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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 IPR2025-00156
Patent No. 11,697,012

PETITIONER'S REPLY TO PATENT OWNER'S RESPONSE

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LIST OF EXHIBITS

Exhibit No.	Description
1001	U.S. Patent No. 11,697,012 (“the ’012 patent”)
1002	Excerpts from the prosecution history of the ’012 patent
1003	Expert Declaration of Troy Thornton
1004	Resume of Troy Thornton
1005	U.S. Patent Publication US 2003/0225379 A1 to Schaffer et al. (“Schaffer”)
1006	U.S. Patent Publication US 2003/0116731 A1 to Hartley (“Hartley”)
1007	U.S. Patent No. 9,980,813 B1 to Eller (“Eller”)
1008	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 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, 32 nd 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.

IPR Petition – Patent 11,697,012
Imperative Care, Inc. v. Inari Medical Inc.

Exhibit No.	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

I. INTRODUCTION

The Board has instituted three IPRs (including this IPR) challenging PO's patents claiming a valve with a filament. (Paper 6; Ex. 2009; Ex. 1018.) Despite variations in how the claims describe the "filament," the Board has preliminarily found that Schaffer or Schaffer combined with Hartley or Eller is reasonably likely to render the independent claims unpatentable. In the current Patent Owner Response ("POR"), PO recycles arguments from the previously considered POPRs. Yet, PO fails to present any new, probative evidence to undermine Petitioner's unpatentability grounds or the Board's preliminary findings.

PO focuses much of its POR on disputing the construction of "filament" and whether Schaffer discloses a "filament." (POR, 22-40.) However, the construction of "filament" impacts only Grounds 1-2 and 5 (Schaffer alone or with Garrison). The construction of "filament" does not impact Grounds 3-4 or 6-7 (Schaffer combined with Hartley or Eller) because PO does not dispute that Hartley and Eller disclose "filaments."

In fact, PO does not dispute that Schaffer combined with Hartley or Eller discloses every limitation of the challenged claims. Instead, PO simply argues that a person of ordinary skill in the art ("POSITA") would not have been motivated to replace Schaffer's U-shaped actuating members with Hartley's string or Eller's wire. (POR, 4.) Yet, as the Board preliminarily found in the Institution Decision,

“Petitioner’s argument and evidence ... support the rationale for modifying Schaffer in view of Hartley [or Eller] as proposed with a reasonable expectation of success.” (Paper 6, 38.) PO fails to rebut Petitioner’s evidence in the POR.

Thus, Petitioner has demonstrated that the challenged claims (Claims 1-9) are unpatentable and respectfully requests a final written decision cancelling the claims.

II. CLAIMS 1-9 ARE OBVIOUS OVER SCHAFFER AND OPTIONALLY GARRISON WITH HARTLEY OR ELLER (GROUNDS 3-4, 6-7)¹

Petitioner 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 2017. (Pet. 42-46, 50-54; Ex. 1003, ¶¶99-103, 114-117.)

PO does not dispute some of these motivations. For example, PO does not contest 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.) Likewise, PO does not dispute that these disclosures would have

¹ PO does not present any unique arguments for Grounds 6-7. (POR, 77.)

motivated a POSITA to combine Hartley’s string or Eller’s wire with Schaffer’s valve. (Pet. 42, 50; Ex. 1003, ¶¶99, 114.)

While PO addresses some of the other motivations raised in the Petition, PO fails to rebut Petitioner’s evidence as discussed below.

A. 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 diameters and shapes for the inserted devices (e.g., other catheters or tools) than Schaffer’s U-shaped actuating members.” (Pet., 42-43, 50.) Petitioner’s expert, Mr. Thornton, explained that a POSITA would have understood that Hartley’s string or Eller’s wire member could eliminate gaps formed between Schaffer’s seal module and some devices. (Ex. 1003, ¶¶100, 115.) The Board preliminarily agreed that “Schaffer’s broader teachings lend support to Petitioner’s position that substituting a flexible string may provide a sealing benefit in the modified valve.” (Paper 6, 42.) 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, 48; *see* Paper 6, 41-42 (addressing this 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, 44 (citing Ex. 2008, ¶¶106-111).) Yet, Figures 30-34 do not require seal member 165. Additionally, Schaffer contradicts this argument. Schaffer describes the embodiments with “selfclosing” seal member 165 as “forming a *nearly* fluid/gas tight seal under very light compression,” not a “complete seal.” (Ex. 1005, [0059] (emphasis added).)

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’ or ‘gelatinous.’” (POR, 46-47 (citing Ex. 2008, ¶115).) PO further argues that Schaffer’s valves “seal completely—including in any embodiments without a ‘sticky’ or ‘self-closing’ characteristics (via the seal member 165).” (*Id.*, 47 (citing Ex. 2008, ¶115).) But PO’s expert, Dr. Zalesky, could not support these arguments in deposition.

For example, 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. 1021, 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 through the valve. (*Id.*, 132:2-7.) In fact, he testified that he had “[n]ot explicitly” formed *any* opinions on

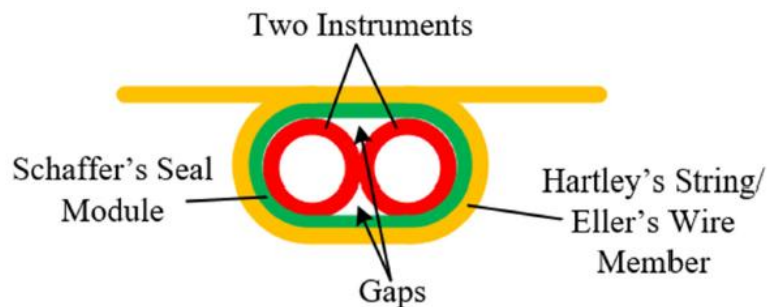
how the diameter of a tool inserted through Schaffer’s valve would impact the seal and that he ***did not even consider*** whether Schaffer’s valve may leak when a non-round device is inserted. (*Id.*, 134:14-23, 135:15-24.)

Dr. Zalesky also admitted that prior to 2017, 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. 1019, 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 U-shaped actuating members. (Ex. 1003, ¶¶100, 115; Ex. 1020, ¶¶29-35.)

Accordingly, Dr. Zalesky’s testimony does not support PO’s argument that Schaffer does not form gaps in any circumstances. In addition, Dr. Zalesky’s confession that he did not consider conditions under which gaps might form leaves Mr. Thornton’s testimony that Schaffer’s U-shaped actuating members may result in small gaps unrebutted. (Ex. 1003, ¶¶100, 115.)

PO also argues that Schaffer combined with Hartley’s string or Eller’s wire would seal “less effectively” when two instruments are inserted. (POR, 52-53.) But an obvious combination is not required to work perfectly in all scenarios. (*See* Paper 6, 46 n.22 (collecting cases).) Further, PO’s argument is not based on a description of Schaffer’s Figures 30-34. Rather, PO cites an 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. The cartoon prepared by PO (below) does not reflect a “compliant” seal but instead reflects a non-compliant seal that does not conform to the instruments. (Ex. 1020, ¶35.)



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

Finally, PO argues that Petitioner and Mr. Thornton acknowledge “that Schaffer’s valve completely seals and that, if it did not, it would not be a ‘hemostasis valve.’” (POR, 48.) 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, ¶115; *see also id.*, ¶100.)

PO also misuses a portion of the Petition addressing Claim 5, which requires that the “lumen of the tubular member is configured to remain constricted and sealed

when a pressure differential exists between” a first and second end of the lumen. (See POR 48 (citing Pet. 70-71); Ex. 1001, Claim 5.) Petitioner explained that such a pressure differential exists whenever a catheter is inserted into a patient’s vasculature due to the difference between blood pressure and air pressure. (Pet., 69-70; Ex. 1003, ¶145.) Petitioner further explained that Schaffer’s valve, like all hemostasis valves, would be configured to remain constricted against blood pressure because if it was not, it would form an ineffective hemostasis valve. (Pet., 70; Ex. 1003, ¶¶145-148.) However, this does not mean that Schaffer’s valve forms a “complete seal” around all tools or that the valve could not be improved, as PO incorrectly suggests.

B. PO Fails To Show That Combining Hartley’s String Or Eller’s Wire With Schaffer 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, 71.) PO identifies three alleged changes to the principle of operation: Hartley’s string and Eller’s wire (1) would not “forcibly disengage” from Schaffer’s seal module, (2) would prevent easy assembly of Schaffer’s valve, and (3) would reduce the durability of Schaffer’s valve. (POR, 71-76.) The Board addressed each argument in the POPR and correctly found each one deficient. (Paper 6, 42-46.)

1. 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 invention and never discusses ease of manufacturing or features that make the valve more durable.

Rather, Schaffer describes sealing a valve by applying a “compressive force 67 (e.g. by a spring 210)” to the ends of the U-shaped actuating members, which in turn 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 U-shaped members to collapse the tube and use buttons to release the constrictive force. (Ex. 1020, ¶¶38-39.)

This principle of operation remains unchanged if Hartley’s string or Eller’s wire is substituted for Schaffer’s actuating members. (Ex. 1003, ¶¶105-107, 120-121; 1020, ¶¶38-39.) Schaffer continues to use springs to apply a constrictive force to the ends of the string/wire member to collapse the tube and pressing the buttons releases that constrictive force. (*Id.*)

2. 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, 72.) PO never defines “forcibly disengage,” but seems to suggest 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. 1021, 144:15-146:8.) Thus, forcibly disengage cannot mean to physically separate from the module.

Rather, “forcibly disengage” refers to the act of applying force to the buttons to release the tension created by the actuating members on the seal module, which in turn allows the seal module “to retract to an uncollapsed configuration[.]” (Ex. 1005, [0077], Fig. 34; Ex. 1020, ¶41.) This forcible disengagement occurs regardless of whether the valve includes the U-shaped actuating members or a string/wire. (*Id.*) In fact, Schaffer applies force to the actuating members in the same way the ’012 patent applies force to its filament(s). (*See* Ex. 1019, 85:3-8 (admitting the filament in the ’011² patent disengages from the tubular member).)

² The ’011 patent shares a specification with the ’012 patent. (*See* Ex. 1022.)

3. PO Fails To Show That The Combination Would Compromise Ease Of Manufacturing

PO argues that Hartley’s string or Eller’s wire member would compromise ease of manufacturing. (POR 73-76.) This argument is unsupported. Schaffer never claims that ease of manufacturing is a “principle of operation.” To the contrary, Schaffer describes the disclosed manufacturing methods as “one option” and “an example.” (Ex. 1005, [0082]-[0083]; Ex. 1020, ¶44.)

Moreover, a POSITA in 2017 would have known many ways to assemble Schaffer’s valve with Hartley’s string or Eller’s wire. (Ex. 1020, ¶¶45-46.) For example, a POSITA could have simply inserted the seal module through loops formed by the string/wire just as the POSITA would have done with the actuating members. (*Id.*) A POSITA could have also used a tapered fixture to hold the string/wire member open while the seal module is inserted. (*Id.*) A POSITA could have also altered the order of assembly to first position Schaffer’s seal module in the valve housing and then loop the strings/wire member around the module. (*Id.*) PO’s suggestion that an experienced engineer could not figure out a simple way to insert a tube through two loops of string or wire is not credible.

4. PO Fails To Show That The Combination Would Compromise Durability

PO also 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. 2008,

¶154)); *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) (affirming Board’s determination that patentee’s declarations were entitled to little weight).

Hartley and Eller describe using a string/wire member for the same purpose as Schaffer’s U-shaped actuating members—constricting a tube. (Ex. 1020, ¶48.) Neither reference suggests that durability is an issue. Moreover, PO’s expert admitted that durable strings and wire materials for medical devices would have been available to POSITAs before 2017. (Ex. 1021, 161:16-23; Ex. 1019, 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. 1020, ¶48.)

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

1. The Combinations Involve Substitution Of Known Elements

PO argues that the combination of 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, 53-61.) PO effectively argues that no single reference discloses the very thing claimed. (*Id.*) The Board addressed this

argument in the '005 Patent IPR and correctly observed that this is not the standard for obviousness. (Ex. 1018, 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.

Here, PO fails to show that combining Schaffer’s valve with Hartley’s string or Eller’s wire would involve any “unknown” elements. Not only were the elements known (Schaffer’s actuating members and Hartley’s string/Eller’s wire), they were known to perform the same function—to constrict the lumen of a hemostasis valve. (Ex. 1005, [0075]-[0077], Figs. 30-34; Ex. 1006, [0031], Figs. 3-4; Ex. 1007, 15:21-40, 17:47-18:3, Figs. 10A-10C; Ex. 1003, ¶¶105-107, 120-121.) As explained in the Petition, attaching each end of the string/wire to one of Schaffer’s actuator buttons was obvious. (Ex. 1003, ¶¶104-106, 118, 120-121; 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.”).

2. The Combinations Would Have Been Simple And Predictable

PO also fails to explain why combining Schaffer's valve with Hartley's string or Eller's wire would not have been simple. (POR, 54-61.) Mr. Thornton described several simple ways to make the combination, including making small holes in each of Schaffer's buttons, threading the string/wire through the holes, and knotting the string/wire to hold it in place. (Ex. 1003, ¶¶104-107; 118-121.) PO does not dispute Mr. Thornton's testimony. Instead, PO cites Dr. Zalesky's assertion that "there are many design considerations" for this substitution. (POR, 68 (quoting Ex. 2008, ¶142.) However, the only "design considerations" Dr. Zalesky identifies are his unfounded arguments regarding manufacturing and durability discredited above. (Ex. 2008, ¶142; *supra* §§II.B.3-4.)

PO also argues that combining Schaffer's valve with Hartley's string or Eller's wire would be unpredictable and that Mr. Thornton's testimony supports this argument. (POR, 65-68 (citing Ex. 2007, 44:21-45:11).) PO is incorrect.

During his deposition, Mr. Thornton observed that a POSITA could not determine whether the filaments in Figures 8-9 of the '012 patent were flexible based on the figures alone. (Ex. 2007, 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 suggests.

Rather, Mr. Thornton testified that a POSITA would have had a reasonable expectation of success in combining the string/wire member with Schaffer’s valve due to the predictability of the components. (Ex. 1003, ¶¶104-108, 118-121.) For example, Mr. Thornton explained that a POSITA could optimize the filament flexibility given other parameters like “spring tension, the tubular member, size and stiffness.” (Ex. 2007, 44:4-20.)

D. 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 identified and known.” (POR, 69 (citing Pet., 43).) PO is incorrect.

PO cites Mr. Thornton’s deposition testimony regarding various “pinch” valves that press on one or both sides of the tube in a hemostasis valve to flatten the tube. (See Ex. 2007, 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, 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 added to the list of available options, a POSITA still would have had a finite number of options to select for sealing a hemostasis valve by closing a tube. (*Id.*, 118:4-15.) Accordingly, PO has failed to rebut Petitioner’s showing that a POSITA

in 2017 would have known of a finite number of ways to constrict the tube of a hemostasis valve. (Ex. 1003, ¶¶102, 117.)

**III. CLAIMS 1-9 ARE ANTICIPATED OR OBVIOUS IN VIEW
OF SCHAFFER ALONE OR WITH GARRISON (GROUNDS 1-2, 5)**

PO argues that Schaffer does not disclose or render obvious a “filament.” (POR, 32-42.) Yet, as discussed below, PO improperly attempts to import limitations into the Board’s construction and misinterprets Schaffer.

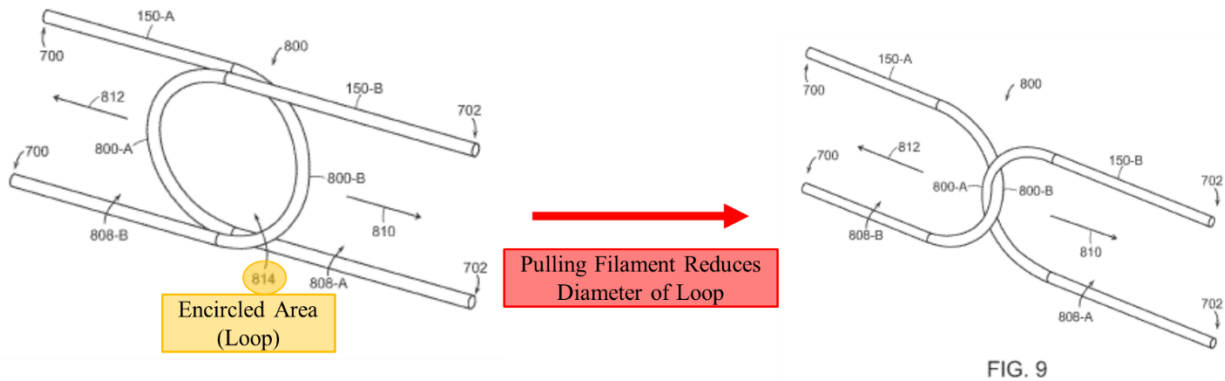
A. The Board Should Not Import “Thin” And “Flexible” Into “Filament”

PO argues the Board should import the unrecited limitations “thin” and “flexible” into the term “filament.” The Board preliminarily agreed with PO’s proposal as to “flexible” in the Institution Decision, finding that the claim language requiring the “filament” to be “formed into a loop” and that pulling on the filament “reduc[es] a diameter of the loop” required flexibility. (Paper 6, 15-21.) As explained below, the “loop” limitations do not support importing “flexible” into the claims.

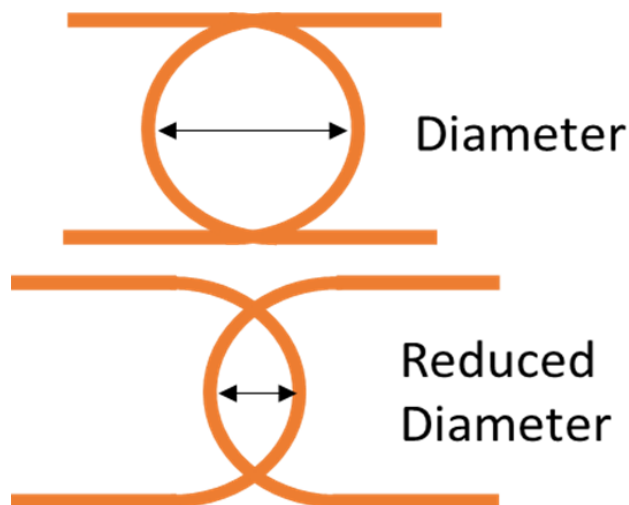
1. The Claims Encompass The “Bight” Embodiments

In the Institution Decision, the Board cited Figure 6 of the ’012 patent and stated that “there appear to be material distinctions between filaments that form a ‘loop’ as claimed versus filaments that form ‘bights.’” (*Id.*, 18.) The Board preliminarily determined these distinctions supported construing “filament” to require flexibility. (*Id.*) However, the “bight” embodiments in Figures 8-9 meet the

claim limitations because the bights collectively form a loop and pulling on the ends of the bights reduces the loop diameter:



(Ex. 1001, 13:52-14:5, Figs. 8-9.) Notably, a “diameter” encompasses irregular shapes like the lower demonstrative below. (Ex. 1023, 3.)



The Board also cited the specification’s description of Figure 6 as a “loop” and Figure 8 as an “encircled area” as suggesting that loops are distinct from encircled areas. (Paper 6, 18-19.) However, while the words are different, “loop” means to “encircle.” (Ex. 1023, 5.) Further, the specification describes the filaments

in Figures 6 and 8-9 as behaving the same way. The specification explains that “a diameter or *size* of the loop ... can *decrease* when the constricting mechanism 141 is moved” (Ex. 1001, 13:26-28 (emphasis added).) Similarly, movement of the constricting mechanism “*decreases* the *size* of the encircled area 814” (*Id.*, 13:61-14:5 (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.”

The Examiner’s restriction requirement also fails to create a clear and unambiguous disclaimer of the bight embodiments. *Plantronics, Inc. v. Aliph, Inc.*, 724 F.3d 1343, 1351-52 (Fed. Cir. 2013) (“The election of an invention in response to an ambiguous restriction requirement in turn cannot be said to provide any guidance forming a basis for narrowing a broadly drafted claim.”). The Examiner’s “restriction requirement did not suggest that the different inventions it found were based on differences in structure” between a “loop” and a “bight.” *Id.*; (Ex. 1002, 180). To the contrary, the Examiner identified Figures 6 and 7 as “distinct sub-species of filament,” yet the specification describes both figures as including “loops.” (Ex. 1002, 180.) Consequently, distinctions between loops and bights could not have formed the basis for the restriction. (*Id.*) Accordingly, PO’s election of sub-species IB in response to the restriction cannot constitute a disclaimer of Figures 8 and 9. *Plantronics*, 724 F.3d at 1351-52. If anything, the restriction

confirms that Claim 1 is broadly drafted to encompass Figures 8 and 9 because the Examiner found that the “application contains claims directed to” the sub-species of Figures 8 and 9. (Ex. 1002, 180; *see also id.*, 179, 4704 (originally filed claims).)

The POR also confirms that PO’s election was not a clear and unambiguous disclaimer. In response to the restriction requirement, PO elected species IB (Fig. 6). (Ex. 1002, 175.) But now PO argues that the claims should ***not*** be limited to Figure 6 but should also cover Figure 7. (POR, 39 n. 3.) The Examiner identified Figure 7 as a distinct sub-species, which was not elected in response to the restriction. (Ex. 1002, 180.) Thus, PO’s current argument acknowledges the ambiguity in the Examiner’s restriction.

2. PO’s Construction Injects Ambiguity Into The Claims

The Board should also reject PO’s construction because it creates ambiguity and 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 and the intrinsic record failed to provide objective boundaries). 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. 2009, 15.)

PO has not identified any objective boundaries that a POSITA could apply to determine whether a material is “flexible” or “thin” enough to constitute a “filament.” (POR, 29-30.) PO merely argues that “the filament must be sufficiently flexible so that it can loosen and reduce in diameter when formed in a loop as shown in Figures 6-7.” (*Id.*, 29.) This argument merely imports an additional subjective term (“loosen”) into the claims, which is not explained in the ’012 patent.

The ’012 patent also does not provide any criteria a POSITA could use to determine whether a material is “flexible.” (Ex. 1020, ¶9.) For example, the patent identifies only exemplary filament dimensions, not mandatory dimensions yielding “flexibility.” (Ex. 1001, 14:11-34.) Likewise, the patent does not describe the filament’s mechanical properties, such as hardness, stiffness, ductility, and malleability, from which a POSITA could glean information about flexibility. (Ex. 1020, ¶9; *see also* Ex. 1019, 108:9-11 (PO’s expert testifying that “I don’t believe that ’011 teaches a very specific measurement of the tensile properties”).) Moreover, a POSITA would have recognized that materials with varying flexibilities can form a loop depending on the force applied to the material, including steel rebar. (Ex. 1020, ¶14.) Yet, the ’012 patent does not describe the force required to form the loop or decrease the size of the loop.

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. 1019, 103:14-20, 107:6-108:14.) PO’s expert confirmed he could not identify the force needed during this “trial and error” testing to constitute a filament. (*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 as to the scope of “filament” and, for that reason, PO’s construction of “filament” should be rejected.

3. PO’s Dictionaries Do Not Justify PO’s Proposed Construction

The dictionary definitions for “filament” cited by PO do not support importing “flexible” into the claims. First, one of PO’s definitions does not even mention flexibility. (Ex. 2003.) Second, PO’s other definition, “a single thread or a thin, flexible threadlike object,” would exclude several “filaments” expressly disclosed in the ’012 patent, such as a “ribbon, flat wire, sheet, or tape,” because they are not “threadlike.” (Ex. 2002; Ex. 1001, 9:21-23.)

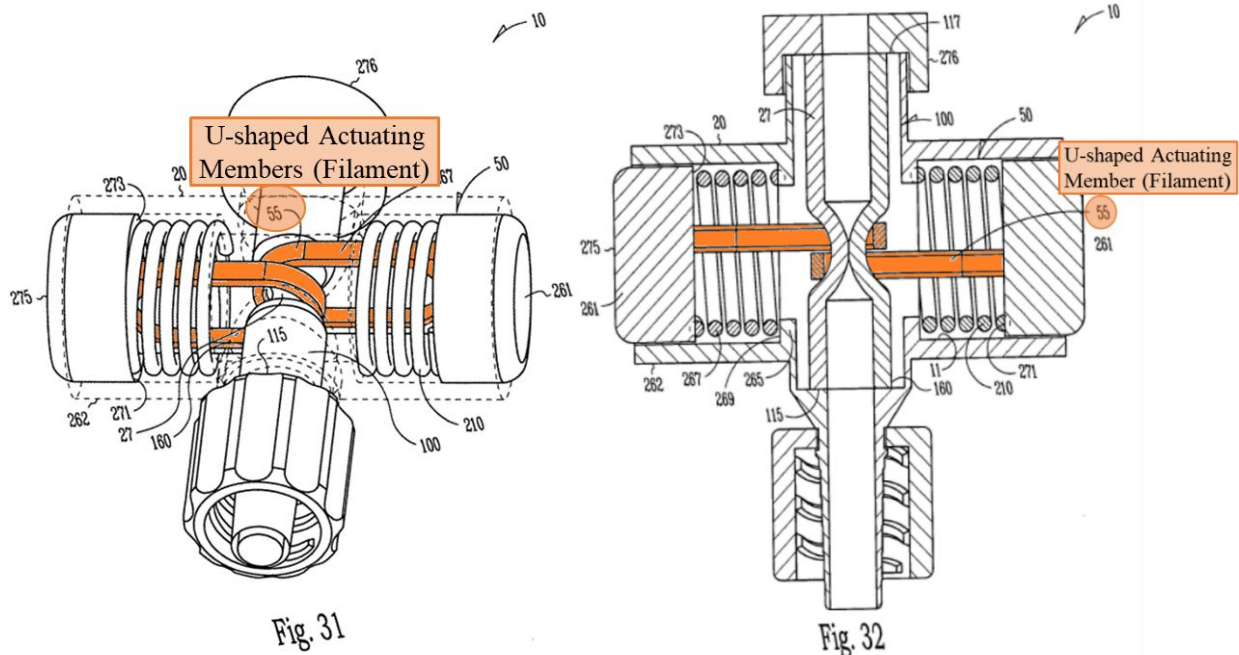
B. Schaffer’s Actuating Members Are A “Filament”

Even if the claims require flexibility, Schaffer’s actuating members are a “filament.” Like the ’012 patent, Schaffer does not expressly describe the flexibility of its filaments. 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, ¶91.)

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.*) Indeed, PO’s expert admitted that a “[a] rigid filament would not be able to accommodate the circular circumference of the internal tubular element.” (Ex. 1019, 101:5-7.)

Further, Schaffer illustrates the actuating members as having 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. (Ex.

1020, ¶¶17-27.) A POSITA would not have concluded that the actuating members are “completely inflexible” or “rigid” as PO argues. (*Id.*; Ex. 1019, 134:4-8.) Indeed, PO’s expert testified that he was unaware of any hemostasis valve components that would be “completely inflexible.” (Ex. 1019, 110:8-14, 134:4-8.)

Accordingly, Schaffer’s U-shaped actuating members are a “filament” even under PO’s proposed construction. (Ex. 1020, ¶¶14-27.)

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, 34-35.) Yet, none of the disclosures requires “rigid” actuating members.

a. PO And Its Expert Misunderstand 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, 34 (citing Ex. 1005, [0077]).) PO argues that “a ‘filament’ cannot ‘forcibly disengage’ because it is flexible and would merely deform when the actuator button is pressed and tension on the filament is reduced.” (*Id.*) But pushing the buttons on Schaffer’s valve is the forcible disengagement (*supra* §II.B.2); thus whether the filaments deform is irrelevant. (Ex. 1020, ¶¶25-26.)

PO's expert has also argued that Schaffer's actuator members must be "rigid" because Schaffer is "imposing substantial external force from two sides of an enclosed tubular element and creating a constriction by the staggered C-shaped or semicircular actuators." (Ex. 1019, 135:11-18; *see also id.*, 148:20-149:7.) However, this is the exact same sealing mechanism employed by the bight embodiments (Figs. 8-9) of the '012 patent and PO's expert argues the bights are flexible. (Ex. 1020, ¶26.) PO's expert was unable to reconcile this inconsistency. (Ex. 1019, 149:8-20.) For example, PO's expert could not identify any differences between the bight embodiments and Schaffer that would support his conclusion that Schaffer's actuating members are "rigid" but the filaments in the bight embodiments are flexible.

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, ¶100; Ex. 1020, ¶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:

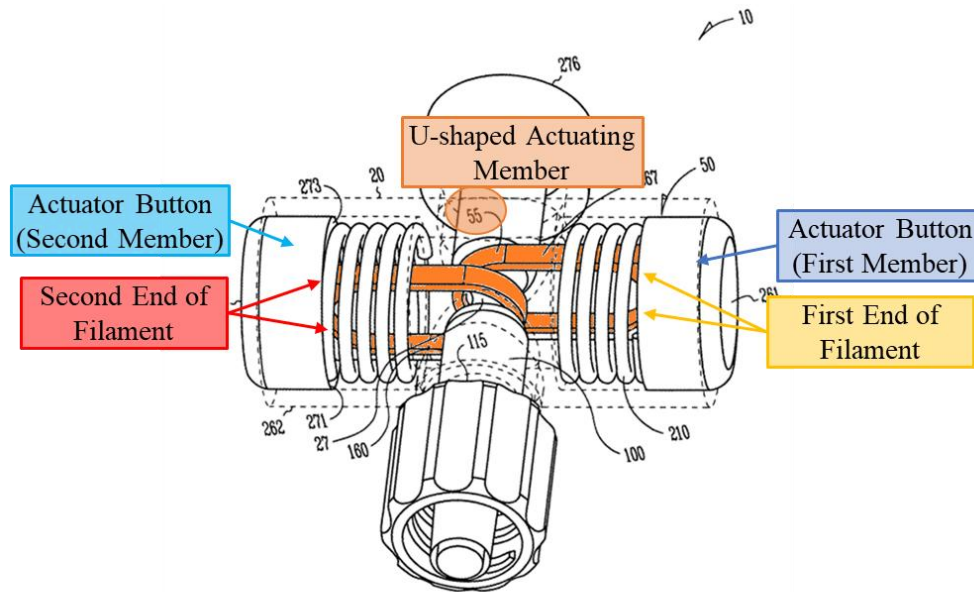
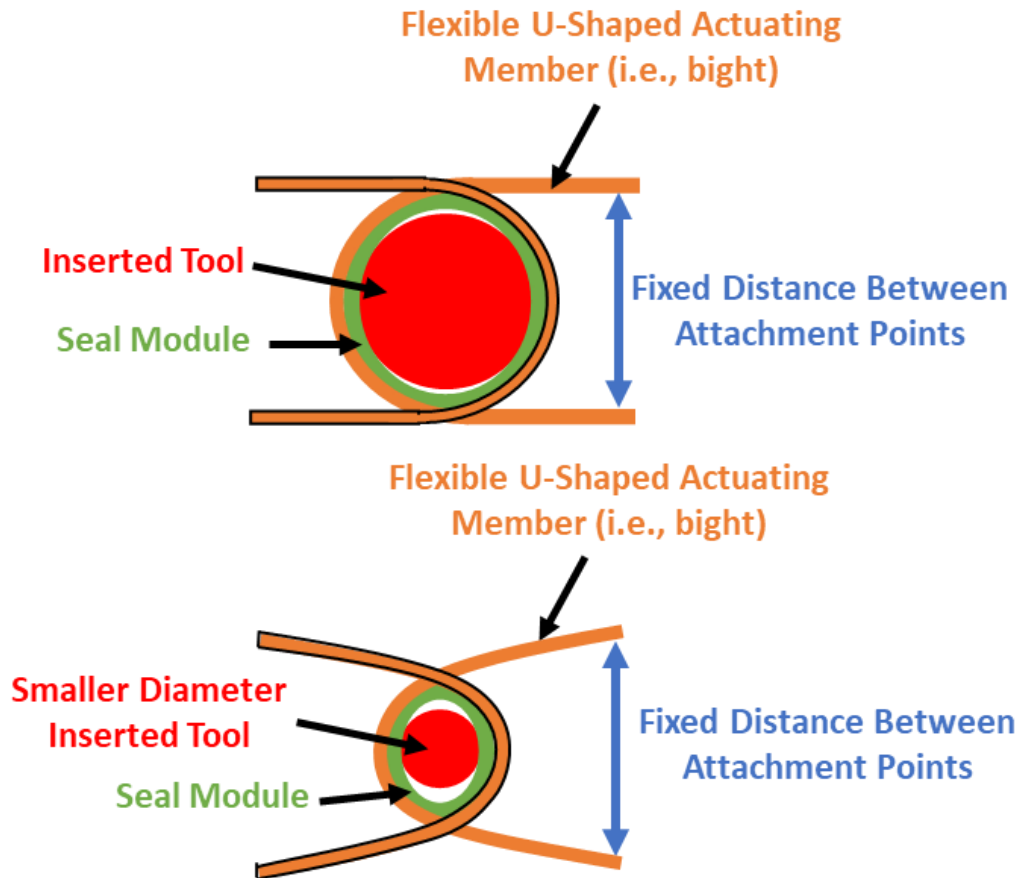


Fig. 31

(Ex. 1020, ¶34; Ex. 1005, Fig. 31.) This fixed attachment to the actuator buttons 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, as illustrated below:



(Ex. 1020, ¶34.)

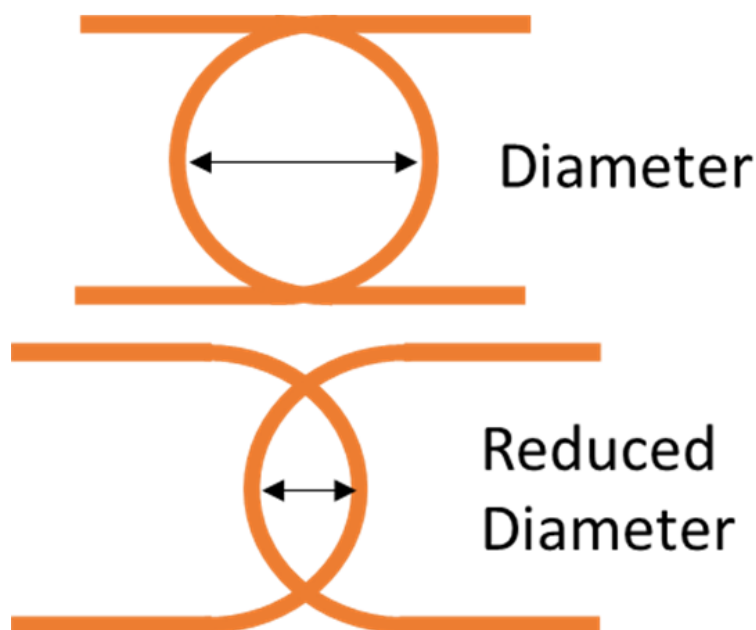
b. Schaffer’s Exemplary Manufacturing Methods Do Not Require “Rigid” Actuating Members

Schaffer’s disclosure that the actuating members can, “*in one option*, [be] made from machining pre-existing amounts of metals and/or plastics” does not mean the actuating members are “rigid.” (Ex. 1005, [0082] (emphasis added).) First, machined parts can be flexible. (Ex. 1020, ¶23.) Second, PO’s expert agrees with Mr. Thornton that POSITAs would have been aware of other manufacturing methods for making flexible metallic or polymeric materials prior to 2017, including rolling or drawing. (Ex. 1019, 96:4-99:17; Ex. 1020, ¶24.)

2. Schaffer’s U-Shaped Actuating Members Form A “Loop”

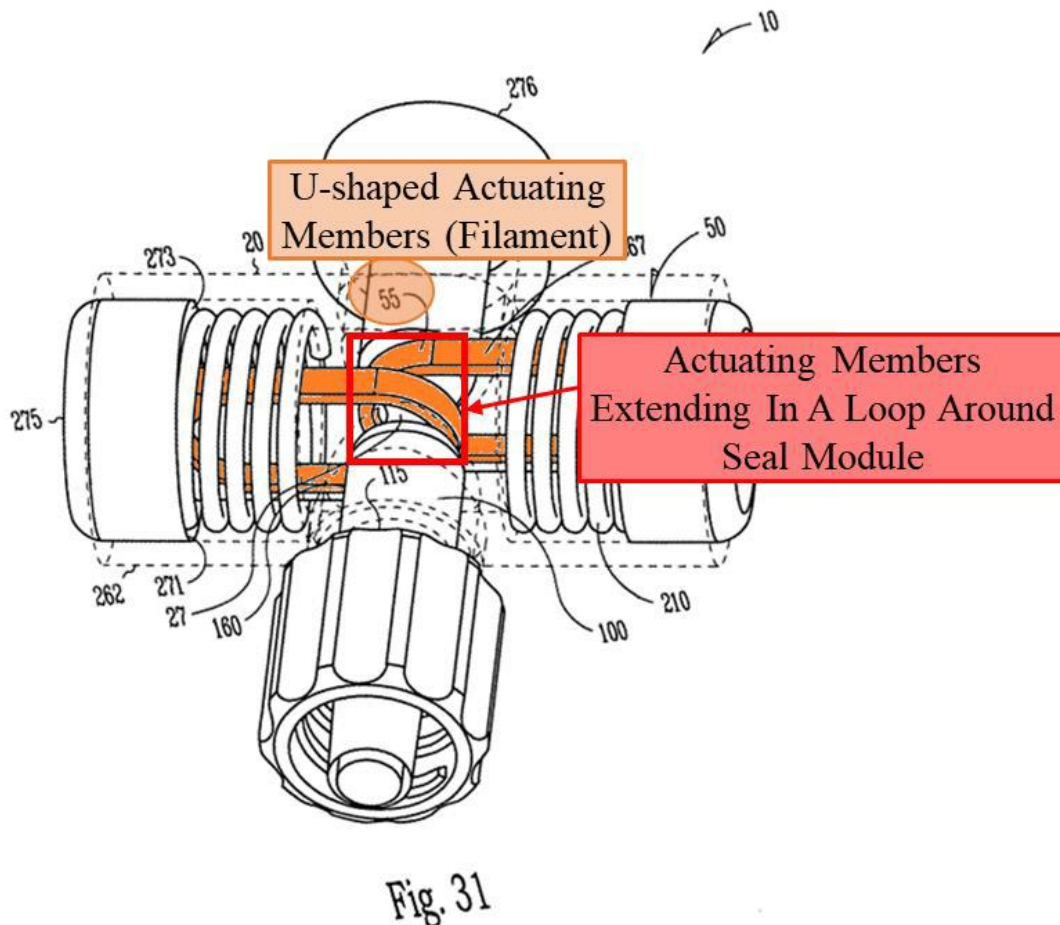
Schaffer’s U-shaped bights collectively form a “loop” around the seal module. (Ex. 1005, [0075]-[0077]; Ex. 1003, ¶¶93.) PO cites a dictionary definition of “bight” which confirms that “bight” means “a slack part or *loop* in a rope.” (Ex. 1024, (emphasis added).) Likewise, the word “loop” means to “encircle.” (Ex. 1023, 5.) The ’012 patent discloses that the bights form an “encircled area” around the elongate member, and that movement of the constricting mechanism “*decreases* the *size* of the encircled area 814” (Ex. 1001, 13:57-14:5 (emphasis added).)

Similarly, the “encircled area” (i.e., “loop”) formed by Schaffer’s actuating members reduces in diameter when the actuator buttons are undepressed, as illustrated by the demonstrative below:



(See also Ex. 1023, 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, 40-41.) But "interlock" is not synonymous with "overlap." As illustrated below, the bights of Schaffer's actuating members "overlap" to form an encircled area, just like the bights in the '012 patent:



(Ex. 1005, Fig. 31; Ex. 1003, ¶93.) This is confirmed by the '012 patent, which discloses that the bights "overlap and define an encircled area" because the bights are next to each other, not because the bights "interlock." (Ex. 1001, 13:52-61.)

PO also attempts to distinguish Schaffer’s loop by arguing that the challenged claims require a *single* filament that forms a loop. (POR, 36-37.) Yet the claims do not say “single filament.” In addition, the specification states that “*the filament 150* can comprise multiple filaments.” (Ex. 1001, 12:61-62 (emphasis added).)

Thus, PO’s own evidence and the ’012 patent confirm that Schaffer’s U-shaped actuating members form a loop as recited in Claim 1 of the ’012 patent.

IV. PETITIONER’S DEFINITION OF A POSITA IS CORRECT

PO argues that Mr. Thornton’s expert declaration should be “afforded little or no weight” because Petitioner’s proposed POSITA does not include experience designing hemostasis valves. (POR, 31-32.) PO’s argument is directly contradicted by its expert. PO’s expert agreed that a POSITA would not need prior experience designing a hemostasis valve or any medical devices. (Ex. 1019, 72:11-75:1.) He further testified: “I don’t believe a POSITA has to have specific experience with different methodologies of hemostasis.” (*Id.*, 82:3-6.) He also testified that a POSITA “wouldn’t have needed to have direct experience with [large-bore catheters] or, in particular, aspiration.” (*Id.*, 86:10-18.) In fact, according to PO’s expert, a POSITA’s experience “could be as simple as bench testing and looking at clinical data” or “an engineer involved in just one aspect of said catheter or device.” (*Id.*, 74:5-17.) The testimony of PO’s expert is consistent with Petitioner’s proposed definition of a POSITA.

V. 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: October 7, 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 5,537 words and therefore complies with the type-volume limitations of 37 C.F.R. § 42.24(c).

Dated: October 7, 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 1018 – Exhibit 1024** are being served electronically on October 7, 2025, to the e-mail addresses shown below:

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