

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

IMPERATIVE CARE, INC.,
Petitioner,

v.

INARI MEDICAL, INC.,
Patent Owner.

Case No. IPR2025-00728
U.S. Patent No. 11,844,921

PATENT OWNER'S SUR-REPLY

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<i>Metalcraft of Mayville, Inc. v. The Toro Company</i> , 848 F.3d 1358 (Fed. Cir. 2017)	7

EXHIBIT LIST

	Petitioner's Exhibits
Exhibit	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.
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)

	Petitioner's Exhibits
Exhibit	Description
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)
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)

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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 (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)

	Petitioner's Exhibits
Exhibit	Description
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	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-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

	Patent Owner's Exhibits
Exhibit	Description
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)
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

	Patent Owner's Exhibits
Exhibit	Description
2024	Declaration of Paul J. Zalesky
2025	Merriam-Webster's Collegiate Dictionary (11 th ed. 2014)
2026	New Oxford American Dictionary (3 rd 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)
2036	Deposition Transcript of Troy Thornton (August 15, 2025)

I. INTRODUCTION

Petitioner has failed to demonstrate that any of Claims 1-7, 9-10, 15-18, or 20-24 (“the Claims”) of the ’921 Patent are unpatentable. Grounds 1-2 (Schaffer alone) fail because Schaffer does not disclose or suggest a “filament,” which requires flexibility, as recited in independent Claims 1, 15, and 21. The Board preliminarily agreed. Institution Decision, pp.27-28. And, in two Final Written Decisions for related IPRs for U.S. Patent Nos. 11,697,011 and 11,697,012 (the “Related FWDs”), the Board found that Schaffer did not disclose or suggest a valve with a “filament.” EX1042, pp.38-40; EX1048, pp.41-42. For those same reasons, grounds 1-2 fail. Petitioner’s Reply to Patent Owner’s Response (“Pet. Reply”; Paper 22) does not contest those findings from the Related FWDs. Pet. Reply, p.3.

Grounds 3-4 (Schaffer in combination with Hartley or Eller) fail for all the reasons set forth in Patent Owner’s Response (“POR”; Paper 18). Petitioner asserts that the Related FWDs resolve all the disputed issues for claims 1-7, 9, 15-18, and 20-24 of the ’921 Patent here. Pet. Reply, p.1. Petitioner is wrong.

For example, Petitioner ignores a new issue that the Board has not finally addressed in this or any related IPR—namely, that Petitioner’s repeated cherry-picking of multiple different substitutions/combinations as the purported simple substitution and/or obvious combination to meet whatever claim limitation is at issue demonstrates that Petitioner’s obvious arguments are based on impermissible

hindsight. Here and in other related IPRs Petitioner and its expert have advanced multiple different and contradictory allegedly obvious combinations (“simple substitutions”) of Schaffer and Hartley/Eller, including: (1) a single string/wire substituted into Schaffer’s valve in a loop (Petition, pp.35-36, 42-43; EX1003, ¶¶85-94, 99-106), (2) two strings/wire substituted for Schaffer’s actuating members to have like U-shapes (Petition, pp.68-70; EX1003, ¶¶154-155, 158), and (iii) two strings/wires substituted into Schaffer’s valve in loops (*Imperative Care, Inc. v. Inari Medical, Inc.*, IPR2025-01562, Paper 2, pp.48-49 & EX1003, ¶¶105-106). Those purported combinations/substitutions are vastly different and contradictory in structure. As such each Petitioner’s proposed particular structural variations is nothing more than the result of “selectively culling” features and combinations from the prior art improperly using the ’921 Patent (and the related patents) as a roadmap. *ATD Corp. v. Lydall, Inc.* 159 F.3d 534, 546 (Fed. Cir. 1998); EX2033, ¶153.

It is also inaccurate that the Board “rejected PO’s unsupported claims of hindsight bias” in the Related FWDs. Pet. Reply, p.11. The Board did not address Patent Owner’s hindsight-bias arguments presented in this IPR and that are based on Petitioner continuing to change what the “simple substitution” and/or “obvious combination” purportedly are to meet the claims of the patent at issue (including the two filaments required by dependent Claim 10 here).

Ground 5 fails because Petitioner's proposed modification to include Eller's torsion spring in Hartley's valve would change Hartley's principle of operation by rendering its ball-and-detent system inoperable for its purpose of retaining Hartley's rotary actuator in different positions corresponding to different valve positions (e.g., open, partially open). POR, 66-71; EX2033, ¶¶186-198.

Newly at issue in this IPR is dependent Claim 10, which narrows Claim 1 by requiring two filaments: a "first filament" and a "second filament." Because Petitioner's proposed substitutions for Claim 1 include only Hartley's *single* string or Eller's *single* wire member, Petitioner provides two different theories why it allegedly would have been obvious to include a "second filament" as recited in Claim 10, both of which fail.

First, Hartley's single string or Eller's single wire member alone do not comprise the claimed "first filament" and "second filament" simply because these structures can "include multiple threads or strands of material" as Petitioner alleges for its first theory of obviousness. Pet. Reply, p.13; Petition, pp.66, 70. As explained in the POR, the '921 Patent describes that twisting multiple strands together to form a filament does not somehow make multiple filaments ("a plurality of strands that can be, for example, twisted, woven, grouped, and/or fused to form **the** filament" and "**the** filament 150 can comprise **one or several** threads, lines, cords, rope, ribbon, flat wire, sheet, or tape"). EX1001, 9:12-16 (emphasis added), FIGS. 6-9;

POR, 61-64; EX2033, ¶¶177-179. And, just like the '921 Patent, Eller recognizes that multiple strands or fibers that are twisted together form a single wire member—not multiple wire members or filaments. EX1007, 15-61-65 (“[a] wire member ... can have any suitable structure and comprise any suitable number of strands and/or fibers that are twisted, or otherwise interconnected to one another”). A single filament is therefore not transformed into a “first filament” and a “second filament” simply by having multiple strands twisted, woven, or otherwise integrated together. Petitioner's theory that an individual one of Hartley's string/ Eller's wire includes the first and second filaments because these structures “include multiple threads or strands of material” fails for at least those reasons.

Second, a POSA would not have “found it obvious to substitute Schaffer's two U-shaped actuating members for two strings or two wires” according to Petitioner's second theory of obviousness for Claim 10. Pet. Reply, p.18; Petition, pp.68-70. That arrangement for Claim 10 including two U-shaped strings/wires in place of Schaffer's rigid U-shaped actuating members and each connected to the same actuator button is radically *different* than Petitioner's purported arrangement for Claim 1, which includes a single string/wire looped around Schaffer's seal module and connected to Schaffer's two opposed actuator buttons. Petitioner cannot be correct that a POSA would have found such a substitution obvious based on its own logic. According to Petitioner and its expert, Schaffer's U-shaped actuating

members are flexible (Petition, p.30; EX1003, ¶79), and those flexible actuating members “form small gaps” that would have motivated a POSA to substitute a *single* looped string/wire from Hartley/Eller into Schaffer as in Petitioner’s purported combination for Claim 1. Petition, pp.36, 43; EX1003, ¶¶86, 100. Thus, according to Petitioner and its own expert, if a POSA would have been motivated to arrive at Petitioner’s arrangement for Claim 1, they would not have been motivated to replace both U-shaped actuating members with separate flexible string/wires like Petitioner’s arrangement for Claim 10 because the valve would form gaps and not seal properly.

In reply, Petitioner misconstrues Dr. Zalesky’s testimony in an attempt to argue that Dr. Zalesky “agrees that using two filaments would benefit a hemostasis valve.” Pet. Reply, p.18. But that testimony refers to a POSA’s understanding of an embodiment shown in FIG. 7 of the ’921 Patent in view of the ’921 Patent’s disclosure, not the prior art or Petitioner’s proposed arrangement. EX1045, 93:17-94:12 (testimony starts with “Q: What are we seeing in Figure 7 of the ’012 Patent”). Dr. Zalesky’s testimony regarding a POSA’s understanding based upon the ’921 patent’s disclosure is not relevant to a POSA’s understanding prior to the date of the claimed invention. It is not relevant to patentability.

For those and the other reasons set forth below and in the POR, Petitioner has failed to demonstrate that any of the Claims are unpatentable under any of grounds 1-5.

II. THE CLAIMS ARE NOT ANTICIPATED BY OR RENDERED OBVIOUS BY SCHAFFER ALONE (GROUNDS 1-2)

Schaffer does not disclose or suggest a “filament,” which requires flexibility. POR, pp.12-28. In the Institution Decision, the Board preliminarily agreed. Institution Decision, pp.27-28. And, in the two Related FWDs, the Board found that Schaffer did not disclose or suggest a valve with a “filament.” EX1042, pp.38-40; EX1048, pp.41-42. Petitioner does not provide any additional arguments or evidence here to contest those findings. Pet. Reply, p.3. As a result, Schaffer does not anticipate or render obvious the Claims and grounds 1-2 fail.

III. THE CLAIMS ARE NOT OBVIOUS OVER SCHAFFER IN VIEW OF HARTLEY OR ELLER (GROUNDS 3 AND 4)

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

Petitioner asserts that the Related FWDs resolve all the disputed issues for Claims 1-7, 9, 15-18, and 20-24 of the '921 Patent here. Pet. Reply, p.1. Petitioner is wrong. For example, Petitioner ignores that the Board has not finally addressed or resolved Petitioner's evolving theories of obviousness that cherry-pick *multiple different and contradicting* substitutions/combinations as the purported simple substitution or obvious combination to meet whatever claim limitation is at issue.

Those changing and contradicting theories demonstrate that Petitioner's obvious arguments are based on impermissible hindsight.

It is well established law that the “[d]etermination of obviousness can not be based on the hindsight combination of components selectively culled from the prior art to fit the parameters of the patented invention.” *ATD Corp. v. Lydall, Inc.* 159 F.3d 534, 546 (Fed. Cir. 1998). That is, it is impermissible to “allow hindsight bias to be the thread that stitches together prior art patches into something that is the claimed invention.” *Metalcraft of Mayville, Inc. v. The Toro Company*, 848 F.3d 1358, 1367 (Fed. Cir. 2017), citing *KSR Intern. Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007).

Here and in other related IPRs Petitioner and its expert have advanced multiple different allegedly obvious combinations (“simple substitutions”) of Schaffer and Hartley/Eller, including:

- 1) Connecting Hartley's single string or Eller's wire between Schaffer's two actuator buttons in place of Schaffer's two U-shaped members. Petition, pp.35-36, 42-43; EX1003, ¶¶85-94, 99-106.
- 2) Or, replacing each of Schaffer's two U-shaped members with a string (from Hartley) or wire (from Eller), such that there are two strings/wires each connected to only one of Schaffer's actuator buttons and each formed in a U-shape. Petition, pp.68-70; EX1003, ¶¶154-155, 158.

- 3) Or, connecting two strings (Hartley) or wires (Eller) to each of Schaffer's actuator buttons such that they each loop around Schaffer's seal module. *Imperative Care, Inc. v. Inari Medical, Inc.*, IPR2025-01562, Paper 2, pp.48-49 & EX1003, ¶¶105-106.

Those contradictory combinations/substitutions are meaningfully different in structure. For example, some of the combinations involve replacing Schaffer's two separate actuating members with a single string/wire, while other combinations entail replacing Schaffer's two separate actuating members with multiple strings/wires. Some of the combinations involve connecting a single string/wire to only one of Schaffer's two actuator buttons, while other combinations involve connecting a single string/wire to both of Schaffer's actuating members. Some of the combinations involve looping the string/wire all the way around Schaffer's seal module, while other combinations involve extending the string/wire only partially around Schaffer's seal module. Petitioner's proposed combinations require a POSA who is "selectively culling" features and combinations from the prior art improperly using the '921 Patent (and the related patents) as a roadmap. *ATD Corp.*, 59 F.3d at 546; EX2033, ¶153.

The testimony of Petitioner's expert (Mr. Thornton) further reflects that reliance upon hindsight bias. Mr. Thornton had no knowledge of or familiarity with any prior art hemostasis valve that employed a filament to constrict a lumen before

reviewing the '921 Patent (or related patent). POR, pp.52-53; EX2034, 14:1-11, 15:16-23, 16:11-17:5. Yet for each of the multiple structurally different combinations he only considered the claimed combination, ignoring any other possibility. Then Petitioner's expert—without ever encountering a hemostasis valve employing a filament prior to this matter despite decades of experience with hemostasis valves—concludes that each of the different and contradictory combinations, none of which are found in the prior art, are “known,” “simple” or “obvious” substitutions to a POSA. To the contrary, a POSA could not have come to such conclusions *without* relying upon the '921 Patent as a roadmap. That is precisely the type of hindsight analysis that *KSR* and other longstanding precedents prohibit.

In reply, Petitioner claims that “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.” Pet. Reply, p.11. But Petitioner's statement does not address Petitioner's impermissible use of hindsight bias because Petitioner's statement *ignores* the other combinations/substitutions Petitioner and its expert advocate for elsewhere. Namely, Petitioner does not square the purported substitutions in which Hartley' string or Eller's wire are attached to Schaffer's opposing actuator buttons with the purported

substitution that “replace[s] each U-shaped actuating member with a string” or wire member. Petition, pp.68, 70. In that combination, each of the strings/wires would be connected to the same actuator button just like Schaffer's U-shaped members.

It is also inaccurate that the “Board agreed in the Related FWD and rejected PO's unsupported claims of hindsight bias.” Pet. Reply, p.11. The Board did not address or resolve Patent Owner's hindsight-bias arguments presented in this IPR that are based on the Petitioner's continually changing and differing theories of obviousness to meet the Claims of the '921 Patent (including dependent Claim 10) and other related patents.

Petitioner's changing assertions of the simple substitution and obvious combination from one, to another, to yet another depending on the challenged claims demonstrates that each is hindsight motivated only by the need to arrive at a particular claimed configuration.

B. Dependent Claim 10 is Not Obvious Over Schaffer and Hartley/Eller

Claim 10 narrows Claim 1 by requiring two filaments: a “first filament” and a “second filament.” Because Petitioner's proposed substitutions for Claim 1 include only Hartley's single string or Eller's single wire member, Petitioner provides two different theories why it allegedly would have been obvious to include a “second filament” as recited in Claim 10, both of which fail.

1. Hartley's Single String or Eller's Single Wire Do Not Include First and Second Filaments

Hartley's single string or Eller's single wire member do not comprise the claimed "first filament" and "second filament" simply because these structures can "include multiple threads or strands of material" as Petitioner alleges for its first theory of obviousness. Pet. Reply, p.13; Petition, pp.66, 70. Patent Owner does not dispute that a single string can "typically include several threads twisted together" or that a single "wire member can include two or more strands or fibers." Petition, pp.66, 70.

But as explained in the POR, the '921 Patent describes that twisting multiple strands together to form a filament does not somehow make multiple filaments ("a plurality of strands that can be, for example, twisted, woven, grouped, and/or fused to form **the** filament" and "**the** filament 150 can comprise **one or several** threads, lines, cords, rope, ribbon, flat wire, sheet, or tape"). EX1001, 9:12-16 (emphasis added); EX2033, ¶¶177-179. Consistent with that description, the '921 Patent describes FIG. 6 (reproduced below) as being "a single filament 150," regardless of whether it is composed of multiple strands twisted together.

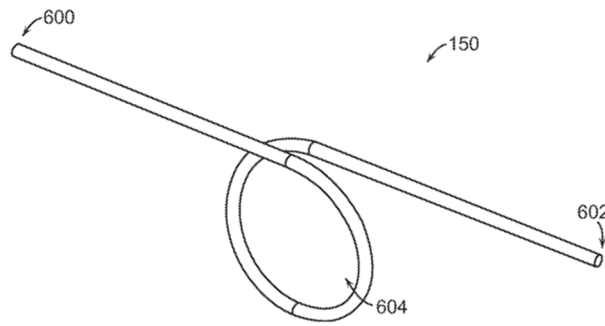
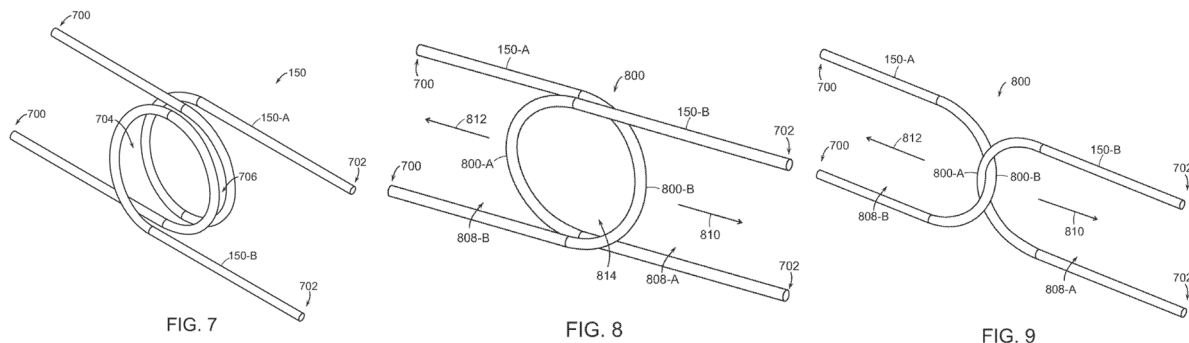


FIG. 6

EX1001, 12:37-41; EX2033, ¶¶177-179. The '921 Patent then provides examples of embodiments with first and second filaments in FIGS. 7-9 (reproduced below), which clearly show the second filament as being a distinct structure from the first filament, not merely a strand woven together with the first filament.



EX1001, 12:54-57; EX2033, ¶¶177-179. A single filament is therefore not transformed into a “first filament” and a “second filament” simply by having multiple strands twisted, woven, or otherwise integrated together.

Just like the '921 Patent, Eller disclose that “[a] wire member, such as the first wire member 22, the second wire member 24, and the third wire member 26, can have any suitable structure and comprise any suitable number of strands and/or fibers

that are twisted, or otherwise interconnected to one another.” EX1007, 15:61-65. That is, Eller also recognizes that multiple strands or fibers that are twisted together form a single wire member—not multiple wire members or filaments.

In reply, Petitioner first argues that Patent Owner's proposed construction of filament as “a thin, flexible length of material formed by one or more strands of material” supports that each twisted or wound strand of a string or wire member is equivalent to a “filament.” Pet. Reply, pp.13-14. But as set forth above and in the POR, both the specification of the '921 Patent and Eller make clear that because a single filament can be comprised of one strand or multiple strands does not mean that a filament formed of multiple woven/twisted strands satisfies the limitations for both a “first filament” and a “second filament.” EX2033, ¶178.

Petitioner misleadingly states that “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.” Pet. Reply, p.14 (emphasis added). Indeed, Dr. Zalesky testified how that “could be” by explaining that, consistent with the disclosures of the '921 Patent and Eller, the individual strands of a woven/twisted filament do not form individual “filaments” themselves when they are twisted together. Only if they are separated/unwound could they be considered separate filaments:

Question: If you have two threads within the same string, as we just discussed, would each of those threads be a different or a distinct filament?

[Objection]

Dr. Zalesky: If they're wound within or around each other, they constitute a single filament in combination.

Question: Earlier you testified that if you had multiple threads in a string and those threads were unwound, each would be a filament; correct?

[Objection]

Dr. Zalesky: Each could be a filament on its own, yes.

EX1047, 31:16-32:5. Despite what Petitioner asserts, this testimony does not support that multiple twisted strands constitute multiple filaments.

Petitioner likewise quibbles with the disclosure of the '921 Patent (Pet. Reply, pp.15-17) but, again, the '921 Patent and Eller are clear that because a single filament can be comprised of one strand or multiple strands does not mean that a filament formed of multiple woven/twisted strands satisfies the limitations for both a "first filament" and a "second filament." Despite Petitioner's assertions otherwise, that Claim 10 requires distinct structures for the first and second filaments—as opposed to multiple strands woven together—does not import unrecited terms into Claim 10. Pet. Reply, pp.15-17. Instead, as explained above, that is the only logical conclusion flowing from the '921 Patent and from Patent Owner's (and Petitioner's) proposed

constructions of the term filament, both of which recite that an *individual* filament can be composed of *one or more* strands/threads/etc. Pet., p.17.

And, Petitioner again misstates Dr. Zalesky's testimony to argue that the "interlocking embodiments" of the '921 Patent (including FIGS. 8-9) would be excluded from the scope of Claim 10. Pet. Reply, p.15. Specifically, Dr. Zalesky "testified that two threads would not be 'separate' filaments if they interlock" outside the context of any embodiments of the '921 Patent. *Id.* For example, in the testimony cited by Petitioner (EX1047, 39:15-41:23), Dr. Zalesky explained that "the difference between a separate thread and a separate filament" is that "two or more threads intertwined are wound or otherwise integrated constitute a single filament as a single element in a configuration." EX1046, 40:13-16. Thus, just like disclosed in the '921 Patent and Eller, when multiple threads/strands are intertwined or otherwise physically integrated together they form a single filament. And, Claim 10 cannot be construed to exclude the interlocking embodiments from its scope as for, example, Claim 14 (which depends from Claim 10) directly recites an interlocked embodiment: "wherein the first filament extends in a loop around the elongate member, and wherein the second filament *extends through the loop of the first filament* around the elongate member." EX1001, cl.14 (emphasis added).

Petitioner's theory that an individual one of Hartley's strings/Eller's wires includes the first and second filaments because these structures "include multiple threads or strands of material" fails for at least those reasons.

2. It Would Not Have Been Obvious to Have Replaced Schaffer's U-Shaped Actuating Members with Two Strings or Wires

Petitioner's second theory for the obviousness of Claim 10 is that a POSA would have "found it obvious to substitute Schaffer's two U-shaped actuating members for two strings or two wires" such that each string/wire is connected to only one actuator button and has a U-shape. Pet. Reply, p.18; Petition, pp.68-70. That arrangement for Claim 10 is radically *different* than Petitioner's purported arrangement for Claim 1, which includes a single string/wire looped around Schaffer's seal module and connected to Schaffer's two opposed actuator buttons.

Petitioner cannot be correct that a POSA would have found such a substitution obvious based on its own logic. According to Petitioner and its expert, it "is inaccurate" that "Schaffer's actuating members are 'rigid.'" Petition, p.30; EX1003, ¶79 ("a person of ordinary skill in the art would have understood that Schaffer's U-shaped actuating members would have preferably been formed from a thin, flexible material.") Therefore, they are flexible according to Petitioner. Petitioner and its expert then contend that those flexible actuating members "may form small gaps" as its motivation to substitute a *single* looped string/wire from Hartley/Eller into

Schaffer. Petition, pp.36, 43; EX1003, ¶¶86, 100. Petitioner further argued in the IPR for the related U.S. Patent No. 11,697,011 (the “‘011 Patent”) that such “[g]aps 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.” *Imperative Care, Inc. v. Inari Medical, Inc.*, IPR2024-01157, Paper 18, pp.22-24 (emphasis added) & EX1014, ¶34; *see also* EX2036, 43:24-46:16.

Thus, according to Petitioner and its expert, replacing Schaffer's U-shaped actuating members with a flexible string or wire (just as Petitioner contends for Schaffer's allegedly flexible actuating members) would result in gaps that Petitioner asserts would have purportedly motivated a POSA to modify Schaffer to include a *single* looped wire or string like Petitioner proposed for Claim 1. Therefore, by their own logic, if a POSA would have been motivated to arrive at Petitioner's arrangement for Claim 1, they would not have been motivated to replace both U-shaped actuating members with separate filaments like Petitioner's arrangement for Claim 10 because that modified valve would form gaps and not seal properly.

Even Petitioner's expert cannot keep track of the different and contradictory hindsight combinations of Schaffer, Hartley, and Eller. In his declaration in support of this Petition executed March 9, 2025, Mr. Thornton makes the allegations above that it would have been obvious to replace each of Schaffer's two actuating members

with a string or wire member. EX1003, ¶¶154-155, 158. But, a mere ten days later in the related '011 IPR, Mr. Thornton testified that he had never considered using two of Hartley's strings to replace Schaffer's two actuating members. EX2030, pp.54:25-55:14. Indeed, obviousness of both arrangements cannot be correct. A POSA that is purportedly motivated to include a single string in place of Schaffer's two U-shaped members because the two U-shaped strings would not seal cannot have also been motivated to include two U-shaped strings in place of Shaffer's U-shaped members knowing that such an arrangement would not seal.¹

In reply, Petitioner misconstrues Dr. Zalesky's testimony in an attempt to argue that Dr. Zalesky "agrees that using two filaments would benefit a hemostasis valve." Pet. Reply, p.18. The testimony quoted by Petitioner about "two filaments" being able "to apply a greater total amount of force of constriction" specifically refers to the embodiment shown in FIG. 7 of the '921 Patent. EX1045, 93:17-94:12 (testimony starts with "Q: What are we seeing in Figure 7 of the '012 Patent"). In that embodiment, the two filaments each extend in a loop and have opposing ends connected to opposite actuators. But Petitioner alleges a completely different

¹ In fact, neither arrangement is obvious and Petitioner's expert's contradictory testimony demonstrates improper hindsight using the claims as a roadmap to arrive at the different claimed arrangements as explained above.

structure than FIG. 7 in its second obviousness theory for Claim 10—namely, replacing Schaffer's two U-shaped actuating members with two U-shaped flexible strings/wires that would, like Schaffer's actuating members, each be attached to the same actuator button. Pet. Reply, p.18; Petition, pp.68-70. Any theoretical advantage associated with the two-filament embodiment of FIG. 7 therefore does not support that a POSA would have been motivated to include two filaments in a completely different arrangement. Petitioner's later argument about Dr. Zalesky's testimony regarding the manufacturability of valves having two filaments suffers the same fatal flaw. Pet. Reply, pp.21-22.

Moreover, as further explained in the POR, a POSA would not have replaced Schaffer's U-shaped members with strings or wires because the substitution would not yield a predictable result because, among other possibilities, the flexible strings/wires would be able to move laterally along Schaffer's seal modules when Schaffer's actuator buttons 261 are depressed. POR, 64-66; EX2003, ¶182. Petitioner's various replies are unavailing.

First, Petitioner's assertion that "PO also fails to address simple solutions to the hypothetical problem, *such as using a stiffer string or wire*" does not demonstrate that using two strings/wires would have been obvious. Pet. Reply, p.19 (emphasis added). In this scenario, Petitioner apparently alleges that a POSA would have first substituted Schaffer's original, rigid U-shaped members for Hartley's

flexible string or Eller's flexible wire, and then upon realizing the problem this created, made Hartley's flexible string or Eller's flexible wire inflexible, ***just like the original device taught by Schaffer***. But Petitioner's "simple solution" of stiff wires not only fails to disclose the limitations of Claim 10 (which require two *flexible* filaments), but also undermines Petitioner's argument that it would have been obvious to modify Schaffer to have flexible filaments in the first place.

Second, Petitioner's assertion that PO "never explains why this hypothetical movement [of the strings/wires] would deter a POSITA from using strings/wires" or "how the possible interference between the strings/wires would reduce 'sealing effectiveness'" is incorrect. Pet. Reply, p.19. Patent Owner does precisely that, explaining that "when Schaffer's actuator buttons are depressed one of Hartley's strings or Eller's wire members ***might move underneath the other***, potentially ***reducing the sealing effectiveness of the valve***." POR, p.65 (emphasis added); EX2033, ¶182. Reducing the sealing effectiveness of the valve would make such a combination unpredictable and deter a POSA from using multiple strings/wires in the manner alleged by Petitioner. *Id.*

Third, that Eller discloses multiple filaments is not dispositive as Eller does not disclose the arrangement proposed by Petitioner for Claim 10 in which the wire extends in a U-shape with both ends of the same wire connected to the same actuator. Instead, each wire in Eller is connected at one end to the valve housing or itself. Pet.

Reply., pp.19-20; EX1007, 15:21-40, 17:38-18:8; EX2033, ¶183. And, Petitioner's assertion regarding the bight embodiments in FIGS. 8-9 of the '921 Patent that the "'921 patent never suggests that filaments could slide laterally along the elongate member and never describes any solutions to this hypothetical problem" is incorrect. Pet. Reply, p.20. Sliding is not an issue in the embodiment shown in FIGS. 8-9 because the illustrated bights "interlock" rather than being positioned parallel to one another as in Petitioner's proposed combination. EX1001, 13:29-35.

Fourth, more generally, Petitioner's argument that the '921 Patent does not suggest that the filaments could slide laterally along the elongate member in embodiments with two filaments is irrelevant. Pet. Reply, p.20. The question is not whether the problem of lateral sliding was identified or discussed in the '921 Patent. The question is whether a POSA would have expected lateral sliding to be a potential issue before the effective filing date of the '921 Patent, such that the potential problem would have been taken into consideration when assessing whether there was motivation to combine the references and the predictability of such a combination. A POSA would have expected lateral sliding to be an issue before the effective filing date of the '921 Patent. EX2033, ¶182.

Fifth, Petitioner's assertion that a POSA's concern about lateral movement would not have outweighed a POSA's motivation to include a second filament is also misinformed. Pet. Reply, p.21. Petitioner did not cite any testimony from its

expert, or any other evidence specific to the lateral movement issue, to support this conclusion. *Id.* As such, this argument is an unsupported conclusion that should be afforded little or no weight. Moreover, if the inclusion of the second filament was expected to be so advantageous as to outweigh the potential problem presented by lateral sliding, then why did Petitioner rely on a ***different*** combination of Schaffer and Hartley/Eller (a single string extending between two different actuation members) to allegedly render Claim 1 obvious? Petitioner has offered no evidence in support of its conclusion and, as set forth above, it is contradictory.

Finally, Petitioner does not dispute that the mechanism of action in Petitioner's proposed substitutions is contrary to that of both Hartley and Eller such that the substitutions are not a mere simple substitution. POR, pp.65-66; EX2033, ¶183. In Hartley the single string 14 has both ends attached to the same rotary actuator 12 such that the two ends of the string are moved away from one another to constrict when the actuator is actuated and, in Eller, each of the wire members has one end attached to itself or to the housing and the other end attached to the actuator such that one end of the string is moved away from the other when the actuator is actuated. *See* EX1006, ¶[0031]; EX1007, 15:21-40, 17:38-18:8; EX2033, ¶183. In contrast, in Petitioner's proposed combinations, the ends of each of Hartley's strings or Eller's wire members are attached to the same linear actuator such that ends

cannot be moved away from one another in the manner taught by Hartley and Eller.
EX2033, ¶183.

For all those reasons and the reasons set forth in the POR, Petitioner has failed to demonstrate that it would have been obvious to have substituted Schaffer's two U-shaped actuating members for two flexible wires or strings in the manner alleged by Petitioner.

IV. CONCLUSION

For the reasons set forth herein and in the POR, Petitioner has failed to demonstrate that any of Claims 1-7, 9-10, 15-18, or 20-24 are unpatentable over grounds 1-5.

Respectfully submitted,

Dated: May 21, 2026

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

CERTIFICATE OF COMPLIANCE

Pursuant to 37 C.F.R. § 42.24(d), I, Joseph Hamilton, certify that **PATENT OWNER'S SUR-REPLY** contains 4,885 words, excluding those portions identified in 37 C.F.R. § 42.24(a), as measured by the word-processing system used to prepare this paper.

Dated: May 21, 2026

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

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), I certify that on May 21, 2026, a copy of
PATENT OWNER'S SUR-REPLY and EXHIBIT 2036 were served upon the
below-listed counsel by electronic mail:

Joshua J. Stowell
Joshua.Stowell@knobbe.com
Joseph R. Re
Joe.Re@knobbe.com
Brian C. Barnes
Brian.Barnes@knobbe.com
BoxImperative921@knobbe.com

Dated: May 21, 2026

By: / Kate Rose /
Kate Rose
Senior Paralegal