

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. IPR2026-00169
U.S. Patent No. 12,156,669

PATENT OWNER'S RESPONSE

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EXHIBIT LIST

Petitioner's Exhibits

Exhibit	Description
1001	U.S. Patent No. 12,156,669 (“the ’669 patent”)
1002	’669 Patent Prosecution History
1003	Expert Declaration of Troy Thornton
1004	Resume of Troy Thornton
1005	WIPO Publication No. WO 2006/124307 A2 to Goff et al. (“Goff”)
1006	U.S. Patent Publication No. 2015/0173782 A1 to Garrison et al. (“Garrison”)
1007	U.S. Patent Publication US 2003/0225379 A1 to Schaffer et al. (“Schaffer”)
1008	U.S. Patent Publication No. 2003/0116731 A1 to Hartley (“Hartley”)
1009	Certified File History of U.S. Patent Application 10/371,190 (Schaffer File History)
1010	WIPO Publication No. WO 2018/019829 A1 to Brady et al. (“Brady”)
1011	U.S. Patent No. 11,432,835 B2 to Pons et al. (“Pons”)
1012	U.S. Patent No. 6,776,770 B2 to Trerotola
1013	Inari’s Supplemental Infringement Contentions (without claim charts) from <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , No. 24-cv-3117 (N.D. Cal.) (served February 7, 2025)
1014	Merriam-Webster’s Collegiate Dictionary (11th ed. 2014), definitions of “port” and “tighten”
1015	Merriam-Webster’s Collegiate Dictionary (11th ed. 2014), submitted by Patent Owner as Exhibit 2009 in IPR2024-00157

Exhibit	Description
1016	Deposition Transcript of PO's Expert Paul Zalesky, Ph.D. dated June 23, 2025
1017	Deposition Transcript of PO's Expert Paul Zalesky, Ph.D. dated August 27, 2025
1018	Deposition Transcript of PO's Expert Paul Zalesky, Ph.D. dated November 7, 2025
1019	U.S. Provisional Patent Application No. 62/554,931
1020	Order Regarding Case Schedule and Motion to Stay in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 5:24-cv-03117-EKL (N.D. Cal.)
1021	U.S. Patent No. 11,697,011 ("the '011 patent")
1022	U.S. Provisional Application No. 62/474,383
1023	U.S. Provisional Application No. 62/516,582
1024	Decision Granting Institution of <i>Inter Partes</i> Review for U.S. Patent No. 11,697,011 (Paper 7) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2024-01157 (P.T.A.B. Jan. 23, 2025)
1025	Decision Granting Institution of <i>Inter Partes</i> Review for U.S. Patent No. 11,697,012 (Paper 6) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-00156 (P.T.A.B. Apr. 22, 2025)
1026	Decision Granting Institution of <i>Inter Partes</i> Review for U.S. Patent No. 11,554,005 (Paper 10) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-00289 (P.T.A.B. June 18, 2025)
1027	Decision Granting Institution of <i>Inter Partes</i> Review for U.S. Patent No. 11,844,921 (Paper 13) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-00728 (P.T.A.B. Oct. 10, 2025)
1028	Decision Granting Institution of <i>Inter Partes</i> Review for U.S. Patent No. 11,865,291 (Paper 10) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-00989 (P.T.A.B. Oct. 23, 2025)
1029	U.S. Patent Publication No. 2015/0352325 to Quick ("Quick")

Exhibit	Description
1030	Patent Owner's Response for U.S. Patent No. 11,697,011 (Paper 13) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2024-01157 (Apr. 18, 2025)
1031	U.S. Patent Publication No. 2010/0042118 A1 to Garrison et al.
1032	U.S. Patent No. 5,938,645 to Gordon ("Gordon")
1033	U.S. Patent Publication No. 2014/0296868 A1 to Garrison et al.
1034	U.S. Patent Publication No. 2017/0043066 A1 to Laub ("Laub")
1035	U.S. Patent No. 8,734,374 B2 to Aklog et al. ("Aklog")
1036	Penumbra, Optimizing Direct Aspiration (May 2013)
1037	AXS Universal Aspiration Set Brochure (2017)
1038	U.S. Patent No. 12,109,384
1039	Supplemental Declaration of Paul Zalesky Ph.D. submitted by Patent Owner as Exhibit 2008 in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2024-01157, U.S. Patent No. 11,697,011
1040	International Standards Organization, Small-bore Connectors for Liquids and Gasses in Healthcare Applications Part 7: Connectors for Intravascular or Hypodermic Applications, 80369-7 (Edition 1, 2016) ("ISO 80369-7")
1041	O. Nikoubashman et al., Under Pressure: Comparison of Aspiration Techniques for Endovascular Mechanical Thrombectomy, <i>Am J. Neuroradiol.</i> (May 2018) ("Nikoubashman")
1042	Record of Oral Hearing held on October 29, 2025 in <i>Inter Partes</i> Review for U.S. Patent No. 11,697,011 (Paper 34) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2024-01157 (P.T.A.B. Nov. 17, 2025)
1043	Dorland's Illustrated Medical Dictionary, 32nd ed. (2012) - Definition of "Port"
1044	U.S. Patent No. 9,526,864 B2 to Quick

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1045	Decision Granting Institution of <i>Inter Partes</i> Review for U.S. Patent No. 11,969,333 (Paper 15) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-01021 (P.T.A.B. Dec. 11, 2025)
1046	Decision Granting Institution of <i>Inter Partes</i> Review for U.S. Patent No. 11,974,910 (Paper 15) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-01025 (P.T.A.B. Dec. 11, 2025)
1047	Final Written Decision Determining All Challenged Claims Unpatentable, IPR2024-01157
1048	Final Written Decision Determining All Challenged Claims Unpatentable, IPR2025-00156
1049	Final Written Decision Determining All Challenged Claims Unpatentable, IPR2025-00289

Patent Owner's Exhibits

Exhibit	Description
2001	Declaration of Brian Brown
2002	Deposition Transcript of Petitioner's Expert, Troy L. Thornton (August 11, 2026)
2003	U.S. Patent No. 11,849,963 to Quick ("the '963 Patent")
2004	Non-Final Office Action in the '963 Patent (mailed September 15, 2022)
2005	Deposition Transcript of Petitioner's Expert, Troy L. Thornton (February 18, 2026) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-01264
2006	Supplemental Declaration of Paul Zalesky (EX2026) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-00289
2007	U.S. Patent No. 11,697,012 ("the '012 Patent")
2008	U.S. Patent No. 11,554,005 ("the '005 Patent")
2009	Supplemental Declaration of Paul Zalesky (EX2009) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-00989
2010	Supplemental Declaration of Paul Zalesky (EX2033) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-00728
2011	Deposition Transcript of Troy Thornton (June 25, 2025) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-00156
2012	Petition for <i>Inter Partes</i> Review for U.S. Patent No. 12,016,580 (Paper 1) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-01264 (P.T.A.B. July 8, 2025)
2013	Santos, Emilie M M et al. "Automated Entire Thrombus Density Measurements for Robust and Comprehensive Thrombus Characterization in Patients with Acute Ischemic Stroke." PloS one vol. 11,1 e0145641. 14 Jan. 2016, doi:10.1371/journal.pone.0145641

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2014	Aghayev, Ayaz et al. "The rate of resolution of clot burden measured by pulmonary CT angiography in patients with acute pulmonary embolism." AJR. American journal of roentgenology vol. 200,4 (2013): 791-7. doi:10.2214/AJR.12.8624

I. INTRODUCTION

Petitioner challenges Claims 1-5, 8, 10-12, 14-19, 22, 24-28, and 30 of U.S. Patent No. 12,156,669 (“the ’669 Patent”). Petition (Paper 2), p.1. Petitioner has not shown by a preponderance of the evidence that Claims 4, 8, 10, 12, 18, 22, 24, and 26-28 of the ’669 Patent are unpatentable. Those claims recite specific aspects of the systems for treating blood clots disclosed by the ’669 Patent. Although Patent Owner believes that all claims of the ’669 Patent are patentable over the disclosed art, Patent Owner focuses on the narrower dependent claims, which recite particularly innovative features.

Occlusions (blockages) in blood vessels are a major cause of disease and death worldwide. EX1001, 1:40-2:7; EX2001, ¶30. Venous thromboembolism (“VTE”) involves blood-clot formation in veins. *Id.* Pulmonary embolism (“PE”) and deep vein thrombosis (“DVT”) are common and particularly dangerous types of VTE. *Id.* The ’669 Patent discloses systems and methods for removing clot material from a blood vessel of a human patient to treat VTE, including PE and DVT. EX1001, 1:30-32. The ’669 Patent describes that those systems and methods are intended to avoid the risks and trauma associated with more invasive surgical techniques, as well as delays and hemorrhage risks associated with chemical clot-dissolving agents. *See* EX1001, 2:8-61; EX2001, ¶¶34-37.

The ’669 Patent includes two independent claims—Claims 1 and 15—

directed to aspiration systems. The dependent claims discussed below incorporate the limitations of those independent claims. Claim 1 recites, among other elements, a vacuum source, connection tubing, a catheter, a filter chamber, a flow controller, and a hemostasis valve. EX1001, cl.1. The filter chamber includes a housing and a filter within the housing. *Id.* The housing includes a port configured to be fluidically coupled to the catheter and a fluid connector configured to be fluidically coupled to the vacuum source via the connection tubing. *Id.* Claim 15 recites a similar aspiration system, but does not recite “connection tubing,” and recites that the filter chamber housing has a first port and a second port. *Id.* at cl.15.

Claims 4, 8, 10, 12, 18, 22, 24, and 26-28 recite specific and narrower aspiration-system features that Petitioner's asserted art does not disclose or render obvious. For example, Claims 4 and 18 narrow independent Claims 1 and 15, respectively, by reciting that the “catheter is fluidically connected *in serial* to the filter chamber.” *Id.* at cls.4, 18. The prior art relied on by Petitioner, specifically Figure 34 of Garrison, shows that the catheter 2030 is fluidically coupled to filter 3418 through a flow path that is *parallel* to and divergent from the flow path from arterial access device 2010. EX2001, ¶¶54-55. The paths join at valve 3325. *Id.* Such a parallel/divergent structure is the opposite of a serial arrangement, and Petitioner's expert even agreed that the flow paths connecting the catheter 2030 and arterial access device 2010 to the filter 3418 are not in series. EX2002, 49:20-22 (“[Q.] So

then where the flows diverge, those flows are not in series; is that correct? [Mr. Thornton.] I wouldn't say they're in series."). Grounds 1-3 challenging Claims 4 and 18 fail for that reason.

Claims 8 and 22 add a requirement that the "filter" of Claims 1 and 15, respectively, "is removable from within the housing." EX1001, cls.8, 22. Neither Garrison nor Trerotola, which Petitioner cites in support of Ground 2 (although ground 2 is purportedly based on Garrison alone), discloses a removable filter. Petitioner concedes that Garrison does not expressly do so (Petition, p.49), and Garrison provides no details at all of its filter 3418 other than that element 3418 is a "filter." EX1006, ¶[0131]. Trerotola discloses a nonremovable filter fixed within a housing; although the housing may be opened to access the filter for cleaning, Trerotola does not disclose that the filter is removable from the housing. EX2001, ¶¶61-62; EX1012, 5:65-6:1, 6:55-58. Ground 2 therefore fails.

Ground 2 for Claims 8 and 22 also fails because Petitioner does not establish any adequate reason why a person of ordinary skill in the art ("POSA") would have been motivated to modify Garrison to make its filter removable. Specifically, (1) clots in the neurovasculature that Garrison intends to treat are small enough that the filter does not need to be cleaned or replaced during use; and (2) replacing or removing Garrison's filter would slow Garrison's neurovasculature treatment when time is critical. EX2001, ¶¶64-68; EX1006, ¶[0043] ("[i]n the setting of acute

ischemic stroke ... ‘time is brain’”). While Goff discloses a removable filter (EX1005, ¶[0015]), ground 3 challenging Claims 8 and 22 fails for the same reasons: a POSA would not have been motivated to modify Garrison to incorporate Goff’s filter because a removable filter is not needed where the aspirated clots are of such small size and would slow Garrison’s time-critical procedure. EX2001, ¶¶69-70.

Claims 10 and 24 narrow independent Claims 1 and 15, respectively, by reciting other specifics of the filter, including that the “filter *encloses a region* within the housing” and that the “fluid connector [or second port] *is proximal to* the enclosed region along the first fluid path.” EX1001, cls.10, 24. The enclosed region must be positioned on the fluid-connector/second-port side of the filter chamber such that the fluid connector or second port is proximal to that enclosed region as shown in Figures 3A-3B of the ’669 Patent. EX2001, ¶75. Neither Garrison nor Goff discloses a filter that encloses a region in the required orientation. *Id.* at ¶¶79-82. Grounds 1-3 challenging Claims 10 and 24 fail for that reason. Petitioner also does not identify that Garrison’s filter encloses any particular region. Petition, pp.50-51. There is no such disclosure in Garrison, which does not describe its filter. And because filters may take different forms, including many forms that do not enclose a region, Petitioner has not shown that Garrison discloses this limitation expressly or inherently. EX2001, ¶77-78. Grounds 1-2 challenging Claims 10 and 24 fail for that additional reason.

Lastly, Claims 12 and 26-28 recite a hemostasis-valve configuration that includes a particular arrangement with a flexible “filament.” The term “filament” has been addressed in related IPR proceedings involving related patents. Grounds 8-9 challenging those claims fail because Schaffer fails to disclose or suggest a “filament,” which requires flexibility, as the Board has repeatedly found in final written decisions for related patents. EX1047, pp.38-40; EX1048, pp.41-42; EX1049, p.31. Grounds 10-11 fail because Petitioner's further proposal to modify Schaffer using Hartley rests on hindsight, requires changes that undermine Schaffer's operation and stated objectives, and lacks an adequately supported rationale.

For these reasons, and for the additional reasons below, Petitioner has not established by a preponderance of the evidence that Claims 4, 8, 10, 12, 18, 22, 24, and 26-28 are unpatentable under any asserted ground.

II. BACKGROUND

A. Overview of the '669 Patent

The '669 Patent is directed to improved clot treatment systems for removing clot material from a blood vessel of a human patient. EX1001, 1:30-32. In particular, the '669 Patent is directed to aspiration systems that include, among other components, a vacuum source, a catheter, a filter chamber, a flow controller, and a hemostasis valve. EX1001, cl.1. The disclosed systems are particularly well-suited

for treating venous thromboembolism (“VTE”), a disease caused by blood clot formation in the veins of the body that is a major cause of both death and disease worldwide. EX1001, 1:40-2:7; EX2001, ¶30. Pulmonary embolism (“PE”) and deep vein thrombosis (“DVT”) are common and particularly dangerous types of VTE. *Id.* DVT is a thrombus that typically forms in the deep veins of a limb, such as the leg. EX1001, 1:53-55; EX2001, ¶33. If part of the thrombus breaks away and travels to the pulmonary vasculature, it can cause PE. *Id.* PE is a life-threatening condition that occurs when a clot breaks free and becomes lodged in the arteries of the lungs, blocking the oxygenation of blood necessary to sustain the entire body. EX1001, 1:64-2:7; EX2001, ¶33.

Historically, PE and DVT have been treated with thrombolytic agents or more invasive procedures. EX1001, 2:8-15, 32-34; EX2001, ¶34. However, those approaches have significant drawbacks. For example, thrombolytic agents do not always work, take hours or even days to be successful, can cause hemorrhage, and cannot be used at all in many patients. EX1001, 2:34-37; EX2001, ¶¶35-36.

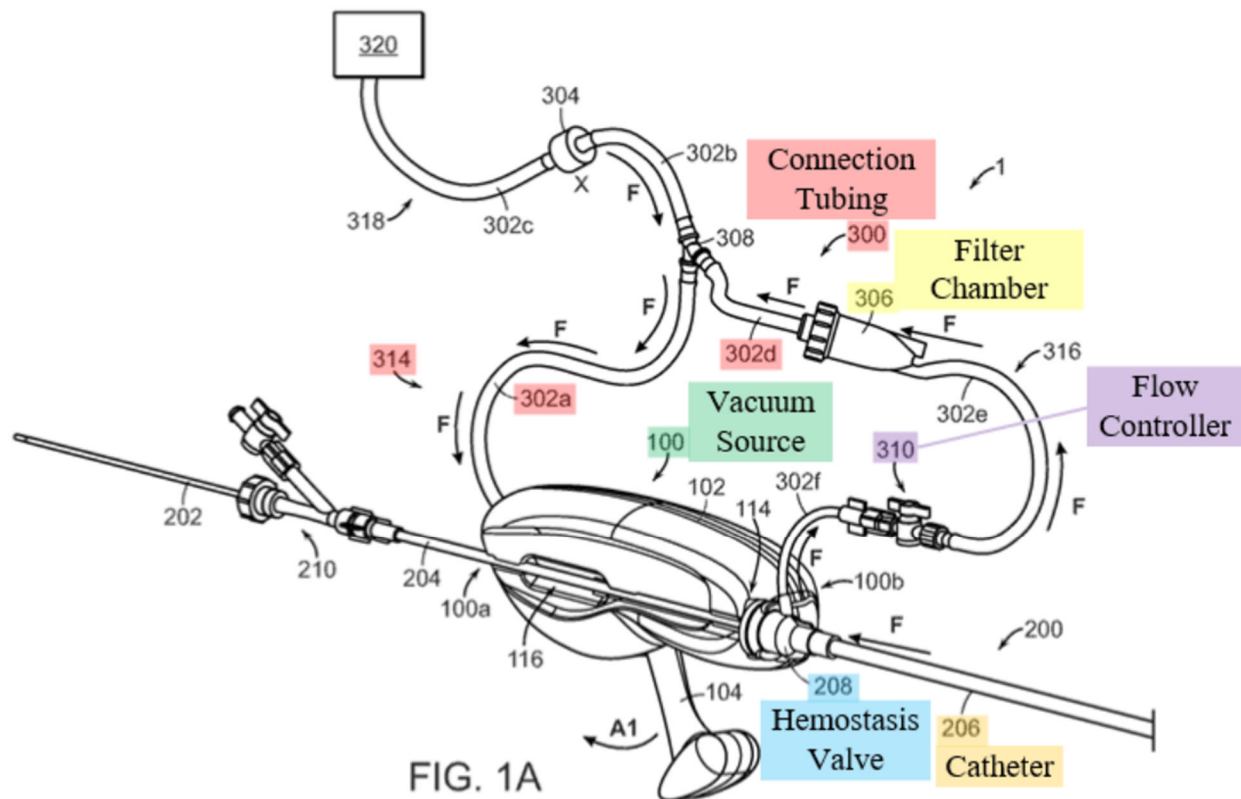
The '669 Patent has two independent claims—Claims 1 and 15—directed to aspiration systems, such as for aspirating clot material from a human patient. EX1001, cls.1, 15, 1:30-32. Claim 1 recites an aspiration system comprising: “a vacuum source; connection tubing fluidically coupled to the vacuum source; a catheter fluidically coupled to the vacuum source; [and] a filter chamber fluidically

coupled to the connection tubing at a location apart from the vacuum source.”

EX1001, cl.1. The filter chamber includes a “housing and a filter within the housing,” and the housing includes “a port configured to be fluidically coupled to the catheter; and a fluid connector configured to be fluidically coupled to the connection tubing.” *Id.* The filter is “in the housing along a first fluid path,” such that “the first fluid path fluidically couples the port and the fluid connector,” and “the catheter is fluidically coupled to the vacuum source via the filter chamber along the first fluid path.” *Id.* The system further comprises “a flow controller fluidically coupling the filter chamber to the catheter, wherein the flow controller is along the first fluid path between the filter chamber and the catheter,” and “a hemostasis valve fluidically coupled to the catheter along a second fluid path at least partially different than the first fluid path.” *Id.* The “hemostasis valve is configured to maintain hemostasis by inhibiting proximal fluid flow along the second fluid path when an interventional device is inserted through the hemostasis valve and the catheter.” *Id.*

Claim 15 includes many features similar to those of Claim 1. EX2001, ¶38. However, it omits “connection tubing,” and instead recites that the catheter is fluidically coupled to the vacuum source through a first fluid path and that the filter chamber is along that first fluid path. EX1001, cl.15. Claim 15 also requires a housing with a first port configured to be fluidically coupled to the catheter and a second port configured to be fluidically coupled to the vacuum source. *Id.*

Figures 1A and 1B of the '669 Patent illustrate an example aspiration system consistent with Claims 1 and 15. EX2001, ¶39; EX1001, 4:42-45. System 1 includes a vacuum source 100, catheter 206, filter chamber 306, flow controller 310, hemostasis valve 208, and connection tubing 300. The connection tubing includes a first portion 314, which includes tubing sections 302a and 302d that fluidically couple filter chamber 306 to vacuum source 100:



EX1001, 4:42-64, 6:1-7:28; EX2001, ¶39.

The vacuum source can be a syringe. EX1001, 6:4-5. The '669 Patent also incorporates by reference (*id.* at 4:56-64) U.S. Patent No. 9,526,864 (EX1044), which describes other suitable vacuum sources, including electrical and mechanical

pumps. EX1044, 5:19-24. The catheter 206 is fluidically coupled to the vacuum source 100 via the filter chamber 306 “to enable material (e.g., blood and clot material) aspirated from the catheter system 200 to flow into the tubing system 300” with the filter chamber 306 capturing the clot material while permitting blood to pass therethrough. EX1001, 4:52-56, 9:34-37; EX2001, ¶39. The flow controller 310 can be a stopcock or similar device that regulates fluid flow through the tubing system 300 between the filter chamber 306 and the catheter 206. EX1001, 7:19-23. The filter chamber 306 is fluidically coupled to the connection tubing 300 at a location apart from the vacuum source 100 by, for example, the separation of tubing sections 302a, 302d of the first portion 314 of the connection tubing 300. EX2001, ¶39.

Figures 3A-3C of the '669 Patent illustrate the filter chamber 306 in more detail. EX1001, 8:62-64; EX2001, ¶40. The filter chamber 306 includes a housing 322, a filter 321 positioned within the housing 322 (e.g., a chamber 323 thereof), a port 324 configured to be fluidically coupled (e.g., distally, downstream) to the catheter 206, and a fluid connector 332 configured to be fluidically coupled (e.g., proximally, upstream) to the connection tubing 300:

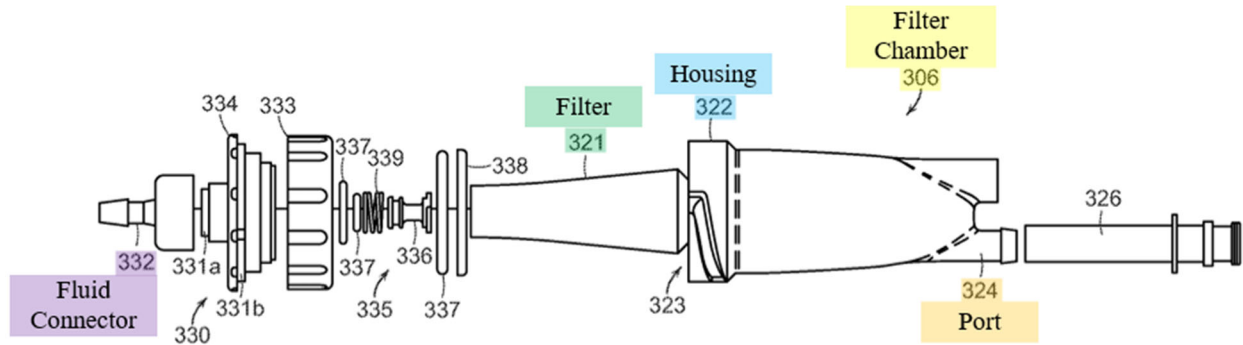


FIG. 3A

EX1001, 8:54-9:3, 9:11-13; EX2001, ¶40. The filter 321 is in the housing along a first fluid path that fluidically couples the port 324 and the fluid connector 332:

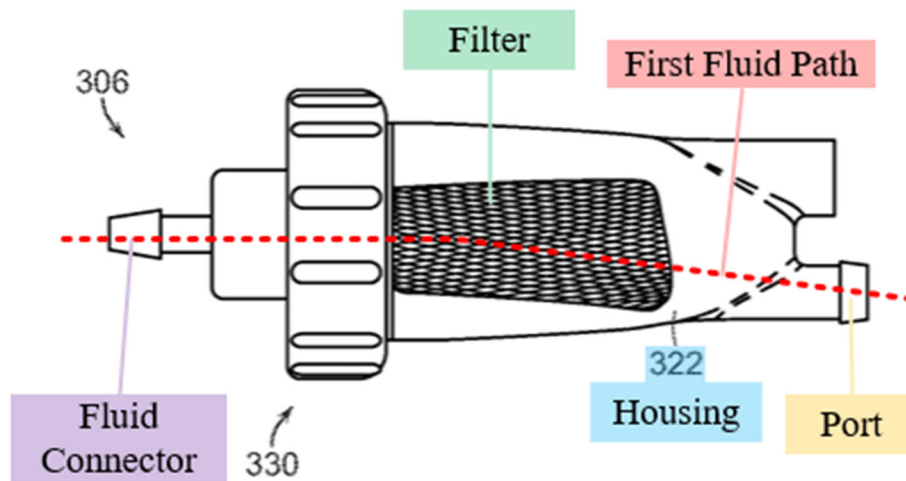
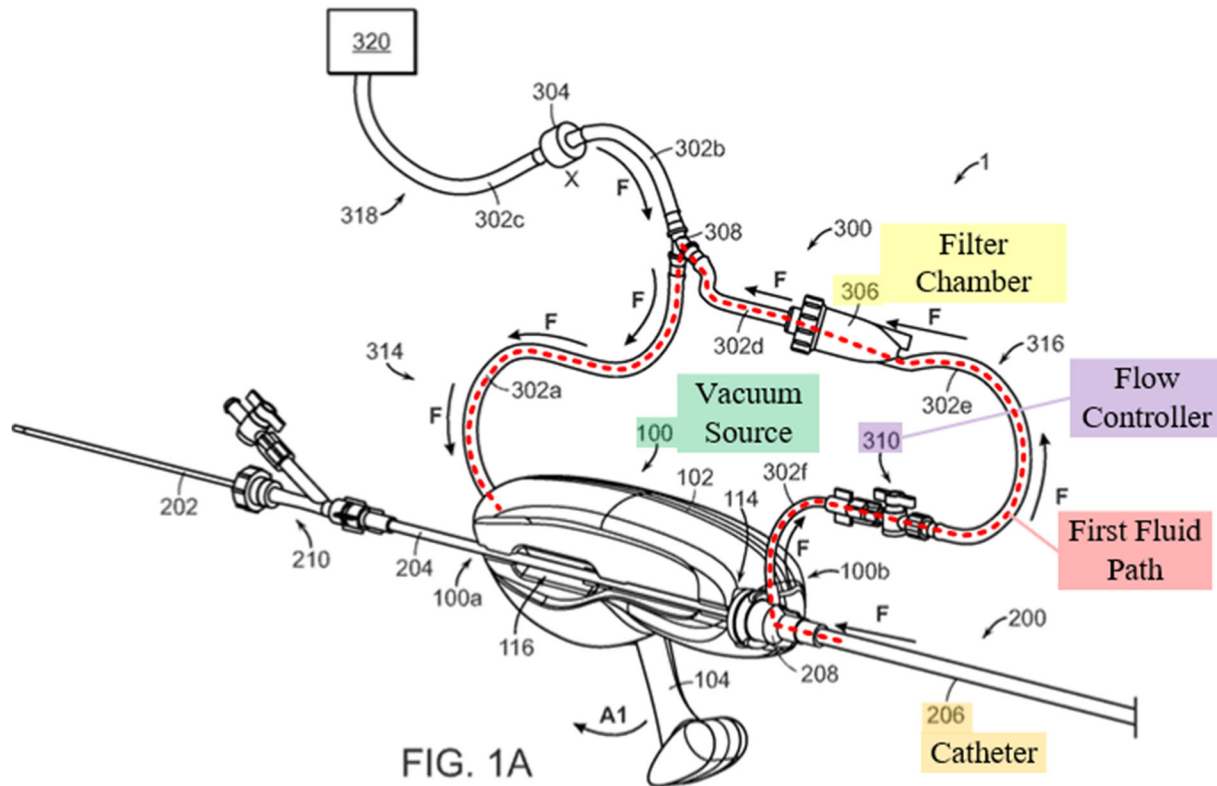


FIG. 3B

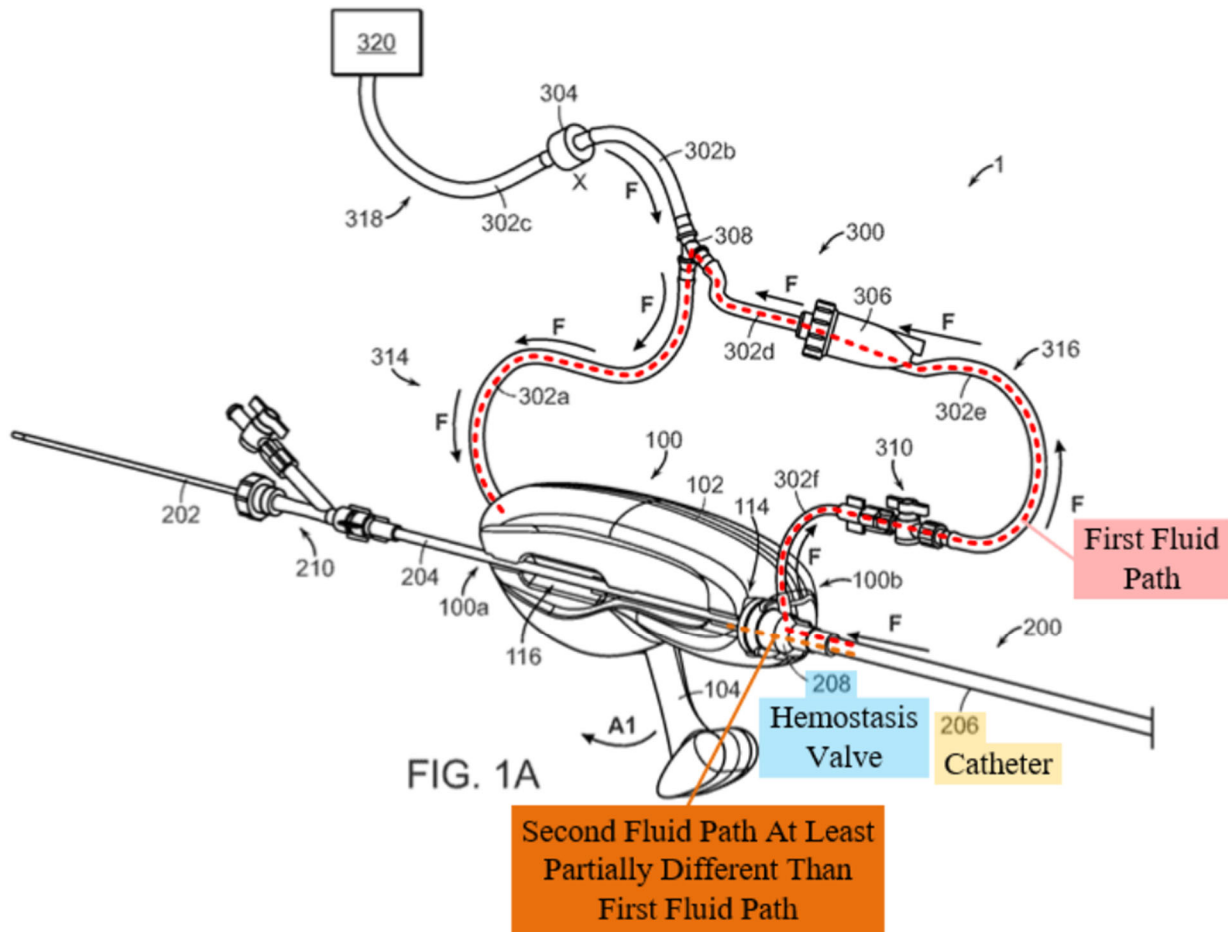
EX1001, 9:31-37; EX2001, ¶40.

Referring again to Figures 1A and 1B of the '669 Patent, the catheter 206 is fluidically coupled (in series) to the vacuum source along the first fluid path, and the

flow controller 310 is positioned along that first fluid path between the catheter 206 and the filter chamber 306:



EX2001, ¶41. More specifically, the first fluid path extends from the catheter 206 to the flow controller 310, the filter chamber 306, and the vacuum source 100 via the tubing section 302f (e.g., a side port). *Id.*; EX1001, 10:9-13, 17:53-56. The hemostasis valve 208 is coupled to the proximal end of the catheter 206 such that the hemostasis valve 208 is fluidically coupled to the catheter 206 along a second fluid path at least partially different than the first fluid path:



EX2001, ¶41; EX1001, 6:17-22, 10:4-6, 17:48-52.

The hemostasis valve 208 is configured to maintain hemostasis by inhibiting proximal fluid flow along that second fluid path when an interventional device (e.g., interventional device ID shown in Figures 2A-2F) is inserted through the hemostasis valve 208 and the catheter 206. EX2001, ¶42; EX1001, FIGS.13A-13B, 17:38-18:59.

Figures 11 and 13A-13B of the '669 Patent illustrate a garrote-type hemostasis valve 1108 that may be used in the system of Figure 1:

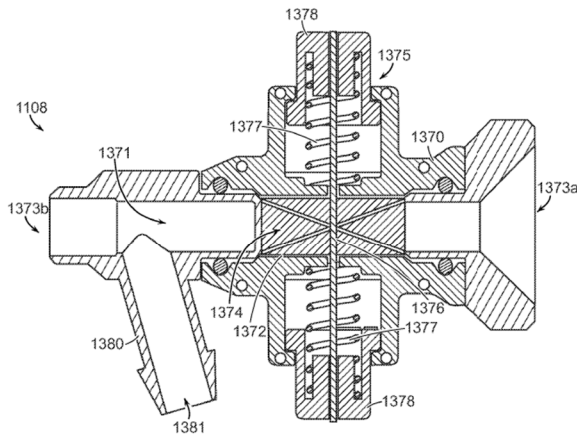


FIG. 13A

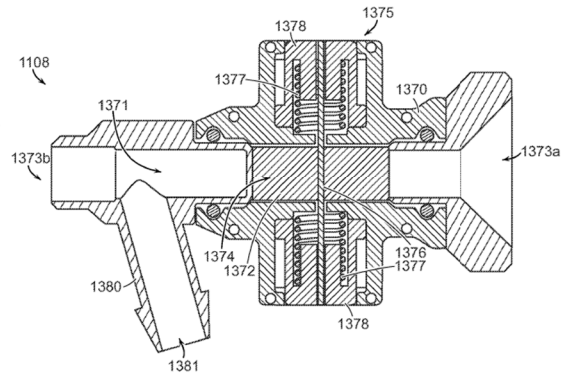


FIG. 13B

EX1001, 17:38-42. The '669 Patent further incorporates by reference and attaches as an appendix U.S. Provisional Patent Application No. 62/554,931 ("the '931 Application"; EX1019), which further supplements the description of a garrote-type hemostasis valve illustrated in Figures 11 and 13A-13B of the '669 Patent. EX1001, 17:41-47.

The '669 Patent¹ explains that "traditional hemostasis valves" are useful for preventing blood loss during intravascular procedures, but "they have some drawbacks." EX1019, ¶[0004]. For example, "some valves may not seal adequately for all interventional applications or tools, and/or the operation of some valves may be complicated for operator use." *Id.* The '669 Patent addresses those drawbacks by

¹ Reference is made herein to the disclosure of the '669 Patent with citations to the incorporated disclosure of the '931 Application (EX1019) where appropriate.

providing a hemostasis valve (i.e., a valve that inhibits or prevents blood loss) with easy one-handed operation and a strong seal around a variety of different-sized instruments, both of which are particularly important for hemostasis valves used in the aspiration systems claimed in the '669 Patent. *Id.* at ¶[0032]; EX2006, ¶¶42-43.

The '669 Patent's garrote-type hemostasis valve can include a tubular member 1372, an actuation mechanism 1375 having at least one button 1378, and one or more filaments 1376. EX1001, 17:64-18:6, 18:6-15. The filament 1376 is coupled to the button 1378 and the tubular member 1372 such that the filament selectively constricts, collapses, and/or seals the lumen of the tubular sidewall based on the movement and/or position of the button 1378. *Id.* at 18:15-40; EX2006, ¶46. The button 1378 can be biased by a spring 1377 to "maintain the tubular member 1372 in the collapsed" and sealed state. EX1001, 18:24-32. Depressing the button 1378 loosens the filament 1376 to allow the tubular member 1372 to expand. *Id.* at 18:12-14, 18:36-40. In its expanded state, the tubular member 1372 provides a continuous lumen that allows the interventional device to be safely and easily inserted and retracted from the catheter 206. *Id.* at 18:48-59. The spring 1377 is biased to collapse the tubular member 1372 by tightening and constricting the filament 1376, thereby creating a hemostatic seal (either with or without an inserted instrument) when the button 1378 is not depressed. *Id.* at 18:24-32.

B. Prosecution History

In the sole Office Action, the Examiner allowed then-pending claims 1-9 and 11-22 and stated that “no art of record alone or in combination teach[es] an aspiration system that includes the combination of recited limitations.” EX1002, pp.319-320. In that Office Action, however, the Examiner rejected dependent claim 10 as being indefinite under 35 U.S.C. § 112(b). *Id.* at p.320.

In response, and based on a telephone interview with the Examiner, Patent Owner made clarifying amendments to claims 1, 4, 10-12, 15, and 20-22 and added new claims 23-30. *Id.* at pp.298-307. The Examiner subsequently allowed claims 1-30, which issued as Claims 1-30 of the '669 Patent. *Id.* at p.275. In the Notice of Allowance, the Examiner repeated the reasons for allowance given in the Office Action. *Id.* at pp.275-276.

Petitioner's primary references Garrison, Hartley, and Goff were cited in an information disclosure statement and considered by the Examiner. *Id.* at pp.337, 347, 355, 478, 488, 496. Accordingly, Garrison, Hartley, and Goff appear on the face of the '669 Patent. EX1001, pp.5, 7, 8. Moreover, the Examiner was aware of and considered Garrison—Petitioner's primary reference for all grounds—during prosecution of the parent U.S. Patent No. 11,849,963 (“the '963 Patent”; EX2003), of which the '669 Patent is a direct continuation. *See* EX2004, pp.6-9 (Office Action citing and applying Garrison as a primary reference); EX1001, p.1. This record

confirms that the Examiner considered Garrison, Goff, and Hartley during prosecution of the '669 Patent. That history provides relevant context, but Patent Owner's arguments here independently establish that Petitioner has not met its burden.

C. Person of Ordinary Skill in the Art ("POSA")

A POSA as of January 26, 2018 (the earliest priority date of the '669 Patent) would have been (1) a person with a Bachelor of Science degree in engineering or an equivalent field, with two to four years of academic or industry experience in the mechanical thrombectomy industry or comparable industry experience who would, where necessary or desired, work or consult with others including a physician to develop thrombectomy devices; or (2) an interventional radiologist or pulmonologist with at least three years of experience developing and/or using medical devices in thrombectomy procedures, and who would, where necessary, work or consult with others including an engineer to develop such a medical device. EX2001, ¶45.

Petitioner's proposed definition of a POSA omits the field of the invention of the '669 Patent and should be rejected. Specifically, Petitioner proposes that a POSA would have "an undergraduate degree in mechanical engineering or a related engineering discipline and 2-4 years of catheter design experience and, where necessary, would have consulted with a physician regarding the methods of treatment." Petition, p.16.

There is no meaningful dispute regarding the field of the invention of the '669 Patent. EX1001, 1:30-32. Petitioner's purported expert, Mr. Thornton, testified that he agrees that the field of the invention of the '669 Patent is "devices and methods for the intravascular treatment of emboli and/or thrombi within a blood vessel of a human patient." EX2002, 13:25-14:14.

Although Petitioner's proposed definition of a POSA includes a similar level of education, Petitioner's proposed POSA omits any experience in the field of the invention of the '669 Patent. Instead, Petitioner asserts that only "catheter design experience" is necessary, proposing that a POSA has "2-4 years of catheter design experience." Petition, p.16. Petitioner's proposed definition does not account for the relevant technical field of the '669 Patent.

Experience in the field of the invention is critical to a POSA's understanding of the relevant design considerations. EX2001, ¶46. For example, as set forth below in §IV, an understanding of the type of clot a device is designed to treat (e.g., neurovascular or PE/DVT) meaningfully affects the design considerations. *Id.*

D. The Testimony of Petitioner's Purported Expert Should be Afforded Little or No Weight

Petitioner's purported expert testimony should be afforded little weight and should not be credited over the testimony of Patent Owner's expert, Brian Brown. Petitioner's expert, Mr. Thornton, has no experience in the field of the invention,

which he characterizes as “devices for aspirating unwanted material from a patient and hemostasis valves used during intravascular procedures,” or which the '669 Patent describes as “devices and methods for the intravascular treatment of emboli and/or thrombi within a blood vessel of a human patient.” EX1003, ¶38; EX1001, 1:30–32. Mr. Thornton testified that:

[Q.] Have you ever designed a catheter to aspirate emboli, blood clot, or a thrombus from a patient?

[MR. THORNTON] No. The catheters that I developed, though, I would argue are more complex and have probably more design requirements than the single lumen aspiration catheters that are disclosed in these patents.

[Q.] Have you ever designed any device intended to be used to aspirate a blood clot, thrombus, or emboli?

[MR. THORNTON] No.

[Q.] Have you ever designed any catheter intended to be used to aspirate a blood clot, thrombus, or emboli?

[MR. THORNTON] I'll answer no again.

EX2005, 49:24-50:10.

Further, while Petitioner proposes that a POSA, “where necessary, would have consulted with a physician,” there is no evidence that Mr. Thornton consulted with a physician in preparing his opinions in this matter. Just as in other IPRs

challenging Patent Owner's patents, Mr. Thornton does not provide any testimony that he incorporated discussions with physicians or other persons with relevant expertise in forming his opinions. Moreover, in one of the IPRs for a related patent, Mr. Thornton expressly testified that he did not do so while preparing his declaration:

[Q.] And did you consult with any physician in preparing your declaration with respect to the '910 patent?

[MR. THORNTON] No.

[Q.] Did you rely on any statement from any physician in preparing your declaration with respect to the '910 patent?

...

[MR. THORNTON] I don't believe so.

EX2005, 43:9-17.

Because Mr. Thornton's opinions do not reflect the perspective of the properly defined POSA, and because he lacks experience in the relevant field of the '669 Patent, the Board should afford his testimony little weight. By contrast, Patent Owner's expert, Brian Brown, is qualified to offer opinions in the relevant field and has experience designing thrombectomy devices. EX2001, ¶¶7-16.

E. Claim Construction

In an IPR, a claim is construed "using the same claim construction standard

that would be used to construe the claim in a civil action” and “in accordance with the ordinary and customary meaning as understood by a POSITA and the prosecution history pertaining to the patent.” 37 C.F.R. § 42.100(b). In *Phillips v. AWH Corp.*, the Federal Circuit explained that “words of a claim ‘are generally given their ordinary and customary meaning’” and that “the ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application.” 415 F.3d 1303, 1312-13 (Fed. Cir. 2005) (cleaned up). “To act as its own lexicographer a patentee must clearly set forth a definition of the disputed claim term other than its plain and ordinary meaning and must clearly express an intent to redefine the term.” *Kyocera Senco Indus. Tools Inc. v. Int’l Trade Comm’n*, 22 F.4th 1369, 1378 (Fed. Cir. 2022) (emphasis added). “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.” *Hill-Rom Services, Inc. v. Stryker Corp.*, 755 F.3d 1367, 1371 (Fed. Cir. 2014) (internal citations omitted).

Petitioner proposes a claim construction for the term “filament,” recited in dependent Claims 12 and 26-28, under which: “a POSITA would have understood ‘filament’ to mean at least ‘one or more threads, lines, cords, ropes, ribbons, flat wires, sheets, or tapes.[’]” Petition, p.19. But a POSA would understand that the

term “filament” recited in Claims 12 and 26-28 should be accorded its plain and ordinary meaning: “a thin, flexible length of material formed by one or more strands of material.” The Board in related IPRs has adopted this construction.

The core claim construction dispute here relates to whether the term “filament” requires flexibility. Petition, p.17; *see also* EX1049, p.15. ***The Board has already found that it does.*** In particular, the '669 Patent discloses in Figures 11 and 13A-13B a hemostasis valve including a filament having the same configuration disclosed in related patents, including U.S. Patent Nos. 11,697,011 (“the '011 Patent”; EX1021), 11,697,012 (“the '012 Patent”; EX2007), and 11,554,005 (“the '005 Patent”; EX2008), each of which has received a final written decision (collectively, “the related FWDs”; EX1047-EX1049). The '669 Patent incorporates by reference U.S. Provisional Patent Application No. 62/554,931 (“the '931 Application”; EX1019), which further describes the garrote-type hemostasis valve shown in Figures 11 and 13A-13B. EX1001, 17:41-47. Both the '011 Patent and the '012 Patent claim priority to and include disclosures identical in all relevant respects to the '931 Application. EX1021, p.2; EX2007, p.2. The '005 Patent wholly incorporates U.S. Patent Application No. 16/117,519, which is a parent to both the '011 and '012 Patents and has an identical disclosure. EX2008, 5:49-54.

Each of the related FWDs construing the same term “filament” based on the same disclosure “agreed with Patent Owner that the claimed filament requires

flexibility.” EX1049, p.16; EX1047, pp.14-24; EX1048, pp.16-23. The Board found that the term “filament” requires flexibility even in the '011 Patent that Petitioner asserts Claims 12 and 26-28 “most closely resemble.” Petition, p.17; EX1047, pp.14-24.

For example, Claims 12 and 26 (and Claims 27 and 28, which depend from Claim 26 and incorporate all of its limitations) each require a flexible filament because “the button is configured to be actuated from a first position to a second position to *loosen* the filament to allow the tubular member to expand.” EX1001, cls.12, 26. Likewise, Claim 27 further specifies that “the button is movable from the second position to the first position to *tighten* the filament to allow the tubular member to collapse.” *Id.* at cl.27. The ability of the filament to loosen and tighten in the claimed manner requires flexibility. EX1047, pp.18-19; EX2006, ¶¶79-81.

The '669 Patent disclosure further supports that a “filament” is flexible. For example, the “loop” embodiments in Figures 6-7 of the '931 Application “*necessarily* require a flexible structure.” EX1047, p.20; *see also* EX2006, ¶80. And, there is nothing “beyond conjecture to suggest ‘inflexible’ filaments are embraced by the bight embodiments” in Figures 8-9 of the '931 Application either. EX1047, p.21; *see also* EX2006, ¶81. In sum, as the Board found, “the patent does not describe any inflexible filament structures in any detail (even if a rigid bight was theoretically possible) or unambiguously redefine the term filament to have a

broader meaning that would read on inflexible structures.” EX1047, p.21.

Petitioner also notes various differing constructions proposed by the parties in the co-pending litigation for additional terms recited in the claims, including “interventional device,” “proximal,” and “distal.” Petition, p.19. While maintaining its proposed constructions of those terms, Patent Owner does not believe that construction of those additional terms is necessary to resolve this proceeding.

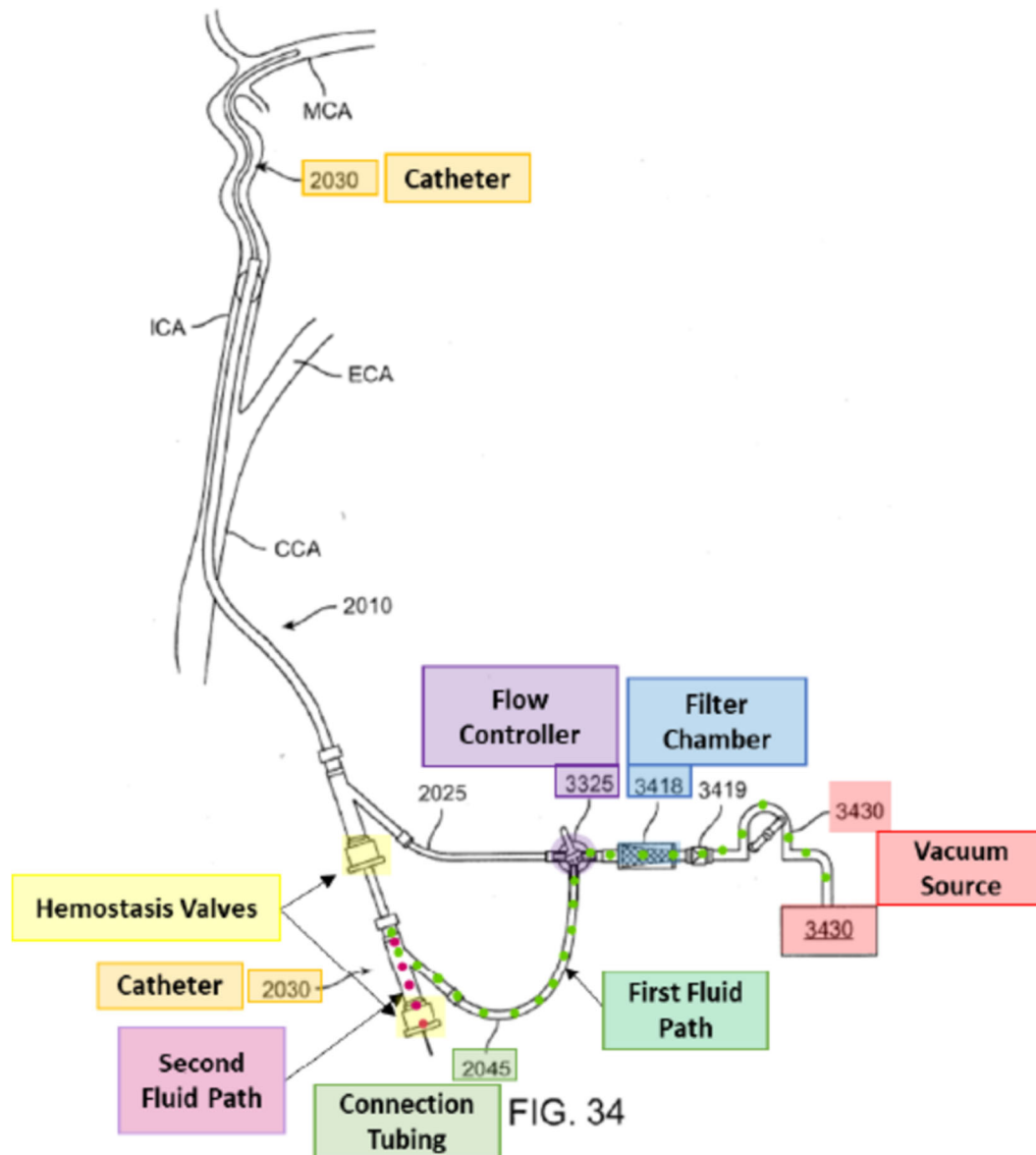
III. DEPENDENT CLAIMS 4 AND 18 ARE NEITHER ANTICIPATED (GROUND 1) NOR RENDERED OBVIOUS (GROUND 2) BY GARRISON, NOR ARE THEY RENDERED OBVIOUS BY GARRISON IN COMBINATION WITH GOFF (GROUND 3)

Petitioner fails to demonstrate by a preponderance of the evidence that Claims 4 and 18 of the '669 Patent are anticipated or rendered obvious by Garrison under grounds 1-3. Anticipation requires that a single reference disclose “each and every element of the claimed invention” either explicitly or inherently and that the “elements must be arranged or combined in the same way as in the claim.” *In re Gleave*, 560 F.3d 1331, 1334 (Fed. Cir. 2009). A claim is not obvious if a limitation of the claim is missing in the cited art, and the record does not provide an adequately supported reason why a POSA would have been motivated to supply that limitation. *See CFMT, Inc. v. Yieldup Int'l Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003) (citing *In re Royka*, 490 F.2d 981, 985 (CCPA 1974)); *see also Aug. Tech. Corp. v. Camtek, Ltd.*, 655 F.3d 1278, 1290 (Fed. Cir. 2011) (finding asserted claims not obvious

where prior art does not disclose the missing element).

Independent Claim 1 recites “a catheter fluidically coupled to [a] vacuum source,” a “filter chamber” having a “housing” with a filter “in the housing along a first fluid path,” and “wherein the catheter is fluidically coupled to the vacuum source via the filter chamber along the first fluid path.” EX1001, cl.1. Independent Claim 15 similarly requires “a catheter fluidically coupled to [a] vacuum source via a first fluid path” and “a filter chamber along the first fluid path.” *Id.* at cl.15. Dependent Claims 4 and 18 narrow independent Claims 1 and 15, respectively, by further requiring that the “catheter is fluidically connected *in serial* to the filter chamber along the first fluid path.” *Id.* at cls.4, 18.

Here, the prior art (Garrison) does not disclose that the “catheter is fluidically connected in serial to the filter chamber along the first fluid path.” It discloses the opposite. Petitioner alleges that “Garrison’s aspiration catheter 2030 is fluidically connected in serial to the filter 3418 (i.e., filter chamber) along the first fluid path,” as shown in Petitioner’s annotations to Figure 34 of Garrison:



Petition, p.45; EX1003, ¶117.

But Petitioner and its expert ignore that the catheter 2030 is fluidically connected to the filter 3418 *together with* the arterial access device 2010 via the same valve 3325. EX2001, ¶54. The three-way valve 3325 forms a Y-connection that separately and selectively connects each of the catheter 2030 and the arterial

access device 2010 to the filter 3418:

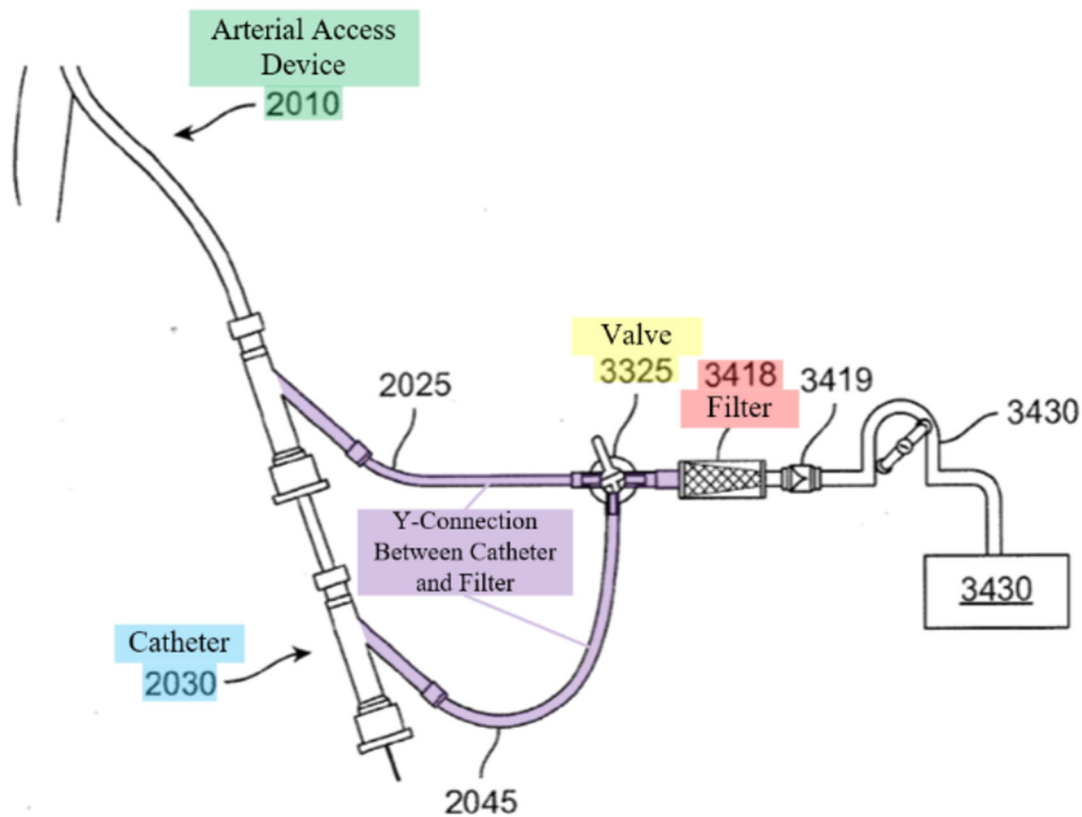


FIG. 34

EX2001, ¶54; EX1006, FIG.34 (enlarged). The valve 3325 controls the Y-connection between the catheters 2010/2030 and “may enable one device, the other device, both devices, or neither device to be connected to the aspiration source at any given time.” EX1006, ¶[0132]; EX2001, ¶54.

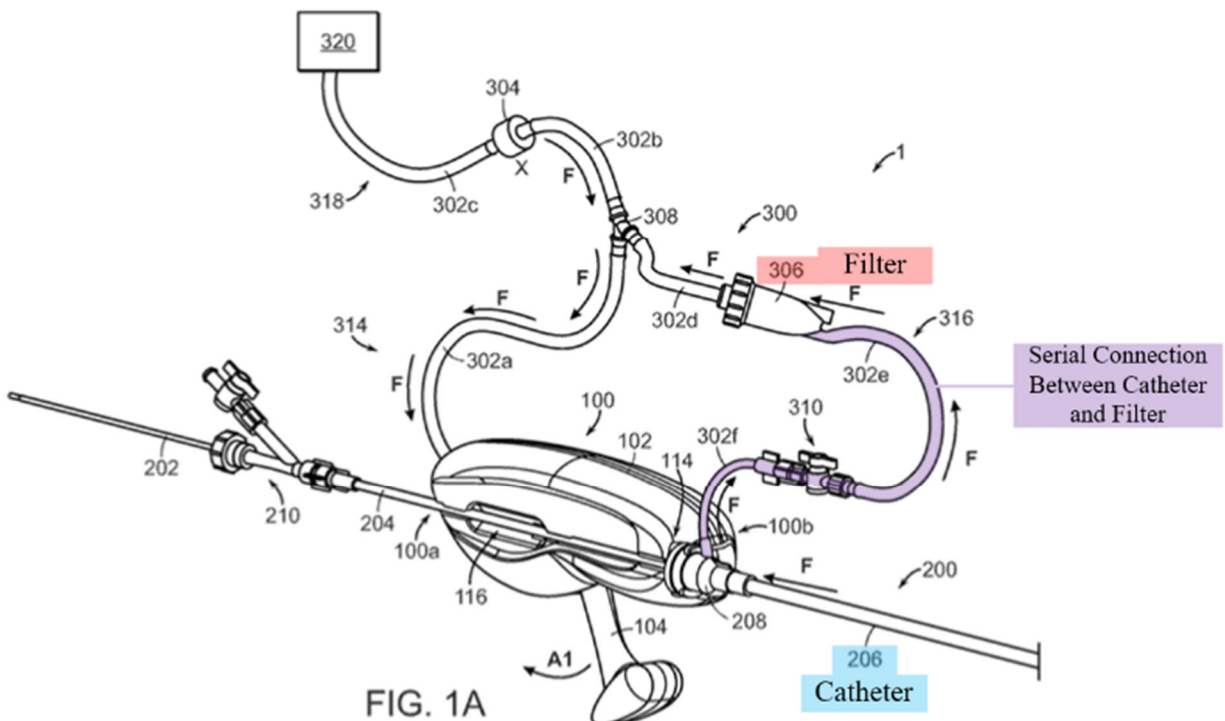
Accordingly, the catheter 2030 is fluidically coupled to the filter 3418 *in parallel* with the arterial access device 2010 (e.g., the flow path 2045 to the catheter 2030 diverges from the flow path 2025 to the arterial access device 2010), rather than “fluidically connected *in serial* to” the filter 3418 as required by Claims 4 and

18. Petitioner's expert admitted during deposition that the flow paths connecting the catheter 2030 and arterial access device 2010 to the filter 3418 are "certainly not in series" when, for example, Garrison's valve 3325 connects both the catheter 2030 and the arterial access device 2010 to the filter 3418:

[Q.] And if the stopcock [3325 in Garrison] is not closed so that there are two fluid paths, is that depicting two parallel fluid paths?

[MR. THORNTON]: I'm not sure I'd use that term. ***They're certainly not in series. They are different fluid paths that are joined together.***

EX2002, 51:3-8 (emphasis added). The '669 Patent, in direct contrast to Garrison, illustrates a single, serial fluidic connection between the catheter 206 and the filter chamber 306, as shown generally by the arrows F:



EX2001, ¶55; EX1001, FIG.1A. Rather than switching connections between two catheters like the three-way valve in Garrison, the flow controller 310 “is externally operated to regulate the flow of liquid through the second portion 316 of the tubing system 300.” EX1001, 7:19-23.

Garrison discloses a serial connection similar to the '669 Patent in a *different and incompatible* embodiment in Figure 33, which *does not* include the valve 3325 (i.e., the alleged “flow controller”), but instead includes separate filters 3418 and aspiration sources 3125/3425 connected to the arterial access device 2010 and the catheter 2030. EX2001, ¶55; EX1006, FIG.33. Accordingly, while that embodiment illustrates a serial connection, it does not include the required “flow controller,” and its structure and operation therefore differ from the claimed system in material respects. EX2001, ¶55. Notably, a flow controller is not needed in Figure 33 because the arterial access device 2010 and the catheter 2030 are connected to separate aspiration sources that can each be operated independently (e.g., turned on or off) such that there is no reason to include the valve 3325 from Figure 34. *Id.* Regardless, Petitioner has not relied on that embodiment in grounds 1-3.

Because the embodiments of Garrison on which Petitioner relies do not disclose a catheter “fluidically connected in serial to [a] filter chamber,” Petitioner has not shown that Garrison anticipates or renders obvious Claims 4 and 18 under grounds 1 and 2. Petitioner likewise does not rely on Goff to supply this missing

limitation. Ground 3 therefore fails as well.

IV. DEPENDENT CLAIMS 8 AND 22 ARE NEITHER RENDERED OBVIOUS BY GARRISON ALONE (GROUND 2) NOR RENDERED OBVIOUS BY GARRISON IN COMBINATION WITH GOFF (GROUND 3)

A claim is not obvious if a limitation of the claim is missing in the cited art, and the record does not provide an adequately supported reason why a POSA would have been motivated to supply that limitation. *See CFMT, Inc. v. Yieldup Int'l Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003) (citing *In re Royka*, 490 F.2d 981, 985 (CCPA 1974)); *see also Aug. Tech. Corp. v. Camtek, Ltd.*, 655 F.3d 1278, 1290 (Fed. Cir. 2011) (finding asserted claims not obvious where prior art does not disclose the missing element). Moreover, to demonstrate obviousness, Petitioner must provide an adequate reason why a POSA would have been motivated to modify/combine the prior art to achieve the claimed invention. *Innogenetics, N.V. v. Abbott Labs.*, 512 F.3d 1363, 1374 (Fed. Cir. 2008); *see also Axonics, Inc. v. Medtronic, Inc.*, 73 F.4th 950, 957 (Fed. Cir. 2023) (“When an obviousness challenge asserts a combination of identified prior art, the motivation-to-combine portion of the inquiry is ‘whether a ‘skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention.’”).

Here, ground 2 fails because Garrison does not disclose that its filter 3418 is removable from a housing. EX2001, ¶61. Garrison discloses nothing about element

3418 beyond that it is a filter. Nor does Trerotola (which Petitioner does not actually rely on as a prior art reference for ground 2) cure that deficiency: Trerotola discloses detachable housing portions that permit access to, and cleaning of, a filtering valve that is fixed—not removable—within the housing. EX2001, ¶¶61-62.

Ground 2 also fails because there is no reason a POSA would have been motivated to modify Garrison's filter to make it removable. Given the small clot burden in the neurovascular procedures that Garrison addresses, a removable filter would provide little benefit and could increase procedure time where Garrison emphasizes that "time is brain." *Id.* at ¶¶64-68; EX1006, ¶[0043]. That is, a POSA would understand that concerns for increased procedure speed in Garrison would predominate over any small risk of clot material clogging the system. EX2001, ¶64. Ground 3 fails for those same reasons—a POSA would not have been motivated to modify Garrison in view of Goff to make Garrison's filter removable. *Id.* at ¶¶69-70.

A. Garrison Alone Does Not Render Claims 8 or 22 Obvious (Ground 2)

Petitioner concedes that "Garrison does not expressly disclose that the filter is removable from the filter housing." Petition, p.49. Petitioner is correct that Garrison does not disclose (nor imply or otherwise render obvious) a removable filter. Garrison's disclosure of the filter is very scant. It only refers to the filter 3418

in a single paragraph and provides no description of the structure at all other than that element 3418 is a “filter.” EX1006, ¶[0131]; EX2001, ¶60. To attempt to cure that deficiency, Petitioner and its expert allege that a POSA would have been motivated to modify Garrison’s filter to make it removable from within the housing “so that the physician could retrieve samples, empty the housing, and clean or replace the filter,” citing Trerotola as one example of a filter housing “that could be unscrewed (bottom left) or unclaspd (bottom right) so that the filter could be removed.” Petition, p.49; EX1003, ¶123. Petitioner cites Trerotola as evidence of what a person of ordinary skill in the art would have known; it does not assert Trerotola as part of a separately identified obviousness combination for these claims.

First, Petitioner’s attempt to rely on Trerotola conflicts with its stated basis for Ground 2, which asserts obviousness based on Garrison alone rather than any combination of references.

What’s more, Trerotola, like Garrison, does not disclose a removable filter at all. EX2001, ¶¶61-62. Rather, Trerotola discloses a filtering device having a housing 22 with first and second housing portions 30, 40 (but not the filter itself) that “are detachable so that the valve can be cleaned if needed during the procedure”:

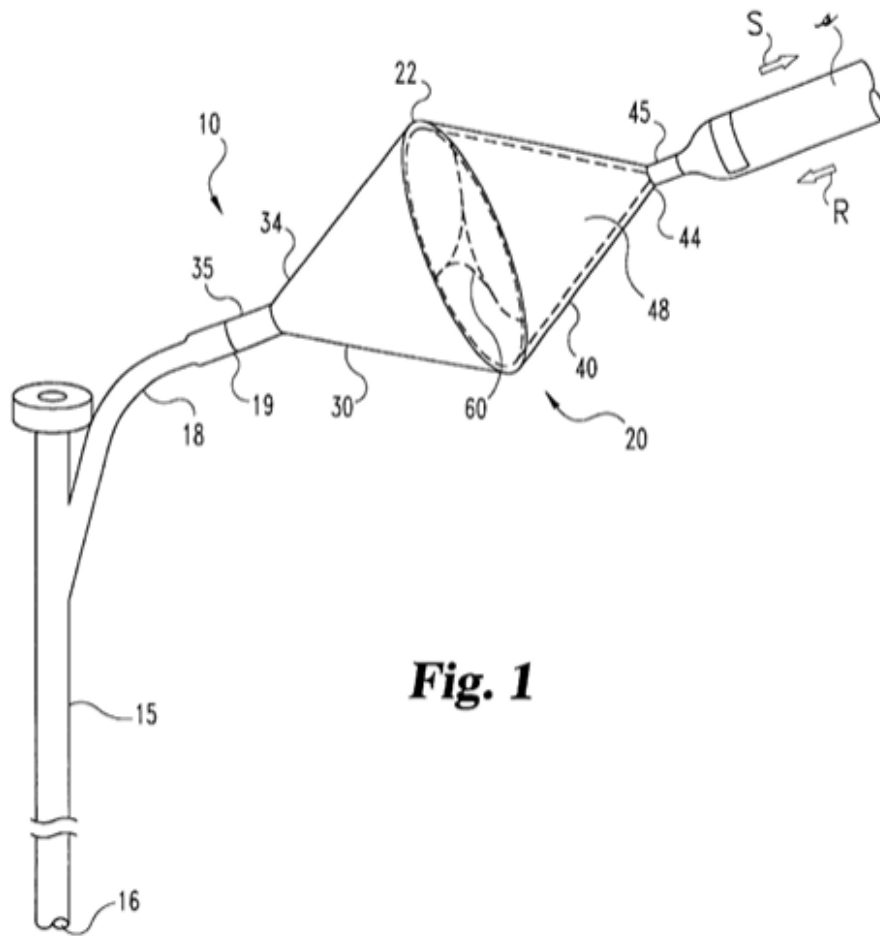


Fig. 1

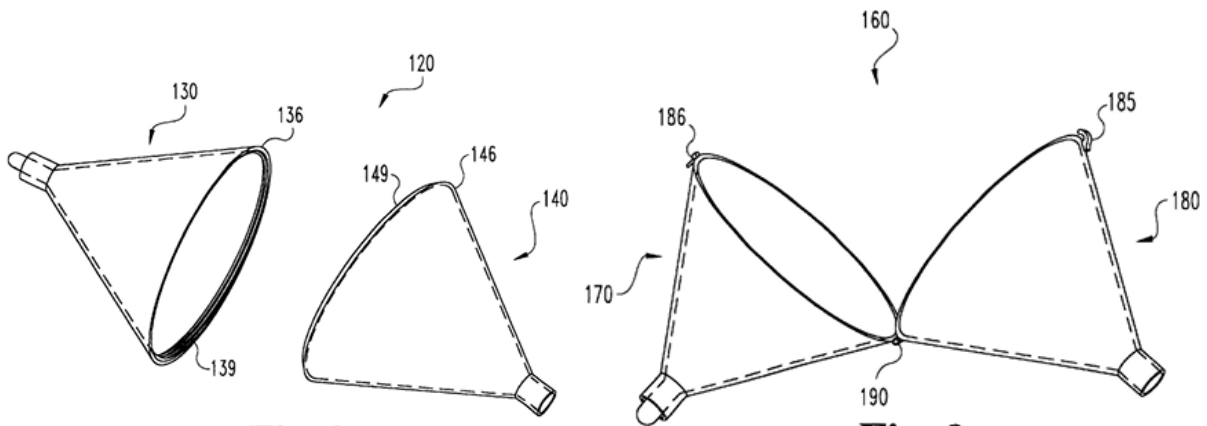


Fig. 8

Fig. 9

EX1012, 4:30-31, 5:65-6:1, FIGS.1, 8, and 9. The valve 60 in Trerotola “is fitted into the opposite end 36 of first housing portion 30” and “includes a plurality of

valvate leaflets 61, 62, 63 that resemble the valves of a human heart”:

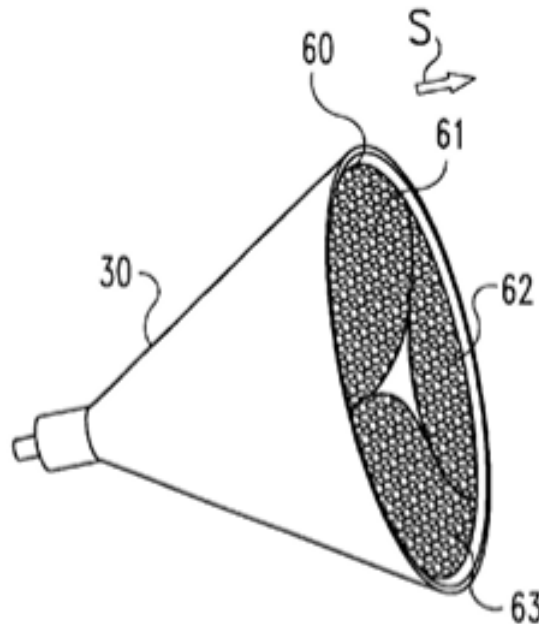


Fig. 4

Id. at 4:66-5:1, 5:29-34, FIG.4. The leaflets 61-63 are disposed on an interior surface of the housing portion 30 such that they “are deformable from [a] closed position to [an] open position in which their tips or ends 61', 62', 63' are deflected toward the direction of the suction force S.” *Id.* at 5:38-44; EX2001, ¶61.

Accordingly, a POSA would have understood that the filter (filtering valve 60) in Trerotola is not removable, and instead that it is fixed within the housing such that the leaflets 61-63 are able to deflect at their tips under the suction force S. EX2001, ¶62. And Trerotola provides no disclosure of the filter 60 being removable or any reason to make it so. *Id.* Instead, a POSA would have understood that when Trerotola discloses that housing portions 30, 40 “are detachable so that the valve can

be cleaned if needed during the procedure”—this means that housing 22 is opened to allow cleaning of the valve 60, which is fixed in the housing, without removing the valve 60. EX1012, 5:65-6:1; EX2001, ¶62. Trerotola confirms that when it states that “[i]f the valve becomes full or clogged, the housing portions can be disengaged to access and clean the valve.” EX1012, 6:55-58; EX2001, ¶62. Thus, Trerotola discloses that the valve is accessed but not removed by opening the housing portions 30, 40. EX2001, ¶62. Trerotola also discloses that its valve is “preferably disposable,” further reducing any need for a removable filter. EX1012, 5:65-66; EX2002, 44:24-45:1.

Ground 2 therefore fails as to Claims 8 and 22 because Petitioner has not shown that Garrison alone—or, even if ground 2 were treated as a combination, Garrison in view of Trerotola—discloses or teaches a filter that “is removable from within the housing.” Neither reference discloses the claimed feature, defeating Petitioner's obviousness theory.

Ground 2 also fails because a POSA would not have modified Garrison to make the filter 3418 removable—there would be no motivation to modify Garrison in such a way. First, the clots in the neurovasculature that Garrison intends to treat are small enough that the filter does not need to be cleaned or replaced during use. EX2001, ¶64. Second, replacing or removing Garrison's filter would slow Garrison's neurovascular treatment of acute ischemic stroke, when time is critical,

such that increased procedure speed predominates over any small risk of clot material clogging the system. *Id.* And third, Trerotola's nonremovable filter addresses many of Petitioner's purported motivations (e.g., to retrieve samples, to empty the housing, to clean the filter) for modifying Garrison to include a removable filter. A removable filter is simply not needed in Garrison.

As Petitioner had to admit over the course of the IPR proceedings related to the '669 Patent, "Garrison focuses on the 'treatment of cerebral occlusions.'" *See*, e.g., EX2012, p.24 (Petition for *Inter Partes* Review of the parent U.S. Patent No. 12,016,580, of which the '669 Patent is a continuation). Indeed, Garrison's disclosure is directed "to medical methods and devices for the treatment of acute ischemic stroke" and, more particularly, to "methods and systems for transcarotid access of the cerebral arterial vasculature and treatment of cerebral occlusions." EX1006, ¶[0002]. For example, in Figure 34 of Garrison relied on by Petitioner, like other disclosures in Garrison, the catheter 2030 is positioned in the middle cerebral artery (MCA):

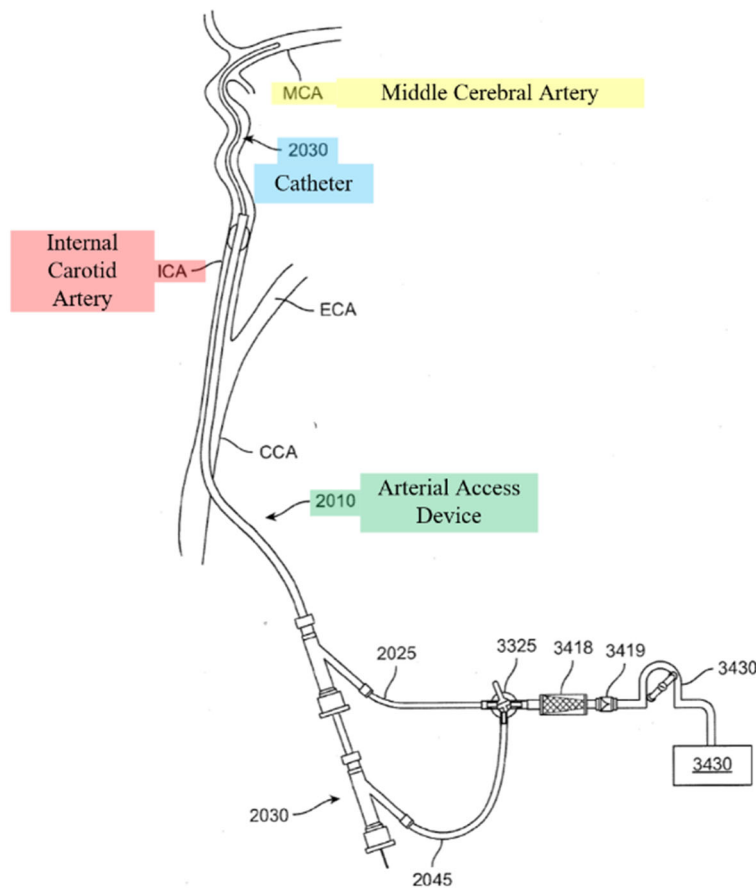


FIG. 34

EX2001, ¶64. The other arterial access device catheter 2010 is positioned in the internal carotid artery (ICA). *Id.*

The cerebral clots causing ischemic stroke that Garrison intends to treat in those neurovascular structures are small. EX2001, ¶65. For example, the average volume of clots causing ischemic stroke in the ICA and MCA is about 52 cubic millimeters (mm³)—about the size of a match head or single unpopped kernel of popcorn. *Id.*; EX2013, pp.6-7. Therefore, a POSA would have understood that clearing, emptying, or declogging Garrison's filter would not be necessary, because

the clot burden is so small that it is unlikely to clog or interfere with the filter in any meaningful way. EX2001, ¶65. Accordingly, a POSA would not have modified Garrison's filter to be removable in a manner not taught by Garrison or Trerotola "so that the physician could retrieve samples, empty the housing, and clean or replace the filter" as alleged by Petitioner. *Id.*; Petition, p.49.

By contrast, the '669 Patent, unlike Garrison, is particularly directed to systems for treating PE and DVT within a patient. EX1001, 1:32-2:61; EX2001, ¶66. DVT and PE clots are significantly larger than those found in the cerebral vessels and, in the case of PE, the clot material can have a complex geometry that extends into branch vessels. EX2001, ¶66. For example, the average volume of PE clots has been found to be 3403 mm³—about 65 times larger than the cerebral clots Garrison is designed to treat. EX2014, p.1. That significantly larger clot burden is much more likely to impact the function of a filter, such that for PE and DVT systems designing features to allow for removal of the filter for clearing or cleaning is advantageous rather than detrimental. EX2001, ¶66.

A POSA also would not have been motivated to modify Garrison to make the filter removable because replacing or removing Garrison's filter would slow Garrison's neurovascular treatment where time is critical. EX2001, ¶67. Garrison discloses that a principal advantage of its disclosed system for treating acute stroke is decreased procedure time, namely that "[i]n the setting of acute ischemic stroke

where “time is brain,”” any “extra [procedural] difficulties have a significant clinical impact.” EX1006, ¶[0043]. Modifying Garrison to make Garrison’s filter 3418 removable would provide no benefit where the aspirated clots are of such small size and, if implemented during a procedure as Petitioner suggests “so that the physician could retrieve samples, empty the housing, and clean or replace the filter” (Petition, p.49), would simply slow Garrison’s procedure while the physician opened, removed, and replaced the filter—which could have a significant clinical impact where “time is brain.” EX2001, ¶67; EX1006, ¶[0043].

Because Garrison (even in view of Trerotola) does not disclose or render obvious “the filter is removable from within the housing,” and because it would not have been obvious to a POSA to have made Garrison’s filter removable, Petitioner has failed to demonstrate that Claims 8 and 22 are unpatentable over Garrison.

B. Garrison in Combination with Goff Does Not Render Claims 8 or 22 Obvious (Ground 3)

Goff discloses that “[i]n an exemplary embodiment, the filter housing has an upper shell and a lower shell which may be taken apart to permit introduction, removal, and replacement of the filter element in the interior of the housing.” EX1005, ¶[0015]. But for the same reasons explained in §IV.A, it would not have been obvious to a POSA to have modified Garrison in view of Goff to make Garrison’s filter removable. EX2001, ¶69. Namely, a POSA would have understood

that such a modification would provide no benefit given the small size of the neurovascular clots Garrison intends to treat, and such a feature (removability of the filter) would either go unused or slow Garrison's procedure if used. *Id.*

Additionally, Goff is directed to devices generally for "separating materials in fluid aspirates removed from a hollow body structure" such as "blood vessels, cysts, pseudocysts, abscesses, blood vessel grafts, lung passages, bile ducts, ureters, urethras, fallopian tubes, ear canals, joint capsules, the gastrointestinal tract, and the like." EX1005, ¶¶[0007]-[0008]. Unlike the treatment of small neurovascular clots in the MCA and ICA, the structures Goff intends to treat are more likely to have large material removed (e.g., pus, cyst material, bile, and the like) for which replacement or removal of a filter for cleaning or clearing has utility. EX2001, ¶70. Treating those structures and material constituents is generally not as time-critical as treating acute ischemic stroke where "time is brain." *Id.*; EX1006, ¶[0043].

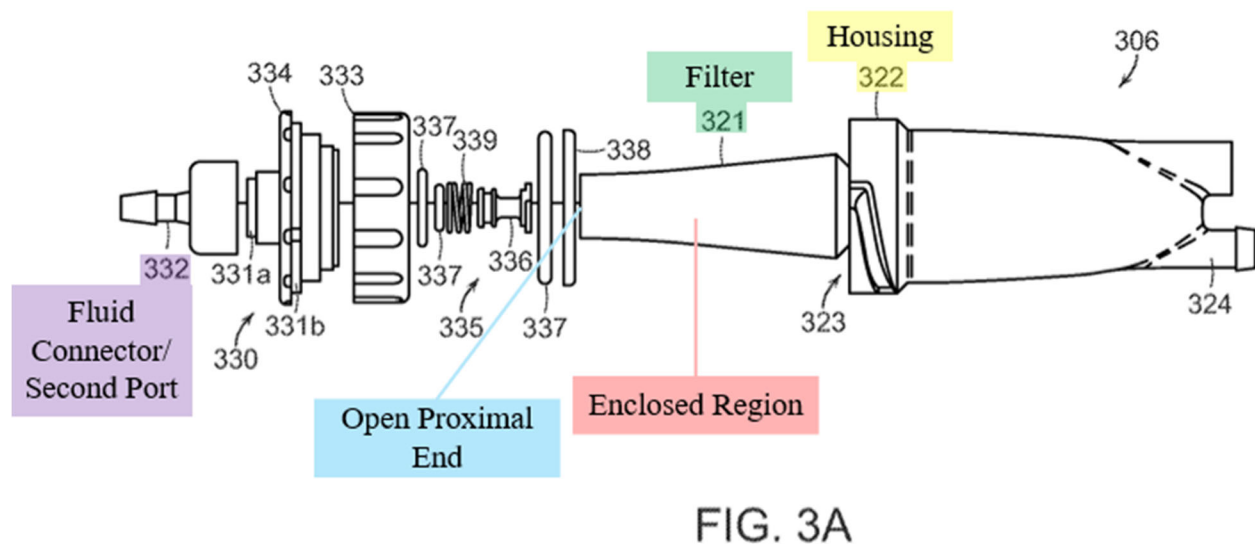
Accordingly, because it would not have been obvious to a POSA to have made Garrison's filter removable, Petitioner has failed to demonstrate that Claims 8 and 22 are unpatentable over the combination of Garrison and Goff.

V. DEPENDENT CLAIMS 10 AND 24 ARE NEITHER ANTICIPATED (GROUND 1) NOR RENDERED OBVIOUS (GROUND 2) BY GARRISON, NOR ARE THEY RENDERED OBVIOUS BY GARRISON IN COMBINATION WITH GOFF (GROUND 3)

Dependent Claims 10 and 24 narrow independent Claims 1 and 15,

respectively, by further requiring that the “filter *encloses a region* within the housing” and that the “fluid connector [or second port] *is proximal to the enclosed region* along the first fluid path.” EX1001, cls.10, 24. The second port or fluid connector is “configured to be fluidically coupled to the vacuum source.” *Id.* at cls.1, 15. This filter structure also is not disclosed or rendered obvious by the art relied on by Petitioner.

Claims 10 and 24 require a filter structure in which an enclosed region is positioned on the fluid-connector/second-port side of the filter chamber such that the fluid connector or second port is “proximal to” that enclosed region. EX2001, ¶75. The '669 Patent illustrates that arrangement in which the filter encloses a region within the housing and opens at a proximal end toward the fluid connector or second port such that the fluid connector or second port is proximal to that enclosed region:

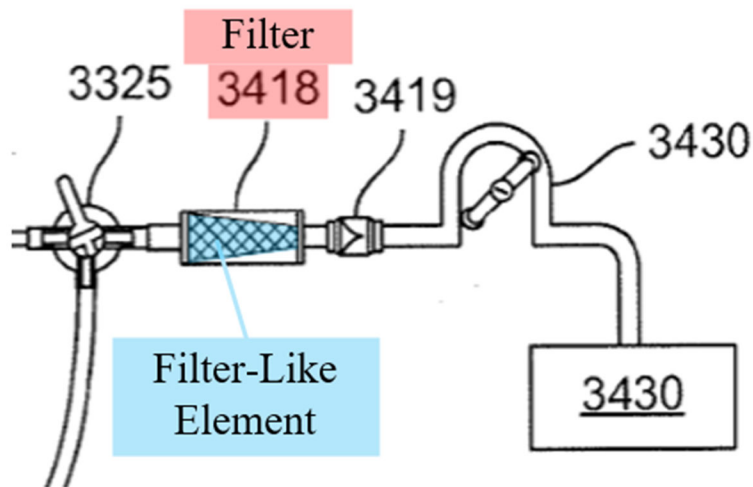


Id.; EX1001, FIG.3A.

A. Garrison Alone Does Not Anticipate (Ground 1) or Render Claims 10 or 24 Obvious (Ground 2)

For the limitation of Claims 10 and 24 that the “filter encloses a region within the housing,” Petitioner simply asserts that “Garrison’s filter encloses a region within the filter housing” based on Figure 34 in Garrison. Petition, pp.50-51; *see also* EX1003, ¶126. That assertion is conjecture because Garrison discloses no details of its filter structure. Petitioner does not identify any region enclosed by Garrison’s filter. Petitioner therefore presumes, without support or explanation, that Garrison’s filter encloses a region simply because it is a filter. But a filter, including Garrison’s, does not necessarily or inherently enclose a region—let alone the “enclosed region” specified by Claims 10 and 24 in which the “fluid connector [or second port] is proximal to the enclosed region.”

Again, Garrison’s only reference to the filter 3418 is in a single paragraph that states that element 3418 is a “filter.” EX1006, ¶[0131]. There is no more. Although Garrison labels element 3418 a “filter,” it provides no description of the filter’s structure. The same filter 3418 is illustrated in each of Figures 32-34 of Garrison and depicts a filter-like element having a truncated conical shape that spans entirely between the inflow and outflow ends of filter 3418:

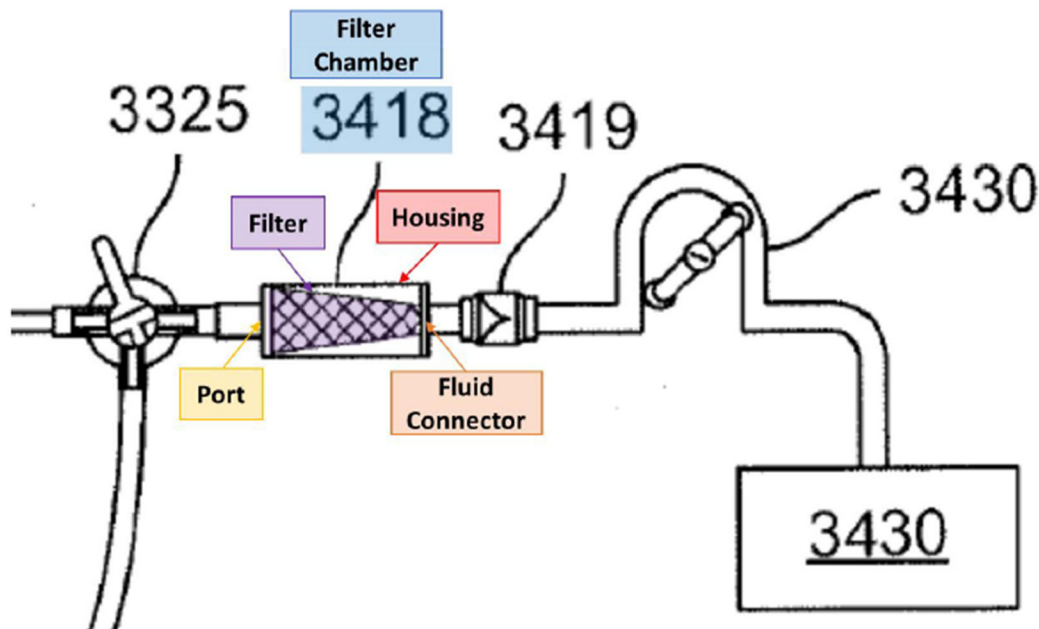


EX2001, ¶77; EX1006, FIG.34 (enlarged).

Petitioner does not identify or explain what, if any region, is enclosed by Garrison's filter and Garrison provides no relevant details at all. Importantly, there are many types of filters, not all of which "enclose[] a region." EX2001, ¶78. Garrison's filter could have a solid porous body that fills the entire volume of the filter. *Id.* For example, the filter could comprise gauze, foam, sintered metal, and/or the like. *Id.* Alternatively, the filter could have a non-enclosed structure by having a simple planar mesh screen that by its two-dimensional nature does not enclose any region. *Id.* Accordingly, because Garrison provides no disclosure of the filter, and because the filter could have many different structures, a POSA would understand that the filter element within Garrison's filter 3418 does not necessarily or inherently "enclose[] a region." *Id.*

Further, as shown in Petitioner's annotations to Figure 34 of Garrison, the

filter is illustrated abutting the alleged fluid connector and the port:



Petition, p.51; *see also* EX1003, ¶126. In that illustrated arrangement, a POSA would have understood the filter to be solid, as explained above, or to have an open end at the distal port and a closed end at the proximal fluid connector (e.g., like a bag or pocket filter). EX2001, ¶79. Such an arrangement with an opening at the distal filter end would permit clot to flow into that interior of the filter and would prevent the clot from flowing entirely through the filter and out of the fluid connector (i.e., without filtering). *Id.* In that arrangement, the alleged fluid connector is not “proximal to the enclosed region.” Rather, the enclosed region would be on the side of the filter opposite the arrangement illustrated in the ’669 Patent, in which the filter opens proximally toward the fluid connector or second port:

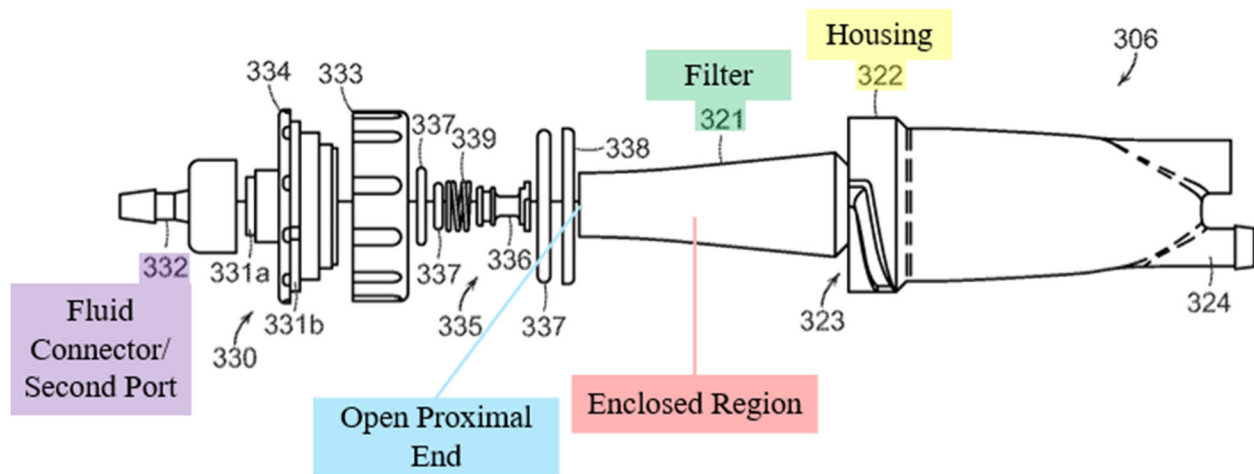


FIG. 3A

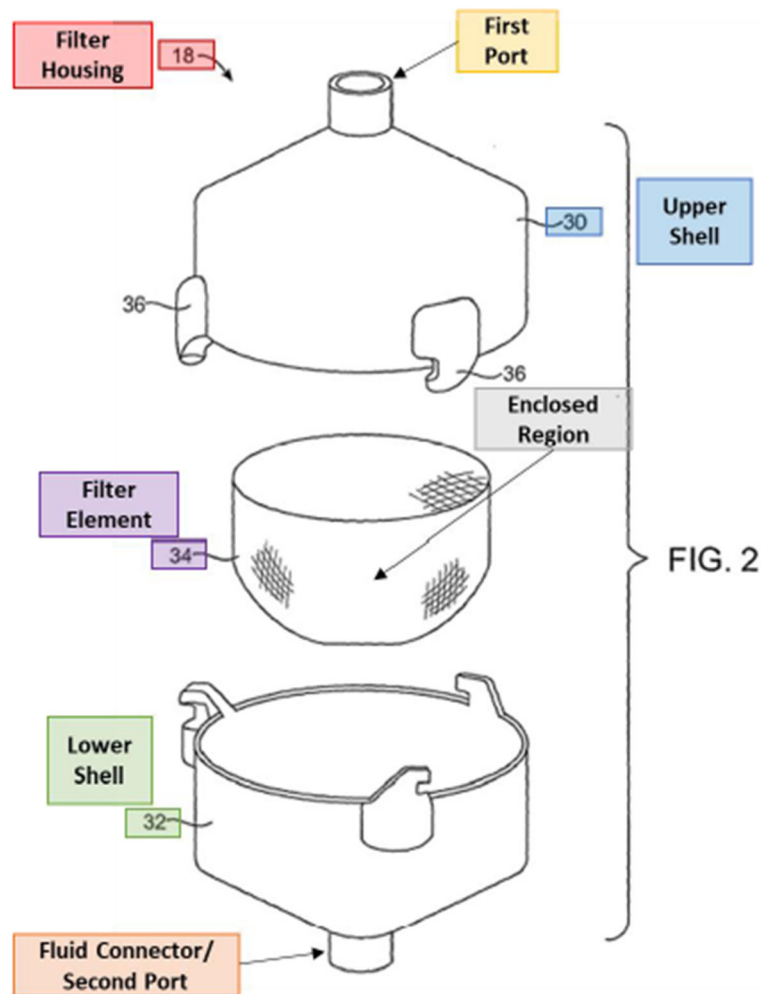
Id.

Because Garrison does not expressly or inherently disclose all the limitations of Claims 10 and 24 including that the “filter encloses a region within the housing” and that the “fluid connector [or second port] is proximal to the enclosed region along the first fluid path,” Petitioner has failed to demonstrate that Claims 10 and 24 are unpatentable over Garrison.

B. Garrison in Combination with Goff Does Not Render Claims 10 or 24 Obvious (Ground 3)

For the limitation of Claims 10 and 24 that the “filter encloses a region within the housing,” Petitioner simply asserts that “Goff’s filter element encloses a region within the filter housing (i.e., the region enclosed by the cylindrical filter element).” Petition, pp.73-74. But, like Garrison, Goff’s filter element 34 abuts the alleged fluid connector/second port and does not enclose a region within the housing because the

“filter element 34 is constructed so that it nests within the lower shell 32 of the filter assembly” (EX1005, ¶[0026]), as shown in Petitioner’s annotations to Figure 2 of Goff:



Petition, p.73.

Accordingly, if Goff’s filter element 34 were not a solid porous structure, which would not enclose a region, a POSA would understand the filter element 34 to have an open distal end facing the alleged port or first port rather than the alleged

fluid connector or second port that connects to the vacuum source. EX2001, ¶82. But in that arrangement, the alleged fluid connector is not “proximal to the enclosed region” because the enclosed region is opposite that of the '669 Patent, in which the filter encloses a region within the housing and opens at a proximal end toward the fluid connector/second port such that the fluid connector/second port is proximal to that enclosed region. *Id.*

Thus, because Goff does not expressly or inherently supply all the limitations of Claims 10 and 24 missing from Garrison, including that the “fluid connector [or second port] is proximal to the enclosed region along the first fluid path,” Petitioner has failed to demonstrate that Claims 10 and 24 are unpatentable over Garrison in combination with Goff.

VI. DEPENDENT CLAIMS 12 AND 26-28 ARE NOT RENDERED OBVIOUS BY GARRISON IN COMBINATION WITH SCHAFFER AND OPTIONALLY GOFF (GROUNDS 8-9), NOR ARE THEY RENDERED OBVIOUS BY GARRISON IN COMBINATION WITH SCHAFFER AND HARTLEY AND OPTIONALLY GOFF (GROUNDS 10-11)

Grounds 8 and 9, directed to claims reciting specific hemostasis valve configurations, also fail because Schaffer does not disclose or otherwise teach the claimed “filament,” which requires flexibility. Grounds 10-11 fail because Petitioner's proposed modifications and combinations are based on impermissible hindsight, and because a POSA would not have modified Schaffer in view of Hartley

as Petitioner proposes.

A. Garrison and Schaffer, With or Without Goff, Do Not Disclose the Claimed “Filament” (Grounds 8 and 9)

A claim is not obvious if a limitation of the claim is missing in the cited art. *See Aug. Tech. Corp. v. Camtek, Ltd.*, 655 F.3d 1278, 1290 (Fed. Cir. 2011) (finding that asserted claims are not rendered obvious in view of the cited prior art because they do not supply the missing element for purposes of obviousness analysis). Here, Garrison and Schaffer fail to disclose the “filament” recited in Claims 12 and 26-28.

As set forth above in §II.E, and as the Board has found in multiple final written decisions for related patents, the term “filament” in Claims 12 and 26-28 of the '669 Patent means “a thin, flexible length of material formed by one or more strands of material.” In particular, the term “filament” requires flexibility. EX1049, p.16. Petitioner does not allege that either Garrison or Goff disclose a “filament” for the hemostasis valve and instead relies on Schaffer's U-shaped actuating members 55 to satisfy the “filament” limitation. Petition, pp.93-94. But the U-shaped actuating members in Schaffer are rigid, not flexible. EX2006, ¶¶94-105; EX2009, ¶¶81-88; EX2010, ¶¶91-100. And, in the related FWDs, the Board found that Schaffer alone and Schaffer in combination with Garrison did not disclose or suggest a valve with a “filament.” EX1049, p.31 (“Petitioner has not shown by a preponderance of the evidence that claim 1 would have been obvious over Garrison and Schaffer”);

EX1047, pp.38-40; EX1048, pp.41-42.

Petitioner provides no new evidence here, and has therefore failed to demonstrate by a preponderance of the evidence that the combinations of Garrison and Schaffer (ground 8) or Garrison, Goff, and Schaffer (ground 9) render Claims 12 and 26-28 obvious.

B. Claims 12 and 26-28 Are Not Obvious Over the Combination of Garrison, Schaffer, and Hartley and Optionally Goff (Grounds 10-11)

As Patent Owner has argued in the IPRs for the related '011, '012, and '005 Patents that have received the related FWDs, as well as in pending IPRs for related U.S. Patent Nos. 11,865,291, 11,844,921, and 12,109,384 (collectively, “the related IPRs”), a POSA would not have been motivated to replace Schaffer’s U-shaped actuating members with Hartley’s string and then substitute that modified valve into Garrison as Petitioner alleges. Petition, pp.94-98; EX2006, ¶¶130-191; EX2009, ¶¶103-163; EX2010, ¶¶114-174.

Petitioner’s proposed modifications and combinations are the product of hindsight. They require a POSA to first manufacture a nonexistent problem with Schaffer—gaps or poor sealing—by omitting Schaffer’s third seal member which seals without gaps, and then to modify Schaffer to remedy that nonexistent problem in a manner that fundamentally changes Schaffer’s principles of operation. EX2006, ¶¶134-156; EX2009, ¶¶107-131; EX2010, ¶¶118-141. Moreover, Petitioner’s

proposed substitution is not a simple substitution of one known element for another (Petition, pp.95-96) because none of Petitioner's references disclose a single member (e.g., Schaffer's U-shaped members or Hartley's string) coupled to and controlled by two actuators as in Petitioner's only proposed combination (Petition, p.98). EX2006, ¶¶157-168; EX2009, ¶¶132-143; EX2010, ¶¶142-154.

Petitioner and its expert also admit that there are several more plausible alternative modifications to seal Schaffer's valve, including those expressly disclosed in Schaffer. EX2006, ¶¶184-186; EX2009, ¶¶159-161; EX2010, ¶¶170-172. And, Petitioner's modification—adding a flexible string to Schaffer—would fundamentally change Schaffer's mode of operation, reduce the predictable sealing of Schaffer's valve, and would render Schaffer's valve inoperable for its intended purposes of durability and easy manufacturing. EX2006, ¶¶169-183; EX2009, ¶¶144-158; EX2010, ¶¶155-169.

Likewise, Petitioner's expert admits there were an unknown number, rather than a finite and identified number, of options for constricting a tubular member in a hemostasis valve in 2017, contradicting Petitioner's reliance on an apparent "obvious-to-try" rationale. EX2011, 105:24-106:4, 106:12-24, 107:3-13, 108:14-20, 110:7-19, 111:9-23, 112:5-114:24.

Further, Garrison's readily available and easy-to-use rotatable/passive hemostasis valves sufficiently "allow introduction of devices ... while preventing or

minimizing blood loss during the procedure” (EX1006, ¶[0098]) such that a POSA would not have been motivated to substitute Schaffer's ineffectively sealing valve into Garrison and then further modify Schaffer's valve in view of Hartley. EX2006, ¶¶187-189.

The related FWDs support Patent Owner's construction of “filament” and confirm that Schaffer's U-shaped actuating members do not disclose that limitation. *See* EX1047, EX1048, EX1049. Although the Board ultimately found certain claims of related patents unpatentable on other grounds or combinations (*see id.*), those decisions do not establish that the specific combinations asserted here satisfy the claims of the '669 Patent. Patent Owner maintains that the hemostasis valve limitations of Claims 12 and 26-28 are patentable over Petitioner's references for the reasons explained above and in further detail in those IPRs.

Moreover, here, Petitioner has failed to establish by a preponderance of the evidence that Claims 12 and 26-28 are unpatentable for reasons not previously addressed by the Board in the related FWDs or the related IPRs. Namely, here and in other related IPRs Petitioner and its expert have advanced multiple different allegedly obvious combinations (“simple substitutions”) of Schaffer and Hartley including:

- (1) A single string substituted into Schaffer's valve in a loop (Petition, pp.97-98; EX1003, ¶230);

(2) Two strings substituted for Schaffer's actuating members and each having a U-shape (*see, e.g., Imperative Care, Inc. v. Inari Medical, Inc.*, IPR2025-00728, Paper 1, pp.68-70 and EX1003, ¶¶154-155, 158); **and**

(3) Two strings substituted into Schaffer's valve in loops (*see, e.g., Imperative Care, Inc. v. Inari Medical, Inc.*, IPR2025-01562, Paper 2, pp.48-49 and EX1003, ¶¶105-106).

Those purported combinations and substitutions are vastly different and structurally contradictory. Each of Petitioner's proposed structural variations therefore reflects nothing more than the result of "selectively culling" features and combinations from the prior art using the '669 Patent and related patents as a roadmap. *ATD Corp. v. Lydall, Inc.*, 159 F.3d 534, 546 (Fed. Cir. 1998).

For those reasons and the reasons explained in the related IPRs, grounds 10-11 fail.

VII. CONCLUSION

Petitioner has failed to establish by a preponderance of the evidence that Claims 4, 8, 10, 12, 18, 22, 24, and 26-28 of the '669 Patent are unpatentable. Accordingly, for the foregoing reasons, Patent Owner respectfully requests that the Board confirm the patentability of Claims 4, 8, 10, 12, 18, 22, 24, and 26-28.

Respectfully submitted,

Dated: August 25, 2026

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

CERTIFICATE OF COMPLIANCE

Pursuant to 37 C.F.R. § 42.24(d), I, Joseph P. Hamilton, certify that **PATENT OWNER'S RESPONSE** contains 9,660 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 25, 2026

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

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), I certify that on August 25, 2026, a copy of
PATENT OWNER'S RESPONSE and Exhibits 2001-2014 were served upon the
below-listed counsel by electronic mail:

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Dated: August 25, 2026

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