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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

IMPERATIVE CARE, INC.,
Petitioner,

v.

INARI MEDICAL INC.,
Patent Owner.

Case IPR2025-00289
Patent No. 11,554,005

PETITIONER'S REPLY TO PATENT OWNER'S RESPONSE

TABLE OF CONTENTS

Page No.

I.	INTRODUCTION	1
II.	CLAIMS 1-15 ARE OBVIOUS OVER GARRISON AND SCHAFFER WITH HARTLEY OR ELLER (GROUNDS 2-3)	2
A.	A POSITA Would Have Been Motivated To Substitute Schaffer’s Actuating Members For Hartley’s String Or Eller’s Wire	2
1.	PO Does Not Rebut Petitioner’s Evidence That Hartley’s String Or Eller’s Wire May Seal More Effectively	3
2.	PO Fails To Show That The Combination Changes Schaffer’s “Principles Of Operation”	6
a.	PO Fails To Define The “Principle Of Operation”	7
b.	Hartley’s String Or Eller’s Wire Permit Forcible Disengagement	8
c.	PO Fails To Show The Combination Would Compromise Manufacturing Or Durability	9
3.	The Combination Would Have Been A Simple Substitution Of Known Elements	10
a.	The Combinations Involve Substitution Of Known Elements	10
b.	The Combinations Would Have Been Simple And Predictable	11

TABLE OF CONTENTS
(*cont'd*)

	Page No.
4. A Finite Number Ways Existed To Constrict A Hemostasis Valve.....	12
B. PO Does Not Rebut Petitioner’s Evidence That A POSITA Would Have Combined Schaffer’s Valve With Garrison.....	13
C. Garrison Discloses An On-off Control “In The Flow Path”	15
III. CLAIMS 1-12, 14-15 ARE OBVIOUS OVER GARRISON AND SCHAFFER.....	19
A. Schaffer’s Actuating Members Are A “Filament”	19
1. Schaffer’s Actuating Members Are Not “Rigid”	21
a. PO Misunderstands Schaffer’s Sealing Mechanism.....	21
b. Schaffer’s Exemplary Manufacturing Methods Do Not Require “Rigid” Actuating Members	23
2. Schaffer’s Actuating Members “Circumferentially Constrict” The Tubular Member.....	24
3. Schaffer’s U-Shaped Actuating Members Form A “Loop”	25
B. The Board Should Not Import “Thin” And “Flexible” Into “Filament”	27
1. The Claims Encompass The “Bight” Embodiments.....	27
2. PO’s Construction Renders The Claims Ambiguous	29
3. Dictionaries Do Not Justify PO’s Construction.....	31

TABLE OF CONTENTS
(*cont'd*)

	Page No.
IV. CONCLUSION.....	31

TABLE OF AUTHORITIES

Page No(s).

<i>In re Advanced Cell Diagnostics, Inc.</i> , No. 2023-1063, 2024 WL 3451829 (Fed. Cir. July 18, 2024)	9
<i>Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.</i> , 776 F.2d 281 (Fed. Cir. 1985)	9
<i>Facebook, Inc. v. Windy City Innovations, LLC</i> , 973 F.3d 1321 (Fed. Cir. 2020)	11
<i>Fleming v. Cirrus Design Corp.</i> , 28 F. 4th 1214 (Fed. Cir. 2022)	10
<i>Interval Licensing LLC v. AOL, Inc.</i> , 766 F.3d 1364 (Fed. Cir. 2014)	29
<i>Masimo Corp. v. Apple Inc.</i> , No. 2022-1894, 2024 WL 111647 (Fed. Cir. Jan. 10, 2024).....	10
<i>Micron Tech., Inc. v. Lone Star Innovations, LLC</i> , IPR2017-01561, 2018 WL 6584977 (P.T.A.B. Dec. 12, 2018)	9
<i>Vitronics Corp. v. Conceptronic, Inc.</i> , 90 F.3d 1576 (Fed. Cir. 1996)	16

LIST OF EXHIBITS

Exhibit No.	Description
1001	U.S. Patent No. 11,554,005 (“the ’005 patent”)
1002	Excerpts from the prosecution history of the ’005 patent
1003	Expert Declaration of Troy Thornton
1004	Resume of Troy Thornton
1005	U.S. Patent Publication US 2003/0225379 A1 to Schaffer et al. (“Schaffer”)
1006	U.S. Patent Publication No. 2003/0116731 A1 to Hartley (“Hartley”)
1007	U.S. Patent No. 9,980,813 B1 to Eller (“Eller”)
1008	Drawings Submitted During Prosecution of U.S. Patent Application No. 10/371,190 dated June 18, 2003
1009	U.S. Patent No. 5,429,616 to Schaffer (“Schaffer ’616”)
1010	U.S. Patent Publication US 2011/0144592 A1 to Wong et al. (“Wong”)
1011	U.S. Patent Publication No. 2015/0173782 A1 to Garrison et al. (“Garrison”)
1012	RESERVED
1013	RESERVED
1014	U.S. Patent No. 4,723,550 to Bales et al.
1015	U.S. Patent No. 5,895,376 to Schwartz et al.
1016	U.S. Patent No. 12,109,384 B2 to Merritt et al.
1017	U.S. Patent Application No. 16/117,519 (the “’519 application”)

Petitioner's Reply – Patent 11,554,005
Imperative Care, Inc. v. Inari Medical Inc.

Exhibit No.	Description
1018	U.S. Patent No. 7,775,501 B2 to Kees (“Kees”)
1019	U.S. Patent Publication No. 2016/022041 A1 to Garrison et al. (“Garrison ’741”)
1020	U.S. Patent No. 6,776,770 B2 to Treretola
1021	U.S. Patent Publication No. 2010/0042118 A1 to Garrison et al.
1022	U.S. Patent No. 5,938,645 to Gordon (“Gordon”)
1023	U.S. Patent Publication No. 2014/0296868 A1 to Garrison et al.
1024	WIPO Publication No. WO 2006/124307 A2 to Goff et al.
1025	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)
1026	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)
1027	United States District Courts – National Judicial Caseload Profile (Dec. 2024)
1028	Imperative Care’s Opposition to Inari’s Motion for Leave to File Third Amended Complaint (Dkt. #98) in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 24-cv-03117-EKL (N.D. Cal.) (filed March 26, 2025)
1029	Imperative Care’s Reply in Support of Motion to Stay Pending <i>Inter Partes</i> Review (Dkt. #108) in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 24-cv-03117-EKL (N.D. Cal.) (filed May 7, 2025)
1030	Decision Denying Institution of <i>Inter Partes</i> Review for U.S. Patent No. 11,744,691 (Paper 10) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2024-01257 (P.T.A.B. Feb. 7, 2025)

Petitioner's Reply – Patent 11,554,005
Imperative Care, Inc. v. Inari Medical Inc.

Exhibit No.	Description
1031	Standing Order for Patent Cases Before Judge Eumi K. Lee (Aug. 16, 2024)
1032	<i>Yangtze Memory Techs. Co., Ltd. v. Micron Tech., Inc.</i> , No. 23-cv-05792-RFL, Dkt. 243 (N.D. Cal. Mar. 14, 2025)
1033	<i>Jawbone Innovations, LLC v. Google LLC</i> , No. 23-cv-00466-TLT, Dkt. 137 (N.D. Cal. Apr. 27, 2023)
1034	Joint Claim Construction and Prehearing Statement Pursuant to Patent Local Rule 4-3 (Dkt. #107) in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 24-cv-03117-EKL (N.D. Cal.) (filed Apr. 28, 2025)
1035	Declaration of Joshua J. Stowell in Response to Patent Owner's Objections to Imperative Care's Evidence [SERVED ONLY]
1036	Certified File History of U.S. Patent Application 10/371,190 [SERVED ONLY]
1037	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)
1038	Deposition Transcript of PO's Expert Paul Zalesky, Ph.D. dated August 27, 2025
1039	Deposition Transcript of PO's Expert Paul Zalesky, Ph.D. dated June 23, 2025
1040	Supplemental Expert Declaration of Troy Thornton
1041	U.S. Patent No. 11,697,011 ("the '011 patent")
1042	Deposition Transcript of PO's Expert Paul Zalesky, Ph.D. dated November 7, 2025
1043	New Oxford American Dictionary, 3rd ed. (2010) – definitions of "diameter," "filament," and "loop"

Exhibit No.	Description
1044	Merriam-Webster's Collegiate Dictionary (11th ed. 2014), submitted by Patent Owner as Exhibit 2009 in IPR2024-00157
1045	Decision Granting Institution of <i>Inter Partes</i> Review for U.S. Patent No. 11,844,921 (Paper 13) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-00728 (P.T.A.B. Oct. 10, 2025)
1046	Decision Granting Institution of <i>Inter Partes</i> Review for U.S. Patent No. 11,865,291 (Paper 10) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-00989 (P.T.A.B. Oct. 23, 2025)
1047	Record of Oral Hearing held on October 29, 2025 in <i>Inter Partes</i> Review for U.S. Patent No. 11,697,011 (Paper 34) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2024-01157 (P.T.A.B. Nov. 17, 2025)

I. INTRODUCTION

The Board has instituted five IPRs (including this IPR) challenging PO's patents claiming a valve with a filament. (Paper 10; Exs. 1025-1026, 1045-1046.) Despite variations in how the claims describe the "filament," the Board has preliminarily found that Schaffer or Schaffer with Hartley or Eller is reasonably likely to render the filament claims unpatentable. In the current POR, PO recycles arguments from the previous POPRs, PORs, and oral arguments. PO fails to present any new, probative evidence to undermine Petitioner's unpatentability grounds or the Board's preliminary findings.

The only POR argument the Board has not already considered is PO's assertion that Garrison does not disclose an on-off control "in the flow path" that "extend[s] through the housing." This argument fails because it requires a claim construction that improperly excludes every disclosed embodiment, and PO's expert contradicted the argument during his deposition.

PO also continues to dispute the construction of "filament" and whether Schaffer discloses a "filament." (POR, 23-32, 40-50.) However, the construction of "filament" impacts only Ground 1 (Garrison + Schaffer). The construction of "filament" does not impact Grounds 2-4 (Garrison + Schaffer + Hartley or Eller, Garrison + Hartley + Eller) because PO does not dispute that Hartley and Eller disclose "filaments." For grounds 2-4, PO simply argues that a POSITA would not

have been motivated to replace Schaffer's actuating members with Hartley's string or Eller's wire. (POR, 50-76.) Yet, as the Board preliminarily found, "Petitioner's argument and evidence ... support the rationale for modifying Schaffer's valve in view of Hartley [or Eller] as proposed." (Paper 10, 36.) PO fails to rebut Petitioner's evidence supporting a motivation to combine.

Petitioner has demonstrated that the challenged claims (Claims 1-15) are unpatentable and respectfully requests a final written decision cancelling the claims.

II. CLAIMS 1-15 ARE OBVIOUS OVER GARRISON AND SCHAFFER WITH HARTLEY OR ELLER (GROUNDS 2-3)

A. A POSITA Would Have Been Motivated To Substitute Schaffer's Actuating Members For Hartley's String Or Eller's Wire

The Petition demonstrated a POSITA would have been motivated to combine Hartley's string or Eller's wire with Schaffer's valve for multiple reasons, including (1) the combinations entailed a simple substitution of one known element for another, (2) Hartley and Eller encourage using a string/wire member for constricting a valve, (3) Hartley's string and Eller's wire may seal more effectively across more device shapes and dimensions, and (4) POSITAs had a finite number of predictable materials to select for constricting a tubular member in a hemostasis valve in 2018. (Pet. 50-52, 57; Ex. 1003, ¶¶123-126, 137-140.)

PO does not dispute that Hartley and Eller encourage using a string/wire to seal around devices of varying sizes in a hemostasis valve. (See Ex. 1006, [0037];

Ex. 1007, 15:21-40, 17:38-43, 18:3-8.) Instead, PO argues the use of a string/wire in Schaffer's valve would have been unnecessary or not simple. Yet, as discussed below, PO fails to rebut Petitioner's evidence.

1. PO Does Not Rebut Petitioner's Evidence That Hartley's String Or Eller's Wire May Seal More Effectively

One reason a POSITA would have been motivated to combine Schaffer with Hartley or Eller is because "Hartley's string [or Eller's wire] may seal more effectively across a wider range of tool diameters and shapes for the inserted devices ... than Schaffer's U-shaped actuating members." (Pet., 51-52, 57.) Petitioner's expert, Mr. Thornton, explained that Hartley's string or Eller's wire could eliminate gaps formed between Schaffer's seal module and some devices. (Ex. 1003, ¶¶124, 138.) The Board preliminarily agreed that "Schaffer's broader teachings support Petitioner's position that substituting a flexible string may provide a sealing benefit in the modified valve." (Paper 10, 39.) PO provides no reason for the Board to deviate from its preliminary analysis.

Instead, PO repeats its POPR argument that Schaffer's valve would not form any gaps because it "forms a complete seal" due to seal member 165. (POR, 53; *see* Paper 10, 38-39 (addressing argument).) PO argues that "every illustrated embodiment of Schaffer includes the third seal member 165 that seals without gaps across a wide range of tool/device diameters and shapes." (POR, 53 (citing Ex. 2026, ¶¶68, 137-139).) Yet, Figures 30-34 do not require seal member 165. Schaffer

also contradicts PO, stating that “selfclosing” seal member 165 forms “a nearly fluid/gas tight seal under very light compression,” not a “complete seal.” (Ex. 1005, [0059].)

PO also argues that Schaffer's valve would not form gaps because Schaffer requires a “highly-compliant seal member 165 to effect sealing under compression, whether or not it is ‘sticky’ and ‘gelatinous.’” (POR, 55 (citing Ex. 2026, ¶143).) PO further argues that Schaffer's valve “seals regardless of whether it is ‘sticky’ or ‘self-closing.’” (*Id.*, (citing Ex. 2026, ¶140).) But PO's expert, Dr. Zalesky, could not support these arguments in deposition.

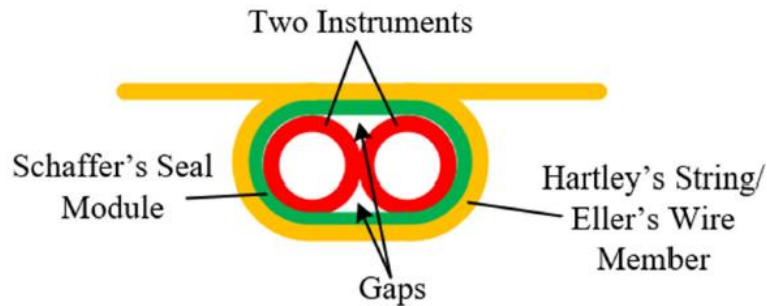
When asked whether “Schaffer's valve will seal perfectly regardless of the diameter of the device that's inserted through the valve,” Dr. Zalesky testified: “That wasn't really part of my assignment and ***I certainly wouldn't say perfectly.***” (Ex. 1038, 131:17-25 (emphasis added).) Dr. Zalesky further testified that he had “no opinion” on whether Schaffer would seal perfectly when a device that is much smaller than Schaffer's lumen is inserted. (*Id.*, 132:2-7.) In fact, he testified that he had “[n]ot explicitly” formed ***any*** opinions on how tool diameter would impact the seal and that he ***did not consider*** whether Schaffer's valve may leak when a non-round device is inserted. (*Id.*, 134:15-23, 135:15-24.)

Dr. Zalesky also admitted that prior to 2018, POSITAs would have recognized that “cinching” a hemostasis valve would more effectively seal around large-bore

catheters due to “simple mechanical engineering and physics.” (Ex. 1039, 86:19-87:4.) This confirms Mr. Thornton’s testimony that a POSITA would have expected Hartley’s string or Eller’s wire to have sealing advantages over Schaffer’s actuating members. (Ex. 1003, ¶¶124, 138; Ex. 1040, ¶¶29-35.)

Accordingly, Dr. Zalesky’s testimony does not support PO’s argument that Schaffer’s valve always seals perfectly. Further Dr. Zalesky’s confession that he did not consider conditions where gaps might form leaves Mr. Thornton’s testimony on those conditions un rebutted. (Ex. 1003, ¶¶124, 138; Ex. 1040, ¶37.)

PO also argues that Schaffer with Hartley’s string or Eller’s wire would seal less effectively when two instruments are inserted. (POR, 59-60.) But an obvious combination is not required to work perfectly in all scenarios. (See Paper 10, 40.) Further, PO’s argument is not based on Schaffer’s Figures 30-34, the relevant embodiments. Rather, PO cites a different embodiment having a three-part seal where a third seal member “is so compliant that it forms a seal around the instruments 260 even if the instruments 260 are irregularly shaped.” (Ex. 1005, [0068].) PO never explains why this hyper “compliant” seal would not work equally well with Hartley’s string or Eller’s wire. PO’s demonstrative (below) does not reflect a “compliant” seal but instead reflects a non-compliant seal that does not conform to the instruments. (Ex. 1040, ¶35.)



This demonstrative would look the same if the string/wire were replaced with two U-shaped actuating members. (*Id.*) Thus, the demonstrative does not evidence that Schaffer's valve would work less effectively with a string/wire. (*Id.*)

Finally, PO argues that Petitioner acknowledged "that Schaffer's valve completely seals and that, if it did not, it would not be a 'hemostasis valve.'" (POR, 56-57.) PO is incorrect; Petitioner never argued that Schaffer forms a "complete seal" around every instrument. To the contrary, Mr. Thornton explained that "if a tool did not fit the size of Schaffer's U-shaped members, small gaps could form between the tool and the valve's lumen." (Ex. 1003, ¶138; *see also id.*, ¶124.)

2. PO Fails To Show That The Combination Changes Schaffer's "Principles Of Operation"

PO repeats its POPR argument that combining Hartley's string or Eller's wire with Schaffer's valve would "change Schaffer's principles of operation." (POR, 73.) PO identifies three alleged changes to the principle of operation: the string/wire would not "forcibly disengage" from Schaffer's seal module, and would prevent easy assembly and reduce durability of Schaffer's valve. (POR, 73-77.) The Board

correctly found each argument deficient in the Institution Decision. (Paper 10, 40-43.)

a. PO Fails To Define The “Principle Of Operation”

PO presumes that forcible disengagement, easy assembly, and durability define Schaffer's “principle of operation.” But PO identifies no part of Schaffer that supports this presumption and none exists. Schaffer never identifies these factors as being critical to the principle of operation.

Rather, Schaffer describes sealing a valve by applying a “compressive force 67 (e.g. by a spring 210)” to the ends of the actuating members, which constricts the tube within the valve. (Ex. 1005, *abstract*, [0008], [0075]-[0077].) The tube can also “retract to an uncollapsed configuration” when the user pushes buttons on the valve to release the force. (*Id.*) Thus, Schaffer's principle of operation is to use springs to apply a constrictive force to the ends of the actuating members to collapse the tube and buttons to release the force. (Ex. 1040, ¶¶40-41.)

This principle of operation remains unchanged if Hartley's string or Eller's wire is added to Schaffer. (Ex. 1003, ¶¶129-131, 143-144; 1040, ¶¶40-41.) Schaffer continues to use springs to apply a constrictive force to the ends of the string/wire to collapse the tube and pressing the buttons releases that constrictive force. (*Id.*)

b. Hartley's String Or Eller's Wire Permit Forcible Disengagement

PO also argues that “Hartley’s string/ Eller’s wire would never disengage—let alone forcibly disengage—Schaffer’s seal module.” (POR, 75.) PO never defines “forcibly disengage,” but suggests the term means Schaffer’s actuating members physically separate from the seal module. (*Id.*) However, Schaffer always depicts the actuating members in contact with the seal module, even after they “forcibly disengage.” (*See* Ex. 1005, Fig. 34; Ex. 1038, 144:15-146:8.) Thus, “forcibly disengage” cannot mean physically separates.

Rather, “forcibly disengage” references applying force to the buttons to release the tension created by the actuating members on the seal module, which allows the seal module “to retract to an uncollapsed configuration[.]” (Ex. 1005, [0077], Fig. 34; Ex. 1040, ¶43.) This forcible disengagement occurs regardless of whether the valve includes the actuating members or string/wire. (*Id.*) In fact, Schaffer applies force to the actuating members in the same way the ’005 patent applies force to its filament(s). (*See* Ex. 1039, 85:3-8 (admitting ’011 patent’s filament¹ disengages from tubular member).)

¹ The ’011 patent shares a specification with the ’519 application. (*See* Ex. 1041.)

c. PO Fails To Show The Combination Would Compromise Manufacturing Or Durability

PO argues in one sentence that Hartley's string or Eller's wire would "introduce assembly difficulties and undermine the durability of Schaffer's valve." (POR, 75-76.) PO fails to develop these arguments and, therefore, has waived them. *See, e.g., Micron Tech., Inc. v. Lone Star Innovations, LLC*, IPR2017-01561, 2018 WL 6584977, at *13 (P.T.A.B. Dec. 12, 2018) (finding PO waived undeveloped argument).

Moreover, PO's arguments are unsupported. Schaffer never claims that ease of manufacturing is a "principle of operation" and describes the disclosed manufacturing methods as merely "one option" and "an example." (Ex. 1005, [0082]-[0083]; Ex. 1040, ¶46.) The evidence reflects that a POSITA in 2018 would have known many ways to assemble Schaffer's valve with a string/wire. (Ex. 1040, ¶¶47-48.)

Similarly, PO fails to provide any evidence that Hartley's string or Eller's wire would compromise the durability of Schaffer's valve. (POR, 75 (citing Ex. 2026, ¶¶169-180)); *see, e.g., Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 294 (Fed. Cir. 1985) ("Lack of factual support for expert opinion going to factual determinations, however, may render the testimony of little probative value in a validity determination."); *In re Advanced Cell Diagnostics, Inc.*, No. 2023-1063, 2024 WL 3451829 at *6 (Fed. Cir. July 18, 2024) (similar). PO's

expert admitted that durable strings and wires for medical devices were available to POSITAs before 2018, and PO never explains why a POSITA would not have used one of those strings/wires. (Ex. 1038, 161:16-23; Ex. 1039, 169:16-170:11.) Accordingly, durability would not have dissuaded POSITAs from combining Hartley's string or Eller's wire with Schaffer's valve. (Ex. 1040, ¶50.)

3. The Combination Would Have Been A Simple Substitution Of Known Elements

a. The Combinations Involve Substitution Of Known Elements

PO argues that combining Schaffer with Hartley's string or Eller's wire would not be a simple substitution because "a single actuating member ... having two ends coupled to and controlled by different actuators was not 'known' from any of Petitioner's references." (POR, 61-67.) PO effectively argues that no single reference discloses the very thing claimed. (*Id.*) The Board correctly observed in its Institution Decision that this is not the obviousness standard. (Paper 10, 36-37 (citing *Masimo Corp. v. Apple Inc.*, No. 2022-1894, 2024 WL 111647 at *3 (Fed. Cir. Jan. 10, 2024)); *see also Fleming v. Cirrus Design Corp.*, 28 F. 4th 1214, 1222 (Fed. Cir. 2022). The relevant "question is not whether the prior art disclosed the very thing claimed; it is whether, in light of the prior art, the claimed invention would have nonetheless been *obvious* to a [POSITA] as of the relevant date." *Masimo Corp.*, 2024 WL 111647, at *3.

PO fails to show that combining Schaffer with Hartley's string or Eller's wire would involve any "unknown" elements. Not only were the elements known (actuating members, string, and wire), they were known to perform the same function—constricting the lumen of a hemostasis valve. (Ex. 1003, ¶¶129-131, 143-144.) As explained in the Petition, attaching each end of the string/wire to one of Schaffer's actuator buttons was obvious. (Ex. 1003, ¶¶128, 141; Ex. 1005, [0075]-[0077]); *see also Facebook, Inc. v. Windy City Innovations, LLC*, 973 F.3d 1321, 1343 (Fed. Cir. 2020) ("[T]he fact that it would take some creativity to carry out the combination does not defeat a finding of obviousness.").

b. The Combinations Would Have Been Simple And Predictable

PO also fails to explain why combining Schaffer with Hartley's string or Eller's wire would not have been simple. (POR, 61-71.) Mr. Thornton described several simple ways to combine the elements, including making small holes in Schaffer's buttons, threading the string/wire through the holes, and knotting the string/wire to hold it in place. (Ex. 1003, ¶¶128-132; 141-144.) PO does not dispute Mr. Thornton's testimony. Instead, PO states "the movement of the string/wire member would not be precisely controlled because either of Schaffer's buttons could be depressed independently to move the string/wire unpredictably." (POR, 71.) PO does not explain how or why such an arrangement, the same arrangement disclosed

in the '005 patent, would create imprecision. (*Id.*) PO cites its expert for support, but he similarly fails to provide any explanation. (*See* Ex. 2026, ¶167.)

PO also argues that the combination would be unpredictable and that Mr. Thornton's testimony supports this argument. (POR, 70-71 (citing Ex. 2029, 44:21-45:11).) PO is incorrect.

Mr. Thornton observed that a POSITA could not determine whether the filaments in Figures 8-9 of the '519 application were flexible based on the figures alone. (Ex. 2029, 43:19-22, 45:1-6.) Mr. Thornton explained that flexible filaments would probably not be perfectly straight and that he would need more information to determine their exact orientation. (*Id.*, 45:1-11.) Mr. Thornton did not testify that a POSITA "would be unable to know how the filament would act" as PO argues.

Rather, Mr. Thornton testified that a POSITA would have reasonably expected success in combining the string/wire with Schaffer because the components are predictable. (Ex. 1003, ¶¶128-132, 141-144; Ex. 2029, 44:4-20.)

4. A Finite Number Ways Existed To Constrict A Hemostasis Valve

PO argues that "Petitioner has failed to demonstrate that the options and solutions for 'constricting a tubular member in a hemostasis valve' were finite, identified and known." (POR, 72.) PO is incorrect.

PO cites Mr. Thornton's deposition regarding various "pinch" valves that press on a tube in a hemostasis valve to flatten the tube. (*See* Ex. 2029, 115:22-

116:2; *see also id.*, 105:10-118:18.) Mr. Thornton correctly explained that pinch valves use a different sealing mechanism than Schaffer's actuating members (pinching versus circumferentially surrounding), Hartley's string, and Eller's wire. (*Id.*, 108:2-23, 114:25-115:18, 117:8-21.) Further, Mr. Thornton testified that even if pinch valves were included among the available options, a POSITA still would have had a finite number of options for sealing a tube (Schaffer/Hartley/Eller + pinch valves). (*Id.*, 118:4-15.) Accordingly, PO has failed to rebut Petitioner's showing of a finite number of ways to constrict the tube of a hemostasis valve in 2018. (Ex. 1003, ¶¶126, 140.)

B. PO Does Not Rebut Petitioner's Evidence That A POSITA Would Have Combined Schaffer's Valve With Garrison

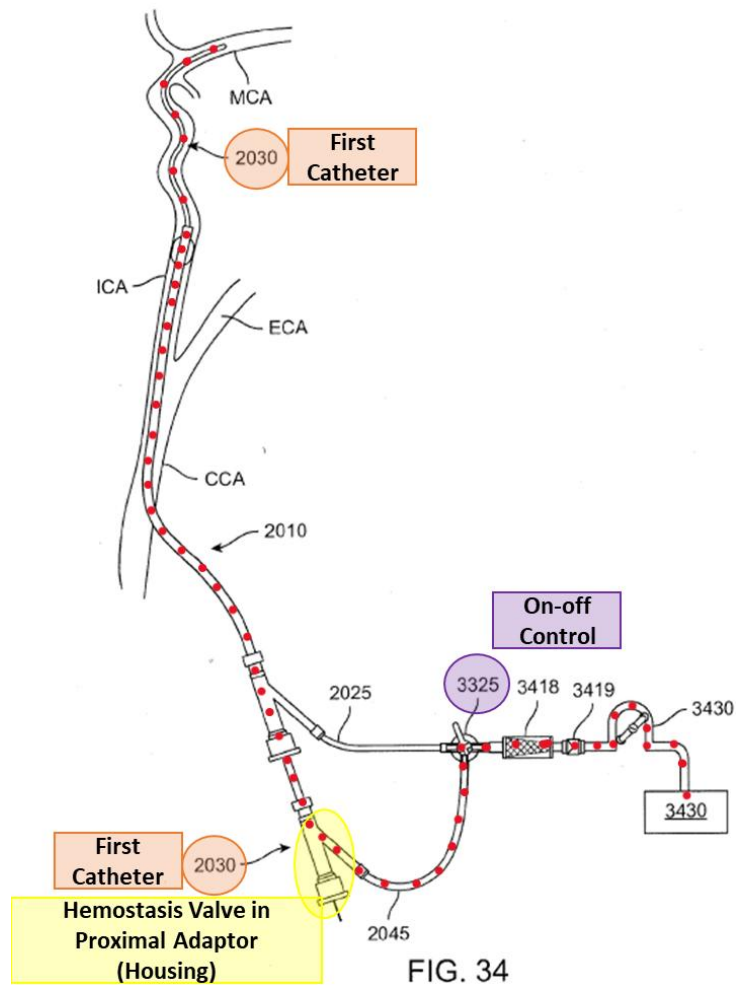
A POSITA would have been motivated to combine Schaffer's valve, with or without Hartley's string or Eller's wire, with Garrison's aspiration system for multiple reasons, including (1) the combinations entailed a simple substitution of one known element for another, (2) Schaffer's valve is an "adjustable opening valve"—one of the exemplary hemostasis valves listed in Garrison, (3) Schaffer's valve would allow introduction of tools into Garrison's catheter while preventing blood loss, (4) Schaffer's valve would simplify Garrison's system, and (5) POSITAs had a finite number of predictable hemostasis valves to choose in 2018. (Pet. 35-37; Ex. 1003, ¶¶94-99.) PO does not dispute these motivations.

Instead, PO creates a strawman—arguing that Petitioner's grounds rely on Schaffer's valve being “ineffective”—and then argues that a POSITA would not have been motivated to use an “ineffective” valve. (POR, 76-77.) But as the Board preliminarily found, “Petitioner never argued Schaffer's unmodified valve is ‘ineffective’ but instead proposed that a POSA would have recognized that such a valve may be further modified, with potential improvement, by adding Hartley's string.” (Paper 10, 44-45.) PO's mistaken “ineffective valve” argument therefore fails to rebut Petitioner's evidence. (Ex. 1003, ¶¶94-99.)

Moreover, “Schaffer itself suggests that its valves have advantages over Tuohy-Borst valves like disclosed in Garrison, giving a reason for the POSA to have looked beyond Garrison's teachings.” (Paper 10, 45.) PO's expert agreed that the Tuohy-Borst and passive hemostasis valves described in Garrison had known drawbacks in 2018. (Ex. 1042, 93:13-95:2, 102:10-103:20.) For example, those valves “don't seal well on large devices or complex configuration devices [that] are not circular” and traditional rotating valves “take many turns to seal larger bore catheters.” (*Id.*) PO's expert also admitted that biasing springs and opposing actuators, as in Schaffer's valve, would address those concerns and provide easy one-handed operation. (*Id.*, 95:17-96:4, 100:6-102:6.) Mr. Thornton similarly testified that Schaffer's valve would simplify Garrison's system and save time during procedures. (Ex. 1003, ¶97.)

C. Garrison Discloses An On-off Control “In The Flow Path”

Garrison's system includes a housing with a hemostasis valve [yellow], a flow path that extends through that housing [red dots], and an on-off control in that flow path [purple]:



(Pet., 22-25.) PO argues that Garrison's on-off control is not “in the flow path” because Garrison's valve 3325 is not within the same housing as its hemostasis valve. (POR, 33-40.) PO's argument depends on an unsupported claim construction

requiring an “on-off control” *in the housing*. (*Id.*) The Board should reject PO’s construction for several reasons.

First, PO’s construction would exclude every embodiment disclosed in the ’005 patent, a result that is “rarely, if ever, correct.” *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1583 (Fed. Cir. 1996). The ’005 patent does not disclose an on-off control in the same housing as a hemostasis valve. Instead, every disclosed system has a separate on-off control connected to the hemostasis valve housing via tubing. (*See* Ex. 1001, 5:18-7:16.) PO’s expert confirmed that “Figure 1 of the ’005 Patent shows a vacuum aspiration system with *a flow path extending through a housing*, [and] *a valve 126 in the flow path (e.g., an on-off control)*.” (Ex. 2026, ¶36 (emphases added).) He also annotated Figure 1 to illustrate the “flow path extending through a housing”:

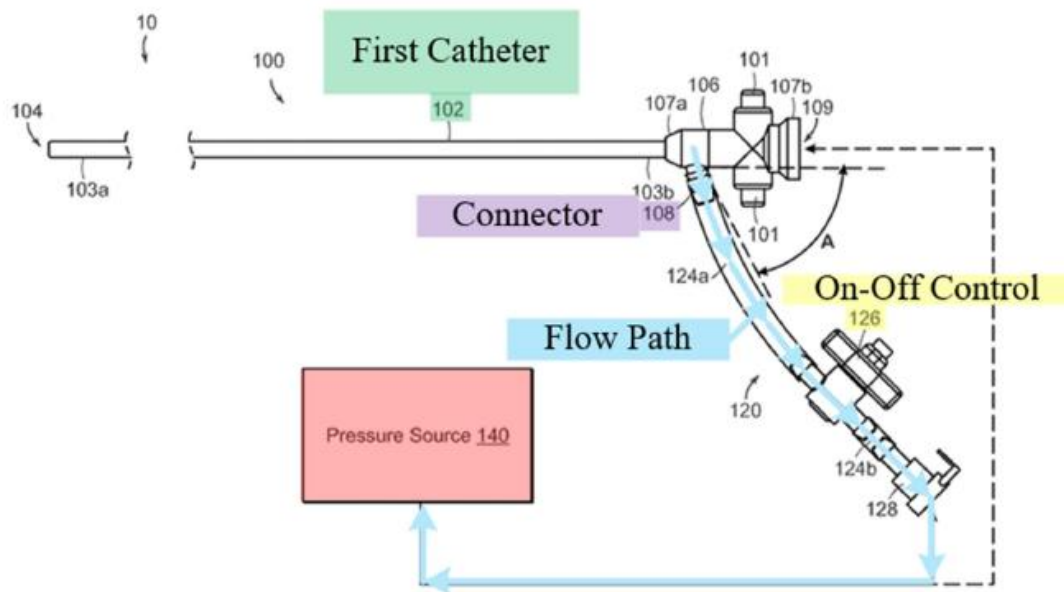
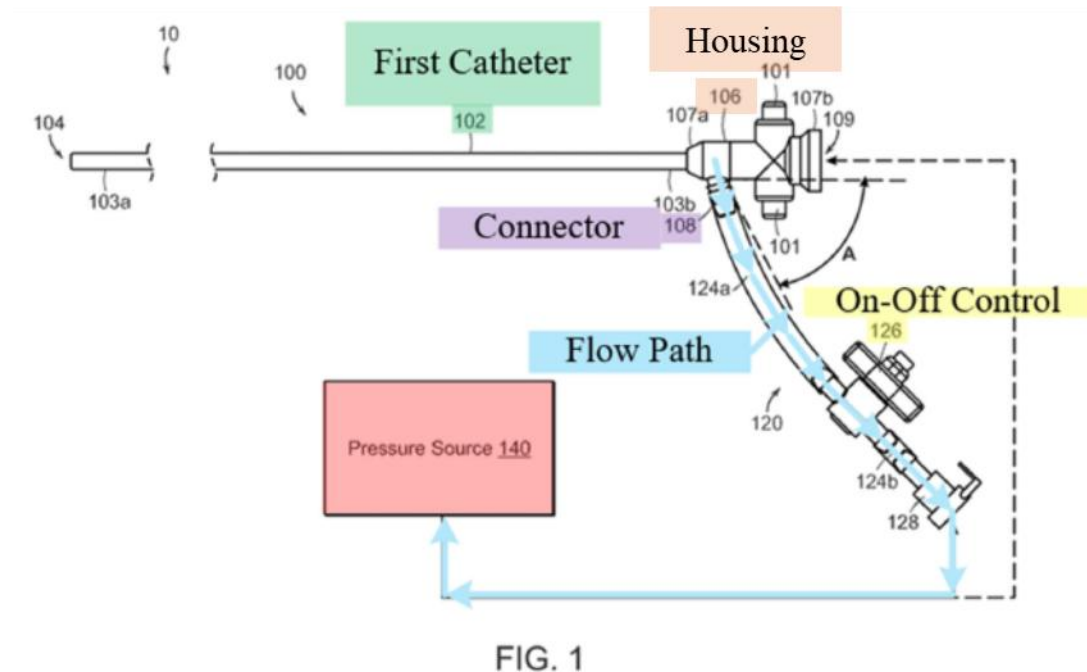


FIG. 1

(*Id.*; Ex. 1042, 46:15-47:10.) PO's expert confirmed that item 106 is the "housing," and that the "on-off control" 126 *is not* located within the "housing":



(Ex. 2026, ¶36 (additional "housing" label by Petitioner); Ex. 1042, 46:46:15-49:2.) He admitted the same applied to every figure in the '005 patent. (*Id.*, 62:1-64:6, 64:13-65:21, 67:1-68:23, 69:4-71:18, 71:23-72:14, 72:15-73:16.)

Like the figures, the written description solely describes a separate on-off control connected to the hemostasis valve housing via tubing, never within the housing. (*See* Ex. 1001, 5:18-7:16.) PO cites the following description of the tubing subsystem 120 in support of its argument:

In other embodiments, the **tubing subsystem 120** can have more or fewer tubing sections, connectors, and/or fluid control devices, and can have other suitable configurations. In some embodiments, one or more of the components can be permanently connected and/or integrally formed.

(Ex. 1001, 6:45-49 (emphasis added); POR, 37-38.) However, the hemostasis valve housing 106 is part of the catheter subsystem 100, **not** the tubing subsystem 120. (Ex. 1001, 5:21-29; Ex. 1042, 79:15-20.) Thus, the description does not support that the fluid control valve is part of the hemostasis valve housing. (See Ex. 1042, 79:1-7 (PO's expert admitting disclosure is "describing configurations of the tubing subsystem 120").

Second, PO's expert contradicted PO's proposed construction. The on-off control 126 **is not** located within the same housing as the hemostasis valve in Figure 1. (Ex. 1001, 5:18-6:16, Fig. 1.) Yet PO's expert testified that Figure 1 includes "a flow path extending through a housing, [and] **a valve 126 in the flow path** (e.g., an on-off control)." (Ex. 2026, ¶36 (emphasis added); Ex. 1042, 46:15-47:10.) He also testified that claim 1 encompasses Figure 1. (Ex. 1042, 91:1-6.) He even testified that claim 1 **does not** require the on-off control to be in the hemostasis-valve housing:

Q. You are construing claim 1 to require that the on-off control is in the housing. Correct?

A. **No. That is one option. It is not constrained to that.**

Q. What are the other options?

A. In the flow path but not in the housing.

Q. So it is your opinion that the on-off control recited in claim 1 does not need to be in the housing. Is that right?

A. I am allowing for the two options, in or not in the housing.

(*Id.*, 84:3-15 (emphasis added); *see also id.*, 87:11-88:14, 89:6-11.) With respect to Garrison, PO's expert admitted that claim 1 encompasses Garrison's configuration where "the on-off control is segregated from the hemostasis valve." (*Id.*, 89:13-90:5.) Accordingly, the experts agree that the challenged claims do not require the on-off control to be within the same housing as the hemostasis valve. (*Id.*; Ex. 1003, ¶¶70-80.)

III. CLAIMS 1-12, 14-15 ARE OBVIOUS OVER GARRISON AND SCHAFFER

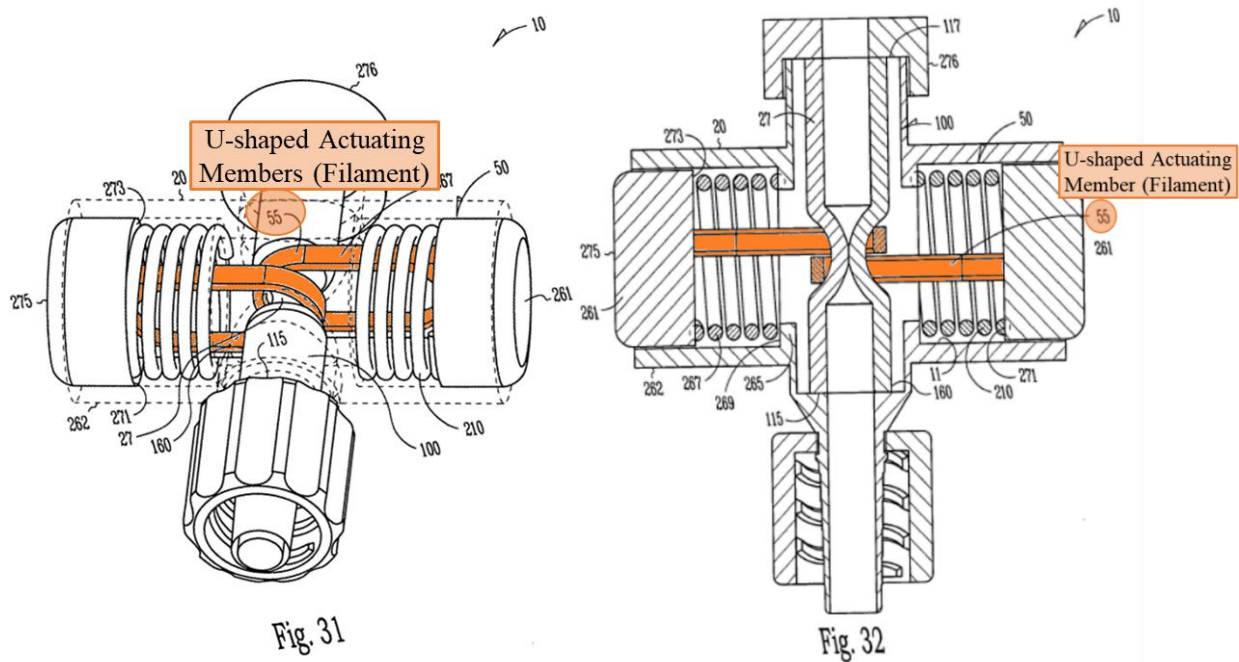
PO argues that Schaffer does not disclose or render obvious a "filament." (POR, 42-49.) Yet, as discussed below, PO misinterprets Schaffer and improperly imports limitations into filament.

A. Schaffer's Actuating Members Are A "Filament"

Even if the Board determines that "filament" requires flexibility (as PO argues), Schaffer's actuating members are a "filament." Like the '005 patent, Schaffer does not expressly describe the flexibility of its actuating members. However, a POSITA "would have understood that Schaffer's U-shaped actuating members would have preferably been formed from a thin, flexible material." (Ex. 1003, ¶113.)

A thin, flexible “material would have permitted the actuating members to conform, as much as possible, to the outer surface of the seal module and tool inserted through the valve.” (*Id.*) A POSITA would have recognized that flexibility would have been particularly beneficial for non-circular instruments. (*Id.*) PO’s expert admitted that a “[a] rigid filament would not be able to accommodate the circular circumference of the internal tubular element.” (Ex. 1039, 101:5-7.)

Further, Schaffer illustrates the actuating members with a thickness substantially less than their length:



(Ex. 1005, Figs. 31, 32.) A POSITA would have recognized that the elongated actuating members would be flexible, even if formed from metal or plastic, and not “completely inflexible” or “rigid” as PO argues. (Ex. 1040, ¶¶17-26; Ex. 1039,

134:4-8.) PO's expert testified that he was unaware of any hemostasis valve components that would be "completely inflexible." (Ex. 1039, 110:8-14, 134:4-8.)

Accordingly, Schaffer's U-shaped actuating members are a "filament" even under PO's proposed construction. (Ex. 1040, ¶¶16-26.)

1. Schaffer's Actuating Members Are Not "Rigid"

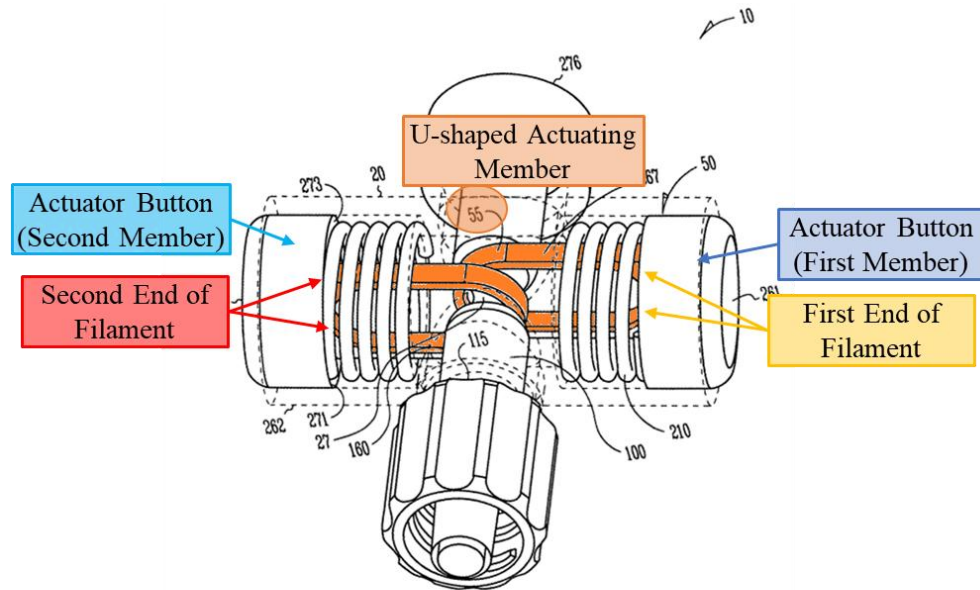
Schaffer never describes the actuating members as "rigid" or "non-conforming." Thus, PO attempts to infer rigidity from other disclosures in the specification. (POR, 40-42.) Yet, none of the disclosures requires "rigid" actuating members.

a. PO Misunderstands Schaffer's Sealing Mechanism

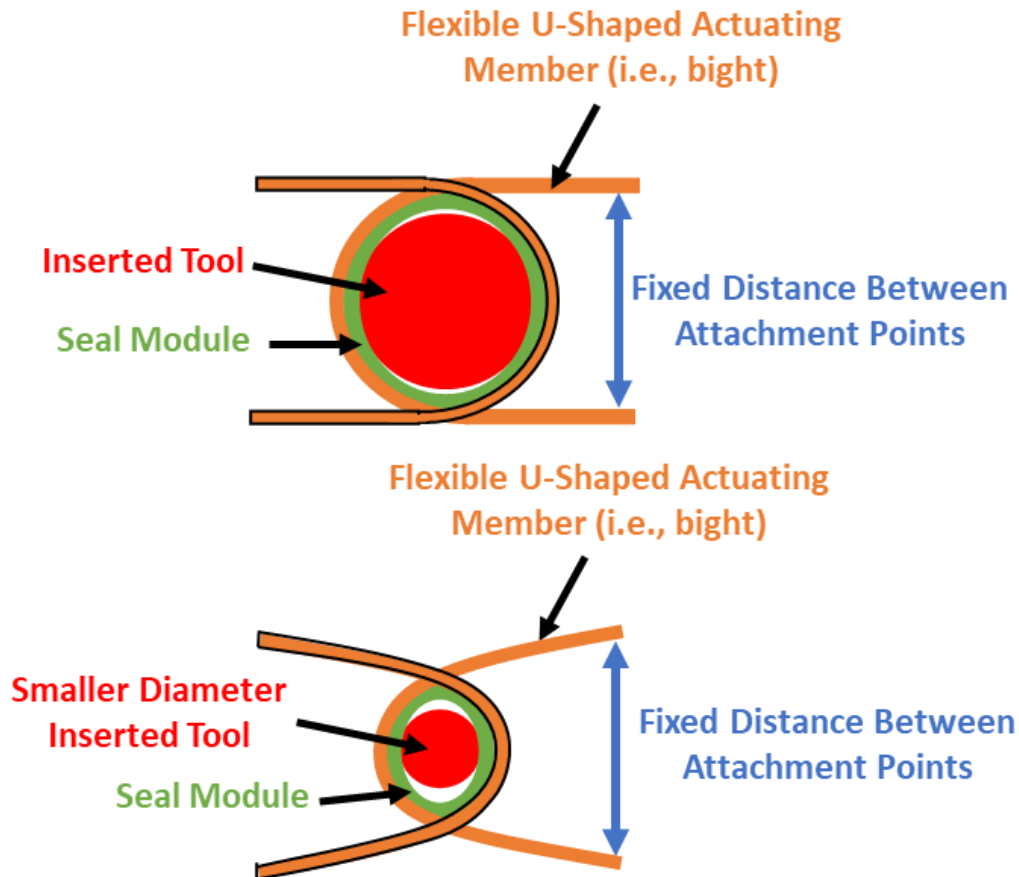
Schaffer states that depressing the actuator buttons "allows each engaged actuating member 55 to forcibly disengage opposing outer walls 27 of the seal module 100." (POR, 41 (citing Ex. 1005, [0077]).) PO argues that "a 'filament' cannot 'forcibly disengage' because it is flexible and would merely loosen/slacken, not 'forcibly disengage.'" (*Id.*) But pushing the buttons on Schaffer's valve is the forcible disengagement (*supra* §II.A.2.b); whether the filaments deform is irrelevant. (Ex. 1040, ¶¶24-25.)

Likewise, Petitioner's argument that Schaffer's valve could result in small gaps between the seal module and tool does not mean that the actuating members are "rigid." (Ex. 1003, ¶124; Ex. 1040, ¶34.) Gaps can form if the members are

rigid *or* flexible because each U-shaped actuating member is secured to the actuator buttons at two fixed, spaced-apart points:



(Ex. 1040, ¶34; Ex. 1005, Fig. 31.) This fixed attachment can prevent the U-shaped actuating members from completely conforming to the exterior of a tool with, for example, a smaller diameter than the distance between the attachment points:



(Ex. 1040, ¶34.)

b. Schaffer's Exemplary Manufacturing Methods Do Not Require "Rigid" Actuating Members

During the oral hearing for the '011 Patent IPR, Judge Majors stated that Schaffer's disclosure that the "actuators [are made] out of machined aluminum or machined plastic, and they're -- want to slide along the exterior of the housing" suggests that the actuating members may be rigid. (Ex. 1047, 27:23-28:9.) However, both experts agree that machined parts can be flexible. (Ex. 1040, ¶22.) And the experts agree that POSITAs would have been aware of other manufacturing

methods for making flexible metallic or polymeric materials prior to 2018, including rolling or drawing. (Ex. 1039, 96:4-99:17; Ex. 1040, ¶23.)

In addition, Schaffer's disclosure that the "the actuators 50 are configured cylindrically to slide along the cylindrical interior wall 11 of the housing" does not require the actuating members, which are attached to the actuators 50, to be rigid. (Ex. 1005, [0076].) Because the actuating members are secured to the actuator buttons, the actuating members move within the housing as the actuator buttons are pressed and released, regardless of whether the actuating members are flexible or rigid. (Ex. 1040, ¶22.)

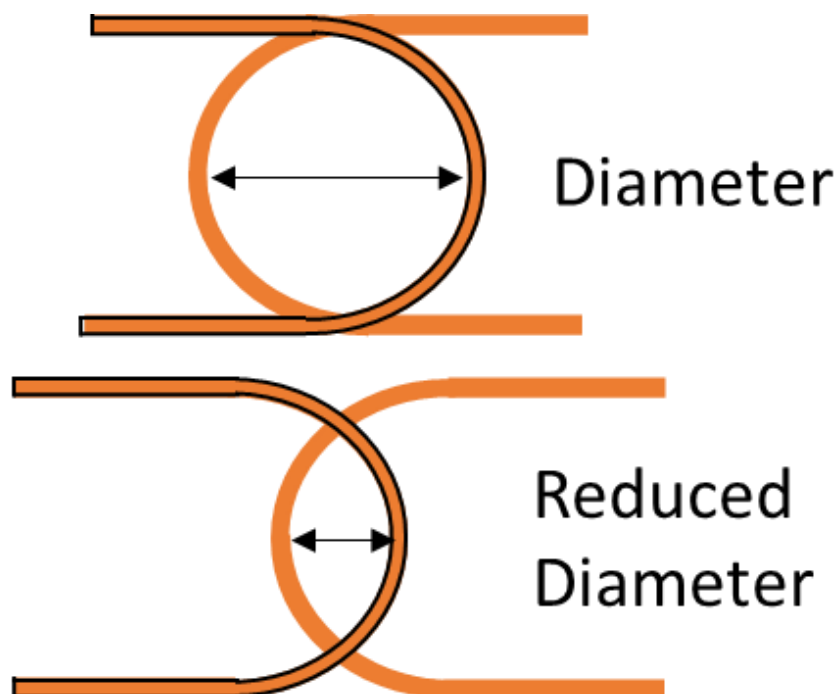
2. Schaffer's Actuating Members "Circumferentially Constrict" The Tubular Member

Schaffer's actuating members are "circumferentially disposed about the portion 108 of the seal module" and constrict the seal module. (Ex. 1005, [0077]; Ex. 1003, ¶¶118.) PO's expert admitted that the bights in the '005 patent, which have the same configuration as Schaffer's actuating members, "circumferentially constrict" the tubular member. (Ex. 1039, 100:11-22, 126:10-13.) He admitted circumferential constriction occurs regardless of whether the bights are interlocking or non-interlocking as in Schaffer. (Ex. 1038, 102:24-103:10.) Thus, the testimony confirms that Schaffer's actuating members "circumferentially constrict" the valve lumen.

3. Schaffer's U-Shaped Actuating Members Form A "Loop"

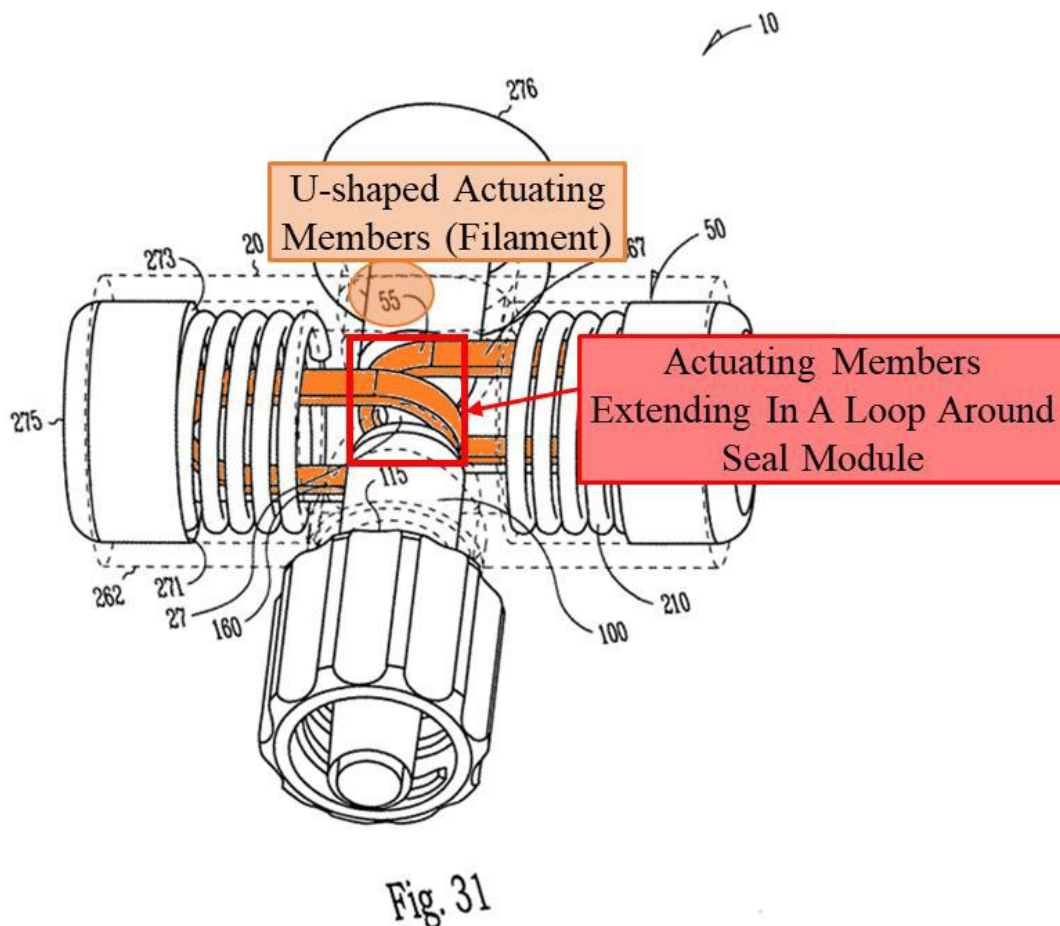
Schaffer's actuating members collectively form a "loop" around the seal module. (Ex. 1005, [0075]-[0077]; Ex. 1003, ¶151.) PO counters that the '005 patent distinguishes "bights," which form an "encircled area," and a "loop." While the words differ, the meanings do not. PO's dictionary definition of "bight" confirms that "bight" means "a slack part or *loop* in a rope." (Ex. 1044, 4 (emphasis added).) Likewise, the word "loop" means to "encircle." (Ex. 1043, 5.)

Further, Schaffer's actuating members behave the same as the "bight" embodiments. The '519 application states movement of the constricting mechanism "*decreases the size of the encircled area* 814" (Ex. 1017, [0069] (emphasis added).) Similarly, Schaffer's actuating members decrease the size of the encircled area when the actuator buttons are undepressed:



(Ex. 1040, ¶28; *see also* Ex. 1043, 3 (defining “diameter”).)

PO also argues that Schaffer's actuating members do not form an “encircled area” (i.e., loop) because they are not interlocking and therefore do not “overlap.” (POR, 45.) But “interlock” is not synonymous with “overlap.” As illustrated below, Schaffer's actuating members “overlap” (i.e., are side-by-side) to form an encircled area:



(Ex. 1005, Fig. 31; Ex. 1003, ¶151.) This is confirmed by the '519 application, which states that the bights “overlap and define an encircled area” because the bights are side-by-side, not because they “interlock.” (Ex. 1017, [0069].)

PO also attempts to distinguish Schaffer by arguing that the challenged claims require a *single* filament that forms a loop. (POR, 45-49.) Yet the claims do not say “single filament.” In addition, the ’519 application states that “*the filament 150* can comprise multiple filaments.” (Ex. 1017, [0065] (emphasis added).)

Thus, PO’s own patent and evidence confirm that Schaffer’s U-shaped actuating members form a loop as recited in Claim 10 of the ’005 patent.

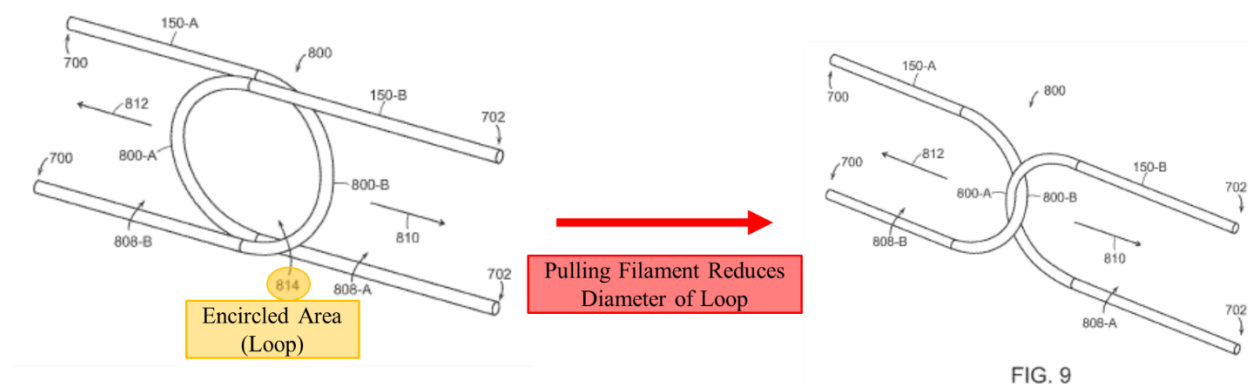
B. The Board Should Not Import “Thin” And “Flexible” Into “Filament”

PO also argues the Board should import the unrecited limitations “thin” and “flexible” into the term “filament.” In the Institution Decision, the Board preliminarily rejected PO’s construction for claim 1 but agreed to import “flexible” into claim 10, finding that claim 10’s limitations “formed into a loop” and “reduc[es] a diameter of the loop” required flexibility. (Paper 10, 16-18.) As explained below, the “loop” limitation does not support importing “flexible” into the claims.

1. The Claims Encompass The “Bight” Embodiments

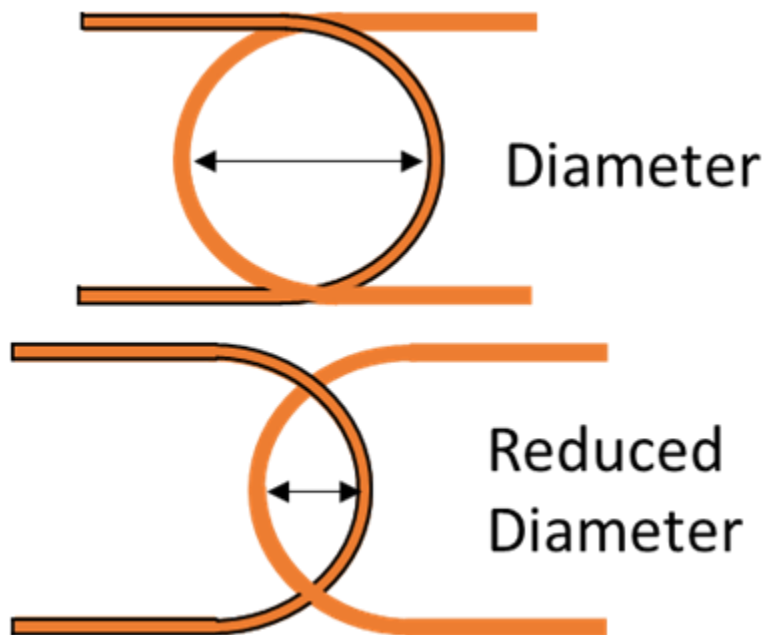
In the Institution Decision, the Board cited Figure 6 of the ’519 application and stated that “the intrinsic evidence distinguished between filaments that form a ‘loop’ as claimed versus filaments that form ‘bights.’” (*Id.*, 17.) The Board preliminarily determined these distinctions supported construing “filament” to require flexibility in claim 10. (*Id.*) However, the “bight” embodiments in Figures

8-9 meet the claim limitations because the bights collectively form a loop and pulling on the bights reduces the loop diameter:



(Ex. 1017, [0069], Figs. 8-9.) Notably, a “diameter” encompasses irregular shapes.

(Ex. 1043, 3.)



The Board also cited the '519 application's description of Figure 6 as a “loop” and Figure 8 as an “encircled area.” (Paper 10, 17-18.) However, while the words are different, “loop” means to “encircle.” (Ex. 1043, 5.) Further, the '519

application describes the filaments in Figures 6 and 8-9 as behaving the same way. The '519 application explains that “a diameter or *size* of the loop ... can *decrease* when the constricting mechanism 141 is moved.” (Ex. 1017, [0066] (emphasis added).) Similarly, movement of the constricting mechanism “*decreases* the *size* of the encircled area 814.” (*Id.*, [0069] (emphasis added).) Given the plain meaning of “loop” and “encircle,” the specification does not clearly and unmistakably disavow the “bight” embodiments from the scope of “filament.”

2. PO's Construction Renders The Claims Ambiguous

The Board should also reject PO's construction because it leaves a POSITA without objective boundaries for determining whether a material constitutes a “filament.” *See, e.g., Interval Licensing LLC v. AOL, Inc.*, 766 F.3d 1364, 1370-1375 (Fed. Cir. 2014) (holding “unobtrusive manner” indefinite because it is a “highly subjective” term). In the related '011 Patent IPR, the Board correctly stated:

[T]he words ‘thin’ and ‘flexible’ inject potential ambiguities as relative terms. For example, because flexibility and rigidity exist along a spectrum, how ‘flexible’ would a metal wire or cable need to be to qualify as a ‘filament’ as claimed?

(Ex. 1025, 15.)

PO has not identified objective boundaries a POSITA could apply to determine whether a material is “flexible” or “thin” enough to constitute a “filament.” (POR, 32.) PO argues “the filament must be sufficiently flexible so that it can loosen and reduce in diameter when formed in a loop, or circumferentially

constrict.” (*Id.*) This argument merely imports an additional subjective term (“loosen”) into the claims, which is not explained in the ’005 patent.

The ’005 patent also does not provide criteria a POSITA could use to determine whether a material is “flexible.” (Ex. 1040, ¶9.) For example, the ’519 application does not specify the dimensions or mechanical properties necessary to yield “flexibility.” (Ex. 1001, [0070]; Ex. 1040, ¶9; *see also* Ex. 1039, 108:9-11.) Moreover, whether a material can form a loop heavily depends on the force applied to the material, which also is not described in the ’005 patent. (Ex. 1040, ¶12.)

PO’s expert confirmed that PO’s construction of “filament” yields ambiguity. PO’s expert testified that identifying a filament was “very qualitative” and requires “[p]rimarily trial and error” that would involve “wrap[ping] [the material] around a pencil or a finger and see what force is required and how well it coapted.” (Ex. 1039, 103:14-20, 107:6-108:14.) PO’s expert could not identify the force needed during this “trial and error” testing. (*Id.*) PO’s expert also testified that a paper clip that could be wrapped around a pencil would qualify “in the outermost extreme of what a filament’s properties would possess.” (*Id.*, 104:9-15.) PO’s “very qualitative” assessment would leave a POSITA without reasonable certainty regarding the scope of “filament” and, thus, PO’s construction should be rejected.

3. Dictionaries Do Not Justify PO's Construction

The dictionary definitions for “filament” cited by PO do not support importing “flexible” into the claims. One of PO's definitions does not mention flexibility. (Ex. 2003.) PO's other definition, “a single thread or a thin, flexible threadlike object,” would exclude several “filaments” expressly disclosed in the '519 application, such as a “ribbon, flat wire, sheet, or tape,” because they are not “threadlike.” (Ex. 2002; Ex. 1017, [0047].)

IV. CONCLUSION

Petitioner has established by a preponderance of the evidence that the challenged claims are unpatentable and, therefore, requests that the Board cancel the claims.

Respectfully submitted,

KNOBBE MARTENS OLSON & BEAR, LLP

Dated: December 3, 2025 By: /Joshua J. Stowell/
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CERTIFICATE OF COMPLIANCE

Pursuant to 37 C.F.R. § 42.24(d), the undersigned certifies that this **PETITIONER'S REPLY TO PATENT OWNER'S RESPONSE** contains 5,564 words and therefore complies with the type-volume limitations of 37 C.F.R. § 42.24 (c).

Dated: December 3, 2025 By: /Joshua J. Stowell/
Joshua J. Stowell (Reg. No. 64,096)
KNOBBE MARTENS OLSON & BEAR, LLP

CERTIFICATE OF SERVICE

I hereby certify that, pursuant to 37 C.F.R. § 42.6(e), a true and correct copy of **PETITIONER'S REPLY TO PATENT OWNER'S RESPONSE and EXHIBIT 1038 – EXHIBIT 1047** are being served electronically on December 3, 2025, to the e-mail addresses shown below:

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