

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

IMPERATIVE CARE, INC.,
Petitioner,

v.

INARI MEDICAL, INC.,
Patent Owner.

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

PATENT OWNER'S SUR-REPLY

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EXHIBIT LIST

	Petitioner's Exhibits
Exhibit	Description
1001	U.S. Patent No. 11,697,012 (“the ’012 Patent”)
1002	’012 Patent Prosecution History Excerpts
1003	Expert Declaration of Troy Thornton
1004	Resume of Troy Thornton
1005	U.S. Patent Publication US 2003/0225379 A1 to Schaffer et al. (“Schaffer”)
1006	U.S. Patent Publication US 2003/0116731 A1 to Hartley (“Hartley”)
1007	U.S. Patent No. 9,980,813 B1 to Eller (“Eller”)
1008	Drawings Submitted During Prosecution of U.S. Patent Application No. 10/371,190
1009	U.S. Patent No. 5,429,616 to Schaffer (“Schaffer ’616”)
1010	U.S. Patent Publication US 2011/0144592 A1 to Wong et al. (“Wong”)
1011	U.S. Patent Publication US 2015/0173782 A1 to Garrison et al. (“Garrison”)
1012	U.S. Patent No. 9,216,277 B2 to Myers (“Myers”)
1013	Dorland’s Illustrated Medical Dictionary, 32nd ed. (2012) - Definition of “Catheter”
1014	U.S. Patent No. 4,723,550 to Bales et al.
1015	U.S. Patent No. 5,895,376 to Schwartz et al.
1016	U.S. Patent No. 12,109,384 B2 to Merritt et al.

	Petitioner's Exhibits
Exhibit	Description
1017	Order Denying Motion for Preliminary Injunction (Dkt. #136) in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 24-cv-03117-EKL (N.D. Cal.) (issued September 29, 2025)
1018	Decision Granting Institution of IPR, IPR2025-00289, U.S. Patent No. 11,554,005 B2
1019	Deposition Transcript of PO's Expert Paul Zalesky, Ph.D. dated June 23, 2025
1020	Supplemental Expert Declaration of Troy Thornton Submitted as Exhibit 1014 in IPR2024-01157, involving U.S. Patent No. 11,697,011
1021	Deposition Transcript of PO's Expert Paul Zalesky, Ph.D. dated August 27, 2025
1022	U.S. Patent No. 11,697,011 ("the '011 patent")
1023	New Oxford American Dictionary, 3rd ed. (2010) – definitions of "diameter," "filament," and "loop"
1024	Merriam-Webster's Collegiate Dictionary (11th ed. 2014), submitted by Patent Owner as Exhibit 2009 in IPR2024-00157

	Patent Owner's Exhibits
Exhibit	Description
2001	Declaration of Paul J. Zalesky
2002	Merriam-Webster's Collegiate Dictionary (11th ed. 2014)
2003	New Oxford American Dictionary (3rd ed. 2010)
2004	U.S. Patent Application Publication No. 2018/0193043
2005	Deposition Transcript of Troy Thornton (September 30, 2024)
2006	Deposition Transcript of Troy Thornton (March 19, 2025)
2007	Deposition Transcript of Troy Thornton (June 25, 2025)
2008	Supplemental Declaration of Paul J. Zalesky
2009	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)
2010	Errata to Paul J. Zalesky, Ph.D. deposition transcript, dated August 27, 2025
2011	Declaration of Troy L. Thornton in Support of Inter Partes Review of U.S. Patent No. 11,697,011
2012	Declaration of Troy Thornton in Support of Opposition to Plaintiff's Motion for Preliminary Injunction
2013	Deposition Transcript of Troy Thornton (August 15, 2025)
2014	Deposition Transcript of Troy Thornton (November 20, 2025)

I. INTRODUCTION

Petitioner has failed to demonstrate that any one of Claims 1-9 of the '012 Patent are unpatentable. Regarding grounds 1-2 that rely on Schaffer alone, Petitioner has failed to demonstrate that Schaffer discloses the “filament” recited in the sole independent Claim 1, specifically a flexible one, much less a filament that is “formed into a loop around the collapsible tubular sidewall” wherein “a diameter of the valve lumen decreases in response to reducing a diameter of the loop,” a structure that necessitates flexibility. As explained in the Patent Owner Response (“POR,” Paper 12), the term “filament” means “a thin, **flexible** length of material formed by one or more strands of material.” POR, pp.22-30. The Board agreed that “flexibility is necessary.” Paper 6, p.15. Schaffer’s U-shaped actuating members are rigid, not flexible. *Id.* at pp.34-35. For that reason, Schaffer does not disclose the “filament” as recited in Claim 1. Moreover, Schaffer also does not disclose any structure that is “formed into a loop,” or having a diameter that can be reduced as also recited in Claim 1. POR, pp.36-41.

Grounds 3-7, relying upon a combination of Schaffer and optionally Garrison with Hartley or Eller, also fail. Petitioner’s alleged reason to modify Schaffer’s valve to incorporate Hartley’s string or Eller’s wire is pure hindsight, motivated only by reference to the claims. *Infra*, §III.A. Specifically, the embodiment shown in Figures 30-34 of Schaffer (the embodiment relied upon by Petitioner) seals completely and

without gaps by virtue of including “a third seal member” that “is so compliant that it forms a seal around” different instruments. EX1005, ¶¶[0068], [0075], [0081]. Because Schaffer’s valves—including the embodiment relied upon by Petitioner—seal completely, Petitioner’s motivation to modify Schaffer (the presence of gaps) is nonexistent and contrary to Schaffer’s disclosure. Only by removing that seal member from Schaffer would the purported problem that requires modifying Schaffer (gaps) potentially exist, but a POSA would not have removed the seal member against Schaffer’s teachings. EX2008, ¶116. Petitioner has not met its burden to show a “skilled artisan would have been motivated to combine the teachings.” *Axonics, Inc. v. Medtronic, Inc.*, 73 F.4th 950, 957 (Fed. Cir. 2023).

Grounds 3-7 also fail because Petitioner’s proposed modification replacing Schaffer’s members with Hartley’s string or Eller’s wire and then further modifying the combination is not a simple substitution *Infra*, §III.B. Petitioner’s proposed combination requires a single string/wire be controlled by two independently operable actuators. Petition, pp.43-44, 51-52. But, as admitted by Petitioner’s expert, none of the applied references disclose such an arrangement, instead each have a single actuator controlling, respectively, a single U-shaped member (Schaffer), string (Hartley), or wire (Eller). EX2007, 57:7-22 (Schaffer), 77:12-22 (Hartley), 80:11-19 (Eller). That fundamental difference between the prior art and Petitioner’s proposed combination is not a substitution at all, let alone a simple one.

Grounds 3-7 further fail because the solutions for constricting a tubular member in a hemostasis valve were not finite, identifiable, or known. *Infra*, §III.C. Petitioner argued there were three options for “constricting a tubular member in a hemostasis valve,” but Petitioner’s expert has now admitted that there were many more ways, including unknown and unconsidered ways, to do so. Petition, p.43; EX2007, 107:3-13. Petitioner therefore has failed to demonstrate that “the options and solutions [were] identified and known.” *Tech. Co., Inc. v. Polaris Innovations Ltd.*, IPR2016-01623, 2018 WL 851884, at *5 (P.T.A.B. Feb. 9, 2018). For this reason, Petitioner’s apparent “obvious to try” rationale fails.

For those and the other reasons set forth below, Petitioner has failed to demonstrate that any of Claims 1-9 are unpatentable under any of grounds 1-7.

II. CLAIM 1 IS NOT ANTICIPATED BY OR OBVIOUS OVER SCHAFFER (GROUNDS 1-2)

Schaffer does not disclose or render obvious the claimed filament, let alone a “first filament formed into a loop around the collapsible tubular sidewall” wherein the “diameter of the valve lumen decreases in response to reducing a diameter of the loop,” as required by claim 1.

A. The Term Filament Requires Flexibility

The claim term “filament” is properly construed as “a thin, flexible length of material formed by one or more strands of material.” POR, pp.22-30. This is consistent with the plain and ordinary meaning of the term “filament” and with the

Board's position in the Institution Decision, in which the Board observed that "flexibility is necessary" for the filament to form a loop and reduce in diameter as claimed. p.15.

Petitioner's expert admitted that the plain meaning of filament includes flexibility. EX2005, 123:1-3. Thus, Petitioner must meet the high burden of showing that the '012 Patent clearly and ambiguously redefined the term "filament" to omit the requirement of "flexibility." *Kyocera Senco Indus. Tools Inc. v. Int'l Trade Comm'n*, 22 F.4th 1369, 1378 (Fed. Cir. 2022); *see also Hill-Rom Services, Inc. v. Stryker Corp.*, 755 F.3d 1367, 1371 (Fed. Cir. 2014) (internal citations omitted) ("We depart from the plain and ordinary meaning of claim terms based on the specification in only two instances: lexicography and disavowal...The standards for finding lexicography and disavowal are exacting."). Petitioner has not provided any basis to depart from the plain meaning, particularly for claims that recite a loop structure requiring flexibility.

First, Petitioner's argument that the filament should not be construed as requiring flexibility because "the claims encompass the 'bight' embodiments" is wrong. Paper 17, pp.15-18. Claim 1 expressly recites that each filament is "formed into a loop." And the '012 Patent describes the "loop" configurations (Figures 6-7) and the "bight" configurations (Figures 8-9) as distinct embodiments. Paper 17, p.16. To put it simply, a "bight" is not a "loop." The Board agreed, noting that "the

Specification describes [loops and bights] separately—using different terminology to describe how loops and bights are formed....” Paper 6, p.18. Petitioner’s annotations to Figures 8 and 9 does not change that the intrinsic evidence clearly demonstrates that the claimed “loop” embodiment does not encompass a structure with only “bight(s).” And as the Board recognized, for the “loop” embodiments, “flexibility is necessary.” Paper 6, p.15.

A POSA would also readily understand the degree of “flexibility” in a manner that does not inject ambiguity into the claims. POR, pp.29-30. For example, while flexibility exists along a spectrum, a POSA would readily understand the flexibility required for the claimed filament to constrict a hemostasis valve as described in the ’012 Patent. EX2008, ¶74. Despite Petitioner’s assertion otherwise, Mr. Zalesky’s testimony at deposition confirms this (Question: “How would a person of ordinary skill in the art go about determining whether a given material is compliant enough to be a filament?” Answer: “Primarily trial and error...[to assess] its coaptability or its adaptability to a structure it’s circumscribing and its coaption to the external surface of the structure.”). EX1019, 103:14-104:8. Thus, Mr. Zalesky’s testimony, in which he did not answer whether a hypothetical metal structure could be a “filament,” does not inject ambiguity into the term “filament,” but rather reflects that neither the structure, nor any other aspect of a hemostasis valve employing that structure, was available to enable Mr. Zalesky to assess whether such structure

would be a “filament” as claimed. In other words, Petitioner's hypothetical was incomplete.

Petitioner's expert has also agreed that whether a filament is flexible could be readily determined:

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

MR. THORNTON: I think a person skilled in the art would be able to engineer the right balance of material properties for the filament, the compression tube, or tubular sidewall, the springs, et cetera, in order to make the design work well.

EX2007, 38:22-39:7. In sum, a POSA could readily determine how flexible the filament need be for the hemostasis valve to function as claimed in the '012 Patent.

B. Schaffer does not Disclose Flexible Actuating Members.

Schaffer's actuating members are rigid. POR, pp.34-45; EX2008, ¶¶81-88; Paper 6, p.32. Petitioner's supplemental argument that Schaffer's actuating members would anticipate the claimed filament even under Petitioner's construction because “Schaffer's actuating members are not rigid” is therefore wrong. Paper 17, pp.22-25. As Patent Owner has explained, Schaffer's U-shaped actuating members are necessarily rigid because, *e.g.*, they are designed to “forcibly disengage” to open and forcibly pinch to close the seal module, and are manufactured by machining or

injection molding. POR, pp.34-35. The Board agreed in the Institution Decision. Paper 6, pp.32-33. And Petitioner's expert admitted that "[t]he material properties of the U-shaped actuating members are not clearly defined in the Schaffer application." EX2006, 115:16-23. As such, Schaffer cannot anticipate claim 1. POR, pp.34-35.

C. Schaffer does not Disclose a Filament Formed into a Loop or Reduce in Diameter.

Schaffer's rigid actuating members are U-shaped, side-by-side, and designed to retain their shape during operation and as such do not disclose the claimed "loop" or a reduction in diameter of that loop. POR, pp.41, EX1005, ¶[0076]; EX2008, ¶¶89-97. Petitioner relies upon the '012 Patent's "bight" embodiments to allege that Schaffer's two U-shaped actuating members collectively form a "loop." Paper 17, pp.26-27. Such reliance is improper—as set forth above in Section II.A., 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. They are not. Moreover, as opposed to the embodiment of Figure 8 and 9 with interlocking bights, Schaffer's U-shaped members are side-by-side and thus, even if taken together, do not for a loop that can reduce in diameter.

III. CLAIM 1 IS NOT OBVIOUS OVER SCHAFFER AND HARTLEY OR ELLER (GROUNDS 3-4)

A. Petitioner's Alleged Motivation to Modify Schaffer's Valve Does Not Exist.

Petitioner's asserted motivation to modify Schaffer's valve to remove the rigid U-shaped members and replace them with a wire/string is inadequate and contrary to Schaffer because Schaffer's valve already solves the purported goal motivating the modification—sealing without gaps.

First, Figures 30-34 of Schaffer—the embodiment relied upon by Petitioner—include Schaffer's seal member 165, just like every other embodiment of Schaffer. POR, pp.44-45; *see also* EX2008, ¶¶58, 109. At deposition, Petitioner's expert agreed that the seal member 165 is included in every illustrated embodiment in Schaffer: Schaffer Embodiment: Figures 1-4 (EX2007, 69:12-70:3), Schaffer Embodiment: Figures 5-19 (*id.* at 70:5-71:23), Schaffer Embodiment: Figures 20-22 (*id.* at 71:24-72:19), Schaffer Embodiment: Figures 23-26 (*id.* at 72:20-73:2), Schaffer Embodiment: Figure 27 (*id.* at 73:3-5), Schaffer Embodiment: Figures 28-29 (*id.* at 73:6-9), and Schaffer Embodiment: Figures 30-34 (*id.* at 73:13-77:3). Petitioner's unsupported assertion that the seal member is not required does not rebut this. Paper 17, p.34.

Second, the presence of the seal member in Figures 30-34 means this embodiment seals without gaps across a wide range of tool/device diameters and

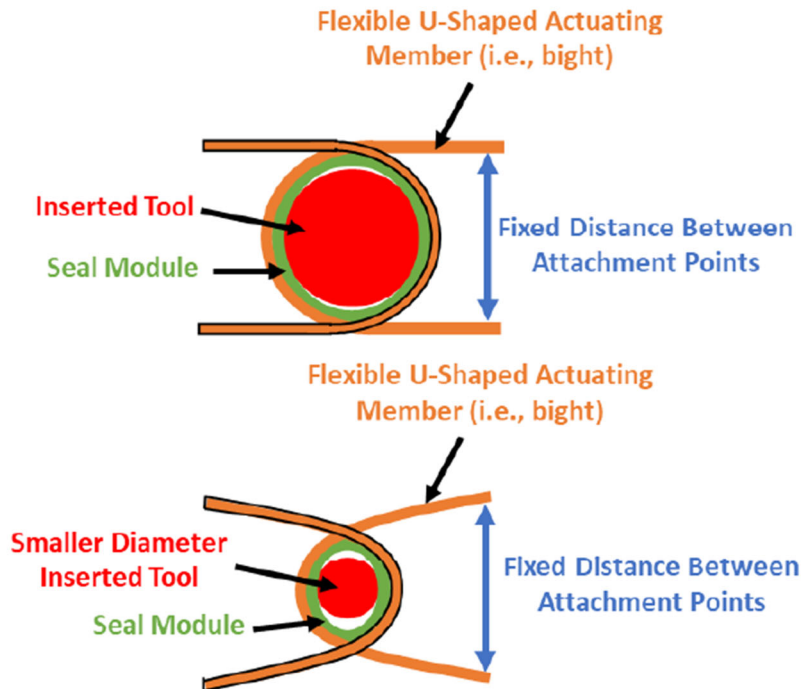
shapes. POR, pp.45-47; EX2008, ¶109. The seal member 165 seals completely by being highly compliant to conform to different shapes. EX2008, ¶¶110-111; EX1005, ¶[0060] (“the highly compliant third central seal member 165 seals around a variety of profile shapes 192 and diameters 194 of the lumen”), ¶[0068] (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.”). Indeed, sealing without gaps is an express purpose of Schaffer, which 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 within the gas/fluid path.” EX1005, ¶¶[0006], [0008]. A POSA would have understood that Schaffer's valves—including the embodiment in Figures 30-34—are designed to do just that via the highly compliant seal member 165. EX2008, ¶¶134-36.

Petitioner mischaracterizes Dr. Zalesky's testimony to allege that Dr. Zalesky could not support that Schaffer's seal member 165 seals without gaps. Paper 17, pp.4-5. Petitioner repeatedly asked Dr. Zalesky incomplete hypotheticals at deposition, and relied upon Dr. Zalesky's lack of opinion about such incomplete hypotheticals to support that Schaffer's seal member 165 does not form a seal in

various situations. EX1021, 131:17-135:24; Paper 17, p.4-5. But Dr. Zalesky did **not** testify that the seal member 165 would fail to seal or would introduce gaps, even around multiple or irregular instruments. Indeed, at deposition Dr. Zalesky specifically referenced his Supplemental Declaration in response to a question about whether the size of the instrument could result in leakage. EX1021, 135:7-9. And, in his Supplemental Declaration, Dr. Zalesky explains that “a POSITA would understand that Schaffer’s valve is explicitly designed to—and does—seal effectively and completely (i.e., without gaps) in the presence of a wide range of instruments, or without any instruments inserted therethrough.” EX2008, ¶108. Indeed, Schaffer itself explicitly states this: “the highly compliant third central seal member 165 seals around a variety of profile shapes 192 and diameters 194” and “the material 166 of the third central seal member 165 is so compliant that it forms a seal around [multiple instruments] 260 [inserted therethrough] even if the instruments 260 are irregularly shape.” EX1005, ¶¶ [0060], [0068].

Petitioner’s made-up graphics showing purported gaps do not refute Schaffer’s express disclosure that its valves seal. The graphic in Petitioner’s reply, reproduced below, shows at most a schematic representation of a generic seal module and does not reflect how Schaffer’s seal module would actually work because it does not include the “seal member [that] ‘is so compliant that it forms a

seal” around all types of instruments—a fundamental feature of Schaffer’s seal module as recognized by Petitioner. Paper 17, pp.5-6.

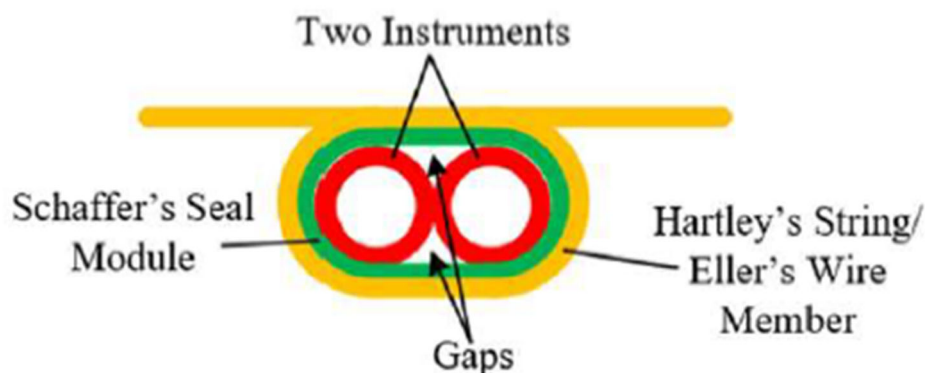


Id. at 25. If Petitioner’s cartoon included Schaffer’s highly-compliant seal member which Schaffer includes as part of the embodiment Petitioner’s cartoon is based on, then there would be no gaps. EX2008, ¶¶110-13. And without gaps, Petitioner’s alleged motivation to modify Schaffer is non-existent.

Moreover, in a related Petition, Petitioner (citing its same expert here) asserted the opposite, namely, that a POSA would have simply changed the material for each U-shaped actuating member to make it flexible because “such members would have had the flexibility to conform to the outer surface of the cylindrical seal module.” IPR2024-01157, Pet. at 32 (citing [EX2011], ¶75). But because that modification

does not meet the claim limitations or support Petitioner's proposed combination, on Reply Petitioner and its expert reverse course and argue the opposite, that one would not replace each member and instead would only substitute a single string or wire in a configuration not found in any reference. Petitioner and its expert's conclusory and contradictory arguments are not credible and demonstrate hindsight.

Even Petitioner recognizes that its cartoons (unjustifiably) excise Schaffer's compliant seal module demonstrating that Petitioner's proposed combination does not improve, and in fact decreases, Schaffer's ability to seal. A POSA would not be motivated to make such a modification that degrades Schaffer's design. For example, when discussing Patent Owner's figure reproduced below with a similarly simple construction, Petitioner states "[t]he cartoon...reflects a non-compliant seal that does not conform to the instruments...[t]hus, the cartoon does not evidence that Schaffer's valve would work less effectively...." Paper 17, p.6.



Schaffer discloses a valve that seals without gaps by virtue of the highly-compliant seal member. EX2008, ¶¶108-11. Only by removing Schaffer's compliant seal member would Petitioner's purported gaps potentially exist—but a skilled artisan would not have had any reason to remove that compliant seal member. *Id.* at ¶116.

And even if a POSA had removed the compliant seal member to, for some reason, make Schaffer's valve leak (they would not have), Petitioner's proposed solution of using Hartley's string/ Eller's wire would not address the gaps. As demonstrated by Patent Owner's above graphic, a combination of Schaffer and Hartley/ Eller that omitted Schaffer's compliant seal member would not seal completely without gaps around multiple instruments and/or irregularly-shaped instruments—scenarios for which Schaffer's valve is designed to form a complete seal. POR, pp.52-53. Indeed, without Schaffer's compliant seal member, Schaffer's valve would have gaps regardless of whether rigid U-shaped actuating members or a string/wire were used. EX1020, ¶35 (“Because of the non-compliant seal depicted in the illustration, the same gaps would exist with U-shaped actuating members”); EX2013, 16:15-23. In other words, including a filament in Schaffer does not rectify the issues created by removing the compliant seal member. To seal completely without gaps, a POSA would need to reintroduce Schaffer's disclosed solution—the

compliant seal module, rendering the petition's proposed modifications to Schaffer superfluous and disadvantageous. *Id.*

Thus, because Figures 30-34 include the seal member 165 and that seal member forms a complete seal without gaps, Petitioner's alleged problem (gaps) does not exist. As a result, there would have been no motivation to modify Schaffer in the manner advanced by Petitioner: "[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*, IPR2018-00701, 2018 WL 4090629, at *4 (P.T.A.B. Aug. 27, 2018), citing *In re Schweickert*, 676 F. App'x 988, 995-996 (Fed. Cir. 2017) (emphasis added). For example, Petitioner's expert admitted at deposition that if Schaffer forms a complete seal, there would be no need to modify Schaffer's actuating members. *See* EX2006, 116:18-117:2. That is the case here—Schaffer's valve seals for the range of tools by virtue of the compliant seal member 165. According to even Petitioner's expert, in that instance a POSA would not have been motivated to modify Schaffer to incorporate Hartley's string or Eller's wire. Which would degrade the seal and negate all the advantages of Schaffer's design including rigid U-shaped actuating members.

As a hedge, for the first time in reply Petitioner then apparently tries to circumvent the fact that Schaffer does not form "gaps" by arguing that "PO never explains why this hyper 'compliant' seal would not work equally well with Hartley's

string or Eller's wire." Paper 18, p.6. But, if the highly-complaint seal member was included there would be no reason to substitute Hartley's string/ Eller's wire in the first instance. In fact, Schaffer's rigid U-shaped actuating members would result in a better seal than a string or wire as Petitioner proposes, first because "a harder material would be able to deform a softer material more readily" (EX2007, 36:11-12), and second because Schaffer's U-shaped members would be more likely to deform more of the highly-complaint material to fill in any gaps than a string/wire disclosed in Hartley and Eller because the rigid U-shaped members would have a greater contact area, and thus compression area, with the seal module, all while maintaining the multiple advantages of Schaffer's rigid U-shaped members. (Compare EX2007, 40:11-16, 41:15-24 with 43:2-8).

And as explained below, the proposed modification to use a string/wire in Schaffer would require wholesale changes to Schaffer's express method of manufacturing its U-shaped members and assembling its valve and would reduce reliability and control. EX2008, ¶¶143-54. A POSA would not have made Petitioner's proposed modification and introduced all those disadvantages, particularly where the modification would not even remedy Petitioner's non-existent issue.

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

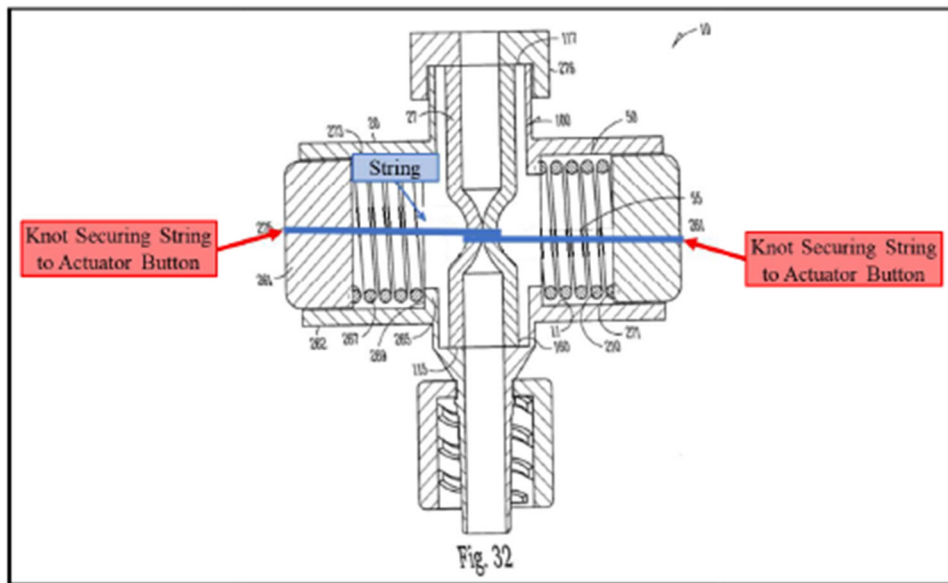
Petitioner's "simple substitution" rationale for modifying Schaffer's U-shaped members is also wrong. Paper 18, p.12. First, the cited references do not disclose all of the limitations of Claim 1. For example, none of Petitioner's references disclose a single wire/string including two ends attached to and controlled by different independently movable actuating members. EX2008, ¶¶131-40. Petitioner's expert agrees. EX2014, 55:22-56:7.

Thus, instead of involving a simple substitution, Petitioner's proposed combination requires additional modifications, including:

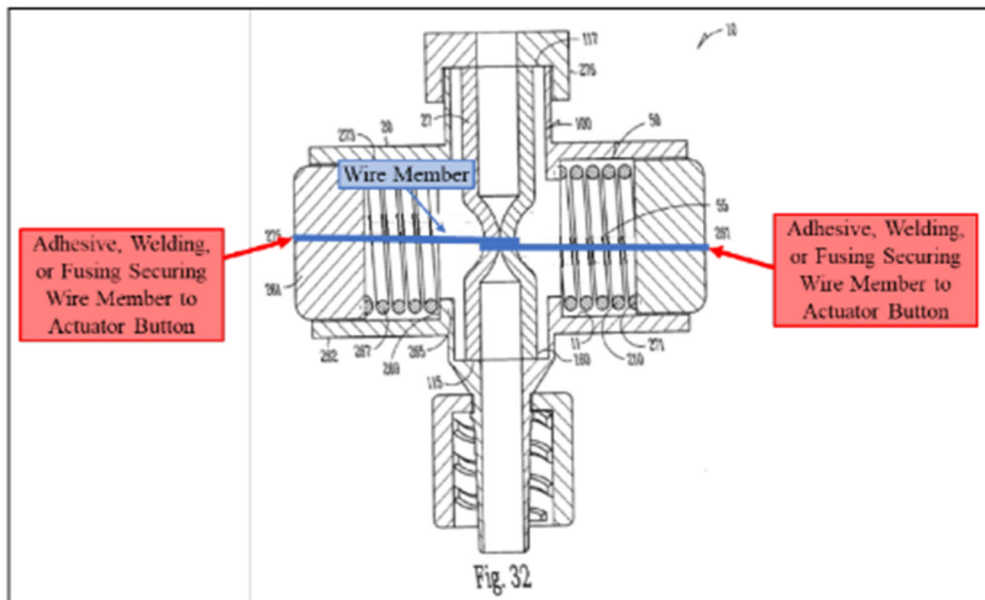
- (1) Removing **both** of Schaffer's U-shaped actuating members that are independently coupled to different actuators;
- (2) Replacing Schaffer's U-shaped actuating members with a **single** string/wire; and
- (3) Coupling the ends of the **single** string/wire to two **different** actuators, rather than the same one.

Petition, pp.43-44, 51-52. In that combination, each of Schaffer's actuator buttons independently control movement of one end of the string/wire, as shown in Petitioner's demonstrative illustrations:

Demonstrative Illustration
Schaffer + Hartley's String



Demonstrative Illustration
Schaffer + Eller's Wire Member



Id. at pp.44, 53. Thus, Petitioner's arrangement including a string/wire having two ends attached to two separate and independently movable actuators was not a "known element" and instead is pure hindsight based on the claims. EX2008, ¶141.

Petitioner does not explain why this additional modification would be obvious or why a POSA would make that particular modification other than that is what the claims require and the '012 patent discloses. For example, at best for Petitioner, a simple substitution would be to simply replace each of Schaffer's rigid U-shaped members with a string or wire and that is exactly what Petitioner and its expert asserted that a POSA would do in a related Petition. *See, e.g.*, EX2011, ¶75. Yet here in Reply, Petitioner and its expert argue the opposite, that a POSA would not have replaced each rigid U-shaped member with a string or wire and instead come up with a new configuration not found in the prior art at all, again based on the imaginary gaps. Reply, p.21 (citing EX1020, ¶34). That flip-flop in Reply is not credible and demonstrates impermissible hindsight using the claims as a roadmap.

Moreover, Petitioner's expert attempts to mask his hindsight bias by opining that string or wire was a known substitute for Schaffer's rigid U-shaped members. First, whether or not it was a known substitute does not motivate a POSA to follow the claimed arrangement of attaching a single string/wire to two independent actuators—that requires hindsight using the claims as a roadmap. And second, 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. EX2014, 14:1-11. Petitioner's expert had no familiarity at all with using a string or wire in a hemostasis valve until seeing the '012 patent (or related patent), or observing Petitioner's accused product in connection with a co-pending related litigation. EX2014, 16:11-17:5. Even now, Petitioner's expert has not 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. EX2014, 15:16-23. His after-the-fact testimony that the two were known and simple substitutes prior to the '012 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* at 1397.

As such, Petitioner has failed to show that the claimed arrangement existed in the prior art, let alone provide a reason to modify the references to include that arrangement. Even if the arrangement existed generally that would not provide a motivation to combine Schaffer with Hartley or Eller in the ways Petitioner asserts. *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.)

Second, a POSA would not have been motivated to substitute Hartley's string/eller's wire for Schaffer's U-shaped members because a POSA would understand there are comparably more plausible substitutions—some even admitted by Petitioner—that would not require departing from Schaffer's principles of operation and yet would still maintain all the advantages of Schaffer that are lost with Petitioner's proposed modification. *R.J. Reynolds Vapor Co. v. Fontem Holdings I B.V.*, IPR2016-01268, Paper 63, at 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.*, 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 provides no reason why a POSA would chose the claimed solution over the myriad of other options, including other configurations using a string or a wire.

When addressing Schaffer's alleged disclosure of Claim 5, Petitioner states there are a number of comparably simpler ways Schaffer itself discloses to maintain

or improve its seal. For example Schaffer discloses “adjusting Schaffer’s spring strength to apply additional force, adjusting the resilience and compressibility of the seal module that forms the valve’s lumen, and/or adjusting the shape...and/or dimensions of the actuating members to more closely conform to the shape of the seal module and any tool(s) inserted therethrough.” Petition, p.71. Both Parties’ experts agree that these simple adjustments would work, whether or not there was a pressure differential across the valve. EX2007, 121:21-122:12; EX2008, ¶¶158-60.

Petitioner’s expert also testified that he did not consider yet other potential plausible substitutions, such as replacing each of Schaffer’s U-shaped actuating members with separate strings/wires or using a single string attached to two buttons:

QUESTION: You didn’t consider any of those other configurations; is that correct?

MR. THORNTON: Which other configurations are you talking about?

QUESTION: For example, two U-shaped strings.

MR. THORNTON: Yeah, I’ve said **my declaration didn’t include replacing those with two U-shaped strings.**

QUESTION: Another example would be a single string that is attached on one end to a button, wraps all the way around a tubular member, and then is attached back to the same button at the other end. You didn’t consider that option as well; is that right?

MR. THORNTON: **I did not consider that.**

EX2014, 41:17-42:5. Both of those combinations that Petitioner did not consider would require less of a departure from Schaffer's original design than the combination Petitioner proposes. But instead of considering those comparably simpler substitutions, Petitioner immediately jumped to the combination that suited them—the embodiment disclosed and claimed in the '012 Patent. Such leap cannot be a simple or know substitution and instead is grounded in impermissible hindsight.

Third, Petitioner's proposed combination would not yield the predictable result of sealing Schaffer's valve and is not suitable for sealing around multiple/irregularly-shaped instruments (POR, pp.52-53; EX2008, ¶118), both of which are express purposes of Schaffer's valve. EX1005, ¶¶[0006]-[0008], [0060], [0068]. For this reason alone, Petitioner's proposed substitution is not simple or even desirable. *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.'). A POSA would understand the results of substituting Hartley's flexible string/Eller's flexible wire for Schaffer's rigid actuating members to be unpredictable. EX2008, ¶87. That unpredictability is exacerbated by Petitioner's proposed modification because Hartley and Eller—the only references that disclose a flexible member—precisely control movement of that flexible member with a **single** movable actuator. EX2008, ¶¶135-39. In Petitioner's combination, the

movement of the string/wire would not be precisely controlled in that manner by a single actuator because either of Schaffer's buttons could be depressed independently to move the string/wire unpredictably. *Id.* at ¶141.

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.

C. Petitioner Fails to Establish There Were Finite, Identified and Known Solutions for Constricting a Tubular Member in a Hemostasis Valve.

Petitioner also advances what appears to be an "obvious to try" rationale for substituting Hartley's string/Eller's wire for Schaffer's U-shaped members. Petition, pp.43, 50; *see KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007) (discussing "obvious to try," and stating "[w]hen there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp."). To reach a determination that the claimed invention would have been obvious to try, "the possible approaches and selection to solve the problem must be 'known and finite.'" *Rolls-Royce, PLC v. United Techs. Corp.*, 603 F.3d 1325, 1339 (Fed. Cir. 2010) (citing *Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341, 1351 (Fed. Cir. 2008)). "The important question is whether the invention is an

‘identified, predictable solution’ and an ‘anticipated success.’” *Id.* (citing *Abbott Labs.*, 544 F.3d at 1352). “Thus, it is not enough for there to be a finite number of solutions, **the options and solutions must have been identified and known.**” *Kingston Tech. Co., Inc. v. Polaris Innovations Ltd.*, 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 the lumen of a tubular member in a hemostasis valve” were finite, identified, and known. Petition, p.43. Petitioner proposes only three options: “Hartley and Schaffer disclose two such materials: Hartley’s string and Schaffer’s actuating members formed from metal or plastic ... Eller discloses a third option: one or more wire members.” *Id.*; EX1003, ¶102. But at deposition, Mr. Thornton admitted that there were many more than just three ways to constrict a tubular member in a hemostasis valve, including those disclosed in Schaffer ’616 (EX2007, 105:24-106:4, 106:12-14), Wong (*id.* at 106:15-19), Kees (*id.* at 108:14-20, 110:7-19), Myers (*id.* at 111:9-23), his previous work on a hemostatic-type clamp prototype (*id.* at 106:20-24), and more (*id.* at 112:5-114:24). In fact, Petitioner’s expert admitted that he did not know how many options exist:

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

[Objection]

MR. THORNTON: Could be other ways that exist.

QUESTION: How many other?

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

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

[Objection]

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

EX2007, 107:2-13 (emphasis added). And, as explained above in §III.B., Petitioner's proposed combination that requires a single flexible string/wire connected to two independent actuator buttons was not known at all from Petitioner's art. Petitioner's "obvious to try" argument fails for this reason alone—the options and solutions for compressing a tubular member in a hemostasis valve were not "known," "finite" or "identified" as confirmed by Petitioner's own expert.

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

In addition to the reasons set forth in the POR, and regardless of whether Petitioner's proposed combination of Schaffer and Hartley/Eller includes or omits the seal-effectuating highly-compliant sealing member, there is no reason a POSA would have included the modified arrangement of Hartley's string/Eller's wire in

Schaffer's valve because neither would have improved Schaffer's sealing and instead may even have sealed less effectively. *Supra*, §III.A. And because Petitioner's proposed combination would not have improved sealing, a POSA would have had no reason to have deviated from Schaffer's advantageous mode of operation, and express methods of manufacturing the U-shaped members and assembling the device. *Id.* Schaffer's express purpose is to provide a device that seals yet provides a balance of "closing force, opening force, friction, compression and durability" so as not to damage or allow the insertion of delicate instruments and catheters and to allow a user to manipulate and advance those tools while compression is applied and the valve is sealed. EX1005, ¶[0007]; EX2013, 60:20-61:15. Schaffer's rigid compression members and highly compliant internal seal member accomplish that purpose by, e.g., sealing "under very light compression." EX1005, ¶[0059]. Petitioner's proposed combination ignores that express purpose and fundamentally changes how Schaffer seals. A POSA would not make such a modification contrary to Schaffer's express disclosure, particularly where the modification does not improve, and could impair, the seal "in the presence of a wide range of instruments or in the presence of multiple instruments." EX1005, ¶[0006].

IV. CLAIM 1 IS NOT OBVIOUS OVER THE COMBINATION OF SCHAFFER WITH GARRISON, OR OVER THE COMBINATION OF SCHAFFER, GARRISON AND EITHER OF HARTLEY OR ELLER (GROUNDS 5-7)

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

V. CLAIM 2

Claim 2 recites “a second actuator” and that “the filament further comprises a second end portion extending away from the loop in a different direction than the first end portion and connected to the second actuator.” Petitioner cites no reference that discloses a string/wire attached to and controlled by two independently movable actuators, nor provides any reason why it would have been obvious to have modified Schaffer to have such configuration. Grounds 1-7 fail for the reasons set forth in Patent Owner's Response and herein.

VI. CONCLUSION

For the reasons set forth herein, Petitioner has failed to demonstrate that any of Claims 1-9 are unpatentable over Grounds 1-5.

Respectfully submitted,

Dated: December 5, 2025

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

CERTIFICATE OF COMPLIANCE

Pursuant to 37 C.F.R. § 42.24(d), I, Joseph Hamilton, certify that **PATENT OWNER'S SUR-REPLY** contains 5,597 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: December 5, 2025

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

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), I certify that on December 5, 2025, a copy of **PATENT OWNER'S SUR-REPLY, and EXHIBITS 2011-2014** were served upon the below-listed counsel by electronic mail:

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