

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. IPR2025-01562
U.S. Patent No. 12,109,384

PATENT OWNER'S RESPONSE

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EXHIBIT LIST

	Petitioner's Exhibits
Exhibit	Description
1001	U.S. Patent No. 12,109,384 ("the '384 patent")
1002	Prosecution History of the '384 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	Certified File History of U.S. Patent Application 10/371,190 (Schaffer File History)
1009	U.S. Patent No. 5,599,305 to Hermann ("Hermann")
1010	U.S. Patent Publication US 2011/0144592 A1 to Wong et al. ("Wong")
1011	RESERVED
1012	RESERVED
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	Deposition Transcript of PO's Expert Paul Zalesky, Ph.D. dated June 23, 2025

	Petitioner's Exhibits
Exhibit	Description
1017	Deposition Transcript of PO's Expert Paul Zalesky, Ph.D. dated August 27, 2025
1018	Deposition Transcript of Troy Thornton dated March 19, 2025
1019	RESERVED
1020	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)
1021	RESERVED
1022	U.S. Patent No. 11,697,011 ("the '011 patent")
1023	U.S. Patent No. 11,697,012 ("the '012 patent")
1024	RESERVED
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	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.)
1028	Order Regarding Case Schedule and Motion to Stay in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 5:24-cv-03117-EKL (N.D. Cal.)
1029	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)

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Exhibit	Description
1030	Patent Owner Response for <i>Inter Partes</i> Review for U.S. Patent No. 11,697,011 (Paper 3) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2024-01157 (P.T.A.B. Apr. 18, 2025)
1031	Supplemental Declaration of Paul J. Zalesky submitted in IPR2024-01157
1032	Robert C. Allen, <i>The Gore DrySeal Sheath</i> , Supp. Endovascular Today (Feb. 2011) ("Allen")
1033	Cara M. Michelson, et al., <i>Use of a Modified Cardiopulmonary Bypass Circuit for Suction Embolectomy with the Angiovac Device</i> , 49 J. Extra Corpor. Tech., 299-303 (2017) ("Michelson")
1034	Jacques Kpodonu, Manual of Thoracic Endoaortic Surgery (2010) ("Kpodonu")
1035	510(k) Summary – K123990, Sentrant Introducer Sheath with Hydrophilic Coating (Apr. 26, 2013) ("Sentrant")
1036	Matthew Kruse, <i>Thoracic Endovascular Aortic Repair (TEVAR) Sheaths</i> , CTSNet (Jan. 18, 2011) ("Kruse")
1037	Cook Medical, Endovascular Aortic Repair – Abdominal: Zenith Endovascular Grafts (2012) ("Zenith Brochure")
1038	U.S. Patent No. 8,137,321 B2 to Argentine ("Argentine")
1039	U.S. Patent Pub. No. 2017/0080200 A1 ("Bickhart")
1040	U.S. Patent No. 11,730,942 B2 to Fantuzzi ("Fantuzzi")
1041	U.S. Patent No. 8,777,893 B2 to Malewicz ("Malewicz")
1042	U.S. Patent No. 5,125,903 to McLaughlin ("McLaughlin")
1043	U.S. Patent No. 8,808,350 B2 to Schreck ("Schreck")

	Petitioner's Exhibits
Exhibit	Description
1044	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)
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	Decision Granting Institution of <i>Inter Partes</i> Review for U.S. Patent No. 11,969,333 (Paper 15) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-01021 (P.T.A.B. Dec. 11, 2025)
1048	Decision Granting Institution of <i>Inter Partes</i> Review for U.S. Patent No. 11,974,910 (Paper 15) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-01025 (P.T.A.B. Dec. 11, 2025)
1049	Notice of Decision Granting Institution of <i>Inter Partes</i> Review for U.S. Patent No. 12,016,580 (Paper 11) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-01264 (P.T.A.B. Dec. 11, 2025)
1050	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)
1051	Decision Referring the Petition to the Board (Paper 9) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-00728 (P.T.A.B. July 31, 2025)
1052	Decision Referring the Petitions to the Board (Paper 11) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-01021 (P.T.A.B. Oct. 10, 2025)

	Petitioner's Exhibits
Exhibit	Description
1053	Decision Referring the Petitions to the Board (Paper 11) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-01025 (P.T.A.B. Oct. 10, 2025)
1054	Notice of Decisions on Institution (Paper 10) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-01264 (P.T.A.B. Nov. 20, 2025)
1055	Patent Owner's Request for Discretionary Denial of <i>Inter Partes</i> Review for U.S. Patent No. 11,844,921 (Paper 5) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-00728 (P.T.A.B. June 16, 2025)
1056	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	Declaration of Paul J. Zalesky
2002	Merriam-Webster's Collegiate Dictionary (11th ed. 2014)
2003	Declaration of Troy L. Thornton in Support of <i>Inter Partes</i> Review of U.S. Patent No. 11,697,011
2004	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)
2005	Petition for <i>Inter Partes</i> Review (Paper 1) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-00728 (P.T.A.B. Mar. 3, 2025)
2006	Petition for <i>Inter Partes</i> Review (Paper 1) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2024-01157 (P.T.A.B. Jul. 8, 2024)
2007	Deposition Transcript of Troy Thornton (November 20, 2025) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-00156
2008	Supplemental Declaration of Paul J. Zalesky (EX2009) in <i>Inter Partes</i> Review of U.S. Patent No. 11,865,291
2009	Deposition Transcript of Troy L. Thornton dated May 28, 2026
2010	Supplemental Declaration of Paul J. Zalesky (EX2008) in <i>Inter Partes</i> Review of U.S. Patent No. 11,697,012
2011	Deposition Transcript of Troy L. Thornton dated June 25, 2025, in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-00156
2012	Deposition Transcript of Troy L. Thornton dated August 15, 2025, in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2024-01157

I. INTRODUCTION

Petitioner has failed to demonstrate that any of Claims 1-4, 6-18, and 20-30 (“the Claims”) of the ’384 Patent are unpatentable.¹ Although the ’384 Patent is related to several other patents for which IPR proceedings have been instituted (collectively the “related IPRs”²), two of which have received Final Written Decisions (the “related FWDs”³), the issues here are materially different because the Claims of the ’384 Patent recite different limitations. Specifically, independent Claims 1, 15, and 23 each recite, *inter alia*, a “valve assembly” comprising a “first

¹ The Petition does not challenge the patentability of Claims 5 and 19.

² See U.S. Patent No. 11,697,011 (*Imperative Care, Inc. v. Inari Medical, Inc.*, IPR2024-01157, Paper 7); U.S. Patent No. 11,697,012 (*Imperative Care, Inc. v. Inari Medical, Inc.*, IPR2025-00156, Paper 6), U.S. Patent No. 11,844,921 (*Imperative Care, Inc. v. Inari Medical, Inc.*, IPR2025-00728, Paper 13), U.S. Patent No. 11,865,291 (*Imperative Care, Inc. v. Inari Medical, Inc.*, IPR2025-00989, Paper 10), and U.S. Patent No. 11,554,005 (*Imperative Care, Inc. v. Inari Medical, Inc.*, IPR2025-00186, Paper 10).

³ See U.S. Patent No. 11,697,011 (*Imperative Care, Inc. v. Inari Medical, Inc.*, IPR2024-01157, Paper 35) and U.S. Patent No. 11,697,012 (*Imperative Care, Inc. v. Inari Medical, Inc.*, IPR2025-00156, Paper 33).

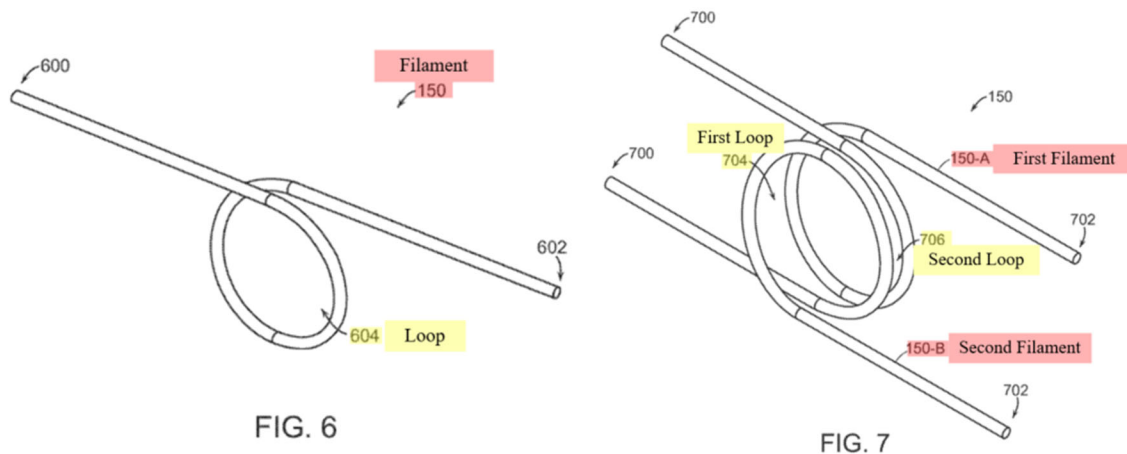
filament [extending/configured] in a first loop” *and* a “second filament [extending/configured] in a second loop.” The Claims therefore require two separate filaments, each forming a loop. None of Petitioner’s references discloses or suggests that claimed two-filament, two-loop configuration.

In grounds 1-2, Petitioner advances a “first way” obviousness theory based on Schaffer combined with either Hartley (ground 1) or Eller (ground 2). That theory relies on the same art and arrangements Petitioner proposed in the related IPRs, and that the Board addressed in the related FWDs. Under Petitioner’s theory, the first end of Hartley’s single string (or one of Eller’s wire members) is secured to Schaffer’s first actuator button, the string or wire member wraps around Schaffer’s seal module, and the second end is secured to Schaffer’s second actuator button. Petition, pp.35, 44-46. But even accepting for the sake of argument that a person of ordinary skill in the art (“POSA”) would have been motivated to combine the references in that manner—which Patent Owner also disputes here—grounds 1-2 fail. Namely, neither Hartley’s single string nor Eller’s single wire member comprises both a “first filament” and a “second filament” as the Claims require.

That Hartley’s string or Eller’s wire member can be formed from multiple threads or wires “twisted together” does not disclose both a “a first filament [extending/configured] in a first loop” and “a second filament [extending/configured] in a second loop” as claimed. Petitioner’s attempt to treat a

single twisted string or wire as satisfying both filament limitations—and both loop limitations—is directly contradicted by the disclosure and prosecution history of the '384 Patent. Petition, pp.28, 41-42.

The '384 Patent itself draws the critical distinction. Figure 7 discloses an embodiment with two filaments—a first filament 150-A and a second filament 150-B—each forming its own loop, namely a first loop 704 and a second loop 706. EX1001, 13:18-25; EX2001, ¶¶66, 91. By contrast, Figure 6 discloses a different embodiment with a single filament 150 forming a single loop 604:



Id. Figure 7, not Figure 6, corresponds to a multi-filament, multi-loop embodiment recited in the Claims. EX2001, ¶66. The specification further confirms that a single filament can be formed from a single strand or a “plurality of strands,” but a single filament does not become both a first filament and a second filament merely because it includes multiple twisted strands. EX1001, 9:16-21; EX2001, ¶68. Eller confirms the same understanding: multiple strands or fibers 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”).

The prosecution history confirms that conclusion. In response to a Restriction Requirement, Patent Owner expressly elected and identified the two-filament, two-loop embodiment shown in Figure 7, rather than the one-filament, one-loop embodiment shown in Figure 6. EX1002, p.220. Based on that election and the distinct disclosure in Figures 6-7, the claimed “first filament” and “second filament” require *separate* filaments forming *separate* loops, as shown in Figure 7—not a single filament forming a single loop, even if that filament is made of different strands or threads, as shown in Figure 6 and in Petitioner’s proposed combinations. EX2001, ¶¶66, 91. Petitioner’s proposed interpretation also conflicts with the Office’s finding in the Notice of Allowance that Hartley “fails to disclose ... a second filament.” EX1002, p.20; EX2001, ¶¶67, 91.

Recognizing that Hartley’s single string and Eller’s single wire member do not disclose the claimed separate filaments, Petitioner next offers an alternative “second way” obviousness theory for grounds 1 and 2. Under that theory, Petitioner asserts that a POSA would have replaced Schaffer’s U-shaped actuating members with two of Hartley’s strings or two of Eller’s wire members. Petition, 37-40, 47-50. That alternative theory also fails. Hartley discloses only a single string 14. EX2001,

¶71. And although Eller discloses embodiments involving multiple wire members, those wire members do not extend in a “loop”; instead, they extend only partially around a tubular sleeve. EX2001, ¶¶94-101. But, Petitioner's own expert confirmed that, in the context of the '384 Patent, a filament forms a loop only when it extends “completely around the tubular member.” EX2009, 19:19-24.

The “second way” for ground 1—obviousness over Schaffer and Hartley—also lacks any reasoned motivation to duplicate Hartley's string and use two strings in Schaffer's valve. Petitioner relies on Hartley's disclosure that its string “is wound preferably twice around the cylindrical diaphragm.” Petition, p.37; EX1003, ¶79; EX1006, ¶[0031]. But Petitioner's expert testified that, contrary to that disclosure, a POSA would not have double-wound Hartley's string because doing so would provide no benefit and could create negative consequences, including increased friction and reduced compression. EX2009, 42:11-20, 44: 22-24, 45:4-10, 45:16-18. Those same considerations would equally apply to two separate filaments. Indeed, Petitioner's expert concluded that the “most obvious” arrangement was a “single string wrapped around once,” not two filaments or strings. *Id.* at 45:16-18. Thus, Petitioner cannot show that a POSA would have been motivated to use “two separate strings” instead of “a single string looped twice around the tubular member,” because Petitioner's own expert rejected the premise that a POSA would have used even the double-wound single string in the first place. Petition, pp.37-38.

Even accepting Hartley's "preferably" double-wound disclosure at face value, Petitioner's reasons for modifying that arrangement into two separate strings still fail. Contrary to Petitioner's assertions, the proposed combination would not increase sealing width or reduce friction between Hartley's string(s) and Schaffer's seal module; it would further complicate Hartley's double-wound single-string arrangement. Petition, pp.37-38; EX2001, ¶¶73-78. Nor would redundancy or durability have motivated the proposed modification, particularly in light of Petitioner's and its expert's contrary positions in this and the related IPRs. *See* EX2009, 53:14-16 (it is "[p]robably very unlikely that durability couldn't be addressed with one string").

Petitioner's "second way" for ground 2—obviousness over Schaffer and Eller—fails for the same reasons, and additionally because Petitioner's proposed combination of Schaffer and Eller is not a "simple substitution." Petition, pp.48-50; EX2001, ¶¶102-104. Petitioner's combination does not merely substitute Eller's wire members for Schaffer's U-shaped actuating members, but further requires that each wire member be attached to a separate actuator at each end and be arranged in a loop. That arrangement is not found anywhere in Schaffer, Eller, or any other reference. EX2001, ¶¶94-101.

More broadly, Petitioner's theories of "simple substitution" or obvious combination have shifted across this IPR and the related IPRs to match whatever

filament arrangement appears in the challenged claims. Specifically, Petitioner and its expert have advanced multiple, materially different Schaffer-Hartley/Eller combinations, including: (1) a single string/wire substituted into Schaffer's valve in a loop (Petition, pp.30, 45, 42-43; EX1003, ¶¶70-77), (2) two strings/wire substituted for Schaffer's actuating members to have like U-shapes (EX2005, pp.68, 70; EX2006, p.32; EX2003, ¶75), and (3) two strings/wires substituted into Schaffer's valve in loops (Petition, pp.37-40, 47-50; EX1003, ¶¶78-84, 102-106). Those shifting combinations/substitutions are meaningfully different in structure and function. Petitioner's shifting theories therefore reflect improper hindsight reconstruction—"selectively culling" features from the prior art using the '384 Patent and related patents as a roadmap. *ATD Corp. v. Lydall, Inc.*, 159 F.3d 534, 546 (Fed. Cir. 1998); EX2001, ¶103.

Petitioner's expert testimony further reflects that same improper reliance upon hindsight. Mr. Thornton testified that, in preparing his declaration, he "certainly did not opine on any differences between a single loop [or filament] or a double loop [or filament] type of design or the potential benefits or negatives of each of those." EX2009, 17:10-19. In other words, despite proposing multiple different combinations in this IPR and the related IPRs, Mr. Thornton did not analyze the differences among them or their respective benefits and drawbacks. Indeed, when asked about the differences between using one string or wire in Schaffer versus two

strings or wires, he testified that the “most obvious” arrangement was a “single string wrapped around once,” not two filaments or wire members. EX2009, 45:16-18. And when asked why a POSA would want to use two filaments, he answered, “I don’t know.” *Id.* at 14:4-7. The only reasonable conclusion from that testimony is that he simply used the ’384 Patent (or related patent) as a roadmap to arrive at the particular claimed arrangement in each instance.

Grounds 1-2 fail for those reasons distinct from those addressed in the related IPRs and related FWDs. Ground 3 (obviousness over Schaffer in combination with both Hartley and Eller) fails for the same reasons. Combining both Hartley and Eller with Schaffer does not cure the absence of the claimed first and second filaments extending in first and second loops.

Grounds 1-3 also fail for the reasons raised in the related IPRs: a POSA would not have modified Schaffer to replace Schaffer’s rigid U-shaped actuating members with a flexible string or wire member in the first instance. Grounds 4-6, which add Hermann only for limitations specific to dependent claims, fail for the same reasons as grounds 1-3.

For these reasons, and the additional reasons set forth below, Petitioner has failed to demonstrate that any of Claims 1-4, 6-18, and 20-30 are unpatentable under any of grounds 1-6.

II. BACKGROUND

A. Overview of the '384 Patent

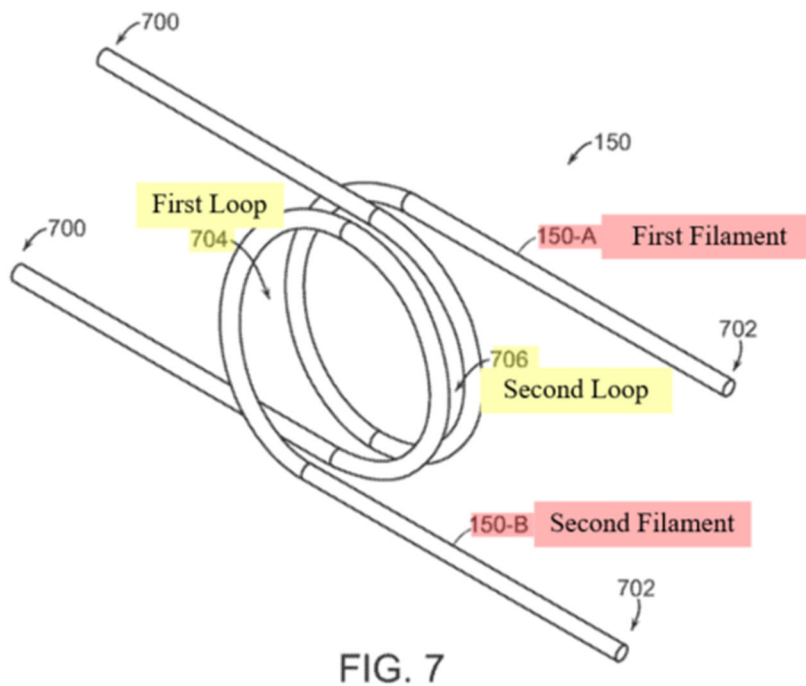
The '384 Patent explains that while “traditional hemostasis valves are greatly beneficial for intravascular access, they have some drawbacks. For example, some valves may not seal adequately for all interventional applications or tools, and/or the operation of some valves may be complicated for operator use.” EX1001, 1:52-56. So, to address those drawbacks, the '384 Patent discloses a hemostasis valve, “referred to as a garrote valve,” that “can seal with or without a tool extending through the valve.” EX1001, 5:56-58.⁴ This hemostasis valve enables medical professionals to easily operate the valve while maintaining a robust seal to prevent blood loss during procedures, such as aspiration thrombectomy procedures with large bore catheters in large vessels for treating deep vein thrombosis or pulmonary embolism, in which ease of use and a robust seal are particularly important. EX2001, ¶¶33-35; EX1001, 1:64-2:14, 5:17-23, 5:58-6:6, 16:7-31.

The '384 Patent's “garrote” valve includes a collapsible tubular member defining a valve lumen and a constricting mechanism. EX1001, 7:11-57, 8:5-16. The constricting mechanism includes two filaments that are each formed into a loop

⁴ Merriam-Webster defines “garrote” to mean “an implement (as a wire with a handle at each end) for strangulation.” EX2002, p.516.

around the tubular member and a pair of actuators connected to different ends of the filaments for tensioning the filaments to (1) tighten and constrict in one position to seal the valve and (2) loosen in another position to allow the valve to at least partially open and unseal. *Id.* at 8:5-12, 13:17-29.

Figure 7 illustrates the embodiment of the filaments claimed in the '384 Patent including a first filament 150-A and a distinct second filament 150-B that each form an individual loop—a first loop 704 and a second loop 706, respectively—about a tubular member 132:



EX1001, 13:21-25; EX2001, ¶43. In other embodiments of the '384 Patent, the filament(s) can have different configurations. EX2001, ¶¶42-46. For example,

Figure 6 illustrates a single filament 150 forming a single loop 604 around the tubular member:

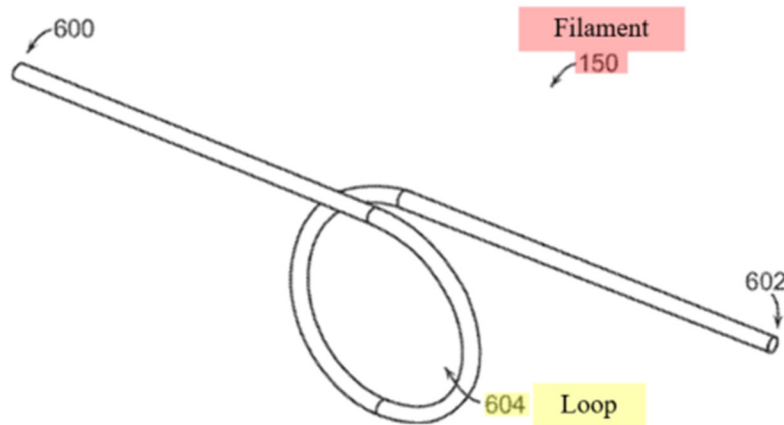
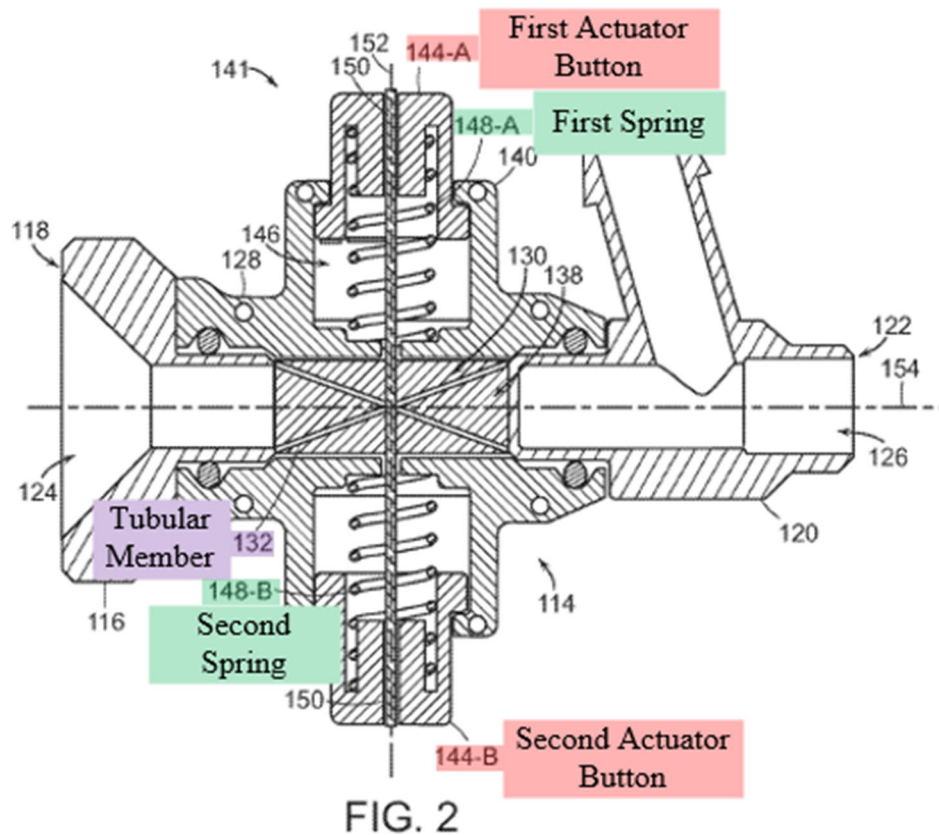


FIG. 6

EX1001, 13:17-21; EX2001, ¶43. And Figures 8-9 illustrate non-loop embodiments having two filaments formed into two U-shaped bights. EX1001, 13:30-33; EX2001, ¶45.

The pair of actuators may be manual buttons, enabling easy one-handed use. EX1001, 8:23-30; EX2001, ¶40. Specifically, the actuator buttons pull the filaments to decrease a diameter of each of the loops, thereby collapsing and sealing the tubular member. EX1001, 8:12-16, 13:17-29; EX2001, ¶¶40, 44. The actuator buttons (144-A, 144-B) can be biased (e.g., via springs 148-A, 148-B) towards a sealed position as shown in Figure 2:



EX1001, 8:38-44; EX2001, ¶40. In the sealed position, the tubular member is collapsed/sealed with the buttons in an undepressed position. EX1001, 8:40-46; EX2001, ¶40. The buttons can be depressed to move the valve to an unsealed position shown in Figure 3 in which the filaments are loosened, thereby allowing the tubular member to expand and unseal:

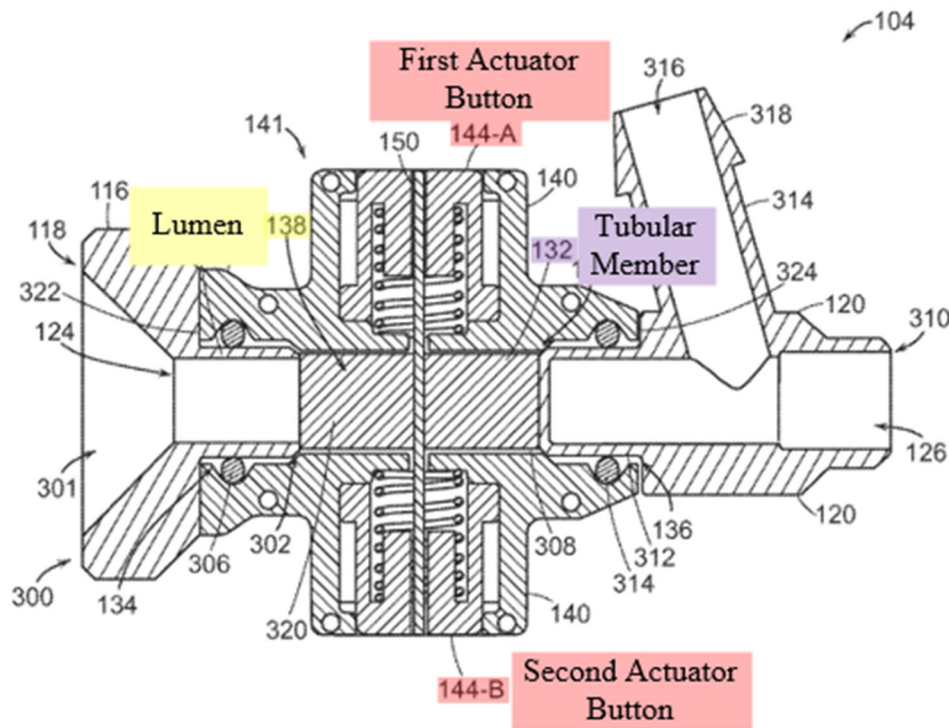


FIG. 3

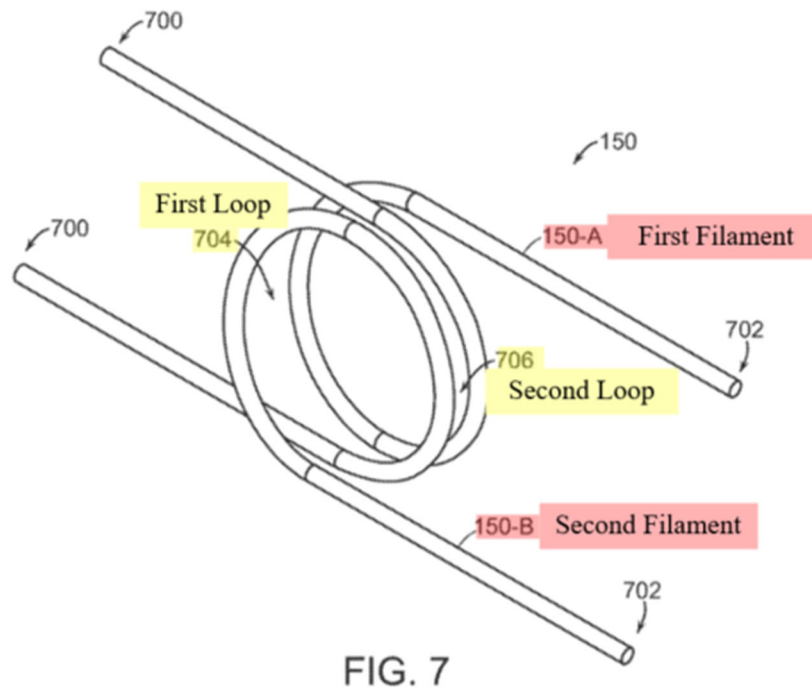
EX1001, 9:54-62; EX2001, ¶40.

B. Prosecution History

The only substantive Office action during prosecution of the '384 Patent before allowance was a Restriction Requirement mailed May 8, 2024. EX1002, pp.229-234. In that Restriction Requirement, the Examiner required an election between different species ((I) claims 1-14; (II) claims 15-22; or (III) claims 23-30) and between different sub-species ((1) Figs. 1-4; (2) Fig. 5; (3) Fig. 6; (4) Fig. 7; (5) Fig. 8; (6) Fig. 9; or (7) Fig. 12). EX1002, pp.231-232.

Before filing a response to the Restriction Requirement, Patent Owner and the Examiner conferred in a telephone interview where “[b]oth [Patent Owner’s attorney] and examiner Vu agreed that the sub-species (filament) in either one of the Figs 6-9 should be examined or combined into the delivery device system in Figs. 1-4.” *Id.* at p.172. That is, the Examiner agreed that the different filament arrangements in Figures 6-9 of the ’384 Patent are not distinct from the valve in Figures 1-4 but instead are different filament arrangements that can be used in the valve of Figures 1-4. *Id.*; EX2001, ¶52.

In response to the Restriction Requirement, Patent Owner elected species (I) including claims 1-14 and sub-species (4) directed to Figure 7, and withdrew claims 15-30. EX1002, p.220. The embodiment in Figure 7 discloses two filaments, a first filament 150-A and a second filament 150-B, that are separate from one another and that each separately form an individual loop—a first loop 704 and a second loop 706, respectively:



EX1001, 13:21-25; EX2001, ¶53. In contrast, the non-elected embodiment in Figure 6 of the '384 Patent discloses a single filament forming a single loop, and the non-elected embodiment in Figures 8-9 of the '384 Patent disclose two filaments each forming an individual bight. EX1001, 13:18-36; EX2001, ¶53.

In the subsequent Notice of Allowance, the Examiner found claims 1-14 allowable and withdrew the restriction of claims 15-30 because those claims “require[] all the limitations of an allowable claim.” EX1002, p.18. The Examiner further identified Hartley and Eller (the same references asserted by Petitioner here) as the “closest prior art of record” before finding that both references fail to “disclose the device” recited in the claims that issued in the '384 Patent. *Id.* at pp.20-21. Specifically, the Examiner explained that Hartley “fails to disclose that the actuator

is as a pair of actuators; a second filament” and that Eller “fails to disclose that the actuator is a pair” *Id.* Accordingly, the Examiner expressly found that Hartley fails to disclose a second filament and a pair of actuators, and that Eller fails to disclose a pair of actuators. And the Examiner was correct that Hartley and Eller do not disclose those features. EX2001, ¶54.

Schaffer was also cited during prosecution in an information disclosure statement and appears on the face of the '384 Patent. EX1002, p.274; EX1001, p.5. Accordingly, each of Petitioner's references for grounds 1-3 directed to the independent Claims was before the Office.

C. Claim Construction: “Filament”

In an IPR, a claim is construed “in accordance with the ordinary and customary meaning as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent.” 37 C.F.R. § 42.100(b). Independent Claims 1, 15, and 23 each recite a “first filament” and a “second filament.” A POSA would understand that the term filament as recited in Claims 1, 15, and 23 should be accorded its plain and ordinary meaning: “a thin, flexible length of material formed by one or more strands of material.” EX2001, ¶59. Petitioner's proposed construction omits the requirement that a filament is flexible (Petition, pp.17-19), and the Board found in the related FWDs that the term filament requires flexibility. EX2004, p.24; EX1056, p.23.

While that construction remains correct, here the Board need not construe “filament” because Petitioner’s grounds 1-6 fail regardless of the construction. EX2001, ¶59. Namely, none of Petitioner’s references disclose or suggest the “first filament [extending/configured] in a first loop” and the “second filament [extending/configured] in a second loop” recited in each of independent Claims 1, 15, and 23.

D. Person of Ordinary Skill in the Art

A POSA in September 2017 would have had an undergraduate degree in mechanical engineering or a related engineering discipline and 2-4 years of product design or engineering experience designing medical devices in the field of the ’384 Patent. EX2001, ¶55. A person with less education but more relevant practical experience, or more relevant education but less practical experience, may also meet this standard. *Id.* While Petitioner’s proposed definition of a POSA includes a similar level of education, Petitioner’s definition omits any requirement of experience in designing medical devices generally, let alone in the field of the ’384 Patent. Petition, p.16.

That experience designing medical devices in the field of the ’384 Patent is necessary as the Board found in the related FWDs. EX2004, p.24; EX1056, p.13. Accordingly, the declaration of Petitioner’s expert is not from the perspective of a POSA but rather from the too broad perspective of a person having no experience

designing medical devices. Petitioner's arguments and reliance upon that declaration from an incomplete perspective having no understanding of the design considerations including medical procedures and tools used therewith should be afforded little weight. For example, a POSA, under Petitioner's definition, would have no understanding why Petitioner's proposed substitutions including two of Hartley's strings or two of Eller's wire members could introduce a region for stagnant blood formation that could complicate any procedure using Petitioner's modified valves. EX2001, ¶78. Indeed, Petitioner's expert demonstrated just that lack of requisite experience by testifying that he never considered such a scenario or the ramifications thereof. EX2009, 50:15-51:8

Regardless of the definition of a POSA, even under Petitioner's definition, grounds 1-6 fail as explained herein.

III. INDEPENDENT CLAIMS 1, 15, AND 23 ARE NOT OBVIOUS OVER THE COMBINATION OF SCHAFFER AND HARTLEY OR ELLER (GROUNDS 1-2)

A claim is not obvious if an element of the claim is missing in the cited art. *See Aug. Tech. Corp. v. Camtek, Ltd.*, 655 F.3d 1278, 1290 (Fed. Cir. 2011). Petitioner's grounds 1-2 fail because Schaffer, Hartley, and Eller fail to disclose the "first filament [extending/configured] in a first loop" and the "second filament [extending/configured] in a second loop." Unlike in the related IPRs, Petitioner does not contend that Schaffer alone discloses the claimed filament configuration.

Petition, p.26 (“Schaffer’s filament configuration is ... different from the filament configuration recited in claim 1.”). Hartley and Eller also fail to disclose those limitations. Hartley discloses only a single string 14. EX2001, ¶¶64-80. And although Eller discloses embodiments involving multiple wire members, those wire members do not extend in a “loop” but, instead, only partially around a tubular sleeve. *Id.* at ¶¶94-103. In contrast to Eller’s wire members, Petitioner’s own expert confirmed that, in the context of the ’384 Patent, a filament forms a loop only when it extends “completely around the tubular member.” EX2009, 19:19-24.

To try and overcome that lack of disclosure, Petitioner identifies two alternative and wrong “ways” that Schaffer in combination with Hartley or Eller allegedly renders obvious the limitations of a “first filament” and a “second filament” required by independent Claims 1, 15, and 23. First, Petitioner argues that Hartley’s single string or a single one of Eller’s wire member are, alone, a “first filament” and a “second filament.” Petition, pp.27-37, 40-47. But that interpretation contradicts the specification, the prosecution history, and common sense as explained in §III.A below. EX2001, ¶¶64-69, 89-91. Second, Petitioner argues that a POSA “would have found it obvious to substitute two of Hartley’s strings [or Eller’s wire members]” for Schaffer’s two U-shaped actuating members. *Id.* at pp.37-40, 47-50. It would not have been as explained in §§III.B-C below. EX2001, ¶¶70-80, 92-104.

Additionally, as explained in §III.D below, Schaffer, Hartley, and Eller fail to disclose any filament—let alone two separate filaments that are each formed in a loop—acted upon by *two* actuators as recited in the Claims. *See, e.g.,* EX1001, cl.1 (each of the first filament and the second filament “includes a first portion operably acted upon by a first one of the actuators and a second portion operably acted upon by a second one of the actuators”). Instead, each of Schaffer's U-shaped members, Hartley's string, and Eller's wire member(s) are attached to and controlled by only a *single* actuator.

Finally, as explained in §III.E below, Petitioner's shifting theories of “simple substitutions” or obvious combinations of Schaffer and Hartley or Eller over the course of this and the related IPRs to purportedly meet whatever arrangement of filament(s) is claimed demonstrates impermissible hindsight.

Accordingly, because Schaffer, Hartley, and Eller do not disclose all the limitations of Claims 1, 15, and 23, and a POSA would not have modified Schaffer as claimed, grounds 1-2 fail.

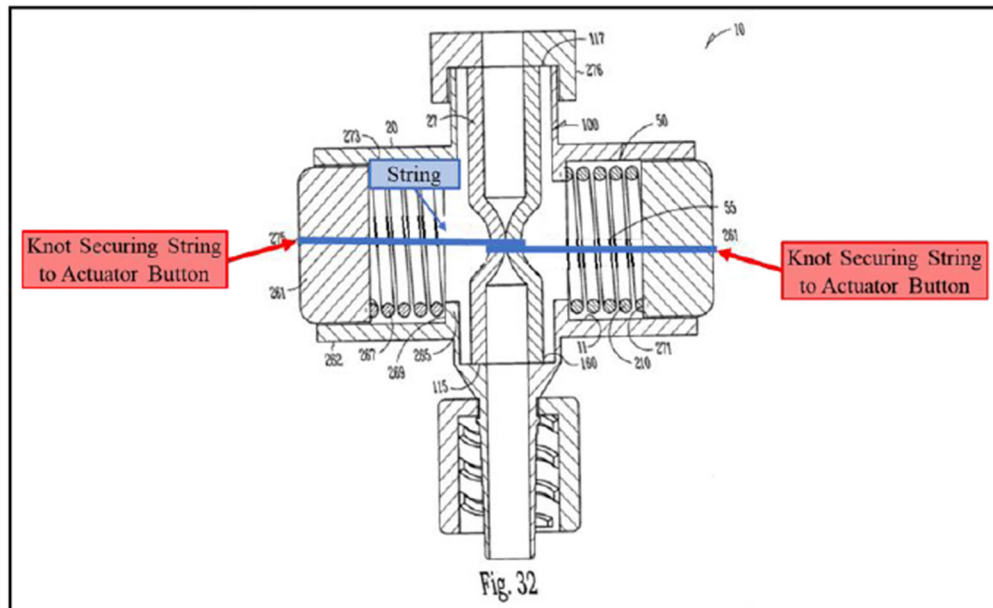
A. Hartley's String and Eller's Wire Member Do Not Disclose or Render Obvious Two Filaments as Required by Independent Claims 1, 15, and 23

Petitioner's “first way” that Schaffer in combination with Hartley or Eller renders obvious independent Claims 1, 15, and 23 is incorrect because neither Hartley's single string 14 nor a single one of Eller's wire members is a “first

filament” and a “second filament” as required by those Claims. Petitioner contends that in its proposed combination the first end of Hartley’s string/ Eller’s wire member would be secured to Schaffer’s first actuator button, Hartley’s string/ Eller’s wire member would loop around Schaffer’s seal module, and the second end of Hartley’s string/ Eller’s wire member would be secured to Schaffer’s second actuator button, as shown in Petitioner’s demonstrative illustrations:

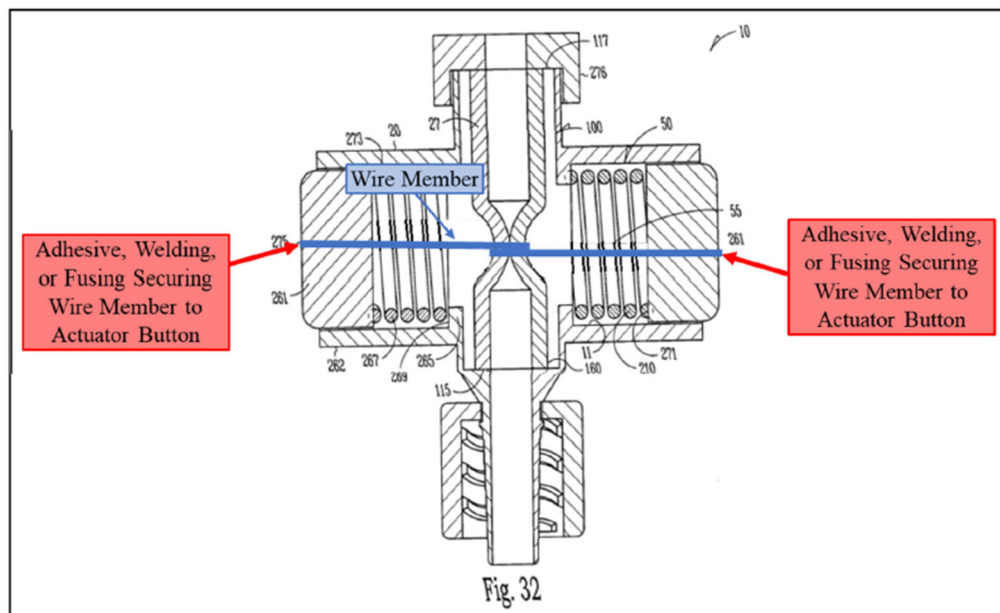
Demonstrative Illustration

Schaffer + Hartley's String



Demonstrative Illustration

Schaffer + Eller's Wire Member

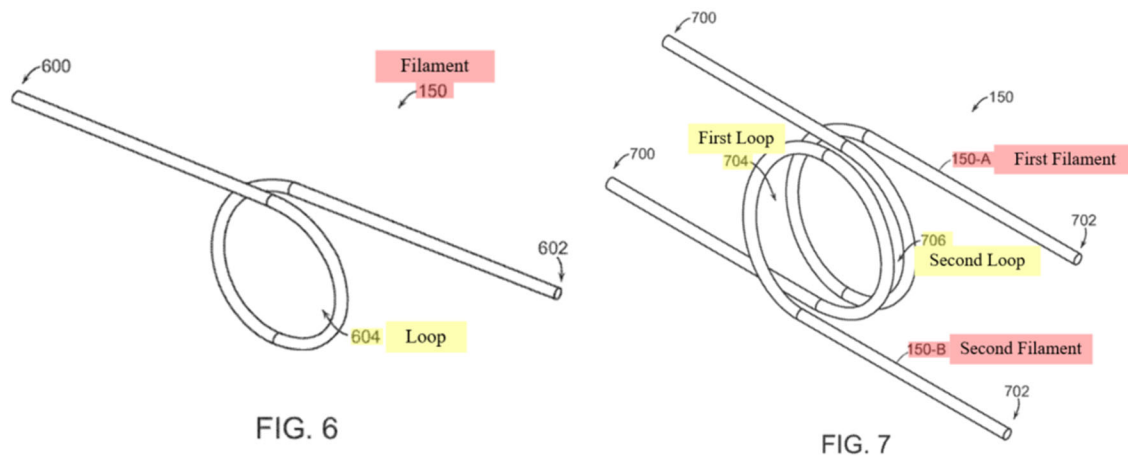


Petition, pp.35, 44-46. According to Petitioner, in the combination with Hartley, Hartley's string 14 is both the "first filament" and the "second filament" because a

“POSITA would have understood that Hartley’s string 14 would be formed from at least two threads twisted together” and that “[e]ach thread forming the string is a ‘filament.’” *Id.* at p.28. Likewise, in the combination with Eller, Eller’s wire member is allegedly a “first filament” and a “second filament” because a “POSITA would have ... understood that Eller’s wire member would be formed from at least two filaments twisted together” and that “the twisted ‘strands and/or fibers’ comprising Eller’s wire member are each a flexible filament.” *Id.* at pp.41-42.

Petitioner’s proposed combinations for this first alternative argument are identical to those proffered by Petitioner in the related IPRs and addressed by the Board in the related FWDs. Patent Owner maintains that it would not have been obvious to a POSA to have substituted Hartley’s string or Eller’s wire member into Schaffer’s valve for the reasons explained in those related IPRs and below in §III.F. EX2001, ¶¶65, 90. Nevertheless, ***the related FWDs do not resolve the controversy here*** because, even assuming for the sake of argument that a POSA would have made Petitioner’s proposed substitutions, grounds 1-2 still fail because Hartley’s string or Eller’s wire member do not include both a “first filament [extending/configured] in a first loop” and “second filament [extending/configured] in a second loop” as required by the Claims. *Id.* Petitioner’s interpretation of the first and second filaments contradicts both the intrinsic evidence, extrinsic evidence, and the common understanding of “filament.”

First, the '384 Patent discloses two distinct embodiments in Figures 6-7: (1) in Figure 7 two filaments 150-A and 150-B each forming an individual first loop 704 and a second loop 706, respectively, and (2) in Figure 6 a single filament 150 forming a single loop 604.



EX1001, 13:18-25; EX2001, ¶¶66, 91. Petitioner's expert agrees that "Figure 6 shows a single filament and a single loop" (EX2009, 15:10-11) and that Figure 7 shows "two separate [filaments] that are next to each other" that form "multiple loops" (*id.* at 19:3-18). Accordingly, a POSA would understand based on the disclosure of Figures 6-7 that the "first filament [extending/configured] in a first loop" and the "second filament [extending/configured] in a second loop" as recited in the independent Claims require separate first and second filaments as shown in Figure 7 rather than a single filament composed of different threads or strands as Petitioner asserts and similar to Figure 6 of the '384 Patent. EX2001, ¶¶66, 91.

Indeed, the Patent Office required an election between the different embodiments in Figure 6 having a single filament loop and Figure 7 having two filaments and two loops. EX1002, pp.231-232. In response to that Restriction Requirement, Patent Owner expressly elected the embodiment in Figure 7 and not the embodiment in Figure 6. *Id.* at p.220. That election further confirms that the “first filament” and the “second filament” recited in the Claims are *separate* filaments forming *separate* loops as shown in Figure 7 of the '384 Patent and not a single filament forming a single loop (even if made of different strands) as shown in Figure 6 and in Petitioner's proposed combination. EX2001, ¶¶66, 91.

Further, the '384 Patent is explicit that a single filament can comprise a single strand (e.g., monofilament) or a “plurality of strands,” but a single filament does not become both a first and second filament simply because of multiple strands twisted together. EX1001, 9:16-21 (“In some embodiments, the filament can comprise a single strand such as, for example, a monofilament, and in some embodiments, the filament can comprise a plurality of strands that can be, for example, twisted, woven, grouped, and/or fused to form the filament.”); EX2001, ¶68. Just like the '384 Patent, Petitioner's reference Eller confirms the understanding that multiple strands or fibers that are twisted together form a single wire member—not multiple wire members or filaments—by disclosing that “[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.” EX1007, 15:61-65.

Second, interpreting Hartley's string or Eller's wire member to comprise a “first filament” and a “second filament” as Petitioner asserts would be directly contrary to the Office's finding in the Notice of Allowance that Hartley “fails to disclose ... a second filament.” EX1002, p.20; EX2001, ¶¶67, 91. The Office correctly understood that a single string (or wire member) comprises a single “filament” rather than multiple filaments as recited in the Claims of the '384 Patent. EX2001, ¶¶67, 91.

Third, Petitioner's reliance on Claim 6 of the '384 Patent as “confirm[ing] that the threads of Hartley's string are a ‘first filament’ and ‘second filament’” is misplaced. Petition, p.28; EX2001, ¶68. Claim 6 depends from independent Claim 1 and recites that that the first filament and second filament “each comprise a plurality of strands woven together.” That recitation confirms the disclosure of the '384 Patent which distinguishes different embodiments in which each filament “can comprise a single strand such as, for example, a monofilament” or “a plurality of strands that can be, for example, twisted, woven, grouped, and/or fused to form the filament.” EX1001, 9:16-21; EX2001, ¶68. A POSA would have understood based on Claim 6 and the foregoing disclosure of the '384 Patent that the “first filament” and the “second filament” recited in Claim 1 could each either be a single strand or

multiple woven strands, and that Claim 6 requires the “first filament” and the “second filament” to each comprise multiple strands woven together in contrast to a single strand (e.g., monofilament). EX2001, ¶68. Therefore, Claim 6 supports that a single string made up of twisted or woven fibers cannot comprise both the first and second filaments and the first and second loops recited in the Claims.

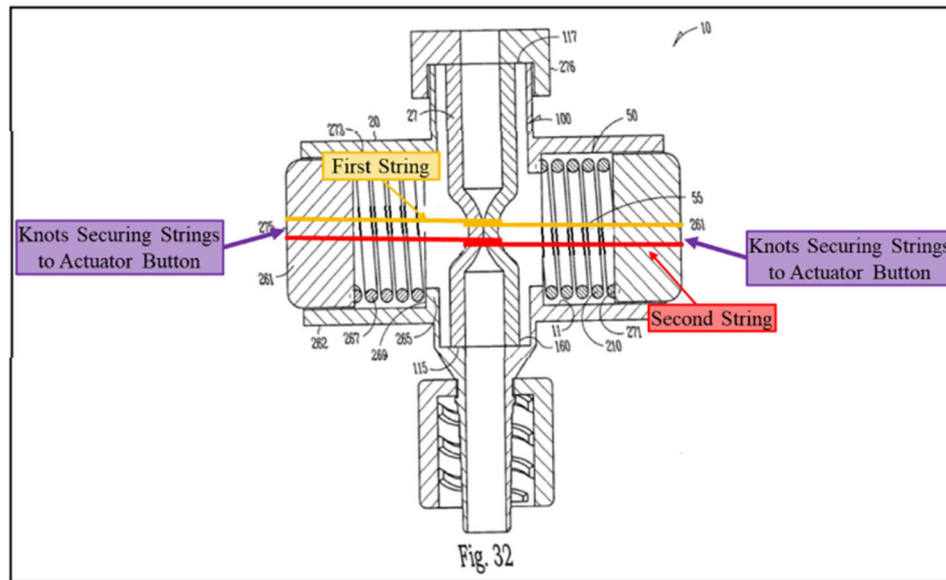
The inconsistency in Petitioner's interpretation that different wound strands of a single filament can comprise multiple filaments to meet the limitations of the Claims is highlighted by its own expert's testimony. For example, when asked “with respect to Claim 1, if I have two strings comprising two threads each, how many filaments do I have?” Mr. Thornton testified that “[i]f you're equating filament to string in Claim 1, what you described is each filament has multiple strands, which is really what Claim 6 is saying.” EX2009, 38:9-15; *see also id.* at 36:18-38:8. In other words, according to Petitioner's own expert in that arrangement there are two filaments (each of two wound strands)—not four filaments counting each individual strand. Mr. Thornton's contradictory testimony that a POSA could pick and choose the meaning of filament (to support his contradictory obviousness positions) would render the term filament meaningless and cannot be correct. EX2009, 39:12-40:1 (“I think a person of skill in the art would be able to pick from that range [in column 9 of the '384] in how they were using the term ‘filament’ and how they would use the term ‘string.’”).

For the foregoing reasons, neither Hartley's single string nor Eller's wire member are "a first filament [extending/configured] in a first loop" and "a second filament [extending/configured] in a second loop" as recited in the independent Claims. Petitioner's "first way" of obviousness for grounds 1 and 2 therefore fails.

B. It Would Not Have Been Obvious to a POSA to Have Duplicated Hartley's Single String and Substituted Those Two Strings for Schaffer's U-Shaped Actuating Members

Petitioner's "second way" that Schaffer in combination with Hartley renders obvious independent Claims 1, 15, and 23 is incorrect because it would not have been obvious to a POSA to have duplicated Hartley's single string and substituted those two strings for Schaffer's U-shaped actuating members. EX2001, ¶¶70-80. In that alternative combination, Petitioner asserts that a POSA would have further modified and changed the proposed structure to include two of Hartley's strings in Schaffer's valve, with the first end of each string secured to Schaffer's first actuator button, each string looping around Schaffer's seal module, and the second end of each string secured to Schaffer's second actuator button, as shown in Petitioner's demonstrative illustration of the proposed substitution:

Demonstrative Illustration
Schaffer + Hartley's Strings



Petition, p.40.

However, every embodiment of Hartley includes only a *single* string 14, and Hartley does not suggest any other arrangement with more than the single string 14. EX2001, ¶71. Schaffer's two U-shaped actuating members 55 are not "filaments" and neither extends in a loop, as Petitioner concedes: the configuration of the actuating members is "*opposed* to the claimed configuration that requires two filaments that each form a loop around the tubular member." Petition, p.26 (emphasis added); EX2001, ¶71. Accordingly, neither Schaffer nor Hartley disclose "a first filament [extending/configured] in a first loop" and "a second filament [extending/configured] in a second loop" as recited in the independent Claims. Petitioner's "second way" for ground 1 fails for that reason alone.

Despite that lack of disclosure, Petitioner and its expert simply conclude that a POSA would have, with little reason, duplicated Hartley's single string 14 and included those two strings in Schaffer's valve to "provide a more robust and reliable seal" based on Hartley's disclosure that its string 14 "is wound preferably twice around the cylindrical diaphragm." Petition, p.37; EX1003, ¶79; EX1006, ¶[0031]. Specifically, Petitioner asserts that a POSA "would have been motivated to use two separate strings, each looped once around the tubular member, as opposed to a single string looped twice around the tubular member, for a few reasons": (1) "to reduce friction," (2) "to ensure that the sealing area is wider," and (3) to "provide[] a redundancy to the valve that cannot be accomplished with a single string." *Id.* at pp.37-38; EX1003, ¶¶80-82. But, even assuming that a POSA would have been motivated to substitute Hartley's single string into Schaffer as Petitioner asserts for its "first way" of obviousness (which Patent Owner disputes), a POSA would not have duplicated Hartley's string in a manner not taught by either Hartley or Schaffer for any of the "few reasons" Petitioner proposes. EX2001, ¶¶73-80.

First, Petitioner's motivation to make the modification duplicating Hartley's strings is based on the disclosure in Hartley that its string 14 "is wound preferably twice around the cylindrical diaphragm." Petition, p.37; EX1003, ¶79; EX1006, ¶[0031]. But Petitioner's expert testified that, contrary to that disclosure, a POSA would not have double wound Hartley's string in the first instance:

Q. If your option was to wrap around two times or use two strings, why might a person of ordinary skill in the art use one string to wrap around twice?

[Mr. Thornton]. I think I said I don't see where a person of skill in the art would -- would wrap around twice.

EX2009, 45:4-10. Mr. Thornton explained that a POSA would not have double wound Hartley's string because there would no benefit to doing so or even negative consequences like friction and reduced compression:

Q. ... So what would a person of ordinary skill -- or why would a person of ordinary skill wrap around twice?

[Mr. Thornton]. Yeah. I'm not sure that a person of ordinary skill would necessarily wrap it twice. I think it could have some negatives of adding additional friction and make it more difficult to compress the tubular member if it were wrapped twice around. So I'm not sure there would be any benefit to doing so.

Id. at 42:11-20. Indeed, Mr. Thornton concluded that it would be "counterintuitive to wrap a string around twice when you are trying to compress a tubular member within it." *Id.* at 44:22-24. Therefore, according to Petitioner's own expert a POSA would not "have been motivated to use two separate strings ... as opposed to [Hartley's disclosure of] a single string looped twice around the tubular member"

for any of the reasons Petitioner provides because a POSA would not have used a single string looped twice in the first instance. Petitioner's expert even agrees: "I just think a person of skill in the art would find it most obvious to use a single string wrapped around once." *Id.* at 45:16-18. In fact, Petitioner's expert does not know why a person of ordinary skill in the art would want to use two filaments:

Q: Why would a person of ordinary skill in the art want to use two filaments?

[Objection]

[Mr. Thornton]: Yeah. I don't know.

Id. at 14:4-7. Petitioner's second theory of obviousness for ground 1 fails for that reason alone.

And accepting Hartley's disclosure that the string 14 is "preferably" wound twice, Petitioner's reasons for modifying that arrangement into two separate strings still fail. First, Petitioner's purported reason to duplicate Hartley's single string and include those duplicated strings in Schaffer that a "POSITA would have been motivated to use two separate strings to reduce the friction" because "a single string looped twice around the tubular member will create more friction [than two separate strings] because more of the string is in contact with the surface of the tubular member" is inaccurate and would not have motivated a POSA. Petition, p.37; EX2001, ¶74. In Petitioner's purported arrangement, Hartley's duplicated strings

each extend in a loop around Schaffer's seal module 160. Petition, p.40; EX2001, ¶75. Each string contacts Schaffer's seal module along its loop. EX2001, ¶75. Likewise in Hartley, where the string 14 "is wound preferably twice around the cylindrical diaphragm," the string 14 contacts the tubular diaphragm along each of the two windings. EX1006, ¶[0031]; EX2001, ¶75. Accordingly, in Petitioner's purported arrangement including two strings and in Hartley's express disclosure of the single string 14 wound "twice around" the tubular diaphragm, the same total amount of string contacts the tubular member. EX2001, ¶75.

Because the *same amount (e.g., length) of string* contacts the diaphragm/seal module in each arrangement (whether wound twice or formed in two separate loops), a POSA would have understood that *the friction is the same* in Petitioner's proposed two-string arrangement as in what Hartley actually discloses—a single-string double-wound arrangement. *Id.* For that reason, a POSA would not have been motivated to complicate and add expense to the valve by using two of Hartley's string 14 instead of one to reduce friction. *Id.* And, Petitioner's expert agrees that adding a second string would be more costly, that the increased cost would be a consideration of a POSA, and that "[u]sing one component is usually better than using two components from a cost and manufacturing standpoint" EX2009, 16:7-9; 45:23-46:2 ("A second string wrapped around once would be more costly

than a one string wrapped around once. Those are the two considerations that I think a person of skill in the art would think about.”).

And, contrary to the testimony in his declaration, at deposition Petitioner's expert admitted that he did not know what the friction would be in each arrangement (two looped strings or one double-wound string):

Q. But the total friction where there is a first string and a second string compared to one string wrapped around twice would be the same; right?

[Mr. Thornton]. I don't know. I think it depends on the coefficient of friction of the tube of the strings, the surface area, and contact. ***It's unknown how that -- how the friction would stack up.***

EX2009, 43:6-13 (emphasis added).

Even if there were somehow more friction using a single, twice-wound string, a POSA still would not have been motivated to deviate from Hartley's disclosure to duplicate its single string. As Petitioner's expert testified a POSA “would find it most obvious to use a single string wrapped once” at least in part because of the “negatives of additional friction.” EX2009, 42:11-20, 45:16-17. That is, if friction were a concern in Hartley, a POSA would have found it obvious to use a single once-wound string which has less friction—not two strings with more friction—at least according to Petitioner's expert.

Additionally, Petitioner's reasoning that any increased friction may cause Schaffer's springs to "need to exert more pulling force on the string to constrict the tubular member, and the tubular member will need greater resiliency to overcome the friction and return to its expanded configuration" would not have been a concern to a POSA as set forth in Petitioner's and its expert's own statements. Petition, p.38. For example, Petitioner and its expert allege for its "first way" of obviousness that "if the resiliency of Schaffer's lumen required adjustment to function with Hartley's string, a POSITA would have possessed the skills and knowledge to select an appropriate material with the proper resiliency." Petition, p.36; EX1003, ¶76. Likewise, in the related IPRs, Petitioner and its expert have similarly asserted that "POSITAs would have found it obvious to make adjustments ... including ... adjusting Schaffer's spring strength to apply additional force" and to "exert more tension on the filament by, for example, changing the spring material or adjusting the springs coils." See, e.g., *Imperative Care, Inc. v. Inari Medical, Inc.*, IPR2025-00156, Paper 2, p.71. Accordingly, Petitioner and its expert have contradictorily asserted for a different proposed combination that a POSA would have easily been able to adjust the resiliency of Schaffer's seal module and/or the strength of Schaffer's springs to function with Hartley's string and any friction therefrom without having to duplicate Hartley's strings in an arrangement not taught by Hartley or Schaffer. EX2001, ¶76.

Second, Petitioner's purported reason to modify Schaffer to include two of Hartley's strings 14 "to ensure that the sealing area is wider" is again inaccurate and would not have motivated a POSA. *Id.* at ¶77. As set forth above, in Petitioner's purported arrangement the two strings each extend in a loop around Schaffer's seal module 160 and contact the seal module along its loop. *Id.* Likewise, in Hartley the single string 14 contacts the tubular diaphragm along each of its two windings when it "is wound preferably twice around the cylindrical diaphragm." EX1006, ¶[0031]; EX2001, ¶77. Petitioner and its expert allege that Hartley's string 14 seals where it contacts the tubular member: "Hartley's string may seal more effectively across a wider range of tool diameters and shapes than Schaffer's U-shaped actuating members ... because the string more precisely conforms to the tool diameters and shapes." Petition, pp.30-31; EX1003, ¶71.

Thus, the purported "sealing area" in Petitioner's proposed combination is not "wider" than the sealing area of Hartley's single string 14 wound twice around the tubular diaphragm. EX2001, ¶77. Instead, the sealing area is the *same* as the single string 14 of Hartley. *Id.* Namely, Hartley's single string seals where the two windings contact the tubular diaphragm and Petitioner's purported two strings seal where the two strings contact Schaffer's seal module. *Id.* That is, whether wound twice or formed into two loops, the windings and loops have the same sealing width. *Id.* Petitioner's expert agrees:

Q. Would two strings wrapped around once provide a wider sealing area than a single string wrapped around twice?

[Mr. Thornton]. Assuming that two strings are right next to each other, then I think it would be the same width of sealing -- width of string that is touching the tubing.

EX2009, 49:18-24. For that reason, a POSA would not have been motivated to duplicate Hartley's string 14 to arrive at a more costly, complex, and not advantageous arrangement—found in neither Hartley nor Schaffer—to widen the sealing area because Hartley's disclosure of a single string 14 wound twice has the same sealing width. *Id.* at ¶¶77, 79.

In addition to not widening the sealing area, a POSA would have understood that forming a “small gap between the strings that remains after use,” as Petitioner proposes, would introduce a region for stagnant blood formation that could complicate any procedure using the valve, dissuading a POSA from choosing such a configuration. Petition, p.38; EX2001, ¶78. In particular, the gap between the strings could create a stagnant blood pool from back bleed, that could lead to thrombus (clot) formation in the gap. EX2001, ¶78. Highlighting the experience in the field required by a POSA that Mr. Thornton does **not** possess (*see* §II.D above)—he never considered such a scenario or the ramifications thereof. EX2009, 50:15-

51:8. A POSA would not have been motivated to arrive at Petitioner's proposed combination for that additional reason. *Id.*

Third and finally, Petitioner's purported reason to modify Schaffer to include two of Hartley's strings 14 to "provide a redundancy" that allegedly "ensures that the valve seals even if one string fails to tighten around the tubular member" would not have sufficiently motivated a POSA to modify Schaffer and Hartley in a manner not taught by either of those references. Petition, p.38; EX1003, ¶82; EX2001, ¶79. A POSA would understand that, in Petitioner's purported modification using two strings, the two strings might interfere with one another. EX2001, ¶79. For example, after Schaffer's actuator buttons are depressed one or more times to loosen Hartley's strings and/or if the valve were tilted relative to gravity, the loosened strings may move uncontrollably along the seal module such that one of Hartley's strings extends under the loop of the other string or otherwise overlaps and interferes therewith (e.g., preventing a repeatable and reliable seal). *Id.* Thus, a POSA would have understood that any redundancy of using two strings may be offset by the possibility of failure or reduced sealing effectiveness where the two strings interfere with one another. *Id.*

Additionally, Petitioner's purported reason to "provide a redundancy" is directly contrary to Petitioner's arguments in the related IPRs. For example, in response to Patent Owner's arguments that a POSA would not have substituted Hartley's single string for Schaffer's actuating members at least in part because such

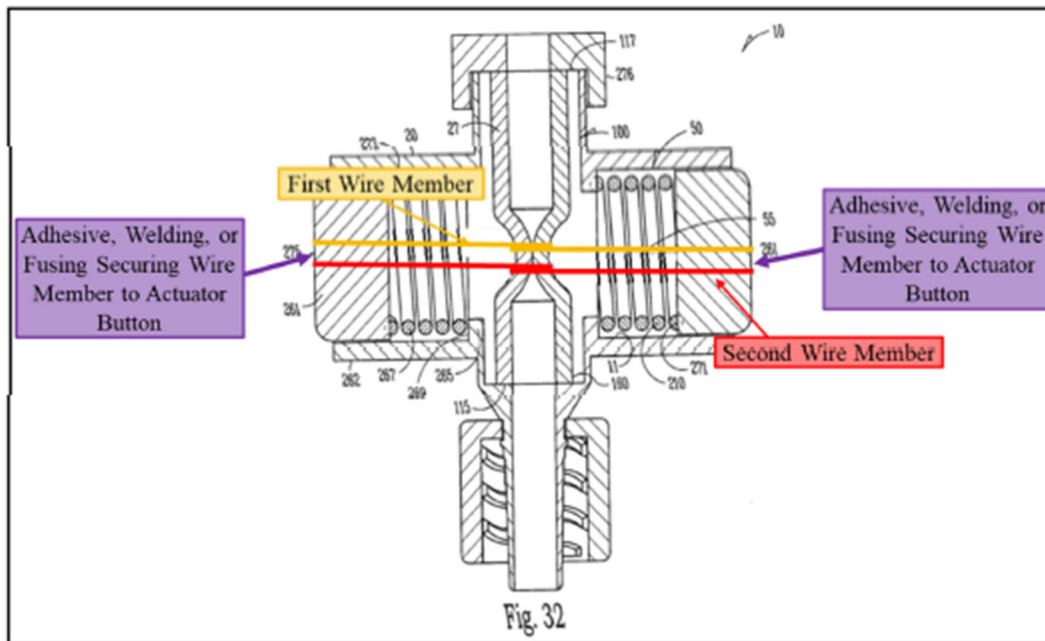
a substitution would undermine the durability of Schaffer's valve compared to Schaffer's rigid U-shaped members, Petitioner and its expert argued that Hartley does not "suggest[] that durability is an issue," that "durable strings and wire materials for medical devices would have been available to POSITAs before 2017," and that "durability would not have dissuaded POSITAs from combining Hartley's string ... with Schaffer's valve." *See, e.g., Imperative Care, Inc. v. Inari Medical, Inc.*, IPR2025-00156, Paper 17, p.11; *id.* at EX1020, ¶¶48-49. When questioned about those statements, Petitioner's expert admitted that it is "[p]robably very unlikely that durability couldn't be addressed with one string." EX2009, 53:14-16. Based on those assertions by Petitioner and its expert that Hartley's string is sufficiently durable, a POSA would not have been motivated to duplicate Hartley's single string and include that duplication in Schaffer's valve to provide redundancy because a POSA would have understood Hartley's single string to be sufficiently durable.

Thus, Petitioner has not met its burden of showing that a POSA would have been motivated to duplicate Hartley's string and substitute those two strings for Schaffer's U-shaped members.

C. It Would Not Have Been Obvious to a POSA to Have Substituted Two of Eller's Wire Members for Schaffer's U-Shaped Actuating Members

Petitioner's "second way" that Schaffer in combination with Eller renders obvious independent Claims 1, 15, and 23 also fails because it would not have been obvious to a POSA to have substituted two of Eller's wire members for Schaffer's U-shaped actuating members such that the wire members are "[extending/configured] in a first loop" and "[extending/configured] in a second loop" as required by those Claims. EX2001, ¶¶92-104. In that alternative configuration, Petitioner asserts that a POSA would have included two of Eller's wire members in Schaffer's valve, with the first end of each wire member attached to Schaffer's first actuator button, each wire member looping around Schaffer's seal module, and the second end of each wire member secured to Schaffer's second actuator button, as shown in Petitioner's demonstrative illustration:

Demonstrative Illustration Schaffer + Eller's Wire Member



Petition, pp.48-50.

Petitioner provides three theories as to why their purported combination of Schaffer and Eller is obvious: (1) Eller discloses the use of multiple wire members; (2) the combination is a simple substitution; and (3) a POSA would have been motivated to use two wire members with Schaffer's valve to "provide a more robust and reliable seal for the reasons explained above with respect to Hartley." *Id.* at pp.48-49. Each of those reasons fails. First, Eller does not disclose any embodiment including more than a single wire member forming a loop. EX2001, ¶¶94-101. Second, the proposed combination is not a simple substitution because it does not involve the substitution of a known element for another but, instead, a new

construction that differs from the arrangements taught by both Schaffer and Eller. *Id.* at ¶¶102-103. Third, a POSA would not make the proposed combination because it would not provide a more robust and reliable seal for the reasons discussed above with respect to Hartley. *Id.* at ¶104.

1. Eller does not disclose or suggest a valve including more than one wire member extending in or configured in a loop.

A POSA would not have found it obvious to arrive at Petitioner's purported combination based on Eller's disclosure that its hemostasis valve "can include any suitable number of wire members" because Eller does not disclose multiple wire members that each form loops as required by the Claims. Petition, p.48; EX1007, 16:7-19, EX2001, ¶¶94-101. For example, as discussed above in §III.A, any single one of Eller's wire members does not constitute multiple filaments—even if constructed from two or more strands wound together—and, as discussed below, none of the embodiments in Eller that have multiple wire members disclose that the wire members individually form loops, or suggest multiple loops at all.

The disclosure of Eller relied on by Petitioner that its hemostasis valve "can include any suitable number of wire members" relates to the embodiment illustrated in Figures 1-10C of Eller. EX2001, ¶94. Those figures illustrate a "selective fluid barrier valve device 10 that has ... a housing 16, an actuator 18, a sleeve 20, a first wire member 22, a second wire member 24, [and] a third wire member 26":

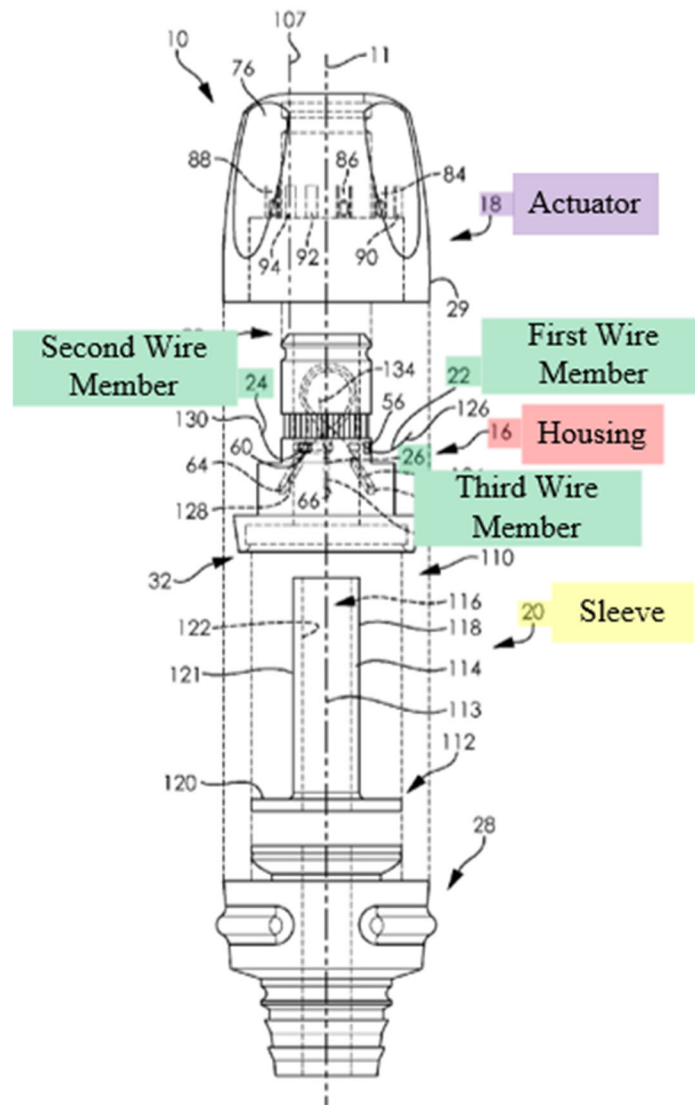
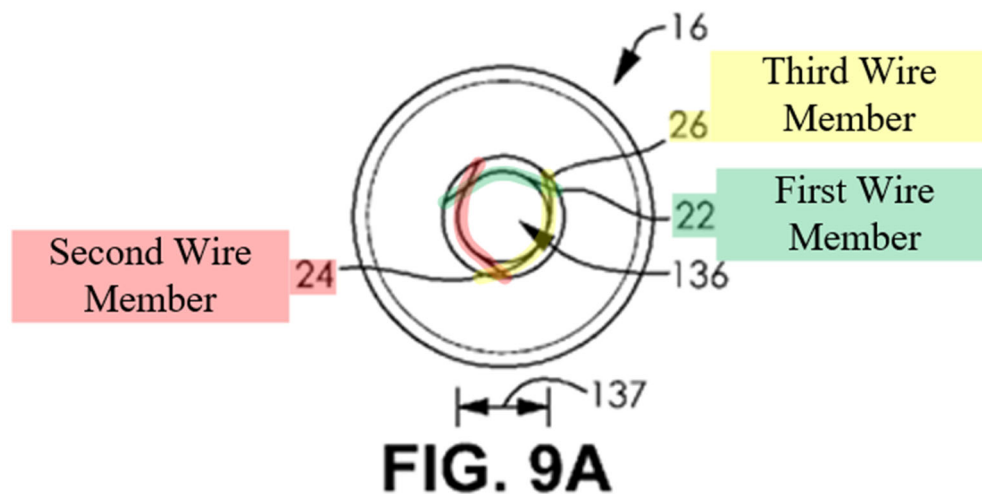


FIG. 2

EX1007, 5:2-6; EX2001, ¶95. The “wire member has a first end 124 attached to the housing 16 and a second end 126 attached to the actuator 18.” EX1007, 12:52-58. The second wire member 24 and the third wire member 26 likewise have a first end attached to the housing 16 and a second end attached to the actuator 18. *Id.* at 12:21-14:27; EX2001, ¶95. As best seen in Figures 9A-10C of Eller (Figure 9A annotated by Patent Owner's expert, Dr. Zalesky, below) (i) the “first wire member 22 extends

... around ***a portion*** of the outer surface 121 of the sleeve 20,” (ii) the “second wire member 24 extends ... around ***a portion*** of the outer surface 121 of the sleeve 20,” and (iii) the “third wire member 26 extends ... around ***a portion*** of the outer surface 121 of the sleeve 20”:



EX1007, 12:58-64, 13:27-33, 13:64-14:3 (emphasis added); EX2001, ¶95. None of the wire members 22-26 extend in a “loop” because each of the wire members extends only partially around “a portion” of the sleeve 20. EX2001, ¶95. Petitioner’s expert, Mr. Thornton agrees that to form a “loop” the filament must extend around more than just “a portion” of a tubular member:

Q. What is a loop?

[Objection]

[Mr. Thornton]: I think how they are using it in this patent as it relates to these embodiments, it is a – it's forming a shape around – completely around the tubular member.

EX2009, 19:19-24. Indeed, here Petitioner does not assert that partially extending around a tubular member by itself forms a “loop” as claimed. *See* Petition, p.6 (asserting that “Schaffer’s two u-shaped filaments *collectively* form a loop around the tubular member.” (emphasis added)). Accordingly, the embodiment relied on by the Petitioner fails to disclose or suggest any wire member “extending in” or “configured in” in a loop—let alone a “first filament [extending/configured] in a first loop” and a “second filament [extending/configured] in a second loop” as required by the Claims. *Id.*

Figures 11-14 of Eller illustrate “another selective fluid barrier valve device 210 ... similar to the selective fluid barrier valve device 10 illustrated in [Figures 1-10C.]” EX1007, 20:12-17. The wire members 22-26 have the same configuration in Figures 11-14 such that this embodiment of Eller also fails to disclose any wire member “extending in” or “configured in” a loop—let alone two filaments each extending in a loop as required by the Claims. *Id.* at 20: 17-27; EX2001, ¶96.

Figures 15-17 of Eller illustrate “another selective fluid barrier valve device 410 ... similar to the selective fluid barrier valve device 10 illustrated in [Figures 1-10C.]” EX1007, 21:37-42. In this embodiment, “the selective fluid barrier valve

device 410 omits the inclusion of a second wire member (e.g., second wire member 24) and a third wire member (e.g., third wire member 26),” and includes a first wire member 422 with a “first end 524 attached to the actuator 418” and a “second end 526 attached to the first wire member 422 between the first end 524 and the second end 526”:

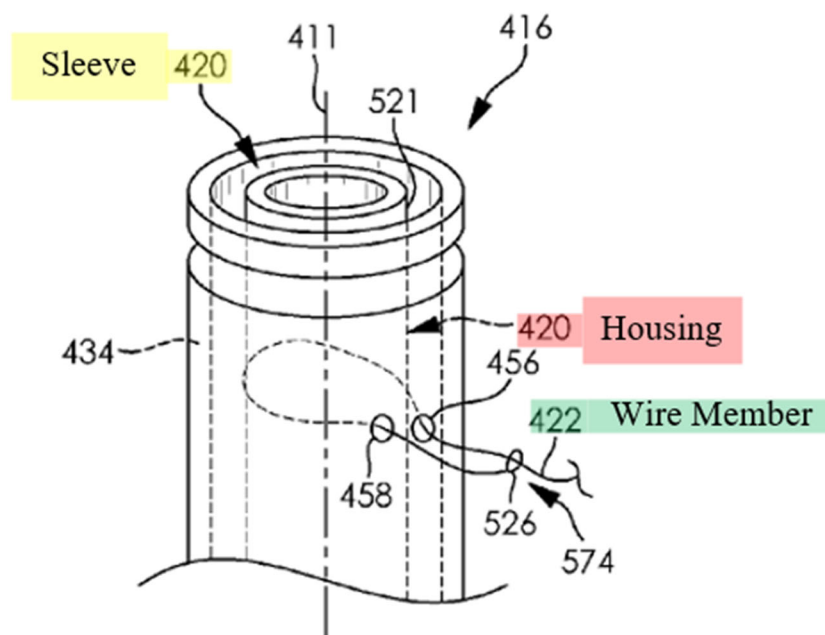
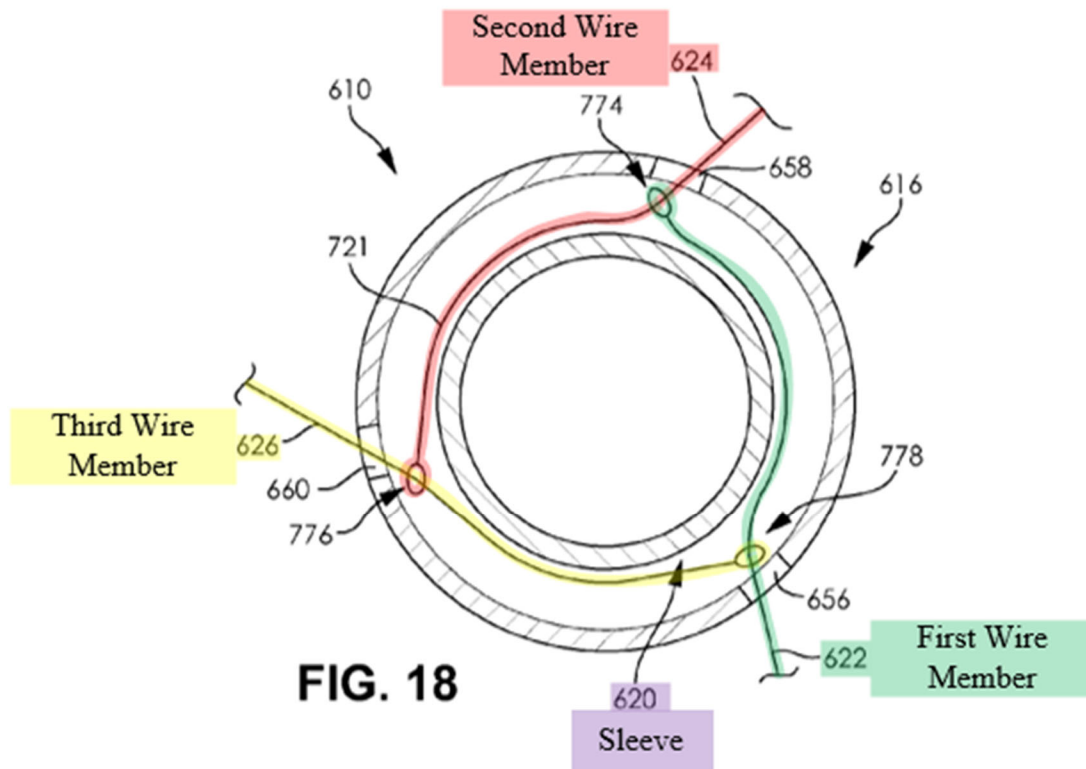


FIG. 16

Id. at 21:49-22:10; EX2001, ¶97. In this embodiment, the “**single** wire member” is “disposed around more than 50% of the outer surface 521 of the sleeve 42[0]” and in “alternative embodiments can include a single wire member that is disposed around more than 75% of the outer surface of the sleeve or that is disposed around more than 100% of the outer surface of the sleeve ... [f]or example, the wire member

can be positioned such that it extends at least one full revolution around the outer surface of the sleeve.” EX1007, 22:11-24 (emphasis added). Accordingly, the embodiment in Figures 15-17 of Eller discloses that in a valve having a *single* wire member, that single wire member can be positioned to extend a full revolution around the sleeve. EX2001, ¶97. But, this embodiment fails to disclose multiple wire members, let alone a “first filament” (e.g., a first wire member) “[extending/configured] in a first loop” and a “second filament” (e.g., a second wire member) “[extending/configured] in a second loop” as required by the Claims. EX2001, ¶97.

Figures 18-19 of Eller illustrate “another selective fluid barrier valve device 610 ... similar to the selective fluid barrier valve device 10 illustrated [Figures 1-10C].” EX1007, 22:32-37. The valve device 610 has a first wire member 622, a second wire member 624, and a third wire member 626 that, like the embodiment in Figures 1-10C, each extend only partially around a sleeve 620:



Id. 22:52-23:23; EX2001, ¶98. Accordingly, this embodiment of Eller also fails to disclose or suggest any wire member “extending in” or “configured in” in a loop—let alone a “first filament [extending/configured] in a first loop” and a “second filament [extending/configured] in a second loop” as required by the Claims. EX2001, ¶98. Petitioner’s expert agrees:

Q. Does the 721 wire member form a loop around the tubular member?

[Mr. Thornton]. I would characterize it as the three wire members together form a loop around the tubular member.

Q. But that wire member or that filament or filaments does not form a loop around the tubular member; correct?

[Mr. Thornton]. On its own, I wouldn't characterize it that way.

EX2009, 15:15-24

Figures 20-22 of Eller illustrate “another selective fluid barrier valve device 810 ... similar to the selective fluid barrier valve device 10 illustrated in [Figures 1-10C].” EX1007, 23:50-55. The valve device 810 includes a housing 816, an actuator 818, a sleeve 820, and a single first wire member 822 having “a first end 924 attached to the housing 816 ... and a second end 926 attached to the actuator 818”:

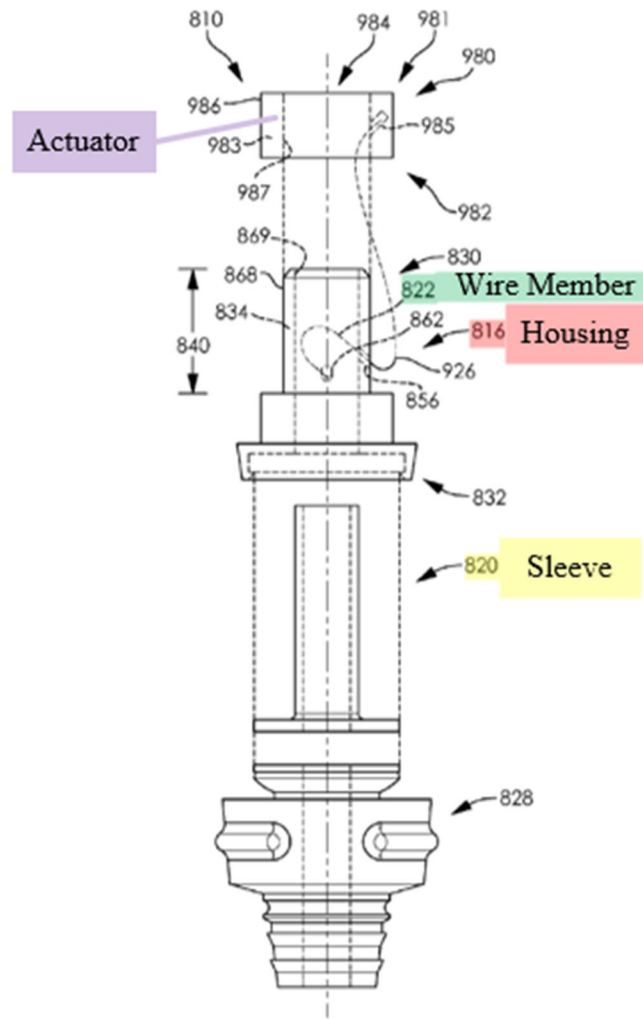


FIG. 20

Id. at 23:50-62, 24:50-52; EX2001, ¶99. The single wire member 822 in this embodiment does not extend fully around the sleeve 820 as best seen in Figure 22 of Eller. EX2001, ¶99. Accordingly, this embodiment of Eller similarly fails to disclose or suggest any wire member “extending in” or “configured in” in a loop—let alone a “first filament [extending/configured] in a first loop” and a “second filament [extending/configured] in a second loop” as required by the Claims.

The last embodiment in Eller is shown in Figures 24-27, which illustrate “another selective fluid barrier valve device 1110 ... similar to the selective fluid barrier valve device 10 illustrated in [Figures 1-10C].” EX1007, 31:29-34. The valve device 1110 includes a first wire member 1122, a second wire member 1124, and a third wire member 1124 that have the same configuration as in Figures 1-10C such that this embodiment of Eller also fails to disclose any wire member “extending in” or “configured in” in a loop—let alone the “first filament [extending/configured] in a first loop” and the “second filament [extending/configured] in a second loop” required by the Claims. *Id.* at 31: 40-44; EX2001, ¶100.

Accordingly, despite Eller's disclosure of certain configurations that have multiple wire members, Eller ***does not*** disclose any embodiment with two wire members configured in or extending in a loop as required by the Claims. EX2001, ¶101. In each embodiment with multiple wire members, the wire members extend only partially around the sleeve rather than in a loop. *Id.* And, Eller discloses only a single embodiment in Figures 15-17 in which a “***single*** wire member ... can be positioned such that it extends at least one full revolution around the outer surface of the sleeve.” *Id.*; EX1007, 22:11-24 (emphasis added). As such a POSA would not have found it obvious to “use two wire members with Schaffer's valve based on the teachings of Eller” in the arrangement Petitioner suggests, because Eller does not disclose any embodiment including a first wire member “[extending/configured] in

a first loop” and a second wire member “[extending/configured] in a second loop” as required by the Claims. Petition, p.48; EX2001, ¶101.

2. Petitioner's proposed combination is not a simple substitution.

Petitioner advances a “simple substitution” rationale for modifying Schaffer to eliminate its U-shaped members and add two of Eller's wire members. Petition, pp.48-49; *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007). But the proposed modification is not a substitution, much less a simple one, as it requires a particular arrangement that is not found in either Schaffer or Eller. Namely, Petitioner's proposed combination does not merely substitute Eller's wire members for Schaffer's U-shaped actuating members, but further modifies the allegedly substituted wire members into a configuration not disclosed by Eller or Schaffer in which (i) each wire member is formed into a loop and (ii) each wire member has opposing ends attached to and controlled by two different actuators. Petition, pp.48-50.

At most, Eller discloses one loop embodiment with a *single* wire member that can extend a full revolution around a sleeve and that is attached to an actuator at one end only. EX2001, ¶102; *supra* at §III.C.1. In each embodiment that Eller discloses multiple wire members, however, each of the multiple wire members extends only partially around the sleeve and not in a loop. *Id.* Thus, Petitioner's proposed

substitution would not have “entailed merely substituting one known element (Eller’s two wire members) for another (Schaffer’s two actuating members).” *Id.*; Petition, p.48. Instead, that substitution requires substituting two wire members and arranging each of them in a configuration (two loops) not found anywhere in Schaffer or Eller. EX2001, ¶102.

And as Patent Owner has explained in the related IPRs, Petitioner’s proposed substitution is also not simple because neither Schaffer nor Hartley disclose a single filament—let alone two filaments—controlled by two actuators as in Petitioner’s proposed combination. *Id.* at ¶103. Instead, in Schaffer each of the actuating members 55 is attached to only one of the actuator buttons 261 such that movement of a single one of the buttons controls movement of a single one of the actuating members. *Id.* And, in each of Eller’s various selective fluid barrier devices, the various wire members have a first end coupled to either a housing of the selective fluid barrier device or to the wire member and a second end coupled to a single actuator, such that the wire member is controlled by the single actuator. *Id.* Petitioner’s proposed substitution is also not “simple” for that reason. *Id.*

In sum, neither Schaffer nor Eller disclose first and second filaments arranged in first and second loops respectively, nor any element (U-shaped actuating member or wire member) attached to separate, individually-controlled buttons as in

Petitioner's proposed combination, nor is there a motivation to modify the references as Petitioner proposes. Ground 2 fails for that reason alone.

3. Petitioner's other purported motivations would not have motivated a POSA.

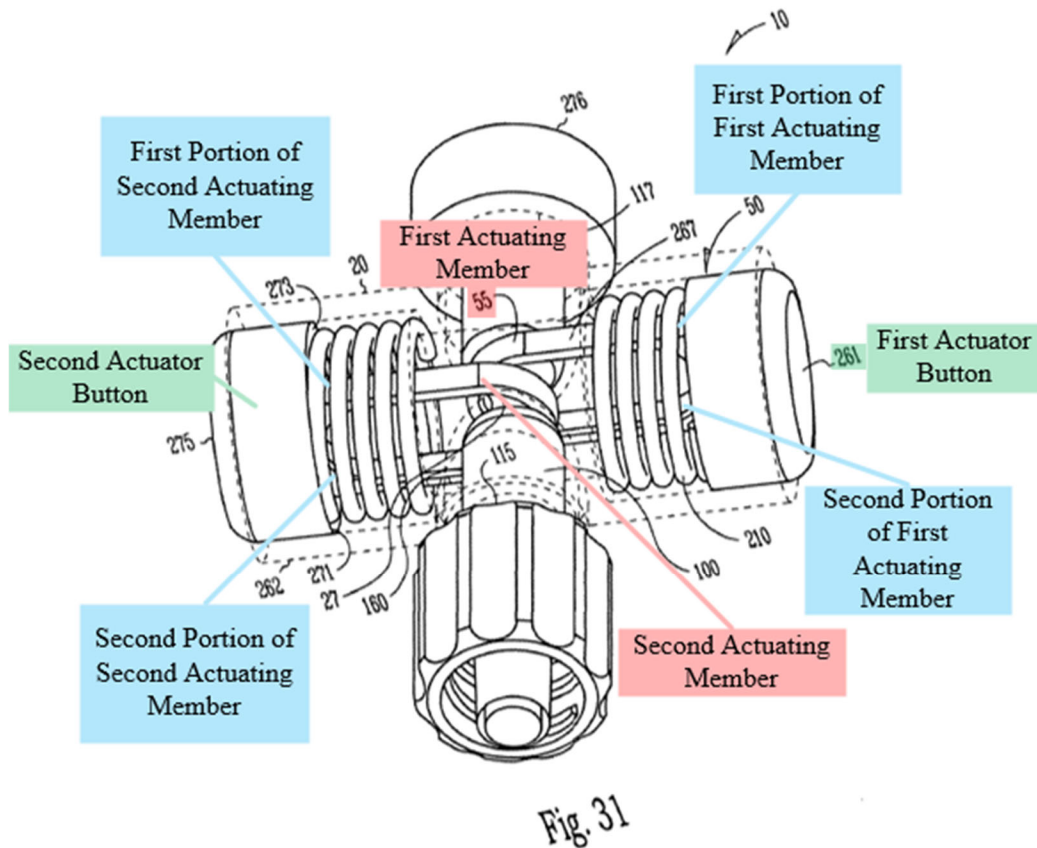
Petitioner's assertion that "a POSITA would have been motivated to use two wire members with Schaffer's valve to provide a more robust and reliable seal for the reasons explained above with respect to Hartley (e.g., creating a larger sealing area, allowing the manufacturer to optimally space the strings, adding redundancy to the system)" fails for the same reasons described in §III.B above with respect to Hartley. Petition, p.49; EX2001, ¶104. Namely, a POSA would understand that using two wire members (like Hartley's two strings) would not reduce friction, increase the sealing width, or provide any advantageous redundancy. EX2001, ¶¶70-80. And, Petitioner's expert testified that he does not know why a POSA would have used two filaments (EX2009, 14:4-7) and that the obvious arrangement was to use a "single string wrapped around once" rather than two filaments or wire members. (*Id.* at 16-18).

D. None of Schaffer, Hartley, and/or Eller Disclose a Filament Acted Upon by a Pair of Opposing Actuators

Independent Claim 1 of the '384 Patent requires a "pair of actuators movable from a first position to a second position" wherein *each of* the first filament and the second filament "includes *a first portion operably acted upon by a first one of the*

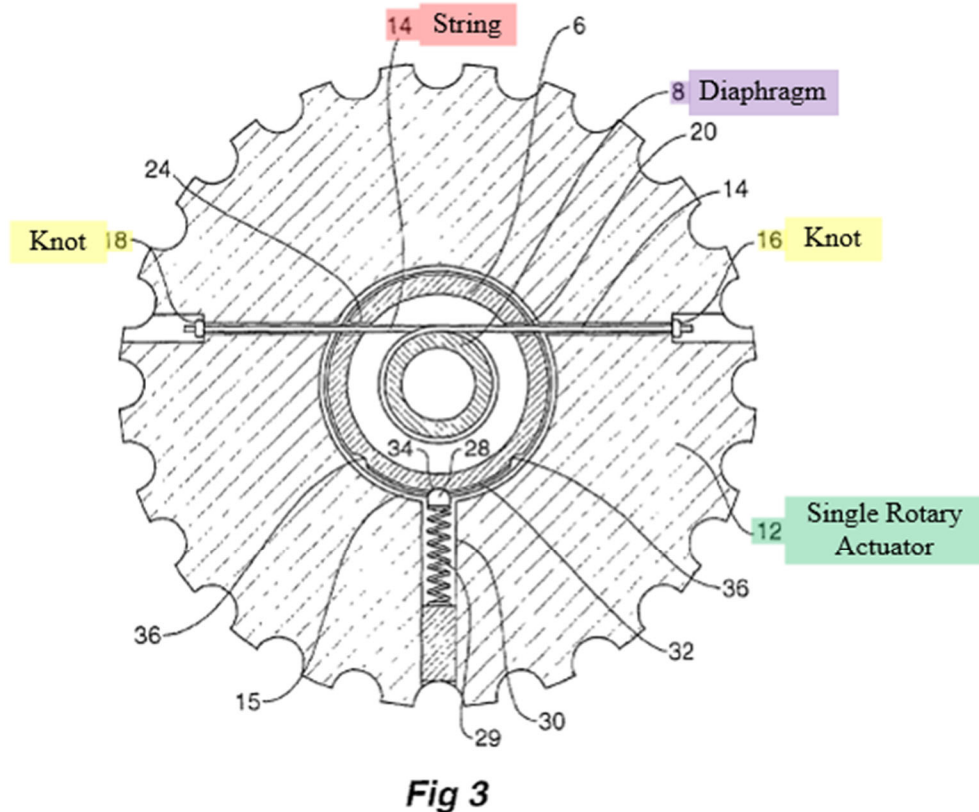
actuators and *a second portion operably acted upon by a second one of the actuators.*” Neither Schaffer, Hartley, nor Eller disclose any U-shaped member, string, wire member, or other member with different portions operably acted upon by a pair of actuators as required by independent Claim 1. EX2001, ¶¶81, 105.

For example, in Schaffer each of the actuating members 55 is attached to only one of the actuator buttons 261 (e.g., at a first portion and at a second portion) such that each of the two buttons operably acts on only one of the actuating members:



EX1005, Fig. 31; EX2001, ¶¶82, 106.

In Hartley, the *single* string 14 extends around a cylindrical elastomeric diaphragm 8 and is attached by knots 16 and 18 at each end to a *single* rotary actuator 12 that controls movement of both ends of the string 14:



EX1006, ¶[0031]; EX2001 ¶83. Thus, Hartley discloses a single actuator 12 that operably acts on the single string 14. EX2001, ¶83.

Likewise, Eller discloses various selective fluid barrier devices that include one or more wire members each having one end coupled to an actuator and the other end coupled to itself or a housing—not to the same or different actuator:

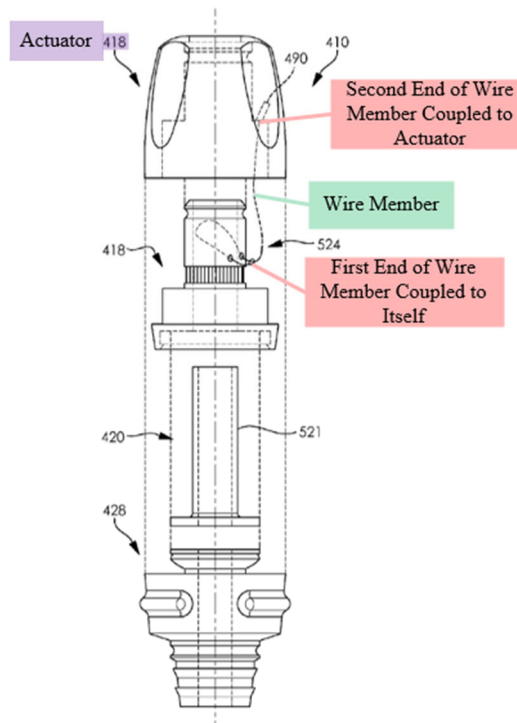


FIG. 15

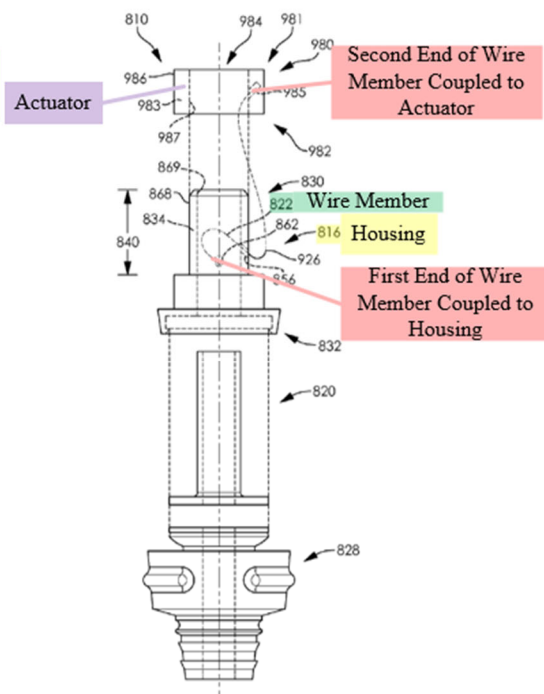


FIG. 20

EX2001, ¶106; *see, e.g.*, EX1007, 12:52-58, 23:50-62, 24:50-52, 21:37-67.

Accordingly, independent Claim 1 is not rendered obvious by the combinations of Schaffer and Hartley or Eller because none of Schaffer, Hartley, or Eller disclose any filament—let alone a first filament and a second filament—having “a first portion operably acted upon by a first one of the actuators” and “a second portion operably acted upon by a second one of the actuators.” EX2001, ¶¶84, 107. Rather, any U-shaped member, string, or wire is acted upon by only a single actuator. *Id.* Independent Claims 15 and 23 are also not rendered obvious by the combinations of Schaffer and Hartley or Eller for the same reasons because they include similar limitations. *See, e.g.*, EX1002, p.2 (Notice of Allowance withdrawing the restriction

of independent Claims 15 and 23 from independent Claim 1 because they “require[] all the limitations of an allowable claim.”).

E. Petitioner's Proposed Substitutions are Based on Impermissible Hindsight

Petitioner's evolving theories of obviousness over this and the related IPRs that cherry-pick multiple different substitutions/combinations to meet whatever claim limitation is at issue demonstrate that Petitioner's obviousness 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).

For example, at best for Petitioner, a simple substitution might be to simply replace each of Schaffer's U-shaped members with a string (from Hartley) or wire member (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. And that is exactly what Petitioner and its expert asserted that a POSA would do in some of the related

IPRs to allegedly meet the claims there. For example, Petitioner and its expert have asserted that “POSITAs would have also found it obvious to replace each U-shaped actuating member with a string” and “POSITAs would have found it obvious to replace each of Schaffer’s U-shaped actuating members with a wire member.” EX2005, pp.68, 70. Likewise, Petitioner and its expert have alleged that it would have been simple and obvious for a POSA to make Schaffer’s U-shaped actuating members flexible to better conform to Schaffer’s seal module. EX2006, p.32; EX2003, ¶75.

At the same time, here and in the other related IPRs, Petitioner asserts that the purported “simple substitution” or obvious combination was not to simply substitute a string/wire for each of Schaffer’s U-shaped members, but to replace both with a single string/wire that is connected between both actuator buttons. Petition, pp.30, 45; *see also*, e.g., EX2006, pp.35, 44. Now, Petitioner claims *yet another* allegedly simple, but actually significant modification of Schaffer and Hartley/Eller—this time connecting two strings (Hartley) or wires (Eller) to each of Schaffer’s actuator buttons such that they each loop around Schaffer’s seal module. Petition, pp.37-40, 47-50.

Each of Petitioner’s shifting 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 '384 Patent (and the related patents) as a roadmap. *ATD Corp.*, 159 F.3d at 546; EX2001, ¶103.

The testimony of Petitioner's expert (Mr. Thornton) further reflects that reliance upon hindsight bias. He testified at deposition that in preparing his declaration: "I certainly did not opine on any differences between a single loop [or filament] or a double loop [or filament] type of design or the potential benefits or negatives of each of those." EX2009, 17:10-19. That is, Mr. Thornton testified that despite the multiple combinations he has put forward in this and the related IPRs he did not consider any differences between those combinations, including any benefits or drawbacks. The only reasonable conclusion from that testimony is that he used the '384 Patent as a roadmap to interpret the prior art. Indeed, when questioned about potential differences between the different combinations he put forward in this

IPR—one of Hartley's strings or Eller's wire members in Schaffer versus two of Hartley's strings or Eller's wire members in Schaffer—he concluded that the “most obvious” arrangement was to use a “single string wrapped around once” rather than two filaments or wire members. EX2009, 45:16-18. And, at his deposition when asked why a person of ordinary skill in the art would want to use two filaments, he responded, “I don't know.” *Id.* at 14:4-7.

Further, Mr. Thornton had no knowledge of or familiarity with any prior art hemostasis valve that employed a filament or filaments to constrict a lumen before reviewing the '384 Patent (or related patent). EX2007, 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 or filaments prior to this matter despite decades of experience with hemostasis valves—concludes that each of the different 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 '384 Patent (and related patents) as a roadmap. That is precisely the type of hindsight analysis that *KSR* and other longstanding precedents prohibit. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007) (“[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.”).

F. A POSA Would Not Have Been Motivated to Combine Schaffer with Hartley or Eller

Despite the findings in the related FWDs, Patent Owner maintains that a POSA would not have been motivated to remove Schaffer's rigid U-shaped members and replace them with a flexible member at all, let alone with a first and second filament as claimed because Schaffer's valve already solves the purported goal motivating 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. *See* EX2010, ¶¶58-61, 109, 114-115. At deposition in one of the related IPRs, Petitioner's expert agreed that the seal member 165 is included in every illustrated embodiment in Schaffer: Schaffer Embodiment: Figures 1-4 (EX2011, 69:12-70:3), Schaffer Embodiment: Figures 5-19 (*id.* at 70:5-71:23), Schaffer Embodiment: Figures 20-22 (*id.* at 71:24-72:19), Schaffer Embodiment: Figures 23-26 (*id.* at 72:20-73:2), Schaffer Embodiment: Figure 27 (*id.* at 73:3-5), Schaffer Embodiment: Figures 28-29 (*id.* at 73:6-9), and Schaffer Embodiment: Figures 30-34 (*id.* at 73:13-77:3).

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. EX2010, ¶¶58-61, 109. The seal member 165 seals completely by being highly compliant to conform to different shapes. *Id.* at ¶¶110-111; 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. EX2010, ¶¶134-36.

Thus, because Figures 30-34 include the seal member 165 and that seal member forms a complete seal without gaps, Petitioner's alleged problem (gaps) does not exist. As a result, there would have been no motivation to modify Schaffer in the manner advanced by Petitioner: “[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), citing *In re Schweickert*, 676 F. App’x 988, 995-996 (Fed. Cir. 2017).

Indeed, 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. EX2010, ¶¶143-54. A POSA would not have made Petitioner’s proposed modification and introduced all those disadvantages, particularly where the modification would not remedy Petitioner’s non-existent issue.

Petitioner’s apparent “simple substitution” rationale for modifying Schaffer’s U-shaped members is also wrong. Pet., pp.35, 45. First, as explained above, the cited references do not disclose all the limitations of Claim 1. For example, none of Petitioner’s references disclose a single wire/string—let alone two strings/wires—including two ends attached to and controlled by different independently movable actuating members, let alone two filaments. EX2010, ¶¶131-40. Petitioner’s expert agrees. EX2007, 55:22-56:7.

Thus, instead of involving a simple substitution, Petitioner’s proposed combinations require 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;
- (3) Coupling the ends of the single string/wire to two different actuators, rather than the same one; and
- (4) Adding a second string or wire in the same configuration.

Moreover, a POSA 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 all 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); *see also Philip Morris Prods. S.A. v. RAI Strategic Holdings, Inc.*, 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 have chosen the claimed solution over the myriad of other options, including other configurations using a string or a wire.

Third, Petitioner's proposed combination would not yield the predictable result of sealing Schaffer's valve and is not suitable for sealing around multiple/irregularly-shaped instruments, 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. EX2010, ¶87. That unpredictability is exacerbated by Petitioner's proposed modification because Hartley and Eller—the only references that disclose a flexible member—precisely control movement of that flexible member with a single movable actuator. EX2010, ¶¶135-39. In Petitioner's combination, the movement of the string/wire would not be controlled in that manner by a single actuator because either of Schaffer's buttons could be depressed independently to move the string/wire unpredictably. *Id.* at ¶141. Petitioner's proposed combinations of Schaffer and Hartley/Eller therefore not only depart from the intended purpose and express disclosure of these references in which

a single U-shaped actuating member/string/wire are controlled by a single actuator, but do not predictably seal.

Moreover, 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, pp34, 45. At deposition in one of the related IPRs, 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 U.S. Patent No. 5,429,616 (EX2011, 105:24-106:4, 106:12-14), U.S. Patent Application Publication No. 2011/0144592 (*id.* at 106:15-19), U.S. Patent Application Publication US 2008/0087853 (*id.* at 108:14-20, 110:7-19), U.S. Patent No. 9,216,277 (*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. EX2011, 107:2-13 (emphasis added).

And, as explained above Petitioner's proposed combination that requires multiple flexible strings/wires connected to two independent actuator buttons was not known at all 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.

And because Petitioner's proposed combination would not have improved sealing, 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. EX2010, ¶¶143-157. 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]; EX2012, 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].

IV. INDEPENDENT CLAIMS 1, 15, AND 23 ARE NOT OBVIOUS OVER THE COMBINATION OF SCHAFFER, HARTLEY, AND ELLER (GROUND 3)

Petitioner's argument that Schaffer in combination with both Hartley and Eller renders independent Claims 1, 15, and 23 obvious fails for the same reasons

discussed above in §III with respect to grounds 1-2. EX2001, ¶¶108-110. Specifically, Petitioner only contends in a conclusory manner that “Eller’s disclosure of a hemostasis valve having first and second wire members that constrict the lumen to form a seal would have further motivated a POSITA to use a similar configuration when replacing Schaffer’s actuating members with Hartley’s strings.” Petition, pp.79-80.

But, a POSA would not have been motivated to or found it obvious to modify Schaffer in view of Hartley and Eller, either alone or in combination, to arrive at the features of the independent Claims including the “first filament [extending/configured] in a first loop” and “second filament [extending/configured] in a second loop.” EX2001, ¶108. In particular, Hartley discloses only a single string 14 and, while Eller discloses valves having multiple wire members, Eller fails to disclose any embodiment including a first wire member “[extending/configured] in a first loop” and a second wire member “[extending/configured] in a second loop” as required by the Claims. In every embodiment of Eller having multiple wire members, each of the wire members extends only partially—and not in a loop—around Eller’s tubular sleeve.

V. DEPENDENT CLAIMS 2-4, 6-14, 16-18, 20-22, AND 24-30 ARE NOT OBVIOUS OVER SCHAFFER IN COMBINATION WITH HARTLEY, ELLER, AND/OR HERMANN

A. Dependent Claims 2-4, 6-14, 16-18, 20-22, and 24-30

Claims 2-4, 6-14, 16-18, 20-22, and 24-30 depend from one of independent Claims 1, 15, or 23 and include all the features of their respective base claim. Accordingly, those claims are also not rendered obvious by Schaffer in combination with Hartley (ground 1), Eller (ground 2), or Hartley and Eller (ground 3).

Petitioner and its expert also allege that Schaffer in combination with Hartley and Hermann (ground 4), Eller and Hermann (ground 5), or Hartley, Eller, and Hermann (ground 6) render obvious dependent Claims 11-14, 20-22, and 28-30. Petitioner relies on Hermann only for disclosing various diameters of the claimed valve assemblies. Petition, pp.80-85; EX2001, ¶113. Hermann fails to cure the deficiencies of Schaffer, Hartley, and Eller explained herein with respect to the independent Claims. Accordingly, these Claims are also not rendered obvious by the combination of Schaffer, Hartley, Eller, and/or Hermann for the reasons set forth above.

B. Dependent Claim 9

Dependent Claim 9 further narrows independent Claim 1 by requiring that the valve assembly comprise a “rigid housing” and that “the actuators are *movably coupled* to the housing.” In all grounds, Petitioner relies on Schaffer's housing 20 to

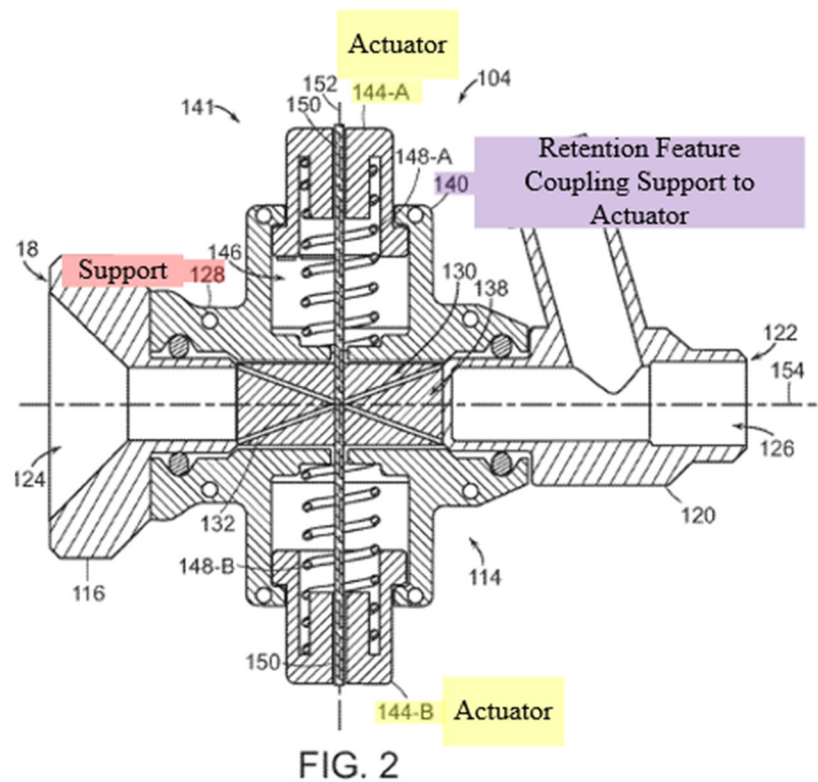
disclose the “rigid housing” and alleges that Schaffer’s actuator buttons 261 are “movably coupled to” that housing because Schaffer’s “actuators 50 are configured cylindrically to slide along the cylindrical interior wall 11 of the housing 20 from a first position to a second position.” Petition, pp.63-64; EX1005, ¶[0076]. That is incorrect—Schaffer’s actuator buttons 261 are not “movably coupled to” the housing 20. EX2008, ¶¶97-99.

Instead, Schaffer discloses that its actuator buttons 261 are inserted into opposing sides of the housing 20 and coupled only to the actuating members 55 which extend around the seal module 100. *Id.* at ¶98; EX1005, ¶[0083]. The actuator buttons 261 and the actuating members 55 are held in place only by the resistive force of the seal module 100 against the U-shaped actuating members 55. EX2008, ¶98. Thus, neither the actuator buttons 261 nor the components that the actuator buttons 261 are actually connected to (the actuating members 55) are coupled to the housing 20.

In contrast, Claim 9 recites that “the actuators are movably coupled to the housing,” and Claim 1 (from which Claim 9 depends) recites a “tubular member, a “first filament extending in a first loop around the tubular member,” and a “second filament extending in a first loop around the tubular member.” Petitioner asserts that Schaffer’s “seal module 100” is the claimed “tubular member” (Petition, p.24) and that Hartley’s string(s) or Eller’s wire member(s) are the claimed “filaments” (*Id.* at

pp.25-50) when looped around the seal module 100 and attached to Schaffer's actuator buttons 261 in Petitioner's purported combinations. So, coupling Schaffer actuator buttons 261 to either the seal module 100 or Hartley's string/ Eller's wire cannot meet the additional limitation of Claim 9 that "the actuators are movably coupled to the housing." Stated otherwise, the actuator buttons 261 are neither directly "coupled to" Schaffer's housing 20 nor indirectly coupled via Hartley's string or Eller's wire to the housing 20. EX2008, ¶99.

Indeed, the '384 Patent discloses that that the housing 128 includes "one or several retention features 140" that "engage with and retain all or portions of the constricting mechanism 141 of the valve 104," and more specifically that "retain the actuator 142 and/or can couple the actuator 142 to the housing 128":



EX1001, 8:17-23; EX2008, ¶99.

Accordingly, a POSA would understand that for the “actuators” to be “movably coupled” to the housing requires just that, coupling to the housing, not the other claimed features including the tubular member and filament. EX2008, ¶99. And, as set forth above, Schaffer’s actuator buttons 261 are not coupled to the housing 20 but simply inserted into the cylindrical openings. *Id.* Without the seal module 100, Schaffer’s actuator buttons 261 would simply fall out of the housing 20. *Id.* In other words, Schaffer’s buttons are not coupled to the alleged housing at all. Therefore, Schaffer does not disclose the “the actuators are movably coupled to the housing” as recited in dependent Claim 9.

VI. CONCLUSION

For all the above reasons, Petitioner has failed to establish by a preponderance of evidence that the Claims of the '384 Patent are unpatentable. Accordingly, for each of the above reasons, Patent Owner respectfully requests that the Board find all the Claims patentable.

Respectfully submitted,

Dated: June 9, 2026

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

CERTIFICATE OF COMPLIANCE

Pursuant to 37 C.F.R. § 42.24(d), I, Joseph Hamilton, certify that **PATENT OWNER'S RESPONSE** contains 13,761 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: June 9, 2026

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

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), I certify that on June 9, 2026 a copy of **PATENT OWNER'S RESPONSE and EXHIBITS 2004-2012** was 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
BoxImperative384@knobbe.com

Dated: June 9, 2026

By: / Kate Rose /
Kate Rose