

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

IMPERATIVE CARE, INC.,
Petitioner,

v.

INARI MEDICAL, INC.,
Patent Owner.

IPR2025-00728
Patent 11,844,921 B2

Before JEFFREY N. FREDMAN, ERIC C. JESCHKE, and
TIMOTHY G. MAJORS, *Administrative Patent Judges*.

MAJORS, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Determining All Challenged Claims Unpatentable
35 U.S.C. § 318(a)

I. INTRODUCTION

Imperative Care, Inc. (“Imperative” or “Petitioner”) filed a Petition (Paper 1, “Pet.”) requesting *inter partes* review of claims 1–7, 9, 10, 15–18, and 20–24 of U.S. Patent No. 11,844,921 B2 (Ex. 1001, “the ’921 patent”). Pet. 1, 20 (Table listing Grounds 1–5). Inari Medical, Inc. (“Inari” or “Patent Owner”) filed a Preliminary Response (Paper 6).

We instituted trial on October 10, 2025. Paper 13 (“Inst. Dec.”). During trial, Patent Owner filed a Patent Owner Response. Paper 18 (“PO Resp.”). Petitioner filed a Reply (Paper 22 (“Pet. Reply”)) and Patent Owner filed a Sur-reply (Paper 23 (“PO Sur-reply”)). We held an oral hearing on July 23, 2026, and a transcript of that hearing is of record. Paper 32 (“Tr.”).

We have jurisdiction under 35 U.S.C. § 6(b). After considering the full record through trial, we determine that Petitioner has proved by a preponderance of the evidence that the challenged claims are unpatentable. *See* 35 U.S.C. § 316(e). Our reasoning is explained below, and we issue this Final Written Decision under 35 U.S.C. § 318(a).

II. BACKGROUND

A. *Real Parties-in-Interest*

Petitioner identifies itself as the real party-in-interest. Pet. 95. Patent Owner identifies itself as the real party-in-interest and states that it is a wholly owned subsidiary of Stryker Corporation. Paper 3, 2.

B. *Related Matters*

The parties identify several related IPR proceedings. Pet. 95–96; Paper 3, 2–3. The related matters include the following: IPR2024-01157 (Final Written Decision entered Jan. 16, 2026 (Ex. 1042), finding all challenged claims unpatentable); IPR2024-01257 (institution denied);

IPR2025-00156 (Final Written Decision entered Apr. 7, 2026 (Ex. 1048), finding all challenged claims unpatentable); IPR2025-00289 (Final Written Decision entered June 9, 2026 (Ex. 1049), finding all challenged claims unpatentable; notice of appeal filed); IPR2025-00989 (instituted and pending); IPR2025-01021 (instituted and pending); IPR2025-01025 (instituted and pending); IPR2025-01264 (instituted and pending); IPR2025-01562 (instituted and pending); IPR2026-00169 (instituted and pending); and IPR2026-00215 (instituted and pending).

Although Patent Owner appealed the Final Written Decisions from the 1157 and 156 IPRs (*see, e.g.*, IPR2024-01157, Paper 37 (March 19, 2026, Inari’s Notice of Appeal)), the parties have since stipulated to voluntarily dismiss those appeals. Ex. 1051. The U.S. Court of Appeals for the Federal Circuit ordered those appeals dismissed on September 4, 2026. Ex. 1052 (order and mandate).

The parties also identify the following lawsuit involving assertion of the ’921 patent (and other related and unrelated patents): *Inari Medical Inc. v. Imperative Care, Inc.*, No. 24-cv-3117 (N.D. Cal.). Pet. 95; Paper 3, 2.¹ That district court lawsuit is now stayed. *See, e.g.*, Ex. 1041. If there is any perceived inconsistency between our determinations in this Final Written Decision and the district court’s order on a motion for preliminary injunction concerning the ’921 patent, we point the reader to our discussion on that issue in related proceedings, which we adopt here. Ex. 1042, 3–4 (IPR2024-01157, Paper 35 at 3–4); *see also* Ex. 1038 (order denying Inari’s motion for preliminary injunction). Among other things, as we explained previously,

¹ Patent Owner further states that *Inari Medical, Inc. v. Inquis Medical, Inc.*, No. 24-1023-CFC (D. Del.) “may involve related issues.” Paper 3, 2.

the court did not address any claim construction dispute or expressly construe the claims of the '921 patent in route to determining that Imperative had raised a substantial question of validity based, for example, on the teachings of Schaffer alone. Ex. 1042, 3–4; Ex. 1038, 13–17.

C. The '921 Patent (Ex. 1001)

The '921 patent is titled “Hemostasis Valves and Methods of Use.” Ex. 1001, code (54). The patent issued December 19, 2023, from an application filed April 29, 2021, and claims priority to a provisional application filed September 6, 2017. *Id.* at codes (22), (45), (60).

According to the '921 patent, “the desire for improved patient outcomes has led to the development of hemostasis valves that facilitate minimally invasive surgery.” *Id.* at 1:24–26. “In minimally invasive surgery, small incisions are created through a blood vessel [into] which one or several catheters are inserted.” *Id.* at 1:27–29. “These catheters are moved to a position proximate to tissue, nerves, or other body structures targeted by the surgery, and then tools for performing the procedure are inserted through the lumens of some or all of these catheters.” *Id.* at 1:30–34. “To minimize blood loss, prevent delivery of air into the vasculature, and to facilitate maintenance of sterility within the patient’s body . . . , these catheters are equipped with hemostasis valves.” *Id.* at 1:35–38. The patent states that “new and improved” valves “are desired.” *Id.* at 1:53–54.

The '921 patent discloses that “[t]he valve can include a tubular [elongate] member that can be constricted, collapsed, and/or sealed by one or several tensioning mechanisms.” *Id.* at 1:59–62. According to the patent, “[t]he tensioning mechanism can include at least one filament that extends around at least a portion of the tubular member,” and such “filament can interact with the tubular member to constrict, collapse, and/or seal the

tubular member via manipulation of the tensioning mechanism(s).” *Id.* at 1:62–2:5 (disclosing that such valve, by action of the tensioning mechanism and filament, “can seal around a wide range of tool sizes and shapes” that are passed through the tubular member). The patent discloses that, in embodiments, the tensioning mechanism can include an actuator coupled to the filament, which actuator can be operated to control movement of the filament from a first position (where the central lumen is constricted and sealed) to a second position (where the central lumen is un-constricted and open). *Id.* at 2:44–57. Moreover, the patent explains, an actuator can be biased toward the first or second positions. *Id.* at 2:57–59.

We reproduce below the ’921 patent’s Figure 4 including annotations provided by Petitioner, with additional annotations added by the Board.

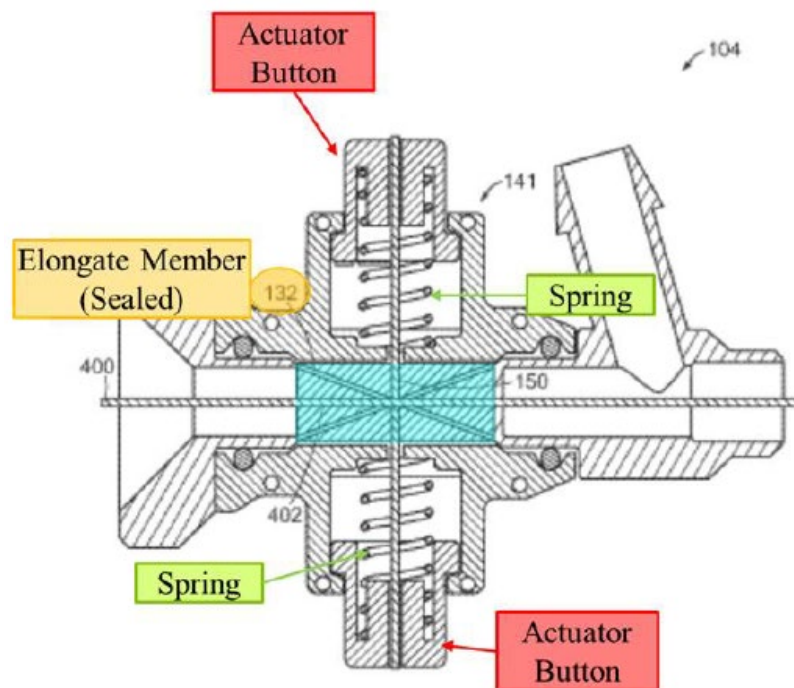


FIG. 4

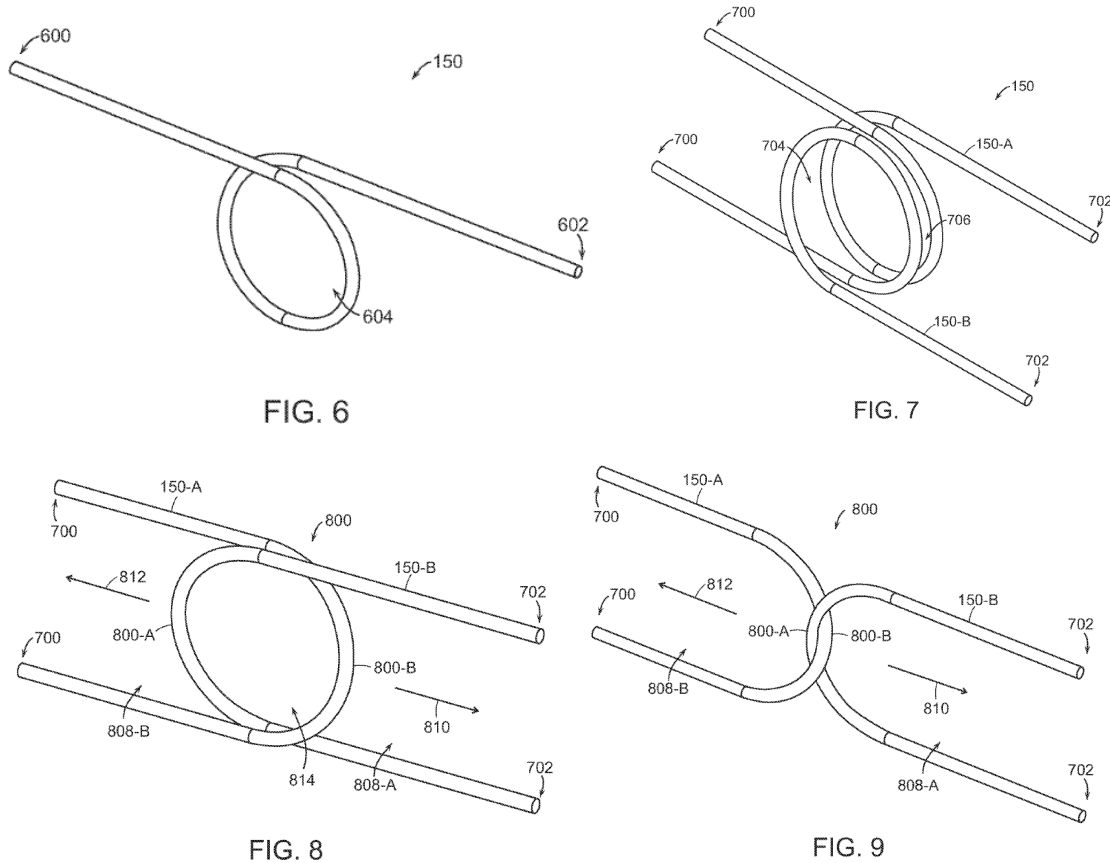
Pet. 3 (modified by blue highlight added by Board); Ex. 1001, Fig. 4.

Figure 4, as depicted above, is a side cross-sectional view of an embodiment

of valve (104) described in the '921 patent. Ex. 1001, 5:27–29. The valve includes, *inter alia*, a housing, elongate member 132 (orange highlight) defining a central lumen and having a tool (400) inserted through that lumen, constricting mechanism 141, filament 150, and oppositely disposed actuator buttons (red highlights). *Id.* at 11:57–12:8; *see also id.* at Fig. 2 (additional view of the illustrative valve in a first/closed configuration), 8:32–50. In the embodiment shown above, the filament is disposed around the elongate member and coupled to both actuator buttons (which are undepressed); the buttons are biased towards a first (closed) configuration by a bias feature (e.g., springs (green highlights)) such that the elongate member is collapsed and sealed by the filament in the area highlighted blue. *Id.* at 8:32–50. Although not shown above, when the buttons are depressed, the constricting mechanism moves to a second (open) configuration where the “the filament 150 is loosened,” allowing expansion of the elongate member and unsealing of the central lumen. *Id.* at 9:48–54, Fig. 3 (showing open configuration).

According to the '921 patent, the “filament 150 can be arranged in a variety of configurations.” *Id.* at 13:10–11. For example, the filament can comprise a “single loop 604 that can extend around the elongate member 132 and/or through which the elongate member 132 can be received as shown in FIG. 6.” *Id.* at 13:11–14. Alternatively, the filament may comprise one or more “U-shaped section[s]” or “bight[s]” like depicted in Figures 8 and 9. *Id.* at 13:23–33 (disclosing that “filament 150 can be configured to form a bight 800, which bight 800 can be a single bight or multiple bights” and, “[a]s used herein, a ‘bight’ refers to a U-shaped section between the two ends of the filament 150”). The patent further discloses that the “filament can be made from a variety of materials including, for example, a polymer, a synthetic, and/or a metal.” *Id.* at 9:7–9.

Figures 6–9, showing multiple filament embodiments, are included below.



Ex. 1001, Figs. 6–9. Figures 6–9 above illustrate various filament configurations: “single loop” (Fig. 6), “multiple loops” (Fig. 7), or one or more “bights” (Figs. 8 and 9), which can be non-interlocking or interlocking. *Id.* at 13:10–22 (describing loop embodiments), 13:23–65 (describing bight embodiments).

The ’921 patent discloses that, in “loop” embodiments like shown in Figures 6 and 7, a filament can be configured to form a “loop” (or “loops”) “that can extend around the elongate member 132 [(not shown)] and/or through which the elongate member can be received.” *Id.* at 13:11–17. Further, the patent discloses, “a diameter or size of the loop 604, or of the

loops 704, 706 can decrease when the constricting mechanism 141 is moved from the second configuration to the first configuration.” *Id.* at 13:19–22.

Figures 8 and 9 show a filament comprising first and second “bights” 800-A, 800-B that extend around respective portions of an elongate member. *Id.* at 13:23–44. The “bights” together define an “encircled area 814” into which the elongate member can be received, and movement of those bights in the directions indicated by arrows 812 and 810 “decreases the size of the encircled area 814 and constricts, collapses, and/or seals the elongate member 132 extending through the encircled area.” *Id.* at 13:54–65.

D. Illustrative Claims

Petitioner challenges claims 1–7, 9, 10, 15–18, and 20–24. Claim 1 is illustrative and is reproduced below:

1. A valve, comprising:
 - an elongate member defining a lumen;
 - an active tensioning mechanism including an actuator coupled to the elongate member via a filament extending at least partially around the elongate member, wherein the actuator is moveable between (a) a first position wherein the lumen is constricted and sealed and (b) a second position wherein the lumen is at least partially open; and
 - a biasing member configured to bias the actuator to the first position.

Ex. 1001, 22:12–22. Illustrating some of the dependent claims, claim 3 depends from claim 1 and recites “wherein the filament extends in a loop around the elongate member.” *Id.* at 22:25–26. Claim 10 depends from claim 1 and recites as follows:

10. The valve of claim 1 wherein the actuator is a first actuator, wherein the filament is a first filament, wherein the biasing member is a first biasing member, and wherein the active tensioning mechanism further comprises:

- a second actuator coupled to the elongate member via a second filament extending at least partially around the elongate member, wherein the second actuator is moveable between (a) a first position wherein the lumen is constricted and sealed and (b) a second position wherein the lumen is at least partially open; and
- a second biasing member configured to bias the second actuator to the first position.

Id. at 22:53–59.

E. Prior Art and Asserted Grounds

Petitioner asserts that claims 1–7, 9, 10, 15–18, and 20–24 are unpatentable based on the following grounds:

Grounds	Claims Challenged	35 U.S.C. § ²	Reference(s)/Basis
1	1–7, 9, 10, 15–18, 20–24	102	Schaffer ³
2	1–7, 9, 10, 15–18, 20–24	103	Schaffer
3	1–7, 9, 10, 15–18, 20–24	103	Schaffer, Hartley ⁴
4	1–7, 9, 10, 15–18, 20–24	103	Schaffer, Eller ⁵

² The Leahy-Smith America Invents Act (“AIA”), Pub. L. No. 112–29, 125 Stat. 284, 285–88 (2011), revised 35 U.S.C. §§ 102, 103 effective March 16, 2013. Based on the uncontested assertion that September 6, 2017, is the earliest possible priority date for the ’921 patent, we apply the AIA versions of §§ 102 and 103 in this Decision. Pet. 16.

³ Schaffer et al., US 2003/0225379 A1, published Dec. 4, 2003 (Ex. 1005 (“Schaffer”)).

⁴ Hartley, US 2003/0116731 A1, published June 26, 2003 (Ex. 1006 (“Hartley”)).

⁵ Eller, US 9,980,813 B2, issued May 29, 2018 (Ex. 1007 (“Eller”)).

5 ⁶	1–3, 5, 6, 9, 15–18, 21–24	103	Hartley, Eller
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Petitioner also relies on testimony from Troy L. Thornton in support of its challenge. Exs. 1003 and 1039.⁷ In response, Patent Owner relies on testimony from Paul J. Zalesky, Ph.D. Ex. 2033.

Deposition testimony from Mr. Thornton and Dr. Zalesky is also of record. Exs. 1037, 1045, 1047 (Zalesky transcripts); Exs. 2028, 2030, 2031, 2034–2036 (Thornton transcripts).

III. ANALYSIS

A. *Legal Standards*

“In an [*inter partes* review], the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable.” *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016) (citing 35 U.S.C. § 312(a)(3)).

The dispositive question regarding anticipation is whether one skilled in the art would reasonably understand or infer from the prior art reference’s disclosure that every claim element was disclosed in that single reference. *Dayco Prods., Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1368 (Fed. Cir. 2003). “Because the hallmark of anticipation is prior invention, the prior art reference—in order to anticipate under 35 U.S.C. § 102—must not only disclose all elements of the claim within the four corners of the document, but must also disclose those elements arranged as in the claim.”

⁶ The Petition includes a heading labeled as “Grounds 5–7 . . .” (Pet. 76) and a table where claim 10 is listed as being challenged under Ground 5 (Pet. 20). There are, however, no Grounds 6 or 7 and claim 10 is not addressed under Ground 5. We treat the above as typographical errors.

⁷ We address Patent Owner’s objection to Exhibit 1039 in Section IV below.

Net MoneyIN, Inc. v. VeriSign, Inc., 545 F.3d 1359, 1369 (Fed. Cir. 2008) (internal quotation marks omitted).

A claim is unpatentable under 35 U.S.C. § 103 if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious at the time the invention was made⁸ to a person having ordinary skill in the relevant art. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and (4) secondary considerations (i.e., objective indicia) of nonobviousness when presented.⁹ *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

To show unpatentability based on a combination of teachings, “[a]n obviousness determination [also] requires finding both that a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so.” *CRFD Rsch., Inc. v. Matal*, 876 F.3d 1330, 1340 (Fed. Cir. 2017) (internal quotation marks omitted).

⁸ The AIA revised § 103 such that obviousness is assessed “before the effective filing date of the claimed invention,” but *KSR* and other obviousness precedents cited herein remain applicable despite this change in the timing of the obviousness inquiry.

⁹ Petitioner states that it is not aware of any objective indicia of nonobviousness (Pet. 92) and Patent Owner does not provide argument about any objective indicia in this proceeding. *See generally* PO Resp.; Ex. 2033 ¶ 199 (testifying “I have not rendered any opinions on secondary considerations”).

B. Level of Ordinary Skill in the Art

Petitioner proposes that the person of ordinary skill in the art (“POSA”) “would have had an undergraduate degree in mechanical engineering or a related engineering discipline and 2–4 years of product design or engineering experience.” Pet. 16 (citing Ex. 1003 ¶ 35).

Patent Owner elaborates on Petitioner’s proposed POSA definition. PO Resp. 10–12. Patent Owner states that the POSA “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 ’921 Patent.*” *Id.* at 11 (citing Ex. 2033 ¶¶ 60–61) (emphasis added). Patent Owner critiques Petitioner’s proposed POSA level because it “omits any requirement of experience in designing medical devices generally, let alone in the field of the ’921 Patent.” *Id.*

Petitioner’s proposed POSA definition lacks specificity. That definition, if interpreted generically, could mean that a person may qualify as a POSA if they had, for example, a B.S. in mechanical engineering and only two years of experience designing *any type of product in any field*. That is too broad.

We find that a POSA would have had the agreed-upon educational credentials—an undergraduate degree in mechanical engineering or a related engineering discipline. Ex. 1003 ¶ 35; Ex. 2033 ¶ 61.

We find that a POSA would also have had 2–4 years of design or engineering experience related to products in the field of the invention, which involves endovascular devices and the surgical procedures that use such devices. Ex. 1001, 1:16–54 (background of the invention). Such devices include, but are not limited to, hemostasis valves and catheters for

minimally invasive vascular surgeries. *Id.* And, consistent with the testimony of the parties' experts, the POSA need not have had first-hand experience *designing* hemostasis valves. *See, e.g.*, Ex. 1037 (Zalesky Tr.), 72:11–73:7 (testifying direct experience “designing” hemostasis valves or aspiration catheters is not necessary, but “general experience with vascular devices and procedures” is required). Further, as Dr. Zalesky testified, the POSA's experience related to developing such devices “could be as simple as bench testing and looking at clinical data.” *Id.* at 74:5–75:1. Lastly, a POSA would have understood such devices' design requirements as determined by the needs of the physician, patient, and procedure, which understanding may be informed by work experience or study. Ex. 2030, 24:5–21.

Mr. Thornton and Dr. Zalesky each have at least the qualifications of a POSA and can testify about the patentability of the claims from a POSA's perspective. *See, e.g.*, Ex. 1003 ¶¶ 5–14 (summarizing background and qualifications); Ex. 2033 ¶¶ 7–19 (same). Patent Owner's contention that Mr. Thornton's opinions should be rejected because they apply a POSA level that is “too broad” is unavailing. PO Resp. 12. Patent Owner's expert, Dr. Zalesky, concedes that his opinions are also rendered under Petitioner's POSA level and, in related IPRs covering substantially the same hemostasis valve technology, and where substantively identical issues were raised and adjudicated, we found that Mr. Thornton and Dr. Zalesky were qualified and we weighed their testimony accordingly. *See, e.g.*, Ex. 1042, 14 (Final Written Decision in 1157 IPR) (rejecting Inari's position that Thornton's testimony should be discredited as applying a broader POSA level); *see also* Ex. 1049, 13 (Final Written Decision in 289 IPR) (noting Inari's concession that Petitioner's POSA level “doesn't make any difference in this case”).

C. Claim Construction

In an IPR, we construe claims using the same claim construction standard used in a civil action before the courts under 35 U.S.C. § 282(b), including construing claim language in accordance with its ordinary and customary meaning as understood by the POSA, in view of the patent’s specification and considering the patent’s prosecution history. 37 C.F.R. § 42.100(b). We need only construe terms where the parties dispute a term’s meaning and only to the extent needed to resolve the controversy. *Realtime Data, LLC v. Iancu*, 912 F.3d 1368, 1375 (Fed. Cir. 2019).

The parties dispute the interpretation of the term “filament,” which appears in each of the challenged claims. Pet. 17–20; PO Resp. 12–22. We address this dispute below.

Independent claim 1 recites, among other limitations, “an active tensioning mechanism including an actuator coupled to the elongate member via a *filament* extending at least partially around the elongate member.” *See supra* Section II.D. (emphasis added). Claim 3 depends from claim 1 and recites that the “filament extends in a loop around the elongate member.” *Id.*

According to Petitioner, a POSA would have understood a “filament” to mean “at least ‘one or more threads, lines, cords, ropes, ribbons, flat wires, sheets, or tapes.’” Pet. 17 (citing Ex. 1003 ¶¶ 49–59). Petitioner contends that this interpretation is consistent with the Board’s observation that such structures (e.g., thread, ribbon, etc.) are listed as examples of filaments in the disclosure of the related patent challenged in the 1157 IPR. *Id.* at 17–18 (citing Ex. 1017, 12–13); *see also id.* at 19 (citing Ex. 1001, 9:15–17 (disclosing “the filament 150 can comprise one or several threads, lines, cords, rope, ribbon, flat wire, sheet, or tape”))).

Petitioner also argues the claimed “filament” *need not* be thin or flexible. Pet. 18. According to Petitioner, the challenged patent never uses the word “flexible” when describing the filament, construing the term to require flexibility injects ambiguity into the claim, and, in a related patent, the claims recite a filament that “is flexible”—demonstrating that flexibility is not an inherent property of filaments. *Id.* (citing, e.g., Ex. 1003 ¶¶ 51–54; Ex. 1016, claim 1).

For its part, Patent Owner argues that a “filament” should be “accorded its plain and ordinary meaning,” which a POSA would have understood as “a thin, flexible length of material formed by one or more strands of material.” PO Resp. 12–13. According to Patent Owner, this interpretation is consistent with the claims, Specification, and prosecution history and is further supported by extrinsic evidence, including dictionary definitions and the testimony of Petitioner’s own declarant. *Id.* at 14–22 (citing, e.g., Ex. 1001, claim 1, 9:36–37, 9:53–56, Figs. 6–9; Ex. 2028, 123:1–3; Ex. 2030, 131:16–132:12; Ex. 2033 ¶¶ 66–89).

As the parties’ arguments reveal, the issue in dispute is whether the claimed filament must be “flexible.” This dispute has special relevance to Grounds 1 and 2, where Schaffer is the only asserted reference. According to Patent Owner, because filaments require flexibility, Schaffer’s “rigid” actuating members cannot be a filament and, thus, Petitioner has not shown that Schaffer discloses all elements of the valves as claimed. *See, e.g.*, PO Resp. 23–25. Conversely, for Grounds 3–5 there is no dispute that a “filament” is disclosed in the combined teachings of the relied-upon art supporting those grounds, for example, Schaffer plus Hartley (Ground 3). Pet. 22–23, 34–35 (citing Hartley’s “flexible member,” i.e., a “string” as meeting the filament limitation (Ex. 1006 ¶¶ 17, 31)).

We agree with Petitioner that a “filament” encompasses one or more threads, lines, cords, rope, ribbon, flat wire, sheet, or tape. The ’921 patent lists those as exemplary structures that may comprise a filament. Ex. 1001, 9:15–17 (“In some embodiments, the filament 150 can comprise one or several threads, lines cords, rope, ribbon, flat wire, sheet, or tape.”).

That does not, however, address the dispute about “flexibility.” On that issue, the evidence favors Patent Owner’s position that a “filament” as claimed is flexible.¹⁰ We discuss below.

Patent Owner cites intrinsic evidence in support of its interpretation, which include claim 1’s recitation of an “active *tensioning* mechanism” comprising the filament and the Specification’s description of a filament that can be both “loosened” and “tightened.” PO Resp. 14–17 (citing, e.g., Ex. 1001, 9:36–37, 9:53–56 (teaching “the filament 150 is tightened” when the actuator buttons are released and “the filament 150 is loosened” when the buttons are pressed to open the valve)); *see also* Ex. 2025, 1288 (defining “tension” as to “tighten to a desired or appropriate degree”). These descriptions from the patent are more consistent with the view that the filament is characteristically flexible, not rigid.

¹⁰ We reached the same conclusion, based on substantially the same records, in the Institution Decision and the Final Written Decisions in the 1157, 156, and 289 IPRs. Inst. Dec. 14–18; Ex. 1042, 14–24; Ex. 1048, 16–23; Ex. 1049, 14–17 (noting the parties’ agreement at oral hearing that there was no additional argument or evidence about whether a filament requires flexibility that was not already addressed in related matters). After we construed the “filament” term to require flexibility at institution, Petitioner provided no further argument or evidence on this issue in its authorized trial briefing or at oral hearing. *See generally* Pet. Reply.

So too, as we explained in related matters, the '921 patent's loop embodiments (where the filament forms one or more loops like depicted and described in Figures 6–7) require a flexible structure. *See, e.g.*, Ex. 2032, 15–16 (explaining that the device would not work to constrict the tubular sidewall and lumen (analogous to the elongate member defining a lumen of the claims here) if the filament forming the loop(s) was inflexible); Ex. 1001, Figs. 6–7 (filament 150, with sub-filaments 150-A and 150-B). Although flexibility of the filament in the patent's "bight" embodiments (e.g., as shown in Figures 8 and 9) is less clear, there is a dearth of evidence from Petitioner—either intrinsic or extrinsic to the patent—showing why a POSA would have understood the bights as embracing rigid structures. *See* Ex. 1001, Figs. 8–9. Moreover, as admitted by Petitioner's expert, that a filament may be made from various materials described in the patent (e.g., synthetics or metals) does not, absent more information, lead to a conclusion that a filament is "rigid." Ex. 2030, 125:2–126:4 (testifying "the relative stiffness or rigidity is not clear from those . . . materials without knowing much more information").

Patent Owner also cites excerpts of the prosecution history in support of its proposed construction. PO Resp. 19–21. As Patent Owner points out, the Examiner cited only flexible structures in the prior art as satisfying the claimed "filament" for the '921 patent and related applications and never cited inflexible/rigid valve features as doing so. *Id.* (arguing Examiner understood and applied Hartley's string as being the "filament"—not the "rigid actuating structure[s]" of other cited references); Ex. 1002, 25–26, 29; Ex. 2033 ¶¶ 76–87 (reviewing prosecution history and testifying that the Examiner's express or tacit determination that the slider, pinch elements, and clamp/rib of Wong, Kees, and Williams did not teach a "filament" is

consistent with a determination that the plain and ordinary meaning of a filament is not rigid and instead requires flexibility).

Extrinsic evidence also lends support to Patent Owner’s interpretation of a “filament” as requiring flexibility. Patent Owner cites, for example, dictionaries that define a filament as “a single thread or a thin flexible threadlike object, process, or appendage” and “a slender threadlike object or fiber.” PO Resp. 21 (citing Ex. 2025 (Merriam-Webster Collegiate Dictionary), 467; Ex. 2026 (New Oxford American Dictionary), 644). And Patent Owner cites Mr. Thornton’s concession at deposition in related court proceedings that “in the ordinary meaning of filament, it has flexibility.” *Id.* at 13 (quoting Ex. 2028, 123:1–3); *see also* Ex. 2029 (Thornton patent), 8:7–9, 8:53 (equating a “filament” with a “thread-like element” that can be “laced or threaded” through other structures).

Petitioner’s argument that the ’921 patent never uses the word “flexible” to describe the filament is literally true but not decisive. *See* Pet. 18–19 (counterarguments against construing to require flexibility). Neither does the patent use the words “rigid,” “inflexible,” or the like to describe a filament. And Petitioner has not accounted for the intrinsic and extrinsic evidence discussed above, which would require flexibility or is at least more suggestive that, in its plain and ordinary meaning, a filament is flexible.

As to whether requiring that a filament be “flexible” injects ambiguity into the claims (as potentially a term of degree), evidence indicates a POSA would have understood the level of flexibility needed for the claimed valves to work as described. *See* Ex. 2033 ¶ 90 (testifying the filament would be flexible to the degree needed to loosen or slacken when the actuator is depressed); Ex. 2031, 44:14–20 (testifying, in response to the question “a person of ordinary skill in the art in 2017 would have understood what that

level of flexibility would be, wouldn't they?" that "I think they could figure it out").

Finally, the recitation in a related patent's claim that a "first filament is flexible" fails to demonstrate persuasively that flexibility is not a requirement of the term "filament" alone. Pet. 18 (citing Ex. 1016, claim 1). The claim in question from the related patent is an apparent instance of redundancy in the language chosen because additional claim elements already suggest that the filament is flexible—and would do so even if the express recitation of "flexible" was missing. *See ERBE Elektromedizin GmbH v. Canady Tech. LLC*, 629 F.3d 1278, 1286 (Fed. Cir. 2010) (explaining that "surplusage may exist in some claims"). That additional language includes, for example, "a first filament extending in a first loop around the tubular member" with first and second portions of the filament operably connected, respectively, to first and second actuators, as well as the requirement that the actuators are positioned to "tension" and "loosen" the filament when those actuators are operated. Ex. 1016, claim 1. Based on the current record, we are unpersuaded that this evidence justifies construing the term "filament" in the challenged claims of the '921 patent as encompassing flexible *and inflexible* structures.

For the reasons above, and consistent with our claim construction determinations in related matters challenging related patents, we conclude that the evidence supports Patent Owner's position and a POSA would have understood the plain and ordinary meaning of filament as a flexible length of material (e.g., one or more string(s), wire(s), tape(s)). *SightSound Techs., LLC v. Apple Inc.*, 809 F.3d 1307, 1316 (Fed. Cir. 2015) ("Where multiple patents derive from the same parent application and share many common

terms, we must interpret the claims consistently across all asserted patents.”) (internal quotation marks omitted).

To the extent the parties may disagree about the scope or application of other aspects of the claims, we address such disagreements below when analyzing the mapping of the prior art to the claims.

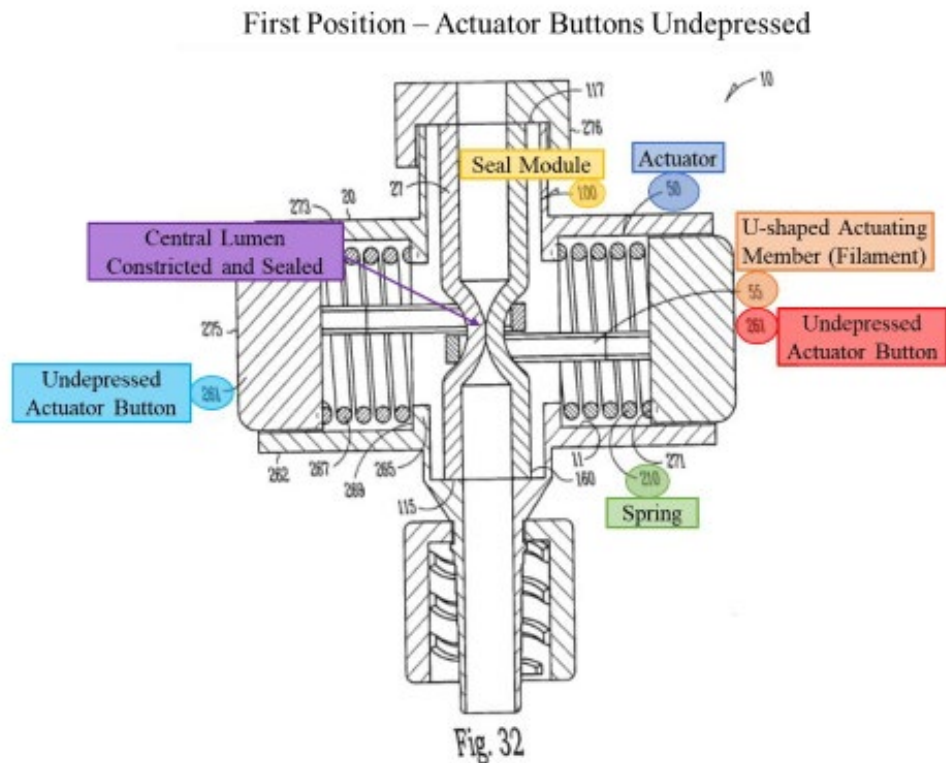
D. Asserted References

Petitioner asserts, and Patent Owner does not dispute, that Schaffer, Hartley, and Eller are each prior art under 35 U.S.C. § 102(a)(1). Pet. 20.

1. Schaffer (Ex. 1005)

Schaffer is a U.S. patent application that published December 4, 2003. Ex. 1005, code (43). Schaffer is titled “Composite Stasis Valve” and describes a “valve for blocking the flow of gas or fluid with or without an instrument in place within the gas/fluid path.” *Id.* at Abstr., code (54); *see also id.* ¶¶ 2–3 (disclosing that Schaffer “relates to catheters, in particular to composite fluid-stasis valves for use with catheters” and “[f]luid stasis mechanisms are commonly used to prevent loss of fluids from the insertion site of a catheter”).

An embodiment of Schaffer’s fluid-stasis valve, including Petitioner’s annotations, is shown below.



Pet. 28 (Ex. 1008, Fig. 32¹¹ (annotated)); Ex. 1005, Fig. 32, ¶ 75 (“FIGS. 30–34 illustrate one embodiment of the stasis valve 10 including a seal module 100 having a lumen sized to allow the passage of fluids or gases.”); Ex. 1008, 16–19 (Figs. 30–34). Schaffer’s Figure 32, above, is a cross-sectional view of valve 10 in a “first position,” where actuator buttons 261 (light blue and red highlights) are undepressed, allowing seal module 100 (yellow highlight) to take on a collapsed configuration such that a central lumen (purple highlight) is at least partially collapsed/constricted and sealed by a compressive force provided by spring(s) (green highlight), which force is applied to U-shaped actuating member(s) 55 (orange highlight) that Petitioner argues are a “filament.” Ex. 1005, Fig. 32, ¶¶ 75–77; Pet. 28.

¹¹ Petitioner uses drawings from the Schaffer application submitted during prosecution (Ex. 1008) due to those drawings’ improved clarity versus the version of the drawings appearing in Schaffer as published. Pet. 4 n.2.

Schaffer discloses that, in the first position, actuating members 55 “are, in one option, disposed at least partially circumferentially [*sic*] disposed about” the seal module “depressing and at least partially collapsing a portion 108 of the containment structure 160 by a compressive force 67 (e.g., by a spring 210).” Ex. 1005 ¶ 77. Schaffer teaches actuating members may optionally comprise aluminum or plastic. *Id.* ¶¶ 81, 82 (actuating members and buttons may, for example, be machined from aluminum).

When the actuator buttons are pressed, the valve takes on a “second [open or unsealed] position.” Ex. 1005 ¶ 77, Fig. 34 (showing the valve with both buttons depressed such that central portion of the valve lumen/seal module retracts to an unsealed configuration). According to Schaffer:

In the second position, the actuators 50 are disposed away from a portion 108 of the seal module 100 by a compressive force 67 (e.g., by depressing the distal end 275 of the actuator button 261). As each actuator button 261 is depressed, each actuator 50 slides along the cylindrical interior wall 11 of the housing 20. The proximal end 273 of each actuator button 261 compresses the distal end 271 of each resilient member 267 which in turn, the proximal end 269 of each resilient member 267 compresses against the inner flange wall 265 of the housing 20. Such movement allows each engaged actuating member 55 to forcibly disengage opposing outer walls 27 of seal module 100 allowing the portion 108 of the containment structure 160 to retract to an uncollapsed configuration where gases and fluids can pass therethrough.

Id. ¶ 77, Fig. 34.

2. *Hartley (Ex. 1006)*

Hartley is a U.S. patent application that published June 26, 2003. Ex. 1006, code (43). Hartley is titled “Access Valve” and relates to an access valve for laparoscopic or intraluminal deployment devices. *Id.* at Abstr., code (54); *see also id.* ¶ 3 (“The invention will be discussed in . . .

relation to fluid flow prevention and access valves in medical applications for instance where it is desired to seal around a catheter or other instrument . . . to prevent loss of blood or other fluid.”).

Hartley’s Figure 5 is reproduced below.

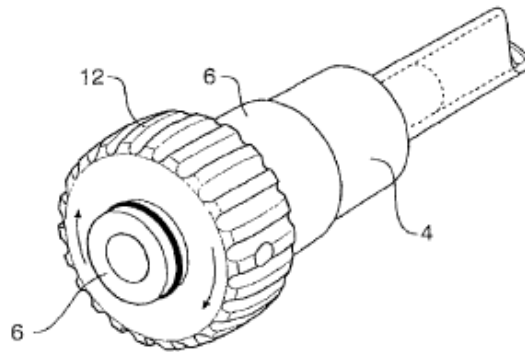


Fig 5

Ex. 1006, Fig. 5. Figure 5 above is a perspective view of an illustrative delivery catheter and constriction valve described in Hartley. *Id.* ¶ 29. The valve includes, *inter alia*, catheter body 4, cylindrical housing 6, and rotary actuator 12. *Id.* ¶ 31.

The action of Hartley’s valve is more clearly seen in Figures 3 and 4, reproduced side-by-side below.

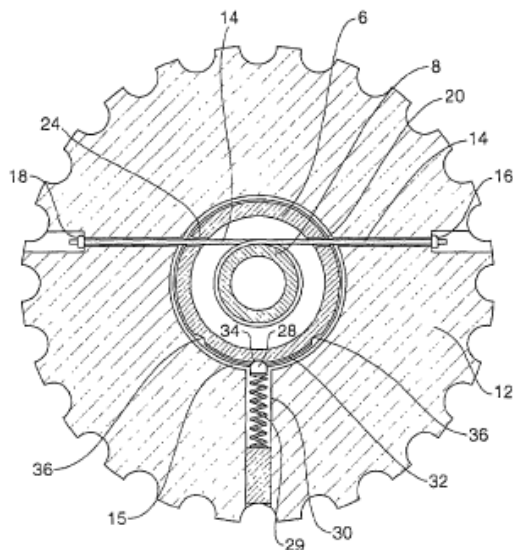


Fig 3

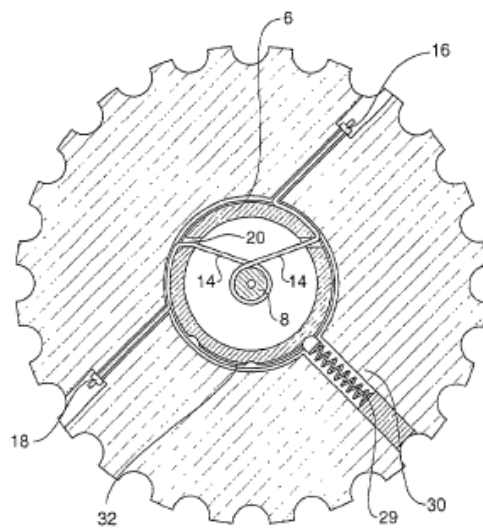


Fig 4

Ex. 1006, Figs. 3–4. Figures 3 and 4 of Hartley are top, cross-sectional views of a constriction valve, showing, respectively, the valve in an open and closed configuration. *Id.* ¶¶ 27–28, 31–34. In the open configuration (above left), rotary actuator 12 is mounted to cylindrical housing 6, and a string 14 is mounted to portions of the rotary actuator with knots 16, 18. *Id.* ¶ 31. String 14 (or another suitable flexible member) is wound around a cylindrical elastomeric diaphragm 8. *Id.*; *see also id.* ¶¶ 16–17 (“The flexible member may be a string, suture or band or other suitable material.”).

Hartley teaches that “[r]otation of the rotary actuator 12 with respect to the cylindrical housing 6 will cause the string 14 to be pulled in both directions at once and hence the cylindrical diaphragm 8 to be constricted” and sealed as shown in Figure 4 (above right). Ex. 1006 ¶¶ 31, 34. According to Hartley, its invention provides “an access or constriction valve arrangement which will close over a range of diameters of devices passed through the valve or can close completely down to be self[-]sealing.” *Id.* ¶ 37.

3. *Eller (Ex. 1007)*

Eller is a U.S. patent that issued May 29, 2018, from an application filed April 17, 2015. Ex. 1007, codes (22), (45). Eller relates to “[s]elective fluid barrier valve devices” and methods of treatment using such devices. *Id.* at Abstr.

Eller describes “a selective fluid barrier device compris[ing] a housing, an actuator, a sleeve, a wire member, and a connector.” Ex. 1007, Abstr. “The sleeve defines a passageway that extends through the [valve]” and “[t]he actuator is movable between a first position and a second position” where the first position allows fluid to pass through the sleeve and, in the second position, fluid cannot pass through the sleeve. *Id.*

An embodiment of Eller's selective fluid barrier valve device is shown in Figure 15 below.

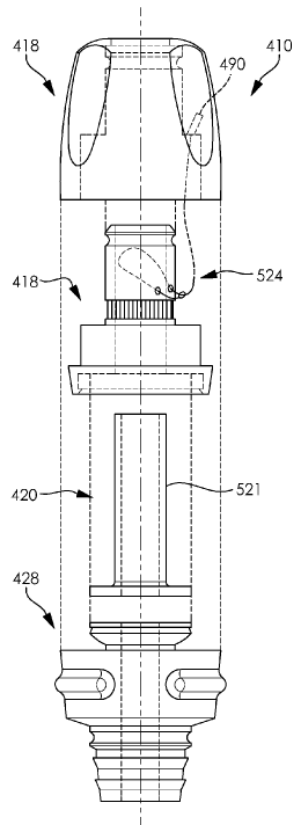


FIG. 15

Ex. 1007, Fig. 15; *see also id.* at Figs. 1–2 (perspective and exploded views of similar valve device). Figure 15, reproduced above, is an exploded view of an illustrative selective fluid barrier valve of Eller. The valve device 410 includes, among other features, actuator 418, sleeve 420, and a wire member 422 (not labeled) with a first end 524 attached to actuator 418 within cavity 490. *Id.* at 21:37–22:24 (“wire member can be positioned such that it extends at least one full revolution around the outer surface of the sleeve”); *see also id.* at Figs. 16–17 (showing wire 422 looped around sleeve 420 within housing 416). As disclosed in Eller, movement (e.g., rotation) of the actuator from its first position to its second position pulls the wire member to constrict and close sleeve 420. *See, e.g., id.* at 22:25–31, 1:55–2:6

(disclosing that, in the second configuration, “the sleeve passageway is closed and prevents fluid from passing”). Eller further teaches that the valve device can “be biased to the second [(closed)] configuration” by, for example, using a spring. *Id.* at 19:22–30.

Eller teaches that its disclosure applies to many types of actuators. Ex. 1007, 8:27–44. According to Eller, “while a rotatable member 29 has been illustrated, a selective fluid barrier valve device can include any suitable actuator capable of moving . . . between a first configuration and a second configuration. Skilled artisans will be able to select a suitable actuator” and “[e]xample actuators . . . include rotatable actuators, linear actuators, slidable actuators . . . and any other actuator considered suitable for a particular embodiment.” *Id.*

Eller discloses 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.” Ex. 1007, 15:61–16:6 (teaching “wire member can comprise a suture or a cable”). Eller discloses that “[a]ttachment between a wire member and a housing and/or an actuator can be accomplished using any suitable method or technique” including, for example, “adhesives, welding, [or] fusing.” *Id.* at 14:37–53.

E. Anticipation by Schaffer (Ground 1)

Petitioner contends that Schaffer describes a valve having all the elements of claims 1–7, 9, 10, 15–18, and 20–24, and, thus, Schaffer anticipates those claims. Pet. 21–75.¹² We focus on claim 1 below, noting that each of the challenged claims requires a valve comprising, among other

¹² Petitioner intersperses its anticipation and obviousness analyses for Grounds 1–4 throughout pages 21–75 of the Petition.

that Schaffer describes a valve with a filament as claimed. If, as construed above (*supra* Section III.C), a filament requires flexibility, Petitioner has not demonstrated that Schaffer describes that feature in its valves. Instead, Patent Owner persuades us that Schaffer describes “*rigid* U-shaped actuating members—not a ‘filament.’” PO Resp. 23–24.¹³ We find Dr. Zalesky’s interpretation of Schaffer more credible than Mr. Thornton’s on the question of whether a POSA would have regarded Schaffer’s actuating members as being substantially rigid structures. Ex. 2033 ¶¶ 91–100 (testifying, *inter alia*, that a POSA would have understood from Schaffer’s disclosure about making the actuator and actuating members from machining pre-existing amounts of metals and/or plastics, and further explaining that flexible parts would deform and be difficult to machine through conventional techniques); Ex. 1005 ¶¶ 81–82.

Mr. Thornton testifies that Schaffer’s disclosed manufacturing techniques for the actuator/actuating members are only examples and “a person of ordinary skill in the art could have simply purchased pre-made [and flexible] flat wire or plastic tapes or ribbons.” Ex. 1003 ¶ 79. Such testimony invokes, at best, obviousness-based reasoning. This does not establish that Schaffer alone describes a filament sufficient to anticipate the claims. *Trintec Indus., Inc. v. Top-U.S.A. Corp.*, 295 F.3d 1292, 1296 (Fed.

¹³ At institution, we also found persuasive Patent Owner’s argument that Petitioner “implicitly admits” that Schaffer’s actuating members are rigid insofar as Petitioner argues those members would form gaps for fluid leakage around tools inserted through the central lumen when in use and compared to the use of a flexible string or wire (of Hartley or Eller). Inst. Dec. 26. Petitioner provided no response on this point here, and did not raise any argument in its authorized Reply or at oral hearing on the asserted anticipation by Schaffer (i.e., Ground 1). *See generally* Pet. Reply.

Cir. 2002) (explaining that the “test for novelty” requires “strict identity”); *Jamesbury Corp. v. Litton Indus. Prods., Inc.*, 756 F.2d 1556, 1560 (Fed. Cir. 1985) (holding “anticipation is not shown by a prior art disclosure which is only ‘substantially the same’ as the claimed invention”), *overruled on other grounds*, *A.C. Aukerman Co. v. R.L. Chaides Constr. Co.*, 960 F.2d 1020 (Fed. Cir. 1992) (en banc).

For the reasons above, Petitioner has not shown that Schaffer anticipates the challenged claims.¹⁴

F. Obviousness over Schaffer (Ground 2)

Petitioner argues that, even if Schaffer did not disclose filaments having a structure and flexibility sufficient to constrict and seal the central lumen against leakage, a POSA “would have found it obvious to modify the actuating members to closely conform to the seal module” where, for instance, a POSA “could have selected a thin, flexible sheet or flat ribbon of aluminum or plastic to form the actuating members.” Pet. 32–33 (citing Ex. 1003 ¶ 81).

Petitioner’s analysis and evidence for Ground 2 is threadbare and unpersuasive. Under this ground, Petitioner cites, for example, no disclosure of “thin, flexible sheet[s] or flat ribbon[s]” representing the claimed

¹⁴ In related cases and based on materially identical records, we likewise determined in final written decisions that Schaffer’s valves did not anticipate the challenged claims due to the lack of any disclosed “filament.” *See, e.g.*, Ex. 1042, 30–38 (“Petitioner does not persuade us that Schaffer’s U-shaped actuating members satisfy claim 1’s ‘filament’ limitation.”); Ex. 1048, 33–41 (same); *see also* Ex. 1049, 26–32 (rejecting Petitioner’s challenge based on obviousness over another reference (Garrison) combined with Schaffer, and applying the same reasoning because Schaffer was relied on as teaching the alleged “filament”). Our reasoning from these related cases applies here.

“filament” in any reference.¹⁵ We explained this deficiency in Petitioner’s showing at institution (*see* Inst. Dec. 27–28), and Petitioner raised no further argument or evidence in support of Ground 2 during the trial phase. *See generally* Pet. Reply (providing arguments on Grounds 3–5 only); PO Sur-reply 6 (“Petitioner does not provide any additional arguments or evidence here to contest those findings” on Grounds 1 and 2); *see also* Tr. (no distinct argument from Petitioner on Grounds 1 or 2).

For the above reasons, we conclude that the preponderance of the evidence does not demonstrate obviousness of the challenged claims over Schaffer alone (i.e., Petitioner’s Ground 2).

G. Obviousness over Schaffer and Hartley (Ground 3) or Schaffer and Eller (Ground 4)

Petitioner contends that claims 1–7, 9, 10, 15–18, and 20–24 would have been obvious over Schaffer and Hartley (Ground 3) or Schaffer and Eller (Ground 4). Pet. 21–47 (allegations related to claim 1), 47–75 (remaining challenged claims). The discussion above concerning whether the claims require a “flexible” filament and whether Schaffer discloses this subject matter is not decisive because there is no dispute that both Hartley and Eller disclose a “filament” within the scope of the claims. *See, e.g., id.* at 33–39 (discussing Hartley’s teaching of, *inter alia*, a flexible string that may be wrapped around seal module of the modified Schaffer valve), 40–46 (same with respect to Eller’s wire).

¹⁵ To the extent this position is read as a prelude to Petitioner’s much more developed arguments under Grounds 3 and 4, where Petitioner expressly relies on Hartley’s and/or Eller’s undisputed disclosure of a “filament” in a hemostasis valve for use in combination with Schaffer’s teachings, we address those grounds in the sections below.

Because of the overlap in Petitioner’s arguments for Grounds 3 and 4, as well as the overlap in Patent Owner’s rebuttal for those grounds, our discussion below addresses both grounds together, and we focus on claim 1 as illustrative. We discuss dependent claim 10, and the separate arguments that Patent Owner raised on that claim, in a separate subsection below.

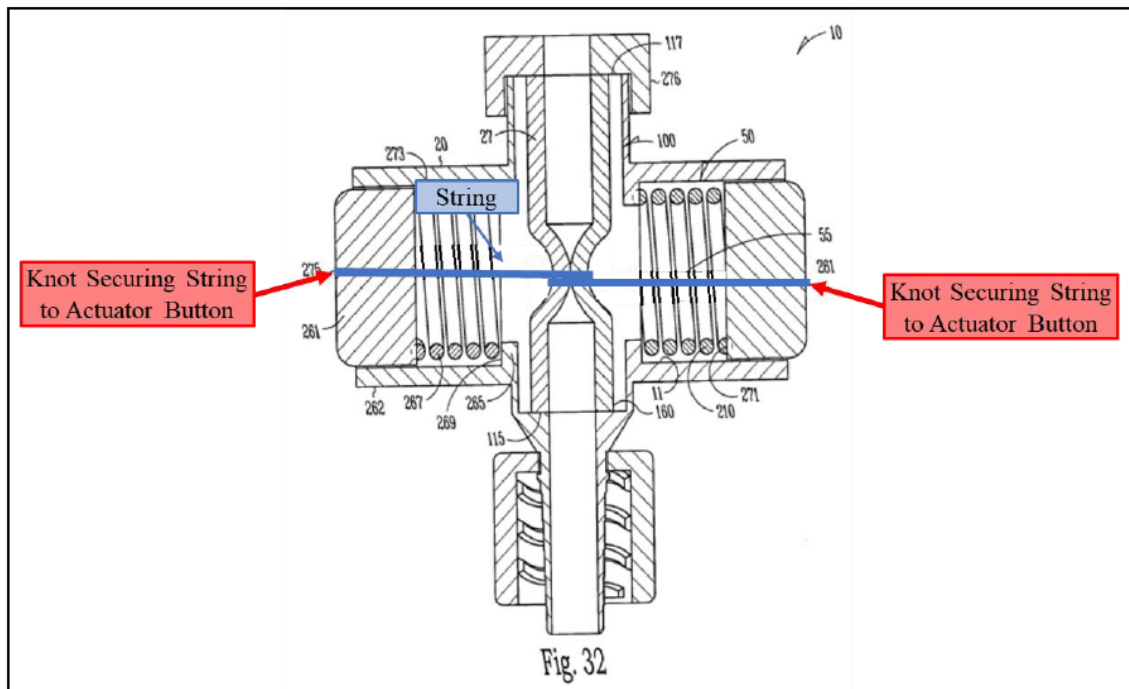
I. Petitioner’s Contentions

Petitioner argues that Schaffer teaches a hemostasis valve of claim 1 comprising, *inter alia*, an actuator that allows the valve to move from a first (closed or sealed) position to a second (open or unsealed) position. Pet. 24–29 (citing, e.g., Schaffer’s actuator buttons on opposite sides of the valve housing; Ex. 1005 ¶¶ 75–77, Figs. 31–32, 34). Petitioner argues that Schaffer discloses a “biasing member” as claimed, which comprises Schaffer’s two resilient members or “springs” that bias Schaffer’s actuator buttons to the first (closed) position. *Id.* at 46–47 (citing Ex. 1005 ¶ 76, Fig. 31; Ex. 1003 ¶¶ 107–109). Petitioner further argues that Schaffer discloses an elongate member that defines a lumen, the opening and closing of which is controlled by the pressing and releasing of Schaffer’s spring-activated actuator buttons. *Id.* at 24–27 (citing Ex. 1005 ¶¶ 49, 51, 54, 74–75, Fig. 12 (showing seal module 100 defining valve lumen 193), Figs. 32 (showing buttons released and valve lumen closed), 34 (showing buttons pressed and valve lumen open)). Petitioner contends Schaffer teaches that each actuator button is coupled to an actuating member (where each member is, in one option, “U-shaped”) and that the “actuating members couple the actuator buttons to the elongate member.” *Id.* at 27 (citing, e.g., Ex. 1005 ¶ 76, Fig. 32). Petitioner’s argument and evidence on the above points is undisputed.

For Grounds 3 and 4, Petitioner proposes substituting the U-shaped actuating members in Schaffer's valves with another structural lumen-sealing feature used in the hemostasis valves of Hartley or Eller. Pet. 33–46. Petitioner, citing Hartley's flexible string as a "filament," argues that it would have been obvious to substitute Hartley's string for Schaffer's two U-shaped actuating members and, Petitioner contends, that modification would meet claim 1's recited active tensioning mechanism comprising a "filament." *Id.* at 33–39 (citing, e.g., Ex. 1006 ¶¶ 31, 34, 37, Figs. 1–4); Ex. 1003 ¶ 87 (testifying the combination of Hartley's string and Schaffer's valve "would have merely entailed the substitution" of one known element (Hartley's string) for another (Schaffer's actuating members)). Petitioner makes essentially the same argument concerning substitution of Schaffer's actuating members for Eller's flexible wire member as the claimed "filament." *Id.* at 40–46 (citing, e.g., Ex. 1007, 5:1–5, 15:41–16:19, Figs. 2, 15, 16; Ex. 1003 ¶¶ 95–106).

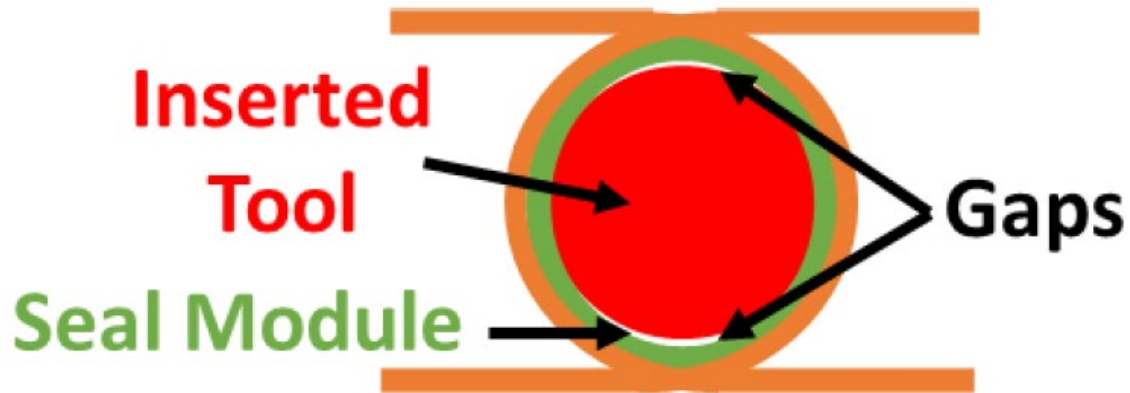
The image below illustrates Petitioner's proposed combination of Schaffer and Hartley.

Demonstrative Illustration Schaffer + Hartley's String



Pet. 37–38 (Petitioner’s annotated/modified version of Schaffer’s Figure 32). The above image shows Schaffer’s valve in cross section (from Schaffer’s Figure 32) modified to replace Schaffer’s actuating members with Hartley’s string (blue highlight), which wraps around the outer wall of a central portion of seal module 100. *Id.* (citing Ex. 1003 ¶¶ 89–94; Ex. 1006 ¶ 31). Petitioner contends that, by a “simple” technique taught in Hartley, a POSA would have been able to attach the string’s ends (e.g., by knots) to the respective actuator buttons of Schaffer (red highlights). *Id.*

Petitioner further contends that a skilled artisan would have recognized that, depending on the diameter and shape of the tool inserted into the valve’s central lumen during surgical procedures, Hartley’s string may provide a more effective seal than Schaffer’s U-shaped actuating members. Pet. 36 (citing, e.g., Ex. 1003 ¶¶ 85–86). The graphic below helps illustrate Petitioner’s reasoning.



Id. The above graphic shows a longitudinal view of a seal module (i.e., tubular body with a tubular sidewall) defining a lumen (green) with a tool/device (red) with a circular diameter inserted through that lumen. *Id.* The graphic shows two opposing and overlapping U-shaped features (orange) that represent Schaffer’s U-shaped actuating members as they are being pulled against the outer walls of the tubular member (e.g., seal module) to form a fluid seal in the lumen. *Id.* But, as Petitioner argues and the graphic shows, “small gaps” (white space labeled “Gaps”) may form between the valve’s lumen and the outer surface of the inserted tool or device in this arrangement, possibly allowing fluid/blood leakage. *Id.*

According to Petitioner and Mr. Thornton, “Hartley’s string could improve upon this potential issue because the string more precisely conforms to the tool diameters and shapes.” Pet. 36 (citing Ex. 1003 ¶ 86). In other words, because the single string would encircle the compressible seal module, when its ends are pulled in opposite directions and the string is placed under tension, the string could more precisely conform to the outer dimensions of the seal module and the shapes of tools inserted into the lumen of such seal module and reduce the formation of such gaps. Ex. 1003 ¶ 86 (testifying “Hartley’s string encircles and, depending on the materials, may conform to the size and shape of a wider range of tools used with the

valve,” which ability to accommodate a range of tool sizes and shapes “would have been a highly desirable feature” in 2017); *see also* Ex. 1006 ¶ 37 (teaching that Hartley’s string can “close over a range of diameters of devices passed through the valve or can close completely down to be self-sealing”). According to Petitioner, this possible benefit would have provided further reason for the POSA to make the proposed modification. Pet. 36; Ex. 1003 ¶ 86.

Furthermore, Petitioner contends, POSAs had “a finite number of materials to use for constricting a tubular member in a hemostasis valve in 2017.” Pet. 37 (citing Ex. 1003 ¶ 88). According to Petitioner, Hartley and Schaffer disclose two such options: Hartley’s string and Schaffer’s plastic or metal U-shaped actuating members. *Id.* Petitioner contends that “Eller discloses a third option: wire members.” *Id.* Petitioner contends that a POSA “would have found it obvious to select from these finite, predictable options” for use in sealing a lumen of a hemostasis valve. *Id.*

Petitioner contends a POSA would have reasonably expected success modifying the Schaffer valve as proposed. Pet. 37–39. According to Petitioner, Hartley’s string would function in a similar way to Schaffer’s U-shaped actuating members—constricting and collapsing the valve’s central lumen due to a force applied by the opposing springs and actuator buttons that pulls the string in opposite directions. *Id.* (citing, e.g., Ex. 1005 ¶ 77; Ex. 1006 ¶¶ 31, 34; Ex. 1003 ¶¶ 89–94). Petitioner contends that straightforward techniques (like knotting taught in Hartley) would have been suitable for connecting the ends of the string to Schaffer’s actuator buttons. *Id.* at 37–38 (citing Ex. 1006 ¶ 31; Ex. 1003 ¶ 90). And, if selection of more or less resilient materials would have been necessary, Petitioner contends such materials were known in the art and that such adjustments would have

involved no more than ordinary skill. *Id.* at 39 (citing Ex. 1005 ¶ 81; Ex. 1007, 36:27–60; Ex. 1003 ¶¶ 92–94).

As noted above, Petitioner’s proposed combination of Schaffer and Eller (Ground 4) is similar, but uses Eller’s flexible “wire member” as the alleged “filament” in essentially the same way as Hartley’s string is used and depicted above in the modified Schaffer valve. Pet. 40–46. The stated reasons for making the wire member substitution and reasonable expectation of success echo the Schaffer-Hartley combination discussed above. *Id.* (citing, e.g., Ex. 1007, 14:37–49, 15:21–40, 17:47–18:3; Ex. 1003 ¶¶ 95–106). Further, Petitioner points out, Eller teaches that any suitable wire-attachment technique (e.g., welding, friction fit, adhesives) can be used and its disclosures can be applied with any suitable actuator, including rotatable actuators or linear actuators like Schaffer. *Id.*; *see, e.g.*, Ex. 1007, 8:27–39.

2. Patent Owner’s Counterargument

Patent Owner argues that Petitioner’s reasoning for modifying Schaffer’s valve based on the alleged formation of small gaps (potential leak paths for fluid) is flawed because Schaffer’s valve allegedly has no leakage problem requiring any solution. PO Resp. 29–38. According to Patent Owner, Schaffer teaches that its valves form a “complete” fluid seal. *Id.* (citing, e.g., Ex. 1005 ¶¶ 6, 8, 60, 68, 77; Ex. 2033 ¶¶ 53–57, 121–130). If Schaffer’s valve provided a complete seal, Patent Owner reasons, there would have been no need to make changes based on Hartley’s string or Eller’s wire. *Id.*

Patent Owner further argues Schaffer’s valve forms a complete seal with or without instruments inserted, and even around multiple instruments. PO Resp. 32–36. According to Patent Owner, Schaffer, through the use of rigid U-shaped members that compress a highly compliant third seal

member (165), which member comprises a material that can be compared to a sticky or gelatinous substance, produces a complete fluid seal. *Id.* (citing, e.g., Ex. 1005 ¶ 68 (disclosing “seal member 165 is so compliant that it forms a seal around [multiple] instruments 260 even if the instruments are irregularly shaped”), Figs. 16–19); *see also* Ex. 1005 ¶ 59 (disclosing valve creates “nearly fluid/gas tight seal under very light compression” using material that “can be compared to a gelatinous substance”). In contrast, Patent Owner argues, Petitioner’s proposed combination would seal less effectively around multiple instruments if “two circular instruments were inserted side-by-side through Schaffer’s seal module.” PO Resp. 37–38 (depicting a hypothetical two-instrument scenario and “Gaps” if Hartley’s string was used). Thus, Patent Owner argues the proposed modification would have been an unsuitable solution.

Patent Owner also argues that there would have been no motivation to modify Schaffer as proposed because doing so would change Schaffer’s principle of operation. PO Resp. 55–61. According to Patent Owner, Schaffer uses “rigid” actuating members and replacing those members with a string or wire would not allow “forcible disengagement” from the seal module. *Id.* at 56–57 (arguing Hartley’s string “would never disengage” Schaffer’s seal module); Ex. 1005 ¶ 77 (disclosing that depressing the two buttons in Schaffer’s valve, such as shown in Figs. 30–34, “allows each engaged actuating member 55 to forcibly disengage outer walls 27 of the seal module 100 allowing the portion 108 of the containment structure 160 to retract to an uncollapsed configuration where gases and fluids can pass”). Patent Owner also argues the proposed change to a string or wire would make assembling the valve more difficult and undermine its durability. PO Resp. 57–61 (citing Ex. 2033 ¶¶ 149–160). Patent Owner cites Schaffer’s

exemplary manufacturing and assembly techniques that produce, or benefit from, rigid actuating members. *Id.* (citing Ex. 1005 ¶¶ 82–83).

Patent Owner also argues that Petitioner’s proposed modification of Schaffer to include a flexible string or wire is “not a simple substitution.” PO Resp. 38–45. According Patent Owner, each of Schaffer’s actuating member is attached to its own actuator button. *Id.* at 42. In Hartley and Eller, however, Patent Owner contends the string and wire are not attached to *two* independently controllable actuators. *Id.* at 42–45 (explaining that Hartley’s string is wound around a lumen and its ends are attached to a single rotary actuator that places tension on the string; explaining that Eller’s wire is disposed around a collapsible lumen and has one end attached to a stationary point (e.g., a valve housing) and the other end attached to a movable (e.g., rotatable) actuator). According to Patent Owner, Petitioner’s arrangement including a string/wire having its ends attached to two separate actuators is not known in the art and, thus, the modification proposed by Petitioner is not simple. *Id.*; Ex. 2033 ¶¶ 151–152.

Patent Owner further argues that, even if a POSA would have understood that Schaffer’s valve could form gaps for fluid leakage, more plausible alternatives existed that would have improved Schaffer’s seal and solved the problem. PO Resp. 46–49. Patent Owner contends that “simple” changes, including options suggested in Schaffer, could address sealing issues, including adjusting the spring strength, or modifying the resilience or compressibility of the seal module. *Id.* (citing, e.g., Ex. 2033 ¶¶ 170–172; Ex. 1005 ¶ 59). Thus, Patent Owner argues, a POSA would have adopted such simpler fixes, not the modifications proposed by Petitioner. *Id.*

Patent Owner also argues that the possible options for constricting a tubular member in a hemostasis valve were not finite, identifiable, or known,

and, thus, Petitioner has not shown that it would not have been “obvious to try” the proposed modifications using Hartley’s string or Eller’s wire in Schaffer’s valve. PO Resp. 54–55. According to Patent Owner, Mr. Thornton admitted that there were more than three ways of sealing a hemostasis valve, undermining his initial testimony that the options were limited. *Id.* (citing, e.g., Ex. 2031, 107:3–13).

Lastly, Patent Owner argues that Petitioner’s advancement of multiple simple substitution theories in this IPR (and the related IPRs) shows a hindsight bias. PO Resp. 51–53. Patent Owner cites three theories raised by Petitioner: (1) substituting a single string for both of Schaffer’s actuating members as argued in this and several earlier-filed cases; (2) replacing each of Schaffer’s actuating members with a string (i.e., two strings with one string attached to one button and the other string attached to the opposite button) as urged for dependent claim 10 here; and (3) substituting two strings for the actuating members where each string has an end attached to each button (i.e., duplicating the arrangement of theory number (1) above), as asserted in a more recently filed case. *Id.* at 52 (citing, e.g., IPR2025-01562, Paper 2 at 48–49). Patent Owner also argues that, contrary to the alleged simplicity of these theories, Petitioner’s expert had never seen a string or wire being used to constrict hemostasis valve’s lumen prior to his work on this family of related IPRs. *Id.* (citing Ex. 2034, 14:1–11); PO Sur-reply 7–10 (arguing hindsight is revealed through Petitioner’s different and “continually changing” theories).

3. *Analysis*

a) *Claim 1*

For reasons discussed below, Petitioner persuades us that claim 1 would have been obvious over the art asserted under Grounds 3 and 4, and Patent Owner’s counterargument is unavailing.

Petitioner explains persuasively, with evidence-backed argument, where each of the features of the hemostasis valve of claim 1 are taught or suggested in the *combined* teachings of Schaffer and Hartley (or Eller). Pet. 24–47 (addressing, *inter alia*, where Schaffer discloses a “valve” as recited in the preamble (if limiting), as well as the “elongate member,” “actuator,” and “biasing member” limitations); Ex. 1005, Figs. 31–32; Ex. 1008 (same); Ex. 1003 ¶¶ 65–109. Although Schaffer alone does not disclose the claimed “filament,” Petitioner shows that limitation is taught in Hartley (or Eller) and that, in combination with Schaffer, claim 1’s “active tensioning mechanism” recitation would be met. Pet. 26–46 (citing, e.g., Ex. 1006 ¶¶ 5, 17 (“flexible member may be a string, suture or band or other suitable material”), 31, Figs. 1–4), 40–46 (citing Ex. 1007, 15:41–60 (wire member “can be formed of any suitable material . . . and skilled artisans will be able to select a suitable material” appropriate to the embodiment, including “metals such as steel, stainless steel, titanium” and “polymers” such as “polypropylene” and “Nylon”), 15:61–16:6 (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”))). Patent Owner does not argue otherwise.¹⁶

¹⁶ If any of Patent Owner’s argument against the reasons for modifying Schaffer with Hartley or Eller are somehow construed as an argument that

We also agree with Petitioner that a POSA would have had reasons for combining the teachings of Schaffer and Hartley (or Eller) in the manner proposed and done so with a reasonable expectation of success in producing the valve of claim 1. *See, e.g.*, Pet. 33–39. We credit Mr. Thornton’s testimony in support of Petitioner’s challenge. *See, e.g.*, Ex. 1003 ¶¶ 82–94 (providing several reasons why a POSA would have been motivated to combine Schaffer and Hartley).

We find that a POSA would have considered the modification of Schaffer’s valve to include Hartley’s string or Eller’s wire to involve little more than combining known prior art features according to those features’ known functions to yield a predictable result. Hartley’s string and Eller’s wire were known and used for a similar purpose as Schaffer’s U-shaped actuating members—to constrict a tubular member and lumen and provide a fluid seal in hemostasis valves, with or without instruments inserted therethrough. *See, e.g.*, Ex. 1005 ¶ 77 (disclosing actuating members “at least partially circumferentially [*sic*] disposed about the portion 108 of the seal module 100 depressing and at least partially collapsing” the seal module); Ex. 1006 ¶¶ 5 (“flexible member [*is*] passed circumferentially around the cylindrical diaphragm and extending radially and/or tangentially therefrom and an extension arrangement to pull the flexible member . . . to constrict the diaphragm to at least partially close off the longitudinal

some aspect of the filament limitation is missing, that argument would be unpersuasive because it does not account adequately for the art’s *combined* teachings. PO Resp. 38–39 (arguing the substitution is not simple because no reference shows a single string attached to two separate actuators); *see Fleming v. Cirrus Design Corp.*, 28 F.4th 1214, 1222 (Fed. Cir. 2022); *Bradium Techs. LLC v. Iancu*, 923 F.3d 1032, 1050 (Fed. Cir. 2019).

aperture”), 17 (“The flexible member may be a string, suture or band or other suitable material”), 37 (describing a “constriction valve arrangement which will close over a range of diameters of devices passed through the valve or can close down completely to be self[-]sealing”), Figs. 3–4 (showing flexible member constricting central diaphragm/lumen); Ex. 1003 ¶¶ 85–94 (testifying use of Hartley’s string for its known purpose would have yielded the predictable result of constricting the lumen of Schaffer’s valve to form a seal), 99–106 (similar testimony on Eller’s wire); Ex. 1007, 15:21–40, 17:38–43 (describing Eller’s wire actuated to put the wire under tension around a sleeve to selectively close and open the fluid passageway defined by the sleeve), 18:3–8 (disclosing “the material that forms the sleeve . . . contacts a portion of one or more of the medical devices [passed through the passageway] to close the passageway . . . such that fluid is prevented from passing”).

That Hartley and Eller contemplate use of their respective string and wire for constricting a lumen and providing a seal against leakage of bodily fluids during surgical procedures also suggests that the disclosed strings and wires would have been regarded as effective and sufficiently durable for medical devices—and hemostasis valves, in particular. *See, e.g.*, Ex. 1007, 1:13–16, 15:41–56 (listing suitable biocompatible materials for the wire member, such as polypropylene, stainless steel, and titanium).

We further agree with Petitioner that a POSA would have considered the proposed modification to be straightforward, and within the POSA’s ordinary capabilities. For example, as proposed by Petitioner, the ends of Hartley’s string or Eller’s wire could have been (and predictably would have been) attached to Schaffer’s opposing actuator buttons according to known techniques, such as knotting or welding. Ex. 1003 ¶ 90 (proposing a

“simple” knotting attachment); Ex. 1006 ¶ 31 (“string 14 is mounted into the rotary actuator with a knot 16”), Fig. 3 (showing string 14 connected to actuator at both ends with knots); *see also* Ex. 1007, 14:37–54 (disclosing “skilled artisans will be able to select any suitable method or technique” for attaching a flexible wire to an actuator of a fluid stasis valve; describing use of “adhesives, welding, fusing, [and] providing a friction fit” for attaching a wire to an actuator). A POSA would have recognized that Hartley’s string or Eller’s wire could have been used more broadly with valves of the type described in Schaffer—and not limited to rotary valves—as evidenced by at least Eller’s teachings. Ex. 1007, 8:27–44 (disclosing “[s]killed artisans will be able to select any suitable actuator to include on a selective fluid barrier device” and identifying “rotatable actuators, *linear actuators*, slidable actuators, [and] pivotable actuators” among others) (emphasis added). As Mr. Thornton explains, a POSA “would have understood that Schaffer’s actuator is an example of a linear and slidable actuator” and Eller’s teaching about the range of suitable actuators “would have reinforced” the reasonable expectation that Eller’s wire could be successfully used in Schaffer’s valve with its linear actuator buttons. Ex. 1003 ¶ 104.

Petitioner also persuades us that the proposed modification of Schaffer’s valve to include a single flexible string or wire that replaces the two U-shaped actuating members would have been seen by the POSA as potentially advantageous—giving further reason for the POSA to have made that change. Pet. 35–37. We credit Mr. Thornton’s testimony that a POSA would have understood that Schaffer’s U-shaped actuating members may form small gaps for fluid leakage around the exterior of certain tools inserted into the lumen. Ex. 1003 ¶ 86. On the other hand, a POSA would have recognized that a single flexible string or wire that is looped completely

around the exterior of the seal module/lumen would have provided more uniform and precise constriction around the entire outer diameter of some commonly used tools and for tools with diverse shapes and sizes. *Id.*

As we pointed out in related proceedings, Patent Owner’s expert, Dr. Zalesky, agrees that a flexible string or wire would have carried this advantage. *See* IPR2024-01157, Paper 35 (Ex. 1042) at 54 (citing testimony (Ex. 2008 ¶ 75) that a “filament changes shape dynamically, allowing for better adaptability to the contours of the valve lumen as it is constricted”). Indeed, Dr. Zalesky admitted that a POSA prior to 2017 would have recognized the “cinching” effect provided by a filament would be more effective for sealing around tools like large-bore catheters as a matter of “simple mechanical engineering and physics.” Ex. 1037, 86:19–87:4.

In sum, we find that the reasons given by Petitioner support modifying Schaffer to include Hartley’s flexible string or Eller’s flexible wire, and that such modification would have been made with a reasonable expectation of success in arriving at the subject matter of claim 1. Patent Owner’s argument, addressed below, is insufficient to undermine Petitioner’s challenge under Grounds 3 and 4.

Patent Owner’s counterarguments (summarized in Section III.G.2) against the proposed combinations of Schaffer and Hartley, or Schaffer and Eller, mirror arguments that we already considered and determined were unavailing on substantially identical records in final decisions from several related IPRs.¹⁷ That includes: Patent Owner’s contentions that Schaffer

¹⁷ As noted above, the Final Written Decisions in the 1157 and 156 IPRs were appealed and then later dismissed at the parties’ request, and the Final Written Decision in the 289 IPR remains on appeal at the Federal Circuit.

provides a complete seal and, thus, no benefit would be seen in substituting a string or wire; that any problems with Schaffer's valves could be fixed by more plausible changes; that the proposed substitution is not simple and runs counter to Schaffer's principle of operation; and that the substitution would not have been obvious to try. *See* Ex. 1042, 45–68; Ex. 1048, 47–70; Ex. 1049, 39–43, 51–62. Our reasoning from those related cases applies here too and Patent Owner identifies no new material evidence that persuades us that we should revisit and reach a different determination on those issues. Indeed, in Patent Owner's Sur-reply and at the oral hearing in this case, Patent Owner decided against rearguing those issues—focusing its argument instead on alleged hindsight shown by Petitioner's pursuit of multiple § 103 theories and Petitioner's challenge to dependent claim 10. *See generally* PO Sur-reply. We highlight some of the reasons and evidence why Patent Owner's arguments remain unpersuasive here before turning to the issues for which Patent Owner provided unique argument in this case.

Patent Owner argues that Schaffer's *unmodified* valve provides a complete seal and, thus, there is no reason to change it. PO Resp. 29–36. We disagree. Even if Schaffer is interpreted as describing valves aimed at addressing a need for a complete seal—and that at least some embodiments do so—that does not mean a POSA would forego efforts to improve on Schaffer's teachings. *Pro-Mold & Tool Co., Inc. v. Great Lakes Plastics, Inc.*, 75 F.3d 1568, 1573 (Fed. Cir. 1996) (“We start from the self-evident proposition that mankind, in particular, inventors, strive to improve that which already exists.”). Even Schaffer's preferred embodiments that use a highly compliant “sticky” or “gelatinous” material that “exhibits a ‘self closing’ nature” for the third seal member do not provide a perfect seal. Ex. 1005 ¶ 59 (describing “forming a *nearly* fluid/gas tight seal”) (emphasis

added). Moreover, Petitioner and Mr. Thornton present scenarios where Schaffer's valves may not seal completely or perfectly, suggesting such valves would have been ready for improvement. *See, e.g.*, Pet. 36–37; Ex. 1003 ¶¶ 85–86 (addressing formation of potential gaps with Schaffer's U-shaped actuating members around certain tools).

Patent Owner also argues that Petitioner's proposed modification and any improvement to sealing would only arise if one assumes Schaffer's highly compliant third central seal member material was not used. PO Resp. 30–35 (citing Ex. 2033 ¶¶ 120–123). Yet, Patent Owner argues, Schaffer requires the highly compliant third central seal member material and, thus, it would not be omitted. *Id.* (citing testimony allegedly confirming the third seal member 165 is included in every illustrated embodiment in Schaffer, including Figures 30–34 (e.g., Ex. 2031, 73:13–77:3)).

We disagree with Patent Owner's argument because the prior art's teachings are not limited to the art's examples and preferred embodiments. *Merck & Co., Inc. v. Biocraft Labs., Inc.*, 874 F.2d 804, 807 (Fed. Cir. 1989). The third central seal member comprising a highly compliant material is preferred, but not required, in Schaffer. *See, e.g.*, Ex. 1005 ¶ 59 (“In one embodiment, the third central seal member 165 includes material 166 that is highly elastic, deformable, compliant and yet virtually non-compressible,” and “in one option” such material “is extremely soft and compliant and intrinsically ‘sticky’”); *see also id.* (describing the highly compliant material forming the third central seal member “[f]or illustrative purposes only”). Moreover, in introducing the embodiment of Figures 30–34, Schaffer discloses that the valve's “seal module 100 is formed of *one or more seal members*” and “[i]n another option, *the seal module 100 and/or any of its respective seal members can be formed of one or more materials*,

including their relative properties, as discussed above.” *Id.* ¶ 75 (emphases added). We find that Schaffer suggests that the third central seal member with its highly compliant seal member material is optional (even if preferred). Ex. 1003 ¶ 86 (testifying that Schaffer’s seal module may be made of various materials, including modified vinyl, silicone, polyurethane, and combinations or modifications thereof, which would not be a sticky or gelatinous substances) (citing Ex. 1005 ¶ 59).

Patent Owner’s argument that the proposed modification of Schaffer could provide a less effective seal in certain scenarios is also unavailing. PO Resp. 37–38 (showing alleged “Gaps” when a string is used and two instruments are inserted side-by-side). Obviousness does not require that a proposed prior art modification provide superior performance in all circumstances. Combinations that “may be inferior for certain purposes” may still be obvious. *In re Mouttet*, 686 F.3d 1322, 1334 (Fed. Cir. 2012) (“This court has further explained that just because better alternatives exist in the prior art does not mean that an inferior combination is inapt for obviousness purposes”); *In re Fulton*, 391 F.3d 1195, 1200 (Fed. Cir. 2004) (“[O]ur case law does not require that a particular combination must be the preferred, or the most desirable, combination described in the prior art in order to provide motivation for the current invention.”).

We also find unpersuasive Patent Owner’s argument that the proposed modification of Schaffer changes its principle of operation. PO Resp. 55–60. Patent Owner argues, for example, that Petitioner’s modification would prevent “forcible disengagement” of Schaffer’s actuating members from the seal module, and that a string or wire would result in a less durable valve. *Id.* (citing, e.g., Ex. 1005 ¶¶ 8, 59, 80–82; Ex. 2033 ¶¶ 155–169).

We disagree that a modification of Schaffer with Hartley’s string or Eller’s wire would lack durability. The evidence supports the opposite conclusion. Eller, for instance, teaches that its wire can be comprised of braided materials, polypropylene, polyurethane, stainless steel, or titanium. Ex. 1007, 15:41–56. Materials such as these would have been considered extremely durable. *See, e.g.*, Ex. 1039 ¶ 48 (testifying a POSA in 2017 would have known of many durable materials usable for forming a string or wire in a medical device, “such as polypropylene or other suture material”); Ex. 1037, 169:16–170:11 (admitting that “polypropylene, polyurethane, suture catgut are amazingly durable” as well as “small-braid” wire, and a POSA would have had access to those materials before 2017).¹⁸

We are also unpersuaded that Hartley’s string or Eller’s wire—in the modified valve of Schaffer—would not “forcibly disengage” the seal module. When the buttons are pressed, a force is applied that releases the actuating members (or the string/wire in the case of the modification) to disengage the seal module, allowing it to return to an open configuration. Ex. 1040 ¶¶ 38–39. Patent Owner appears to interpret “forcibly disengage” as meaning the actuating members must physically come out of contact with the seal module. PO Resp. 56–57 (stating that, if Schaffer’s seal module expands against Hartley’s string when tension is released, the string would never forcibly disengage the seal module). Schaffer never shows that. Schaffer depicts the actuating members staying in contact with the seal

¹⁸ Mr. Thornton also addresses the other concerns Patent Owner raises with the proposed modification, such as alleged assembly difficulties. *See, e.g.*, Ex. 1003 ¶ 87; Ex. 1039 ¶¶ 42–47. We credit this testimony and are unpersuaded that Schaffer’s optional manufacturing or assembly techniques translate into a definition of Schaffer’s principle of operation.

module, whether the valve is open or closed. Ex. 1008, Figs. 32–34; Ex. 1045, 144:15–146:8 (admitting, “[a]s depicted here, the compressive elements appear to be in contact” with the seal module).

Patent Owner’s argument that the proposed modification is not “simple” because no single prior art reference shows a hemostasis valve with a flexible string or wire attached to two actuators is unavailing. PO Resp. 61–67. Patent Owner’s argument is tantamount to a complaint that none of Schaffer, Hartley, or Eller is anticipating. The challenge is obviousness and “it suffices . . . that a person of ordinary skill in the art would have been motivated to combine the prior art in a way such that the combination discloses the claim limitation.” *Masimo Corp. v. Apple Inc.*, 2024 WL 111647 at *3 (Fed. Cir. Jan. 10, 2024) (internal quotation marks and brackets omitted). As explained above, we find that a POSA would have been motivated to make the proposed changes to Schaffer’s valve and that the implementation details needed for those changes would have drawn on known techniques (e.g., knotting of ends of string), obviously extended to a linear actuator like Schaffer’s valve.

Patent Owner’s argument that “more plausible” changes would have been made to Schaffer’s valve does not undermine Petitioner’s challenge. PO Resp. 46–49 (arguing a POSA could have simply adjusted Schaffer’s spring force or the properties of the seal module to address any perceived sealing issue). That a POSA might have considered the alternative changes to Schaffer’s valve suggested by Patent Owner—or even considered those changes to be superior to those proposed by Petitioner—does not negate a showing of obviousness. Obviousness is not limited to the best or simplest solution. *Intel Corp. v. Qualcomm Inc.*, 21 F.4th 784, 800 (Fed. Cir. 2021) (“[It is] not necessary to show that a combination is the *best* option, only that

it be a *suitable* option.”) (internal quotation marks omitted). As discussed above, we find the POSA would have had reasons to modify Schaffer’s valve as proposed and reasonably expected the modified valve would be at least suitable, if not potentially improved.

For similar reasons, we find unavailing Patent Owner’s argument that Petitioner’s challenge under Grounds 3 and 4 is rooted in hindsight, which is allegedly shown by Petitioner raising multiple obviousness theories in this and related IPRs. PO Resp. 51–53 (identifying three allegedly different theories advanced in related IPRs concerning the substitution of a string or wire into Schaffer’s valve). The law does not limit the obviousness inquiry to only one, optimal substitution theory. *See Intel*, 21 F.4th at 800. One, two, or more options for modifying the art—or none of them—might be obvious depending on the particular facts of the case.

We are unpersuaded that Petitioner’s obviousness theories, which advance different ways in which strings or wires could have been used to constrict a hemostasis valve lumen, reveal hindsight simply because there are more than one such theory. The cited prior art teaches multiple ways in which strings/wires can be used for that purpose. *See* Ex. 1006, Figs. 3–4 (showing string 14 wrapped around central lumen and knotted to opposing sides of a rotating actuator); Ex. 1007, Figs. 15–17 (showing first wire member 422 wrapped around sleeve/lumen and having a first end pulled through a loop formed in the wire’s second end); Figs. 9–10 (showing several wire members (22, 24, 26) surrounding sleeve and cooperating to constrict a lumen). Indeed, Eller further teaches that a hemostasis valve “can include any suitable number of wire members,” that “[s]killed artisans will be able to select a suitable number of wire members,” and that suitable examples “include one, at least one, two, a plurality, three, four, five, and

any other number considered suitable for a particular embodiment.”

Ex. 1007, 16:7–19. Although Hartley and Eller may not depict a string or wire being used in the same exact arrangement as Petitioner’s modification to Schaffer, the prior art is evidence that many and varied uses of strings and wires in hemostasis valves were already known.¹⁹ And, the skilled artisan possesses “ordinary creativity”—they are “not an automaton.” *KSR*, 550 U.S. at 421; *Facebook, Inc. v. Windy City Innovations, LLC*, 973 F.3d 1321, 1343 (Fed. Cir. 2020) (“[T]he fact that it would take some creativity to carry out the combination does not defeat a finding of obviousness.”). For reasons discussed above, we find that a POSA, in the exercise of ordinary skill and creativity, would have modified Schaffer in the manner proposed to substitute Schaffer’s actuating members with Hartley’s string or Eller’s wire.

b) Claim 10

Claim 10 depends from claim 1 and recites, among other elements, that “the filament is a *first filament*,” and further requires “a second actuator coupled to the elongate member via a *second filament* extending at least partially around the elongate member.” *See* Section II(D) (reproducing claim 10 in full) (emphases added). Petitioner argues that the “first filament” and “second filament” limitations would have been obvious over the combinations of Schaffer and Hartley, or Schaffer and Eller, in two alternative ways. Pet. 64–70; Ex. 1003 ¶¶ 152–159. We discuss below.

¹⁹ That Mr. Thornton had not “encountered” a string or a wire being used to constrict a hemostasis valve lumen in his years of experience before this case is not decisive. Ex. 2034, 14:1–11; PO Resp. 52. Hartley and Eller show that such uses were known and the POSA is presumed to be aware of all pertinent prior art. *In re Carlson*, 983 F.2d 1032, 1037 (Fed. Cir. 1992) (explaining the POSA is a “hypothetical person . . . who is charged with knowledge of all the contents of the relevant prior art”).

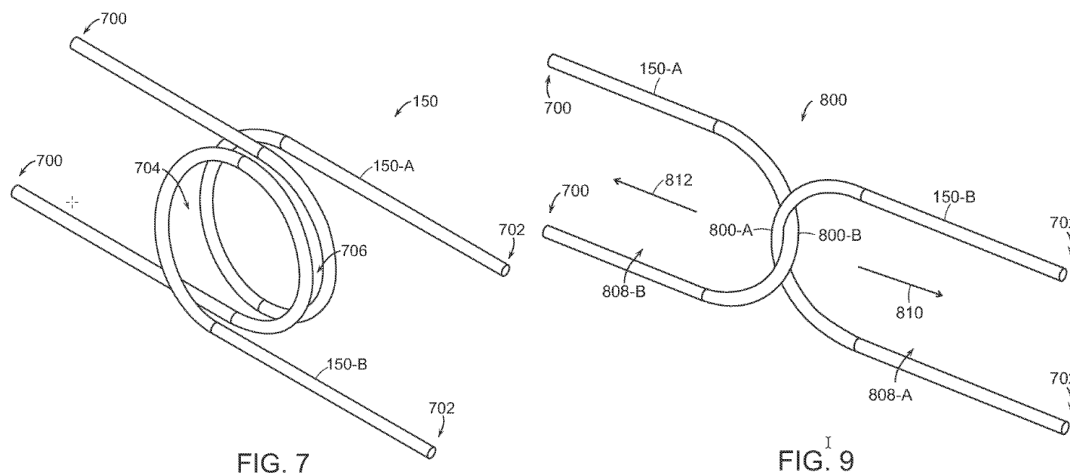
First, Petitioner argues that the combination of Schaffer and Hartley (or Eller) discussed above for claim 1 would also meet the limitations of claim 10 because a POSA would have recognized that a string/wire can be comprised of multiple threads or strands that have been twisted together to form such string/wire. Pet. 66 (citing Ex. 1014 (definition of string as “material consisting of threads of cotton, hemp or other material twisted together to form a thin length”); Ex. 1007, 15:61–16:6 (disclosing that a wire member “can have any suitable structure and comprise any suitable number of strands and/or fibers that are twisted”)). Thus, Petitioner argues, if a single string or wire was substituted for Schaffer’s two actuating members (like shown in Petitioner’s demonstrative in Section III.G.1 above (Pet. 67)), and that string/wire was formed with at least two twisted fibers, claim 10’s “first filament” and “second filament” limitations would be met.

Petitioner’s first alternative for how the asserted combination of prior art meets claim 10 is based on an inchoate claim interpretation. But, for reasons explained below, we agree with Patent Owner that a single string or wire does not satisfy *both* the “first filament” and “second filament” as recited in claim 10. PO Resp. 61–64; PO Sur-reply 11–15.

The intrinsic evidence does not support Petitioner’s interpretation. Claim 10 recites the “first filament” and “second filament” separately, suggesting they are distinct elements—not just twisted or fused fibers making up a single string or wire. Moreover, the Specification states: “In some embodiments, *the filament* can comprise a single strand such as, for example, a monofilament, and in some embodiments, *the filament* can comprise a plurality of strands that can be, for example, twisted, woven, grouped, and/or fused to form *the filament*.” Ex. 1001, 9:10–15 (emphases added). If Petitioner’s interpretation were correct, the patent’s multi-strand

embodiment would not be described as “the [singular] filament.” Thus, consistent with the ’921 patent, a filament can be made up of one strand or many strands. But when those strands are twisted, fused, or interwoven into one cohesive structural unit, the product is described as one filament, not two filaments or a plurality of filaments. *Id.*; *see also id.* at 9:15–17 (“In some embodiments, the filament 150 can comprise one or several threads, lines, cords, rope, ribbon, flat wire, sheet, or tape.”).

Other parts of the Specification and drawings further undermine Petitioner’s interpretation. The only time the Specification describes a “first filament” and a “second filament,” they are distinct physical structures. Indeed, the patent states: “the filament 150 can comprise multiple filaments, and specifically, as shown in FIGS. 7 through 9, the filament 150 can comprise a **first filament** 150-A and a **second filament** 150-B.” Ex. 1001, 12:54–57 (emphases added). Figure 7 (and likewise Figs. 8 and 9) show the first filament and second filament as separate and distinct. Figures 7 and 9 are illustrative and reproduced below.



Id. at Figs. 7, 9. Nothing in the patent suggests that, when more than one individual strand makes up each discrete filament, those strands are themselves second, third, or more filaments.

If extrinsic evidence is considered, it also cuts against Petitioner’s interpretation. Prior art including Eller discloses that a “wire member, such as the first wire member 22, the second wire member 24 . . . , can have any suitable structure and comprise any suitable number of strands and/or fibers that are twisted or otherwise interconnected to one another.” Ex. 1007, 15:61–65. Thus, like the ’921 patent, Eller recognizes that multiple strands or fibers that are twisted together form *one wire member*, not many wire members—or “filaments.”

Petitioner counters that Patent Owner is seeking to import into the claim a requirement that the first filament and second filament be separate structures. Pet. Reply 14–17 (“Yet, neither Claim 10 nor the patent specification use the term ‘separate’ to describe the filaments”). That is, however, the interpretation that best aligns with claim 10 when read in light of the Specification for the reasons discussed above. Petitioner also argues that all the cited disclosures of the Specification that favor Patent Owner’s interpretation are qualified as being embodiments or examples. *Id.* at 17. But Petitioner points to nothing in the Specification that suggests building blocks (i.e., strands, fibers, threads) that have been aggregated into one unitary filament such as by twisting, fusing, or weaving are a “first filament” and “second filament” like claimed. Petitioner’s expert Mr. Thornton offered no analysis of the Specification on this issue—he simply cited a dictionary definition that “string” can be made by “twisting very thin threads together.” Ex. 1003 ¶ 152. Dr. Zalesky’s testimony, on the other hand, supports Patent Owner. *See, e.g.*, Ex. 1047, 31:16–23 (“Q. If you have two threads within the same string, as we just discussed, would each of those threads be a different or distinct filament? [A] If they’re wound within or around each other, they constitute a single filament.”) (objections omitted);

see also id. at 32:11–13 (“As soon as [individual threads are] integrated into a single outside diameter string, that’s a single filament.”).

For the reasons above, the modification of Schaffer to include only a single multi-strand string or wire does not meet claim 10’s “first filament” and “second filament” recitations. Thus, we determine that Petitioner has not shown by a preponderance of the evidence that claim 10 would have been obvious over the combination of Schaffer and Hartley (or Eller) based on Petitioner’s first mapping of the art to the claim.

Petitioner also raises a second, alternative mapping that does not hinge on claim interpretation. Petitioner argues that, “rather than replace Schaffer’s U-shaped actuating members with a single string extending from the first actuator to the second actuator, [POSAs] would have also found it obvious to replace each U-shaped actuating member with a string.” Pet. 68–69 (citing Ex. 1003 ¶¶ 154–155); *see also id.* at 70 (making analogous assertion related to substitution with two of Eller’s wires); Ex. 1003 ¶¶ 158–159. Petitioner contends that Hartley shows that strings have sufficient strength to constrict a lumen extending through a hemostasis valve and, due to their flexibility, strings would have the ability to conform to tools of various sizes and shapes. Pet. 68–69; Ex. 1006, Abstr., ¶¶ 17, 31, 37. Moreover, Petitioner alleges that a POSA would have been motivated to try using strings (or wires) in this way because those options were among a known and finite number of predictable materials described in the art for constricting a lumen in a user-actuated hemostasis valve and because biocompatible strings, sutures, and wires of the types described in Hartley and Eller were readily available and inexpensive. Pet. 68–69 (citing, e.g., Ex. 1003 ¶¶ 154–155; Ex. 1006 ¶ 17; Ex. 1007, Abstr.).

Petitioner persuades us that modifying Schaffer's valve in this way would have been obvious. Petitioner's modification invokes a simple and straightforward replacement theory where each U-shaped actuating member is replaced with a different material—a string or wire. Ex. 1003 ¶¶ 154–159; Pet. Reply 18. We agree that “replacement of Schaffer's actuating members with a string would merely entail substitution of one known element (Hartley's string) for another (plastic or aluminum members) to yield the predictable result of sealing Schaffer's valve.” Pet. 69. In this modification, each string or wire would, when coupled to the seal member, take on the same configuration (i.e., U-shaped) as Schaffer's actuating members, and the ends of each string/wire could be attached to the actuator buttons with techniques disclosed in Hartley and Eller (e.g., knotting, welding, fusing). Ex. 1006 ¶ 31; Ex. 1007, 14:44–49 (“[T]echniques considered suitable to attach a wire member to a housing and/or an actuator include adhesives, welding, fusing, providing a friction fit . . . , and any other method or technique considered suitable for a particular embodiment”). Prior art also suggests that a POSA would have had the skill needed to choose and use different materials and configurations to constrict a tube in a hemostasis valve. *See, e.g.*, Ex. 1007, 15:41–16:6 (teaching that suitable materials, configurations, and number of wires are a matter of routine selection by the POSA). And, use of the modified valve here would mirror Schaffer's unmodified valve. Just as Schaffer's actuator buttons pull two U-shaped actuating members in opposing directions, those same buttons would work to pull two U-shaped strings or wires in opposing directions, thus constricting the seal member and lumen disposed between them.

Patent Owner does not argue that any limitation of claim 10 is missing in this alternative combination of Schaffer and Hartley (or Eller). PO Resp.

64–66 (addressing Petitioner’s “alternative theory”); PO Sur-reply 16–22. Instead, Patent Owner argues there is no motivation to modify the art in this way. PO Resp. 64–66. Patent Owner argues there is no reason to make Schaffer’s U-shaped members flexible and that such a modification would change Schaffer’s principle of operation and make the valve less durable and more difficult to manufacture and assemble. *Id.* (citing Ex. 2033 ¶ 181). Further, Patent Owner argues, using two wires or strings could permit the strings to move laterally where they “might interfere with one another” when the valve is operated. *Id.* (citing Ex. 2033 ¶ 182). Patent Owner reiterates that, in Hartley and Eller, the strings/wires are not attached to two actuator buttons. *Id.* at 65–66 (noting, for example, that Hartley’s string is attached to a single actuator). And, lastly, Patent Owner argues that Petitioner’s other obviousness theory, where Schaffer’s actuating members are replaced with a single string/wire that loops completely around the elongate member, undercuts its alternative theory for claim 10 because Petitioner previously argued that use of two flexible U-shaped actuating members may still allow small gaps to form. PO Sur-reply 16–18 (citing IPR2024-01157, Paper 18 at 22–24; Ex. 2036, 43:24–46:16).

Having considered Patent Owner’s counterargument and evidence, we find that it is insufficient to undermine Petitioner’s challenge to claim 10. The notion that modifying Schaffer’s valve to use strings or wire would change Schaffer’s alleged principle of operation or produce a less durable valve was addressed above and found unpersuasive. That same reasoning applies here. *See supra* Section III.G.3.a (rejecting argument that using a string/wire would prevent forcible disengagement, and citing evidence that materials like suture catgut and titanium wire would be extremely durable). Moreover, the manufacturing and assembly techniques disclosed in Schaffer

are optional, not a definition of Schaffer's intended purpose. Ex. 1005 ¶¶ 82–83. Mr. Thornton also explains how a POSA would have readily made and assembled Schaffer's valve to use string and wire through simple means (e.g., use of a tapered fixture or forming Schaffer's housing in two parts). *See, e.g.*, Ex. 1003 ¶ 87; Ex. 1039 ¶¶ 42–47.²⁰

Patent Owner's argument that using two strings or wires could raise problems due to possible lateral movement or string-to-string interference is speculative and unavailing. Dr. Zalesky cites no persuasive factual support for the hypothetical downsides he says might exist. *See, e.g.*, Ex. 2033 ¶ 182 (testifying “two strings or wire members might interfere with one another” or “might move underneath the other” when the valve is used). On the other hand, the prior art teaches that a skilled artisan can select one or more wires as desired, and that multiple wires can be used together to constrict a valve lumen without any negative effects. Ex. 1007, 5:1–6, 16:7–19 (teaching “a selective fluid barrier valve can include any suitable number of wire members”). Nor does the '921 patent describe any problem with lateral filament movement or filament-to-filament interference. To the contrary, the patent discloses that the filaments can form one or multiple loops or one or multiple U-shaped bights, where the multiple loops or multiple bights

²⁰ At deposition, Dr. Zalesky conceded that making a valve with two filaments would not be especially difficult. Ex. 1045, 96:23–98:6 (testifying it “could be incrementally more difficult, but not particularly” and answering “[n]o” when asked if “it would have been so much more difficult that it would have discouraged a [POSA] from using two loops”). Although this testimony related to using two filaments to form two loops, which is not Petitioner's theory here, the testimony weakens Patent Owner's position that using two strings or wires would have been seen as difficult and beyond the ordinary capabilities of the skilled artisan.

may be side-by-side or interlocking. Ex. 1001, Figs. 7–9, 13:23–35. Yet there is no disclosure of any movement or interference “problem,” much less any discussion about the solution in the patent. In short, we disagree that any concerns about string or wire movement or interference would have discouraged Petitioner’s modification. If such concerns did exist, the prior art and the patent presume a POSA had the skills needed to address them.

Patent Owner’s position that Hartley’s string and Eller’s wire are not, in those references, connected to actuator buttons in the same manner as proposed by Petitioner and, therefore, the substitution is not “simple” is an argument that remains unavailing. PO Resp. 65–66. This argument strips the POSA of ordinary creativity and is contrary to law as discussed above. The simplicity of Petitioner’s modification of the art stems from the fact that known features (strings and wires) are being used for their known function (constricting a hemostasis valve lumen), and that the modification involves little more than substituting a string or wire for each of Schaffer’s constricting actuating members. That Hartley and Eller may arrange the strings or wires in somewhat different ways in their embodiments, such as attaching one end to a fixed point on the housing and the other end to a movable actuator, does not defeat Petitioner’s challenge. *See, e.g.*, Ex. 1007, 15:21–40, 17:38–18:8. Obviousness is a flexible inquiry and “familiar items may have obvious uses beyond their primary purposes, and in many cases a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle.” *KSR*, 550 U.S. at 420. Indeed, here Hartley’s string or Eller’s wire are not being used for any new purpose. They are used for their established purpose but are being arranged in an *obvious* way when considered in combination with Schaffer’s teachings.

Lastly, Patent Owner's argument that Petitioner is pursuing logically inconsistent theories does not undermine Petitioner's overall challenge. PO Sur-reply 16–18. Patent Owner is correct that Petitioner argued in an earlier IPR that, if Schaffer's actuating members were flexible, gaps for potential fluid leakage could still form. *See* IPR2024-01157, Paper 18 at 22–24; Ex. 1039 ¶ 34 (testifying that, when the U-shaped actuating members are “relatively flexible,” the fixed attachment points to the actuator buttons may prevent the members from completely conforming to the dimensions of some tools, especially those with diameters smaller than the distance between the attachment points).²¹ At most, however, this weakens the notion that a POSA would have expected better sealing performance if Schaffer's two rigid actuating members were replaced with two flexible strings or wires (i.e., Petitioner's alternative theory for claim 10 here). This does not show that the modified valve would produce an unsuitable seal

²¹ We recognize Patent Owner's citation to deposition testimony where Mr. Thornton testified that he had not considered replacing Schaffer's actuating members with two strings, which testimony was taken shortly after he prepared his first declaration in this case. PO Sur-reply 17–18; Ex. 2030, 54:25–55:14. That deposition testimony, however, was specifically taken for the 1157 IPR, where Petitioner had not proposed and Mr. Thornton's declaration did not address use of two strings. *See* Ex. 2030, 1; *see also id.* at 55:18–19 (“It's not something I considered when putting this [(the 1157 IPR Thornton Declaration)] together”). The deposition testimony is, thus, not inaccurate in that context. That deposition was also taken before Mr. Thornton's supplemental declaration was prepared where he opined that Schaffer's actuating members, if made of flexible materials, could result in gaps. Ex. 1039 ¶ 34. In any event, Patent Owner had and took the opportunity to depose Mr. Thornton again specific to his declaration in this IPR (*see* Ex. 2035), but that deposition testimony is cited just once in Patent Owner's Response on an unrelated point (PO Resp. 71), and it not cited at all in Patent Owner's Sur-reply.

compared to Schaffer's unmodified valve, which is also capable of forming gaps as discussed above. Nor does it diminish the merits of Petitioner's primary theory, where one string completely encircles and more precisely conforms to the outer dimension of the seal module and inserted tools, such that a sealing improvement would have been expected. *See supra* Section III.G.3.a (claim 1 analysis). Petitioner's challenge to claim 10 does not rest on improved sealing—Petitioner offers several rationales, including a simple substitution and use of known features for their known function. Pet. 68–70; Pet. Reply 18 (listing reasons). We see no logical inconsistency in Petitioner's positions: it proposed one modification that it argues is superior and would have improved Schaffer's valve, including the valve's sealing performance; and it also proposed an alternative simple substitution for claim 10 that we are persuaded would have produced an effective (i.e., at least suitable) hemostasis valve.

c) Remaining Claims

We have also considered and find persuasive Petitioner's argument and evidence in support of the Ground 3 and Ground 4 challenge to the remaining claims. *See* Pet. 47–64 (analysis for claims 2–7 and 9), 71–75 (analysis for claims 15–18 and 20–24); Ex. 1003 ¶¶ 110–148, 160–173. For claims 3 and 4, for example, Petitioner explains persuasively how the combination of Schaffer and Hartley (or Eller) teaches or suggests winding the string or wire in a loop around the valve's elongate member, and how releasing and pressing the actuator buttons in the proposed combination allows the valve to move from a first (sealed) position to a second (open) position. *See* Pet. 49–53 (citing, e.g., Ex. 1006 ¶ 31 Fig. 3; Ex. 1007, 22:18–24, Fig. 21; Ex. 1005 ¶¶ 75–76, Figs. 31–32, 34). We credit Mr. Thornton's un rebutted testimony in support of the same. Ex. 1003 ¶¶ 115–122. For

claims 2–7, 9, 15–18, and 20–24, Patent Owner does not raise any separate argument or evidence beyond what we addressed above.

4. Conclusion

Upon considering all arguments and evidence presented through trial, we determine that Petitioner has shown by a preponderance of the evidence that claims 1–7, 9, 10, 15–18, and 20–24 would have been obvious under Grounds 3 and 4.

H. Obviousness over Hartley and Eller (Ground 5)

Petitioner argues that claims 1–3, 5, 6, 9, 15–18, and 21–24 would have been obvious over the combination of Hartley and Eller. Pet. 76–92; Ex. 1003 ¶¶ 174–219.

Summarizing Petitioner’s challenge to claim 1 as illustrative, Petitioner contends that Hartley discloses a valve with all the limitations of claim 1 except a “biasing member configured to bias the actuator to the first position.” Pet. 76–85. Petitioner contends, however, that biasing members in hemostasis valves were well known in the art, and Petitioner proposes that it would have been obvious to modify Hartley’s valve with Eller’s biasing member (i.e., torsion spring). *Id.* at 76, 81–85 (citing Ex. 1007, 19:22–30). Petitioner argues, *inter alia*, that a POSA would have been motivated to make this modification to “ensure[] that Hartley’s valve seals quickly when a device is removed through the valve, which minimizes blood loss,” and to simplify operation of Hartley’s valve and eliminate the need to manually seal the valve during procedures. *Id.* at 83–84 (citing Ex. 1003 ¶¶ 187–193); *see also id.* at 84–85 (arguing the POSA would have reasonably expected success because, for example, the valves of Hartley and Eller share many of the same features (e.g., rotational actuators, constricting string/wire, etc.)).

Patent Owner does not dispute that any limitation from claim 1 (or the other challenged claims) is missing in the combination of Hartley and Eller. PO Resp. 66–71. Patent Owner instead argues against making the combination—asserting that a POSA would not have been motivated to add Eller’s torsion spring as a biasing member because it would allegedly “change Hartley’s principle of operation by obviating [Hartley’s] ball-and-detent system.” *Id.* (citing Ex. 2033 ¶¶ 184–198).

Patent Owner’s counterargument is unavailing. Hartley’s ball-and-detent system is an optional feature for its valves. *See* Ex. 1006 ¶ 15 (“***Alternatively*** the rotary actuator may be retained on the cylindrical housing by the ball and detent arrangement discussed in more detail below.”), ¶ 18 (“The rotary actuator ***may have*** a tactile indication of its action by means of a ball or other device acting into detents”) (emphases added). The argument that the ball-and-detent feature is required for fulfillment of Hartley’s principle of operation is undercut if that feature is optional. Ex. 1003 ¶ 193 (testifying that “Hartley makes clear that the ball and detent are optional features” and that, even if the feature remained in a modified valve of Hartley with Eller’s spring, the ball and detent “would continue to provide ‘tactile feedback’ to the user as the user rotates the actuator to open valve” helping to indicate “how ‘open’ the valve is or how quickly the user is opening the valve”). Hartley’s claims are also consistent with other parts of Hartley’s disclosure discussed above, further indicating the valve does not require a ball-and-detent feature. *Compare* Ex. 1006, independent claim 1 (no ball and detent), *with* dependent claim 12 (“including a ball and detent arrangement”).

Altogether, Hartley’s disclosures indicate that the ball-and-detent feature is optional, and not required in its valves. Patent Owner’s argument

and Dr. Zalesky's testimony to the contrary is unpersuasive. *See, e.g.*, PO Resp. 70 (citing Ex. 2033 ¶ 190).²² Instead, we agree with Petitioner and credit Mr. Thornton's testimony, explaining why Hartley makes clear that the ball-and-detent feature is optional and unnecessary to satisfy Hartley's alleged objective of a controllable access valve that can be used to vary the size of an aperture and form a seal against a variety of inserted instruments. Pet. Reply 23; Ex. 1003 ¶ 193 (testifying "Hartley can seal the valve regardless of whether the ball and detent feature is present," and explaining why adding a torsion spring would be compatible with the ball and detent and the functioning of Hartley's valve).

Moreover, when obviousness is the issue, the art is not limited to its preferred embodiments. *Merck*, 874 F.2d at 807. Patent Owner's contention that the ball-and-detent feature, because it appears in Hartley's preferred (and depicted) embodiment, is not optional is at odds with Hartley's other disclosures noted above. PO Resp. 67–68, 70 (citing Ex. 1006, Figs. 3–4, ¶ 33). Patent Owner cites no authority for the proposition that modifying a reference to omit or allegedly override an *optional* feature should lead to a conclusion of nonobviousness. Petitioner, on the other hand, notes that a given course of action often has simultaneous advantages and disadvantages, yet this does not necessarily obviate a motivation to combine. Pet. Reply 9 (citing *Allied Erecting & Dismantling Co. v. Genesis Attachments, LLC*, 825 F.3d 1373, 1381 (Fed. Cir. 2016)). We agree. Even if Petitioner's modification of Hartley would have required omitting the ball-and-detent feature (and a perceived advantage provided by it, such as allegedly

²² We rejected substantially the same arguments from Patent Owner in the related 289 IPR. *See* Ex. 1049, 63–65.

retaining the valve in discrete open positions), Patent Owner does not dispute that adding a self-closing torsion spring would simplify operation of Hartley's valve—avoiding a need for manual sealing and, thus, more quickly sealing the valve to minimize blood loss. We credit Mr. Thornton's testimony that such a change would have been seen as advantageous and desirable. Ex. 1003 ¶¶ 187–190.

We have also considered and we credit Petitioner's argument and evidence for the remainder of the claims challenged under Ground 5. Pet. 86–92 (analysis on claims 2, 3, 5, 6, 9, 15–18, and 21–24); Ex. 1003 ¶¶ 194–219. Patent Owner does not raise any argument on those remaining claims beyond what we addressed above for claim 1. For the foregoing reasons, we determine that Petitioner has proved by preponderance of the evidence that claims 1–3, 5, 6, 9, 15–18, and 21–24 would have been obvious over Hartley and Eller.

IV. PATENT OWNER'S OBJECTION

Patent Owner objected to Exhibit 1039, which is Mr. Thornton's Supplemental Declaration in support of Petitioner's Reply in the related 1157 IPR. Ex. 1039; Paper 29 (Inari's written objection). The Board heard argument about this objection on a conference call held July 20, 2026,²³ and again at the oral hearing. Tr. 64:21–66:2, 70:17–71:1. The crux of Patent Owner's objection is that Petitioner did not timely file Exhibit 1039 in this proceeding and, instead, Petitioner filed the exhibit on July 6, 2026—after the due date for Patent Owner's Sur-reply, and about three weeks before the

²³ If either party maintains a copy of a court reporter's written transcript of this conference call, the parties are instructed to confer and file a copy of such transcript as an exhibit in this proceeding.

oral hearing. Paper 29, 1–2. Thus, Patent Owner argues it did not have a full and fair opportunity to address this exhibit, and Patent Owner contends the exhibit is, among other things, irrelevant and prejudicial. *Id.*

Patent Owner’s objection is overruled. Although Petitioner did not file Exhibit 1039 until July 6, 2026, that exhibit is explicitly identified in Petitioner’s April 9, 2026, Reply. *See* Pet. Reply, Exhibit List, Page 3 (identifying “Exhibit 1039” as “Supplemental Declaration of Troy L. Thornton in Support of Petitioner’s Reply for Inter Partes Review of U.S. Patent No. 11,697,011”). The exhibit also features prominently in Petitioner’s Reply in this case—it is cited at least ten times. *See, e.g., id.* at 9 (“PO is also incorrect that Hartley’s string or Eller’s wire would prevent ‘forcible disengagement.’ (Ex. 1039, ¶41).” And, Patent Owner already had this exhibit in its possession (albeit bearing a different exhibit number) because Petitioner has filed the exhibit in several related IPRs, including in the 1157 IPR where the exhibit was filed roughly one year earlier. *See* IPR2024-01157, Exhibit 1014 (filed July 11, 2025); *see also* IPR2024-00156, Exhibit 1020 (filed October 7, 2025). Indeed, far from being prevented from using this allegedly irrelevant exhibit, Patent Owner expressly cited and relied on it in Patent Owner’s substantive papers in this proceeding. *See, e.g.,* PO Sur-reply 17 (citing and quoting from Exhibit 1014 ¶ 34 from the 1157 IPR).

Exhibit 1039 was also introduced at Mr. Thornton’s January 7, 2026, deposition in this proceeding—many months before the due dates for Petitioner’s Reply and Patent Owner’s Sur-Reply. *See* Ex. 2035, 48:7–50:12 (introducing exhibit over Patent Owner’s objection as beyond the scope of direct). Moreover, although Patent Owner contends that Patent Owner “didn’t have a chance to ask their expert about it” because Petitioner

“introduce[d] that document in the first deposition at the end” (Tr. 70:17–25), that does not appear to be accurate. Patent Owner did ask Mr. Thornton about the exhibit and then decided to conclude the deposition for the day roughly one hour and forty-five minutes after it began (while asserting a reservation of rights and leaving the deposition “open” to recall the witness for more questioning on the exhibit). Ex. 2035, 50:15–53:4. If Patent Owner believed that more questioning about Exhibit 1039 was necessary, it had options. It could have sought to reopen the first deposition, seeking authorization from the Board if needed. And Patent Owner had the opportunity to depose Mr. Thornton a second time in this proceeding after Petitioner’s Reply, which expressly cited Exhibit 1039, was filed.

Petitioner’s late filing of Exhibit 1039 in this case appears to be no more than an innocent oversight. On the other hand, Patent Owner cannot credibly claim that it did not: (i) know what this exhibit was; (ii) already have the exhibit in its possession; or (iii) know Petitioner was affirmatively relying on the exhibit to support its arguments in this IPR. For the reasons discussed above, we determine that Exhibit 1039 is relevant, non-prejudicial, and that Patent Owner had a full and fair opportunity to address it.

V. CONCLUSION²⁴

Petitioner has shown by a preponderance of the evidence that the challenged claims are unpatentable as summarized in the table below.

²⁴ Should Patent Owner wish to pursue amendment of the challenged claims in a reissue or reexamination proceeding after the issuance of this decision, we draw Patent Owner’s attention to the April 2019 *Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding*. See 84 Fed. Reg. 16,654 (Apr. 22, 2019). If Patent Owner chooses to file a reissue application

Claims	35 U.S.C. §	Reference(s)/Basis	Claims Shown Unpatentable	Claims Not shown Unpatentable
1–7, 9, 10, 15– 18, 20– 24	102	Schaffer		1–7, 9, 10, 15–18, 20–24
1–7, 9, 10, 15– 18, 20– 24	103	Schaffer		1–7, 9, 10, 15–18, 20–24
1–7, 9, 10, 15– 18, 20– 24	103	Schaffer, Hartley	1–7, 9, 10, 15–18, 20–24	
1–7, 9, 10, 15– 18, 20– 24	103	Schaffer, Eller	1–7, 9, 10, 15–18, 20–24	
1–3, 5, 6, 9, 15–18, 21–24		Hartley, Eller	1–3, 5, 6, 9, 15–18, 21–24	
Overall Outcome			1–7, 9, 10, 15–18, 21–24	

VI. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that Petitioner has proved by a preponderance of the evidence that claims 1–7, 9, 10, 15–18, and 20–24 are unpatentable; and

FURTHER ORDERED that, because this is a Final Written Decision, parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

or a request for reexamination of the challenged patent, we remind Patent Owner of its continuing obligation to notify the Board of any such related matters in updated mandatory notices. *See* 37 C.F.R. § 42.8(a)(3), (b)(2).

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FOR PETITIONER:

Joshua J. Stowell
Joseph R. Re
Brian C. Barnes
KNOBBE, MARTENS, OLSON & BEAR, LLP
Joshua.Stowell@knobbe.com
Joe.Re@knobbe.com
Brian.Barnes@knobbe.com

FOR PATENT OWNER:

Joseph Hamilton
Paul Parker
PERKINS COIE LLP
hamilton-ptab@perkinscoie.com
parker-ptab@perkinscoie.com