

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 PRELIMINARY 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

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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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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, <i>Manual of Thoracic Endoaortic Surgery</i> (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, <i>Endovascular Aortic Repair – Abdominal: Zenith Endovascular Grafts</i> (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”)

Patent Owner's Exhibits	
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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

I. INTRODUCTION

Patent Owner requests that the Board deny institution because Petitioner has failed to demonstrate a reasonable likelihood that any of Claims 1-4, 6-18, and 20-30 of the '384 Patent are unpatentable.¹ The '384 Patent is related to several other patents for which IPR proceedings have been instituted (collectively the “related IPRs”²), but those proceedings *do not* address the issues in this matter because the Claims of the '384 Patent recite different limitations that define different and narrower structures. Specifically, independent Claims 1, 15, and 23 of the '384 Patent each recite, *inter alia*, a “valve assembly” comprising a “first filament [configured/extending] in a first loop” *and* a “second filament [configured/extending] in a second loop.” Unlike the claims disputed in the related IPRs, here the Claims require *two* separate filaments, each forming a loop. And none

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

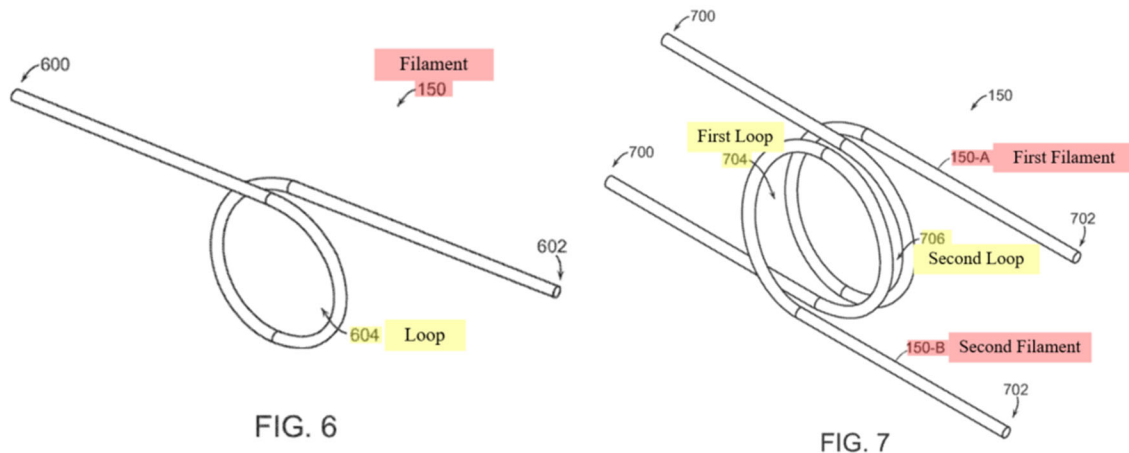
² See U.S. Patent No. 11,697,011 (*Imperative Care, Inc. v. Inari Medical, Inc.*, IPR2024-01157, Paper 7); U.S. Patent No. 11,697,012 (*Imperative Care, Inc. v. Inari Medical, Inc.*, IPR2025-00156, Paper 6), U.S. Patent No. 11,844,921 (*Imperative Care, Inc. v. Inari Medical, Inc.*, IPR2025-00728, Paper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

of Petitioner's references discloses or suggests first and second filaments each forming a loop as required by Claims 1, 15, and 23.

In grounds 1-2, Petitioner first argues a "first way" for obviousness based on combinations of Schaffer with Hartley and Schaffer with Eller. Petitioner relied on the same art and combinations in the related IPRs, and in those proposed combinations 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. Petition, pp.35, 44-46. Here, however, even assuming for the sake of argument that a person of ordinary skill the art ("POSA") would have been motivated to combine the references in that manner to include a single string/wire member between Schaffer's two actuator buttons (which Patent Owner does not concede), grounds 1-2 fail because neither Hartley's string nor Eller's wire member comprises a "first filament" and a "second filament" as required by the Claims. That Hartley's single string or Eller's wire member can be formed from multiple threads or wires "twisted together" does not disclose multiple filaments despite Petitioner's argument otherwise. Petition, pp.28, 41-42. Namely, Petitioner's assertion that a single polyfilament made up of multiple threads or strands twisted together can satisfy both the "first filament" and the

“second filament” and the first and second “loops” is directly contradicted by the disclosure and prosecution history of the '384 Patent.

For example, the '384 Patent discloses in Figure 7 an embodiment having two separate filaments (a first filament 150-A and a second filament 150-B) each forming an individual loop (a first loop 704 and a second loop 706, respectively) and, in contrast, in Figure 6 the '384 Patent discloses an embodiment including a single filament 150 forming a single loop 604:



EX1001, 13:18-25; EX2001, ¶¶66, 91. Figure 7 is the multi-filament, multi-loop embodiment recited in the Claims. The '384 Patent is explicit that a single filament can be a monofilament or it can include a “plurality of strands,” but a single filament does not become both a first filament and a second filament simply because of multiple strands twisted together. EX1001, 9:16-21; EX2001, ¶68.

Further, during prosecution in response to a Restriction Requirement, Patent Owner expressly elected (and identified) the two-filament two-loop embodiment in

Figure 7 of the '384 Patent rather than the one-filament one-loop embodiment in Figure 6. EX1002, p.220. Based on that election and the differing disclosure in Figures 6 and 7 of the '384 Patent, the “first filament” and the “second filament” recited in the Claims require *separate* filaments forming *separate* loops as shown in Figure 7 and not a single filament forming a single loop (even if made of different strands or threads) as shown in Figure 6 and in Petitioner's proposed combinations. EX2001, ¶¶66, 91. Petitioner's proposed interpretation is also 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 made of different strands or threads comprises a single “filament” rather than the multiple filaments recited in the Claims. EX2001, ¶¶67, 91.

Because neither Hartley's string nor Eller's wire member discloses the claimed multiple filaments, Petitioner next alleges an alternative “second way” of combining the references in grounds 1-2, specifically that it would have been obvious to a POSA to have replaced Schaffer's U-shaped actuating members with two of Hartley's single string or two of Eller's wire members. Petition, pp.37-40, 47-50. But neither Hartley nor Eller disclose any embodiment including a “first filament [configured/extending] in a first loop” *and* a “second filament [configured/extending] in a second loop” as claimed.

The purported “second way” of ground 1 (obviousness over Schaffer and Hartley) also fails because a POSA would not have been motivated to duplicate Hartley’s string and include it in Schaffer’s valve based on Hartley’s disclosure that its string 14 “is wound preferably twice around the cylindrical diaphragm.” Petition, p.37; EX1003, ¶79; EX1007, ¶¶0031]. Hartley discloses only a single string 14. EX2001, ¶71. Further, contrary to Petitioner’s assertions, in their proffered combination the sealing width and friction between Hartley’s string and Schaffer’s seal module would not improve and would further complicate Hartley’s double-wound single string. Petition, pp.37-38; EX2001, ¶¶73-78.

The purported “second way” of 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. While Eller discloses embodiments involving multiple wire members, in those structures none of the multiple wire members extend in a “loop” but are instead positioned only partially around a tubular sleeve. EX2001, ¶¶94-101. 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—an arrangement not found anywhere in Schaffer or Eller. *Id.*

And, more generally over the course of the related IPRs, Petitioner's proposed "simple substitution" has metamorphosized to varying structures depending on whatever the arrangement of the filament(s) in the claims at issue in each of the IPRs is. Petitioner's shifting positions for its purported "simple substitution" from one filament configuration to another, and then to another, depending on the filament configuration in the challenged claims demonstrate that in fact none are a simple substitution, but instead are motivated by impermissible hindsight using the claims at issue as a roadmap. Petitioner's impermissible hindsight fails to establish a reasonable likelihood of unpatentability.

Grounds 1-2 fail for those reasons. And, those reasons are distinct from the reasons explained and disputed in the related IPRs.

Ground 3 (obviousness over Schaffer in combination with both Hartley and Eller) fails for the same reasons as grounds 1-2. There is nothing about the combination with both Hartley and Eller that solves the issues in the underlying prior art from grounds 1 and 2. Grounds 4-6 (obviousness over Schaffer and Hermann in combination with Hartley and/or Eller) relate only to limitations specific to dependent Claims and fail for the same reasons as grounds 1-3.

For those and the other reasons set forth herein, Petitioner has failed to demonstrate a reasonable likelihood 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

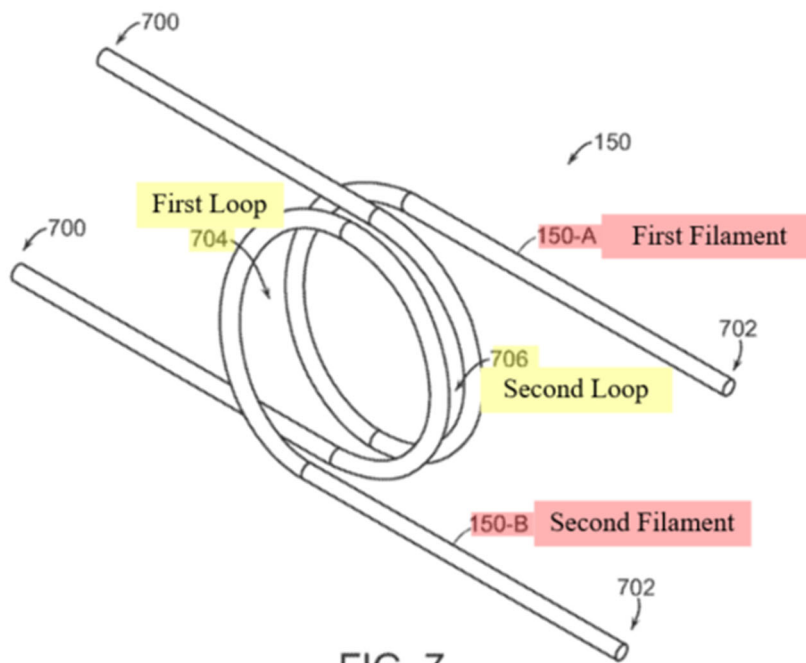
The '384 Patent explains that while “traditional hemostasis valves are greatly beneficial for intravascular access, they have some drawbacks. For example, some valves may not seal adequately for all interventional applications or tools, and/or the operation of some valves may be complicated for operator 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, 5:56-58.³ 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.

So, 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 a filament that is formed into a loop around the

³ Merriam-Webster defines “garrote” to mean “an implement (as a wire with a handle at each end) for strangulation.” EX2002, p.516.

tubular member and an actuator element connected to an end of the filament for tensioning the filament 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.

The filament(s) can have different configurations as shown in Figures 6-9 of the '384 Patent. EX2001, ¶¶42-46. For example, as shown in Figure 7, the filament 150 comprises 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 the tubular member 132:



EX1001, 13:21-25; EX2001, ¶43. In contrast in Figure 6, the filament 150 can be configured to form a single loop 604 that extends around the tubular member:

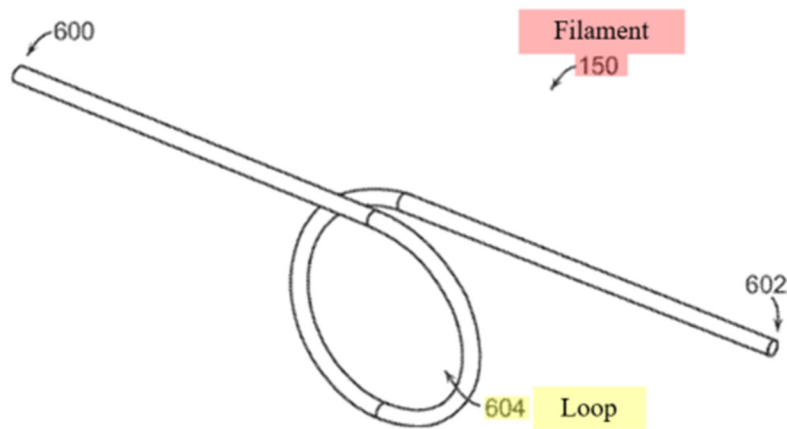
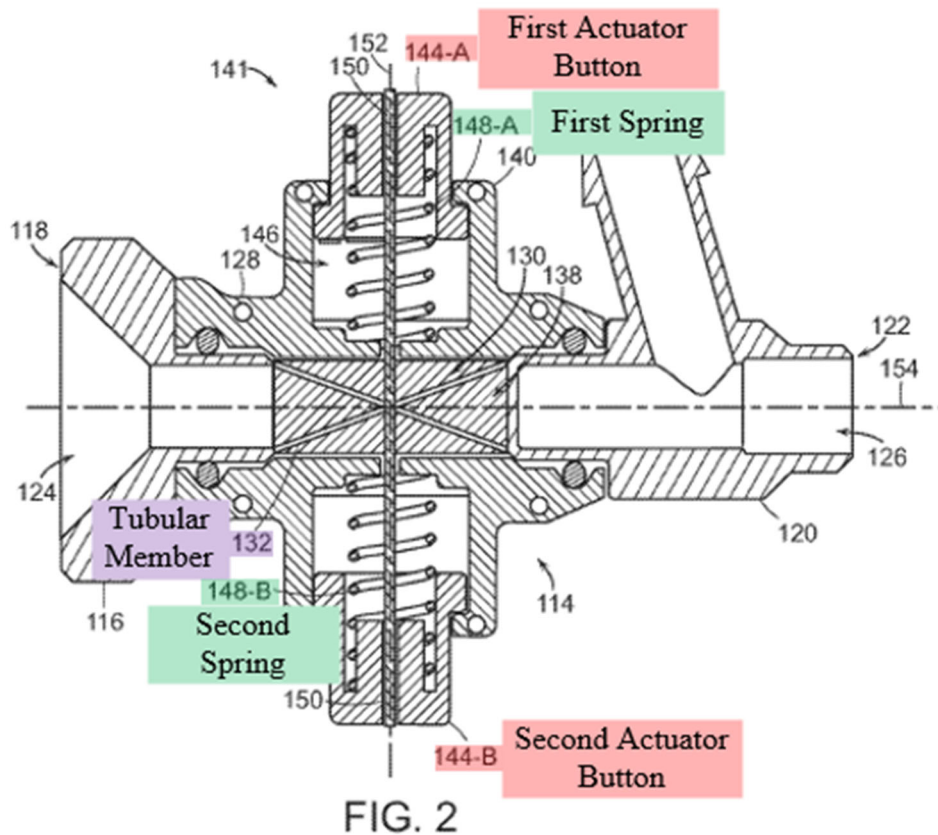


FIG. 6

EX1001, 13:17-21; EX2001, ¶43.

Figures 8 and 9 of the '384 Patent illustrate non-loop embodiments in which the filament 150 is formed into multiple bights. EX1001, 13:30-32; EX2001, ¶45. The '384 Patent specifies that in contrast to a loop, the term “‘bight’ refers to a U-shaped section between the two ends of the filament 150.” EX1001, 13:32-33.

The pair of actuators may be manual buttons, enabling easy one-handed use. *Id.* at 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 can be biased (e.g., via springs) towards a sealed position as shown in Figure 2:



EX1001, 8:38-44; EX2001, ¶40. In the sealed position, depicted in Figure 2 above, the tubular member is collapsed or sealed, with the buttons in an undepressed position. EX1001, 8:40-46; EX2001, ¶40. The first and second buttons 144-A, 144-B can be depressed against the first and second springs 148-A, 148-B, respectively, to move the valve to an unsealed position shown in Figure 3 in which the filaments 150 are loosened, thereby allowing the expansion of the tubular member 132 and the unsealing of the central lumen 138 thereof:

For example independent Claim 1 requires, *inter alia*:

- a first filament extending in a first loop around [a] tubular member, wherein the first filament is flexible;
- a second filament extending in a second loop around the tubular member, wherein the second filament is flexible; [and]
- a pair of actuators movable from a first position to a second position, wherein—
 - the first 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; [and]
 - the second filament includes a first portion operably acted upon by the first one of the actuators and a second portion operably acted upon by the second one of the actuators.

Independent Claim 15 similarly requires, *inter alia*:

- a first actuator;
- a second actuator;
- a first filament configured in a first loop completely around [a] tubular member and having a first portion extending from the first loop toward the first actuator and a second portion extending from the first loop toward the second actuator;
- and
- a second filament configured in a second loop completely around the tubular member and having a first portion extending

from the second loop toward the first actuator and a second portion extending from the second loop toward the second actuator.

Likewise, independent Claim 23 requires, *inter alia*:

a first filament extending in a first loop [a] the tubular member;
a second filament extending in a second loop around the tubular member; and
a pair of actuators biased to circumferentially constrict the first loop and the second loop.

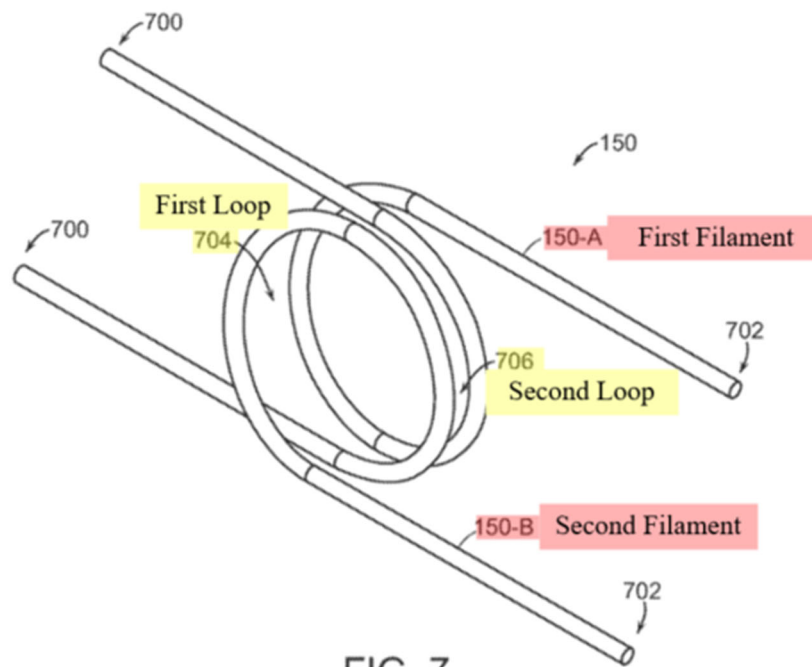
C. Prosecution History

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 embodiments in Figures 8-9 of the '384 Patent disclose two filaments each forming an individual bight. *Id.* at 13:18-21, 13:34-36; 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.

D. 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. The parties have disputed the proper construction of “filament” in the related IPRs. Here, however, 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 [configured/extending] in a first loop” and the “second filament [configured/extending] in a second loop” recited in each of independent Claims 1, 15, and 23. Patent Owner reserves its right to seek to construe the term “filament” as requiring flexibility at a later date, if necessary, and notes that, in other proceedings where the challenged claims expressly recited a loop configuration as the Claims do here, the Board has construed the “filament” formed in the loop to require a flexible filament. *See, e.g.,* EX1023, pp.13-21.

E. 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. Nevertheless, the definition of a POSA is not necessary to resolve the controversy here as, even under Petitioner's definition, grounds 1-6 fail as explained herein. Patent Owner reserves its right to seek to define a POSA at a later date, if necessary.

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 [configured/extending] in a first loop" and the "second filament [configured/extending] in a second loop." Unlike in previous proceedings, Petitioner

does not contend that Schaffer discloses the claimed “first filament” and “second filament.” 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 as Hartley discloses only a single string 14 (EX2001, ¶¶64-80) and, while Eller discloses multiple wire members, in each of those embodiments each of the multiple wire members extends only partially around Eller’s tubular sleeve rather than in a loop (*id.* at ¶¶94-103).

Petitioner identifies two alternative and equally 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 one of Eller’s wire member includes two filaments, but this contradicts the specification, the prosecution history, and common sense. Petition, pp.27-37, 40-47. 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.

Petitioner’s first argument fails because Hartley’s string and Eller’s wire member do not comprise a “first filament” and a “second filament.” EX2001, ¶¶64-60, 89-91. Namely, the ’384 Patent is explicit that a single filament can be a monofilament or it can include a “plurality of strands,” but a single filament does not become both a first and second filament simply because of multiple strands

twisted together. EX1001, 9:16-21; EX2001, ¶68. Likewise, a POSA would understand based on the disclosure in Figure 7 of the '384 Patent that was expressly elected by Patent Owner in response to the Restriction Requirement that Claims 1, 15, and 23 require separate first and second filaments instead of a single filament having different twisted strands. EX2001, ¶¶64-60, 89-91. And, Petitioner's argument is directly contrary to the Office's finding in the Notice of Allowance that Hartley "fails to disclose ... a second filament." EX1002, p.20.

Petitioner's second argument fails because the proposed combination is not a "simple substitution," as Petitioner contends, and a POSA would not have been motivated to include two of Hartley's strings or two Eller's wire members in Schaffer. EX2001, ¶¶70-80, 92-104. Such a substitution would not have reduced friction, widened the sealing area, or improved redundancy. *Id.* at ¶¶70-80, 104. Likewise, Petitioner's second "way" is not a mere substitution, much less a simple one, given that none of Petitioner's references disclose separate first and second filaments configured/extending in first and second loops, respectively. *Id.* at ¶¶102-103.

Additionally, 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

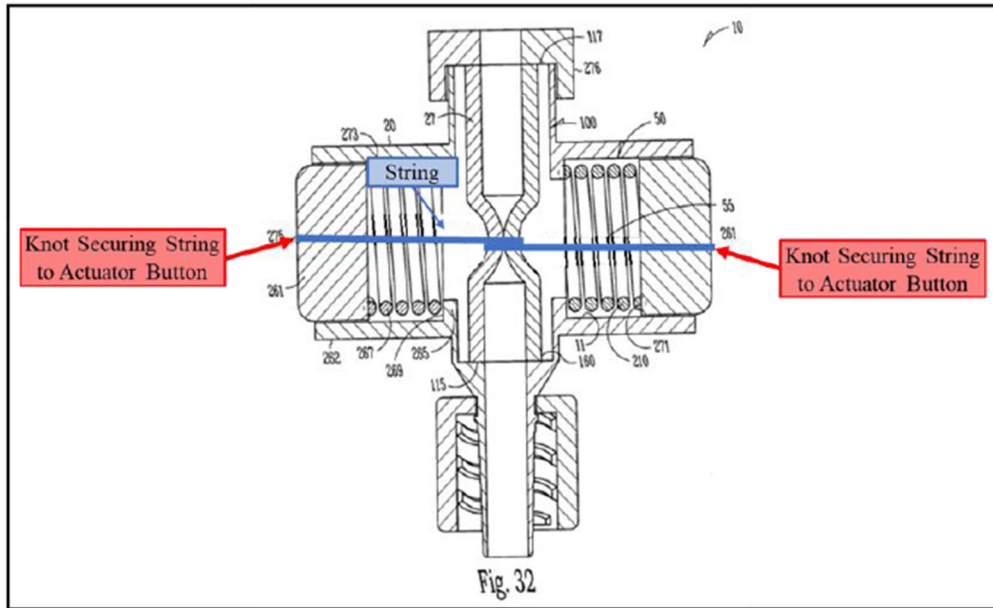
of the actuators and a second portion operably acted upon by a second one of the actuators"). Instead, each of Schaffer's U-shaped members, Hartley's string, and Eller's wire member(s) are attached to and controlled by a *single* actuator.

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.

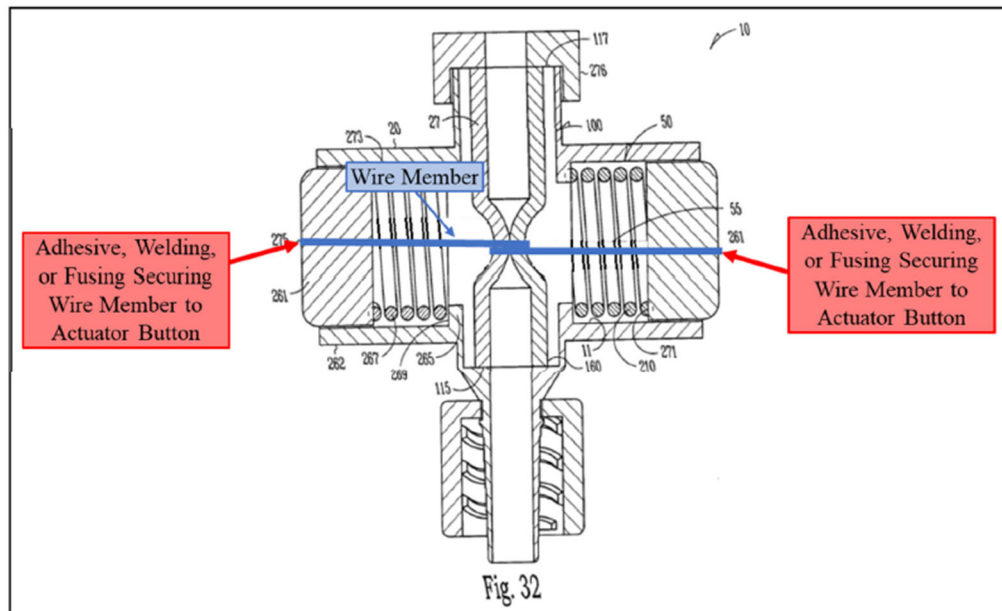
A. Hartley's String and Eller's Wire Member Do Not Comprise or Render Obvious Two Filaments as Required by Independent Claims 1, 15, and 23

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 of the proposed substitutions:

Demonstrative Illustration
Schaffer + Hartley's String



Demonstrative Illustration
Schaffer + Eller's Wire Member



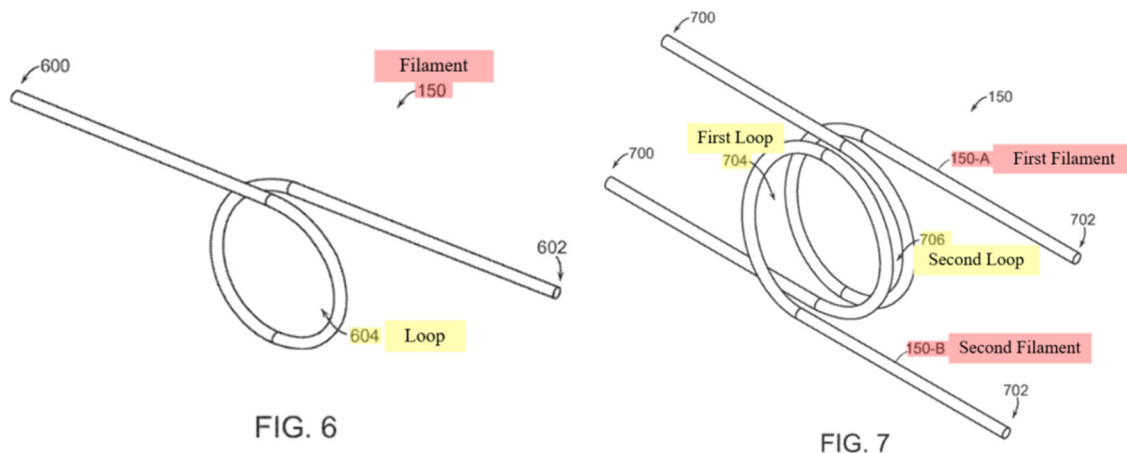
Petition, pp.35, 44-46. According to Petitioner, in the combination with Hartley, Hartley's string 14 is both the "first filament" and the "second filament" in the

proposed combination 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. In those related IPRs, the parties have repeatedly disputed, and the Board has repeatedly considered, whether a POSA would have been motivated to eliminate Schaffer’s U-shaped actuating members 55 and replace them with Hartley’s string or Eller’s wire member based on purported theories of, for example, simple substitution (Petition, pp.30, 44), improved sealing (*id.* at pp.30-33, 44-45), and obvious-to-try (*id.* at pp.33-34, 45). Patent Owner maintains here 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. EX2001, ¶¶65, 90. ***Nevertheless, consideration of those arguments is not necessary to resolve the controversy here because, even assuming that a POSA would have made Petitioner’s proposed***

substitutions of Hartley's string or Eller's wire member (which Patent Owner does not concede), grounds 1-2 still fail because Hartley's string or Eller's wire member do not include both a "first filament" and "second filament" as required by the Claims. Id. Such an interpretation of the first and second filament recited by the Claims defies the intrinsic evidence and common understanding of "filament."

First, the '384 Patent discloses two distinct embodiments in Figures 6 and 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 an embodiment including a single filament 150 forming a single loop 604.



EX1001, 13:18-25; EX2001, ¶¶66, 91. A POSA would understand based on that disclosure that the "first filament [configured/extending] in a first loop" and the "second filament [configured/extending] 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. EX2001, ¶¶66, 91. Further, the '384 Patent is explicit that a single filament can be a monofilament or it can include a “plurality of strands,” but a single filament does not become both a first and second filament simply because of multiple strands twisted together. 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.

Indeed, the Patent Office required Patent Owner to elect between the embodiment directed to a single filament loop (either monofilament or multi-strand filament) as in Figure 6 and the embodiment in Figure 7 with multiple filaments and multiple loops. EX1002, pp.231-232. In response to that Restriction Requirement, Patent Owner expressly elected the embodiment in Figure 7 of the '384 Patent showing two filaments each forming a loop—in direct contrast to the embodiment in Figure 6 showing a single filament and other embodiments in Figures 8 and 9. *Id.*, 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.

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 understand 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 monofilament (i.e., comprising 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

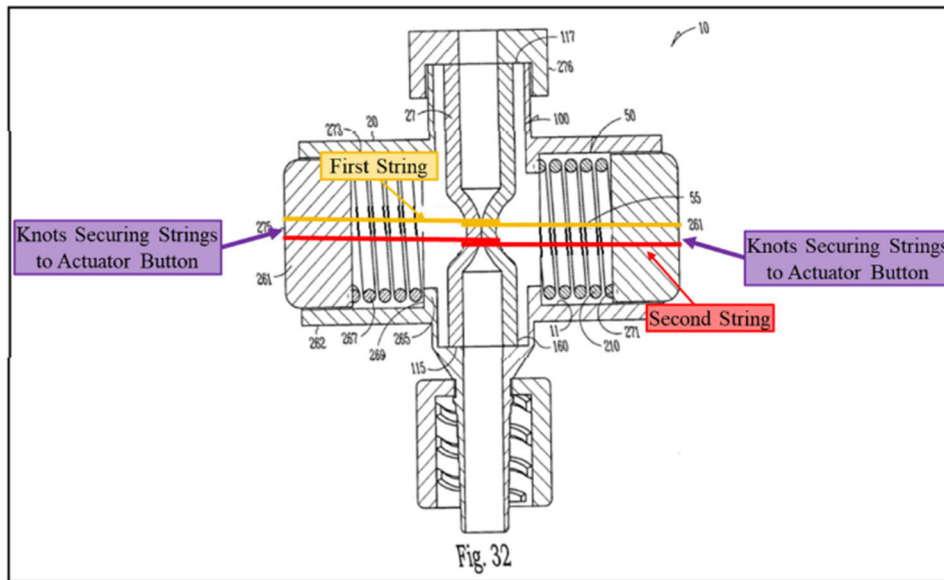
together in contrast to a single strand filament (e.g., monofilament) . EX2001, ¶¶68. Therefore, Claim 6 provides no support for the notion that a single string made up of twisted or woven fibers comprises both the first and second filaments and the first and second loops recited in the Claims.

For the foregoing reasons, neither Hartley's single string nor Eller's wire member are "a first filament [configured/extending] in a first loop" and "a second filament [configured/extending] 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 Also 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, nowhere does Hartley disclose or at all suggest using more than its one, single string 14 in a valve. EX2001, ¶71. Rather, every embodiment of Hartley includes only the *single* string 14. *Id.* Petitioner does not cite to anything in Hartley that even suggests otherwise. And, Schaffer's two U-shaped actuating members 55 are not "filaments" and neither actuating member 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 [configured/extending] in a first loop" and "a second filament [configured/extending] 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 assert 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; EX1007, ¶[0031]. Specifically, they assert 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 14 into Schaffer as Petitioner asserts for its "first way" of obviousness (which Patent Owner does not concede for the reasons described in the related IPRs), 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. Hartley's teaching to double-wind a single filament teaches against adding a second filament rather than motivating a POSA to do so.

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 understand that *the friction is the same* in Petitioner's proposed two-string arrangement as in what Hartley actually discloses—a single-string double-wind 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.*

Moreover, even if there were somehow more friction (which there is not) using a single, twice-wound string, a POSA would not have been motivated to deviate from Hartley's disclosure to duplicate its single string because Schaffer's springs may consequently "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" based on Petitioner and its expert's own statements. Petition, p.38. In particular, 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 easily be 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." EX1007, ¶[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.* For that reason, a POSA would not have been motivated to duplicate Hartley's string 14 to arrive at a more costly and not advantageous arrangement not found in Hartley or 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.

Additionally, a POSA would understand 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, meaning a POSA would not have been motivated to choose 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. 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. For example, a POSA would understand that, in Petitioner's purported modification

using two strings, the two strings might interfere with one another, especially after Schaffer's actuator buttons are depressed one or more times and/or if the valve were tilted relative to gravity such that one string moves toward the other along the seal module—for example, with one of Hartley's strings extending under the loop of the other string. EX2001, ¶79. Thus, a POSA would understand 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 reason to "provide a redundancy" if Hartley's string 14 failed 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, 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. 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 14 and include that duplication in Schaffer's valve

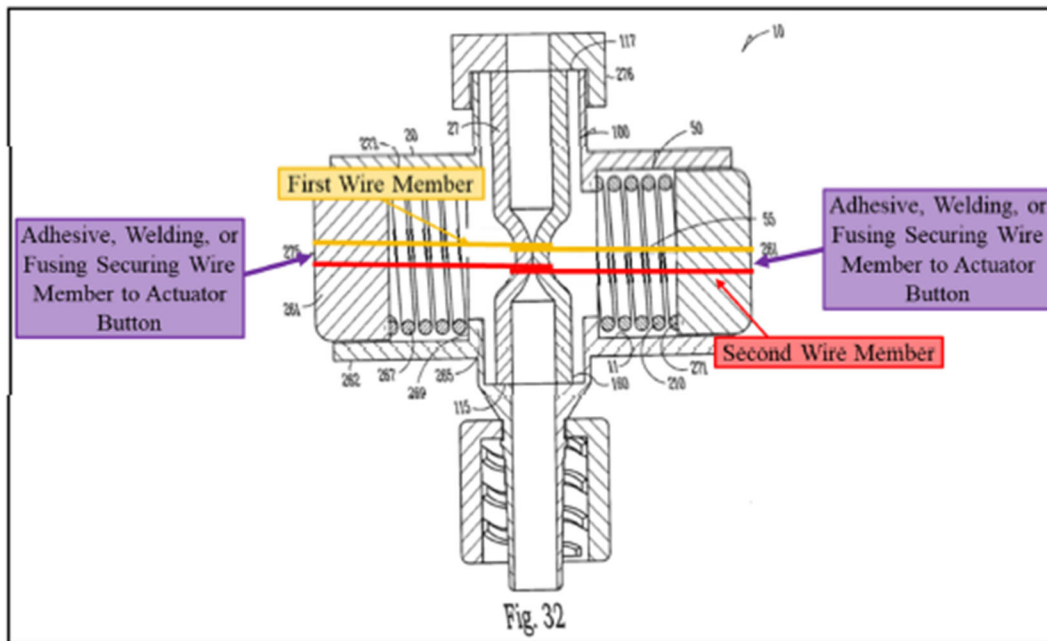
to provide redundancy because a POSA would have understood Hartley's single string to be sufficiently durable. EX2001, ¶80.

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 Also 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 "[configured/extending] in a first loop" and "[configured/extending] in a second loop" as required by those Claims. EX2011, ¶¶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 of the proposed substitution:

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 one, 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 any embodiment including multiple wire members that form first and second 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 ever disclose that the wire members individually form loops, nor does Eller ever 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”:

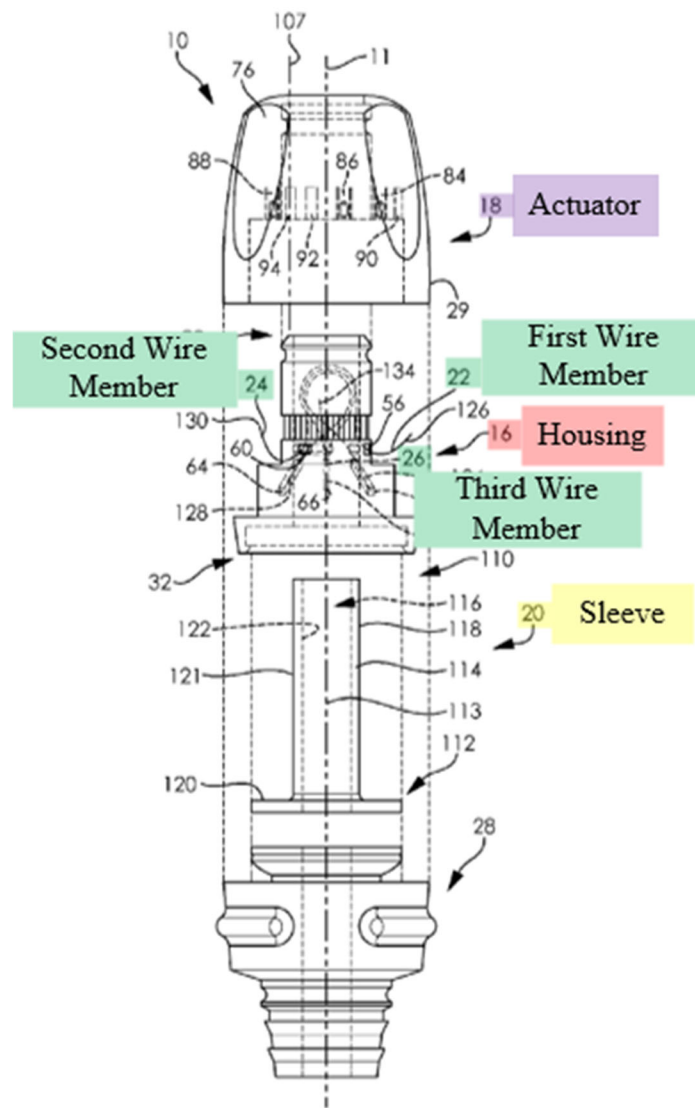
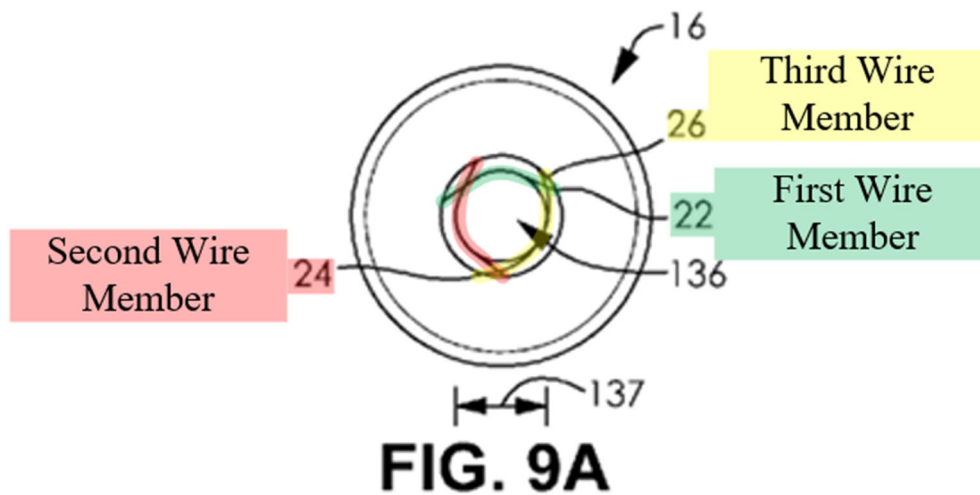


FIG. 2

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. 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 [configured/extending] in a first loop" and a "second filament [configured/extending] 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”:

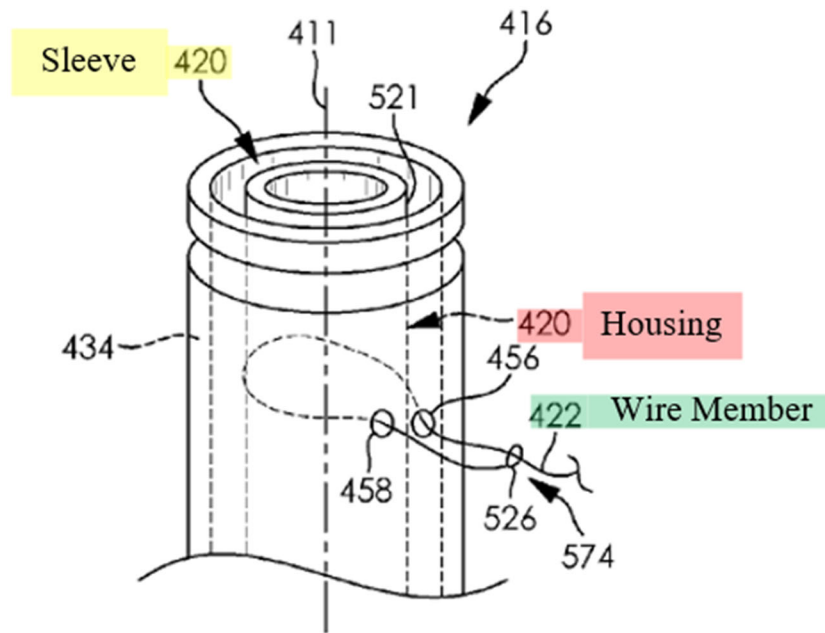
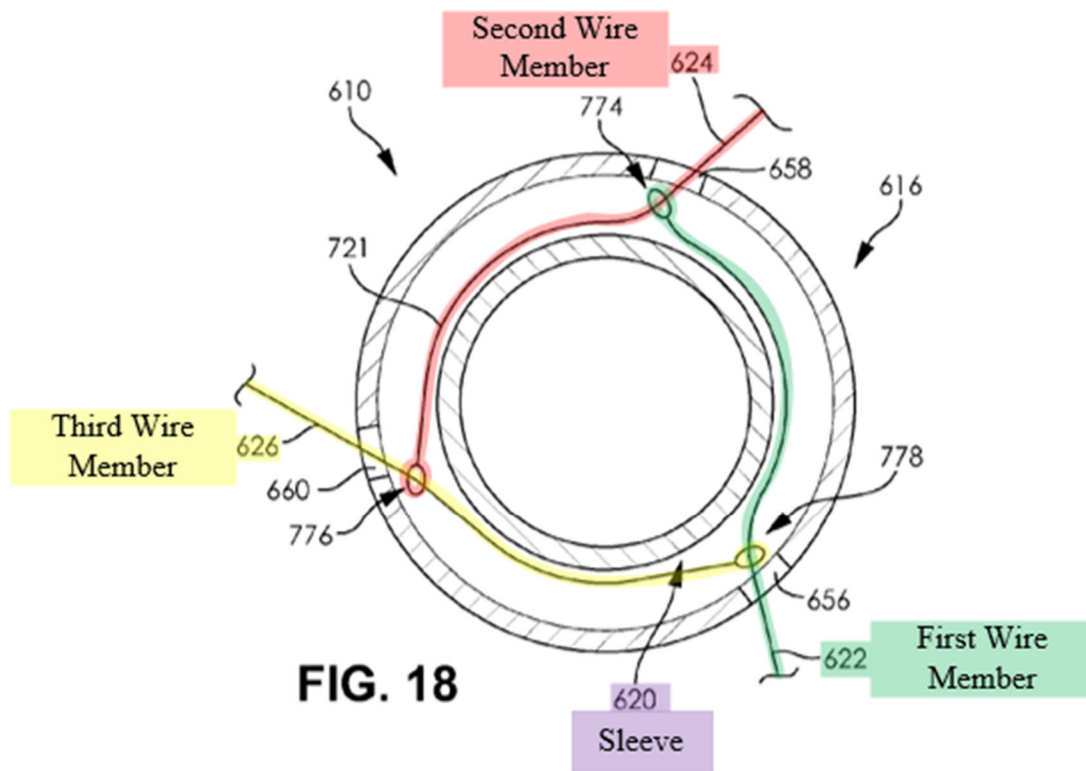


FIG. 16

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) “[configured/extending] in a first loop” and a “second filament” (e.g., a second wire member) “[configured/extending] 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 [configured/extending] in a first loop” and a “second filament [configured/extending] in a second loop” as required by the Claims. EX2001, ¶98.

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”:

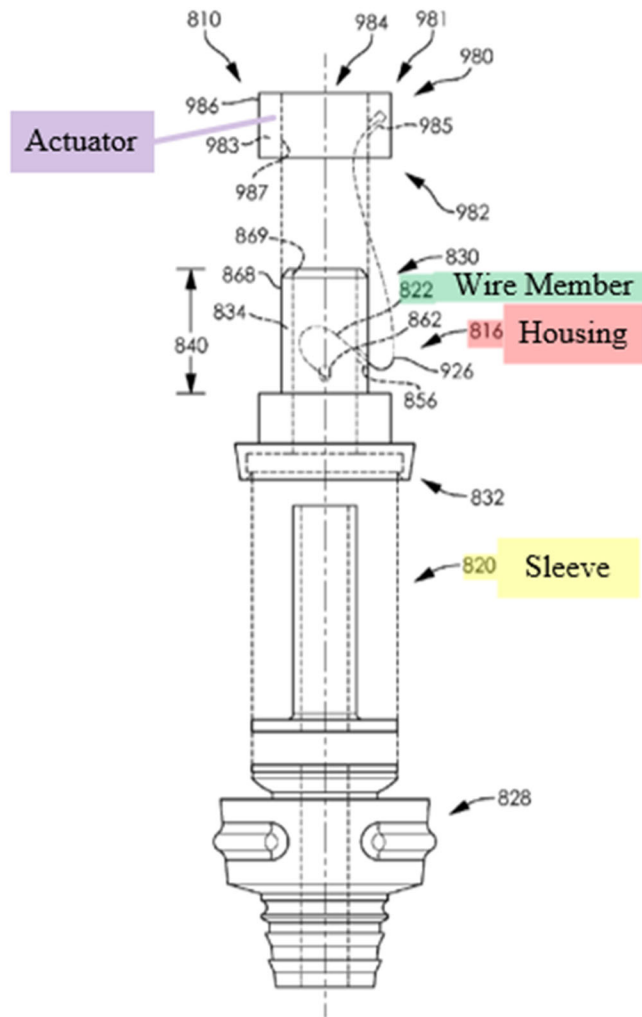


FIG. 20

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 [configured/extending] in a first loop” and a “second filament [configured/extending] 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 [configured/extending] in a first loop” and the “second filament [configured/extending] 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, and Eller **does not** disclose any embodiment with multiple loops either. EX2001, ¶101. In each embodiment including multiple wire members, each of the multiple wire members extends only partially around the sleeve and not 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 “[configured/extending] in a first loop” and a second wire member “[configured/extending] 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. 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 actuator buttons 261 controls movement of a single one of the actuating members 55. *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.*

More generally, over the course of this IPR and the related IPRs, depending on the challenged claims, Petitioner and its expert have proposed that any conceivable arrangement of a string/wire member in Schaffer's valve is a "simple substitution" despite none of those arrangements being found in the prior art. For

example, at best for Petitioner, a simple substitution might be to simply replace each of Schaffer's rigid U-shaped members with a string or wire member, and that is exactly what Petitioner and its expert asserted that a POSA would do in a related Petition. *See, e.g.,* EX2003, ¶75 (“[t]he required adjustments, to the extent any adjustments were needed, would have been simple, including modifying the shape, material, and/or dimensions of the U-shaped actuating members to better conform to the cylindrical shape of the seal module ... [f]or example, the actuating members could be formed from a thin, flexible sheet or flat ribbon of aluminum or plastic.”)

At the same time, here and in other related Petitions, Petitioner asserts that the purported “simple substitution” was not to simply substitute a string or wire member for each of Schaffer's U-shaped members, but to replace both with a single string or wire member. Petition, pp.30, 45; *see also, e.g., Imperative Care, Inc. v. Inari Medical, Inc.*, IPR2024-01157, Paper 1, pp.35, 44. Now, Petitioner claims yet another allegedly simple, but actually significant and not advantageous modification—this time two wire members each formed in a loop with ends of the wire member connected to different independently-actuatable actuators, a configuration found only in the challenged Claims. Petitioner's changing assertions of the simple substitution depending on the challenged claimed configuration demonstrates that each is hindsight motivated only by the need to arrive at a particular claimed configuration. As explained in *KSR*, “[a] factfinder should be

aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007).

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.

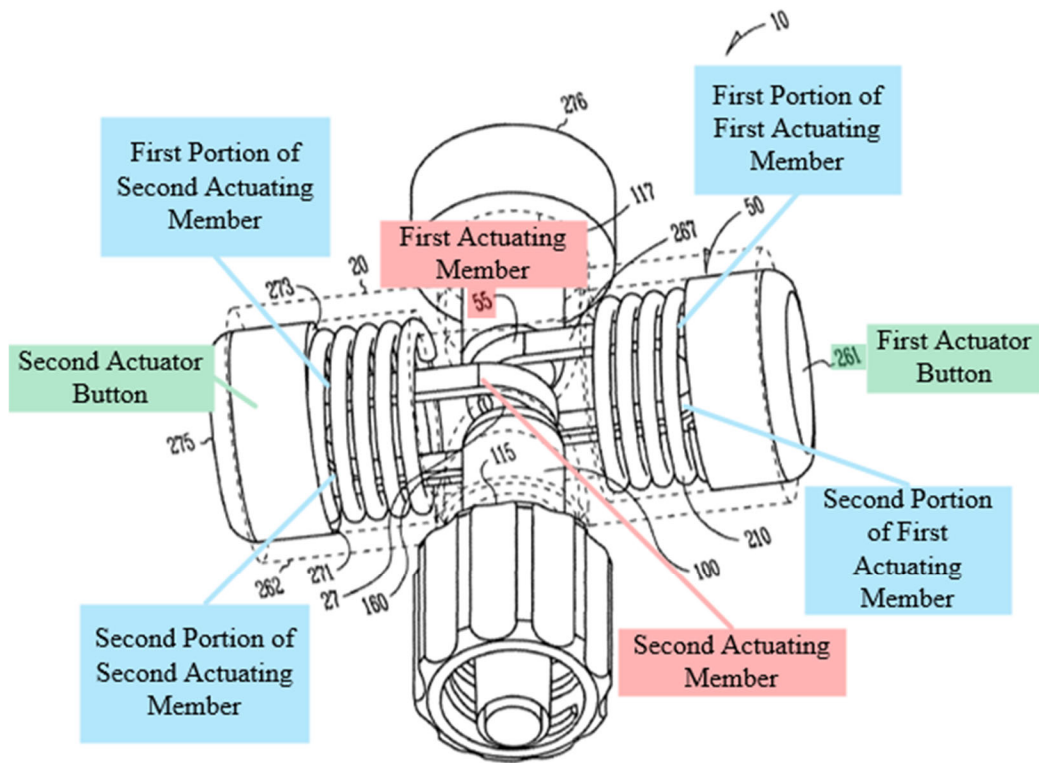
3. Petitioner’s purported motivations to create a larger sealing area, allow the manufacturer to optimally space the strings, and add redundancy to the system would not have motivated a POSA.

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.

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 actuator buttons 261 operably acts on only one of the actuating members 55:



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:

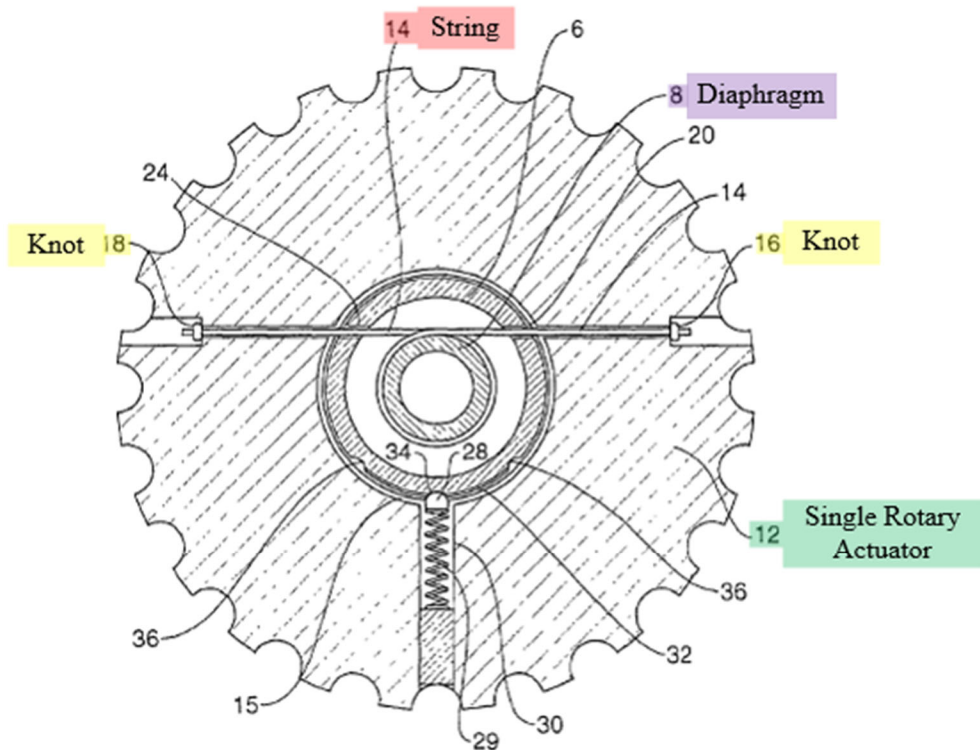
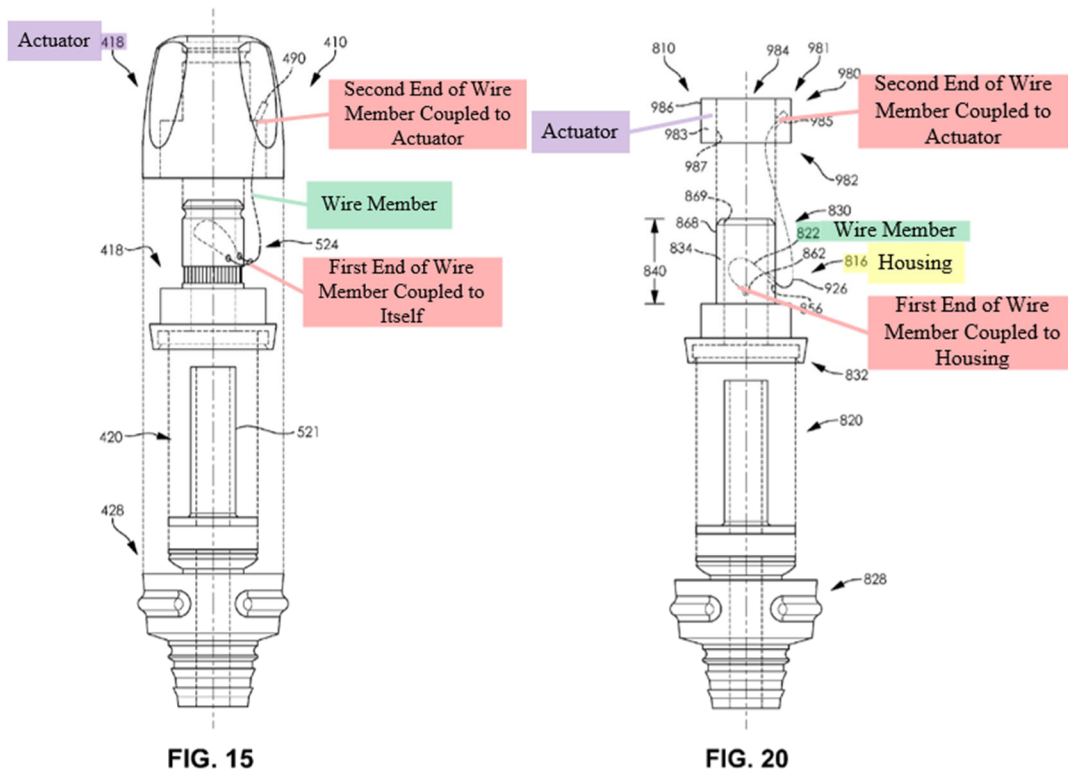


Fig 3

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:



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.”).

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 [configured/extending] in a first loop” and “second filament [configured/extending] 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 “[configured/extending] in a first loop” and a second wire member “[configured/extending] 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

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.

VI. CONCLUSION

For all the above reasons, Petitioner has not met its burden of establishing a reasonable likelihood of success in showing that at least one claim is unpatentable as obvious over the cited art. Patent Owner respectfully requests that the Board deny institution.

Respectfully submitted,

Dated: December 29, 2025

By: /Matthew S. Williams/
Matthew S. Williams
Reg. No. 77,516
Backup Counsel for Patent Owner

CERTIFICATE OF COMPLIANCE

Pursuant to 37 C.F.R. § 42.24(d), I, Matthew S. Williams, certify that **PATENT OWNER'S PRELIMINARY RESPONSE** contains 10,078 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: December 29, 2025

By: *Matthew S. Williams*
Matthew S. Williams
Reg. No. 77,516
Backup Counsel for Patent Owner

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), I certify that on December 29, 2025 a copy of **PATENT OWNER'S PRELIMINARY RESPONSE and EXHIBITS 2001-2003** 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: December 29, 2025

By: / Kate Rose /
Kate Rose