

Filed April 9, 2025

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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 IPR2025-00728
Patent No. 11,844,921

PETITIONER'S REPLY TO PATENT OWNER'S RESPONSE

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LIST OF EXHIBITS

Exhibit No.	Description
1001	U.S. Patent No. 11,844,921 (“the ’921 patent”)
1002	’921 Patent Prosecution History Excerpt
1003	Expert Declaration of Troy Thornton
1004	Resume of Troy Thornton
1005	U.S. Patent Publication US 2003/0225379 A1 to Schaffer et al. (“Schaffer”)
1006	U.S. Patent Publication US 2003/0116731 A1 to Hartley (“Hartley”)
1007	U.S. Patent No. 9,980,813 B1 to Eller (“Eller”)
1008	Certified File History of U.S. Patent Application 10/371,190 (Schaffer File History)
1009	U.S. Patent No. 5,429,616 to Schaffer (“Schaffer ’616”)
1010	U.S. Patent No. 3,438,607 to Williams et al.
1011	U.S. Patent Publication US 2015/0173782 A1 to Garrison et al. (“Garrison”)
1012	U.S. Patent No. 11,697,011 (“the ’011 patent”)
1013	Inari’s Supplemental Infringement Contentions (without claim charts) from <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , No. 24-cv-3117 (N.D. Cal.) (served February 7, 2025).
1014	Google Dictionary Definition of “String”
1015	Cambridge Dictionary Definition of “String”
1016	U.S. Patent No. 12,109,384 B2 to Merritt et al.

Petitioner's Reply – Patent 11,844,921
Imperative Care, Inc. v. Inari Medical Inc.

Exhibit No.	Description
1017	Decision Granting Institution of <i>Inter Partes</i> Review for U.S. Patent No. 11,697,011 (Paper 7) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2024-01157 (P.T.A.B. Jan. 23, 2025)
1018	PCT Patent Publication WO 2018/019829 A1 to Brady et al.
1019	Inari's Notice of Motion and Motion for Leave to File Third Amended Complaint (Dkt. #88) in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 24-cv-03117-EKL (N.D. Cal.) (filed March 5, 2025)
1020	U.S. Patent No. 6,776,770 B2 to Treretola
1021	Case Management & Scheduling Order (Dkt. #54) in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 24-cv-03117-EKL (N.D. Cal.) (issued December 19, 2024)
1022	Decision Denying Patent Owner's Request for Discretionary Denial (Paper 9) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-00289 (P.T.A.B. June 12, 2025)
1023	Order Regarding Case Schedule and Motion to Stay (Dkt. #123) in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 24-cv-03117-EKL (N.D. Cal.) (issued July 3, 2025)
1024	Decision Granting Institution of <i>Inter Partes</i> Review for U.S. Patent No. 11,554,005 (Paper 10) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-00289 (P.T.A.B. June 18, 2025)
1025	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)
1026	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)
1027	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)

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1028	Standing Order for Patent Cases Before Judge Eumi K. Lee (Aug. 16, 2024)
1029	United States District Courts – National Judicial Caseload Profile (Dec. 2024)
1030	<i>Yangtze Memory Techs. Co., Ltd. v. Micron Tech., Inc.</i> , No. 23-cv-05792-RFL, Dkt. 243 (N.D. Cal. Mar. 14, 2025)
1031	<i>Jawbone Innovations, LLC v. Google, LLC</i> , No. 23-cv-00466-TLT, Dkt. 137 (N.D. Cal. Apr. 27, 2023)
1032	U.S. Patent No. 11,697,012 B2 to Merritt et al. (“’012 patent”)
1033	U.S. Patent No. 11,554,005 B2 to Merritt et al. (“’005 patent”)
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	Transcript of Proceedings Before the Honorable Eumi K. Lee on March 28, 2025 (Dkt. #119) in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 24-cv-03117-EKL (N.D. Cal.) (filed June 8, 2025)
1036	Notice of Allowance for U.S. Patent App. No. 17/865,280
1037	Deposition Transcript of PO’s Expert Paul Zalesky, Ph.D. dated June 23, 2025 from IPR2024-01157
1038	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)
1039	Supplemental Declaration of Troy L. Thornton in Support of Petitioner’s Reply for <i>Inter Partes</i> Review of U.S. Patent No. 11,697,011
1040	Joint Stipulation to Continue the Stay of Litigation Pending IPR Decisions and Vacate Upcoming Case Management Conference

Petitioner's Reply – Patent 11,844,921
Imperative Care, Inc. v. Inari Medical Inc.

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	(Dkt. #139) in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 24-cv-03117-EKL (N.D. Cal.) (filed January 21, 2026)
1041	Order Granting Joint Stipulation to Continue the Stay of Litigation Pending IPR Decisions and Vacate Upcoming Case Management Conference (Dkt. #140) in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 24-cv-03117-EKL (N.D. Cal.) (issued January 21, 2026)
1042	Final Written Decision Determining All Challenged Claims Unpatentable (Paper 35) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2024-01157 (P.T.A.B. Jan. 16, 2026)
1043	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)
1044	Notice of Decision Granting Institution of <i>Inter Partes</i> Review for U.S. Patent No. 12,109,384 (Paper 10) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-01562 (P.T.A.B. Mar. 17, 2026)
1045	Deposition Transcript of PO's Expert Paul Zalesky, Ph.D. dated August 27, 2025 from IPR2025-00156
1046	Coke Morgan Stewart, Memorandum Regarding PTAB consideration of prior findings of fact and conclusions of law (Sept. 16, 2025)
1047	Deposition Transcript of PO's Expert Paul Zalesky, Ph.D. dated March 24, 2026
1048	Final Written Decision Determining All Challenged Claims Unpatentable (Paper 33) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-00156 (P.T.A.B. Apr. 7, 2026)

PATENT OWNER'S EXHIBITS	
Exhibit No.	Description
2001	Complaint for Patent Infringement in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 5:24-cv-03117-EKL (N.D. Cal.), Dkt. 1
2002	First Amended Complaint for Patent Infringement in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 4:24-cv-03117-YGR (N.D. Cal.), Dkt. 20
2003	Second Amended Complaint for Patent Infringement in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 5:24-cv-03117-EKL (N.D. Cal.), Dkt. 68
2004	Third Amended Complaint for Patent Infringement in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 5:24-cv-03117-EKL (N.D. Cal.), Dkt. 112
2005	Imperative Care Inc.'s Notice of Motion and Motion to Stay Pending <i>Inter Partes</i> Review in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 5:24-cv-03117-EKL (N.D. Cal.), Dkt. 100
2006	Motion For Preliminary Injunction in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 5:24-cv-03117-EKL (N.D. Cal.), Dkt. 24
2007	Opposition to Motion for a Preliminary Injunction in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 5:24-cv-03117-EKL (N.D. Cal.), Dkt. 36
2008	Corrected Opposition to Motion for a Preliminary Injunction in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 5:24-cv-03117-EKL (N.D. Cal.), Dkt. 40
2009	Stipulated Protective Order in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 5:24-cv-03117-EKL (N.D. Cal.), Dkt. 76
2010	Joint Letter Brief Concerning Plaintiff's Motion to Compel Production of Materials Relating to Defendant's Blood Return System in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 5:24-cv-

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	03117-EKL (N.D. Cal.), Dkt. 94
2011	Order Re Inari Medical's Motion to Compel Production of Materials in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 5:24-cv-03117-EKL (N.D. Cal.), Dkt. 105
2012	Imperative Care, Inc.'s Preliminary Invalidity Contentions and Document Production Accompanying Invalidity Contentions Pursuant to Patent Local Rules 3-3 and 3-4 (omitting accompanying claim charts) in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 5:24-cv-03117- EKL (N.D. Cal.)
2013	Imperative Care, Inc.'s Preliminary Invalidity Contentions and Document Production Regarding U.S. Patent Nos. 12,109,384 and 12,156,669 Pursuant to Patent Local Rules 3-3 and 3-4 (omitting accompanying claim charts) in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 5:24-cv-03117-EKL (N.D. Cal.)
2014	Al-Salam Letter to Truvic (September 29, 2023)
2015	Declaration of Joseph P. Hamilton (April 28, 2025)
2016	Minute Entry for Proceedings Held Before Judge Eumi K Lee in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 5:24-cv-03117-EKL (N.D. Cal.), Dkt. 110
2017	Minute Entry for Proceedings Held Before Judge Eumi K Lee in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 5:24-cv-03117-EKL (N.D. Cal.), Dkt. 111
2018	U.S. Patent Publication US 2008/0087853 A1 to Kees ("Kees")
2019	U.S. Patent Publication US 2011/0144592 A1 to Wong et al. ("Wong")
2020	Notice of Allowance Issued in U.S. Patent Application No. 16/117,519 (January 27, 2021)

PATENT OWNER'S EXHIBITS	
Exhibit No.	Description
2021	Inari's Reply in Support of Motion for Preliminary Injunction in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 5:24-cv-03117-EKL (N.D. Cal.), Dkt. 46
2022	Inari's Report Regarding Claim Construction Schedule and Claim Narrowing in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 5:24-cv-03117-EKL (N.D. Cal.), Dkt. 116
2023	Imperative Care, Inc.'s Proposed Schedule for Claim Construction and Narrowing Asserted Patents and Claims in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 5:24-cv-03117-EKL (N.D. Cal.). Dkt. 117
2024	Declaration of Paul J. Zalesky
2025	Merriam-Webster's Collegiate Dictionary (11th ed. 2014)
2026	New Oxford American Dictionary (3rd ed. 2010)
2027	U.S. Patent Application Publication No. 2018/0193043
2028	Deposition Transcript of Troy Thornton (September 30, 2024)
2029	U.S. Patent No. 7,682,380 to Thornton ("Thornton")
2030	Deposition Transcript of Troy Thornton (March 19, 2025)
2031	Deposition Transcript of Troy Thornton (June 25, 2025)
2032	Decision Granting Institution of <i>Inter Partes</i> Review for U.S. Patent No. 11,697,012 (Paper 6) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-00156 (P.T.A.B. Apr. 22, 2025)
2033	Supplemental Declaration of Paul J. Zalesky
2034	Deposition Transcript of Troy Thornton (November 20, 2025)
2035	Deposition Transcript of Troy Thornton (January 7, 2026)

I. INTRODUCTION

The Board has instituted six IPRs (including this IPR) challenging PO's related patents claiming a valve with a filament. (Paper 13; Exs. 1017, 1024-1025, 1043-1044.) The Board recently issued Final Written Decisions for two of those patents (the "Related FWDs"), finding every challenged claim of Patent Nos. 11,697,011 and 11,697,012 obvious in view of Schaffer combined with Hartley or Eller – the same prior art combination presented for Grounds 3-4 herein. (Ex. 1042, 41-68; Ex. 1048, 43-71.) The Board's patentability determinations from the Related FWDs resolve the disputed issues for challenged claims 1-7, 9, 15-18, and 20-24 of the '921 patent. Specifically, the Related FWDs addressed and rejected the arguments PO raises in the current POR concerning Schaffer combined with Hartley or Eller for those claims. Because the POR fails to present any new evidence, the Board should find claims 1-7, 9, 15-18, and 20-24 unpatentable for the reasons previously articulated in the Related FWDs.

The only arguments in the current POR that the Board did not resolve in the Related FWDs concern dependent Claim 10, which requires a "first filament" and a "second filament." As demonstrated below, PO's arguments regarding Claim 10 fail to rebut Petitioner's invalidity grounds.

Petitioner identified two ways the prior art discloses a "first filament" and a "second filament." First, a person of ordinary skill in the art ("POSITA") would

have understood that Hartley's string and Eller's wire comprise a plurality of threads or strands. The threads/strands that form the string/wire are at least a first and second filament.

PO does not dispute that Hartley's string or Eller's wire comprise a plurality of threads or strands. Instead, PO argues that the threads/strands are not a "first filament" and a "second filament" because Claim 10 requires "separate" first and second filaments. Yet, "separate" appears nowhere in Claim 10 and PO identifies no lexicography or disclaimer in the specification to justify importing "separate" into the claim. Further, PO's own construction of "filament" (that the Board adopted in the Related FWDs) encompasses the threads/strands within Hartley's string or Eller's wire.

Second, a POSITA would have been motivated to substitute two strings or wires for Schaffer's two U-shaped actuating members. Eller, for example, discloses using at least two wires (first and second filaments) to seal a hemostasis valve, and discloses that POSITAs possessed the knowledge needed to optimize the number of filaments for a given application.

PO does not dispute that Eller discloses at least two filaments or that a POSITA would have possessed the knowledge to optimize the number of filaments. Rather, PO argues that a POSITA would have been discouraged from using strings or wires within Schaffer's valve because the string/wire would change Schaffer's

principles of operation, render the valve inoperable, and behave unpredictably. Yet the Board already rejected these arguments in the Related FWDs. PO also speculates that multiple strings/wires *might* interfere with each other. But PO fails to explain why the interference would be so severe as to discourage a POSITA from combining the strings/wires with Schaffer's valve given the admitted advantages.

Accordingly, the challenged claims (Claims 1-7, 9-10, 15-18, 20-24) are unpatentable and Petitioner respectfully requests a final written decision cancelling the claims.

II. CLAIMS 1-7, 9-10, 15-18, 20-24 ARE OBVIOUS OVER SCHAFFER WITH HARTLEY OR ELLER (GROUNDS 3-4)¹

A. Claims 1-7, 9, 15-18, 20-24

The Petition demonstrated that challenged claims 1-7, 9, 15-18, and 20-24 would have been obvious in view of Schaffer's hemostasis valve combined with Hartley's string or Eller's wire. (Petition, §VI.) In the Related FWDs, the Board found those same invalidity grounds (Schaffer + Hartley or Eller) rendered the challenged claims of the related '011 and '012 patents obvious. (Ex. 1042, 49-68; Ex. 1048, 43-71.) The Board's analysis and determinations in the Related FWDs

¹ Petitioner maintains that challenged claims 1-7, 9-10, 15-18, 20-24 are anticipated by Schaffer or would have been obvious in view of Schaffer for the reasons in Grounds 1-2 of the Petition. (Petition, §VI.) However, in view of the Board's findings from the Related FWDs, Petitioner rests on the Petition for those grounds herein.

confirm that challenged claims 1-7, 9, 15-18, and 20-24 of the '921 patent are also unpatentable as obvious. (See Ex. 1046).

As illustrated below, the challenged claims of the '921 patent recite overlapping components with the '011 patent:

'921 Patent – Claim 1	'011 Patent – Claim 1
<p>A valve, comprising: an elongate member defining a lumen;</p>	<p>A valve, comprising: a tubular member defining a lumen configured to slidably receive a catheter;</p>
<p>an active tensioning mechanism including an actuator coupled to the elongate member via a filament extending at least partially around the elongate member, wherein the actuator is moveable between (a) a first position wherein the lumen is constricted and sealed and (b) a second position wherein the lumen is at least partially open; and</p>	<p>a constricting mechanism including at least one filament and an actuator coupled to the filament, the filament comprising a first portion extending around at least a portion of the tubular member and a second portion having a first end extending from the first portion in one direction and a second end extending from the first portion in another direction, and the actuator comprises a first member coupled to the first end of the filament and a second member coupled to the second end of the filament, wherein the first member and the second member of the actuator are moveable between (a) a first position wherein the filament circumferentially constricts the lumen to create a seal and (b) a second position wherein the filament is moved to at least partially open the lumen; and</p>
<p>a biasing member configured to bias the actuator to the first position.</p>	<p>a biasing system configured to bias the first member and the second member to the first position.</p>

(Ex. 1001, Claim 1; Ex. 1012, Claim 1.)²

In the Related FWDs, the Board concluded that Schaffer combined with Hartley or Eller disclosed every limitation of the challenged claims of the '011 and '012 patents. (Ex. 1042, 49-68; Ex. 1048, 43-71.) The same is true for challenged claims 1-7, 9, 15-18, 20-24 of the '921 patent. (Petition, §VI.) The few minor differences between the patent claims (*see e.g.*, '921 Patent, Claim 1 (“an actuator coupled to the *elongate member*”) and '011 Patent, Claim 1 (“an actuator coupled to the *filament*”)) are not material because PO does not dispute that Schaffer combined with Hartley or Eller discloses the limitations of claims 1-7, 9, 15-18, and 20-24. (*See* POR, §V.)

Rather, PO argues merely that a POSITA would not have been motivated to combine Hartley's string or Eller's wire with Schaffer's valve. (*See id.*) PO raised identical arguments in the '011 and '012 IPRs, and the Board found that none of PO's arguments rebutted Petitioner's obviousness evidence. (Ex. 1042, 49-68; Ex. 1048, 47-71.) PO has not identified any issue that the Board misapprehended or overlooked in the Related FWDs. *See* 37 C.F.R. § 42.71(d). As explained below, the Board's conclusions from the Related FWDs resolve every disputed issue concerning claims 1-7, 9, 15-18, and 20-24. Therefore, the Board should find claims

² The claims of the '921 patent also recite overlapping components with the '012 patent. (*Compare* Ex. 1001, Claims 1, 15 *with* Ex. 1032, Claim 1.)

1-7, 9, 15-18, and 20-24 obvious in view of Schaffer with Hartley or Eller for the reasons set out below, in the Petition, and in the Related FWDs. (*See* Ex. 1046.)

1. Hartley's String or Eller's Wire May Seal More Effectively

Petitioner demonstrated that a POSITA would have been motivated to combine Schaffer with Hartley or Eller 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.” (Petition, 36-37, 43.) For example, Hartley’s string or Eller’s wire could eliminate gaps that formed between Schaffer’s seal module and some devices. (Ex. 1003, ¶¶86, 100.) In the Related FWDs, the Board agreed that Hartley’s string or Eller’s wire “would provide more uniform constriction and compression around the outer diameter of some commonly-used tools and including tools with diverse shapes and sizes.” (Ex. 1042, 54; Ex. 1048, 56.) PO provides no reason for the Board to deviate from its prior decisions.

Instead, PO repeats its argument from the '011 and '012 IPRs that Schaffer’s valve would not form any gaps because it “forms a complete seal” due to a gelatinous seal member 165. (POR, 29-33.) The Board rejected this argument for several reasons.

First, Schaffer’s highly compliant, gelatinous seal module is an optional embodiment, and Schaffer discloses many seal module materials that are not

“sticky” or gelatinous. (Ex. 1003, ¶86; Ex. 1042, 58-59; Ex. 1048, 60-61.) Second, PO’s expert, Dr. Zalesky, “does not disagree that a flexible string or wire would have carried [an] advantage” over Schaffer’s actuating members. (Ex. 1042, 54; Ex. 1048, 56; *see also* Ex. 1037, 86:19–87:4.) Third, “even in Schaffer’s preferred embodiments that use a highly-compliant, ‘sticky’ or ‘gelatinous’ material ... Schaffer teaches that such embodiments are capable of forming a *nearly* fluid/gas tight seal.” (Ex. 1042, 57 (emphasis in original); Ex. 1048, 58; Ex. 1005, [0059].) Accordingly, “Schaffer does not ... teach that its valves provide a perfect seal in all embodiments and under all circumstances,” and PO fails to rebut Petitioner’s evidence that a POSITA would have been motivated to substitute Schaffer’s actuating members with Hartley’s string or Eller’s wire. (Ex. 1042, 53-54, 56-57; Ex. 1048, 56-58.)

PO also repeats its argument from the ’011 and ’012 IPRs that Schaffer combined with Hartley’s string or Eller’s wire would seal “less effectively” when two instruments are inserted. (POR, 49-50.) The Board rejected this argument because it “presumes that Schaffer’s valve includes the highly compliant seal module,” which Schaffer describes as an optional feature. (Ex. 1042, 60; Ex. 1048, 62; Ex. 1039, ¶35.) Further, PO’s proposed example would look the same regardless of whether a string/wire or two U-shaped members are used, and therefore, PO fails to show that a string/wire would be inferior to Schaffer’s U-shaped actuating

members even in the circumstances PO identifies. (Ex. 1039, ¶¶35; Ex. 1042, 60-61; Ex. 1048, 62.)

2. **Hartley's String Or Eller's Wire Would Not Change Schaffer's "Principles Of Operation"**

PO also repeats its argument from the '011 and '012 IPRs that combining Hartley's string or Eller's wire with Schaffer's valve would "change Schaffer's principles of operation." (POR, 55-61.) As before, PO identifies three ways the combination would allegedly change the principles 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. (*Id.*) The Board addressed each argument in the Related FWDs and found each one deficient. (Ex. 1042, 62-63; Ex. 1048, 64-69.) The Board should do so again here.

First, 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. Instead, "Schaffer's principle of operation is to use spring-actuated buttons ... to apply a constricting or compressing force ... to selectively collapse and release the tube, thereby selectively closing and opening the valve to fluid flow." (Ex. 1042, 63; Ex. 1048, 65; Ex. 1039, ¶¶38-39.) As the Board found in the Related FWDs, "[t]his principle of operation is materially unchanged if Hartley's string or Eller's wire is substituted for Schaffer's U-shaped actuating

members.” (Ex. 1042, 63; Ex. 1048, 65; Ex. 1003, ¶¶91-93, 105-106; Ex. 1039, ¶¶38-39.)

PO is also incorrect that Hartley's string or Eller's wire would prevent “forcible disengagement.” (Ex. 1039, ¶41.) The Board found in the Related FWDs that a POSITA would have understood that when Schaffer's buttons are depressed, the tension on the string/wire would be disengaged, allowing the seal module to retract to its open configuration. (*Id.*; Ex. 1042, 64; Ex. 1048, 66.) The Board also found that PO's suggestion that forcible disengagement requires the actuating members to physically separate from the seal module is unsupported because “Schaffer never shows that.” (Ex. 1042, 64; Ex. 1048, 66; Ex. 1005, Figs. 32–34.) Thus, Hartley's string and Eller's wire would permit full operation of Schaffer's valve, including “forcible disengagement” to allow the valve to open when the actuator buttons are depressed. (Ex. 1039, ¶41; Ex. 1042, 64-65; Ex. 1048, 66-67.)

The Board also rejected PO's argument that Hartley's string or Eller's wire would weaken the durability of Schaffer's valve. (Ex. 1039, ¶48; Ex. 1042, 63-64; Ex. 1048, 65.) A POSITA would have been aware of many durable materials that could have been used to form a string or wire in 2017. (*Id.*)

Finally, manufacturability concerns would not have dissuaded a POSITA from combining Schaffer with Hartley or Eller. (Ex. 1039, ¶¶45-47; Ex. 1042, 65-66; Ex. 1048, 66-67.) Schaffer does not claim that its valve is easy to assemble,

much less that manufacturability is Schaffer's "principle of operation." (Ex. 1039, ¶43.) And the Board found in the Related FWDs that a POSITA would have known many ways to assemble Schaffer's valve with a string or wire, and thus, "the engineering techniques needed to implement [a string or wire into Schaffer] would have been routine and straightforward." (Ex. 1042, 66; Ex. 1048, 67-68; Ex. 1039, ¶45.)

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

PO also repeats its argument from the '011 and '012 IPRs that combining Schaffer with Hartley's string or Eller's wire would not be a simple substitution of known elements because no single reference discloses a valve with a string/wire attached to two actuators. (POR, 38-53.) In the Related FWDs, the Board found that PO's "argument is tantamount to a complaint that none of Schaffer, Hartley, or Eller is anticipating," which does not undermine Petitioner's obviousness grounds. (Ex. 1042, 66-67; Ex. 1048, 69-70.) PO also fails to explain why substituting Schaffer's actuating members with a string/wire would not have been simple. PO asserts, without explanation, merely that Hartley's string or Eller's wire would not "predictably seal" in Schaffer's valve because "either of Schaffer's buttons could be depressed independently to move one end of a string/wire unpredictably." (POR, 51.) PO's unexplained and unsupported statement fails to rebut Petitioner's

evidence that combining Schaffer with Hartley or Eller would have entailed a simple substitution “requir[ing] no more than ordinary skill.” (Ex. 1042, 67; Ex. 1048, 69; Ex. 1003, ¶¶87, 101.)

PO's related argument that “more plausible” modifications to Schaffer's valve existed also lacks merit. (POR, 46-49.) As the Board recognized in the Related FWDs, “obviousness is not limited to the best or simplest solution,” and PO's argument therefore fails to undercut Petitioner's evidence. (Ex. 1042, 67-68; Ex. 1048, 69-70.)

PO also argues that in related IPRs, “Petitioner and its expert have advanced numerous different theories of simple substitution based on combinations of Schaffer and Hartley and/or Eller.” (POR, 51.) PO is incorrect. Throughout the IPRs, Petitioner and Mr. Thornton have consistently explained that replacing Schaffer's U-shaped actuating members with Hartley's string or Eller's wire would entail a simple substitution that a POSITA could accomplish by attaching the ends of the string/wire to Schaffer's opposing actuator buttons. (*See, e.g.*, Petition, 37-38, 43-44; Ex. 1003, ¶¶90, 103; Ex. 1042, 52-53.) The Board agreed in the Related FWD and rejected PO's unsupported claims of hindsight bias. (Ex. 1042, 52-53; Ex. 1048, 54-55.)

Petitioner's additional argument that a POSITA would have found it obvious to substitute Schaffer's two U-shaped actuating members with two of Hartley's

strings or Eller's wires is not a "shifting" obviousness theory and does not evidence hindsight. (*See infra* §II.B.) The prior art expressly teaches using multiple filaments to seal a hemostasis valve and recognizes that "[s]killed artisans will be able to select a suitable number of wire members to include in a selective fluid barrier valve device." (Ex. 1007, 16:7-15; *infra* §II.B.) Accordingly, none of Petitioner's invalidity grounds rely upon hindsight or present "shifting" theories of simple substitutions as PO argues.

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

PO also repeats its argument from the '011 and '012 IPRs 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, 54-55 (citing Petition, 43).) PO is incorrect. As the Board found in the Related FWDs, the evidence here demonstrates four known options for constricting a hemostasis valve: (1) Schaffer's U-shaped actuating members; (2) Hartley's string/ Eller's wire; (3) a "pressure-assisted collapse valve"; and (4) pinch valves like those in Wong (Ex. 2018) and Kees (Ex. 2019). (Ex. 1042, 55-56; Ex. 1048, 57; Ex. 2031, 118:4-15.) A POSITA would have found it obvious to select any one of these finite, predictable options, which included Hartley's string and Eller's wire. (Ex. 1003, ¶¶88, 102; Ex. 1042, 55-56; Ex. 1048, 57.)

B. Claim 10

The only POR arguments not addressed in the Related FWDs relate to dependent Claim 10 – specifically the “first filament” and “second filament” limitations. (POR, 61-66.) The Petition demonstrated that Claim 10 is obvious for two reasons: (1) Hartley's string or Eller's wire include first and second filaments because they are made of several threads or strands (“filaments”) and (2) a POSITA would have found it obvious to replace Schaffer's two U-shaped actuating members with two of Hartley's strings or Eller's wires. (Petition, 64-70.) The POR fails to rebut either obviousness rationale.

1. Hartley's String/Eller's Wire Include First and Second Filaments

PO does not dispute that a POSITA would have understood that Hartley's string and Eller's wire include multiple threads or strands of material. (Petition, 66, 70; *see also* POR, 61-64.) Each thread/strand forming Hartley's string or Eller's wire is a “filament,” such that the string/wire includes at least a “first filament” and “second filament” as recited in Claim 10. (Petition, 66-67, 70; Ex. 1047, 27:8-25; 31:4-15.)

PO's proposed construction of “filament” in this IPR encompasses the threads/strands forming the string or wire. PO construes “filament” according to its plain and ordinary meaning to mean “a thin, flexible length of material formed by one or more strands of material.” (POR, 12.) The Board agreed with PO's proposed

construction in the Related FWDs. (Ex. 1042, 24; Ex. 1048, 23.) PO does not dispute that the threads/strands forming Hartley's string or Eller's wire are each "a thin, flexible length of material formed by one or more strands of material." (Petition, 66-67, 70; POR, 61-64; Ex. 1047, 27:8-25, 31:4-15.) And PO's expert, Dr. Zalesky, agreed that "each thread" in a string "could be an individual filament" if it has the requisite flexibility and tensile properties. (Ex. 1047, 31:4-15.) Thus, under PO's construction, the threads/strands forming the string or wire include a "first filament" and a "second filament."

Because PO cannot dispute that Hartley's string and Eller's wire comprise first and second filaments under the plain and ordinary meaning of "filament," PO attempts to import an additional limitation into Claim 10. Specifically, PO argues that the terms "first filament" and "second filament" in Claim 10 "require *separate* first and second filaments as shown in Figures 7-9 rather than a *single* filament composed of different threads like Figure 6 as Petitioner alleges." (POR, 63 (emphasis added).) Yet, neither Claim 10 nor the patent specification use the term "separate" to describe the filaments. Likewise, the patent does not describe Figure 6 as illustrating a single filament *composed of different threads*. (See Ex. 1001, 12:37-40.) Thus, the premise for PO's argument is unsupported.

Further, the '921 patent describes "filament" as broadly as possible to include (1) a single strand or (2) a plurality of strands. The patent states: "In some

embodiments, the filament can comprise a **single strand** such as, for example, a monofilament, and in some embodiments, the filament can comprise a **plurality of strands** that can be, for example, twisted, woven, group, and/or fused to form the filament.” (Ex. 1001, 9:10-15 (emphasis added).) The patent continues: “In some embodiments, the filament 150 can comprise **one or several** threads, lines, cords, rope, ribbon, flat wire, sheet, or tape.” (*Id.*, 9:15-17 (emphasis added).) (POR, 63 (emphasis added).)

The patent never discloses that a “single strand” is a filament only if it is “separate” from other strands. Nor does the patent (or PO) provide any explanation for how a POSITA would determine whether strands are “separate” enough to qualify as two filaments under PO’s argument. (*See* Ex. 1047, 39:15-41:23.) For example, PO’s expert testified that two threads would not be “separate” filaments if they interlock. (*Id.*, 40:4-9, 41:18-23.) But the ’921 patent states that the filaments in Figures 7-9 forming loops or bights can be interlocking or non-interlocking. (Ex. 1001, 13:29-35.) PO provides no justification for excluding the interlocking embodiments from the scope of Claim 10.

PO also argues that the Board should import “separate” into Claim 10 based on Figures 6-9 of the ’921 patent. (POR, 62-64.) According to PO, Figure 6 depicts a “single filament 150” while Figures 7-9 depict first and second filaments. (*Id.*) PO, therefore, extrapolates that the Board should limit Claim 10 to the specific

embodiments illustrated in Figures 7-9. (*Id.*) Yet, Figures 7-9 are exemplary, and the description of those figures directly contradicts PO's argument. The introduction to Figures 7-9 explains, "In some embodiments, the filament 150 **can comprise multiple filaments**...." (Ex. 1001, 12:54-55 (emphasis added).) This description confirms that "the filament 150" (i.e., a string) can be made of multiple filaments (i.e., the threads/strands forming the string). The patent continues to explain that Figures 7-9 illustrate specific examples, stating "the filament 150 **can** comprise a first filament 150-A and a second filament 150-B." (*Id.*, 12:55-57 (emphasis added).) The paragraph goes on to describe configurations of the filaments "in some embodiments." (*Id.*, 12:54-13:9.) Nothing in the paragraph restricts first and second filaments to the exact configuration illustrated in Figures 7-9, nor excludes the plurality of strands forming a string or wire.

Importantly, PO fails to identify any disclaimer or lexicography in the specification that would justify restricting Claim 10 to only the embodiments illustrated in Figures 7-9. *See, e.g., MBO Lab 'ys., Inc. v. Becton, Dickinson & Co.*, 474 F.3d 1323, 1333 (Fed. Cir. 2007) ("[P]atent coverage is not necessarily limited to inventions that look like the ones in the figures. To hold otherwise would be to import limitations onto the claim from the specification, which is fraught with 'danger.'"). The mere illustration of embodiments in Figures 7-9 is insufficient to

constitute such a disclaimer or redefinition. *Thorner v. Sony Comp. Ent. Am. LLC*, 669 F.3d 1362, 1366 (Fed. Cir. 2012).

PO also argues that “the ’921 Patent is explicit that a single filament can be a monofilament or it can include a ‘plurality of strands,’ but a single filament does not become both a first and second filament simply because of multiple strands twisted together.” (POR, 63 (citing Ex. 1001, 9:10-15).) But PO’s argument is directly contradicted by the patent. As discussed above, the specification specifically teaches, “*the filament 150* can comprise multiple filaments.” (Ex. 1001, 12:54-55 (emphasis added); *see also id.*, 9:15-17 (“the filament 150 can comprise one or several threads, lines, cords, rope, ribbon, flat wire, sheet, or tape”).)

Further, PO oversimplifies the disclosure. The patent states: “the filament *can comprise a single strand* such as, *for example*, a monofilament” or “the filament *can comprise a plurality of strands* that can be, *for example*, twisted, woven, grouped, and/or fused to form the filament.” (Ex. 1001, 9:10-15 (emphasis added).) Contrary to PO’s argument, the patent uses broad, open-ended terms such as “comprise” and “for example” to ensure that “the filament” encompasses any number of strands in any configuration. The patent never restricts “the filament” to only “separate” strands. Because PO does not dispute that Hartley’s string and Eller’s wire have at least two strands, it cannot credibly dispute that the string/wire have first and second filaments.

2. Replacing Schaffer's U-shaped Actuating Members with Two Strings or Wires Would Have Been Obvious

A POSITA would have also found it obvious to substitute Schaffer's two U-shaped actuating members for two strings or two wires. (Petition, 68-70.) Petitioner and Mr. Thornton explained that there were several reasons why a POSITA would have been motivated to do so, including: (1) the combination would entail a simple substitution of Schaffer's two actuating members for two strings/wires; (2) strings and wires were simple, predictable, and readily available components in 2017; (3) Hartley's strings and Eller's wires perform the same constriction action as Schaffer's actuating members; (4) POSITAs would have had a finite number of predictable options for selecting the number of strings/wires to constrict a hemostasis valve lumen; and (5) Eller explicitly teaches that POSITAs were able to "select a suitable number of wire members to include in a selective" hemostasis valve. (*Id.*, 101-107.)

PO's expert agrees that using two filaments would benefit a hemostasis valve. PO's expert testified that having two filament loops around the lumen of a valve would provide "[t]he ability to apply a greater total amount of force of constriction" compared to a single loop. (Ex. 1045, 94:6-17.) He also testified that having two loops would provide redundancy to the valve that is "an added protective feature." (*Id.*, 98:16-25.) Thus, the experts agree that a POSITA would have recognized advantages to using two of Hartley's strings or Eller's wires to loop around the lumen of Schaffer's valve.

The POR does not dispute any of the above motivations or advantages for using two of Hartley's strings or Eller's wires. (*See* POR, 64-66.) Instead, PO speculates that the strings or wires would “move laterally along Schaffer's seal modules when Schaffer's actuator buttons 261 are depressed” and “*might* interfere with one another” or “*might* move underneath the other, *potentially* reducing the sealing effectiveness of the valve.” (*Id.* (emphasis added).)³ PO never explains why this hypothetical movement would deter a POSITA from using strings/wires when the strings/wires have so many undisputed advantages. Nor does PO explain how the possible interference between the strings/wires would reduce “sealing effectiveness.” PO also fails to address simple solutions to the hypothetical problem, such as using a stiffer string or wire. PO's speculation coupled with its failure to provide any evidence substantiating the argument is insufficient to overcome the obviousness grounds.

PO's speculative argument fails for several other reasons. First, Eller expressly discloses using multiple wires, including first and second wires, to seal the lumen of a hemostasis valve and that such an arrangement is effective. (Ex. 1007, 5:1-6, 16:7-19; Ex. 1047, 43:2-44:3, 45:7-46:10 (PO's expert admitting that Eller

³ PO also argues that a POSITA would not have been motivated to replace Schaffer's actuating members with Hartley's strings or Eller's wires for the reasons discussed in Section II.A above. (*See* POR, 64-66.) As explained above, the Board rejected these arguments in the Related FWDs, and PO offers no reason for the Board to deviate from its prior decision. *Supra* §II.A.

discloses first and second filaments).) Eller does not disclose or suggest that its first and second filaments slide laterally along the seal module or otherwise interfere with one another.

Similarly, the '921 patent discloses the bight embodiments in Figures 8-9 that include two u-shaped filaments. (Ex. 1001, 13:23-65, Fig. 8-9.) The '921 patent never suggests that the filaments could slide laterally along the elongate member and never describes any solutions to this hypothetical problem.

Second, Eller explains that “[s]killed artisans will be able to select a suitable number of wire members to include in a selective fluid barrier valve device according to a particular embodiment based on various considerations, including the material(s) that forms the sleeve of an embodiment.” (Ex. 1007, 16:7-15.) Thus, Eller confirms that a POSITA in 2017 would have possessed the skills to optimize the length and tension of the strings/wires to avoid significant lateral movement along the seal module or other interference. (*Id.*) The '921 patent also presumes that a POSITA would have possessed these skills. The '921 patent merely states that “[i]n some embodiments, the filament 150 can comprise multiple filaments.” (Ex. 1001, 12:54-55.) The '921 patent does not disclose any means for preventing or addressing potential lateral movement of multiple filaments, for example the filaments illustrated in Figures 7-9, and instead presumes that a POSITA would have known how to prevent such issues.

Third, even if a POSITA shared PO's speculative concern regarding lateral movement of the filaments, which is contrary to the prior art and the '921 patent, that concern would not have outweighed the POSITA's motivation to achieve the advantages of a second filament. *See, e.g., Allied Erecting & Dismantling Co. v. Genesis Attachments, LLC*, 825 F.3d 1373, 1381 (Fed. Cir. 2016) (“[A] given course of action often has simultaneous advantages and disadvantages, and this does not necessarily obviate motivation to combine.”). Ultimately, a POSITA's selection of the appropriate number of strings/wires for the hemostasis valve from the finite range of options disclosed by the prior art (one, two, or three) “amounts to an engineering tradeoff--a decision well within the level of ordinarily skilled artisans.” *In re Mouttet*, 686 F.3d 1322, 1330 (Fed. Cir. 2012) (affirming Board decision on motivation to combine because the Board found that “the relative advantages and disadvantages in selecting electrical circuitry in lieu of optical circuitry amounts to an engineering tradeoff--a decision well within the level of ordinarily skilled artisans”); *see also* (Ex. 1007, 16:7-15.)

Finally, PO also argues that substituting Schaffer's two U-shaped actuating members for two strings or wires “would increase the cost and complexity of the proposed valve” such that a POSITA would not have been motivated to make the substitution. (POR, 65.) However, PO's expert contradicted this argument in his prior deposition. PO's expert was asked whether having two filaments would make

a valve more difficult to manufacture, and he testified that “it could be incrementally more difficult, *but not particularly.*” (Ex. 1045, 97:4-22 (emphasis added).) PO's expert further testified:

Q: Do you think it would have been so much more difficult that it would have discouraged a person of ordinary skill in the art from using two loops?

A. *No.*

(*Id.*, 97:24-98:2 (emphasis added).) Thus, PO's expert confirmed that manufacturing cost and complexity would not have discouraged a POSITA from using two strings or wires in a hemostasis valve.

III. CLAIMS 1-3, 5-6, 9, 15-18, AND 21-24 OBVIOUS OVER HARTLEY IN COMBINATION WITH ELLER (GROUND 5)

The Petition also demonstrated, and the Board preliminarily agreed, that Claims 1-3, 5-6, 9, 15-18, and 21-24 would have been obvious in view of the combination of Hartley's hemostasis valve with Eller's biasing system (torsion spring).⁴ (Petition, §VII.) PO disputes that a POSITA would have been motivated to combine Eller's torsion spring with Hartley's valve because doing so would

⁴ In the '011 FWD, the Board found the challenged claims of the '011 patent would not have been obvious in view of Hartley and Eller due to claim language requiring an actuator with a “first member” and a “second member.” (Ex. 1042, 68-69.) That language is not recited in challenged claims 1-3, 5-6, 9, 15-18, and 21-24 of the '921 patent.

“change Hartley’s principle of operation by obviating its ball-and-detent system.” (POR, 66-71.) The Board addressed PO’s argument in the Institution Decision and found it unpersuasive. (Paper 13, 33-35.) The POR fails to identify any reason for the Board to deviate from that preliminary determination.

PO acknowledges that the objective of Hartley’s hemostasis valve is to “provide an access valve which can be controlled to vary the size of the aperture through the valve and be flexible so that a seal may be formed against an instrument.” (POR, 67 (citing Ex. 1006, [0004].) Hartley does not suggest that the ball-and-detent system is necessary to accomplish that objective. To the contrary, Hartley describes the ball-and-detent system as an optional feature for retaining the rotary actuator on the cylindrical housing and providing tactile feedback to the user. (Ex. 1006, [0015], [0018], [0033]; Paper 13, 34.) Given its optional nature, PO has not and cannot show that the ball-and-detent system is the “principle of operation” of Hartley’s hemostasis valve.

Further, the Board correctly explained that obviousness is not limited to the preferred embodiments of a prior art reference. (Paper 13, 34 (citing *Merck & Co., Inc. v. Biocraft Lab ’ys., Inc.*, 874 F.2d 804, 807 (Fed. Cir. 1989)).) And as explained above, that a “given course of action ... has simultaneous advantages and disadvantages ... does not necessarily obviate motivation to combine.” *Allied Erecting & Dismantling Co., LLC*, 825 F.3d at 1381. PO does not dispute that Eller’s

torsion spring would provide benefits to Hartley's valve by biasing the system to its closed position. (Petition, 83-84.) PO also acknowledges that Hartley's ball-and-detent system would still provide benefits of tactile feedback even when Eller's torsion spring is added. (POR, 70-71.) Accordingly, the fact that the ball and detent may not retain the valve in an open position when Eller's torsion spring is added does not negate the obviousness of Petitioner's proposed combination.

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,

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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 5,523 words and therefore complies with the type-volume limitations of 37 C.F.R. § 42.24 (c).

Dated: April 9, 2026

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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 1042 – EXHIBIT 1048** are being served electronically on April 9, 2026, to the e-mail addresses shown below:

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