim 3 recites other elements that require flexibility including the "filament extend[ing] in a loop." As the Board preliminarily found, the loop embodiments "require a flexible structure." Institution Decision, p.15. And, as set forth above, Schaffer's actuating members are rigid not flexible.

Moreover, Schaffer's U-shaped actuating members do not individually or collectively extend in a loop. EX2033, ¶107. Petitioner relies upon the "bight" embodiments of the '921 Patent to allege that Schaffer's two U-shaped actuating members collectively form a "loop." Petition, pp.47-49. Such reliance is improper—the "loop" embodiments and "bight" embodiments are distinct, so any alleged similarities between Schaffer's U-shaped actuating members and the bight embodiments do not support that Schaffer's U-shaped actuating members are loops. EX2033, ¶107. They are not. Moreover, as opposed to the interlocking bights (Figures 8-9), Schaffer's U-shaped members are side-by-side and thus, even collectively, do not form a loop. *Id.*

C. Dependent Claim 10 is Further Not Anticipated by Schaffer Because Schaffer Does Not Disclose a "Second Filament."

Dependent Claim 10 recites that the "filament" of Claim 1 is a "first filament" and then further requires a "second filament" like the "first filament." EX2033, ¶108. For the same reasons explained above that Schaffer does not disclose the "first filament," Schaffer also does not disclose the "second filament" of Claim 10. *Id.* Moreover, Petitioner's assertion that Schaffer's two actuating members 55 individually constitute the "first filament" and the "second filament" of Claim 10 is directly contrary to Petitioner's interpretation for Claim 3 alleging that Schaffer's two actuating members "collectively form" a single filament loop. Petition, pp. 47-

49, 65-66. Even if the “filament” were construed to include rigid structures (which it should not be), a POSA would not have understood Schaffer's two actuating members to comprise both a single filament as in Claim 3 *and* two filaments as in Claim 10. EX2033, ¶109.

IV. THE CLAIMS ARE NOT OBVIOUS OVER SCHAFFER ALONE (GROUND 2)

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

As set forth in §III above, Schaffer does not disclose the claimed “filament.” Petitioner alleges that “even if Schaffer's lumen were not ‘constricted and sealed’ by the actuating members in the first position ... a POSITA would have found it obvious to modify the actuating members to closely conform to the seal module to constrict and seal the lumen” in order “to form a better seal and avoid the potential gaps.” Petition, p.32. But such a modification would not have been obvious for at least the reasons set forth in §V below. In particular, a POSA would have had no motivation to make such a modification because every embodiment of Schaffer includes the seal member 165 that seals completely (i.e., a POSA would understand that there are no “gaps”) and such a modification would fundamentally change the

principles of operations of Schaffer's valve. EX2033, ¶113. "Petitioner's analysis and evidence for Ground 2 is threadbare, unpersuasive, and evokes a hindsight bias." Institution Decision, p.27. Accordingly, because Schaffer does not disclose or render obvious all the limitations of the Claims, Ground 2 fails.

V. THE CLAIMS ARE NOT OBVIOUS OVER SCHAFFER IN VIEW OF HARTLEY (GROUND 3) OR ELLER (GROUND 4)

A POSA would not have been motivated to replace Schaffer's U-shaped actuating members with Hartley's string or Eller's wire member. Petitioner's proposed modification and combinations are hindsight—requiring a POSA to first manufacture a non-existent problem with Schaffer (gaps/poor sealing) by omitting Schaffer's third seal member which seals without gaps, then modify Schaffer to remedy that non-existent problem in a manner that fundamentally changes Schaffer's principles 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. 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. In contrast, a flexible string/wire would

diminish the predictable sealing of Schaffer's valve. Likewise, Petitioner's expert admits there were an unknown—not 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.

A. A POSA Would Not Have Been Motivated to Substitute Hartley's String/Eller's Wire for Schaffer's Actuating 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). Petitioner's asserted motivation to modify Schaffer's U-shaped 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.

Based only on its expert's statements, 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 "Hartley's string may seal more effectively across a wider range

of tool diameters and shapes than Schaffer's U-shaped actuating members." Petition, p.36. Petitioner is wrong. *Every embodiment* of Schaffer discloses a valve that seals across a wide range of instruments without gaps via the seal member 165—indeed, that is the purpose of Schaffer. EX2033, ¶¶120-123.

Each of Schaffer's embodiments—including the embodiment shown in Figures 30-34 relied on by the Petitioner—includes the seal member 165. EX2033, ¶¶53-57, 121-123. For example, Schaffer discloses that the seal module 100 in Figures 30-34 "is formed of one or more seal members, as discussed above" with reference to Figures 1-29 and that (1) in the first sealed position of the valve 10 the "lumen 193 of the **third seal member 165** is at least partially collapsed by the compressive force 67" and (2) in the second unsealed position of the valve 10 the "lumen 193 of the third seal member 165 is able to retract in an unsealed configuration." EX1005, ¶¶[0075], [0077] (emphasis added). Therefore, Schaffer is clear that the embodiment of Figures 30-34 includes the seal member 165. EX2033, ¶121. 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. EX2031, 69:12-70:3 (Figures 1-4), 70:5-71:23 (Figures 5-19), 71:24-72:19 (Figures 20-22), 72:20-73:2(Figures 23-26), 73:3-5(Figure 27), 73:6-9 (Figures 28-29), 73:13-77:3 (Figures 30-34).

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, ¶¶86; EX2033, ¶135. 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. A POSA is not so devoid of common sense.

Indeed, Schaffer discloses that the third seal member 165 (included in every embodiment) seals completely without gaps across a wide range of tool/device diameters and shapes. EX2033, ¶¶120-123. 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):

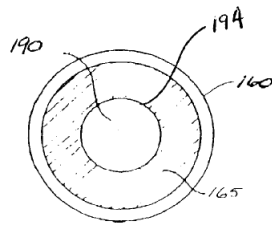


FIG. 16

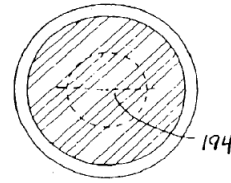


FIG. 17

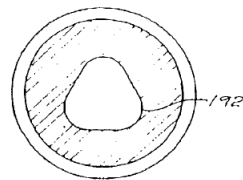


FIG. 18

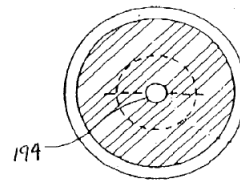


FIG. 19

EX2033, ¶¶122-123 (citing EX1005, ¶[0060]). The seal member 165 seals completely in all those scenarios by being highly compliant to conform to different shapes. *Id.* at ¶126; 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.”).

Notably, the seal member 165 seals whether or not it is “sticky,” “gelatinous,” or “self-closing.” EX2033, ¶¶126-127. Schaffer discloses that “existing devices do not perform a complete seal against leakage in the presence of a wide range of instruments or in the presence of multiple instruments,” and identifies a need for a

“durable stasis valve that blocks the flow of gas or fluid **completely** and immediately **with or without an instrument in place.**” EX1005, ¶¶[0006], [0008] (emphasis added). A POSA would have understood that Schaffer's valves are designed do just that—seal completely—including in any embodiments without “sticky” or “self-closing” characteristics (via the seal member 165). EX2033, ¶¶127-128.

Even Petitioner and its expert acknowledge that “Schaffer discloses a hemostasis valve for use with catheters ‘that blocks the flow of gas or fluid completely and immediately with or without an instrument in place.’” Petition, p.21; EX1003, ¶61. Moreover, Petitioner states: “[i]f Schaffer's valve did not remain closed, blood would leak out of the catheter and the valve would not be a ‘hemostasis’ valve (i.e., a valve that stops blood loss) ... [y]et, Schaffer's valve blocks ‘the flow of gas or fluid’ during such medical procedures and, therefore, remains closed.” Petition, pp.54-55; *see also* EX1003, ¶¶124-125. Accordingly, Petitioner and Mr. Thornton acknowledge—at least when it suits them—that Schaffer's valve completely seals and that, if it did not, it would not be a “hemostasis valve.” This contradicts their purported motivation for substituting Schaffer's U-shaped actuating members with Hartley's string/Eller's wire to “seal more effectively” and avoid the formation of “small gaps.”

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) (denying institution), citing *In re Schweickert*, 676 F. App'x 988, 996 (Fed. Cir. 2017).

Petitioner's expert even 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. EX2030, 116:18-117:2 (“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.”). Dr. Zalesky agrees. EX2033, ¶124. 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 had a motivation 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 that would fail to motivate a POSA to substitute Hartley's string or Eller's wire.

As set forth above, the highly-compliant seal member 165 in every embodiment 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**/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 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 would not solve the manufactured problem.

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]; EX2033, ¶128. 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*

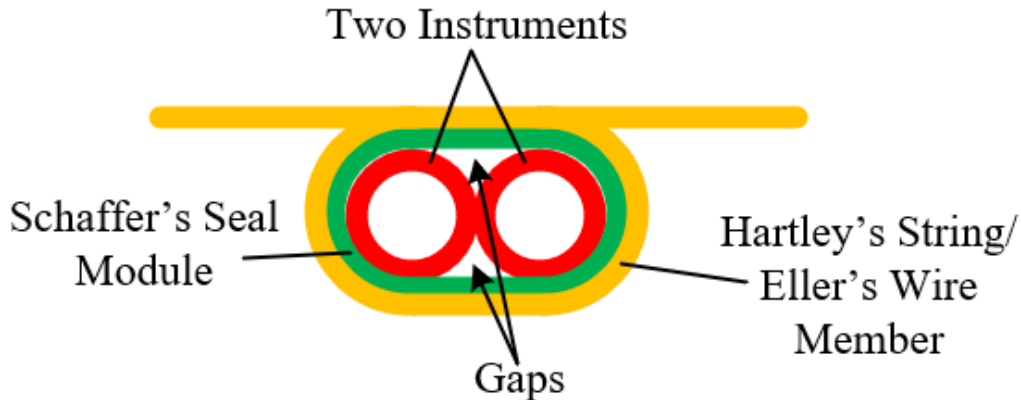
Strategic Holdings, Inc., the Board found Petitioner had failed to establish that a POSA would have been motivated to modify a primary reference Hon based on a secondary reference Whittemore when Hon itself taught modifications that would have addressed the alleged motivation. IPR2020-01602, 2022 WL 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 (emphasis added). The Federal Circuit affirmed explaining that "the proposed combination was based on a purported simplification of Hon beyond what Hon itself teaches." *Philip Morris Prods. S.A. v. RAI Strategic Holdings, Inc.*, No. 2022-1846, 2023 WL 5970786 at *2 (Fed. Cir. Sept. 14, 2023).

Likewise here, Petitioner's motivation for modifying Schaffer requires modifying Schaffer beyond what Schaffer itself teaches. Schaffer itself teaches comparably simple modifications for solving the purported defect of Schaffer if, for some unarticulated reason, a POSA omitted Schaffer's seal member 165. First, a POSA would simply include the seal member: problem solved with no further

modification to Schaffer or need to change Schaffer's principle of operation or express methods of manufacture.

Moreover, Petitioner and its expert admit that Schaffer's valve could be improved—if needed—by simply adjusting properties of the seal module (which is just another way of saying include the seal member 165, or something like it), the spring strength of Schaffer's springs, and the like as explained in detail below in §V.B.2. EX2033, ¶¶170-172. 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 they manufactured.

Third, even if Schaffer were modified to remove the seal member 165, Petitioner's proposed combination would not solve the purported problem (gaps) when sealing around multiple/irregularly-shaped instruments—scenarios for which Schaffer's valve is specifically designed to address. EX2033, ¶130. 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, 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; EX2033, ¶130. A POSA would simply utilize Schaffer's disclosed design. EX2033, ¶130.

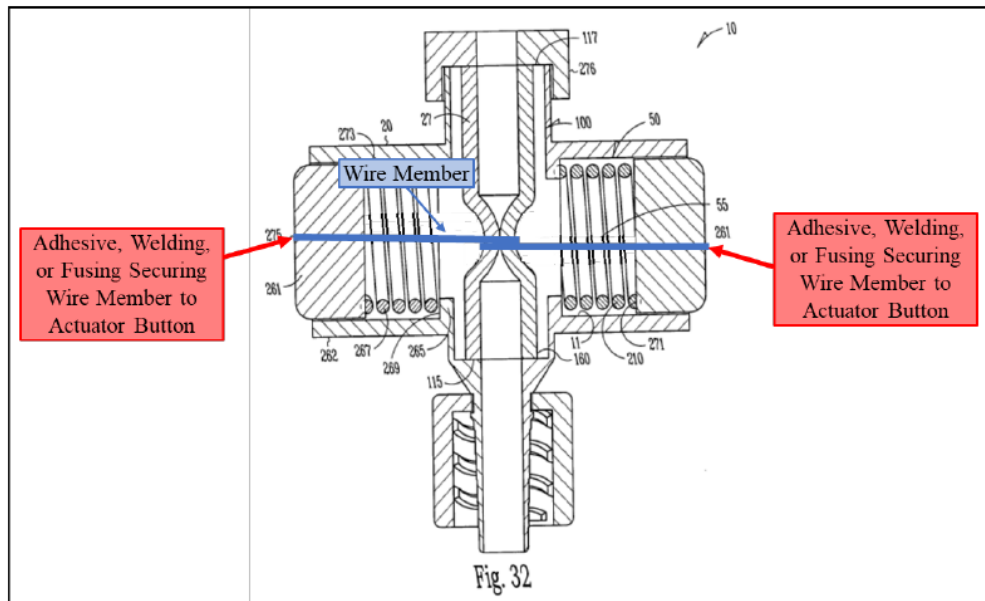
Thus, Petitioner has not met its burden of showing that a POSA would have been motivated to substitute Hartley's string/Eller's wire for Schaffer's U-shaped members to prevent Petitioner's purported gaps.

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

Petitioner advances a "simple substitution" rationale for substituting Hartley's string or Eller's wire member for Schaffer's U-shaped members. Petition, pp.35, 43; *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007). But, a single actuating

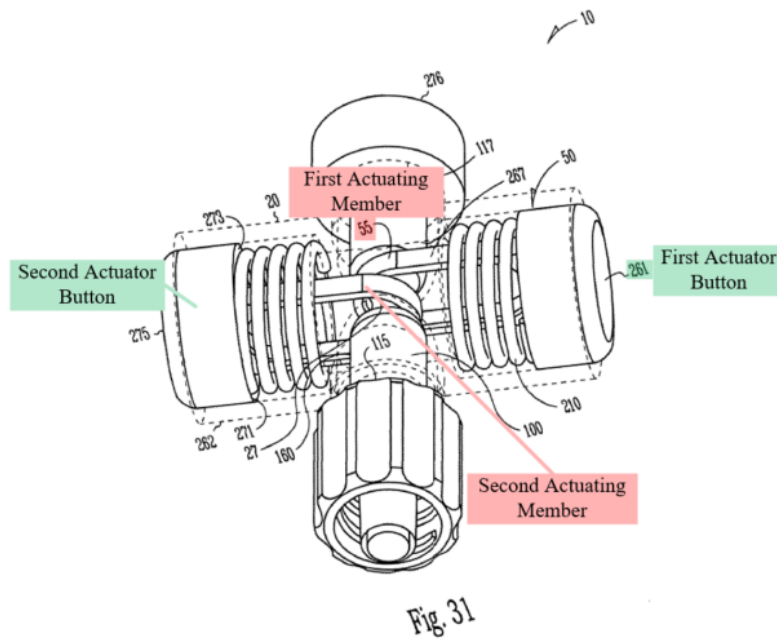
member (U-shaped member, string, or wire) having two ends coupled to and controlled by different actuators is not disclosed in, and thus not “known” from, any of Petitioner’s references. Moreover, a POSA would not have been motivated to substitute Hartley’s string/Eller’s wire for Schaffer’s U-shaped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

Demonstrative Illustration
Schaffer + Eller's Wire Member



Id. at pp.37-38, 43-44. But, as Petitioner's expert has admitted, neither Schaffer, Hartley, nor Eller disclose Petitioner's proposed arrangement. As such, Petitioner's proposed combination cannot be a substitution of strings/wires for Schaffer's actuating members, but requires additional modification to arrive at an arrangement not found in the prior art. And, Petitioner cites no reference disclosing a single string or wire attached to and controlled by two independently movable actuators, let alone provide any reason why a POSA would make that additional modification in its proposed combination or select that filament arrangement over any other filament arrangement.

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



EX2033, ¶145. During deposition in the related '012 IPR, Petitioner's expert agreed. See EX2031, 57:13-22. Schaffer's configuration is required because Schaffer's rigid actuating members could not function if they were attached to Schaffer's two buttons thereby immovably tethering the buttons together. EX2033, ¶145.

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:

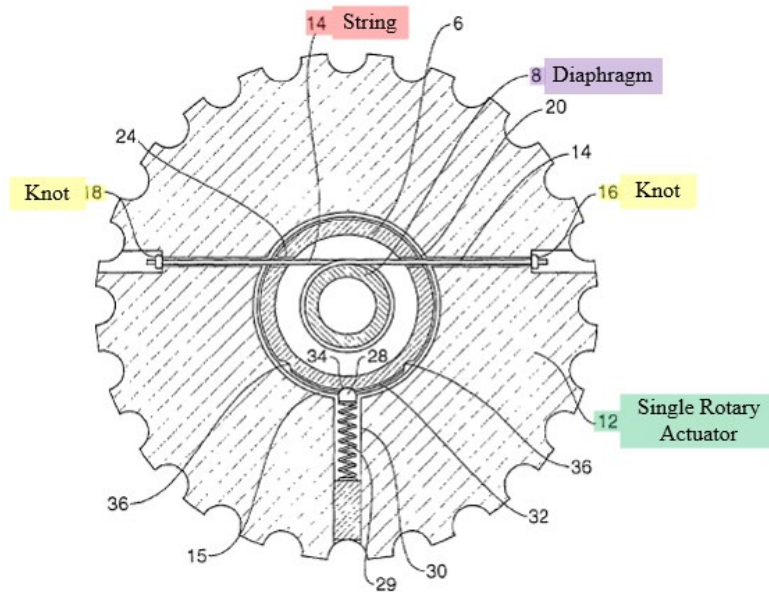
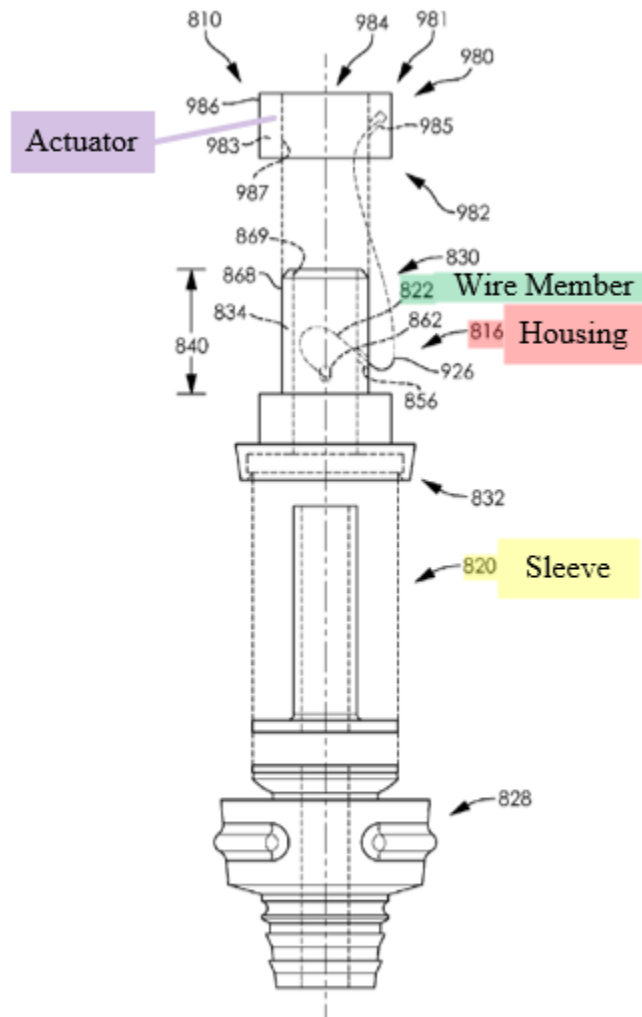


Fig 3

EX1006, ¶[0031]; EX2033, ¶146. The rotary actuator is a single component such that both ends of the string are attached to and controlled by the same actuator. EX2033, ¶146. Neither end of the string can move without the exact same and equal movement of the other end of the string allowing for precise and predictable control of the valve's opening and closing. *Id.* Again, Mr. Thornton agrees. *See* EX2031, 77:12-22.

And, 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”:



EX1007, 23:50-62, 24:50-52. Eller discloses other embodiments with multiple wire members each having the same arrangement. EX2033, ¶¶147-149. In all embodiments, the wires have a first end coupled to a housing and a second end coupled to a single actuator. *Id.* at ¶150. Movement of the single actuator pulls only the second end while the first end remains stationary such that the wire moves predictably and a precise amount. *Id.* Again, Mr. Thornton agrees. *See* EX2031, 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 cannot be a "known element." EX2033, ¶152.

Under Petitioner's proposed combination, a POSA would need to not only *eliminate* both of 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*. EX2033, ¶¶151-152. Petitioner does not explain why this additional modification of the references would be obvious, let alone provide any reason why a POSA would make this additional modification. Even if the arrangement existed generally that would not provide a motivation to combine Schaffer with Hartley/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 member/string/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 other more plausible substitutions/modifications to address any purported sealing issues.

Petitioner's motivation to substitute Hartley's string/Eller's wire for Schaffer's U-shaped members is based on its expert's testimony that the combinations would "seal more effectively" and avoid the formation of "small gaps." Petition, pp.36, 43. 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. Even assuming that Schaffer's valve somehow did not seal in some embodiments, a POSA would not have been motivated to substitute Hartley's string/Eller's wire for 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. 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”).

Here, Petitioner and its own expert provide several other substitutions that are considerably more plausible than the wholesale change to Schaffer’s valve that would result from eliminating the two U-shaped members and replacing them with the single string/wire of Hartley or Eller. For example, when addressing Schaffer’s alleged disclosure of Claim 5, Petitioner asserts that a POSA would have recognized multiple straightforward ways to enhance or maintain Schaffer’s seal with a reasonable expectation of success, but that is a reason why a POSA would not make the wholesale changes that Petitioner proposes. *See* Petition, p.55. Mr. Thornton has testified that those simple adjustments would work, whether or not there was a pressure differential across the valve. EX2031, 121:21-122:12. Dr. Zalesky agrees. EX2033, ¶171.

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, p.55. 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. EX2033, ¶172.

Put differently, a POSA would have known multiple ways that Schaffer could be improved based on its disclosure without the significant and disadvantageous changes required by Petitioners' combination. For example, Mr. Thornton confirmed that adjusting the spring strength would allow Schaffer's valve to be manufactured in the same manner it discloses. EX2031, 123:13-19. Dr. Zalesky agrees. EX2033, ¶¶171-172.

As another example, a POSA would understand that the properties of the seal module could be adjusted to improve the seal, such as its materials and resultant characteristics. EX1005, ¶[0059]. 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 maintain Schaffer's principles of operations. EX2033, ¶171.

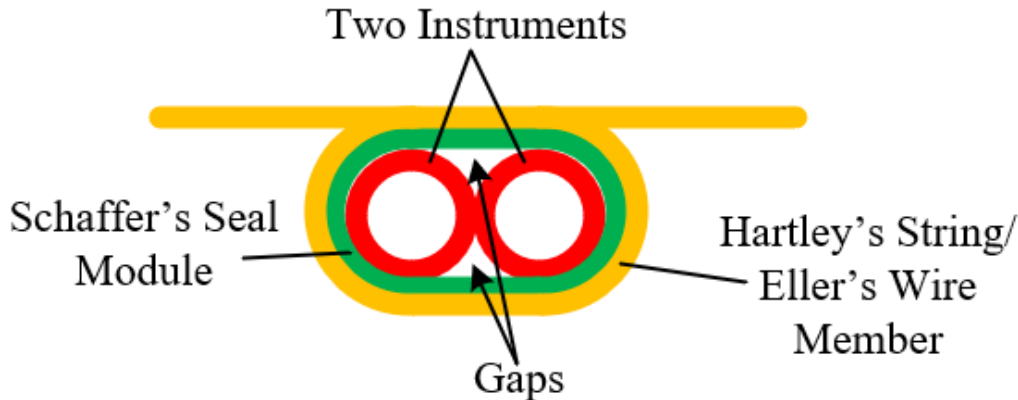
Despite Schaffer's disclosure about the materials/characteristics of the seal member 165, during deposition in the related '012 IPR, Mr. Thornton initially testified that he did not know what those characteristics or materials were based on Schaffer. *See* EX2031, 126:9-22 ("I don't know what the characteristics are of that 165 module" and "that material isn't really specified directly or clearly in the [Schaffer] patent."); 129:4-10 ("I don't believe that they describe the material choice

in enough detail with wall thickness, hardness.”). But Mr. Thornton later reversed course and admitted that a POSA would have understood how to select the materials and properties of the seal member 165 to make Schaffer's valve seal and that the commonly available materials listed by Schaffer would work. *Id.* at 130:22-131:1, 131:15-132:1 . That is, Petitioner's expert acknowledged that forming the seal member from C-flex or Kraton—as Schaffer discloses—would work to seal Schaffer's valve. Dr. Zalesky agrees. EX2033, ¶171.

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 the more complicated hindsight-based modifications that require a wholesale redesign of Schaffer as explained below in §V.D. EX2033, ¶¶170-172.

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

Petitioner's proposed combination would seal less effectively around multiple instruments and/or irregularly-shaped instruments—scenarios for which Schaffer's valve is designed form a complete seal:



EX2033, ¶130. It's therefore not a suitable option or predictable result that Petitioner's proposed simple substitution would seal Schaffer's valve in the manner it is intended to seal 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 8-9 of the '921 Patent, he would be unable to know how the filaments would act. EX2031, 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"). *Id.* 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. EX2033, ¶¶99, 153, 162. For example, the inherent

flexibility of the string/wire could render its relaxed geometry uncontrollable, resulting in non-orthogonal positioning around Schaffer's seal module. *Id.* at ¶162. That unpredictability is exacerbated in Petitioner's proposed combinations 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 and certain amount upon actuation. *Id.* at ¶¶146, 150. In Petitioner's combinations, the movement of the string/wire would not be precisely controlled in that manner by a single actuator as either of Schaffer's buttons could be depressed independently to move one end of a string/wire in an even more unpredictable manner. *Id.* at ¶153.

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.

4. Petitioner's Numerous Simple Substitution Theories Demonstrate Hindsight Bias.

Here and in other related IPRs Petitioner and its expert have advanced numerous different theories of simple substitution based on combinations of Schaffer and Hartley and/or Eller using the particular challenged claims as a roadmap despite none of those arrangements being found in the prior art. For

example, for grounds 3-4 here, Petitioner and its expert allege that the simple substitution is to connect Hartley's single string or one of Eller's wires between Schaffer's two actuator buttons. Petition, pp.35-36, 42-43; EX1003, ¶¶85-94, 99-106. Then for dependent Claim 10, Petitioner alleges that the simple substitution is different—substituting each of Schaffer's actuating members for a string or wire. Petition, pp.68-70; EX1003, ¶¶154-155, 158. And, in an IPR for related U.S. Patent No. 12,109,384 Petitioner and its expert allege that the simple substitution is different again—substituting two of Schaffer's strings or two of Eller's wire members into Schaffer's valve each connected to both actuators. *Imperative Care, Inc. v. Inari Medical, Inc.*, IPR2025-01562, Paper 2, pp.48-49 & EX1003, ¶¶105-106. Those shifting perspectives of Petitioner and its expert demonstrate improper hindsight—Petitioner has simply used the particular challenged claims as a roadmap for its “simple substitution.”

Moreover, despite his 35 years of experience using hemostasis valves, prior to this matter Petitioner's expert was not aware of a single prior art hemostasis valve employing a filament to constrict a lumen in any arrangement, let alone as claimed. Not one. EX2034, 14:1-11. Petitioner's expert had no familiarity at all with using a string or wire in a hemostasis valve until seeing the '921 patent (or related patent), or observing Petitioner's accused product in connection with a co-pending related litigation. *Id.* at 16:11-17:5. Even now, Petitioner's expert has never tested or even

observed the use of a filament in a hemostasis valve sufficient to understand how a filament would function or compare to Schaffer's rigid U-shaped members. *Id.* at 15:16-23. His after-the-fact testimony that there were multiple known simple substitutes prior to the '921 Patent (or related patent) in any arrangement, let alone in the claimed arrangement, is impermissible and unsupported hindsight. As explained in *KSR*, "[a] factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007).

And, even Petitioner's expert cannot keep track of Petitioner's various simple substitutions. In his declaration in support of this Petition executed March 9, 2025, Mr. Thornton alleges that for dependent Claim 10, the simple substitution would be to substitute each of Schaffer's actuating members for a string or wire member. EX1003, ¶¶154-155, 158. But, a mere ten days later in the related '011 IPR, Mr. Thornton testified that he had never considered using two of Hartley's strings to replace Schaffer's two actuating members. EX2030, pp.54:25-55:14. Mr. Thornton is simply not credible.

Petitioner's changing assertions of the simple substitution from one, to another, to yet another depending on the challenged claims demonstrates that each is hindsight motivated only by the need to arrive at a particular claimed configuration.

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

Petitioner advances what appears to be an “obvious to try” rationale for substituting Hartley’s string/ Eller’s wire for Schaffer’s U-shaped members. Petition, pp.37, 43; *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) (emphasis added).

Here, Petitioner has failed to demonstrate that the options and solutions for “constricting a tubular member in a hemostasis valve” were identified and known.

Petition, pp.37, 43. Petitioner and its expert propose only three options: “Hartley and Schaffer disclose two such options: Hartley’s string and Schaffer’s actuating member ... Eller discloses a third option: wire members.” *Id.* at p.37; EX1003, ¶88. But, at deposition in the related ’012 IPR, Mr. Thornton admitted that there were more ways to constrict a tubular member in a hemostasis valve including those disclosed in Schaffer ’616 (EX2031, 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 existed. EX2031, 107:2-13 (“I don’t know how many options could be used to compress a tube.”). Petitioner’s “obvious to try” argument fails for this reason alone—the options and solutions for compressing a tubular member in a hemostasis valve were neither “known” nor “identified” as admitted by Petitioner’s 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 would fundamentally change a reference’s “principle of operation”).

Here, a POSA would understand that Schaffer’s rigid U-shaped actuating members are necessary to “forcibly disengage” when unsealing, necessary for Schaffer’s disclosed method of manufacture, and necessary to provide Schaffer’s various benefits including reliability 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 member because such a modification would prevent forcible disengagement, as described above in §III.A. EX2033, ¶¶167-169. 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]; EX2033, ¶169.

As explained above, Hartley's string/ 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.35-39, 43-44. In this arrangement, Hartley's string/ Eller's wire would never disengage—let alone forcibly disengage—Schaffer's seal module. EX2033, ¶¶168-169. Therefore, this modification would change a principle of operation of Schaffer. *Id.*

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, and as explained above in §§V.B.1-4. EX2033, ¶154. Instead, Petitioner's alleged modification is not found in the art at all and is based on impermissible hindsight stemming from the '921 Patent.

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

Schaffer's U-shaped actuating members 55 are purposefully designed to be rigid and attached to only a single actuator. EX2033, ¶¶149-160. In addition to precise control, that design choice provides simple methods of assembly and manufacturing, and effectively addresses Schaffer's express need for "a durable stasis valve." EX1005, ¶[0008]. Petitioner's proposed substitutions would introduce

assembly difficulties and undermine the durability of Schaffer's valve. EX2033, ¶¶155-166.

Schaffer discloses a method of manufacture that relies upon its U-shaped actuating members being rigid and attached to only a single actuator. EX2033, ¶¶155-165. 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" when the buttons are depressed to form an opening through the actuating members. *Id.*; EX1005, ¶[0083].

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 ¶¶158-161. For example, to achieve Petitioner's proposed modification in which a single string/wire is tethered to both of Schaffer's actuator buttons 261 (Petition, pp.35-38, 43-44), the string/wire would need to be either (1) secured to the actuator buttons before the actuator buttons are inserted into the openings in the housing or (2) secured to the actuator buttons after they are inserted into the openings. EX2033, ¶158. However, the first method of assembly would not be possible because the tethered actuator buttons could not be inserted through the respective openings on either side of the housing while also positioning

the string/wire as alleged by Petitioner. *Id.* at ¶159. Likewise, a POSA would understand the second method of assembly to be unduly difficult because the housing and the actuator buttons would block access to the interior of the housing and prevent the positioning of the string/wire in Petitioner's combination. *Id.* at ¶160.

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 member 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 to easily permit positioning of the seal module therethrough. EX2033, ¶¶161-162. Therefore, a POSA would recognize that the substitution of Hartley's string/Eller's wire for Schaffer's U-shaped actuating members is contrary to Schaffer's disclosed method of assembly. *Id.* at ¶¶163-164.

Schaffer also discloses that its U-shaped members are manufactured by means of machining (the controlled removal of material) plastic or metal. EX1005, ¶[0082]; EX2033, ¶165. Schaffer's standard machining methods to manufacture its rigid U-shaped members would not work well with filaments. EX2033, ¶165. 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.*

Regarding durability, Schaffer's construction enables the valve to endure operational demands and maintain its performance and structural integrity over time. EX2033, ¶166. 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.” EX2032, p.46. But even if these methods are optional, it does not mean that a POSA could have manufactured Petitioner's proposed modification via other techniques without undue experimentation. Indeed, while Petitioner's expert provides an alternative manufacturing technique—a tapered fixture—he only provides a single conclusory sentence stating that such a fixture could be used “to introduce a folded/collapsed seal module through the looped strings.” EX1003, ¶87. Petitioner and its expert do not address the inherent floppiness/flexibility of the string/wire that would collapse and not retain a loop form before inserting the tapered fixture. EX2033, ¶162. 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.

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.

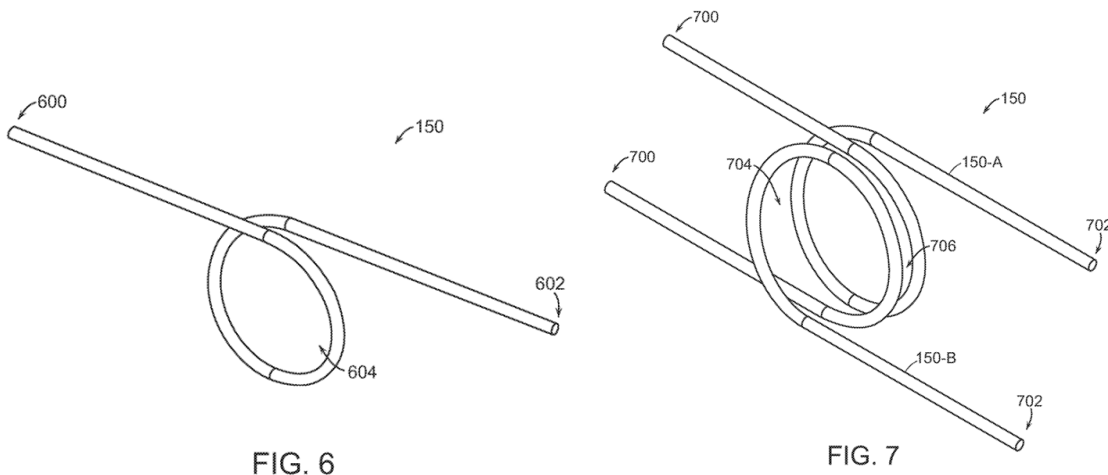
E. The Combinations of Schaffer and Hartley or Eller Further Do Not Render Obvious Dependent Claim 10 Including a "Second Filament"

Dependent Claim 10 narrows independent Claim 1 by requiring that the "filament" and the "actuator" are a "first filament" and a "first actuator," respectively, and further reciting a "second filament" and a "second actuator" configured similarly to Claim 1. But, in Petitioner's proposed combinations of Schaffer and Hartley or Eller, Hartley's *single* string or Eller's *single* wire member extends between Schaffer's two actuator buttons 261. Petition, pp.35-38, 43-44. That is, in those combinations Schaffer's valve includes only one single string or one single wire member and not a "first filament" and a "second filament" as required by Claim 10.

Because of that deficiency, Petitioner first asserts that in its combination of Schaffer and Hartley, Hartley's string 14 is a "first filament" and a "second filament" because "POSITAs would have recognized that Hartley's string 14 encompasses

strings having two or more threads, lines, or cords twisted together and therefore includes at least a first and second filament.” Petition, p.66. Petitioner likewise asserts for their combination of Schaffer and Eller that “POSITAs would have found it obvious to use a wire member made from multiple filaments twisted together (i.e., strands or fibers)” such that the single wire member comprises the recited “first filament” and the “second filament.” *Id.* at p.70.

But even assuming that a POSA would have been motivated to substitute Hartley's single string or Eller's single wire member into Schaffer's valve in the particular manner proposed by Petitioner (which Patent Owner disagrees with for all the reasons set forth above), Hartley's string or Eller's wire member alone does not comprise a “first filament” and a “second filament” as required by dependent Claim 10. First, the '921 Patent discloses in Figure 6 an embodiment including a single filament 150 and in Figure 7 an embodiment including two filaments: a first filament 150-A and a second filament 150-B:



EX1001, 10-17; EX2033, ¶177. Likewise, for the bight embodiments in Figures 8-9, the '921 Patent explains that the “filament 150 can be configured to form ... a single bight or multiple bights,” such as the illustrated first bight 800-A and second bight 800-B. EX1001; 13:23-29; EX2033, ¶177. A POSA would understand based on that disclosure that the “first filament” and the “second filament” require separate first and second filaments as shown in Figures 7-9 rather than a single filament composed of different threads like Figure 6 as Petitioner alleges. EX2033, ¶177.

Moreover, the '921 Patent distinguishes different embodiments in which each filament “can comprise a single strand such as, for example, a monofilament” or “a plurality of strands that can be, for example, twisted, woven, grouped, and/or fused to form the filament.” EX1001, 9:10-15; EX2033, ¶178. That is, the '921 Patent is explicit that a single filament can be a monofilament or it can include a “plurality of strands,” but a single filament does not become both a first and second filament simply because of multiple strands twisted together. EX2033, ¶178. A POSA would further understand based on that disclosure that the “first filament” and the “second filament” require separate first and second filaments (whether formed of multiple strands or a single monofilament) rather than a single filament composed of different threads/strands as Petitioner alleges. *Id.* For those reasons Hartley's string or Eller's wire member (even when inappropriately substituted into Schaffer's valve) do not

comprise a “first filament” and a “second filament” as required by dependent Claim 10. *Id.* at ¶179.

Petitioner then provides an alternative theory of obviousness for Claim 10 alleging that a “rather than replace Schaffer’s U-shaped actuating members with a single string extending from the first actuator to the second actuator, POSITAs would have also found it obvious to replace each U-shaped actuating member with a string” or “would have found it obvious to replace each of Schaffer’s U-shaped actuating members with a wire member.” Petition, pp.68, 70. That is incorrect. EX2033, ¶180.

First, just like a POSA would not have “selected a thin, flexible sheet or flat ribbon of aluminum or plastic to form the actuating members” for the reasons explained above for ground 2, a POSA would not have substituted strings or wire members for Schaffer’s U-shaped actuating members. Petition, p. 33; EX2033, ¶181. Namely, there is no motivation to modify Schaffer to make the U-shaped members flexible (e.g., like Hartley’s string or Eller’s wire member), and such a modification would change Schaffer’s principles of operation and render Schaffer inoperable for its intended purposes of easy manufacturability, durability, and assembly. EX2033, ¶181.

Second, a POSA would understand that in Petitioner’s proposed combinations, the flexible strings or wire members would be able to move laterally

along Schaffer's seal modules when Schaffer's actuator buttons 261 are depressed. EX2033, ¶182. Accordingly, unlike Schaffer's rigid actuating members 55, the two strings/wire members would not maintain their U-shape or their positions relative to one another when the actuator buttons 261 are depressed. *Id.* Thus, contrary to Petitioner, the proposed substitutions would not "yield the predictable result of sealing Schaffer's valve" as the strings/wire members may move in such a way that they do not repeatedly seal. *Id.*; Petition, pp. 69-70. For example, the two strings or wire members might interfere with one another, especially after Schaffer's actuator buttons are depressed one or more times and if the valve were tilted relative to gravity such that one string/wire members moves toward the other along the seal module. EX2033, ¶182. Specifically, when Schaffer's actuator buttons are depressed one of Hartley's strings or Eller's wire members might move underneath the other, potentially reducing the sealing effectiveness of the valve. *Id.* Indeed, Petitioner's proposed arrangement would increase the cost and complexity of the proposed valve without any of Petitioner's proposed advantages. *Id.*

Third, the mechanism of action in Petitioner's proposed substitutions is directly contrary to that of both Hartley and Eller such that the substitutions are not a mere simple substitution. Petition, pp.68-70; EX2033, ¶183 As set forth above, in Hartley the single string 14 has both ends attached to the same rotary actuator 12 such that the two ends of the string are moved away from one another to constrict

when the actuator is actuated and, in Eller, each of the wire members has one end attached to itself or to the housing and the other end attached to the actuator such that one end of the string is moved away from the other when the actuator is actuated. *See* EX1006, ¶[0031]; EX1007, 15:21-40, 17:38-18:8; EX2033, ¶183. In contrast, in Petitioner's proposed combinations, the ends of each of Hartley's strings or Eller's wire members are attached to the same linear actuator such that ends cannot be moved away from one another in the manner taught by Hartley and Eller. EX2033, ¶183. For all those reasons, Claim 10 is also not rendered obvious by the combinations of Schaffer and Hartley or Eller.

VI. THE CLAIMS ARE NOT OBVIOUS OVER HARTLEY IN VIEW OF ELLER (GROUND 5)

Petitioner's proposed combination of Hartley and Eller fails to disclose or render obvious the limitations of the Claims including "a biasing member configured to bias the actuator to the first position."² Petitioner concedes that Hartley does not teach a "biasing member" and asserts that it would have been obvious to a POSA to have included Eller's torsion spring in Hartley to bias Hartley's valve to a sealed

² The Petition does not challenge claims 4, 7-8, 11-14, 19-20 and 25-26 under this ground. Moreover, the Petition fails to address claim 10 under this ground in any way.

position. Petition, pp.81-85. A POSA would not have been so motivated because adding a torsion spring would be contrary to and would change Hartley's principle of operation by obviating its ball-and-detent system and thus rendering that system inoperable for its intended purpose. EX2033, ¶¶184-198.

Hartley's objective is to "provide an access valve which can be controlled to vary the size of the aperture through the valve and be flexible so that a seal may be formed against an instrument." EX1006, ¶[0004]. Hartley achieves that objective through a "detent arrangement" that includes a ball 28 biased by a spring 29 to engage a central recess 34 and end recesses 36 of a housing 6:

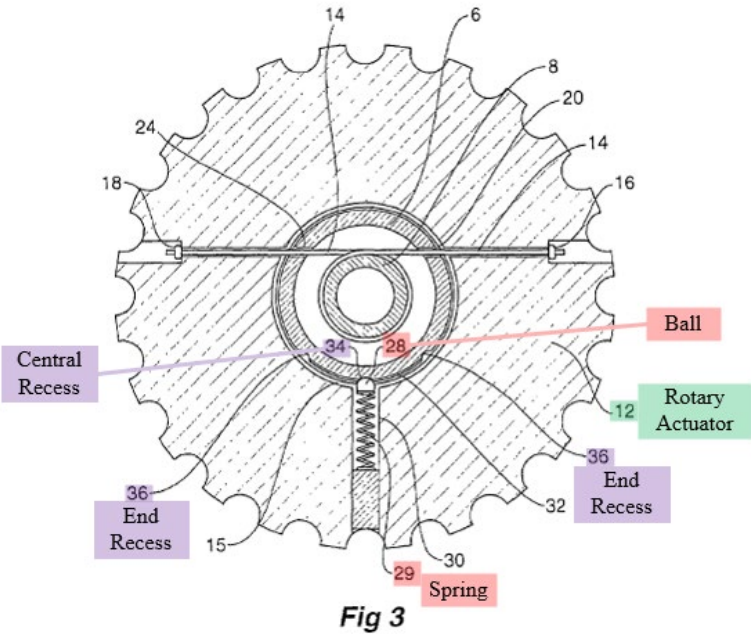


Fig 3

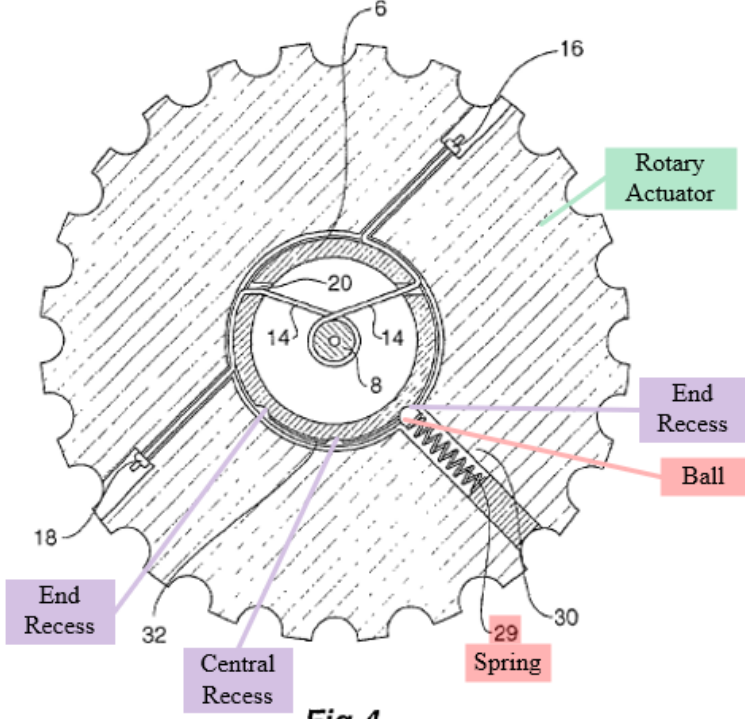


Fig 4

Id. at [0033]; EX2033, ¶187.

The ball-and-detent system *retains* the rotary actuator on the cylindrical housing in a selected position and provides tactile feedback as the rotary actuator is rotated. EX1006, ¶¶[0015], [0018], [0033]; EX2033, ¶¶187-188. Accordingly, the detents provide different locking positions that correspond to different opening sizes for the lumen, and Hartley discloses that additional detents may be provided to allow for additional locked/retained lumen sizes. EX2033, ¶188; EX1006, ¶[0033].

A POSA would understand that modifying Hartley to include Eller's spring "to bias [the] actuator [of Hartley] to a position wherein the lumen of a hemostasis valve is sealed" as proposed by Petitioner (Petition, p.83) would render Hartley's ball-and-detent system inoperable because, by biasing to the closed position, Eller's spring would override the ball-and-detent system and eliminate Hartley's ability to selectively maintain various opening sizes for the lumen—acting to always seal the valve. EX2033, ¶189. For example, Hartley's valve could not be maintained in the open position shown in Figure 3 above in which the ball 28 engages the central recess 34 to maintain the valve in an open position. *Id.*

Further, the pressure exerted by the spring could create significant resistance against any instruments being advanced through Hartley's valve, especially when advancing softer instruments. *Id.* at ¶¶192-198. Accordingly, a POSA would understand that Hartley's ball-and-detent system, which allows for various lumen sizes to be maintained and instruments to be easily advanced, is necessary to

Hartley's principle of operation and that modifying Hartley to include a spring would render that feature inoperable. *Id.*

Petitioner's expert alleges that "Hartley makes clear that the ball and detent are optional features." EX1003, ¶193. Likewise, the Board preliminarily found that the "ball-and-detent system cited by Patent Owner appears to be an optional feature in Hartley." Institution Decision, p.34. But Hartley does not describe the ball-and-detent as optional. EX2033, ¶190. Rather, Hartley's only embodiment includes that arrangement, and Hartley affirmatively states that "[a]s particularly shown in FIGS. 3 and 4 a detent arrangement having a ball 28 loaded by a spring 29 in an aperture 30 in the rotary actuator runs in a groove 32 in the cylindrical housing 6." *Id.*; EX1006, ¶[0033]. In contrast, the same disclosure of Hartley describes when other features are optional: "[t]here **may** also be further recesses or detents between the central recess and the end recesses." *Id.* (emphasis added). Petitioner's citation to the use of "may" for optional inclusion of using the ball/detent for tactile feel, simply means just that, that the system can optionally be used for tactile feel, not that the system is optional. EX1006, ¶18 ("The rotary actuator may have a tactile indication of its action by means of...").

Petitioner also argues that "Hartley's detent mechanism ... would offer benefits even with a torsion spring because it would provide 'tactical [sic] feedback' as the user opens the valve." Petition, p.85. But, even if so, that ignores that

Petitioner's modification would render Hartley's ball-and-detent arrangement completely inoperable for its intended purpose of retaining the rotary actuator in position and thereby maintaining the valve in a selected valve state (open, partially open) as explained above. EX2033, ¶191. And, as Petitioner's expert, Mr. Thornton testified, the Hartley's ball-and-detent system has several purposes including to retain the rotary actuator in position. EX2035, 35:14-22.

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

VII. CONCLUSION

For the reasons set forth herein, Petitioner has failed to demonstrate that any of Claims 1-7, 9-10, 15-18, or 20-24 are unpatentable over Grounds 1-5.

Respectfully submitted,

Dated: January 15, 2026

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 RESPONSE** contains 13,932 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: January 15, 2026

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 January 15, 2026, a copy of **PATENT OWNER'S RESPONSE and EXHIBITS 2033-2035** were served upon the below-listed counsel by electronic mail:

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