

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. IPR2025-00289
U.S. Patent No. 11,554,005

PATENT OWNER'S SUR-REPLY

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EXHIBIT LIST

	Petitioner's Exhibits
Exhibit	Description
1001	U.S. Patent No. 11,697,005 ("the '005 Patent")
1002	Excerpts from the Prosecution History of the '005 Patent
1003	Expert Declaration of Troy Thornton
1004	Resume of Troy Thornton
1005	U.S. Patent Publication US 2003/0225379 A1 to Schaffer et al. ("Schaffer")
1006	U.S. Patent Publication US 2003/0116731 A1 to Hartley ("Hartley")
1007	U.S. Patent No. 9,980,813 B1 to Eller ("Eller")
1008	Drawings Submitted During Prosecution of U.S. Patent Application No. 10/371,190
1009	U.S. Patent No. 5,429,616 to Schaffer ("Schaffer '616")
1010	U.S. Patent Publication US 2011/0144592 A1 to Wong et al. ("Wong")
1011	U.S. Patent Publication US 2015/0173782 A1 to Garrison et al. ("Garrison")
1012	RESERVED
1013	RESERVED
1014	U.S. Patent No. 4,723,550 to Bales et al.
1015	U.S. Patent No. 5,895,376 to Schwartz et al.
1016	U.S. Patent No. 12,109,384 B2 to Merritt et al.
1017	U.S. Patent Application No. 16/117,519 ("the '519 Application")
1018	U.S. Patent No. 7,775,501 B2 to Kees ("Kees")

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Exhibit	Description
1019	U.S. Patent Publication No. 2016/0220741 A1 to Garrison et al. ("Garrison '741")
1020	U.S. Patent No. 6,776,770 B2 to Treretola
1021	U.S. Patent Publication No. 2010/0042118 A1 to Garrison et al.
1022	U.S. Patent No. 5,938,645 to Gordon ("Gordon")
1023	U.S. Patent Publication No. 2014/0296868 A1 to Garrison et al.
1024	WIPO Publication No. WO 2006/124307 A2 to Goff et al.
1025	Decision Granting Institution of <i>Inter Partes</i> Review for U.S. Patent No. 11,697,011 (Paper 7) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2024-01157 (P.T.A.B. Jan. 23, 2025)
1026	Decision Granting Institution of <i>Inter Partes</i> Review for U.S. Patent No. 11,697,012 (Paper 6) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-00156 (P.T.A.B. Apr. 22, 2025)
1027	United States District Courts – National Judicial Caseload Profile (Dec. 2024)
1028	Imperative Care's Opposition to Inari's Motion for Leave to File Third Amended Complaint (Dkt. #98) in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 24-cv-03117-EKL (N.D. Cal.) (filed March 26, 2025)
1029	Imperative Care's Reply in Support of Motion to Stay Pending <i>Inter Partes</i> Review (Dkt. #108) in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 24-cv-03117-EKL (N.D. Cal.) (filed May 7, 2025)
1030	Decision Denying Institution of <i>Inter Partes</i> Review for U.S. Patent No. 11,744,691 (Paper 10) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2024-01257 (P.T.A.B. Feb. 7, 2025)
1031	Standing Order for Patent Cases Before Judge Eumi K. Lee (Aug. 16, 2024)

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Exhibit	Description
1032	<i>Yangtze Memory Techs. Co., Ltd. v. Micron Tech., Inc.</i> , No. 23-cv-05792-RFL, Dkt. 243 (N.D. Cal. Mar. 14, 2025)
1033	<i>Jawbone Innovations, LLC v. Google LLC</i> , No. 23-cv-00466-TLT, Dkt. 137 (N.D. Cal. Apr. 27, 2023)
1034	Joint Claim Construction and Prehearing Statement Pursuant to Patent Local Rule 4-3 (Dkt. #107) in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 24-cv-03117-EKL (N.D. Cal.) (filed Apr. 28, 2025)
1035	Declaration of Joshua J. Stowell in Response to Patent Owner's Objections to Imperative Care's Evidence [SERVED ONLY]
1036	Certified File History of U.S. Patent Application 10/371,190 [SERVED ONLY]
1037	Order Denying Motion for Preliminary Injunction (Dkt. #136) in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 24-cv-03117-EKL (N.D. Cal.) (issued September 29, 2025)
1038	Deposition Transcript of PO's Expert Paul Zalesky, Ph.D. dated August 27, 2025
1039	Deposition Transcript of PO's Expert Paul Zalesky, Ph.D. dated June 23, 2025
1040	Supplemental Expert Declaration of Troy Thornton
1041	U.S. Patent No. 11,697,011 ("the '011 patent")
1042	Deposition Transcript of PO's Expert Paul Zalesky, Ph.D. dated November 7, 2025
1043	New Oxford American Dictionary, 3rd ed. (2010) – definitions of "diameter," "filament," and "loop"
1044	Merriam-Webster's Collegiate Dictionary (11th ed. 2014), submitted by Patent Owner as Exhibit 2009 in IPR2024-00157

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

	Patent Owner's Exhibits
Exhibit	Description
2001	Declaration of Paul J. Zalesky
2002	Merriam-Webster's Collegiate Dictionary (11th ed. 2014)
2003	New Oxford American Dictionary (3rd ed. 2010)
2004	Drawings Submitted During Prosecution of U.S. Patent Application No. 16/117,519
2005	Deposition Transcript of Troy Thornton (September 30, 2024)
2006	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
2007	Docket Report in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 5:24-cv-03117-EKL (N.D. Cal.)
2008	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
2009	Order Granting Joint Stipulated Request for Order Changing Briefing Schedule in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 5:24-cv-03117-EKL (N.D. Cal.), Dkt. 104
2010	Motion For Preliminary Injunction in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 5:24-cv-03117-EKL (N.D. Cal.), Dkt. 24
2011	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
2012	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
2013	Complaint for Patent Infringement in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 5:24-cv-03117-EKL (N.D. Cal.), Dkt. 1

	Patent Owner's Exhibits
Exhibit	Description
2014	Clerk's Notice Resetting Motion Hearing and Setting PI Tutorial in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 5:24-cv-03117-EKL (N.D. Cal.), Dkt. 87
2015	Clerk's Notice Resetting Motions Hearing in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 5:24-cv-03117-EKL (N.D. Cal.), Dkt. 92
2016	Case Management and Scheduling Order in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 5:24-cv-03117-EKL (N.D. Cal.), Dkt. 54
2017	Stipulated Protective Order in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 5:24-cv-03117-EKL (N.D. Cal.), Dkt. 76
2018	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
2019	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
2020	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)
2021	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)
2022	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
2023	Declaration of Joseph P. Hamilton (April 28, 2025)
2024	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

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Exhibit	Description
2025	Inari's Notice of Motion and Motion for Leave to File Third Amended Complaint in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 5:24-cv-03117-EKL (N.D. Cal.), Dkt. 88
2026	Supplemental Declaration of Paul J. Zalesky
2027	Institution Decision 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)
2028	Deposition Transcript of Troy Thornton (March 19, 2025)
2029	Deposition Transcript of Troy Thornton (June 25, 2025)
2030	U.S. Patent No. 7,682,380 to Thornton ("Thornton")
2031	Deposition Transcript of Troy Thornton (August 15, 2025)
2032	Supplemental Expert Declaration of Paul J. Zalesky Submitted as Exhibit 2008 in IPR2025-00156, involving U.S. Patent No. 11,697,012
2033	Deposition Transcript of Troy Thornton (November 20, 2025)
2034	Declaration of Troy Thornton in Support of Inter Partes Review of U.S. Patent No. 11,697,011
2035	Declaration of Troy Thornton in Support of Inter Partes Review of U.S. Patent No. 11,844,921
2036	Deposition Transcript of Troy Thornton (January 5, 2026)

I. INTRODUCTION

Petitioner has failed to demonstrate that any one of Claims 1-15 of the '005 Patent are unpatentable. Ground 1 (Garrison and Schaffer) fails because these references do not disclose or suggest each and every feature of Independent Claims 1 and 10. For example, Petitioner asserts that Garrison discloses an on-off control fluidly coupled to a valve. Paper 1, pp.24-25. But the '005 patent makes clear that “fluidly coupled to” is not the same as “in” as claimed—such that the asserted references do not disclose that limitation of Claims 1 and 10. POR, pp.33-40; *Infra*, §II.A. Further, if properly construed, Garrison and Schaffer do not disclose a “filament” at all, let alone one that “circumferentially constricts” as recited in Claim 1 or that “reduc[es] the diameter of” a “loop” as recited in Claim 10. POR, pp.40-49. Schaffer's rigid, side-by-side U-shaped actuating members are neither filaments nor do they “circumferentially constrict” or form a “loop.” *Infra*, §II.B-C.

Grounds 2 and 3 (Garrison, Schaffer, and Hartley or Eller) also fail. Petitioner's alleged reason to modify Schaffer's valve to incorporate Hartley's string/Eller's wire is hindsight, motivated only by the claims. *Infra*, §III.A. The embodiment in Figures 30-34 of Schaffer (relied upon by Petitioner) seals without gaps by including “a third seal member” that “is so compliant that it forms a seal around” different instruments. EX1005, ¶¶[0068], [0075], [0081]. Because Schaffer's valves seal completely, Petitioner's motivation to modify Schaffer (the

presence of gaps) is nonexistent. Petitioner has not met its burden to show a “skilled artisan would have been motivated to combine the teachings.” *Axonics, Inc. v. Medtronic, Inc.*, 73 F.4th 950, 957 (Fed. Cir. 2023).

Grounds 2 and 3 also fail because Petitioner's proposed substitution replacing Schaffer's members with Hartley's string/Eller's wire and then *further* modifying the combination is not simple. *Infra*, §III.B. Petitioner's proposed combination requires a single string/wire controlled by two opposing actuators. Paper 1, pp.52-54, 58. But, as admitted by Petitioner's expert, none of the applied references disclose such an arrangement. EX2029, 57:7-22 (Schaffer has U-shaped members connected to one actuator each), 77:12-22 (Hartley's single actuator), 80:11-19 (Eller's single actuator). That fundamental difference is not a substitution at all, let alone a simple one.

Grounds 2 and 3 also fail because the solutions for constricting a tubular member in a hemostasis valve were not finite, identifiable, or known. *Infra*, §III.C. Petitioner argued there were three options for “constrict[ing] a tubular member in a hemostasis valve,” but Petitioner's expert has now admitted that there were many more ways, including unknown and unconsidered ways, to do so. Petition, p.52; EX2029, 107:3-13. Petitioner therefore has failed to demonstrate that “the options and solutions [were] identified and known.” *Kingston Tech. Co., Inc. v. Polaris Innovations Ltd.*, IPR2016-01623, 2018 WL 851884, at *5 (P.T.A.B. Feb. 9, 2018).

Ground 4 (Garrison, Hartley, and Eller) fails because inserting Eller's spring into Hartley's valve as Petitioner proposes would render Hartley's valve inoperable for its intended purposes of providing tactile feedback and maintaining a diameter of the valve lumen. EX2026, ¶¶198-201. Ground 4 also fails for Claims 1 and 12, and the claims that depend therefrom, because neither Hartley nor Eller disclose a filament having a "first end extending ... in one direction" and coupled to a "first member" of an actuator and a "second end extending ... in another direction" and coupled to a "second member" of the actuator. Instead, both Hartley and Eller disclose attaching a string or wire to a single unitary actuator. EX2026, ¶¶194-197.

For those and the other reasons set forth below, Petitioner has failed to demonstrate that any of Claims 1-15 are unpatentable under any of grounds 1-4.

II. CLAIMS 1 AND 10 ARE NOT OBVIOUS OVER GARRISON AND SCHAFFER (GROUND 1)

A. Garrison and Schaffer do not Disclose the "Housing" with "a Flow Path Extending Through the Housing" and "On-Off Control in the Flow Path"

Claim 1 requires the "on-off control" and the hemostasis valve be **in the same housing**. POR, pp.33-40. Petitioner does not dispute that Garrison does not disclose an on-off control positioned in the same housing as the hemostasis valve. Paper 21, pp.15-19; EX2036; 35:16-24. Indeed, Petitioner's expert testified that he had never heard of an on-off control and a hemostasis valve being in the same housing. *Id.* at 43:10-18.

Instead, Petitioner argues that the '005 Patent does not support an on-off control in the flow path in the housing and thus the claim language must mean something entirely different, and that Patent Owner's expert allegedly testified that Claim 1 covers embodiments in which the on-off control is not in the flow path in the housing. Paper 21, pp.15-19.

But, the '005 Patent discloses that a single housing can include a flow path with the hemostasis valve and the on-off control. In describing the aspiration assembly 10 of FIG. 1, the '005 Patent recites "the tubing subsystem 120 can have more or fewer tubing sections, connectors, and/or fluid control devices..." and that "[i]n some embodiments, one or more components can be permanently connected and/or integrally formed." EX1001, 6:45-49. As FIG. 1 (reproduced below) demonstrates, the tubing subsystem 120 includes a first tubing section 124a between the on-off control 126 and the housing 106.

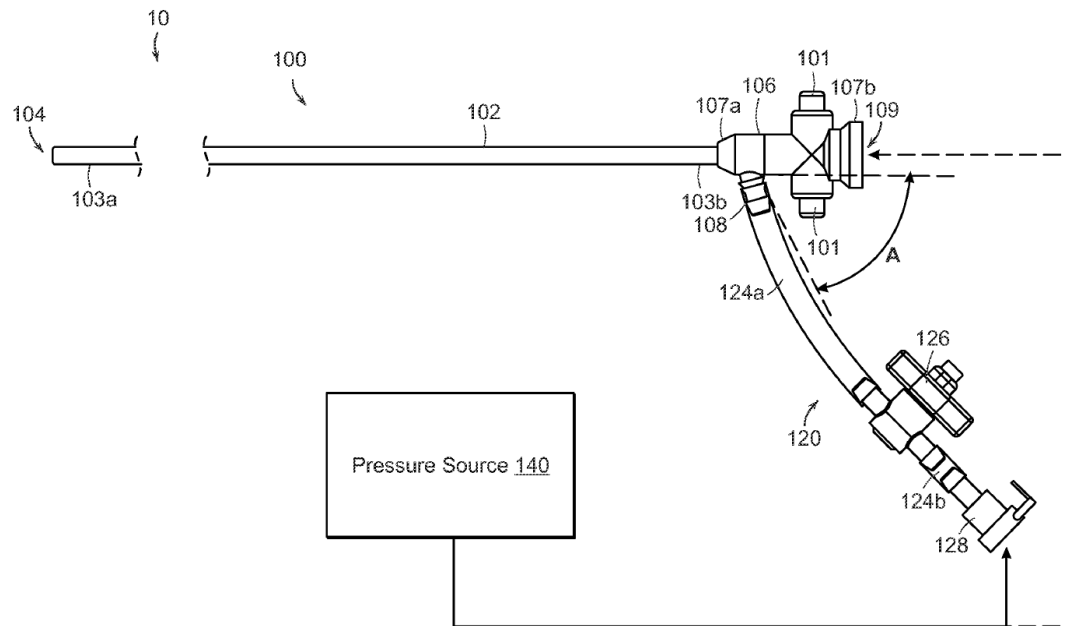


FIG. 1

EX1001, FIG. 1. If the first tubing section 124a is omitted, consistent with one embodiment described in the '005 Patent (“the tubing system 120 can have more **or fewer tubing sections**...” *Id.* at 6:45-46), then the resulting embodiment places the on-off control 126 in the flow path in the housing 106 as recited in Claims 1 and 10. This embodiment is also consistent with the '005 Patent’s description that “one or more of the components can be permanently connected and/or integrally formed,” which notably is **not** limited to the tubing subsystem 120. *Id.* at 6:48-49. Petitioner’s “lack of support” allegation is therefore not only irrelevant, but is also wrong. Paper 21, p.18.

Dr. Zalesky's testimony supports that Claims 1 and 10 require that the on-off control be in the flow path in the housing. EX2026, ¶¶91-93. Specifically, Dr. Zalesky explained that:

[C]laims 1 and 10 use the term '*in*' to describe the relative position of the on-off control relative to the flow path, but use the term '*fluidly coupled to*' to describe the relative position of the clot cannister to the flow path. A POSITA would understand that these terms ('in' versus 'fluidly coupled to') are not the same, **with the former requiring a direct connection** and the latter simply requiring a fluid connection, either direct or via intermediate components.

Id. ¶93. Dr. Zalesky confirmed this testimony at deposition. EX1042, 133:7-134-3. Petitioner's citation of other comments by Dr. Zalesky do not overcome the plain claim language and refute his other testimony. Moreover, Dr. Zalesky's declaration remains unrebutted: Petitioner's expert admitted that he "didn't consider what those terms [in the flow path versus fluidly coupled to] mean similarly or if there are any differences between those two terms." EX2036, 29:11-19 and 36:14-22.

Thus, because Garrison does not disclose an on-off control in the flow path in the housing, Garrison and Schaffer cannot render Claims 1 and 10 obvious.

B. Garrison and Schaffer do not Disclose the Claimed Filament, Which Requires Flexibility

The claim term "filament" should be construed consistent with its plain and ordinary meaning: "a thin, flexible length of material formed by one or more strands of material." POR, pp.23-32. Even Petitioner's expert admitted that the plain

meaning of filament includes flexibility. EX2005, 123:1-3. To demonstrate otherwise Petitioner must meet the high burden of showing that the '005 Patent clearly and unambiguously redefined the term "filament" to omit the requirement of "flexibility." *Kyocera Senco Indus. Tools Inc. v. Int'l Trade Comm'n*, 22 F.4th 1369, 1378 (Fed. Cir. 2022); *see also Hill-Rom Services, Inc. v. Stryker Corp.*, 755 F.3d 1367, 1371 (Fed. Cir. 2014). Petitioner has not.

Regarding claim 1, the Board declined to define filament as requiring flexibility because it was not evident that the bight embodiments required flexibility to be operable. Paper 10, p.16. However, the bight embodiment (Figures 8-9) fails to clearly and unambiguously redefine the term "filament" to omit the plain and ordinary "flexibility" requirement. First, the illustrated bights must be flexible because they are interlocking. EX2026, ¶81. If the two interlocking U-shaped bights were inflexible, they would need to be rotated in opposite directions as they are pulled from the position of Figure 8 to arrive at the position shown in Figure 9. *Id.* The '005 Patent includes no such disclosure. Second, even if an arrangement with side-by side bights (not illustrated) *could* work with rigid members, that example also works with flexible members, meaning that even this hypothetical embodiment does not amount to a clear and unambiguous redefining of the term filament. *Kyocera Senco*, 22 F.4th at 1378.

Regarding claim 10, Petitioner's argument that the filament should not be construed as requiring flexibility because "the claims encompass the 'bight' embodiments" is wrong. Paper 21, pp.27-29. Claim 10 recites that the filament is "formed into a loop," which the '005 Patent describes as distinct from the "bight" configurations. EX1017, Figures 6-9. And as the Board recognized, for the "loop" embodiments, "flexibility is required." Paper 10, p.17.

A POSA would also understand the degree of "flexibility" in a manner that does not inject ambiguity into the claims. POR, pp.32; EX2026, ¶86. Despite Petitioner's assertion otherwise, Dr. Zalesky's testimony at deposition confirms this (Question: "How would a person of ordinary skill in the art go about determining whether a given material is compliant enough to be a filament?" Answer: "Primarily trial and error...[to assess] its coaptability or its adaptability to a structure it's circumscribing and its coaption to the external surface of the structure."). EX1039, 103:14-104:8. Thus, Dr. Zalesky's testimony, in which he did not answer whether a hypothetical metal structure could be a "filament," does not inject ambiguity into the term "filament," but rather reflects that Petitioner's hypothetical was incomplete because the structure was not available to enable Dr. Zalesky to assess whether such structure would be a "filament" as claimed. Petitioner's expert also agreed that whether a filament is flexible could be readily determined. EX2029, 38:22-39:7.

Petitioner relies upon Schaffer's actuating members to allegedly disclose the claimed filament, but Schaffer's actuating members are rigid. POR, pp.40-42; EX2026, ¶¶94-105; Paper 10, p.30. Petitioner's argument that Schaffer's actuating members would anticipate the claimed filament even under Petitioner's construction because "Schaffer's actuating members are not rigid" is therefore wrong. Paper 21, pp.21-24. As Patent Owner has explained, Schaffer's U-shaped actuating members are necessarily rigid. POR, pp.41-42. The Board agreed. Paper 10, p.30. As such, Garrison and Schaffer cannot render claim 1 obvious.

C. Garrison and Schaffer do not Disclose Additional Properties of the Filament Required by Claims 1 and 10.

1. Claim 1

Schaffer does not disclose a filament that "circumferentially constricts" a lumen at least because Schaffer's actuating members are arranged side-by-side and thus cannot individually or collectively form a circumference around a lumen. POR, pp.42-45; EX2026, ¶¶107-110.

Petitioner's reply mischaracterizes deposition testimony. Paper 21, p.24 citing 1039, 100:11-22, 126:10-13. Dr. Zalesky's testimony does not support that Schaffer's U-shaped actuating members would "circumferentially constrict" because Schaffer's members have a fundamentally different structure than those Dr. Zalesky testified about.

The '005 Patent discloses two different embodiments of “semicircular bights”: bights that interlock (illustrated in Figures 8-9 reproduced below) and bights that do not interlock (no corresponding figures). EX1017, 13:48-52.

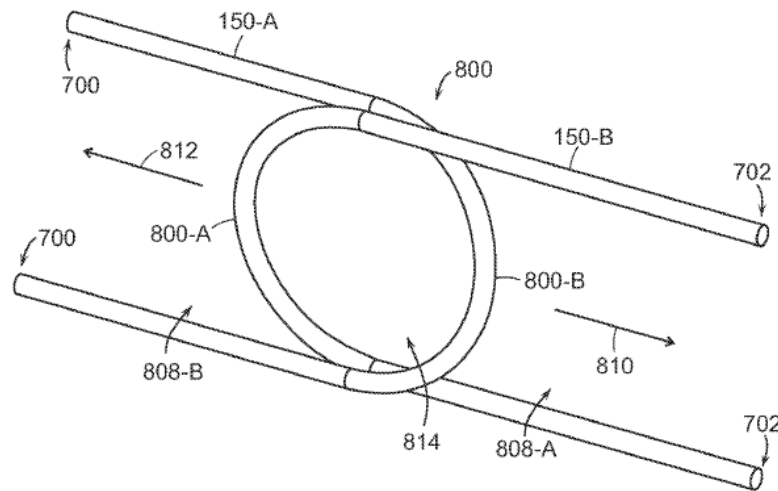


FIG. 8

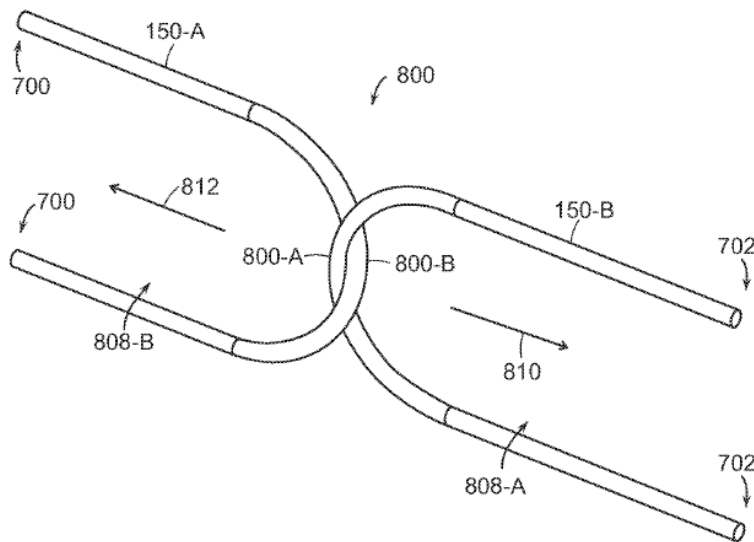
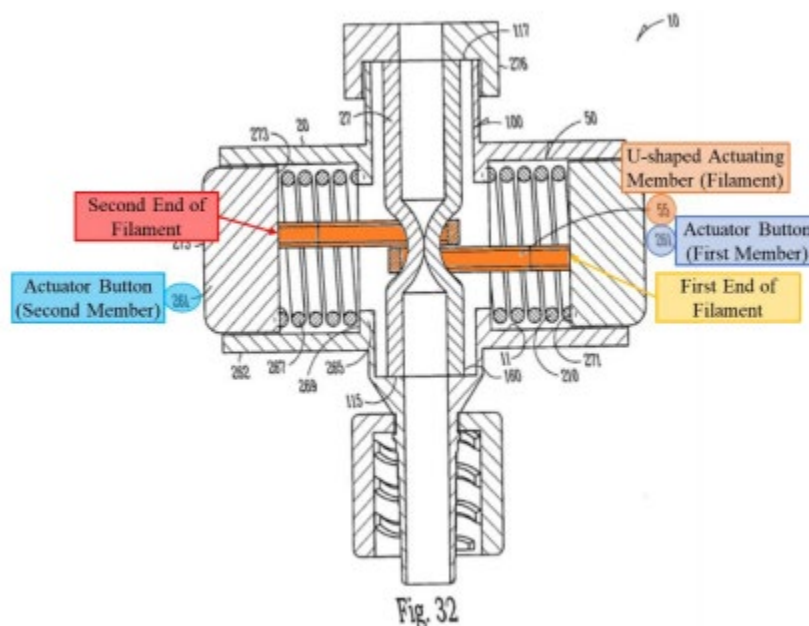


FIG. 9

The '005 Patent explains that interlocking bights illustrated in Figures 8-9 can “circumferentially constrict” precisely because the bights overlap: “the first and

second receiving areas 808-A, 808-B **overlap** and **define an encircled area 814**, also referred to herein as a constricting area 814.” *Id.* at 14:2-6 (emphasis added). For embodiments including an “encircled area,” like the interlocking bights, “the arcuate line of pressure may be a singular substantially circular line or zone that encircles the elongate member at least once.” *Id.* at 14:33-35. Stated otherwise, the bights 808-A, B collectively form an encircled area 814 with a circumference because they interlock, and thus the bights 808-A, B can “circumferentially constrict.”

In contrast, Schaffer discloses side-by-side (parallel) U-shaped members that do not interlock or overlap and thus cannot form an encircled area, as shown in Petitioner’s own annotated Figure 32 from Schaffer:



Petition, p.43. Schaffer's non-interlocking members cannot "circumferentially constrict" because they do not "define an encircled area" and thus do not define any circumference. POR, p.43; EX2026, ¶108.

Dr. Zalesky's testimony cited by Petitioner (Paper 21, p.24 citing 1039, 100:11-22, 126:10-13) correctly characterizes the interlocking embodiment of Figures 8-9 that is different from Schaffer's side-by-side U-shaped members. EX1039, 100:11-16 (Q. What properties of the filament **illustrated in Figures 8 and 9** require flexibility? A. In particular, the ability to circumferentially circumscribe or circumferentially impose a force.); EX1039, 126:10-13 (Q. ...**Figures 8 and 9 would also be circumferentially constricting the lumen.** Is that correct?. A. Yes...) (emphasis added). So, Dr. Zalesky's cited testimony confirms only that *interlocking* bights as shown in Figures 8-9 form an encircled area and thus can circumferentially constrict. Dr. Zalesky further testified that Schaffer's *non-interlocking* U-shaped members cannot "circumferentially constrict" because those members are side-by-side. EX2026, ¶108.

Petitioner also cites deposition testimony by Dr. Zalesky related to U.S. Patent No. 11,697,012. Paper 21, p.24 citing EX1038, 102:24-103:10. But the '012 Patent claims are expressly limited to the "loop" embodiments and do not involve the "bight" embodiments. Even there, Dr. Zalesky clarified that u-shaped members that are side-by-side (such as Schaffer's) cannot circumferentially constrict. EX1038,

185:7-14. Accordingly, Dr. Zalesky's comments during his deposition for the '012 Patent do not contradict Dr. Zalesky's testimony that "because Schaffer's U-shaped members (1) extend only partially around the lumen, and (2) do not overlap, they cannot individually or even collectively form a circumference around the lumen...[and thus] cannot individually or collectively 'circumferentially constrict' Schaffer's lumen." EX2026, ¶108.

That the '005 Patent also discloses non-interlocking bights is of no import. The '005 Patent discloses that the filaments circumferentially constrict in "some embodiments," not all embodiments. EX1017, 4:51-55. Claim 1 is expressly directed to embodiments that "circumferentially constrict."

2. Claim 10

Schaffer's rigid actuating members are U-shaped, side-by-side, and designed to retain their shape during operation and as such do not disclose the claimed "loop" or a reduction in diameter of that loop. POR, pp.45-59, EX1005, ¶[0076]; EX2008, ¶¶117-124. Petitioner relies upon the '005 Patent's "bight" embodiments to allege that Schaffer's two U-shaped actuating members collectively form a "loop." Paper 21, pp.25-27. Such reliance is improper—the "loop" embodiments and "bight" embodiments are distinct, so any alleged similarities between Schaffer's U-shaped actuating members and the bight embodiments do not support that Schaffer's U-shaped actuating members are loops.

III. CLAIMS 1 AND 10 ARE NOT OBVIOUS OVER GARRISON, SCHAFFER, AND HARTLEY OR ELLER (GROUNDS 2-3)

A. Petitioner's Alleged Motivation to Modify Schaffer's Valve Does Not Exist.

Petitioner's asserted motivation to modify Schaffer's valve to remove the rigid U-shaped members and replace them with a wire/string is inadequate and contrary to Schaffer's disclosure because Schaffer's valve already solves the purported problem to be solved by the modification—sealing without gaps.

First, Figures 30-34 of Schaffer—the embodiment relied upon by Petitioner—include Schaffer's seal member 165, just like every other embodiment of Schaffer. POR, pp.13-20; *see also* EX2026, ¶¶71, 137, 142, 151. At deposition, Petitioner's expert agreed. EX2029, 69:12-77:3. Petitioner's unsupported assertion that the seal member is not required does not rebut this. Paper 21, p.3.

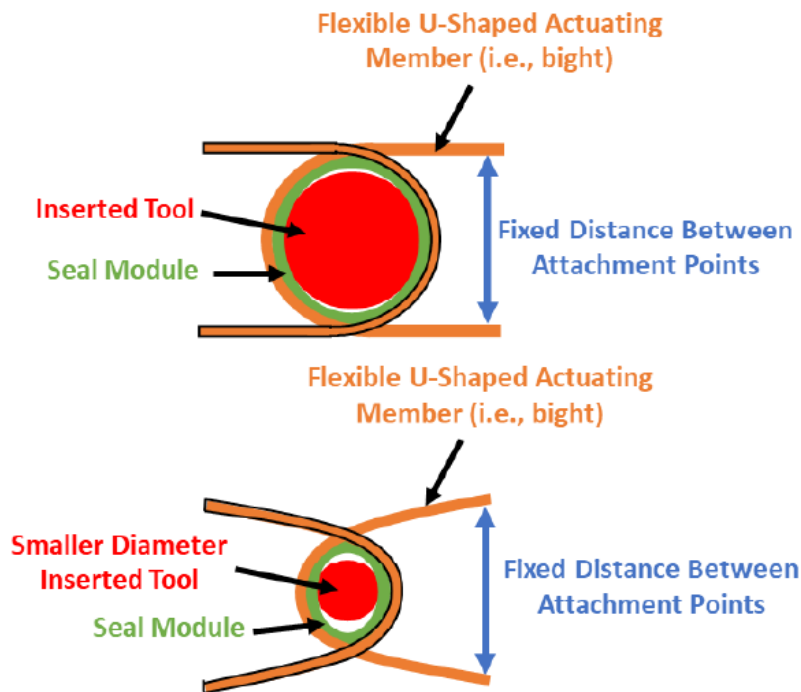
Second, the presence of the seal member in Figures 30-34 means this embodiment seals without gaps across a wide range of tool/device diameters and shapes. POR, pp.54-55; EX2026, ¶134-139. The seal member 165 does so by being highly compliant to conform to different shapes. EX2026, ¶138; EX1005, ¶[0060] (“the highly compliant third central seal member 165 seals around a variety of profile shapes 192 and diameters 194 of the lumen”), ¶[0068] (The “material 166 of the third central seal member 165 is so compliant that it forms a seal around the [multiple] instruments 260 even if the instruments 260 are irregularly shaped.”).

Indeed, sealing without gaps is an express purpose of Schaffer, which discloses that “existing devices do not perform a complete seal against leakage in the presence of a wide range of instruments or in the presence of multiple instruments,” and identifies a need for a “durable stasis valve that blocks the flow of gas or fluid completely and immediately with or without an instrument in place within the gas/fluid path.” EX1005, ¶¶[0006], [0008]. A POSA would have understood that Schaffer’s valves—including the embodiment in Figures 30-34—are designed to do just that via the highly compliant seal member 165. EX2026, ¶139.

Petitioner mischaracterizes Dr. Zalesky’s testimony to allege that Dr. Zalesky could not explain how Schaffer’s seal member 165 seals without gaps. Paper 21, pp.4-5. Petitioner repeatedly asked Dr. Zalesky incomplete hypotheticals at deposition, and now relies upon Dr. Zalesky’s lack of opinion about such incomplete hypotheticals to argue that Schaffer’s seal member 165 does not form a seal in various situations. EX1038, 131:17-135:24; Paper 21, p.4-5. But Dr. Zalesky did **not** testify that the seal member 165 would fail to seal. Indeed, Dr. Zalesky specifically referenced his ’012 Patent Supplemental Declaration in response to a question about whether the size of the instrument could result in leakage. EX1038, 135:7-9. There, Dr. Zalesky explains that “a POSITA would understand that Schaffer’s valve is explicitly designed to—and does—seal effectively and completely (i.e., without gaps) in the presence of a wide range of instruments, or without any instruments

inserted therethrough.” EX2032, ¶108. Schaffer explicitly states this also. EX1005, ¶¶ [0060], [0068].

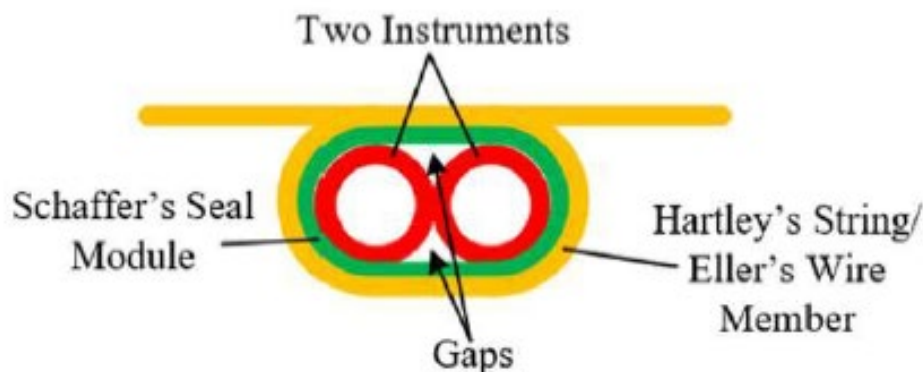
Petitioner's made-up graphics do not refute this. Petitioner's (made up) graphic, reproduced below, shows a schematic representation of a generic seal module and does not reflect how Schaffer's seal module would seal because it does not include the “seal member [that] ‘is so compliant that it forms a seal’” around all types of instruments—a fundamental feature of Schaffer's seal module. Paper 21, pp.5-6.



Id. at 23. If Petitioner's cartoon included Schaffer's highly-compliant seal member—which Schaffer includes as part of the embodiment Petitioner's cartoon is

based on—then there would be no gaps. EX2026, ¶¶141-142. And without gaps, Petitioner's motivation to modify Schaffer is non-existent.

Even Petitioner recognizes that its graphics unjustifiably excise Schaffer's compliant seal member. Paper 21, pp.5-6. When discussing Patent Owner's figure reproduced below with a similarly simple construction, Petitioner states that the figure "reflects a non-compliant seal that does not conform to the instruments...[t]hus, the demonstrative does not evidence that Schaffer's valve would work less effectively...." *Id.*



Only by removing Schaffer's compliant seal member would Petitioner's gaps potentially exist—but a skilled artisan would not have had any reason to remove that compliant seal member. *Id.* at ¶144. And even if a POSA had removed the compliant seal member (they would not have), Petitioner's proposed solution of using Hartley's string/Eller's wire would not address the problem of gaps. As demonstrated by Patent Owner's above graphic, a combination of Schaffer and Hartley/Eller that

omitted Schaffer's compliant seal member would have gaps around multiple instruments and/or irregularly-shaped instruments—scenarios for which Schaffer's valve is designed to form a complete seal. POR, pp.59-60. Indeed, without Schaffer's compliant seal member, Schaffer's valve would have gaps regardless of whether rigid U-shaped actuating members or a string/wire were used. EX1040, ¶24; EX2031, 16:15-23. That is, including a filament in Schaffer does not rectify the issues created by removing the compliant seal member. Instead, Schaffer's compliant seal member would need to be reintroduced, rendering Petitioner's proposed modifications superfluous. *Id.*

In sum, Petitioner's alleged problem (gaps) does not exist because of Schaffer's seal member 165. EX2026, ¶¶137-139. A POSA therefore would not have been motivated to modify Schaffer as Petitioner alleged: “[a] motivation to combine the teachings of references cannot be based on the alleged existence of a problem that does not exist....” *Aruba Networks, Inc. v. Xr Commc'ns LLC*, IPR2018-00701, 2018 WL 4090629, at *4 (P.T.A.B. Aug. 27, 2018). Petitioner's expert agrees. *See* EX2028, 116:18-117:2.

As a hedge, Petitioner argues that “PO never explains why this hyper ‘compliant’ seal would not work equally well with Hartley's string or Eller's wire.” Paper 21, p.5. First, there would be no reason to substitute Hartley's string/Eller's wire if the highly-complaint seal member was included. Second, Schaffer's rigid U-

shaped actuating members would better seal than a flexible string/wire, both because “a harder material would be able to deform a softer material more readily” (EX2031, 36:11-12), and because Schaffer's U-shaped members would likely deform more of the highly-complaint material to fill in any gaps than a filament they have a greater contact, and thus compression, area with the seal module, all while maintaining the multiple advantages of Schaffer's rigid U-shaped members. (Compare EX2031, 40:11-16, 41:15-24 with 43:2-8). And, as explained below, the proposed modification to use a string/wire in Schaffer would require wholesale changes to Schaffer's express method of manufacturing its U-shaped members and assembling its valve and would reduce reliability and control. EX2008, ¶¶169-180. A POSA would not have made Petitioner's proposed modification and introduced all those disadvantages, particularly where the modification would not even remedy Petitioner's non-existent issue.

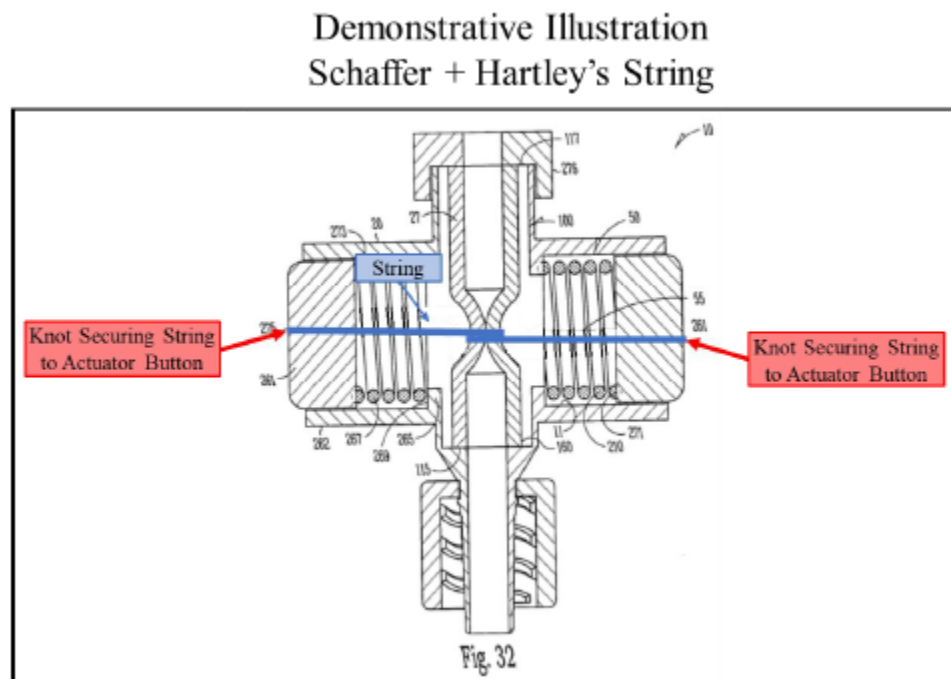
B. Petitioner's Proposed Modification to Include Hartley's String/Eller's Wire is No Simple Substitution.

Petitioner's “simple substitution” rationale for modifying Schaffer's U-shaped members is also wrong. Paper 21, pp.10-12. None of Petitioner's references disclose a single wire/string including two ends attached to and controlled by different independently movable actuating members. EX2026, ¶¶157-168. Petitioner's expert agrees. EX2033, 55:22-56:7. Instead of involving a simple

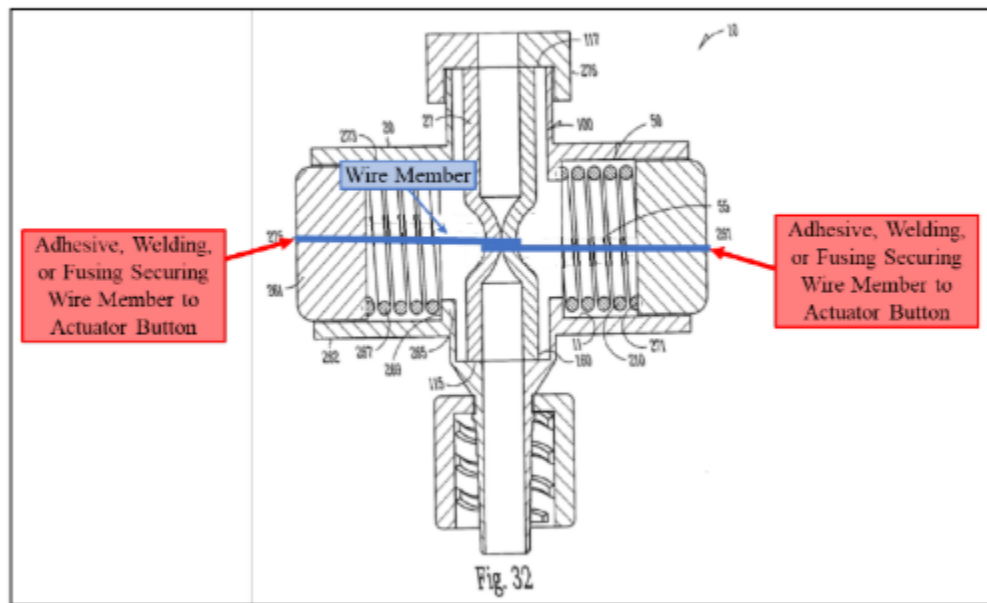
substitution, Petitioner's proposed combination requires additional modifications, including:

- (1) Removing **both** of Schaffer's U-shaped actuating members that are independently coupled to different actuators;
- (2) Replacing Schaffer's U-shaped actuating members with a **single** string/wire; and
- (3) Coupling the ends of the **single** string/wire to two **different** actuators, rather than the same one.

Paper 1, pp.52-54, 58. In that combination, each of Schaffer's actuator buttons independently control movement of one end of the string/wire, as shown in Petitioner's demonstrative illustrations:



Demonstrative Illustration
Schaffer + Eller's Wire Member



Id. at pp.53, 58. Thus, Petitioner’s arrangement including a string/wire having two ends attached to two separate and independently movable actuators was not a “known element” and instead is pure hindsight based on the claims. EX2026, ¶167.

Petitioner does not explain why this additional modification would be obvious. At best for Petitioner, a simple substitution would be to replace each of Schaffer's rigid U-shaped members with a u-shaped string/wire, which is exactly what Petitioner and its expert asserted in related Petitions. *See, e.g.*, EX2034, ¶75 and EX2035, ¶¶154-155. To now allege that the simple substitution is an entirely different construction reflects Petitioner's improper reliance on hindsight.

Petitioner's expert attempts to mask this by opining that string/wire was a known substitute for Schaffer's rigid U-shaped members. EX1003, ¶¶125, 139.

However, whether it was a known substitute does not motivate a POSA to follow the claimed arrangement of attaching a single string/wire to two independent actuators—that requires hindsight using the claims as a roadmap. And, despite his 35 years of experience using hemostasis valves, prior to this matter Petitioner's expert was not aware of a single prior art hemostasis valve employing a filament to constrict a lumen in any arrangement, let alone as claimed. EX2033, 14:1-11. Petitioner's expert had no familiarity with using a string or wire in a hemostasis valve until seeing the '005 patent (or related patent), or observing Petitioner's accused product in connection with co-pending related litigation. *Id.* at 16:11-17:5. Even now, Petitioner's expert has never tested or observed the use of a filament in a hemostasis valve sufficient to understand how a filament would function or compare to Schaffer's rigid U-shaped members. *Id.* at 15:16-23. His after-the-fact testimony that the two were known and simple substitutes in any arrangement, let alone in the claimed arrangement, is impermissible and unsupported hindsight. As explained in *KSR*, “[a] factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon ex post reasoning.” *KSR Int’l Co.*, 550 U.S. at 421.

Petitioner has therefore failed to show that the claimed arrangement existed in the prior art, let alone provide a reason to modify the references to include that arrangement. Even if the arrangement existed generally that would not provide a

motivation to combine Schaffer with Hartley/Eller as Petitioner asserts. *See Virtek Vision Int'l v. Assembly Guidance Sys.*, 97 F.4th 882, 887 (Fed. Cir. 2024) (reversing PTAB finding of obviousness because the “mere fact that these possible arrangements existed in the prior art does not provide a reason that a skilled artisan would have substituted” one for the other.).

Further, a POSA also would not have been motivated to substitute Hartley's string/Eller's wire for Schaffer's U-shaped members because a POSA would understand there are comparably more plausible substitutions—some even admitted by Petitioner—that would not require departing from Schaffer's principles of operation and yet would still maintain the advantages of Schaffer that are lost with Petitioner's proposed modification. *R.J. Reynolds Vapor Co. v. Fontem Holdings I B.V.*, IPR2016-01268, Paper 63, at 17-18 (P.T.A.B. Dec. 19, 2017) (finding Petitioner's proposed simple substitution nonobvious because there was a comparably more plausible substitution to simply replace the primary reference's entire atomizer with the secondary reference's atomizer); *see also Philip Morris Prods. S.A. v. RAI Strategic Holdings, Inc.*, No. 2022-1846, 2023 WL 5970786, at *1 (Fed. Cir. Sept. 14, 2023) (“we view the Board in that case as agreeing with the patent owner's expert testimony that a more plausible ‘simple substitution,’ compared to the petitioner's proposed substitution, would be to replace Hon's entire

atomizer"). Petitioner provides no reason why a POSA would choose the claimed solution over the myriad of other options.

When addressing Schaffer's alleged disclosure of Claim 5, Petitioner acknowledges there are a number of comparably simpler ways Schaffer discloses to maintain or improve its seal. For example, Schaffer discloses "adjusting Schaffer's spring strength to apply additional force, adjusting the resilience and compressibility of the seal module that forms the valve's lumen, and/or adjusting the shape...and/or dimensions of the actuating members to more closely conform to the shape of the seal module and any tool(s) inserted therethrough." Petition, p.69. Both Parties' experts agree that these simple adjustments would work, with or without a pressure differential across the valve. EX2029, 121:21-122:12; EX2026, ¶185.

Petitioner's expert also testified in a related IPR involving the same proposed combination of Schaffer and Hartley/Eller that he did not consider other plausible substitutions, such as replacing each of Schaffer's U-shaped actuating members with separate strings/wires or using a single string attached to a single button. EX2033, 41:17-42:5. Both unconsidered combinations are closer to Schaffer's design than the combination Petitioner proposes. But instead of considering those comparably simpler substitutions, Petitioner jumped to the combination that suited them. Such a leap cannot be a simple or known substitution and instead is grounded in impermissible hindsight.

Petitioner's proposed combination also would not yield the predictable result of sealing Schaffer's valve and is not suitable for sealing around multiple/irregularly-shaped instruments (POR, pp.70-71; EX2008, ¶167), both of which are express purposes of Schaffer's valve. EX1005, ¶¶[0006]-[0008], [0060], [0068]. For this reason alone, Petitioner's proposed substitution is not simple or even desirable. *Intel Corp. v. Qualcomm Inc.*, 21 F.4th 784, 800 (Fed. Cir. 2021) ("It's not necessary to show that a combination is 'the best option, only that it be a suitable option.'). A POSA would understand the results of substituting Hartley's flexible string/ Eller's flexible wire for Schaffer's rigid actuating members to be unpredictable. EX2026, ¶167. That unpredictability is exacerbated by Petitioner's proposed modification because Hartley/ Eller—the only references that disclose a flexible member—precisely control movement of that flexible member with a **single** movable actuator. EX2026, ¶¶161-165. In Petitioner's combination, the movement of the string/wire would not be precisely controlled by a single actuator because either of Schaffer's buttons could be depressed independently to move the string/wire unpredictably. *Id.* at ¶167.

C. Petitioner Fails to Establish There Were Finite, Identified and Known Solutions for Constricting a Tubular Member in a Hemostasis Valve.

Petitioner has failed to demonstrate that the options and solutions for "constricting the lumen of a tubular member in a hemostasis valve" were finite,

identified, and known. Petition, p.52. Petitioner identifies only three options: “Hartley and Schaffer disclose two such methods - Hartley’s single string and Schaffer’s two U-shaped actuating members ... Eller discloses a third option: one or more wire members.” *Id.*; EX1003, ¶126. But at deposition, Mr. Thornton admitted that there were **many more** than just three ways to constrict a tubular member in a hemostasis valve, including those disclosed in Schaffer ’616 (EX2029, 105:24-106:4, 106:12-14), Wong (*id.* at 106:15-19), Kees (*id.* at 108:14-20, 110:7-19), Myers (*id.* at 111:9-23), his previous work on a hemostatic-type clamp prototype (*id.* at 106:20-24), and more (*id.* at 112:5-114:24). In fact, Petitioner’s expert admitted that he did not know how many options exist. EX2029, 107:2-13 (MR. THORNTON: “I don’t know how many options could be used to compress a tube.”). And, as explained above in §III.B., Petitioner’s proposed combination that requires a single flexible string/wire connected to two independent actuator buttons was not known from Petitioner’s art. Petitioner’s “obvious to try” argument fails for this reason alone—the options and solutions for compressing a tubular member in a hemostasis valve were not “known,” “finite” or “identified” as confirmed by Petitioner’s own expert. *Rolls–Royce, PLC v. United Techs. Corp.*, 603 F.3d 1325, 1339 (Fed. Cir. 2010) (citing *Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341, 1351 (Fed. Cir. 2008)).

D. Petitioner's Proposed Modifications Would Violate Schaffer's Principles of Operation.

Regardless of whether Petitioner's proposed combination of Schaffer and Hartley/Eller includes or omits the seal-effectuating compliant sealing member, a POSA would not have pursued the modified arrangement because neither would have improved Schaffer's sealing and instead may even worsen it. *Supra*, §III.A. Because of this, a POSA would have had no reason to have deviated from Schaffer's advantageous mode of operation, and express methods of manufacturing the U-shaped members and assembling the device. *Id.* Schaffer's express purpose is to provide a device that seals yet provides a balance of "closing force, opening force, friction, compression and durability" so as not to damage or allow the insertion of delicate instruments and catheters and to allow a user to manipulate and advance those tools while compression is applied and the valve is sealed. EX1005, ¶[0007]; EX2031, 60:20-61:15. Schaffer's rigid compression members and highly compliant internal seal member accomplish that purpose by, e.g., sealing "under very light compression." EX1005, ¶[0059]. Petitioner's proposed combination ignores that express purpose and fundamentally changes how Schaffer seals. A POSA would not make such a modification contrary to Schaffer's express disclosure, particularly where the modification does not improve, and could impair, the seal "in the presence

of a wide range of instruments or in the presence of multiple instruments.” EX1005, ¶[0006].

E. A POSA Would not have Used Schaffer's Allegedly Ineffective Valve in Garrison

Petitioner's argument that it would have been obvious to have modified Schaffer's valve based on Hartley/Eller is predicated on Schaffer's valve being ineffective. Paper 1, p.51. But Petitioner also argues that a POSA would have incorporated Schaffer's valve into Garrison's catheter because “Schaffer discloses that its hemostasis valve is ‘for use with catheters’ and ‘blocks the flow of gas or fluid completely and immediately...’” *Id.* at 36, citing EX1005, ¶¶[0002], [0008], [0047], and [0049]. Petitioner tries a bait-and-switch here, first alleging that Schaffer's valve is more effective than Garrison's, but then alleging that Schaffer's valve is ineffective to motivate a combination with Hartley/Eller. This contradictory approach confirms Petitioner's reliance upon impermissible hindsight.

IV. CLAIMS 1 AND 10 ARE NOT OBVIOUS OVER GARRISON, HARTLEY, AND ELLER (GROUND 4)

Ground 4 fails for numerous reasons, including (1) none of the references disclose the claimed “on-off control in the flow path” “extending through the housing,” (2) none of the references disclose a filament having “a first end” coupled to a first member of an actuator and a “second end” coupled to a second member of the actuator, as recited in Claims 1 and 12, and (3) a POSA would not have been

motivated to modify Hartley in view of Eller as Petitioner proposes because doing so would be contrary to the purpose of Hartley. POR, pp.77-83. On Reply, Petitioner provided no evidence refuting these reasons that ground 4 fails. Thus, ground 4 fails for the reasons explained in the POR and accepted in the Institution Decision. Paper 10, pp.45-46.

V. DEPENDENT CLAIMS

Claims 2-9 depend from Claim 1 and thus include all the limitations of Claim 1. Claims 11-15 depend from Claim 10 and thus include all the limitations from Claim 10. Accordingly, those claims are also not rendered obvious by any of the combinations of Garrison, Schaffer, Hartley, and Eller (grounds 1-4). POR, pp.83-84. Further, none of Garrison, Schaffer, Hartley, or Eller disclose the features of at least dependent claims 11-15. *Id.* Petitioner's reply does not dispute this.

VI. CONCLUSION

For the reasons set forth herein, Petitioner has failed to demonstrate that any of Claims 1-15 are unpatentable over Grounds 1-4.

Respectfully submitted,

Dated: January 14, 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 5,510 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: January 14, 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 January 14, 2026, a copy of
PATENT OWNER'S SUR-REPLY, and EXHIBITS 2032-2036 were served
upon the below-listed counsel by electronic mail:

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Dated: January 14, 2026

By: / Kate Rose /
Kate Rose