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On behalf of **Imperative Care, Inc.**

By: Joshua J. Stowell (Reg. No. 64,096)
Joseph R. Re (Reg. No. 31,291)
Brian C. Barnes (Reg. No. 75,805)
KNOBBE, MARTENS, OLSON & BEAR, LLP
2040 Main Street, 14th Floor
Irvine, CA 92614
Tel.: (949) 760-0404
Fax: (949) 760-9502
Email: BoxImperative011@knobbe.com

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

IMPERATIVE CARE, INC.,
Petitioner,

v.

INARI MEDICAL INC.,
Patent Owner.

Case IPR2024-01157
Patent No. 11,697,011

PETITIONER'S REPLY TO PATENT OWNER'S RESPONSE

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LIST OF EXHIBITS

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1001	U.S. Patent No. 11,697,011 (“the ’011 patent”)
1002	’011 Patent Prosecution History Excerpt
1003	Expert Declaration of Troy Thornton
1004	Resume of Troy Thornton
1005	U.S. Patent Publication US 2003/0225379 A1 to Schaffer et al. (“Schaffer”)
1006	U.S. Patent Publication US 2003/0116731 A1 to Hartley (“Hartley”)
1007	U.S. Patent No. 9,980,813 B1 to Eller (“Eller”)
1008	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	Declaration of Joshua J. Stowell in Response to Patent Owner’s Objections to Imperative Care’s Evidence [SERVED ONLY]
1013	Certified File History of U.S. Patent Application 10/371,190 [SERVED ONLY]
1014	Supplemental Expert Declaration of Troy Thornton
1015	Deposition Transcript of PO’s Expert Paul Zalesky, Ph.D. dated June 23, 2025

IPR Petition – Patent 11,697,011
Imperative Care, Inc. v. Inari Medical Inc.

Exhibit No.	Description
1016	Decision Granting Institution of IPR, IPR2025-00156, U.S. Patent No. 11,697,012 B2
1017	Decision Granting Institution of IPR, IPR2025-00289, U.S. Patent No. 11,554,005 B2
1018	U.S. Patent No. 12,109,384 B2 to Merritt et al.
1019	New Oxford American Dictionary, 3rd ed. (2010) – definitions of “diameter,” “filament,” and “loop”

I. INTRODUCTION

Since the filing of the Petition, the Board has instituted three IPRs (including this IPR) challenging PO's patents claiming a valve with a filament. (Paper 7; Ex. 1016-1017.) 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 in all three patents unpatentable. In the current Patent Owner Response ("POR"), PO recycles arguments from the instituted IPRs that the Board has preliminarily found unpersuasive. PO fails to present any new, probative evidence to undermine Petitioner's unpatentability grounds or the Board's preliminary findings.

PO dedicates much of its POR to disputing the construction of "filament" and whether Schaffer discloses a "filament." (POR, 24-45.) The Board was correct to preliminarily reject PO's arguments on these issues for the reasons provided herein. However, the construction of "filament" is a secondary issue because it impacts only Grounds 1-2 (Schaffer alone). The construction of "filament" does not impact Grounds 3-4, which combine Schaffer with Hartley or Eller. PO **does not** dispute that Hartley and Eller disclose "filaments," even under PO's restrictive construction. The Board preliminarily found that PO "provides no argument that any limitation is missing in the combination of Schaffer with Hartley." (Paper 7, 36.) That is still true following the POR.

Instead, PO 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, “Petitioner advances multiple reasons why a skilled artisan would have been motivated to combine Schaffer and Hartley [or Eller] with a reasonable expectation of success.” (Paper 7, 36.) As shown below, PO fails to rebut Petitioner’s evidence and instead simply misinterprets or ignores significant portions of the prior art.

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 HARTLEY OR ELLER (GROUNDS 3-4)

PO does not dispute that Schaffer’s valve combined with Hartley’s string or Eller’s wire member discloses every limitation of the challenged claims. (POR, 45-68.) PO disputes only whether a POSITA would have been motivated to combine Hartley’s string or Eller’s wire member with Schaffer’s valve. (*Id.*)

However, Petitioner showed a POSITA would have been motivated make the combinations for multiple reasons, including (1) the combinations entailed a simple substitution of one known element for another, (2) Hartley and Eller confirm the effectiveness of the string/wire member for constricting a valve, (3) Hartley’s string and Eller’s wire member may seal more effectively across a wider range of device shapes and dimensions, and (4) POSITAs had a finite number of predictable

materials to select from to constrict the lumen of a tubular member in a hemostasis valve in 2017. (Pet. 35-36, 44-45; Ex. 1003, ¶¶80-83, 93-96.)

PO does not dispute some of these motivations. For example, PO ignores the express disclosures in Hartley and Eller touting the effectiveness of using the string/wire to seal around varying devices in a hemostasis valve. (See Ex. 1006, [0037]; Ex. 1007, 15:21-40, 17:38-43, 18:3-8.) PO does not dispute that these disclosures would have motivated a POSITA to use Hartley’s string or Eller’s wire in Schaffer’s valve. (Pet. 35-36, 44-45; Ex. 1003, ¶¶80, 93.)

PO also does not dispute that there were a finite number of predictable materials to select from to constrict the lumen of a tubular member in a hemostasis valve September 2017. (Pet. 36, 45; Ex. 1003, ¶¶83, 96.) Thus, Mr. Thornton’s testimony regarding these motivations stands unrebutted.

PO’s other arguments regarding the motivation to combine are premised on misinterpretations of Schaffer and the mistaken assertion that Schaffer’s valve requires a “sticky” seal module that seals perfectly. Accordingly, PO fails to rebut or discredit Petitioner’s evidence and the Board should find claims 1-9 unpatentable based on the combination of Schaffer with Hartley or Eller.

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’s valve with Hartley’s string or Eller’s wire is because “Hartley’s string [or Eller’s

wire] may seal more effectively across a wider range of diameters for the inserted devices (e.g., other catheters or tools) than Schaffer’s U-shaped actuating members.” (Pet., 35-36, 44-45.) Petitioner’s expert, Mr. Thornton, explained that a POSITA would have understood Hartley’s string or Eller’s wire member could eliminate gaps that may form between Schaffer’s seal module and some devices. (Ex. 1003, ¶¶80-88, 93-100.) The Board preliminarily agreed “that the POSA would have considered a more flexible filament (e.g., Hartley’s string or Eller’s wire) as providing expected benefits insofar as such a filament may more precisely and uniformly constrict the lumen against inserted tools of different sizes and shapes.” (Paper 7, 37.) PO provides no reason for the Board to deviate from its preliminary decision.

Instead, PO repeats its POPR argument that Schaffer’s valve would not form any gaps because it “forms a complete seal.” (POR, 46; see Paper 7, 37 (addressing this argument).) PO argues that “Schaffer discloses that its rigid U-shaped members 55 do not result in gaps due to the inclusion of sealing member 165.” (POR, 49 (citing Ex. 1005, [0059]; Ex. 2008, ¶¶128-153).) Yet, the cited portion of Schaffer does not support this argument. Schaffer states, “The material 166 exhibits a ‘selfclosing’ nature in that it sticks occlusively to itself forming a **nearly** fluid/gas tight seal under very light compression.” (Ex. 1005, [0059] (emphasis added).)

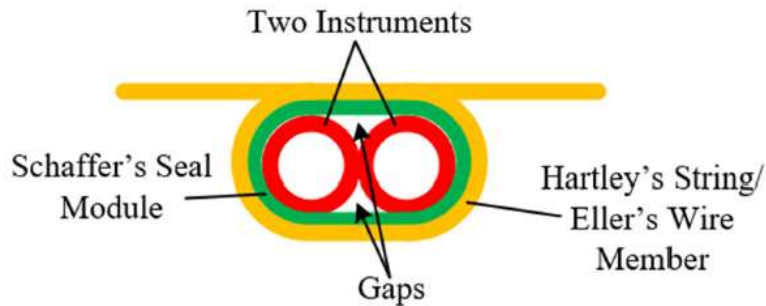
Further, PO’s expert admitted that prior to 2017, POSITAs would have recognized that “cinching” a hemostasis valve, such as through a garrote, would have

more effectively sealed around large-bore catheters due to “simple mechanical engineering and physics.” (Ex. 1015, 86:19-87:4.) This testimony further corroborates that a POSITA would have understood that Hartley’s string or Eller’s wire may provide sealing advantages over Schaffer’s U-shaped actuating members for certain devices. (Ex. 1003, ¶¶81, 94; Ex. 1014, ¶¶29-35.)

PO also continues to argue that Schaffer’s valve would not form gaps because Schaffer requires a “selfclosing” or “sticky” valve. (POR 49-51 (citing Ex. 1005, [0059]-[0060]).) Yet, Schaffer makes clear the “selfclosing” or “sticky” materials are exemplary by using phrases like “[i]n one embodiment,” “in one option,” “as examples,” “in another option,” and “[f]or illustrative purposes only.” (Ex. 1005, [0059].) Schaffer discloses a range of materials for its seal module (e.g., “modified vinyl, silicone, polyurethane”) that are not “sticky” or “selfclosing.” (Ex. 1005, [0081], Ex. 1003, ¶88; Ex. 1014, ¶32.) And Schaffer does not specifically mention a “sticky” or “selfclosing” valve for the embodiment in Figures 30-34 relied upon by Petitioner. (Ex. 1005, [0075]-[0080].) In fact, even PO’s expert admits that Schaffer’s “sticky” valve is an optional feature in one embodiment that is not necessary for Schaffer’s valve to function. (Ex. 1015, 163:7-13.) Thus, the Board correctly observed that the portion of Schaffer relied on by PO “concerns only ‘one embodiment’ of Schaffer’s valve and the ‘sticky’ or ‘selfclosing’ material appears to be simply one optional feature.” (Paper 7, 37 (citing Ex. 1005, ¶59).)

Moreover, a POSITA would have understood that a “sticky” material would not work very well for the embodiment in Figure 30-34. Schaffer explains that the seal module must “retract to an uncollapsed configuration” when the constrictive force of the actuating members is removed. (Ex. 1005, [0077].) A “sticky” or “selfclosing” material that “sticks occlusively to itself” would not easily or quickly retract to an uncollapsed configuration when the constrictive force is removed. (*Id.*, [0059]; Ex. 1014, ¶33.) Notably, PO’s expert agrees that Schaffer’s seal module could not be so sticky that it could not retract in the absence of compressive force. (Ex. 1015, 164:7-17.)

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.) Once again, PO focuses on an “embodiment” other than Figures 30-34. This particular embodiment has 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. (Ex. 1014, ¶35.)



Instead, the cartoon reflects a non-compliant seal that does not conform to the shape of the instruments. (*Id.*) This cartoon would look the same if the string/wire were replaced with two U-shaped actuating members. (*Id.*) Thus, the cartoon is not representative of Schaffer's hyper compliant seal and does not evidence that Schaffer's valve would work less effectively with a string/wire. (*Id.*)

Finally, PO mischaracterizes the positions of Petitioner and Mr. Thornton. PO argues that "Petitioner and its expert repeatedly admit that Schaffer's valve forms a complete seal – even when various instruments are inserted therethrough." (POR, 46.) Yet, PO never argued that Schaffer forms a "complete seal" around every potential 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, ¶81; *see also id.*, ¶75.)

For all of these reasons, PO has failed to rebut Petitioner's evidence that a POSITA would have been motivated to use Hartley's string or Eller's wire to form a more effective seal.

B. PO Fails To Show That Adding Hartley’s String Or Eller’s Wire To Schaffer’s Valve Changes Schaffer’s “Principles Of Operation”

Once again, 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, 52.) PO identifies three ways the combination would allegedly change the principle of operation: Hartley’s string and Eller’s wire member (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, 52-60.) The Board addressed each argument in the POPR and correctly found each one deficient. (Paper 7, 38-41.)

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 – in fact, Schaffer does not even discuss ease of manufacturing or features to make the valve more durable.

Rather, Schaffer’s abstract and background explain that the valve is intended to seal with or without an instrument in place. (Ex. 1005, *abstract*, [0008].) The valve in Figures 30-34 seals by applying force to a tube. (*Id.*, [0075]-[0077].) Specifically, the valve collapses the tube by applying a “compressive force 67 (e.g. by a spring)” to the ends of the U-shaped actuating members and, in turn, the tube

positioned within those members. (*Id.*, [0077].) The tube can also “retract to an uncollapsed configuration” when the user pushes the buttons 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. 1014, ¶¶38-39.)

This principle of operation remains unchanged if Hartley’s string or Eller’s wire member is substituted for Schaffer’s U-shaped actuating members. (Ex. 1003, ¶¶82-87; Ex. 1014, ¶¶38-39.) In the combination, Schaffer continues to use springs to apply a constrictive force to the ends of the string/wire member and the tube, and the buttons to release that constrictive force. (*Id.*)

2. **Hartley’s String Or Eller’s Wire Would Permit Forcible Disengagement**

PO argues that “Hartley’s string or Eller’s wire member would never disengage—let alone forcibly disengage—Schaffer’s seal module.” (POR, 54.) 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” the module. (See Ex. 1005, Fig. 34.) Thus, forcibly disengage cannot mean the actuating members 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[.]” (*Id.*, [0077], Fig. 34; Ex. 1014, ¶41.) Schaffer applies force to the actuating members in the same way the ’011 patent applies force to its filament(s). (See Ex. 1015, 85:3-8 (admitting the filament in the ’011 patent disengages from the tubular member).)

PO argues that Mr. Thornton “conceded” that Schaffer’s “seal module could stick to and retain Hartley’s string or Eller’s wire member in the closed position—rendering Schaffer’s valve inoperable by inhibiting movement of the seal module from the collapsed closed position to the uncollapsed open position.” (POR, 55 (citing IPR2025-00289, Ex. 1003, ¶124).) PO misrepresents Mr. Thornton’s testimony. Mr. Thornton testified that “the ‘sticky’ or ‘gelatinous’ materials would not work well with the seal modules disclosed in Figures 31-34 because those seal modules must ‘retract to an uncollapsed configuration’ when the tension on the module is released by the actuating members.” (IPR2025-00289, Ex. 1003, ¶124.) Mr. Thornton did not discuss the interaction of Hartley’s string or Eller’s wire member with sticky materials. (*Id.*)

3. PO Fails To Show That Hartley’s String Or Eller’s Wire Member Would Compromise Ease Of Manufacturing

PO argues that Hartley’s string or Eller’s wire member would compromise ease of manufacturing. (POR 55-60.) This argument is unsupported. Schaffer never claims that ease of manufacturing is a “principal of operation.” To the contrary,

Schaffer describes the disclosed manufacturing methods as “one option” and “an example.” (Ex. 1005, [0082]-[0083]; Ex. 1014, ¶44.)

Moreover, a POSITA in 2017 would have known many ways to assemble Schaffer’s valve with Hartley’s string or Eller’s wire member. (Ex. 1014, ¶¶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. Schaffer’s valve uses simple, predictable components and a POSITA would have had ample training and experience to manufacture the valve using Hartley’s string or Eller’s wire. (*Id.*)

4. PO Fails To Show That Hartley’s String Or Eller’s Wire 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, 60 (citing Ex. 2008, ¶169)); *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 because they “lacked evidentiary support for the underlying positions”).

Hartley and Eller describe using a string/wire member for the same purpose as Schaffer’s U-shaped actuating members – constricting a tube. (Ex. 1014, ¶48.) Neither reference suggests that durability is an issue. Moreover, PO’s expert admitted that durable strings and wire materials used to manufacture medical devices would have been known and available to POSITAs prior to 2017. (Ex. 1013, 169:16-170:11.) Accordingly, durability concerns would not have dissuaded POSITAs from combining Hartley’s string or Eller’s wire with Schaffer’s valve. (Ex. 1014, ¶48.)

C. Combining Schaffer’s Valve With Hartley’s String Or Eller’s Wire Would Have Been A Simple Substitution Of Known Elements

PO argues that the combination of Schaffer with Hartley’s string or Eller’s wire member would not be a simple substitution of known elements. (POR, 63-68.) Importantly, PO does not dispute that the elements were known. Rather, PO argues that no single reference disclosed the combination of elements (i.e., Schaffer’s valve with Hartley’s string or Eller’s wire member). (POR, 63.) Essentially, PO complains that the references are not anticipating. But that is not the standard for obviousness. *See, e.g., Masimo Corp. v. Apple Inc.*, No. 2022-1894, 2024 WL 111647 at * 3 (Fed. Cir. Jan. 10, 2024) (explaining, “it suffices ... ‘that a person of

ordinary skill in the art would have been motivated to combine the prior art in a way such that the combination discloses the claim limitation”); *see also Fleming v. Cirrus Design Corp.*, 28 F. 4th 1214, 1222 (Fed. Cir. 2022).

PO also fails to explain why the combination of Schaffer’s valve with Hartley’s string or Eller’s wire would not have been simple. (POR, 68.) Mr. Thornton explained that a POSITA could simply make some small holes in each of Schaffer’s buttons, thread the string or wire through the hole, and knot the string/wire to hold it in place. (Ex. 1003, ¶¶84-88; 97-100.) PO does not dispute Mr. Thornton’s testimony. Instead, PO argues without explanation that “controlling a string or wire with two independently movable actuators—rather than one actuator as taught by Schaffer, Hartley, and Eller—would increase the complexity and variability of Schaffer’s valve and make the valve more difficult to manufacture.” (POR, 68 (citing Ex. 2008, ¶128).) Such unsupported testimony cannot rebut a *prima facie* case of obviousness. *See, e.g., Ashland Oil, Inc.*, 776 F.2d at 294; *In re Advanced Cell Diagnostics, Inc.*, 2024 WL 3451829 at *6.

III. CLAIMS 1-9 ARE ANTICIPATED OR OBVIOUS IN VIEW OF SCHAFFER (GROUNDS 1-2)

PO does not dispute that Schaffer discloses every limitation of challenged claims 1-9 except for the “filament.” (POR, 35-45.) As explained below, PO’s arguments regarding Schaffer’s filament are premised on misinterpretations of the

structure and function of Schaffer’s actuating members that are inconsistent with Schaffer and the ’011 patent.

PO also disputes that Schaffer’s actuating members collectively form a “loop” around the tubular member as recited in claim 3. However, PO’s own dictionary definition of “bight” and the ’011 patent confirm that the Schaffer’s actuating members form a “loop” as claimed.

Accordingly, for the reasons below and in the Petition, challenged claims 1-9 are anticipated or obvious in view of Schaffer.

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

PO argues the Board should import the unrecited limitations “thin” and “flexible” into the term “filament.” Notably, however, the ’011 patent never uses the terms thin or flexible to refer to the “filament,” and, thus, the construction lacks written description support. (Paper 7, 15.) For this reason and others, the Board preliminarily rejected PO’s proposed construction. (*Id.*) PO’s arguments in the POR fail to show that the Board erred in its preliminary decision.

1. PO’s Proposed Construction Injects Ambiguity Into The Claims

The Board should not adopt PO’s proposed construction because it injects ambiguity into the claims 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 the term

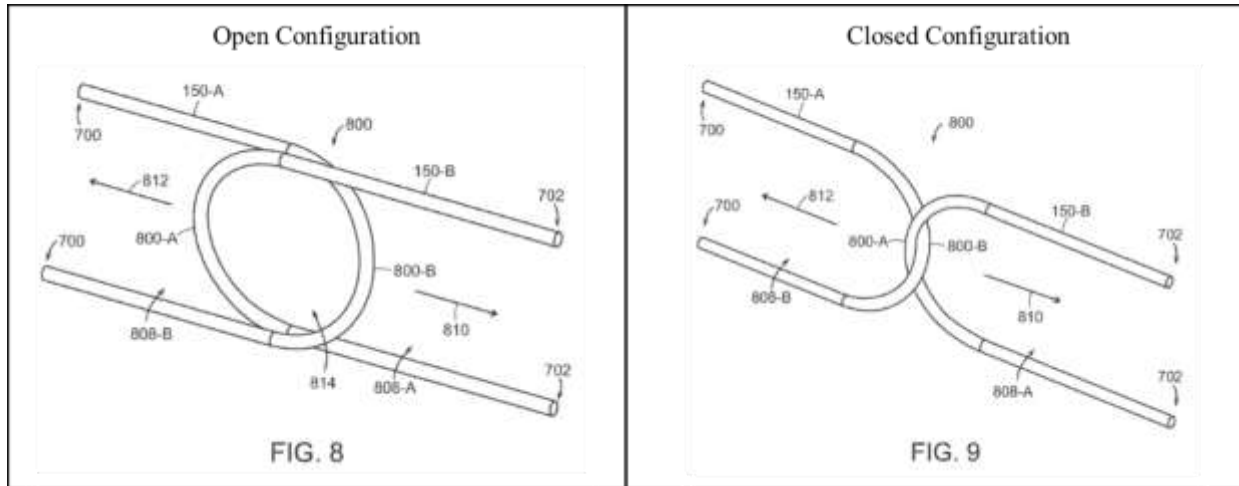
“unobtrusive manner” indefinite because it is a “highly subjective” term and the intrinsic record failed to provide objective boundaries regarding its scope). The Board correctly recognized that:

[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?

(Paper 7, 15.)

PO has not identified any objective boundaries that a POSITA might apply to determine whether a material is “flexible” or “thin” enough to constitute a “filament” under its proposed construction. (POR, 34.) Instead, PO merely asserts that “the filament must be sufficiently flexible so that it can loosen, reduce in diameter when formed in a loop as shown in Figures 6-7, and slacken when formed in a bight as shown in Figures 8-9.” (*Id.*) These arguments merely import additional subjective terms (e.g., “loosen” and “slacken”) into the claims, none of which are explained in the ’011 patent.

For example, the ’011 patent never states that the bights “slacken” as PO asserts, and PO does not explain how Figures 8 and 9 allegedly illustrate a “slacken[ing].” In Figures 8 and 9, the u-shaped bights do not change shape between the opened configuration (Figure 8) and the closed configuration (Figure 9):



(Ex. 1001, 5:38-41, Figs. 8-9.) Notably, PO’s expert argues that Schaffer’s U-shaped actuating members must be “rigid” because the actuating members have a similar shape in the open and closed configurations. (Ex. 2008, ¶96.) However, the same is true for the bights in Figures 8-9 of the ’011 patent. Yet, PO and its expert inconsistently argue that the filaments in Figures 8-9 must be “flexible” and “slacken.” (See Ex. 1015, 101:1-21.) PO does not attempt to reconcile these inconsistent interpretations.

The ’011 patent also does not provide any criteria from which a POSITA could determine whether a specific material is “flexible.” (Ex. 1014, ¶9.) For example, while the patent identifies some potential filament dimensions, the patent states that the dimensions are exemplary. (Ex. 1001, 14:18-31.) Likewise, the ’011 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. 1014, ¶9; see also Ex. 1015, 108:9-11 (PO’s expert testifying

that “I don’t believe that ’011 teaches a very specific measurement of the tensile properties”).)

Moreover, the “filament” in Claim 1 does not form a “loop.” Only dependent Claim 3 requires a “loop” clearly indicating that the “filament” in Claim 1 is not so limited. *See, e.g., Liebel–Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 910 (Fed. Cir. 2004) (“[T]he presence of a dependent claim that adds a particular limitation raises a presumption that the limitation in question is not found in the independent claim.”). Thus, PO’s argument that a “filament” must be flexible enough “to reduce in diameter when formed in a loop” does not apply to Claim 1. Moreover, a POSITA would have recognized that a many materials with varying flexibilities can form a loop depending on the force applied to the material, such as steel rebar. (Ex. 1014, ¶14.) The ’011 patent does not provide guidance regarding the force needed to form the loop or to decrease the “diameter or size of the loop.”

The testimony of PO’s expert adds further ambiguity to “filament” under PO’s proposed construction. 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., 1015, 107:6-108:14.) PO’s expert could not identify how much force would be needed during this “trial and error” testing to constitute a filament. (*Id.*) PO’s expert further 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.

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

The dictionary definitions for “filament,” “loosen,” and “bight” cited by PO do not support the importation of “flexible” into the claims.

First, one of PO’s dictionary definitions for “filament” does not even mention flexibility. (Ex. 2003.) Second, PO’s other dictionary definition, “a single thread or a thin, flexible threadlike object,” would exclude several “filaments” expressly disclosed in the ’011 patent, such as a “ribbon, flat wire, sheet, or tape.” (Ex. 1001, 9:18-20.)

PO’s reliance on the dictionary definition of “loose” is also misplaced. (*See* POR, 28.) The ’011 patent states that “the filament 150 is loosened” when the actuator buttons are depressed. (Ex. 1001, 9:55-59.) PO attempts to equate “loosened” with “flexible.” But, the word “loosened” is not synonymous with “flexible.” (Ex. 1014, ¶12.) The term “loosen” in the dictionary submitted by PO means “to release from restraint” and does not have any relationship to flexibility. (Ex. 2009.) Many relatively inflexible items can be loosened, such as screws and u-bolts. (*See* Ex. 1015, 116:12-17 (PO’s expert admitting inflexible materials can be

“loosened.”).) The filaments in Figures 8-9 of the ’011 patent are “loosened” because they release restraint on the elongate member to allow expansion of the member, even if they are relatively inflexible. (Ex. 1014, ¶12.)

PO also argues that the filaments in the bight embodiments of the ’011 patent must be flexible based on a dictionary definition of “bight” that means a “slack part or loop in a rope.” (POR, 28.) However, PO’s dictionary definition does not mention flexibility, and PO ignores the ’011 patent’s express definition of “bight”: “a U-shaped section between the two ends of the filament 150.” (Ex. 1001, 13:44-45.) PO’s definition also conflicts with the ’011 patent’s description of filaments as including “ribbon, flat wire, sheet, or tape.” (*Id.*, 9:18-20.)

For these reasons, the Board should not import “flexible” or “thin” into the construction of “filament” and should instead adopt Petitioner’s proposed construction.

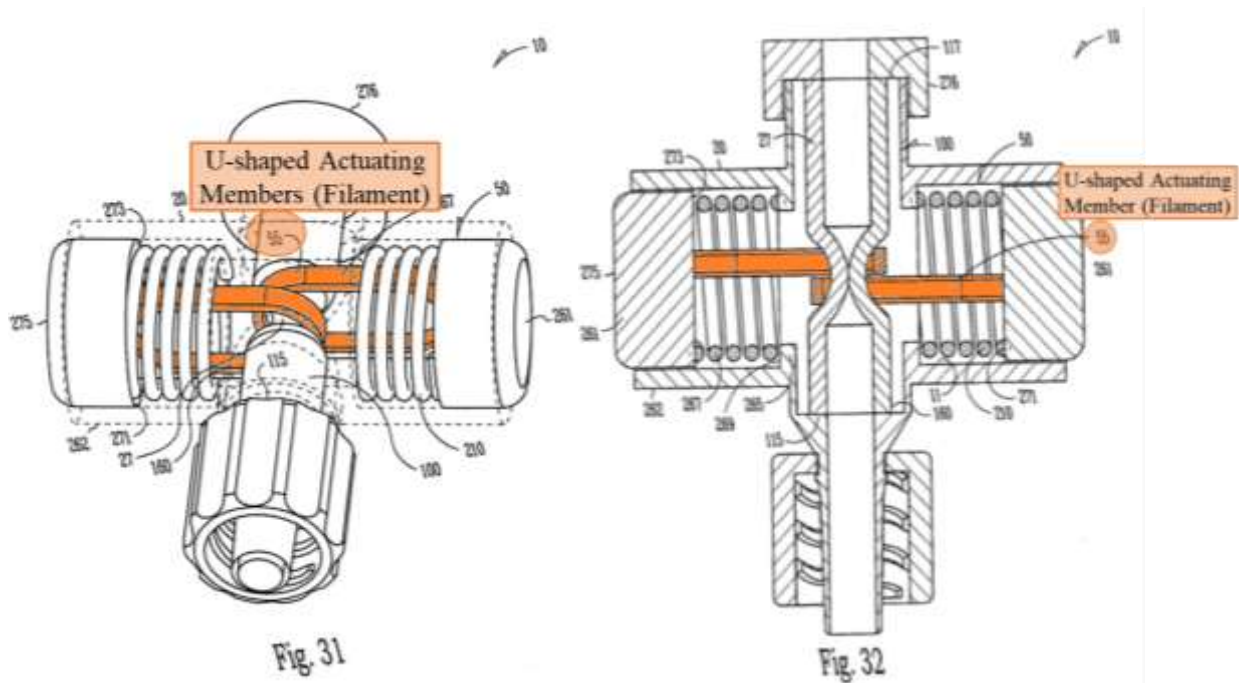
B. Schaffer’s Actuating Members Are A “Filament”

Like the ’011 patent, Schaffer does not expressly describe the flexibility of the 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, ¶71.)

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.” (Ex. 1003, ¶71.) 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. 1015, 101:5-7.)

Further, while Schaffer does not provide precise dimensions for the actuating members, 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. 1014, ¶¶17-27.) A POSITA would certainly not conclude that the actuating members would be “completely inflexible” or lack “any inherent flexibility” as PO

argues. (*Id.*; Ex. 1015, 134:4-8.) Indeed, PO’s expert testified that he was unaware of any components of a hemostasis valve that would be “completely inflexible.” (Ex. 1015, 110:8-14, 134:4-8.)

Accordingly, Schaffer’s U-shaped actuating members are a “filament” even under PO’s proposed construction of that term because they are a “thin, flexible length of material formed by one or more strands of material.” (Ex. 1014, ¶¶14-27.)

1. Schaffer’s Actuating Members Are Not “Rigid”

PO does not allege that Schaffer describes its actuating members as “rigid” or “non-conforming.” Nor could it. Schaffer never uses those terms to describe the members. Instead, PO argues that following disclosures require “rigid” actuating members: (1) the actuating members may “forcibly disengage” the seal module” and (2) the actuating members may be manufactured by machining. (POR, 41-45.) Neither of these disclosures requires “rigid” actuating members as PO asserts.

a. PO And Its Expert Misunderstand Schaffer’s Sealing Mechanism

PO asserts that “[i]n Schaffer, the U-shaped actuating members are intended not to conform to the outer surface of the seal module as compression is applied.” (POR, 43.) Yet, Schaffer does not say this.

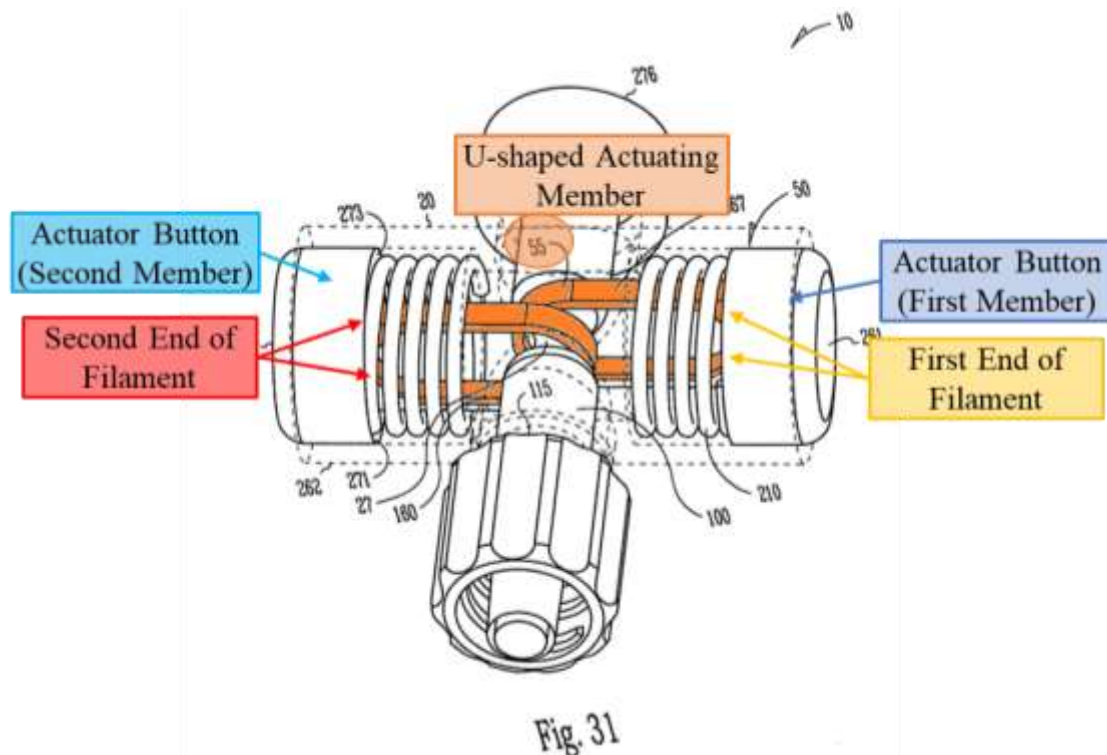
PO reaches its erroneous conclusion by misinterpreting simply Schaffer’s disclosure that depressing the actuator buttons allows the actuator members to “forcibly disengage” the seal module. For example, PO asserts that if Schaffer’s

“actuating members 55 were flexible, they would remain in contact with and never disengage the seal module 100 as the seal module expands.” (POR, 44.) Yet, Schaffer’s actuating members always remain in contact with the seal module. (See Ex. 1005, Figs. 31-34 (actuating members contact seal module).) PO cites no portion of Schaffer that illustrates or describes the members as out of contact with the seal module. (Ex. 1015, 85:3-8.) Thus, PO fails to show the actuator members must be rigid to “forcibly disengage” the seal module. (Ex. 1014, ¶¶25-26.)

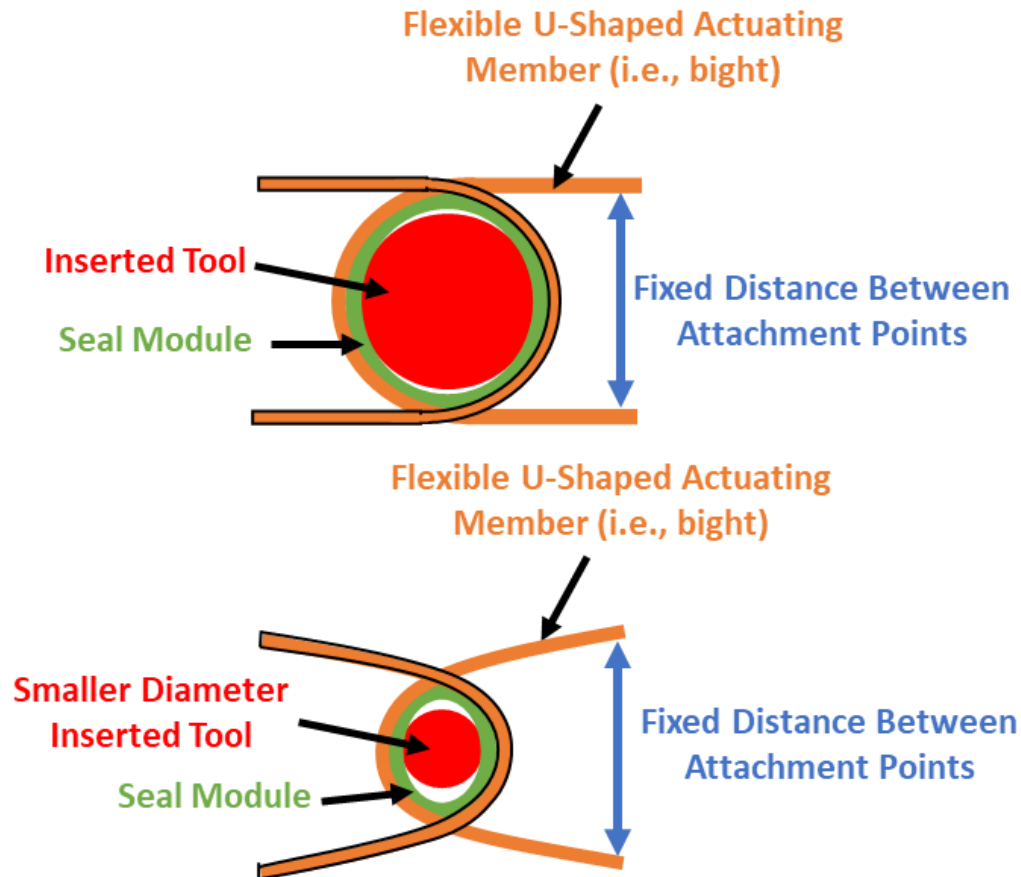
PO’s expert also argues that Schaffer’s actuator members must be rigid because Schaffer is “imposing substantial external force from two sides of an enclosed tubular element and creating a constriction by the staggered C-shaped or semicircular actuators.” (Ex. 1015, 135:11-18; *see also id.*, 148:20-149:7.) However, this is the exact same sealing mechanism employed by the bight embodiments (Figs. 8-9) of ’011 patent. (Ex. 1014, ¶26.) PO’s expert was unable to reconcile this inconsistency. (Ex. 1015, 149:8-20.) For example, PO’s expert could not identify any differences between the references that would support his conclusion that Schaffer’s actuating members are “rigid” but the filaments in Figures 8-9 are flexible. PO’s unsupported distinctions do not justify interpreting Schaffer and the ’011 patent differently.

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, ¶81; Ex. 1014, ¶34.) Gaps will form if the members are rigid, but they will also form if the members are flexible because each U-shaped actuating member is secured to the actuator buttons at two fixed, spaced-apart points:



(Ex. 1014, ¶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. 1014, ¶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 preexisting amounts of metals and/or plastics” does not mean the actuating members are “rigid.” (Ex. 1005, [0082] (emphasis added).) Schaffer identifies machining as “one option” for manufacturing the actuating members. (*Id.*, [0082].) 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. 1015, 96:4-99:17; Ex.1014, ¶24.)

2. Schaffer’s U-Shaped Actuating Members “Circumferentially Constrict” The Tubular Member

Schaffer’s U-shaped actuating members are “circumferentially disposed about the portion 108 of the seal module” and apply opposing constrictive forces on the seal module, which circumferentially constricts the seal module to form a seal. (Ex. 1005, [0077]; Ex. 1003, ¶¶73-74.) PO’s expert admitted that the semicircular bights disclosed in the ’011 patent, which have the same configuration as Schaffer’s U-shaped actuating members, would “circumferentially constrict” the tubular member. (Ex. 1015, 100:11-22, 126:10-13.) Thus, PO’s expert confirmed that the arrangement and mechanism of Schaffer’s actuating members “circumferentially constrict” the lumen of the valve.

3. Schaffer’s U-Shaped Actuating Members Form A “Loop” Around The Tubular Member

Schaffer’s U-shaped actuating members form two semicircular bights around the seal module, which collectively form a circular “loop” around the seal module. (Ex. 1005, [0075]-[0077]; Ex. 1003, ¶¶107-108.) Indeed, the dictionary definition of “bight” offered by PO confirms that “bight” means “a slack part or **loop** in a rope.” (Ex. 2009 (emphasis added).) Similarly, the word “loop” means to “encircle.” (Ex. 1019, 5.) The ’011 patent discloses that the bight embodiments 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, 14:11-17 (emphasis added).) The ’011 patent similarly describes decreasing the diameter of the “loop” to constrict the elongate member when actuator buttons are in the first configuration. (*Id.*, 13:38-41.)

Thus, PO’s own evidence and the ’011 patent confirm that Schaffer’s U-shaped actuating members, or bights, form a loop around the seal module as recited in Claim 3 of the ’011 patent, and therefore, Schaffer anticipates or renders Claim 3 obvious. (Ex. 1003, ¶¶107-108.)

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, 22-23.) PO’s argument is directly contradicted by the deposition testimony of PO’s expert. PO’s expert agreed that a POSITA would not need prior experience designing a hemostasis valve or any medical devices. (Ex. 1015, 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 deposition testimony of PO’s expert is consistent with Petitioner’s proposed definition of a POSITA. The testimony also demonstrates the lack of merit in PO’s arguments regarding Mr. Thornton’s expert declaration.

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.

Dated: July 11, 2025

By: /Joshua J. Stowell/

Joshua J. Stowell (Reg. No. 64,096)

Joseph R. Re (Reg. No. 31,291)

Brian C. Barnes (Reg. No. 75,805)

KNOBBE MARTENS OLSON & BEAR, LLP

Attorneys for Petitioner

Imperative Care, Inc.

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: July 11, 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 1014 - EXHIBIT 1019** are being served electronically on July 11, 2025, to the e-mail addresses shown below:

Joseph Hamilton Reg. No. 51,770 hamilton-ptab@perkinscoie.com Inari-Imperative@perkinscoie.com PERKINS COIE LLP 1888 Century Park East, Suite 1700 Los Angeles, CA 90067-1721 Tel: (310) 788-3271	Paul Parker Reg. No. 38,264 parker-ptab@perkinscoie.com Matthew Williams Reg. No. 77,516 williams-ptab@perkinscoie.com PERKINS COIE LLP 1201 Third Avenue, Suite 4900 Seattle, WA 98101-3099 Tel: (206) 359-8000
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Dated: July 11, 2025

By: /Joshua J. Stowell/

Joshua J. Stowell (Reg. No. 64,096)
KNOBBE MARTENS OLSON & BEAR, LLP