

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

IMPERATIVE CARE, INC.,
Petitioner,

v.

INARI MEDICAL, INC.,
Patent Owner.

Case No. IPR2024-01157
U.S. Patent No. 11,697,011

PATENT OWNER'S SUR-REPLY

TABLE OF CONTENTS

I.	INTRODUCTION	1
II.	CLAIM 1 IS NOT ANTICIPATED BY OR OBVIOUS OVER SCHAFFER	4
A.	Schaffer’s Actuating Members do not “Circumferentially Constrict.”	4
B.	The Term “Filament” Requires “Flexibility,” Consistent with its Plain and Ordinary Meaning.	9
C.	“Flexibility” in the Definition of “Filament” does not Inject Ambiguity into the Claims.	11
D.	Schaffer’s Actuating Members are Rigid, not Flexible.	12
III.	CLAIM 1 IS NOT OBVIOUS OVER SCHAFFER ALONE, OR WITH HARTLEY OR ELLER (GROUNDS 2-4).....	13
A.	Petitioner’s Alleged Motivation to Modify Schaffer’s Valve Does Not Exist.....	13
B.	Petitioner’s Proposed Modification to Include Hartley’s String/Eller’s Wire is Not a Simple Substitution.	20
C.	Petitioner Fails to Establish that the Solutions for Constricting a Tubular Member in a Hemostasis Valve were Finite, Identifiable or Known.	26
D.	Petitioner’s Proposed Modifications Would Change Schaffer’s Principles of Operation.....	28
E.	Claim 3.	30
IV.	CONCLUSION.....	30

TABLE OF AUTHORITIES

CASES

<i>Abbott Labs. v. Sandoz, Inc.</i> , 544 F.3d 1341 (Fed. Cir. 2008)	26, 27
<i>Aruba Networks, Inc. v. Xr Commc'ns LLC</i> , IPR2018-00701, 2018 WL 4090629 (P.T.A.B. Aug. 27, 2018).....	18
<i>Axonics, Inc. v. Medtronic, Inc.</i> , 73 F.4th 950 (Fed. Cir. 2023)	3
<i>Hill-Rom Services, Inc. v. Stryker Corp.</i> , 755 F.3d 1367 (Fed. Cir. 2014)	9
<i>In re Schweickert</i> , 676 F. App'x 988 (Fed. Cir. 2017)	18
<i>Intel Corp. v. Qualcomm Inc.</i> , 21 F.4 th 784 (Fed. Cir. 2021).....	24
<i>KSR Int'l Co. v. Teleflex Inc.</i> , 550 U.S. 398 (2007).....	26
<i>Kyocera Senco Indus. Tools Inc. v. Int'l Trade Comm'n</i> , 22 F.4th 1369 (Fed. Cir. 2022)	9, 10, 11
<i>Philip Morris Prods. S.A. v. RAI Strategic Holdings, Inc.</i> , 2023 WL 5970786 (Fed. Cir. Sept. 14, 2023)	23
<i>R.J. Reynolds Vapor Co. v. Fontem Holdings I B.V.</i> , IPR2016-01268, Paper 63 (P.T.A.B. Dec. 19, 2017)	23
<i>Rolls-Royce, PLC v. United Techs. Corp.</i> , 603 F.3d 1325 (Fed. Cir. 2010)	26, 27
<i>Tech. Co., Inc. v. Polaris Innovations Ltd.</i> , IPR2016-01623, 2018 WL 851884 (P.T.A.B. Feb. 9, 2018)	3, 27
<i>Virtek Vision Int'l v. Assembly Guidance Sys.</i> , 97 F.4 th 882 (Fed. Cir. 2024).....	22

EXHIBIT LIST

	Petitioner's Exhibits
Exhibit	Description
1001	U.S. Patent No. 11,697,011 ("the '011 Patent")
1002	'011 Patent Prosecution History Excerpt
1003	Expert Declaration of Troy Thornton
1004	Resume of Troy Thornton
1005	U.S. Patent Publication US 2003/0225379 A1 to Schaffer et al. ("Schaffer")
1006	U.S. Patent Publication US 2003/0116731 A1 to Hartley ("Hartley")
1007	U.S. Patent No. 9,980,813 B1 to Eller ("Eller")
1008	Drawings Submitted During Prosecution of U.S. Patent Application No. 10/371,190 dated June 18, 2003
1009	U.S. Patent No. 5,429,616 to Schaffer ("Schaffer '616")
1010	U.S. Patent Publication US 2011/0144592 A1 to Wong et al. ("Wong")
1011	U.S. Patent Publication US 2015/0173782 A1 to Garrison et al. ("Garrison")
1012	Declaration of Joshua J. Stowell in Response to Patent Owner's Objections to Imperative Care's Evidence [SERVED ONLY]
1013	Certified File History of U.S. Patent Application 10/371,190 [SERVED ONLY]
1014	Supplemental Expert Declaration of Troy Thornton
1015	Deposition Transcript of PO's Expert Paul Zalesky, Ph.D. dated June 23, 2025

	Petitioner's Exhibits
Exhibit	Description
1016	Decision Granting Institution of IPR, IPR2025-00156, U.S. Patent No. 11,697,012 B2
1017	Decision Granting Institution of IPR, IPR2025-00289, U.S. Patent No. 11,554,005 B2
1018	U.S. Patent No. 12,109,384 B2 to Merritt et al.
1019	New Oxford American Dictionary, 3rd ed. (2010) – definitions of “diameter,” “filament,” and “loop”

	Patent Owner's Exhibits
Exhibit	Description
2001	Declaration of Paul J. Zalesky
2002	Merriam-Webster's Collegiate Dictionary (11 th ed. 2014)
2003	New Oxford American Dictionary (3 rd ed. 2010)
2004	U.S. Patent Application Publication No. 2018/0193043
2005	Deposition Transcript of Troy Thornton (September 30, 2024)
2006	U.S. Patent No. 7,682,380 to Thornton ("Thornton")
2007	Deposition Transcript of Troy Thornton (March 19, 2025)
2008	Supplemental Declaration of Paul J. Zalesky
2009	Merriam-Webster's Collegiate Dictionary (11 th ed. 2014)
2010	Deposition Transcript of Troy Thornton (June 25, 2025)
2011	Deposition Transcript of Troy Thornton (August 15, 2025)

I. INTRODUCTION

Petitioner has failed to demonstrate that any one of Claims 1-9 of the '011 Patent are unpatentable. Regarding grounds 1-2 that rely on Schaffer alone, Petitioner has failed to demonstrate that Schaffer discloses a “constricting mechanism including at least one filament” wherein “the filament *circumferentially constricts* the lumen to create a seal” as expressly recited in the sole independent Claim 1. As explained in the Patent Owner Response (“POR,” Paper 13), the Petition is devoid of any explanation or argument as to why Schaffer “circumferentially constricts.” POR, pp.36-39. To the contrary, Schaffer’s U-shaped actuating members are arranged side-by-side to one another (parallel). *Id.* at p.39. That configuration means that the actuating members do not cross any part of the same portion of the lumen. *Id.* So even taken together, Schaffer’s U-shaped members do not form a circumference around the lumen and thus cannot “circumferentially constrict[] the lumen,” as recited in Claim 1.

Petitioner’s reply on this point is a single paragraph asserting that Patent Owner’s expert purportedly admitted that Schaffer’s U-shaped members would “circumferentially constrict.” Paper 18, p.25. But that testimony relates to the bight embodiment shown in Figures 8-9 of the '011 Patent—not Schaffer’s U-shaped members. EX1015, 100:11-16, 126:10-13. And, as explained in §II.A below, the bight embodiment of Figures 8-9 is different from Schaffer’s parallel side-by-side

U-shaped members because, *inter alia*, those two bights interlock—i.e., one bight extends through the other. EX1001, 13:48-52, 14:2-6. Because the bights shown in Figures 8-9 interlock/overlap, the two bights together define an “encircled area” that has a circumference and thus can “circumferentially constrict.” EX1001, 14:2-6; EX1015, 100:11-22, 126:10-13. In contrast, because Schaffer’s U-shaped members are positioned side-by-side they do not interlock or overlap to define an “encircled area” with a circumference and therefore, cannot “circumferentially constrict.” Grounds 1-2 fail for this reason alone. Grounds 1-2 also fail because the term “filament” requires “flexibility,” and Schaffer’s U-shaped members are rigid not flexible. *Infra*, §II.B-D.

Grounds 3-4 relying upon a combination of Schaffer with Hartley or Schaffer with Eller, respectively, also fail. Petitioner’s alleged motivation to modify Schaffer’s valve to incorporate Hartley’s string or Eller’s wire does not exist. *Infra*, §III.A. Specifically, the embodiment shown in Figures 30-34 of Schaffer (the embodiment relied upon by Petitioner) seals completely and without gaps by virtue of including “a third seal member” that “is so compliant that it forms a seal around” different instruments. EX1005, ¶¶[0068], [0075], [0081]. Because Schaffer’s valves—including the embodiment relied upon by Petitioner—seal completely, Petitioner’s motivation to modify Schaffer (the presence of gaps) is nonexistent and contrary to Schaffer’s teaching. Only by removing this seal member from Schaffer

would Petitioner's purported problem (gaps) potentially exist, but a POSA would not have removed the seal member. EX2008, ¶143. Petitioner has therefore not met its burden of showing that a "skilled artisan would have been motivated to combine the teachings." *Axonics, Inc. v. Medtronic, Inc.*, 73 F.4th 950, 957 (Fed. Cir. 2023).

Grounds 3-4 also fail because Petitioner's proposed modification to include Hartley's string or Eller's wire in Schaffer is not a simple substitution. *Infra*, §III.B. Petitioner's proposed combination requires a **single** string/wire be controlled by **two independently operable** actuators. Petition, pp.37-38, 45-46. But, as admitted by Petitioner's expert, none of the applied references disclose such an arrangement, instead always having a single actuator controlling a single U-shaped member (Schaffer), string (Hartley), or wire (Eller). EX2010, 57:7-22 (Schaffer), 77:12-22 (Hartley), 80:11-19 (Eller). This fundamental difference between the prior art and Petitioner's proposed combination is not a substitution at all, let alone a simple one.

Grounds 3-4 further fail because the solutions for constricting a tubular member in a hemostasis valve were not finite, identifiable, or known. *Infra*, §III.C. Petitioner identified only three options for "constricting a tubular member in a hemostasis valve," but Petitioner's expert has now admitted that there were many more ways, including unknown ways, to do so. Petition, p.36; EX2010, 107:3-13. Petitioner therefore has failed to demonstrate that "the options and solutions [were] identified and known." *Tech. Co., Inc. v. Polaris Innovations Ltd.*, IPR2016-01623,

2018 WL 851884, at *5 (P.T.A.B. Feb. 9, 2018). For this reason, Petitioner's apparent "obvious to try" rationale fails.

Petitioner did not address ground 5 in the reply to the POR. Ground 5 therefore fails for the reasons identified in the POR. POR, pp.68-73.

For those and the other reasons set forth below, Petitioner has failed to demonstrate that any of Claims 1-9 are unpatentable under any of grounds 1-5.

II. CLAIM 1 IS NOT ANTICIPATED BY OR OBVIOUS OVER SCHAFFER

A. Schaffer's Actuating Members do not "Circumferentially Constrict."

Patent Owner explained in the POR that Schaffer does not disclose, nor did Petitioner provide any evidence or reasoning supporting that Schaffer discloses, a "filament [that] circumferentially constricts the lumen to create a seal," as recited in Claim 1. POR, pp.36-39. Specifically, Schaffer's actuating members cannot "circumferentially constrict" at least because Schaffer's actuating members are arranged side-by-side and thus cannot individually or collectively form a circumference around a lumen, let alone "circumferentially constrict" that lumen. POR, p.39; EX2008, ¶88.

Petitioner's sole reply on this issue mischaracterizes deposition testimony claiming that "PO's expert admitted that the semicircular bights disclosed in the '011 patent...would 'circumferentially constrict' the tubular member." Paper 18, p.25

citing EX1015, 100:11-22, 126:10-13. But Dr. Zalesky's testimony does not support that Schaffer's U-shaped actuating members would "circumferentially constrict" because Schaffer's members have a fundamentally different structure than those Dr. Zalesky testified about.

The '011 Patent discloses two different embodiments of "semicircular bights": bights that interlock (as illustrated in Figures 8-9 reproduced below) and bights that do not interlock (no corresponding figures). EX1001, 13:48-52.

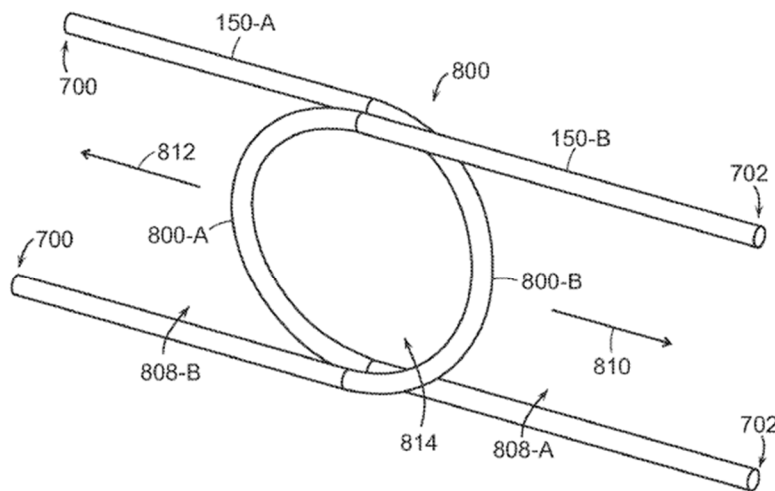


FIG. 8

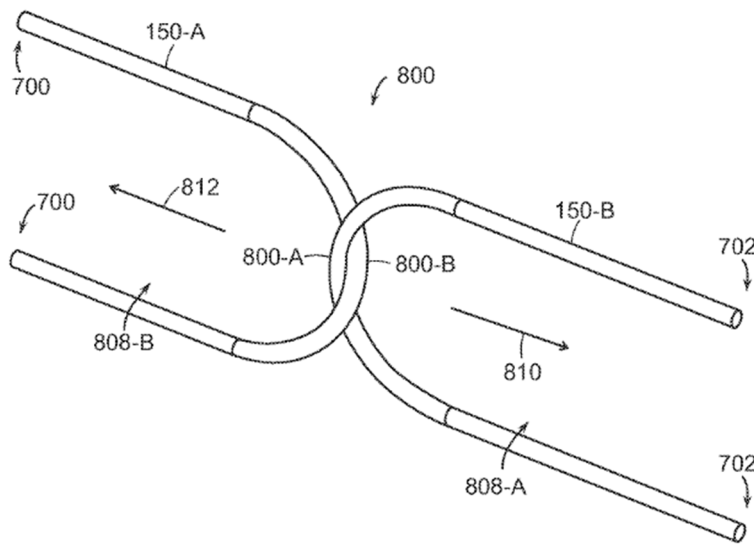
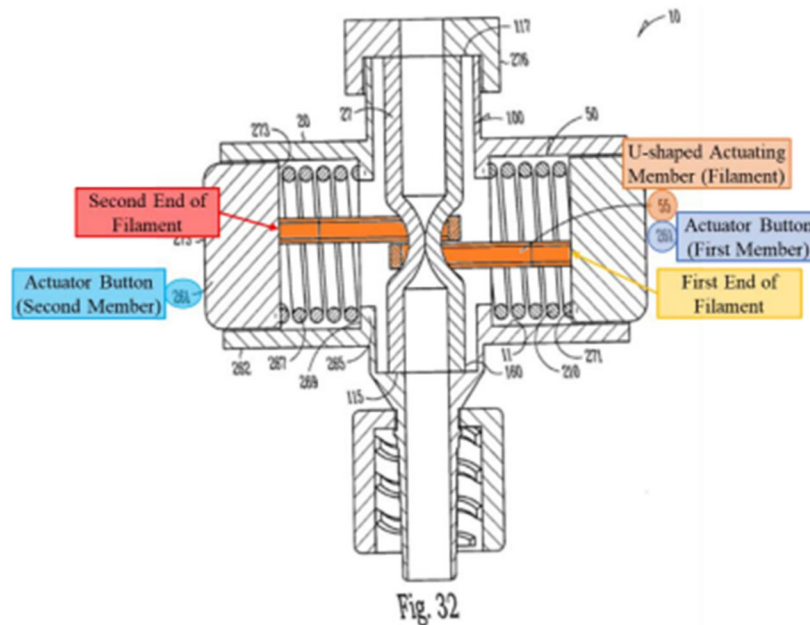


FIG. 9

The '011 Patent explains that the interlocking embodiment illustrated in Figures 8-9 can “circumferentially constrict” precisely because the bights overlap as follows: “the first and second receiving areas 808-A, 808-B **overlap and define an encircled area 814**, also referred to herein as a **constricting area 814**.” *Id.* at 14:2-6 (emphasis added). The '011 Patent further explains that for embodiments including an “encircled area,” like the interlocking bights, “the arcuate line of pressure may be a singular substantially circular line or zone that encircles the elongate member at least once.” *Id.* at 14:33-35. Stated otherwise, the bights 808-A, B collectively form an encircled area 814 with a circumference because they interlock, and thus the bights 808-A, B can “circumferentially constrict.”

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



Petition, p.31. So, Schaffer's non-interlocking U-shaped members cannot "circumferentially constrict" because they do not "define an encircled area" and thus do not define any circumference. POR, p.39; EX2008, ¶88. Because Claim 1 requires a filament that "circumferentially constricts," Schaffer cannot anticipate Claim 1.

Accordingly, Patent Owner's expert, Dr. Zalesky, did not "confirm[]" that the arrangement and mechanism of Schaffer's actuating members 'circumferentially constrict' the lumen of the valve," Petitioner's sole argument on reply. Paper 18,

p.25. Rather, Dr. Zalesky's testimony cited by Petitioner (*id. citing* EX1015, 100:11-22, 126:10-13) correctly characterizes the interlocking bight embodiment of Figures 8-9 that is different from Schaffer's side-by-side U-shaped members. EX1015, 100:11-16 (Q. What properties of the filament **illustrated in Figures 8 and 9** require flexibility. A. In particular, the ability to circumferentially circumscribe or circumferentially impose a force.); EX1015, 126:10-13 (Q. And I believe we covered this already, but **Figures 8 and 9 would also be circumferentially constricting the lumen**. Is that correct?. A. Yes, we did cover that earlier.) (emphasis added). So, Dr. Zalesky's cited testimony merely stands for the premise that interlocking bights as shown in Figures 8-9 form an encircled area and thus can circumferentially constrict.

That testimony does not mean that Schaffer's side-by-side U-shaped members "circumferentially constrict." In fact, Dr. Zalesky testified to the opposite. Schaffer's non-interlocking U-shaped members cannot "circumferentially constrict" because, *inter alia*, those members are side-by-side. EX2008, ¶88.

That the '011 Patent also discloses non-interlocking bights is of no import. The '011 Patent discloses that the filaments circumferentially constrict in "some embodiments," not all embodiments. EX1001, 4:51-55. And, the '011 Patent further contrasts different "zones of pressure" for constriction, explaining that as opposed to an embodiment that "encircles," and thus circumferentially constricts, in "some

embodiments, the arcuate line or zone of pressure may form two opposing arcs.” *Id.* at 14:32-35. But that is not what Claim 1 recites—instead, Claim 1 specifically requires that “the filament circumferentially constricts the lumen.”

Accordingly, Schaffer’s side-by-side U-shaped members cannot “circumferentially constrict” as claimed. Ground 1 fails for this reason alone.

B. The Term “Filament” Requires “Flexibility,” Consistent with its Plain and Ordinary Meaning.

The plain and ordinary meaning of “filament” as used in the ’011 Patent requires “flexibility.” POR, pp.24-25. Petitioner has repeatedly admitted that the plain meaning of filament includes flexibility. *Id.* at 24-26, *citing* EX2005, 123:1-3; EX1003, ¶75. Thus, to prevail with its proposed construction, Petitioner must meet the high burden of showing that the ’011 Patent clearly and ambiguously redefined the term “filament” to omit any requirement of “flexibility.” *Kyocera Senco Indus. Tools Inc. v. Int’l Trade Comm’n*, 22 F.4th 1369, 1378 (Fed. Cir. 2022); *see also Hill-Rom Services, Inc. v. Stryker Corp.*, 755 F.3d 1367, 1371 (Fed. Cir. 2014) (internal citations omitted) (“We depart from the plain and ordinary meaning of claim terms based on the specification in only two instances: lexicography and disavowal...The standards for finding lexicography and disavowal are exacting.”). Petitioner has not done so. POR, pp.26-30.

In reply, Petitioner asserts that the limitation “flexible” is “unrecited” in the claims and that “the ’011 patent never uses the term[] ... flexible.” Paper 18, p.14. But the mere fact that the term “flexible” is not used in the claims or the specification is not a clear and unambiguous redefining of the term filament to exclude the flexibility requirement of filament’s plain and ordinary meaning. *Kyocera Senco*, 22 F.4th at 1378. Indeed, Petitioner does not identify any clear and unambiguous statement in the ’011 Patent specification or prosecution history redefining the term filament.

Moreover, the bight embodiment of Figures 8-9 fails to redefine the term “filament” to omit the “flexibility” requirement. First, the bights of Figures 8-9 must be flexible. EX2008, ¶80. If the two interlocking U-shaped bights in Figures 8-9 were inflexible, they would need to be rotated in opposite directions as they are pulled from the position of Figure 8 to arrive at the position shown in Figure 9. The ’011 Patent includes no such disclosure. So, the embodiment shown in those figures does not support that a filament is inflexible. And, even if in theory, a similar arrangement to the bight embodiment with side-by side bights *could* work with rigid members, that example also works with flexible members. Institution Decision, pp.16-17. At least because the bight embodiment works with flexible filaments, the inclusion of a side-by-side bight embodiment (not illustrated) does not amount to a

clear and unambiguous redefining of the term filament to something other than its plain and ordinary meaning. *Kyocera Senco*, 22 F.4th at 1378.

C. “Flexibility” in the Definition of “Filament” does not Inject Ambiguity into the Claims.

A POSA would understand the degree of “thin and flexible” required by the “filament” in the context of the ’011 Patent claims, despite Petitioner’s assertions otherwise. Paper 18, pp.14-18. While rigidity/flexibility exist along a spectrum, a POSA would readily understand the flexibility required for the claimed filament in the context of a filament to circumferentially constrict a hemostasis valve as described in the ’011 Patent—the filament must be sufficiently flexible so that it can loosen, reduce in diameter when formed in a loop as shown in Figures 6-7, or slacken when formed in a bight as shown in Figures 8-9. EX2008, ¶84; POR, p.34. Stated otherwise, a POSA would understand that in the context of the ’011 Patent’s hemostasis valves, the filament must be flexible to the degree necessary to slacken/loosen when the actuator is actuated (e.g., depressed) as disclosed throughout. *Id.*

Petitioner’s expert *agrees*:

QUESTION: So that level of flexibility, in this context of a hemostasis valve for an aspiration catheter, one skilled in the art would be able to determine what that level of flexibility is, wouldn’t they?

MR. THORNTON: I think a person skilled in the art would be able to engineer the right balance of material properties for the filament, the compression tube, or tubular sidewall, the springs, et cetera, in order to make the design work well.

EX2010, 38:22-39:7. A POSA could readily determine how flexible the filament need be for the hemostasis valve to function as claimed in the '011 Patent.

D. Schaffer's Actuating Members are Rigid, not Flexible.

Petitioner's supplemental argument that Schaffer's actuating members would anticipate the claimed filament even under Petitioner's construction because "Schaffer's actuating members are not rigid" is wrong. Paper 18, pp.21-25. As Patent Owner has explained, Schaffer's U-shaped actuating members are necessarily rigid because, among other reasons, they are designed to "forcibly disengage" the seal module and are manufactured by machining or injection molding. POR, pp.44-45. In an Institution Decision in an IPR for related Patent No. 11,697,012 ("the related '012 IPR"), the Board explained that Schaffer's U-shaped members are rigid for similar reasons. EX1016, pp.32-33. And Petitioner's expert admitted that "[t]he material properties of the U-shaped actuating members are not clearly defined in the Schaffer application." EX2007, 115:16-23.

III. CLAIM 1 IS NOT OBVIOUS OVER SCHAFFER ALONE, OR WITH HARTLEY OR ELLER (GROUNDS 2-4)

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

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

First, Figures 30-34 of Schaffer—the embodiment relied upon by Petitioner—include Schaffer's seal member 165, just like every other embodiment of Schaffer. POR, pp.15-19; *see also* EX2008, ¶65. And, at deposition in the related '012 IPR, Petitioner's expert agreed that the seal member 165 is included in every illustrated embodiment in Schaffer: Schaffer Embodiment: Figures 1-4 (EX2010, 69:12-70:3), Schaffer Embodiment: Figures 5-19 (*id.* at 70:5-71:23), Schaffer Embodiment: Figures 20-22 (*id.* at 71:24-72:19), Schaffer Embodiment: Figures 23-26 (*id.* at 72:20-73:2), Schaffer Embodiment: Figure 27 (*id.* at 73:3-5), Schaffer Embodiment: Figures 28-29 (*id.* at 73:6-9), and Schaffer Embodiment: Figures 30-34 (*id.* at 73:13-77:3).

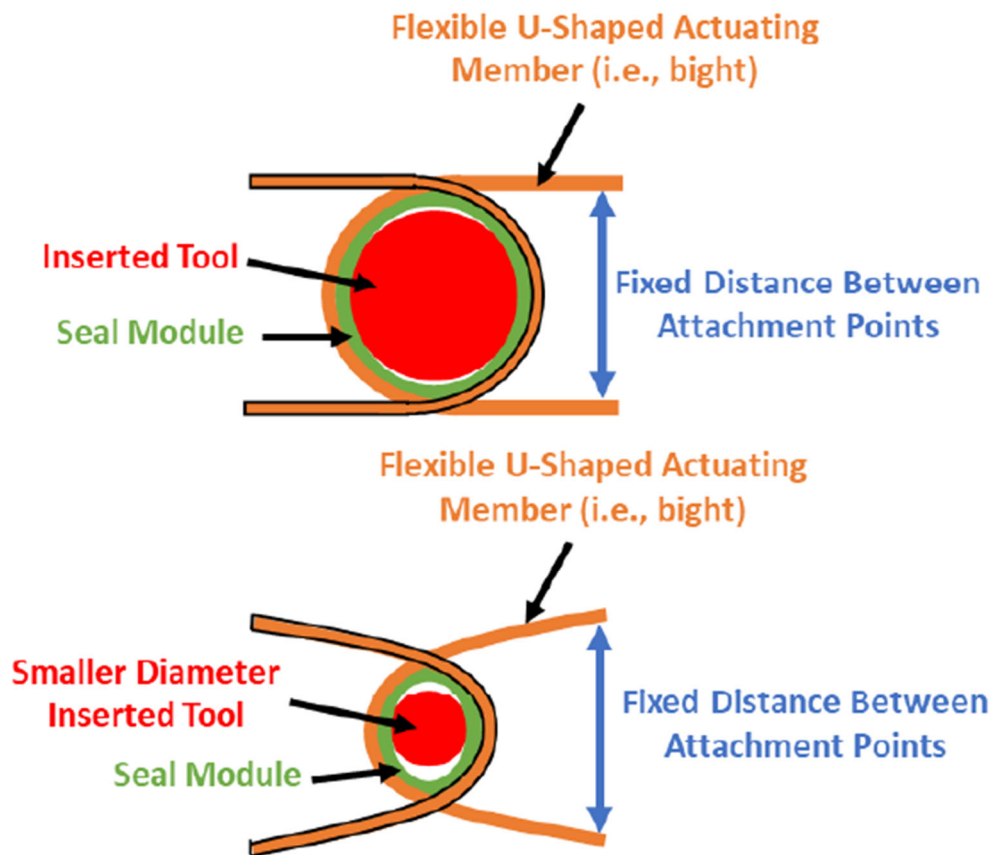
Second, the presence of the seal member in Figures 30-34 means this embodiment seals completely without gaps across a wide range of tool/device diameters and shapes. POR, pp.49-51; EX2008, ¶¶131-136. The seal member 165

seals completely by being highly compliant to conform to different shapes. EX2008, ¶¶134-135; EX1005, ¶[0060] (“the highly compliant third central seal member 165 seals around a variety of profile shapes 192 and diameters 194 of the lumen”), ¶[0068] (The “material 166 of the third central seal member 165 is so compliant that it forms a seal around the [multiple] instruments 260 even if the instruments 260 are irregularly shaped.”). Indeed, sealing without gaps is an express purpose of Schaffer, which discloses that “existing devices do not perform a complete seal against leakage in the presence of a wide range of instruments or in the presence of multiple instruments,” and identifies a need for a “durable stasis valve that blocks the flow of gas or fluid completely and immediately with or without an instrument in place within the gas/fluid path.” EX1005, ¶¶[0006], [0008]. A POSA would have understood that Schaffer's valves—including the embodiment in Figures 30-34—are designed to do just that via the highly compliant seal member 165. EX2008, ¶¶134-136.

Petitioner agrees that the third seal member enables a complete seal, stating the “third seal member ‘is so compliant that it forms a seal around the instruments 260 even if the instruments 260 are irregularly shaped.’” Paper 18, p.6, *citing* EX1005, ¶[0068]; *see also* EX2011, 28:8-10 (“[i]t is a hemostatic valve so it's designed to seal around a variety of instruments, I'm sure.”). Thus, Petitioner's arguments that Schaffer's valves are only optionally “sticky” or “selfclosing” are of

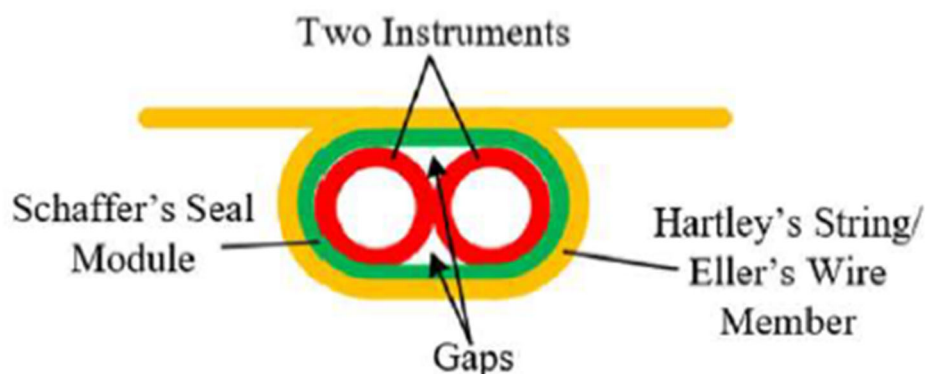
no importance—regardless of whether the valve is “sticky” or “selfclosing,” a POSA would have understood that the valve seals completely via the highly compliant seal member 165. EX2008, ¶¶134-135.

Petitioner's schematic graphics showing purported gaps do not refute this. The graphic in Petitioner's reply, reproduced below, shows at most a schematic representation of a generic seal module and does not reflect how Schaffer's seal module would actually work because it does not include the “seal member [that] ‘is so compliant that it forms a seal’” around all types of instruments—a fundamental feature of Schaffer's seal module as recognized by Petitioner. Paper 18, p.6.



Id. at 24. If Petitioner's cartoon included Schaffer's highly-compliant seal member which Schaffer discloses as part of the embodiment Petitioner's cartoon is based on, then there would be no gaps. EX2008, ¶¶134-136. And without gaps, Petitioner's alleged motivation evaporates.

Even Petitioner recognizes that these simple cartoons excise Schaffer's compliant seal module. For example, when discussing Patent Owner's figure reproduced below with a similarly simple construction, Petitioner states "the cartoon reflects a non-compliant seal that does not conform to the shape of the instruments...[t]hus, the cartoon is not representative of Schaffer's hyper compliant seal and does not evidence that Schaffer's valve would work less effectively...." Paper 18, p.7.



Schaffer seals without gaps by virtue of the highly-compliant seal member. EX2008, ¶¶137-143. Only by removing Schaffer's compliant seal member would

Petitioner's purported gaps potentially exist—but a skilled artisan would not have had any reason to remove that compliant seal member. *Id.* at ¶143.

And even if a POSA had removed the compliant seal member to, for some reason, make Schaffer's valve leak (they would not have), Petitioner's proposed solution of using Hartley's string/Eller's wire would not address the gaps. For example, as demonstrated by Patent Owner's above graphic, a combination of Schaffer and Hartley/Eller that omitted Schaffer's compliant seal member would not seal completely without gaps around multiple instruments and/or irregularly-shaped instruments—scenarios for which Schaffer's valve is designed to form a complete seal. POR, pp.51-52. Indeed, without Schaffer's compliant seal member, Schaffer's valve would have gaps regardless of whether rigid U-shaped actuating members or a string/wire were used. EX1014, ¶35 (“Because of the non-compliant seal depicted in the illustration, the same gaps would exist with U-shaped actuating members”); EX2011, 16:15-23. In other words, including a filament in Schaffer does not improve sealing. To seal completely without gaps, a POSA would need to reintroduce Schaffer's disclosed solution—the compliant seal module, rendering the petition's proposed modifications to Schaffer superfluous and disadvantageous. *Id.*; Paper 18, p.6. Petitioner provides no persuasive evidence explaining why a POSA would not have simply reintroduced the compliant seal member to cure the gaps, if

for some reason the POSA had tried removing the compliant seal member (they would not have).

Thus, because Figures 30-34 include the seal member 165 and that seal member forms a complete seal without gaps, Petitioner's alleged problem (gaps) does not exist. As a result, there would have been no motivation to modify Schaffer in the manner alleged by Petitioner: "[a] motivation to combine the teachings of references **cannot be based on the alleged existence of a problem that does not exist...**" *Aruba Networks, Inc. v. Xr Commc'ns LLC*, IPR2018-00701, 2018 WL 4090629, at *4 (P.T.A.B. Aug. 27, 2018), citing *In re Schweickert*, 676 F. App'x 988, 995-996 (Fed. Cir. 2017) (emphasis added). Even Petitioner's expert admitted at deposition that if Schaffer forms a complete seal, there would be no need to modify Schaffer's actuating members:

Question: So if Shafer's U-shaped members formed a complete seal around multiple tools, there would be no reason to include Ellers' wire member or Hartley's string in Shafer; isn't that correct?

MR. THORNTON: If it worked perfectly for all the range of tools, then there probably wouldn't be a need to make adjustments and move to a string-type member.

EX2007, 116:18-117:2. That is the case here—Schaffer's valve seals for the range of tools by virtue of the compliant seal member 165. According to even Petitioner's

expert, in that instance a POSA would not have been motivated to modify Schaffer to incorporate Hartley's string or Eller's wire.

As a hedge, Petitioner then apparently tries to circumvent the fact that Schaffer does not form "gaps" by arguing that "PO never explains why this hyper 'compliant' seal would not work equally well with Hartley's string or Eller's wire." Paper 18, p.6. But, if the highly-complaint seal member was included there would be no reason to substitute Hartley's string/ Eller's wire because Schaffer would seal via that seal member, not the addition of the string or wire. In fact, Schaffer's rigid U-shaped actuating members could result in a better seal than a string or wire as Petitioner proposes, first because "a harder material would be able to deform a softer material more readily" (EX2011, 36:11-12), and second because Schaffer's U-shaped members would be more likely to deform more of the highly-complaint material to fill in any gaps than a string/wire disclosed in Hartley and Eller because the rigid U-shaped members would have a greater contact area, and thus compression area, with the seal module. (Compare EX2011, 40:11-16, 41:15-24 with 43:2-8).

And, as explained below, the proposed modification to use a string/wire in Schaffer would require changes to Schaffer's express method of manufacturing its U-shaped members and assembling its valve and would reduce reliability and control. EX2008, ¶¶159-169. A POSA would not have made Petitioner's proposed

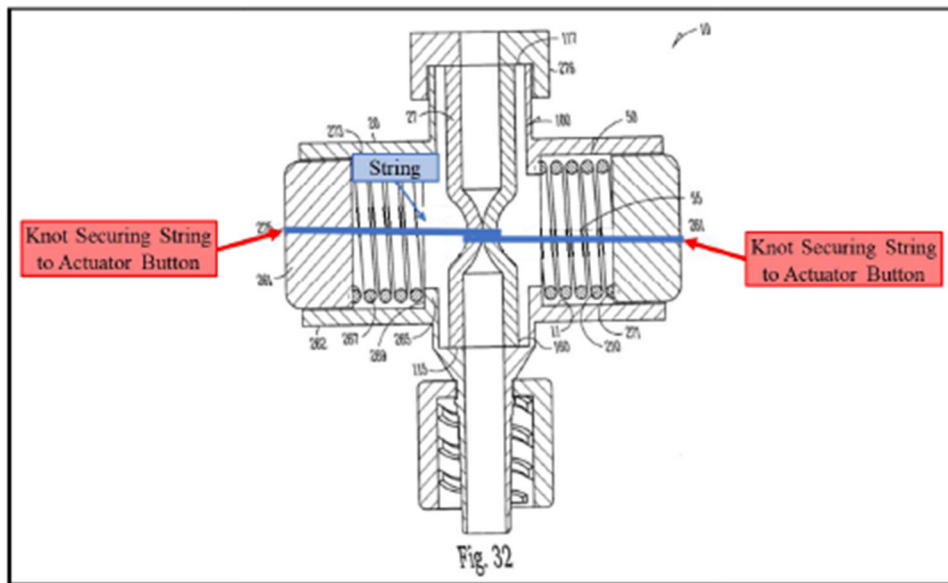
modification with all those disadvantages, particularly where the modification provides no improvement in sealing.

B. Petitioner's Proposed Modification to Include Hartley's String/ Eller's Wire is Not a Simple Substitution.

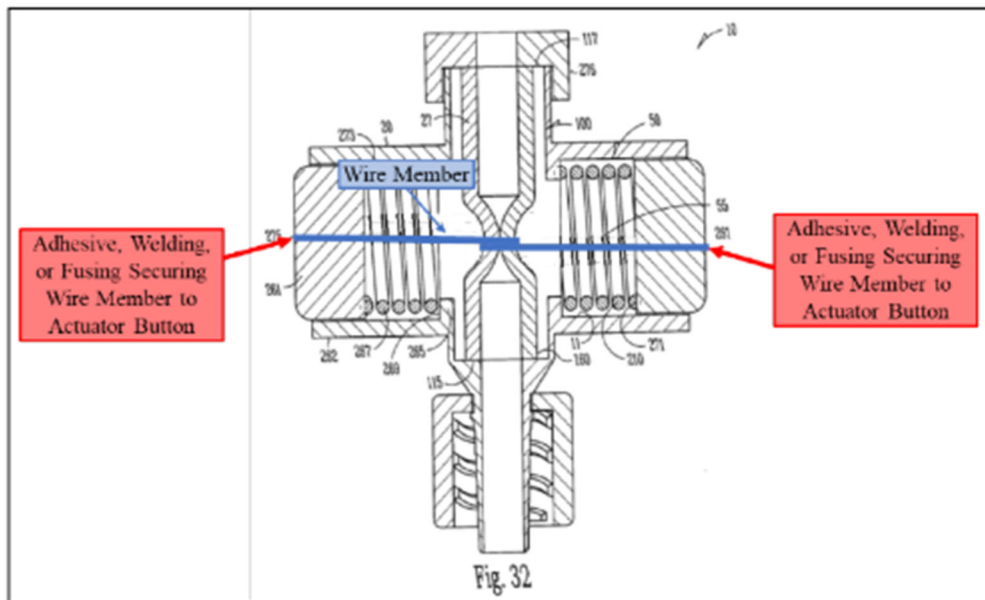
Petitioner's "simple substitution" rationale for modifying Schaffer's U-shaped members is wrong. Paper 18, p.12. First, contrary to Petitioner's assertions, Petitioner's references do not disclose all of the limitations of Claim 1—e.g., Petitioner's references do not disclose an actuating member including two ends attached to and controlled by different actuating members. EX2008, ¶¶117-124. Petitioner's proposed combination requires one end of Hartley's string/ Eller's wire to be attached to one of Schaffer's actuator buttons and the other end to be attached to the other of Schaffer's actuator buttons. Petition, pp.37-38, 45-46. In that combination, each of Schaffer's actuator buttons independently control movement of one end of the string/wire, as shown in Petitioner's demonstrative illustrations¹:

¹ Petitioner's sole proposed modification of Schaffer includes two actuators and a single string/wire. EX2007, 53:13-55:19, 60:12-61:13. *See also* EX2010, 119:16-120:14. .

Demonstrative Illustration
Schaffer + Hartley's String



Demonstrative Illustration
Schaffer + Eller's Wire Member



Id. at pp.38, 46. But, as Petitioner's expert admitted at deposition in the related '012 IPR, neither Schaffer, Hartley, nor Eller disclose such an arrangement. EX2010,

57:7-22 (Schaffer), 77:12-22 (Hartley), 80:11-19 (Eller). Nor does Petitioner cite any other reference that discloses a single string/wire attached to and controlled by two independently movable actuators. Petitioner's arrangement including a string/wire having two ends attached to two separate and independently movable actuators is therefore not disclosed by any of Petitioner's references and was not a "known element." EX2008, ¶125.

Thus, to arrive at Petitioner's proposed combination, a POSA would need to not only eliminate Schaffer's rigid U-shaped actuating members and replace them with a single flexible wire/string, but would also have to modify Schaffer to connect that single wire/string to two different opposed actuators. Petitioner does not explain why this additional modification would be obvious. As such, Petitioner has failed to show that the claimed arrangement existed in the prior art, let alone provide a reason to modify the references to include that arrangement. Even if the arrangement existed generally that would not provide a motivation to combine Schaffer with Hartley/Eller. *See Virtek Vision Int'l v. Assembly Guidance Sys.*, 97 F.4th 882, 887 (Fed. Cir. 2024) (reversing PTAB finding of obviousness because the "mere fact that these possible arrangements existed in the prior art does not provide a reason that a skilled artisan would have substituted" one for the other.)

Second, a POSA would not have been motivated to substitute Hartley's string/Eller's wire for Schaffer's U-shaped members because a POSA would

understand there are comparably more plausible substitutions—admitted by Petitioner—that would not depart from Schaffer's principles of operation including forcible disengagement, ease of manufacturing, and durability. *R.J. Reynolds Vapor Co. v. Fontem Holdings I B.V.*, IPR2016-01268, Paper 63, at 17-18 (P.T.A.B. Dec. 19, 2017) (finding Petitioner's proposed simple substitution nonobvious because there was a comparably more plausible substitution to simply replace the primary reference's entire atomizer with the secondary reference's atomizer); *see also Philip Morris Prods. S.A. v. RAI Strategic Holdings, Inc.*, 2023 WL 5970786, at *1 (Fed. Cir. Sept. 14, 2023) ("we view the Board in that case as agreeing with the patent owner's expert testimony that a more plausible 'simple substitution,' compared to the petitioner's proposed substitution, would be to replace Hon's entire atomizer"). For example, when addressing Schaffer's alleged disclosure of Claim 5, Petitioner states there are a number of comparably simpler ways Schaffer discloses to maintain or improve its seal, if needed, including "adjusting Schaffer's spring strength to apply additional force to seal the valve, adjusting the resilience and compressibility of the seal module that forms the valve's lumen, and/or adjusting the shape...and/or dimensions of the U-shaped actuating members to more closely conform to the shape of the seal module and any tool(s) inserted through the valve." Petition, p.58. During deposition, Petitioner's expert confirmed that these simple adjustments would work,

whether or not there was a pressure differential across the valve. EX2010, 121:21-122:12. Dr. Zalesky agrees. EX2008, ¶¶173-175.

Accordingly, Petitioner and its expert provide a number of comparably simple modifications, including those found expressly in Schaffer's disclosure and that are consistent with that disclosure, that would address any sealing issues in Schaffer. But Petitioner and its expert provide no reason why a POSA would not make those simple modifications rather than their more complicated hindsight-based modifications, that are not found in any prior art reference, and that contradict Schaffer's principles of operation. EX2008, ¶175.

Third, Petitioner's proposed substitution is not "simple" because it would not yield the predictable result of sealing Schaffer's valve and is not suitable for sealing around multiple/irregularly-shaped instruments—express purposes of Schaffer's valve. *Intel Corp. v. Qualcomm Inc.*, 21 F.4th 784, 800 (Fed. Cir. 2021) ("It's not necessary to show that a combination is 'the best option, only that it be a suitable option.'"). Not only would Petitioner's proposed substitution not solve Petitioner's alleged problem for reasons already explained (*see, e.g.*, POR, pp.51-52; EX2008, ¶136), but even Petitioner's expert testified in the related '012 IPR that if flexible strings were used in the embodiment of Figures 8-9 of the '011 Patent, he would be unable to know how the filaments would act:

QUESTION: So let's say those two sub-filaments, as you refer to them, are made of a string. And you had said you're not sure where their orientation would be in an actual device; is that correct?

[Objection]

MR. THORNTON: Yes, if these were a very flexible string, and the buttons were compressed such that it's in the expanding configuration it's unlikely that they would have the shape shown here of – which are perfectly straight lines and your perfectly partial circle on the bight area.

QUESTION: And you had said unknown. You wouldn't know what shape they would take, would you?

MR. THORNTON: Probably not without knowing the rest of the parameters and building prototype devices.

EX2010, 44:21-45:11. Accordingly, Petitioner's expert acknowledges that using a flexible filament rather than rigid actuating members (like Schaffer's) can lead to positional variability that is not predictable without knowing more (e.g., "building prototype devices"). Dr. Zalesky agrees—a POSA would understand the results of substituting Hartley's flexible string/Eller's flexible wire for Schaffer's rigid actuating members to likewise be unpredictable. EX2008, ¶99. That unpredictability is exacerbated by Petitioner's proposed modification because Hartley and Eller—the only references that disclose a flexible member—precisely control movement of

that flexible member with a **single** movable actuator. EX2008, ¶¶126-128. In Petitioner's combination, the movement of the string/wire would not be precisely controlled in that manner by a single actuator because either of Schaffer's buttons could be depressed independently to move the string/wire unpredictably. *Id.* at ¶128.

Petitioner's proposed combinations of Schaffer and Hartley/Eller therefore not only depart from the intended purpose and express disclosure of these references in which a single U-shaped actuating member/string/wire are controlled by a single actuator, but do not predictably seal.

C. Petitioner Fails to Establish that the Solutions for Constricting a Tubular Member in a Hemostasis Valve were Finite, Identifiable or Known.

Petitioner also advances what appears to be an "obvious to try" rationale for substituting Hartley's string/Eller's wire for Schaffer's U-shaped members. Petition, pp.36, 45; *see KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007) (discussing "obvious to try," and stating "[w]hen there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp."). To reach a determination that the claimed invention would have been obvious to try, "the possible approaches and selection to solve the problem must be 'known and finite.'" *Rolls-Royce, PLC v. United Techs. Corp.*, 603 F.3d 1325, 1339 (Fed. Cir. 2010) (citing *Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341,

1351 (Fed. Cir. 2008)). “The important question is whether the invention is an ‘identified, predictable solution’ and an ‘anticipated success.’” *Id.* (citing *Abbott Labs.*, 544 F.3d at 1352). “Thus, it is not enough for there to be a finite number of solutions, **the options and solutions must have been identified and known.**” *Kingston Tech. Co., Inc. v. Polaris Innovations Ltd.*, IPR2016-01623, 2018 WL 851884, at *5 (P.T.A.B. Feb. 9, 2018) (emphasis added).

Here, Petitioner has failed to demonstrate that the options and solutions for “constricting the lumen of a tubular member in a hemostasis valve” were finite, identified, and known. Petition, p.36. Petitioner proposes only three options: “Hartley and Schaffer disclose two such options: Hartley’s string and Schaffer’s two U-shaped actuating members formed from aluminum or plastic...Eller discloses a third option: one or more wire members.” *Id.*; EX1003, ¶83. But at deposition in the related ’012 IPR, Petitioner’s expert admitted that there were more than those three ways to constrict a tubular member in a hemostasis valve including those disclosed in Schaffer ’616 (EX2010, 105:24-106:4, 106:12-14), Wong (*Id.* at 106:15-19), Kees (*Id.* at 108:14-20, 110:7-19), Myers (*Id.* at 111:9-23), his previous work on a hemostatic-type clamp prototype (*Id.* at 106:20-24), and more (*Id.* at 112:5-114:24). In fact, Petitioner’s expert admitted that he did not know how many options exist:

QUESTION: Do you think there’s other ways that exist [to compress a tubular member in a hemostasis valve]?

[Objection]

MR. THORNTON: Could be other ways that exist.

QUESTION: How many other?

MR. THORNTON: **I don't know.**

QUESTION: So when you say, these finite predictable options, you don't know how many other finite predictable options there are; is that correct?

[Objection]

MR. THORNTON: **I don't know how many options could be used to compress [a] tube.**

EX2010, 107:2-13 (emphasis added). And, as explained above in §II.B., Petitioner's proposed combination that requires a single flexible string/wire connected to two independent actuator buttons was not known at all from Petitioner's art. Petitioner's "obvious to try" argument fails for this reason alone—the options and solutions for compressing a tubular member in a hemostasis valve were not "known," "finite" or "identified" as confirmed by Petitioner's own expert.

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

In addition to the reasons set forth in the POR, and regardless of whether Petitioner's proposed combination of Schaffer and Hartley/Eller includes or omits the seal-effectuating highly-compliant sealing member, there is no reason a POSA

would have included the modified arrangement of Hartley's string/Eller's wire in Schaffer's valve because neither would have improved Schaffer's sealing and instead may even have sealed less effectively. *Supra*, §III.A. And because Petitioner's proposed combination would not have improved sealing, a POSA would have had no reason to have deviated from Schaffer's advantageous mode of operation, and express methods of manufacturing the U-shaped members and assembling the device. *Id.* Schaffer's express purpose is to provide a device that seals yet provides a balance of "closing force, opening force, friction, compression and durability" so as not to damage or allow the insertion of delicate instruments and catheters and to allow a user to manipulate and advance those tools while compression is applied and the valve is sealed. EX1005, ¶[0007]; EX2011, 60:20-61:15. Schaffer's rigid compression members and highly compliant internal seal member accomplish that purpose by, e.g., sealing "under very light compression." EX1005, ¶[0059]. Petitioner's proposed combination ignores that express purpose and fundamentally changes how Schaffer seals. A POSA would not make such a modification contrary to Schaffer's express disclosure, particularly where the modification does not improve, and could impair, the seal "in the presence of a wide range of instruments or in the presence of multiple instruments." EX1005, ¶[0006].

E. Claim 3.

Dependent Claim 3 depends from Claim 1 and further requires, *inter alia*, that “the filament extends in a loop completely around the tubular member.” Grounds 1-5 fail for the reasons set forth in Patent Owner's Response and herein. (Paper 13).

IV. CONCLUSION

For the reasons set forth herein, Petitioner has failed to demonstrate that any of Claims 1-9 are unpatentable over Grounds 1-5.

Respectfully submitted,

Dated: August 22, 2025

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

CERTIFICATE OF COMPLIANCE

Pursuant to 37 C.F.R. § 42.24(d), I, Joseph Hamilton, certify that **PATENT OWNER'S SUR-REPLY** contains 5,578 words, excluding those portions identified in 37 C.F.R. § 42.24(a), as measured by the word-processing system used to prepare this paper.

Dated: August 22, 2025

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

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), I certify that on August 22, 2025, a copy of
PATENT OWNER'S SUR-REPLY, and EXHIBITS 2010-2011 were served
upon the below-listed counsel by electronic mail:

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