Joseph R. Re (SBN 134,479)
joe.re@knobbe.com
Joshua J. Stowell (SBN 246,916)
joshua.stowell@knobbe.com
KNOBBE, MARTENS, OLSON & BEAR, LLP
2040 Main Street. 14th Floor
Irvine, CA. 92614
(949) 760-0404 Telephone
(949) 760-9502 Facsimile

Nicholas A. Belair (SBN 295,380)
nick.belair@knobbe.com
KNOBBE, MARTENS, OLSON & BEAR, LLP
333 Bush St., 21st Fl.
San Francisco CA 94104
415-217-8399 - Telephone

Attorneys for Defendant
Imperative Care, Inc.

IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

INARI MEDICAL, INC., Plaintiff, v. IMPERATIVE CARE, INC., Defendant.	Civil Action No. 5:24-cv-03117-EKL-(SVKx) **IMPERATIVE CARE, INC,'S PRELIMINARY INVALIDITY CONTENTIONS AND DOCUMENT PRODUCTION ACCOMPANYING INVALIDITY CONTENTIONS PURSUANT TO PATENT LOCAL RULES 3-3 AND 3-4**

Pursuant to Patent Local Rules ("PLR") 3-3 and 3-4 and the Court's Case Management & Scheduling Order (Dkt. 54), Defendant Imperative Care, Inc. ("Imperative Care") hereby provides these Preliminary Invalidity Contentions to Plaintiff Inari Medical, Inc. ("Inari").

I. GENERAL STATEMENTS

These preliminary contentions are based on information reasonably available to Imperative Care at this time, are necessarily preliminary, and may require subsequent amendment, alteration and/or supplementation. Accordingly, Imperative Care reserves the right to amend, alter and/or supplement these contentions based on further investigation, fact or expert discovery, evaluation of the scope and content of the prior art, any claim construction from the Court, or as a result of Inari's contentions. These contentions may be in the alternative and do not constitute any concession by Imperative Care for purposes of claim construction or non-infringement. *See* Fed. R. Civ. P. 8(d).

Furthermore, these preliminary contentions are provided without prejudice to Imperative Care's right to introduce at trial any subsequently discovered evidence or expert opinions relating to currently known facts and to produce and introduce at trial all evidence, whenever discovered, relating to the proof of subsequently discovered facts. Moreover, facts, documents, and things now known may be imperfectly understood and, accordingly, such facts, documents, and things may not be included in the following contentions. Imperative Care reserves the right to refer to, conduct discovery with reference to, or offer into evidence at the time of trial, any and all facts, expert opinion testimony, documents and things notwithstanding the written statements herein. Imperative Care further reserves its right to refer to, conduct discovery with reference to, or offer into evidence at the time of trial, any and all facts, documents and things that are not currently recalled but might be recalled at some time in the future.

The information set forth below is provided without waiving Imperative Care's right to (1) object to the use of any statement for any purpose, in this action or any other action, on the grounds of privilege, relevance, materiality or any other appropriate grounds; (2) object to any request involving or relating to the subject matter of the statements herein; or (3) revise, correct, supplement or clarify any of the statements provided below at any time.

A. <u>Inari's Identification of Asserted Claims</u>

In its Preliminary Disclosure of Asserted Claims and Infringement Contentions, Inari identified the following asserted claims (collectively, the "Asserted Claims"): (1) claims 1-7, and 9-15 of U.S. Patent Nos. 11,554,005 ("the '005 Patent"); (2) claims 1-7, and 9 of U.S. Patent No. 11,697,011 ("the '011 Patent"); (3) claims 1-7, and 9 of U.S. Patent No. 11,697,012 ("the '012 Patent"); (4) claims 14-22 of U.S. Patent No. 11,744,691 ("the '691 Patent"); (5) claims 1-3, 5-7, 9, and 10 of U.S. Patent No. 11,844,921 ("the '921 Patent"); (6) claims 1-8, 12-17, and 19 of U.S. Patent No. 11,865,291 ("the '291 Patent"); (7) claims 1-4, 6-12, 14-23, 25-31, and 33-38 of U.S. Patent No. 11,969,333 ("the '333 Patent"); (8) claims 1-8, 11-15, and 18-20 of U.S. Patent No. 11,974,910 ("the '910 Patent"); and (9) claims 1, 5, 6, 9-30, and 33-34 of U.S. Patent No. 12,016,580 ("the '580 Patent").

On February 7, 2025, Inari filed a First Amended Complaint, which withdrew the '011 Patent from the lawsuit and added two new asserted patents, U.S. Patent Nos. 12,109,384 ("the '384 Patent") and 12,156,669 ("the '669 Patent"). *See* Dkt. 68. Also on February 7, 2025, Inari served Imperative Care with a Supplemental Preliminary Disclosure of Asserted Claims and Infringement Contentions, which identified asserted claims for each of the '384 and '669 Patents. Accordingly, these Preliminary Invalidity Contentions do not address the '011 Patent, and Imperative Care will serve its Preliminary Invalidity Contentions for the '384 and '669 Patents on or before March 24,

2025. *See* Dkt. 74 (granting leave to file Invalidity Contentions on March 24, 2025).

B. <u>Claim Construction</u>

The Court has not yet construed the Asserted Claims. Nor have the parties proposed any constructions of the Asserted Claims that may be in dispute. Imperative Care's position on the invalidity of particular claims will depend on how those claims are construed by the Court. Imperative Care therefore reserves the right to identify additional prior art and/or to supplement its disclosures or contentions in light of the Court's construction of the Asserted Claims. These Preliminary Invalidity Contentions are based, at least in part, on Imperative Care's present understanding of the Asserted Claims.

To the extent that these Preliminary Invalidity Contentions reflect constructions of claim terms that may be consistent with or implicit in Inari's Preliminary Infringement Contentions, no inference is intended, nor should any inference be drawn, that Imperative Care agrees with such claim constructions. Imperative Care takes no position on any matter of claim construction in these Preliminary Invalidity Contentions other than to allege that certain claim terms are invalid as anticipated under 35 U.S.C. § 102, obvious under 35 U.S.C. § 103, and/or are indefinite, not enabling and/or lacking written description support under 35 U.S.C. § 112, as set forth below. Any statement herein describing or tending to describe any claim element is provided solely for the purpose of understanding the relevant prior art or other basis for invalidity. Imperative Care expressly reserves the right to propose any claim construction it considers appropriate and/or contest any claim construction it considers inappropriate.

In part because claim construction has not been resolved, these Preliminary Invalidity Contentions may be made in the alternative and are not necessarily intended to be consistent with each other, and should be viewed

accordingly. Furthermore, Imperative Care's inclusion of prior art that would render a claim anticipated or obvious based on a particular scope or construction of the claim, including that apparently applied by Inari in its Preliminary Infringement Contentions, is not, and should in no way be seen as, an adoption or admission as to the accuracy of such scope or construction. Imperative Care reserves all rights to further supplement and/or modify the positions and information in these Preliminary Invalidity Contentions, including without limitation, the prior art and grounds of invalidity set forth herein, after the Court has construed the Asserted Claims.

C. <u>Ongoing Discovery and Disclosures</u>

Discovery in this case is in its early stages and Imperative Care's investigation, including Imperative Care's search for prior art, is ongoing. For example, Imperative Care has served document subpoenas on several third parties relating to prior art and those third parties have not yet produced responsive documents. Imperative Care therefore reserves the right to further supplement and/or alter the positions taken and information disclosed in these Preliminary Invalidity Contentions including, without limitation, the prior art and grounds of invalidity set forth herein, to take into account information or defenses that may come to light as a result of these continuing efforts.

Moreover, because expert discovery has not started, Imperative Care reserves the right to amend these Preliminary Invalidity Contentions as a result of new information disclosed through the parties' experts. Therefore, Imperative Care reserves all rights to further supplement and/or amend these Preliminary Invalidity Contentions if and when further information becomes available. Imperative Care also incorporates any invalidity expert reports that it serves in the future, and any *inter partes* review filings related to the Asserted Claims.

/ / /

/ / /

II. IDENTIFICATION OF PRIOR ART (PLR 3-3(A))

Below, and in Appendices A-H, Imperative Care identifies the items of prior art that anticipate one or more of the claims of the Asserted Patents under 35 U.S.C. § 102, and separately or in combination, render obvious one or more of the claims of the Asserted Patents under 35 U.S.C. § 103. Imperative Care further incorporates by reference, in full, all references cited in the following prior art references and their prosecution histories, where applicable. The citations provided below and in Appendices A-H are representative of the references and are not exhaustive. To the extent that similar claim limitations occur in one or more claims, the disclosures below and in Appendices A-H should be read to apply to all similar claim limitations.

Imperative Care intends to rely upon the prior art identified below and in Appendices A-H to establish the scope and content of the prior art, a motivation to combine or modify the prior art, that a person of ordinary skill in the art would have had a reasonable expectation of success in combining the art, or knowledge and level of skill of those of ordinary skill in the art. Imperative Care also may rely on (1) non-prior art patents, patent applications or publications, or other evidence (for example, the prosecution history files of U.S. and foreign patent applications) that may not qualify as prior art under 35 U.S.C. § 102, and (2) admissions made by Inari and its employees or agents, for example in the Asserted Patents or during prosecution of the Asserted Patents, to establish these findings.

If and to the extent that they are prior art, Imperative Care reserves the right to rely upon: (1) foreign counterparts of the U.S. Patents identified below; (2) U.S. counterparts of foreign patents and foreign patent applications identified below; (3) U.S. and foreign patents and patent applications corresponding to articles and publications identified below; and (4) U.S. and foreign patents and patent applications, articles, and publications corresponding

to items of prior art identified below. Imperative Case also reserves the right to rely on any prior art cited or discussed in the prosecution histories of the Asserted Patents or their related applications, as well as any patents and applications, and any prior art produced by Inari or a third party in this action, or identified in any other action(s) involving one or more of the Asserted Patents as a basis for contending that the claims are invalid.

Many of the references discussed herein are representative of additional prior art references in the relevant field. Persons of ordinary skill in the art at the time of the filing of the Asserted Patents would have reviewed the references as a whole and in view of other publications, literature, and/or general knowledge in the relevant field. Imperative Care may rely on all such information, including other portions of the prior art references listed herein and other publications and/or expert testimony to provide context to and to aid in understanding and interpreting the listed references, and/or to establish that it would have been obvious for a person of ordinary skill in the art to modify or combine any of the cited references.

A. <u>Identification of Prior Art Patents and Printed Publications</u>

Number	Country of Origin	Date of Issue/Publication	Reference Name
2003/0225379	United States	Dec. 4, 2003	Schaffer
2003/0116731	United States	June 26, 2003	Hartley
9980813	United States	May 29, 2018	Eller
5429616	United States	July 4, 1995	Schaffer ’616
2011/0144592	United States	June 16, 2011	Wong
2015/0173782	United States	June 25, 2015	Garrison
8734374	United States	May 27, 2014	Aklog
WO 2006/124307	United States	Nov. 23, 2006	Goff

Number	Country of Origin	Date of Issue/Publication	Reference Name
6776770	United States	Aug. 17, 2004	Trerotola
2010/0042118	United States	Feb. 18, 2010	Garrison ’118
8535283	United States	Sept. 17, 2013	Heaton
2005/0004534	United States	Jan. 6, 2005	Lockwood
2015/0352325	United States	Dec. 12, 2015	Quick
5938645	United States	Aug. 17, 1999	Gordon
2014/0296868	United States	Oct. 2, 2014	Garrison ’868
7998104	United States	Aug. 16, 2011	Chang
8157760	United States	Apr. 17, 2012	Criado
6481439	United States	Nov. 19, 2002	Lewis
8075510	United States	Dec. 13, 2011	Aklog ’510
WO 2018/019829	PCT	Feb. 1, 2018	Brady ’829
2019/0239910	United States	Aug. 8, 2019	Brady ’910
9216277	United States	Dec. 22, 2015	Myers
4723550	United States	Feb. 9, 1988	Bales
5895376	United States	Apr. 20, 1999	Schwartz
2016/0220741	United States	Aug. 4, 2016	Garrison ’741
2017/0043066	United States	Feb. 16, 2017	Laub
11096712	United States	Aug. 24, 2021	Teigen
WO2014151209	PCT	Sept. 25, 2014	Grey
6719717	United States	Apr. 13, 2004	Johnson
7775501	United States	Aug. 17, 2010	Kees
20180338770	United States	Nov. 29, 2018	Mogi

Number	Country of Origin	Date of Issue/Publication	Reference Name
11432835	United States	Sept. 6, 2022	Shaffer
8038704	United States	Oct. 18, 2011	Sherburne
6767353	United States	July 27, 2004	Shiber
20090287190	United States	Nov. 19, 2009	Shippert
11589880	United States	Feb. 28, 2023	Aklog '880
10383983	United States	Aug. 20, 2019	Aklog '983
10517617	United States	Dec. 31, 2019	Aklog '617
D744,639	United States	Dec. 1, 2015	Aklog '639

Publication Title	Date of Publication	Author/Publisher	Reference Name
The Penumbra System: A Mechanical Device for the Treatment of Acute Stroke due to Thromboembolism	Aug. 2008	Bose, A et al., 29 Am. J. Neuroradiol. 1409-1413	Bose
System of surgery v.2, 1895	1895	Dennis, F et al., Lea Brothers & Co.	Dennis
Thrombectomy Using Suction Filtration and Veno-venous Bypass: Single Center Experience with a Novel Device	2015	Donaldson, C et al., Catheterization and Cardiovascular Interventions, 86:E81-E87	Donaldson

Publication Title	Date of Publication	Author/Publisher	Reference Name
Utility of Thrombectomy in Primary Percutaneous Coronary Intervention	2013	Dragstedt, C et al., Intervent Cardiol Clin 2 (2013) 361-374	Dragstedt
Acute DVT: Are We Overtreating or Undertreating?	July 2018	Silver, M et al., Endovascular Today (Vol. 17, No. 7; pp. 84-87)	Silver
Use of a Modified Cardiopulmonary Bypass Circuit for Suction Embolectomy with the AngioVac Device	2017	Michelson, C et al., J Extra Coror Technol. 2017;49:299-303	Michelson
AngioVac Procedure: Treatment for Deep Venous Thrombosis	Feb. 2017	Zayed, M., Broadcast Med	Zayed
Successful management of acute massive pulmonary embolism using the Angiovac suction catheter technique in a hemodynamically unstable patient	2014	Pasha, A.K. et al., Cardiovascular Revascularization Medicine 15 (2014), 240-243	Pasha
Catheter directed interventions for acute deep vein thrombosis	2016	Kohi, M et al., Cardiovasc Diagn. Ther., 2016;6(6):599-611	Kohi

Publication Title	Date of Publication	Author/Publisher	Reference Name
Under Pressure: Comparison of Aspiration Techniques for Endovascular Mechanical Thrombectomy	May 2018	Nikoubashmanm O et al., AHNR Am J Neuroradiol 2017, 39:905-909	Nikoubashmanm

B. <u>Physical Prior Art</u>

The following summary of physical prior art is not meant to be comprehensive, and any quotations or citations provided herein are representative of the available printed materials associated with the physicals and are not exhaustive. Imperative Care has served third party subpoenas in this litigation to request additional information and samples relating to some of the physical prior art identified below. The third parties have not yet produced materials in response to those subpoenas. Imperative Care has done its best to identify the relevant information below based on information currently available to it but anticipates that it will update the information as discovery progresses. When the third parties produce the responsive information, Imperative Care will update these contentions as necessary.

Imperative Care reserves the right to rely on drawings or schematics of the listed physical products, other commercial versions of the listed products, any testing of the listed products, other similar products not specifically listed herein, and any combination of the listed products with any of the above-listed prior art patents or publications that a skilled artisan would have been motivated to make as of the earliest priority date of the Asserted Patents.

Item Offered for Sale or Publicly Used or Known	Date the Offer or Use Took Place or the Information Became Known	Identity of the Person or Entity Which Made the Use or Which Made and Received the Offer	Person or Entity Which Made the Information Known or to Whom it was Made Known
Penumbra INDIGO System (+ Pump MAX; Canister)	July 22, 2015	Penumbra, Inc.	Penumbra Inc.; FDA 510(k) Clearance (K142870; K122756)
Penumbra INDIGO System (+ Aspiration Pump (ENGINE); Canister; CATRX	May 24, 2017	Penumbra, Inc.	Penumbra Inc.; FDA 510(k) Clearance (K163618; K180412)
AngioVac Cannula and Circuit	December 11, 2014	AngioDynamics, Inc.	AngioDynamics, Inc.; FDA 510(k) Clearance (AngioVac Brochure; AngioDynamics Patent Marking Page; K142607)
Gore DrySeal Flex introducer sheath	Aug. 31, 2016	Gore & Associates, Inc.	Gore & Associates, Inc. (Gore DrySeal Sheath – Vascular News)

Item Offered for Sale or Publicly Used or Known	Date the Offer or Use Took Place or the Information Became Known	Identity of the Person or Entity Which Made the Use or Which Made and Received the Offer	Person or Entity Which Made the Information Known or to Whom it was Made Known
Merit VacLok (+VacLok AT)	July 27, 2017	Merit Medical Systems, Inc.	Merit Medical Systems, Inc.; FDA 510(k) Clearance (VacLok Negative Pressure Syringe Brochure; K163597)
Medtronic Export Catheter (AP; Advance; XT)	August 16, 2006	Medtronic, Inc.	Medtronic, Inc.; FDA 510(k) Clearance (Medtronic Export Aspiration Catheter IFU; Dragstedt; K100569)
Medtronic Affinity Pump	June 22, 2010	Medtronic, Inc.	Medtronic, Inc.; FDA 510(k) Clearance (K100631)
Enpath Medical Deflectable Catheter	May 19, 2005	Enpath Medical, Inc.	Enpath Medical, Inc.; FDA 510(k) Clearance (K043489)

Item Offered for Sale or Publicly Used or Known	Date the Offer or Use Took Place or the Information Became Known	Identity of the Person or Entity Which Made the Use or Which Made and Received the Offer	Person or Entity Which Made the Information Known or to Whom it was Made Known
Enpath Medical Steerable Sheath	May 18, 2006	Enpath Medical, Inc.	Enpath Medical, Inc.; FDA 510(k) Clearance (K061119)
ENROUTE Transcarotid Neuroprotection System	Feb. 9, 2015	Silk Road Medical	Silk Road Medical; FDA 510(k) Clearance (ENROUTE Transcarotrid NPS IFU 11858.E)
ANGIOJET ULTRA Thrombectomy System (Power Pulse Delivery)	Sept. 2015	Boston Scientific, Corporation	Boston Scientific Corporation (AngioJet Ultra Brochure PI-335503-AA)
Merit ASAP Aspiration Catheter (+ASAPLP; Kit)	Nov. 7, 2013	Merit Medical Systems, Inc.	Merit Medical Systems, Inc.; FDA 510(k) Clearance (K132155; K100569)
AXS Universal Aspiration Set (+ Dominant Flex Surgical Suction Pump)	June 2017	Stryker Corporation	Stryker Corporation (AXS Universal Aspiration Set Brochure)

Item Offered for Sale or Publicly Used or Known	Date the Offer or Use Took Place or the Information Became Known	Identity of the Person or Entity Which Made the Use or Which Made and Received the Offer	Person or Entity Which Made the Information Known or to Whom it was Made Known
Inari ClotTriever	Fe. 16, 2017	Inari Medical, Inc.	Inari Medical, Inc.; FDA 510(k) Clearance (K163549, K180329)
Inari Retraction Aspirator (+ FlowTriever Retrieval/Aspiration System)	Aug. 25, 2015	Inari Medical, Inc.	Inari Medical, Inc.; FDA 510(k) Clearance (K152097; Triever20 IFU)
INVATEC Diver C.E. Max	2013	Carl A. Dragstedt, DO; Anthony A. Bavry, MD, MPH	Elsevier; Carl A. Dragstedt, DO; Anthony A. Bavry, MD, MPH (INVATEC Diver C.E. Max Brochure; Dragstedt)
Pronto V3 Extraction Catheter	Dec. 14, 2006	Vascular Solutions, Inc.	Vascular Solutions, Inc.; FDA 510(k) Clearance (K063371; Dragstedt)

III. INVALIDITY BASED ON 35 U.S.C. §§ 102-103 (PLR 3-3(B))

Imperative Care contends the Asserted Claims are invalid under at least 35 U.S.C. §§ 102 and 103. Exemplary prior-art citations and statements explaining the invalidity of the Asserted Claims under 35 U.S.C. §§ 102 & 103 are specified in the following contentions and corresponding claim charts (Appendices A-H). Imperative Care may rely on cited or uncited portions of the prior art, other documents, and expert testimony to establish (1) the state of the relevant art, (2) the general knowledge of one of skill in the art, and (3) that a person of ordinary skill in the art would have been motivated to combine the prior art so as to render the claim invalid as obvious.

Below, Imperative Case provides exemplary combinations of prior art references and the motivation to combine such references for purposes of its obviousness contentions. Such combinations are exemplary and not exhaustive. Thus, the combinations below should not be construed to suggest that any reference or sub-combination of references would not alone have rendered the Asserted Claims obvious. Imperative Care reserves the right to rely on any combination or combinations of the prior art references cited or otherwise discussed in these contentions, including Appendices A-H. Furthermore, to the extent that similar claim limitations occur in one or more claims, the contentions below applied to a given claim should be read to apply to all similar claim limitations, as should the corresponding prior art disclosures.

A. <u>Anticipation Under 35 U.S.C. § 102</u>

A claimed invention is not novel, and thus invalid as anticipated, if:

> (1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention; or
>
> (2) the claimed invention was described in a patent issued under section 151, or in an application for patent published or deemed published under section 122(b), in which the patent or application,

> as the case may be, names another inventor and was effectively filed before the effective filing date of the claimed invention.

35 U.S.C. § 102(a). "Under 35 U.S.C. § 102 a claim is anticipated 'if each and every limitation is found either expressly or inherently in a single prior art reference.'" *King Pharm., Inc. v. Eon Labs, Inc.*, 616 F.3d 1267, 1274 (Fed. Cir. 2010) (quoting *Celeritas Techs. Ltd. v. Rockwell Int'l Corp.*, 150 F.3d 1354, 1361 (Fed. Cir. 1998)).

B. <u>Obviousness Under 35 U.S.C. § 103</u>

35 U.S.C. § 103 states:

> A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

35 U.S.C. § 103.

Invalidity under 35 U.S.C. § 103 is a legal conclusion based on the following factual inquiries: (1) the scope and content of the prior art; (2) the differences between the prior art and the claims at issue; (3) the level of ordinary skill in the art at the time when the invention was made; and (4) any other evidence of obviousness or nonobviousness. *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17−18 (1966); *see also TQ Delta*, 929 F.3d at 1360 ("Obviousness is a question of law based on underlying findings of fact.") (internal citation and quotations removed).

To determine the level or ordinary skill in the art, the relevant field of art must be identified. Courts accomplish this by looking to "the nature of the problem confronting the inventor." *Verizon Servs. Corp. v. Cox Fibernet*

Virginia, Inc., 602 F.3d 1325, 1338 (Fed. Cir. 2010) (quoting *Bancorp Servs., L.L.C. v. Hartford Life Ins. Co.*, 359 F.3d 1367, 1375 (Fed. Cir. 2004)); *see also Ruiz v. A.B. Chance Co.*, 234 F.3d 654, 666 (Fed. Cir. 2000) ("The determination of the level of ordinary skill in the art is an integral part of the Graham analysis."). A person of ordinary skill in the identified art is presumed to have knowledge of all pertinent prior art. *Custom Accessories, Inc. v. Jeffrey-Allan Indus., Inc.*, 807 F.2d 955, 962 (Fed. Cir. 1986). "A reference qualifies as prior art for an obviousness determination under § 103 only when it is analogous to the claimed invention." *In re Klein*, 647 F.3d 1343, 1348 (Fed. Cir. 2011); *In re Deminski*, 796 F.2d 436, 442 (Fed. Cir. 1986) (quoting *In re Wood*, 599 F.2d 1032, 1036 (C.C.P.A. 1979)); *see also In re Clay*, 966 F.2d 656, 659 (Fed. Cir. 1992) ("A reference is reasonably pertinent if, even though it may be in a different field from that of the inventor's endeavor, it is one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering his problem.").

As the United States Supreme Court held in *KSR Int'l Co. v. Teleflex Inc.*, "[t]he combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." 127 S. Ct. 1727, 1739 (2007). The Supreme Court further held that "[w]hen a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability. For the same reason, if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill." *Id.* at 1740.

Following the initial factual determinations, the legal test for obviousness is a flexible inquiry focused on the objective reach of the claims. *See KSR Int'l*

Co. v. Teleflex Inc., 550 U.S. 398, 415-16, 419 (2007) ("The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results."); *see also Indivior Inc. v. Dr. Reddy's Labs., S.A.*, 930 F.3d 1325, 1352 (Fed. Cir. 2019) ("obviousness demands a more expansive and flexible approach") (internal quotations and citation removed). Importantly, obviousness must be evaluated as of the time of invention so as not to improperly inject hindsight bias into the inquiry. *See Graham*, 383 U.S. at 36 (instructing courts to "resist the temptation to read into the prior art the teachings of the invention in issue" and "'guard against slipping into use of hindsight'") (quoting *Monroe Auto Equip. Co. v. Heckethorn Mfg. & Supply Co.*, 332 F.2d 406, 412 (6th Cir. 1964)); *Para-Ordnance Mfg., Inc. v. SGS Imps. Int'l, Inc.*, 73 F.3d 1085, 1087 (Fed. Cir. 1995) ("Obviousness may not be established using hindsight . . . .").

A patent may be proved obvious under the "teaching, suggestion, or motivation" ("TSM") test "if some motivation or suggestion to combine the prior art teachings can be found in the prior art, the nature of the problem, or the knowledge of a person having ordinary skill in the art." *KSR*, 550 U.S. at 407 (internal citation and quotation marks omitted). Conversely, "when the prior art teaches away from combining certain known elements, discovery of a successful means of combining them is more likely to be nonobvious." *Id.* at 416 (citing *United States v. Adams*, 383 U.S. 39, 51−52 (1966)).

An obviousness determination, however, does not require application of the TSM test. Rather, the inquiry must also "take account of the inferences and creative steps that a person of ordinary skill in the art would employ." *KSR*, 550 U.S. at 418−19. Moreover, a patent may be found obvious when the combination of elements was obvious to try. *Id*. at 420.

> When 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. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under § 103.

Id. at 421. Conversely, the obvious to try standard is not met when "the inventor would have had to try all possibilities in a field unreduced by direction of the prior art." *Bayer Schering Pharma AG v. Barr Labs., Inc.*, 575 F.3d 1341, 1347 (Fed. Cir. 2009); *In re O'Farrell*, 853 F.2d 894, 903 (Fed. Cir. 1988) (foreclosing an obvious to try analysis when the patentee simply "var[ies] all parameters or tr[ies] each of numerous possible choices until [arriving] at a successful result, where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful"); *see also Allergan, Inc. v. Apotex Inc.*, 754 F.3d 952, 972−73.

A claimed invention can be obvious even if there is no teaching, suggestion, or motivation for combining the prior art to produce that invention. 127 S. Ct. 1727, 1741 (2007). In view of the *KSR* decision, the U.S. Patent and Trademark Office incorporated Examination Guidelines in the Manual of Patent Examination Procedure ("MPEP"). Those Guidelines identify various rationales for finding a claim obvious, including those based on other precedents. Those rationales include:

- Combining prior art elements according to known methods to yield predictable results;
- Simply substituting one known element for another to obtain predictable results;
- Using a known technique to improve similar devices (methods or products) in the same way;

- Applying a known technique to a known device (method or product) ready for improvement to yield predictable results;
- Choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success;
- Using known work in one field of endeavor to prompt variations of such work for use in either the same field or a different field based on design incentives or other market forces if the variations would have been predictable to one of ordinary skill in the art;
- Finding some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.

MPEP § 2141.

Importantly, courts must consider all objective evidence of nonobviousness (also called secondary factors or considerations)—such as unexpected results, commercial success, long-felt need, licensing by competitors, and failure of others—before making an obviousness determination. *In re Cyclobenzaprine*, 676 F.3d 1063, 1075-76 ("[A] fact finder . . . may not defer examination of the objective considerations until after the fact finder makes an obviousness finding."); *see also Tokai Corp. v. Easton Enters., Inc.*, 632 F.3d 1358, 1369−70 (Fed. Cir. 2011) (citing *Graham*, 383 U.S. at 17−18). Still, the burden of production is shifted to require the patentee to produce evidence of nonobviousness, which may include objective evidence of nonobviousness, "after the challenger has successfully made his prima facie case demonstrating that the patent might be obvious." *Novo Nordisk A/S v. Caraco Pharm. Labs., Ltd.*, 719 F.3d at 1353. To this point, the Federal Circuit has acknowledged that in some cases, evidence of secondary considerations "simply cannot overcome a strong prima facie case of obviousness." *Wyers v. Master Lock Co.*, 616 F.3d 1231, 1246 (Fed. Cir. 2010).

C. Exemplary Invalidity Grounds

Below, Imperative Care identifies (1) prior art that anticipates one or more of the Asserted Claims and (2) exemplary combinations of prior art that render the Asserted Claims obvious. The prior art combinations identified below are not exhaustive; rather, they are illustrative examples of prior art combinations using the prior art identified above. To the extent Inari contends any of the cited prior art fails to disclose one or more limitations of the Asserted Claims, Imperative Care reserves the right to identify other prior art references that, when combined with the other above prior art, would render the claims obvious despite the allegedly missing limitation.

Patent	Asserted Claim(s)	Basis of Invalidity	Applicable Prior Art
11,554,005	1-7 and 9-15	35 U.S.C. § 103	Garrison in combination with Schaffer, Hartley, and/or Eller
11,697,012	1-7 and 9	35 U.S.C. § 102	Schaffer
	1-7 and 9	35 U.S.C. § 103	Schaffer alone or in combination with Hartley, Eller, and/or Garrison
11,744,691	14-22	35 U.S.C. § 103	Garrison alone or in combination with Goff and/or Aklog
11,844,921	1-3, 5-7, 9, and 10	35 U.S.C. § 102	Schaffer
		35 U.S.C. § 103	Schaffer alone or in combination with Hartley and/or Eller
11,865,291	1-8, 12-17, and 19	35 U.S.C. § 102	Schaffer
		35 U.S.C. § 103	Schaffer alone or in combination with Hartley and/or Eller
11,969,333	1-4, 6-12, 14-23,	35 U.S.C. § 103	Garrison in

	25-31, and 33-38		combination with Aklog, Goff, Laub, Schaffer, Hartley and/or Eller
11,974,910	1-8, 11-15, and 18-20	35 U.S.C. § 103	Garrison in combination with Aklog, Laub, Schaffer, Hartley, and/or Eller
12,016,580	1, 5, 6, 9-30, and 33-34	35 U.S.C. § 103	Garrison in combination with Aklog, Laub, Goff, Schaffer, Hartley, and/or Eller

D. <u>Level of Ordinary Skill in the Art</u>

The analyses presented herein are provided from the perspective of a person having ordinary skill in the relevant art during the relevant time period. The Asserted Patents generally claim two types of devices: a valve or an aspiration system.

For the valve patents, a person of ordinary skill in the art would have had an undergraduate degree in mechanical engineering or a related discipline and 2-4 years of product design or engineering experience. For the aspiration system patents, a person of ordinary skill in the art would have had an undergraduate degree in mechanical engineering or a related engineering discipline and 2-4 years of catheter design experience.

Imperative Care reserves its right to evaluate Inari's proposed level of ordinary skill, if and when it is provided in this case, and to respond accordingly. Likewise, Imperative Care reserves its right to modify these contentions in view of Inari's proposed level of ordinary skill, if and when it is provided in this case.

E. <u>General Motivations to Combine Prior Art References</u>

The prior art references cited herein were within the field of the patentee's endeavor or are at least reasonably pertinent to the field with which the patentee was concerned, that is, valves for use during intravascular procedures and devices for aspirating unwanted material from a patient. Because the Asserted Patents simply arrange well-known elements found in the prior art, with each performing the same function it had been known to perform and yield no more than what one would expect from such an arrangement, the combinations of prior art were obvious. *KSR*, 127 S. Ct. at 1742.

Further, in the prior art, there were well-recognized design needs and market pressures to develop improved valves for use during intravascular procedures and devices for aspirating unwanted material from a patient. Such design needs and market pressures provide ample reason to combine prior art elements in the manner combined. *KSR*, 127 S. Ct. at 1742. Moreover, because there were a finite number of predictable solutions for the elements recited in the Asserted Claims, a person of ordinary skill in the art had good reason to pursue the known options. *Id*. Indeed, a person skilled in the art would have been familiar with all the claim elements that the patentee used to distinguish the prior art during prosecution. The above-identified prior art references merely use those familiar elements for their primary or well-known purposes in a manner well within the ordinary level of skill in the art. Accordingly, common sense and the knowledge of the prior art render the claims invalid under either 35 U.S.C. § 102 or § 103.

Moreover, a person of ordinary skill would have perceived a reason to combine the above prior art based on the nature of the problem to be solved, the teachings of the prior art, and the knowledge of persons of ordinary skill in the art. The identified prior art addresses the same or similar technical issues and suggests the same or similar solutions to those issues. *See In re Inland Steel Co.*, 265 F.3d 1354, 1362 (Fed. Cir. 2001). Some of the prior art refers to or

discusses other prior art, illustrating the close technical relationship among the prior art.

Therefore, for every prior art reference identified herein, it would have been obvious to combine that prior art reference with any other prior art reference identified above. It would also be obvious to combine that prior art reference with any combination of the prior art references identified herein. Exemplary combinations that Imperative Care relies upon are discussed in more detail below.

IV. INVALIDITY OF THE ’005 PATENT

As set forth below, claims 1-7 and 9-15 of the ’005 Patent are invalid at least because they are rendered obvious under 35 U.S.C. § 103 at least by Garrison in combination with Schaffer, Hartley, and/or Eller. In addition to the exemplary arguments presented below, an claim chart is attached as Appendix A that identifies additional prior art references and disclosures that, when combined with other prior art references identified therein, renders the Asserted Claims of the ’005 Patent obvious.

Imperative Care may rely on cited or uncited portions of the prior art, other documents, and expert testimony to establish (1) the state of the relevant art and (2) the general knowledge of one of skill in the art. Furthermore, to the extent similar claim limitations occur in one or more claims, the disclosures below applied to a given claim should be read to apply to all similar claim limitations, as should the prior art descriptions above.

Imperative Care has also filed a petition for *inter partes* review of the ’005 Patent with the Patent Trial and Appeal Board, which challenges claims 1-7 and 9-15 of the ’005 Patent based on the same prior art identified in these contentions. *Imperative Care, Inc. v. Inari Medical, Inc.*, Case No. IPR2025-00289, Dec. 13, 2024. Imperative Care incorporates the invalidity arguments set forth in the petition and supporting documents as if set forth in full herein.

A. Claims 1-7 and 9-15 of the ’005 Patent are Obvious over Garrison in Combination with Schaffer, Hartley, and/or Eller

Claims 1-7 and 9-15 of the ’005 Patent are invalid at least because they are obvious over Garrison, in combination with one or more of Schaffer, Hartley, and/or Eller.

Garrison discloses an aspiration system for removing unwanted material from a patient’s vasculature. As illustrated below, Garrison’s aspiration system includes the components claimed in the ’005 patent, including a catheter [orange], aspiration source [red], connector [green] placing the aspiration source in communication with a flow path, on/off control [purple], and clot cannister [blue]:

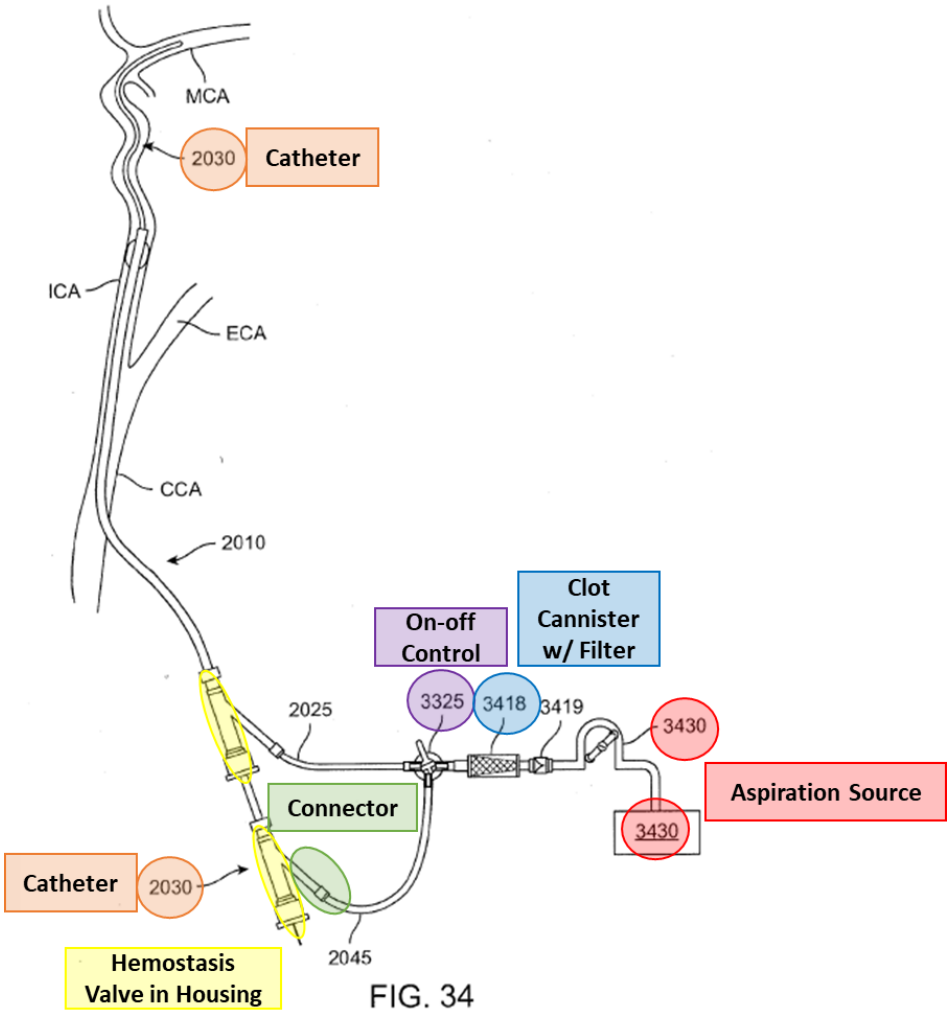
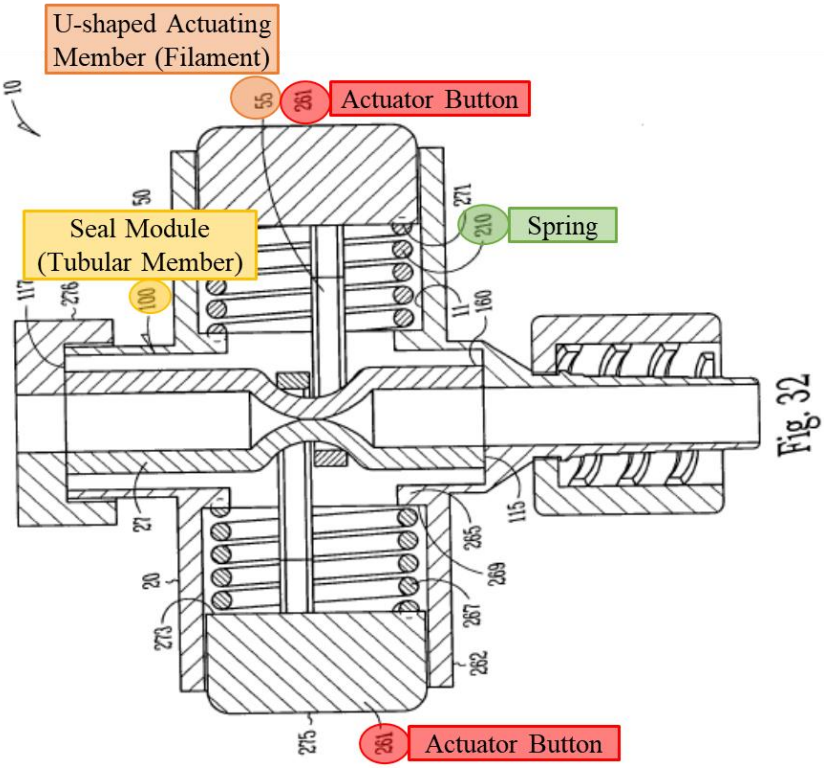


FIG. 34

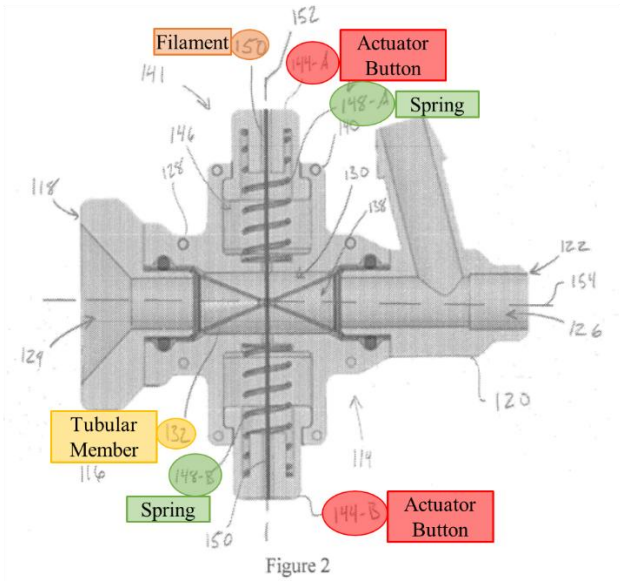
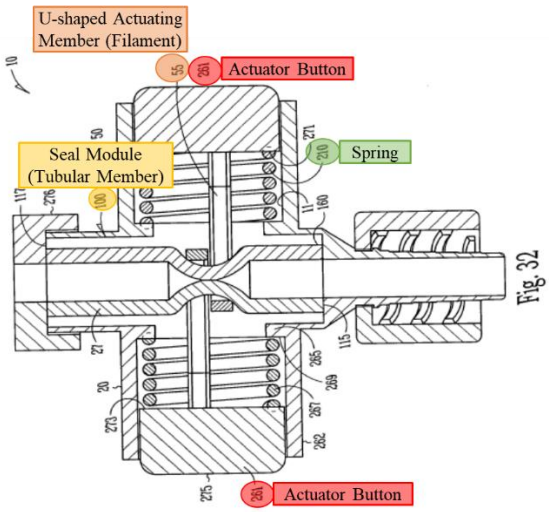
(Garrison, Fig. 34.)

Garrison's aspiration system can also include various hemostasis valves including, "an adjustable-opening valve" and a "rotating hemostasis valve." (*Id*., [0062].) Garrison explains that the hemostasis valves "allow for the introduction of devices therein while preventing or minimizing blood loss via the internal lumen during the procedure." (*Id*.) Garrison presumes a person of ordinary skill in the art would have been familiar with the available hemostasis valves and, therefore, does not describe their structures. However, other prior art references do.

For example, Schaffer discloses an adjustable-opening hemostasis valve for use during minimally invasive intravascular procedures. (Schaffer, [0002], [0008].) Schaffer was ***not*** before the Examiner during prosecution of the '005 patent. Like the claimed valves, Schaffer's valve includes a tubular member that can slidably receive a second catheter, a constricting mechanism including a filament, an actuator coupled to the filament, and a biasing system (e.g., spring):

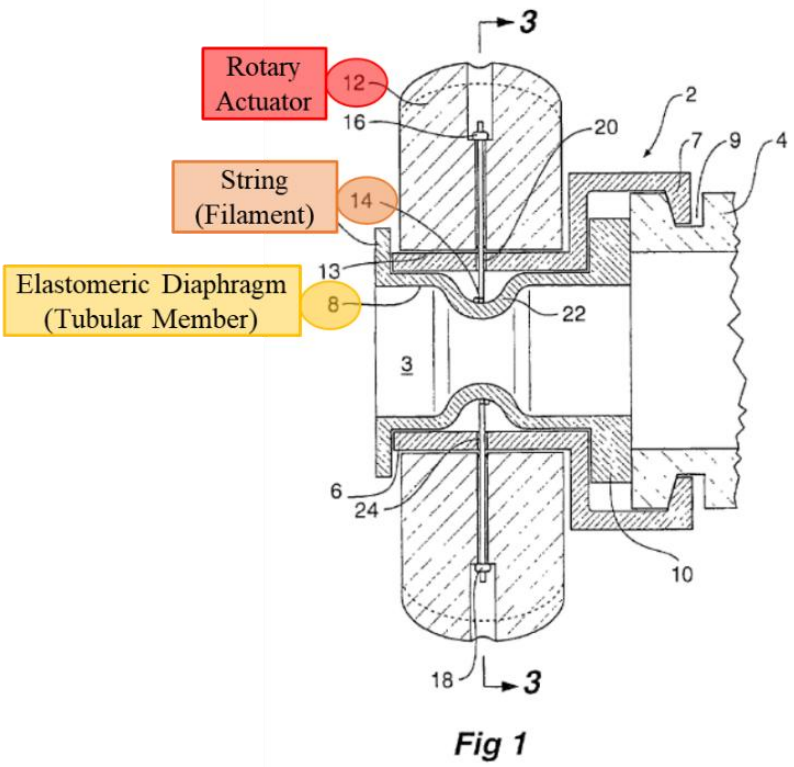


(*Id.*, Fig. 32.)[1] As illustrated below, Schaffer's valve has the same components, in the same arrangement, as the valve claimed in the '005 patent (and described in the '519 application):

'005 Patent ('519 Application)	Schaffer
	

Additionally, Hartley discloses a rotating hemostasis valve for use with catheters to prevent blood loss. (Hartley, [0002]-[0003].) Hartley's valve also includes a tubular member that can slidably receive a second catheter, a constricting mechanism including a filament, and an actuator coupled to the filament:

[1] Imperative Care's contentions use the versions of Schaffer's drawings submitted during prosecution on June 18, 2003 because they more clear than the figures in the issued patent. The drawings became publicly available when Schaffer published on December 4, 2003. 37 C.F.R. §1.11.



(Hartley, [0031], Fig. 1.)

During prosecution of the ’005 patent, the Examiner found that Hartley disclosed every hemostasis-valve limitation in the challenged claims except a movable actuator coupled to a spring. (Oct. 5, 2022 Office Action, 5-6.) However, as shown above, Schaffer discloses movable actuator buttons coupled to springs and satisfies this limitation. Moreover, if Schaffer does not disclose a “filament,” Schaffer combined with Hartley does.

Likewise, Eller discloses a rotating hemostasis valve having a filament that constricts a tubular member upon rotation of an actuator:

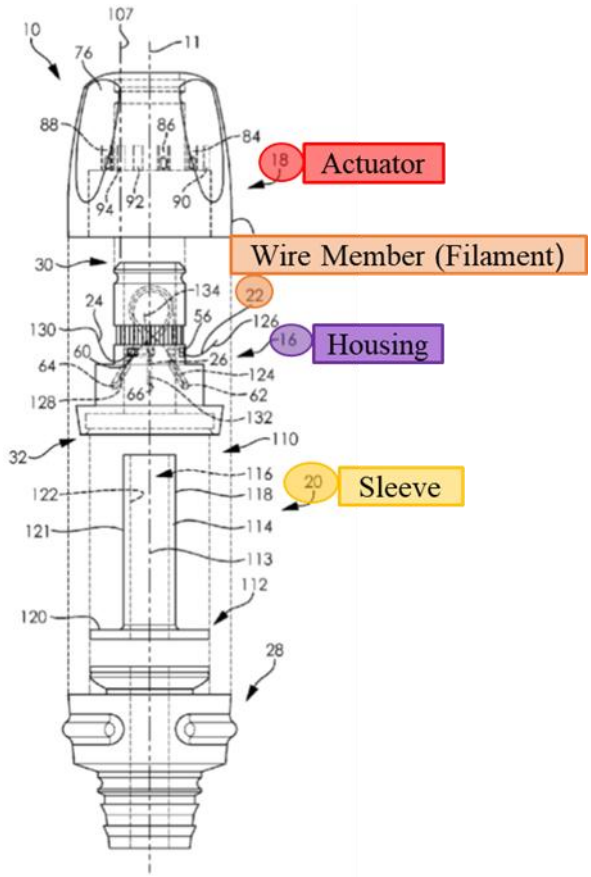


FIG. 2

(Eller, 5:1-12, Fig. 2.) Eller's valve also includes an optional biasing system, such as a torsion spring, that biases the valve toward the sealed state. (*Id.*, 19:22-30.)

A POSITA would have found it obvious to combine Garrison's aspiration system with Schaffer's hemostasis valve, with or without Hartley's or Eller's filaments, for several reasons. First, Garrison teaches that the hemostasis valves used with its system "can be … an adjustable-opening valve." (Garrison, [0062], [0065], [0098].) Schaffer discloses an adjustable-opening valve and, therefore, a POSITA would have been motivated to combine, and reasonably expected success in combining, Schaffer's valve with Garrison.

Second, Schaffer discloses that its hemostasis valve is "for use with catheters" and "blocks the flow of gas or fluid completely and immediately with or without an instrument in place within the gas/fluid path." (Schaffer, [0002],

[0008], [0047], [0049].) Schaffer further discloses that a range of instruments can be used within the valve, such as "a catheter, guidewire, needle, or fiber." (*Id.*, [0056], [0074].) Thus, Schaffer's valve performs the stated function of Garrison's "hemostasis valve" — to "allow introduction of devices … while preventing or minimizing blood loss during the procedure." (Garrison, [0098].) Thus, a POSITA would have been motivated to combine, and reasonably expected success in combining, Schaffer's valve with Garrison.

Third, POSITAs would have recognized that Schaffer's hemostasis valve could simplify operation of Garrison's system. For example, Schaffer's springs bias the valve toward the closed position, eliminating the need to manually seal the valve during procedures as occurred with some prior-art valves.

Fourth, the combination of Schaffer's valve with Garrison's aspiration catheters would merely entail the combination of known elements (Schaffer's valve and catheter 2030) according to known methods (attaching the valve to a catheter's proximal hub or forming it integrally with the hub) to yield the predictable result of minimizing blood loss through the catheter. *See KSR*, 550 U.S. at 416.

Fifth, POSITA's in August 2018 had a finite number of predictable hemostasis valves to choose, including an "adjustable-opening valve" or RHV. A POSITA would have found it obvious to try any of these hemostasis valves with Garrison's catheter 2030. *KSR*, 550 U.S. at 417. The known valves, like Schaffer's adjustable-opening hemostasis valve, were simple mechanical structures that operate in a predictable way. For this additional reason, POSITAs would have reasonably expected success in combining Schaffer's valve with Garrison.

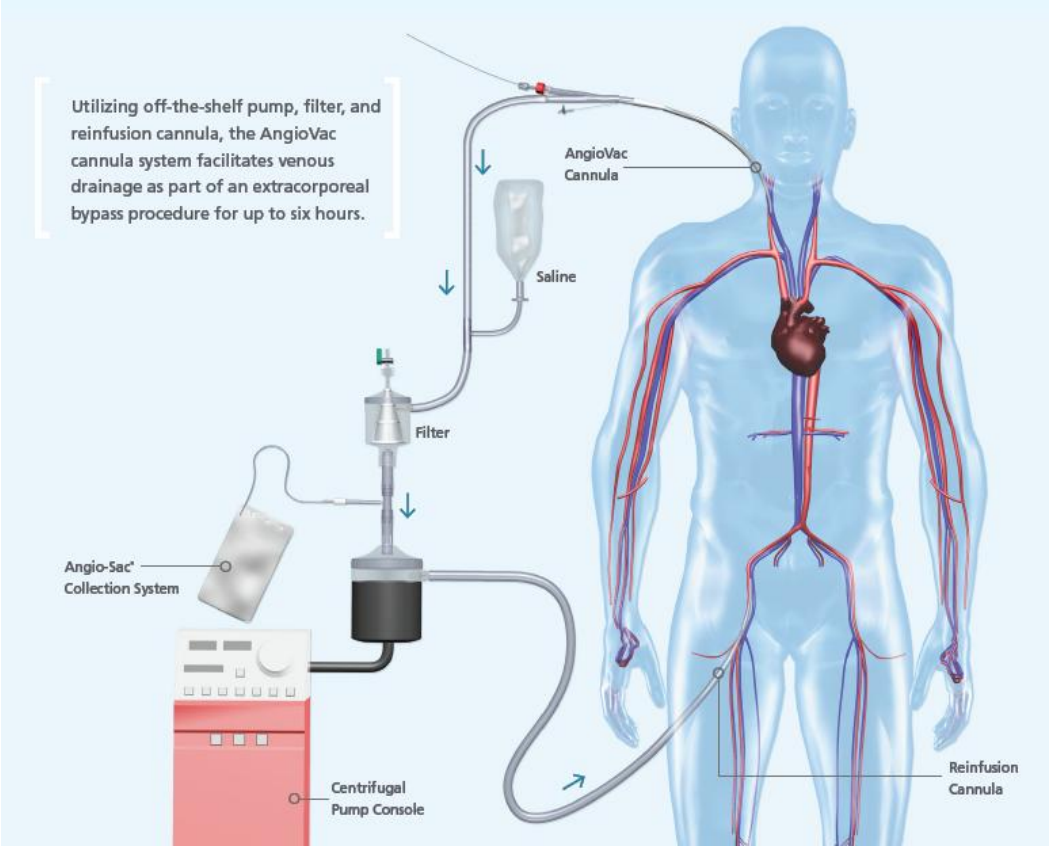
A POSITA also would have found it obvious to combine Eller's torsion spring with Hartley's rotatable hemostasis valve and, therefore the combination of Garrison with Hartley and Eller also renders the challenged claims obvious.

Eller's publication was listed in an Invention Disclosure Statement ("IDS") during prosecution but was not discussed or applied by the Examiner. Thus, the Examiner never addressed the combination of Eller's torsion spring with Hartley's valve.

B. <u>Alternative Obviousness Combinations that Render Claims 1-7 and 9-15 of the '005 Patent Obvious</u>

The exemplary obviousness combination discussed above relies on Garrison's disclosure of a vacuum aspiration system comprising "a housing," "a flow path extending through the housing," "an on-off control," "a first catheter," and "a clot canister," as recited in claim 1 of the '005 Patent. However, the prior art is replete with examples of vacuum aspiration systems containing these elements. Thus, to the extent Inari contends Garrison does not disclose one or more of these elements, it would have been obvious to a person of ordinary skill in the art to combine other prior art aspiration systems with Schaffer, Hartley, and/or Eller to achieve the claimed invention.

For example, Aklog discloses "systems and methods for removing substantially en bloc clots, thrombi, and emboli, among others, from within heart chambers, as well as medium to large vessels." (Aklog, 1:17-24.) The Aklog system, commercially released as the AngioVac system, shown below:



(AngioVac Brochure.)

Likewise, Laub discloses "a system for removing thrombi and other unwanted material from the body of a patient, particularly from the patient's vasculature." (Laub, [0005].) An embodiment of Laub is shown in the figure below:

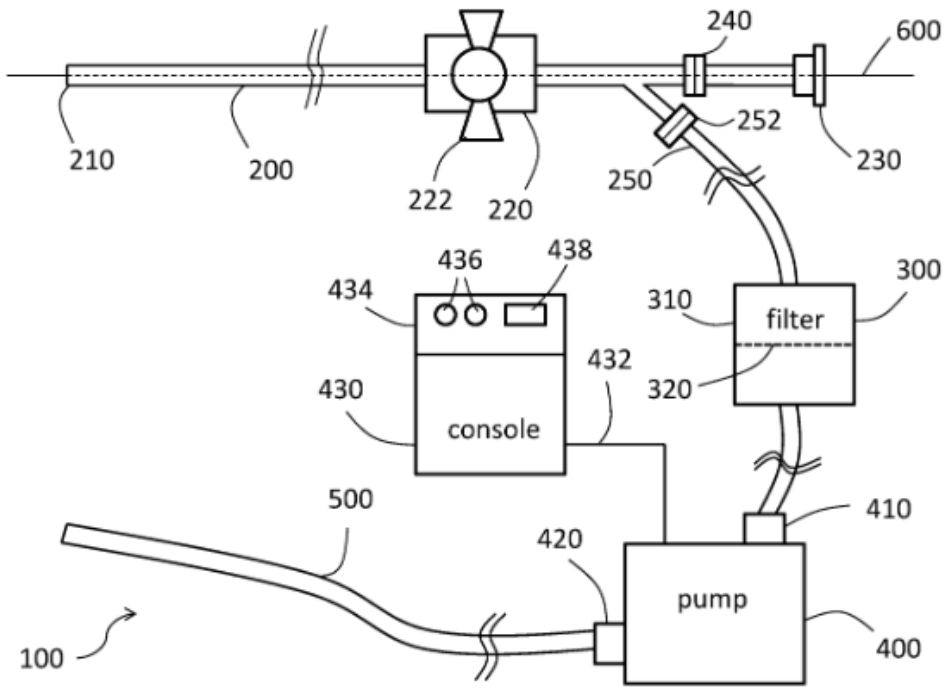
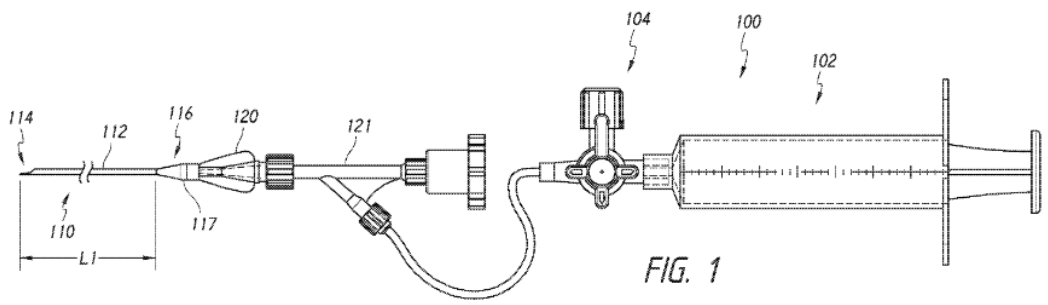


FIG. 1A

(Laub, Fig. 1A.) "In some embodiments … fluid path 250 may optionally connect with aspiration catheter 200 via a separate connector (e.g., connector 252) which may allow detachment of fluid path 250 from aspiration catheter 200." (Laub, [0039].)

In addition, Mogi discloses "an embodiment of an assistive jet aspiration catheter system 100 having a suction source 102 (which can be a Vaclok 30 cc syringe, a pump system such as a Penumbra™ pump, or otherwise), a stopcock or valve 104 to control the suction and flow of fluid through the system 100, and an assistive jet aspiration catheter 110 (also referred to herein as a assistive jet catheter and just an aspiration catheter)." (Mogi, [0154].) This embodiment is shown in the figure below:



(Mogi, Fig. 1.)

Moreover, several aspiration systems were being sold well before the priority date of the ’005 Patent, including AngioDynamic’s AngioVac system (discussed above), Penumbra’s Indigo Aspiration System, Medtronic’s Export Aspiration Catheter, and even Inari’s own FlowTriever and ClotTriever systems.

In addition to Garrison, other prior art references disclose other claimed elements, such as the claimed “on-off control in the flow path,” and/or “clot canister fluidly coupled to the flow path.” For example, Mogi discloses “stopcock or valve 104 to control the suction and flow of fluid through the system 100.” (Mogi, [0154].) Aklog discloses a filter having a “permeable sheet 143 positioned with the fluid flow” that “may include a plurality of pores sufficiently sized, so as to permit fluid from the site of interest to flow therethrough, while preventing undesirable material captured from the site of interest from moving downstream ….” (Aklog, 11:33-40.) Goff discloses the use of a “filter element” to “separate solid particles at a desired particle size cutoff.” (Goff, [0011].) Laub discloses “filter 300 is configured to trap solid material received through aspiration catheter 200 from the body of the patient during use. For example, filter 300 is configured to trap thrombi, emboli, tumor tissue, debris, or other materials aspirated from the patient’s body using system 100.” (Laub, [0040].)

In addition to Garrison, other prior art references disclose the use of

valves, such as hemostasis valves, to facilitate the insertion of treatment devices into the system while minimizing blood loss. For example, Laub discloses "working port 230 is configured to provide a fluid tight seal around stylet 700 or other device inserted through working port 230, for example, so as to prevent leakage of blood out of working port 230 during use." (Laub, [0036].) For the same reasons discussed above in connection with Garrison, in view of these disclosures, a person of ordinary skill in the art would have been motivated to combine the above-referenced aspiration systems with the hemostasis valves of Schaffer, Hartley, and/or Eller to achieve the claimed invention.

In view of this additional prior art, and the other prior art references identified in Appendix A, the asserted claims of the '005 Patent would have been obvious to a person of ordinary skill in the art.

V. INVALIDITY OF THE '012 PATENT

As set forth below, claims 1-7 and 9 of the '012 Patent are invalid at least because they are anticipated under 35 U.S.C. § 102 by Schaffer, or rendered obvious under 35 U.S.C. § 103 at least by Schaffer, alone or in combination with Hartley, Eller, and/or Garrison. In addition to the invalidity arguments described below, an exemplary claim chart is also attached hereto as Appendix B, which identifies additional prior art references and disclosures that, when combined with other prior art references identified therein, renders the Asserted Claims of the '012 Patent obvious.

Imperative Care may rely on cited or uncited portions of the prior art, other documents, and expert testimony to establish (1) the state of the relevant art and (2) the general knowledge of one of skill in the art. Furthermore, to the extent similar claim limitations occur in one or more claims, the disclosures below applied to a given claim should be read to apply to all similar claim limitations, as should the prior art descriptions above.

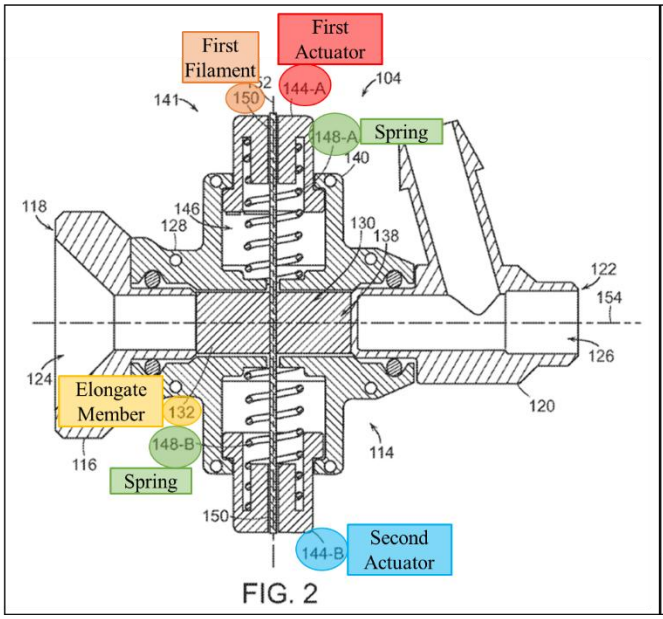
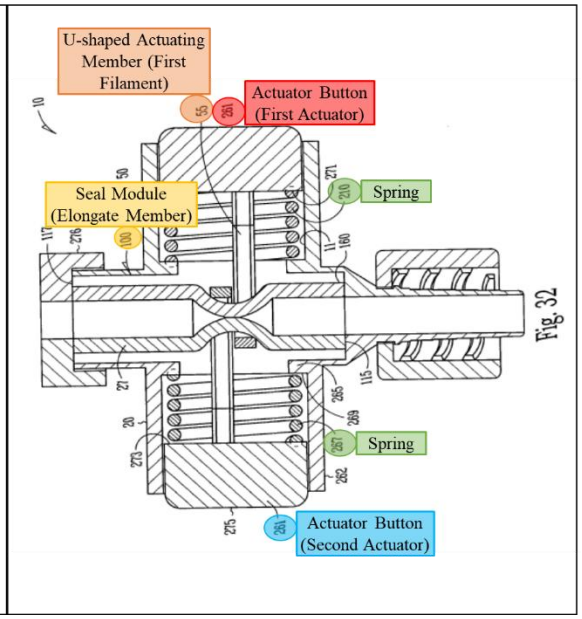
Imperative Care has also filed a petition for *inter partes* review of the

’012 Patent with the Patent Trial and Appeal Board, which challenges claims 1-7 and 9 of the ’012 Patent based on the same prior art identified in these contentions. *Imperative Care, Inc. v. Inari Medical, Inc.*, Case No. IPR2025-00156, Nov. 8, 2024. Imperative Care incorporates the invalidity arguments set forth in the petition and related filings as if set forth in full herein.

A. <u>Claims 1-7 and 9 of the ’012 Patent are Anticipated by Schaffer</u>

Schaffer anticipates Claims 1-7 and 9 of the ’012 Patent. Schaffer discloses a hemostasis valve for use with catheters “that blocks the flow of gas or fluid completely and immediately with or without an instrument in place within the gas/fluid path.” (Schaffer, [0002], [0008].) Schaffer’s hemostasis valve includes “seal module 100 defining a central lumen,” through which “a range of instruments” can be passed and extended into a body passage, such as “a ***catheter***, guidewire, needle, or fiber.” (Schaffer, [0056, [0074] (emphasis added); *see also id.*, [0047] (“The second end-wall 22 of the housing 20 is sized and configured to receive an inserted instrument, catheter or guide wire through a receiving member 45.”).) A person of ordinary skill in the art would have understood that such catheters have an “elongate, flexible tubular body, having a proximal end, a distal end and a central lumen,” as claimed.

Like the valve described in the ’012 patent, Schaffer’s valve includes a collapsible tubular sidewall (called a “seal module 100”) within the valve that can receive other catheters. (*Id.*) Schaffer’s valve also includes a filament (called “actuating member 55”) that can collapse the tubular sidewall to close the valve. (*Id.*, [0076]-[0077].) Also, like the ’012 patent, Schaffer’s actuating members 55 (i.e., filaments) may be moved from a first position to a second position by depressing two actuator buttons 261 connected to two springs 210. (*Id.*) As shown below, Schaffer’s valve has the same components, in the same arrangement, as the valve claimed in the ’012 patent:

’012 Patent	Schaffer
	

B. <u>Claims 1-7 and 9 of the ’012 Patent are Obvious over Schaffer, alone or in combination with Hartley, Eller, and/or Garrison</u>

To the extent Schaffer does not disclose a “filament,” as that term would have been understood by a POSITA, Schaffer combined with Hartley and Eller renders claims 1-7 and 9 of the ’012 Patent obvious. Hartley and Eller disclose hemostasis valves having a filament that loops around and constricts the lumen of a collapsible tubular sidewall to seal a valve.

Hartley discloses a hemostasis valve for use with catheters to prevent blood loss. (Hartley, [0002]-[0003].) Hartley’s valve also includes an actuator that applies tension to a filament looped around a collapsible tube to open and close the valve:

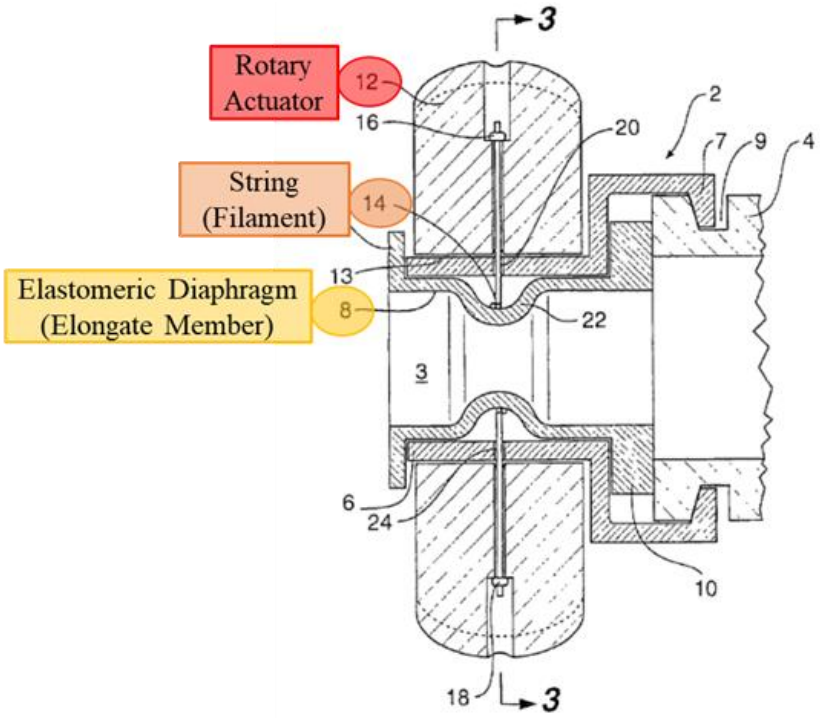


Fig 1

(*Id.*, [0031], Fig. 1.) Hartley was discussed by the Examiner during prosecution but was not combined with any other references, such as Schaffer, as in this Petition. Hartley's "filament" is a "string":

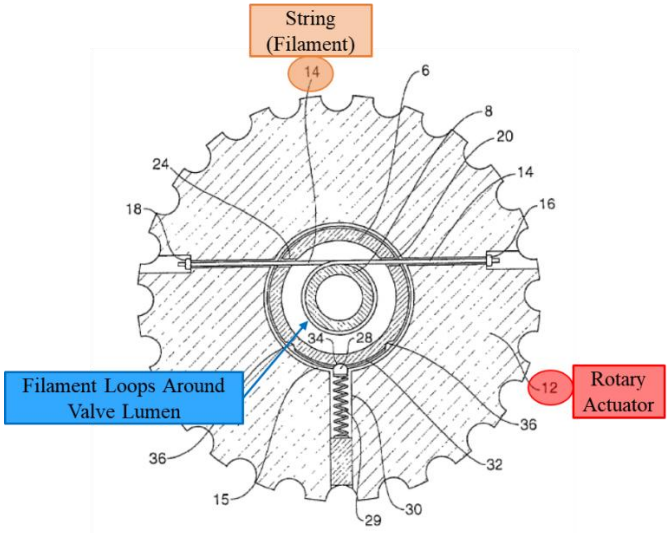


Fig 3

Hartley, [0017], [0031], Fig. 3.)

Eller also discloses a hemostasis valve for use with catheters to prevent

blood loss during medical procedures. (Eller, 1:20-50.) Eller's valve also includes an actuator that applies tension to a filament looped around a collapsible tube to open and close the valve:

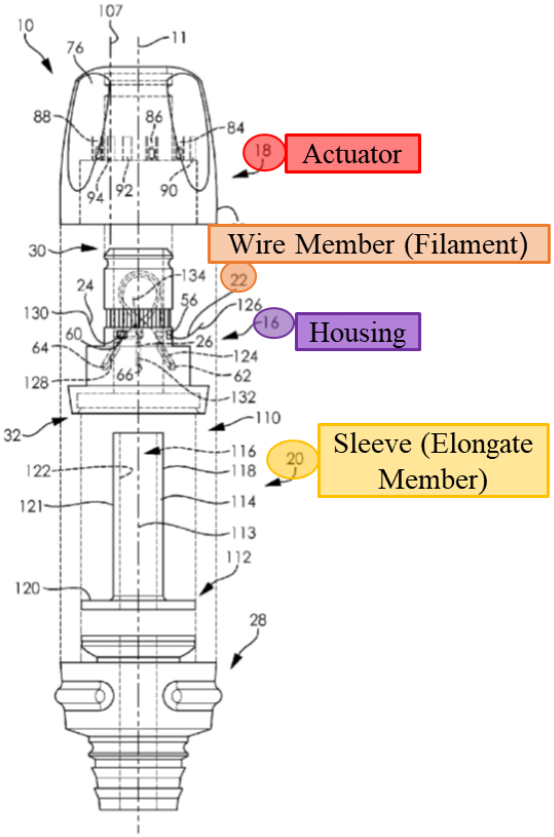


FIG. 2

(Eller, 5:1-12, Fig. 2.) Eller's "filament" is a "wire member." Eller was listed in an Invention Disclosure Statement ("IDS") but was not substantively discussed or applied during prosecution.

A POSITA would have found it obvious to substitute Hartley's or Eller's filaments for Schaffer's actuating members. For example, the combination of Hartley's string and Schaffer's valve, or Eller's wire member and Schaffer's valve, would have merely entailed substitution of one known element (Hartley's string or Eller's wire member) for another (Schaffer's actuating members) to yield the predictable result of constricting Schaffer's valve to form a seal. *KSR*, 550 U.S. at 416.

Hartley's disclosure that its string can "close over a range of diameters of devices passed through the valve or can close completely down to be self-sealing" would have further motivated POSITAs to substitute Hartley's string for Shaffer's actuating members. (Hartley, [0037].) POSITAs would have recognized that Hartley's string may seal more effectively across a wider range of diameters and shapes for the inserted devices than Schaffer's U-shaped actuating members. Likewise, Eller's disclosure that the wire member can form a seal around one or more medical devices passed through the valve would have further motivated POSITAs to substitute Eller's wire member for Shaffer's actuating members. (Eller, 15:21-40, 17:38-43, 18:3-8.)

POSITAs also had a finite number of materials to select from to constrict a tubular member in a hemostasis valve in 2017. Hartley and Schaffer disclose two such materials: Hartley's string and Schaffer's actuating members formed from metal or plastic. Eller discloses a third option: one or more wire members. A POSITA would have found it obvious to select from these finite, predictable options and, as discussed below, would have had a reasonable expectation of success in implementing them. *KSR*, 550 U.S. at 421

POSITAs would have had a reasonable expectation of success in substituting Hartley's string for Schaffer's U-shaped actuating members. Hartley teaches a simple method of attaching the string to the rotary actuator – a knot at each end of the string. (Hartley, [0031].) POSITAs would have reasonably expected that similar knots could be used to secure the ends of Hartley's string to Schaffer's actuator buttons. For example, small holes could be made in each of Schaffer's actuator buttons, and each end of the string could be threaded through the hole and knotted on the other side. This simple modification would have been within a POSITA's skills. In this arrangement, the first end of the string would be secured to the first actuator button, the string would loop at least once around Schaffer's seal module, and the second end of

the string would be secured to the second actuator button.

Also, POSITAs would have recognized that Hartley's string and Schaffer's U-shaped actuating members function in similar ways and, therefore, no other modifications to Schaffer's valve would be necessary. Hartley collapses the valve lumen by pulling the ends of the string in opposite directions. (Hartley, [0031].) Schaffer also collapses the valve lumen by pulling the U-shaped actuating members in opposite directions. (Schaffer, [0077].) Thus, if Hartley's string were incorporated into Schaffer's valve, a POSITA would have reasonably expected Schaffer's springs to pull the ends of the string in opposite directions in the first position, thereby causing the string to constrict Schaffer's seal module. (*Id*.; Hartley, [0031].)

Further, Hartley discloses that looping the string around the central lumen forms an effective seal. (Hartley, [0031], [0037].) Thus, when replacing Schaffer's actuating members with Hartley's string, POSITAs would have been motivated to loop Hartley's string around Schaffer's seal module. POSITAs would have reasonably expected success in using this configuration because Hartley discloses the configuration forms an effective seal.

A POSITA would have also reasonably expected that pressing Schaffer's buttons inwardly (i.e., second position) would release the tension on the string, causing the string to loosen around the seal module and allowing the lumen to at least partially open. (*See* Schaffer, [0077]; Hartley, [0034].) Schaffer's seal module is formed from a "highly deformable, non-compressible material 166 (e.g., plastic)" and is "configured to maintain an open lumen 193 when no compressive force 67 is applied." (Schaffer, [0054].) A POSITA would have reasonably expected Schaffer's seal module to have the resilience to return to its open configuration when the tension on the string is released such that no compressive force is applied to the seal. Moreover, if the resiliency of Schaffer's lumen required adjustment to function with Hartley's string, a

POSITA would have possessed the skills and knowledge to select an appropriate material with the proper resiliency. For example, Schaffer discloses various materials for the seal module, including "modified vinyl, silicone, polyurethane or a combination thereof." (Schaffer, [0081].) Similarly, Eller discloses various materials for its sleeves, including "NuSil MED-4755, NuSil MED-4765, and NuSil MED-4014." (Eller, 36:27-60.)

A POSITA also would have had a reasonable expectation of success in substituting Eller's wire member for Schaffer's actuating members for several reasons. First, Eller discloses that the "[a]ttachment between a wire member and a housing and/or actuator can be accomplished using any suitable method or technique." (Eller, 14:37-43.) Eller further identifies several means for securing its wire member to an actuator, including "using adhesives, welding, fusing, providing a friction fit between the wire member and the … actuator." (*Id.*, 14:43-49.) POSITAs would have reasonably expected success in securing Eller's wire member to Schaffer's actuator buttons using one or more of these simple methods. For example, the first end of the wire member would be adhered or welded to the first actuator button, looped at least once around Schaffer's seal module, and the second end of the wire member would be adhered or welded to the second actuator button.

Second, Eller discloses that its wire member may be used with "any suitable actuator capable of moving the selective fluid barrier valve device between a first configuration and a second configuration" and that "[s]killed artisans will be able to select a suitable actuator to include on a selective fluid barrier valve device according to a particular embodiment based on various considerations, including the number of wire members included in the selective fluid barrier valve device and/or the structural arrangement of the housing." (Eller, 8:27–39.) Eller discloses that suitable actuators include "rotatable actuators, linear actuators, slidable actuators, pivotable actuators, levers, and

any other actuator considered suitable for a particular embodiment." (*Id.*, 8:39–44 (emphasis added).) Given this disclosure, POSITAs would have reasonably expected Eller's wire member to work with Schaffer's buttons, which are linear and/or slidable actuators.

Third, Eller's wire member and Schaffer's U-shaped actuating members function similarly to close the valves. Both Schaffer and Eller create a seal by moving an actuator from a first position to a second position to constrict the seal module/sleeve. (Schaffer, [0077]; Eller, 15:21-40, 17:47-18:3.) In both devices, the actuators pull the wire/actuating members in opposite directions to constrict/compress the valve's central lumen. (Schaffer, [0077], Eller, 15:21-40, 17:47-18:3.)

POSITAs would have recognized that Eller's wire member would function like Schaffer's U-shaped actuating members. In the first position, the springs coupled to Schaffer's actuator buttons would pull the ends of the wire member in opposite directions, thereby causing the wire member to constrict the lumen of Schaffer's seal module. (*See* Schaffer, [0077]; Eller, 15:21-40, 17:47-18:3.) When Schaffer's actuator buttons are pressed inwardly, the tension on the wire member would be relaxed, causing the wire member to loosen around the seal module allowing the lumen to at least partially open. (*See* Schaffer, [0077]; Eller, 15:21-40, 17:47-18:3.) Schaffer discloses that the seal module is formed from a "highly deformable, non-compressible material 166 (e.g., plastic)" and is "configured to maintain an open lumen 193 when no compressive force 67 is applied." (Schaffer, [0054].) Therefore, a POSITA would have expected Schaffer's seal module to have the resilience to return to its open configuration when "no compressive force [] is applied" to the lumen." (*Id.*.)

For at least the reasons stated above, claims 1-7 and 9 of the '012 Patent are obvious over Schaffer, alone or in combination with Hartley and/or Eller.

Moreover, to the extent the preamble of claim 1 is limiting, persons of ordinary skill in the art would have found it obvious to combine known aspiration catheters, such as that disclosed in Garrison, Gordon, Aklog, Indigo, Brady, Laub, Quick, or Mogi, as set forth in Appendix B, with the known filament-based hemostasis valves disclosed in Schaffer, Hartley, or Eller.

VI. INVALIDITY OF THE '691 PATENT

As set forth below, claims 14-22 of the '691 Patent are invalid at least because they are rendered obvious under 35 U.S.C. § 103 at least by Garrison, alone or in combination with Goff, and/or Aklog. In addition to the invalidity arguments described below, an exemplary claim chart is also attached hereto as Appendix C, which identifies additional prior art references and disclosures that, when combined with other prior art references identified therein, renders the Asserted Claims of the '691 Patent obvious.

Imperative Care may rely on cited or uncited portions of the prior art, other documents, and expert testimony to establish (1) the state of the relevant art and (2) the general knowledge of one of skill in the art. Furthermore, to the extent similar claim limitations occur in one or more claims, the disclosures below applied to a given claim should be read to apply to all similar claim limitations, as should the prior art descriptions above.

Imperative Care has also filed a petition for *inter partes* review of the '691 Patent with the Patent Trial and Appeal Board, which challenges claims 14-22 of the '691 Patent based on the same prior art identified in these contentions. *Imperative Care, Inc. v. Inari Medical, Inc.*, Case No. IPR2024-01257, Aug. 12, 2024. Imperative Care incorporates the invalidity arguments set forth in the petition and related filings as if set forth in full herein.

A. <u>Claims 14-22 of the '691 Patent are Obvious over Garrison alone or in Combination with Goff and/or Aklog</u>

Garrison discloses an aspiration system for removing unwanted material

from a patient's vasculature. As illustrated below, Garrison's aspiration system includes the exact same components as Claim 14 of the '691 patent: a negative pressure source (e.g., pump or syringe) [red], an aspiration catheter [orange], a filter [blue], hemostasis valves [yellow], and a user-actuatable valve [purple] that is closed while negative pressure is generated by the pressure source and opened after the negative pressure is generated to cause rapid aspiration through the catheter.

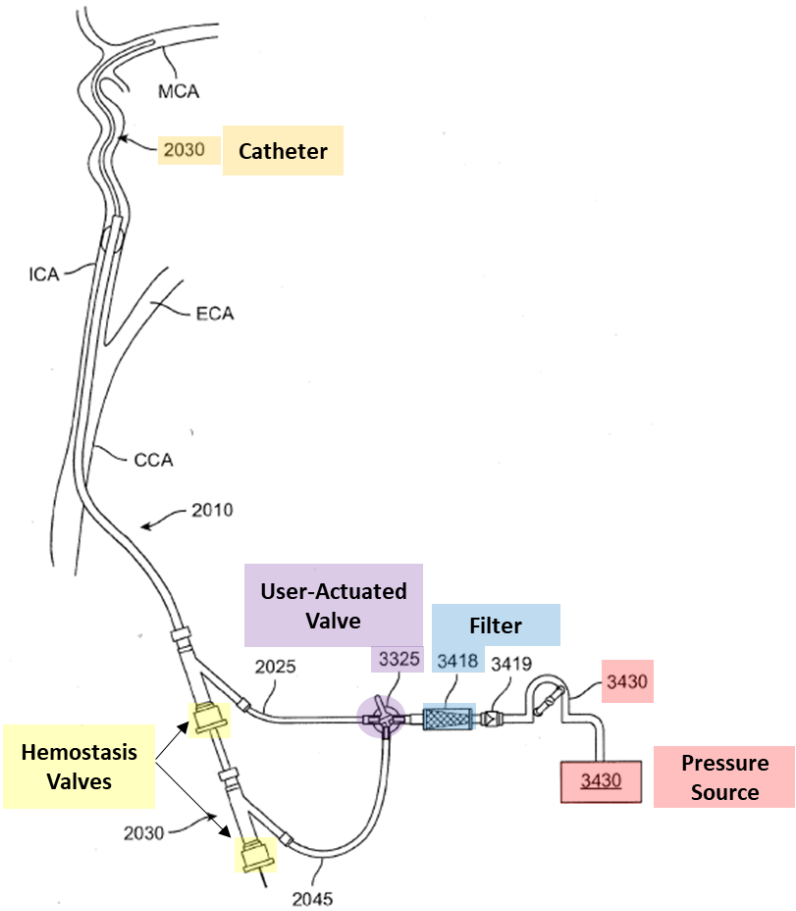


FIG. 34

(Garrison, Fig. 34.) Garrison explains that opening the valve after generating the negative pressure enables "the maximum level of aspiration in a ***rapid fashion*** with one user, something that is not currently possible with existing technologies." (*Id*., [0134] (emphasis added).)

Garrison discloses a coupled assembly including an aspiration catheter

[orange] configured for placement into fluid communication with a first chamber [red] by way of a flow line (i.e. aspiration tube) [green]:

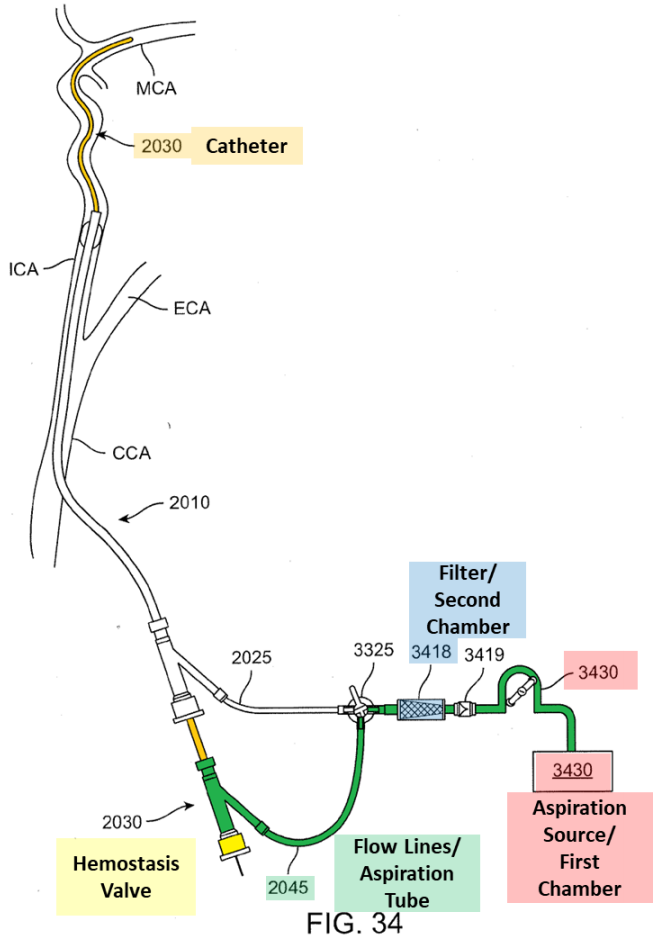


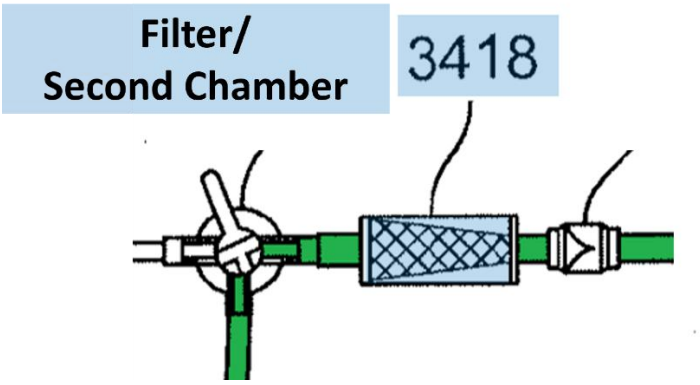
FIG. 34

Garrison, Fig. 34; *see also id.*, [0132] ("both the arterial access device 2010 and catheter 2030 are connected to the same aspiration source via flow lines 2024 and 2045, respectively"), Fig. 32.)

Garrison also discloses that catheter 2030 [orange] can include a hemostasis valve [yellow] in its proximal hub 2065 (item 2065 not pictured in Figure 34). (Garrison, [0098].) "[T]he hemostasis valve may be integral to the catheter proximal adaptor" and, therefore, is part of the coupled assembly. (*Id.*.) Garrison further discloses that the hemostasis valve can take many configurations, including "an adjustable-opening valve such as a Tuohy-Borst or rotating hemostasis valve (RHV)" or "a passive seal hemostasis valve."

(Garrison, [0098].)

Garrison's coupled assembly includes a second chamber having a filter [blue] between the aspiration pump [red] and the aspiration catheter [orange]. (*Id.*, Fig. 34; *see also id.*, [0131] ("A filter 3418 and/or a check valve 3419 may also be coupled with the flow line 2045.").) As shown in Figure 34 (below), the second chamber [blue] is coupled to the aspiration pump and catheter by the flow lines [green] and surrounds the filter. (*Id.*) The flow lines are an aspiration tube.



(Garrison, Fig. 34 (excerpt).) The chamber that surrounds the filter is necessary to prevent the blood from leaking out of the system and to maintain pressure across the aspiration system.

In August 2018, a POSITA would have found it obvious to couple the filter to the tubing using conventional, removable connectors, such as Luer-type connectors (e.g., Luer slip and Luer lock) and barb connectors. (Garrison [0062], [0065], Fig. 11 (illustrating stopcock with standard female connector); Treretola, 4:29-40 (describing the use of Luer type connectors for aspiration catheters); Ex. 1001, 7:61 (describing a "standard luer connector"), 33:24 (describing a "standard Luer or large bore connector").) In fact, Garrison incorporates by reference patents and publications that describe attaching catheter components using "a conventional luer fitting" or improvements to such fittings. (Garrison '118, [0130]; *see also* Gordon, 8:45, 8:63 (describing an

"auxiliary Luer port"); Garrison '868, [0056]-[0059] (describing improvements to the "standardized … locking Luer taper design").) Moreover, the '691 patent acknowledges that Luer type and large bore connectors were known in the art. ('691 patent, 7:58-67 (referencing "a standard luer connector"; 33:24 (referencing "e.g., a standard Luer or large bore connector"); 34:25-28 (referencing "e.g., a standard Luer or large bore connector").)

A POSITA would have been motivated to use conventional, removable connectors, such as Luer type connectors, to removably connect Garrison's filter to the system for several reasons. First, conventional connectors, such as Luer type connectors, allowed physicians to add off-the-shelf tubing and related components simply and quickly. Physicians preferred this flexibility because different procedures and patient conditions may require fewer or additional components, as suggested by the many configurations disclosed in Garrison. Physicians would have been motivated to avoid using unnecessary components due to the additional cost and complexity and would have preferred components that could be easily attached and removed.

Second, the conventional connectors came in standard sizes that made them compatible with other catheter-based medical components, such as tubing and valves. Physicians preferred this compatibility because it increased the options available to the physician during a procedure and, thus, POSITAs were motivated to include these connectors with medical devices.

Third, physicians were familiar with the conventional connectors. This familiarity meant physicians preferred the standard connectors, such as Luer type connectors, because they reduced the risk of complications and increased the speed for assembling the systems. The user preference would have motivated POSITAs to use conventional connectors. Moreover, POSITAs would have reasonably expected success in using these conventional, removable connectors, such as Luer-type connectors, with Garrison's optional filter

because the connectors were simple, widely used, and predictable.

Fourth, combining conventional, removable connectors with Garrison's filter would have merely entailed the combination of known elements (conventional connectors and filter) according to known methods (coupling medical components with conventional connectors) to yield the predictable result of connecting medical components. *KSR*, 550 U.S. at 416; (Ex. 1003, ¶110.)

Additionally, a POSITA would have been motivated to include a removable filter chamber in Garrison's system so that the physician could empty the chamber and clean the filter. Garrison discloses a process for the physician to remove multiple occlusions with Garrison's aspiration system. (*See e.g.*, Garrison, [0166] ("if a second more distal treatment site needs to be reached after removal of a first occlusion, a second, smaller diameter catheter may be inserted through the first catheter").) A POSITA would have recognized that multiple occlusions could clog the filter or fill the chamber, thereby motivating a POSITA to removably couple the chamber to the system so that the chamber and filter could be cleaned and replaced.

In addition to the conventional components discussed above, some of the challenged claims recite additional limitations that also fail to distinguish the challenged claims from the prior art. For example, dependent Claims 21 and 22 require that the aspiration catheter's "distal end portion" is "configured to be positioned proximate to clot material" wherein "the clot material comprises a pulmonary embolism" (hereinafter, "PE") or "a deep vein thrombosis" (hereinafter, "DVT"). Garrison discloses using its aspiration system to remove cerebral occlusions but does not specifically mention PE or DVT.

However, Garrison's catheter is "configured to be positioned" proximate these types of clots because it has the correct size and flexibility. Additionally, a person of ordinary skill in the art would have found it obvious to use and/or

adapt Garrison's cerebral aspiration system to aspirate PE or DVT. Each procedure involves the identical process of advancing a catheter through an artery or vein to reach an embolism and activating a vacuum through the catheter to aspirate the emboli. Unsurprisingly, catheter designers knew well before 2018 how to size catheters to fit the desired vessel.

The use and/or adaptation of Garrison's system to treat PE and DVT is particularly obvious in view of Aklog, which discloses an aspiration system for removing undesirable materials, including PE and DVT, from blood vessels. (Aklog, 2:7-32, 7:27-42.) Aklog also acknowledges that a POSITA could simply adapt aspiration catheters for use in other parts of the vasculature, stating "Although reference is made to medium and large vessels, it should be appreciated that the systems and methods, herein disclosed, can be scaled and adapted for use within smaller vessels within the body, if desired." (*Id.*, 7:43-46.)

Notably, the '691 patent also expressly reinforces the interchangeability of aspiration catheters for different parts of the vasculature by alleging the described catheters are useful for "treating a pulmonary embolism," "intravascular procedures other than the treatment of emboli, intravascular procedures for treating ***cerebral embolism***, intravascular procedures for treating deep vein thrombosis (DVT), etc." ('691 Patent, 4:51-58 (emphasis added).)

Moreover, Aklog's system has similar components to Garrison's system, including a negative pressure source (e.g., pump or syringe) [red], an aspiration catheter [orange], a filter [blue], and a hemostasis valve (described, but not illustrated below).

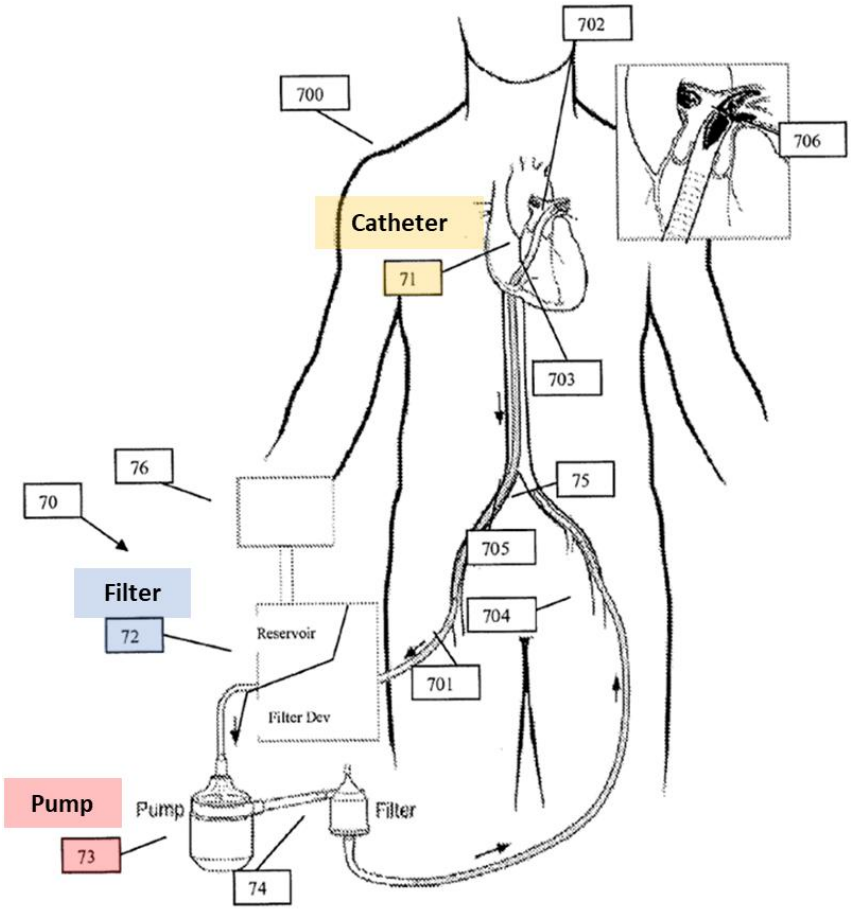
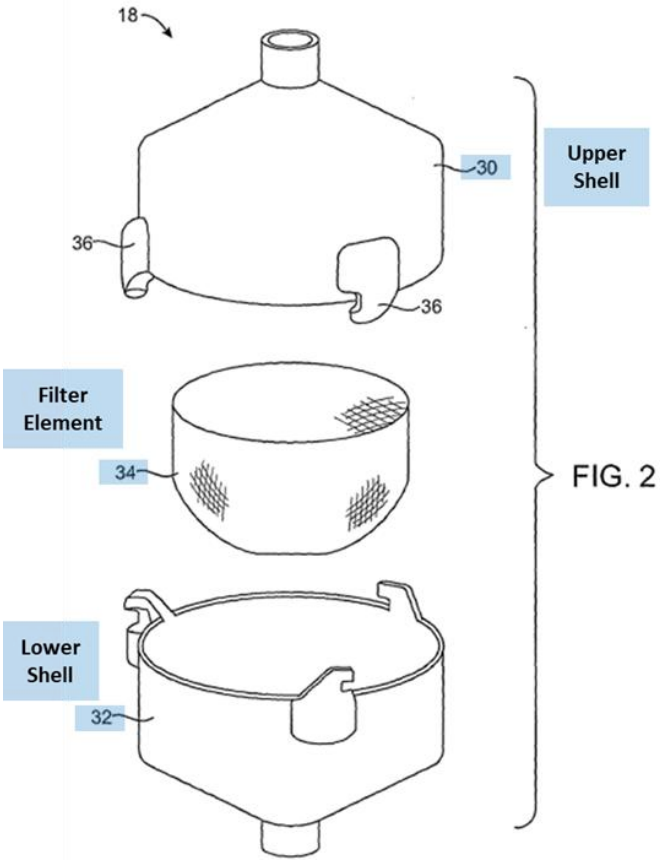


Fig. 7

(*Id.*, Fig. 7.) Aklog also discloses ways to optimize aspiration systems to treat PE and DVT, including, for example, returning the aspirated blood to the patient to reduce blood loss. (*Id.*, 1:17-24.) Garrison also describes this blood-return procedure and, thus, contains the components Aklog identifies as important for treating PE and DVT. (Ex. 1006, [0136]-[0142].) Aklog was not of record during prosecution of the ’691 patent.

Dependent claim 17 further requires that “the filter is removable from within the second chamber.” Goff discloses an aspiration system having a filter housing 18 to “remove solid materials from the aspirate.” (Goff, [0011].) 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.” (*Id.*, [0015] (emphasis added).)



(Goff, Fig. 2.) Goff further discloses that the "housing will further have conventional connectors to permit connection at an upper end to the aspiration catheter and at a lower end to the aspirate receptacle." (*Id.*) The use of conventional connectors, such as Luer-type connectors, means that the housing is removable.

A POSITA would have found it obvious to incorporate Goff's filter device into Garrison's system or modify Garrison's existing filter to make the filter and housing removable as taught in Goff. Goff's filter is used for the same purpose as Garrison's filter – filtering clots from aspirated blood. (Goff, [0001].) Goff's filter is also positioned between the aspiration catheter and first chamber/pressure source. (*Id.*, [0025].) Thus, combining Goff's filter with Garrison's system would have merely entailed the combination of known elements (filter and Garrison's aspiration system) according to known methods (conventional connectors) to yield the predictable result of filtering aspirated

blood. *KSR*, 550 U.S. at 416; (Ex. 1003, ¶115.)

Moreover, the similarities between the Goff and Garrison filters would have given a POSITA a reasonable expectation of success for incorporating Goff's filter into Garrison's aspiration system. For example, Goff discloses that its "filter element will have a pore size or screen size selected to separate solid particles at a desired particle size cutoff," the same requirement for Garrison's filter, which POSITAs would have recognized as a benefit in Garrison's system. (Goff, [0011].) Further, combining Goff's filter with Garrison's aspiration system would have merely entailed the combination of known elements (Goff's filter and Garrison's system) according to known methods (positioning the filter within a chamber in line with the system) to yield the predictable result of removing unwanted particles from the aspirated blood. *KSR*, 550 U.S. at 416; (Ex. 1003, ¶156.) A POSITA would have reasonably expected success in incorporating Goff's removable filter into Garrison because Goff's filter is used to filter blood and filters are simple, predictable devices that both Goff and Garrison acknowledge were well understood in the art.

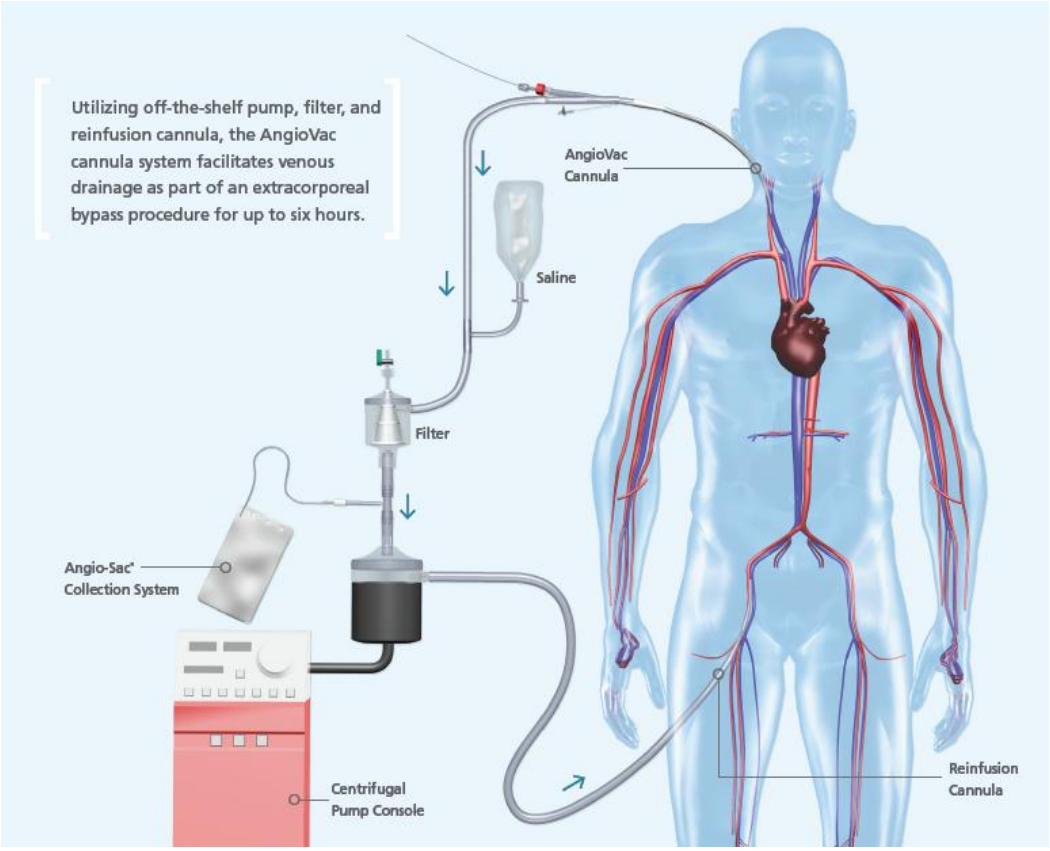
For at least the reasons stated above, claims 14-22 of the '691 Patent are obvious over Garrison, alone or in combination with Goff and/or Aklog.

B. <u>Alternative Obviousness Combinations that Render Claims 14-22 of the '691 Patent Obvious</u>

The exemplary obviousness combination discussed above relies on Garrison's disclosure of a vacuum aspiration system with accelerated response comprising "an aspiration pump," "a first chamber," "an aspiration catheter," "a second chamber," and "a user actuatable valve" as recited in claim 14 of the '691 Patent. However, the prior art is replete with examples of vacuum aspiration systems containing these elements. Thus, to the extent Inari contends Garrison does not disclose one or more of these elements, it would have been obvious to a person of ordinary skill in the art to combine other prior art

aspiration systems with Garrison to achieve the claimed invention.

For example, Aklog discloses "systems and methods for removing substantially en bloc clots, thrombi, and emboli, among others, from within heart chambers, as well as medium to large vessels." (Aklog, 1:17-24.) The Aklog system, commercially released as the AngioVac system, shown below:



(AngioVac Brochure.)

Likewise, Laub discloses "a system for removing thrombi and other unwanted material from the body of a patient, particularly from the patient's vasculature." (Laub, [0005].) An embodiment of Laub is shown in the figure below:

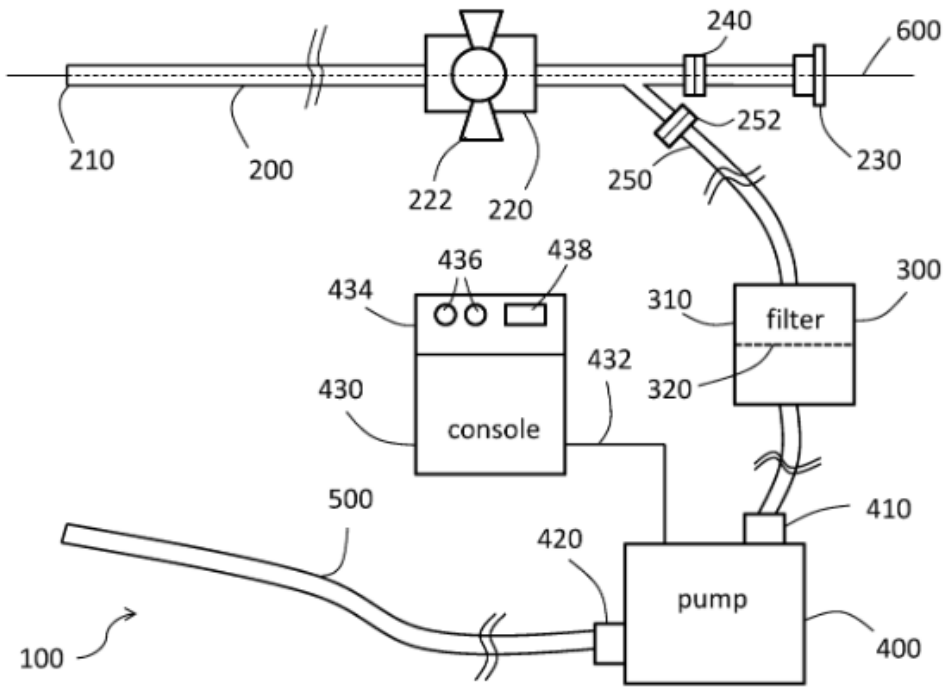
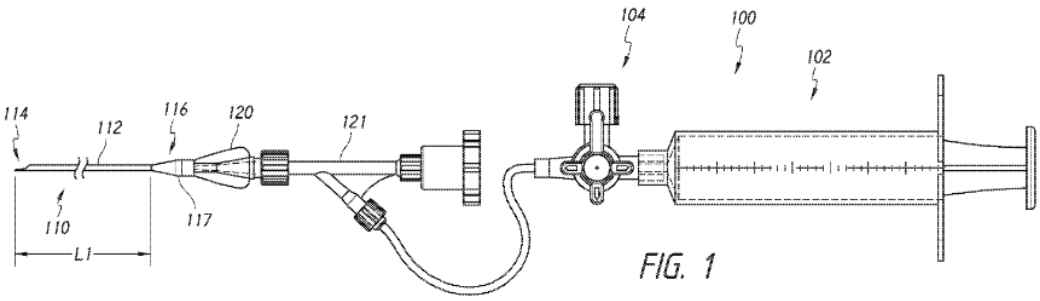


FIG. 1A

(Laub, Fig. 1A.) "In some embodiments … fluid path 250 may optionally connect with aspiration catheter 200 via a separate connector (e.g., connector 252) which may allow detachment of fluid path 250 from aspiration catheter 200." (Laub, [0039].)

In addition, Mogi discloses "an embodiment of an assistive jet aspiration catheter system 100 having a suction source 102 (which can be a Vaclok 30 cc syringe, a pump system such as a Penumbra™ pump, or otherwise), a stopcock or valve 104 to control the suction and flow of fluid through the system 100, and an assistive jet aspiration catheter 110 (also referred to herein as a assistive jet catheter and just an aspiration catheter)." (Mogi, [0154].) This embodiment is shown in the figure below:



(Mogi, Fig. 1.)

Moreover, several aspiration systems with the claimed elements were being sold well before the priority date of the ’691 Patent, including AngioDynamic’s AngioVac system (discussed above), Penumbra’s Indigo Aspiration System, Medtronic’s Export Aspiration Catheter, and even Inari’s own FlowTriever and ClotTriever systems.

In addition to Garrison, other prior art references disclose other claimed elements, such as the claimed “user actuatable valve,” and/or removable “filter” in the second chamber. For example, Mogi discloses “stopcock or valve 104 to control the suction and flow of fluid through the system 100.” (Mogi, [0154].) Aklog discloses a filter having a “permeable sheet 143 positioned with the fluid flow” that “may include a plurality of pores sufficiently sized, so as to permit fluid from the site of interest to flow therethrough, while preventing undesirable material captured from the site of interest from moving downstream ….” (Aklog, 11:33-40.) Goff discloses the use of a “filter element” to “separate solid particles at a desired particle size cutoff.” (Goff, [0011].) Laub discloses “filter 300 is configured to trap solid material received through aspiration catheter 200 from the body of the patient during use. For example, filter 300 is configured to trap thrombi, emboli, tumor tissue, debris, or other materials aspirated from the patient’s body using system 100.” (Laub, [0040].)

In view of this additional prior art, and the other prior art references identified in Appendix C, the asserted claims of the ’691 Patent would have

been obvious to a person of ordinary skill in the art.

VII. INVALIDITY OF THE ’921 PATENT

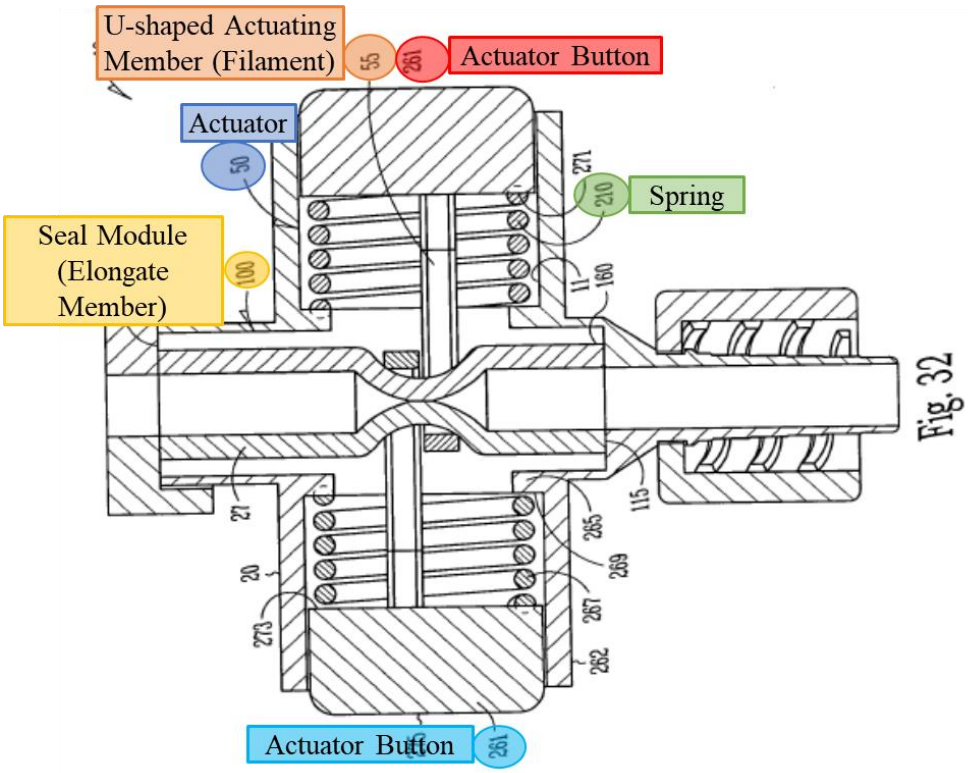
As set forth below, claims 1-3, 5-7, 9, and 10 of the ’921 Patent are invalid at least because they are anticipated under 35 U.S.C. § 102 by Schaffer, or rendered obvious under 35 U.S.C. § 103 at least by Schaffer, alone or in combination with Hartley and/or Eller. In addition to the invalidity arguments described below, an exemplary claim chart is also attached hereto as Appendix D, which identifies additional prior art references and disclosures that, when combined with other prior art references identified therein, renders the Asserted Claims of the ’921 Patent obvious.

Imperative Care may rely on cited or uncited portions of the prior art, other documents, and expert testimony to establish (1) the state of the relevant art and (2) the general knowledge of one of skill in the art. Furthermore, to the extent similar claim limitations occur in one or more claims, the disclosures below applied to a given claim should be read to apply to all similar claim limitations, as should the prior art descriptions above.

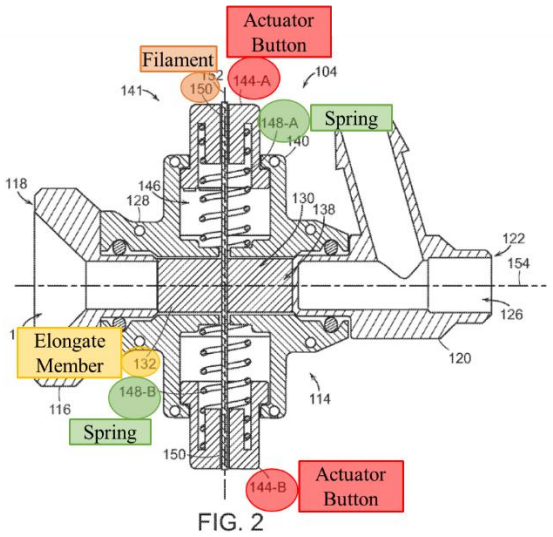
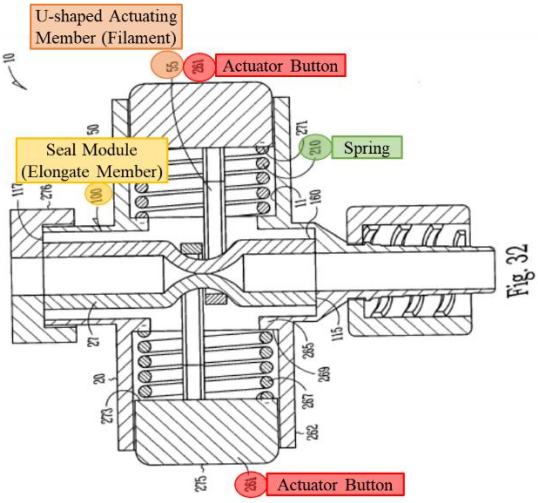
Imperative Care has also addressed the invalidity of the claims of the ’921 Patent in the preliminary injunction proceedings pending before the Court. Imperative Care incorporates those arguments as if set forth in full herein.

A. <u>Claims 1-3, 5-7, 9, and 10 of the ’921 Patent are Anticipated by Schaffer</u>

Schaffer discloses a hemostasis valve for use during minimally invasive intravascular procedures. Schaffer was ***not*** before the Examiner during prosecution of the ’921 patent. Like the claimed valves, Schaffer’s valve includes an elongate member having a lumen, an actuator (e.g., button) coupled to a filament, and a biasing system (e.g., spring):



(Schaffer, Fig. 32.) As illustrated below, Schaffer's valve has the same components, in the same arrangement, as the valve claimed in the '921 patent. Thus, Schaffer anticipates or renders obvious the challenged claims.

'921 Patent	Schaffer
	

B. Claims 1-3, 5-7, 9, and 10 of the '921 Patent are Obvious over Schaffer, alone or in combination with Hartley and/or Eller

Schaffer also renders claims 1-3, 5-7, 9, and 10 of the '921 Patent obvious in combination with the "filaments" described in Hartley or Eller. Hartley discloses a hemostasis valve having a filament that constricts the lumen of an elongate member:

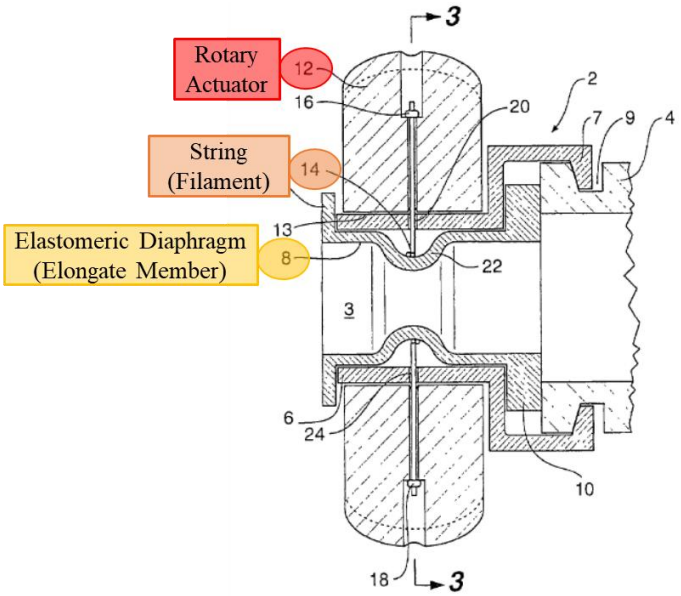
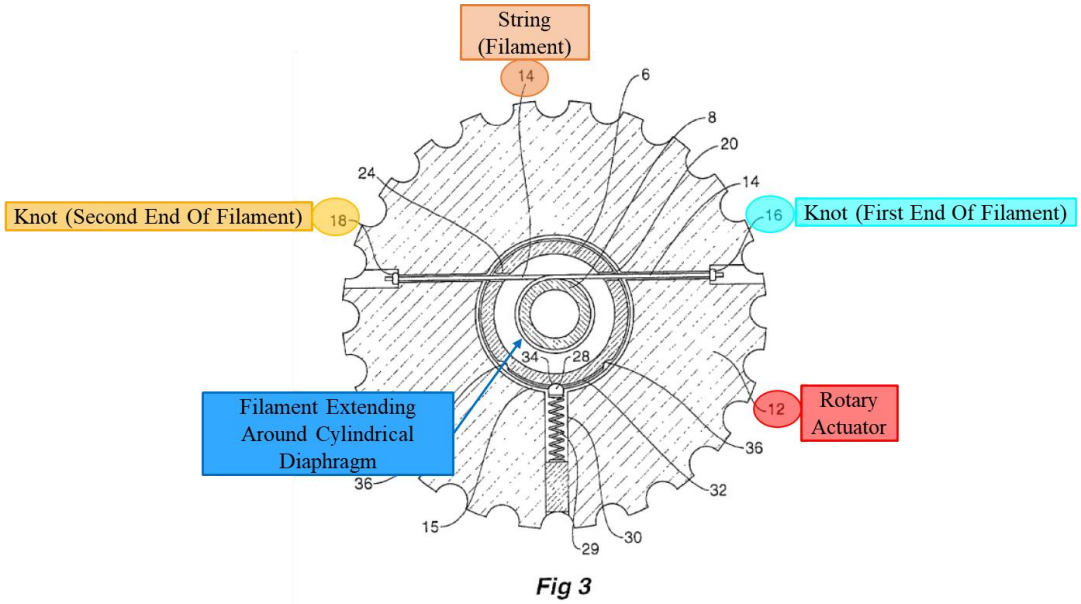


Fig 1

(Hartley, [0031], Fig. 3.) Hartley's valve also includes a "string 14 … mounted into the rotary actuator." (*Id.*) Hartley's string 14 is a "filament" because the string is made of at least one or more threads, lines, or cords.

Hartley's filament is attached to a rotary actuator that applies tension to the filament. Rotation of the actuator in one direction constricts the lumen while rotation in the opposition direction opens the lumen.



(Hartley, [0031], Fig. 3). Hartley discloses that "[r]otation of the rotary actuator 12 with respect to the cylindrical housing 6 will cause the string 14 to be pulled in both directions at once and hence the cylindrical diaphragm 8 to be constricted." (*Id*, [0031], [0034], Fig. 4.) Hartley further discloses that its valve "will close over a range of diameters of devices passed through the valve or can close completely down to be self sealing." (*Id.*, [0037].)

Eller discloses a rotatable hemostasis valve like the valve disclosed in Hartley. Eller's hemostasis valve includes a filament that constricts an elongate member to seal the valve:

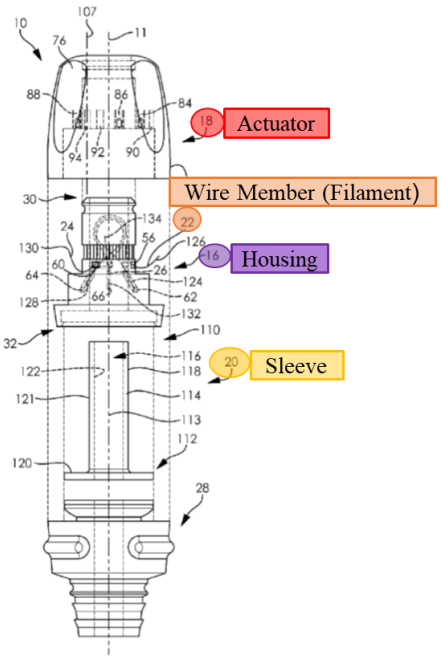


FIG. 2

(Eller, 5:1-12, Fig. 2.)

To the extent Schaffer's actuating members do not comprise "filaments," a POSITA would have found it obvious to replace Schaffer's actuating members with the filaments in Hartley or Eller for the same reasons discussed in connection with the '012 Patent, above. Thus, for at least the reasons discussed above, claims 1-3, 5-7, 9, and 10 of the '921 Patent are obvious over Schaffer, alone or in combination with Hartley and/or Eller.

In addition, claims 1-3, 5-7, 9, and 10 of the '921 Patent are obvious over Hartley, in combination with Eller. During prosecution of the '921 patent, the Examiner did not issue any office actions or make any prior-art based rejections. However, in the Notice of Allowance, the Examiner found that Hartley taught each limitation of the '921 patent's independent claims except the "biasing member." (Oct. 18, 2023, Notice of Allowance, 3.) The Examiner never addressed whether a POSITA would have found it obvious to combine a biasing mechanism with Hartley. Yet, valves combining a biasing mechanism with a rotating actuator, such as that disclosed in Eller, were well-known by September

2017.

Eller combines a torsion spring with a rotational actuator to bias the valve toward the closed position. (Eller, 19:22-30.) A POSITA would have found it obvious to combine Eller's torsion spring with Hartley's rotatable hemostasis valve. Eller was listed in an Information Disclosure Statement ("IDS") during prosecution but was not discussed or applied by the Examiner, and the Examiner never particularly address the combination of Eller's torsion spring with Hartley's valve presented herein.

VIII. INVALIDITY OF THE '291 PATENT

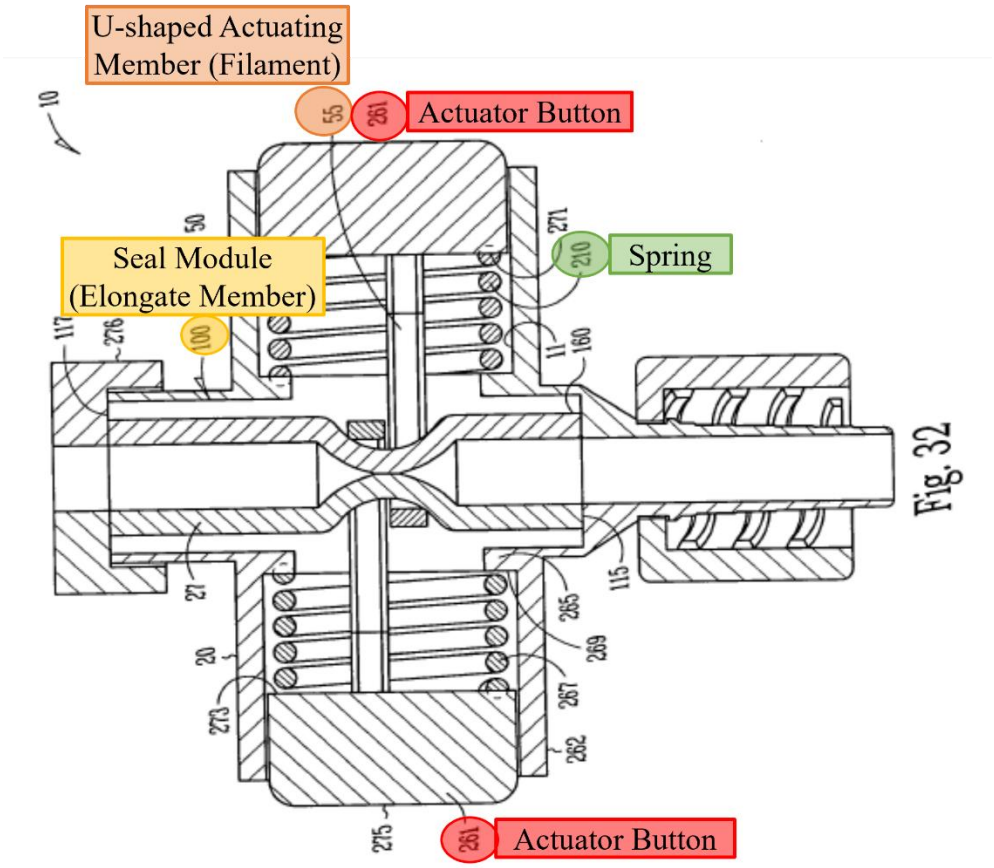
As set forth below, claims 1-8, 12-17, and 19 of the '291 Patent are invalid at least because they are anticipated under 35 U.S.C. § 102 by Schaffer or rendered obvious under 35 U.S.C. § 103 at least by Schaffer, alone or in combination with Hartley and/or Eller. In addition to the invalidity arguments described below, an exemplary claim chart is also attached hereto as Appendix E, which identifies additional prior art references and disclosures that, when combined with other prior art references identified therein, renders the Asserted Claims of the '291 Patent obvious.

Imperative Care may rely on cited or uncited portions of the prior art, other documents, and expert testimony to establish (1) the state of the relevant art and (2) the general knowledge of one of skill in the art. Furthermore, to the extent similar claim limitations occur in one or more claims, the disclosures below applied to a given claim should be read to apply to all similar claim limitations, as should the prior art descriptions above.

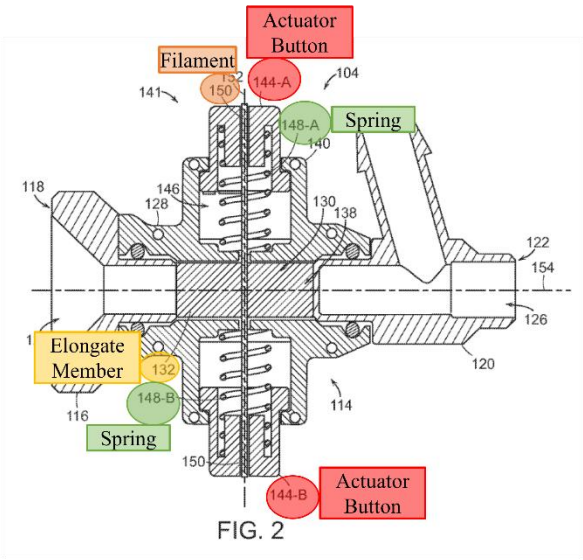
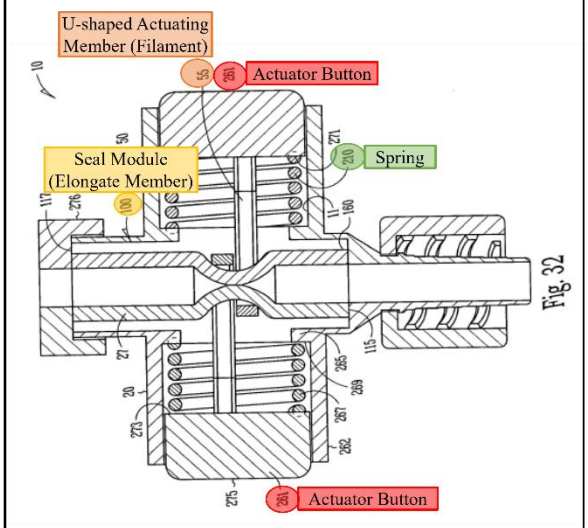
A. <u>Claims 1-8, 12-17, and 19 of the '291 Patent are Anticipated by Schaffer</u>

Schaffer discloses a hemostasis valve for use during minimally invasive intravascular procedures "that blocks the flow of gas or fluid completely and immediately with or without an instrument in place within the gas/fluid path."

(Schaffer, [0002], [0008].) Schaffer was ***not*** before the Examiner during prosecution of the ’291 patent. Like the claimed valves, Schaffer’s valve includes an elongate member that can slidably receive a second catheter, a constricting mechanism including a filament, an actuator coupled to the filament, and a biasing system (e.g., spring):



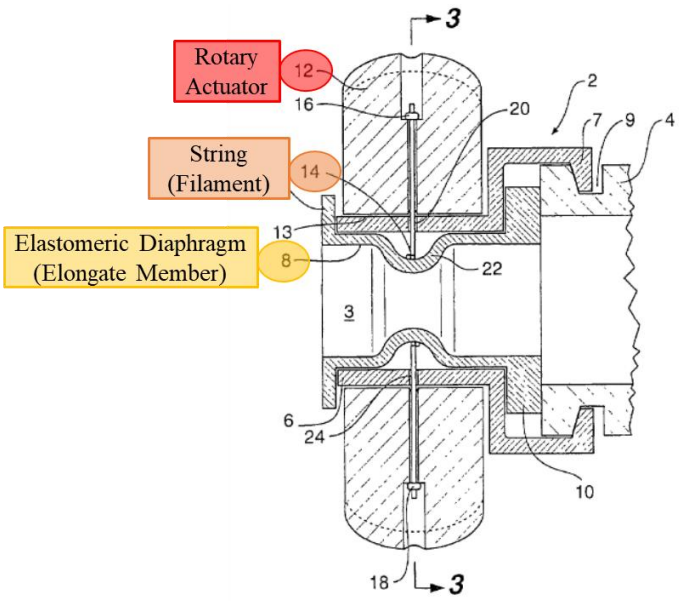
(*Id.*, Fig. 32.) As illustrated below, Schaffer’s valve has the same components, in the same arrangement, as the valve claimed in the ’291 patent:

’291 Patent	Schaffer
	

B. <u>Claims 1-8, 12-17, and 19 of the ’291 Patent are Obvious over Schaffer, alone or in combination with Hartley and/or Eller</u>

Schaffer also renders claims 1-8, 12-17, and 19 of the ’291 Patent obvious in combination with Hartley, Eller, and Garrison.

Hartley discloses a hemostasis valve having a filament that constricts the lumen of an elongate member:



(Hartley, [0031], Fig. 3.) Hartley's valve also includes a "string 14 … mounted into the rotary actuator." (*Id.*) Hartley's string 14 is a "filament" because the string is made of at least one or more threads, lines, or cords.

Hartley's filament is attached to a rotary actuator that applies tension to the filament. Rotation of the actuator in one direction constricts the lumen while rotation in the opposition direction opens the lumen.

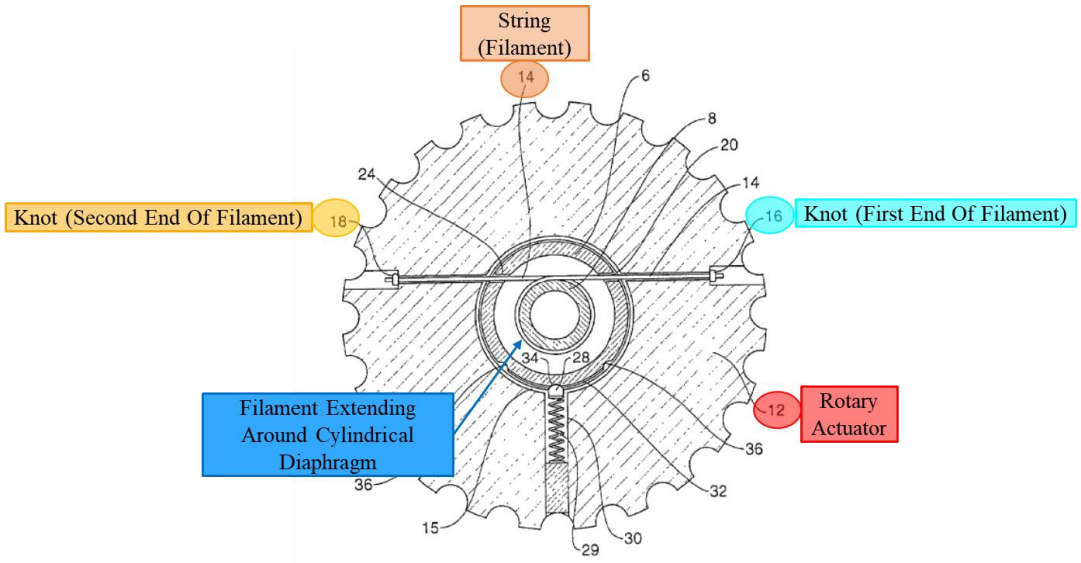


Fig 3

(Hartley, [0031], Fig. 3). Hartley discloses that "[r]otation of the rotary actuator 12 with respect to the cylindrical housing 6 will cause the string 14 to be pulled in both directions at once and hence the cylindrical diaphragm 8 to be constricted." (*Id*, [0031], [0034], Fig. 4.) Hartley further discloses that its valve "will close over a range of diameters of devices passed through the valve or can close completely down to be self sealing." (*Id.*, [0037].)

Eller discloses a rotatable hemostasis valve like the valve disclosed in Hartley. Eller's hemostasis valve includes a filament that constricts an elongate member to seal the valve:

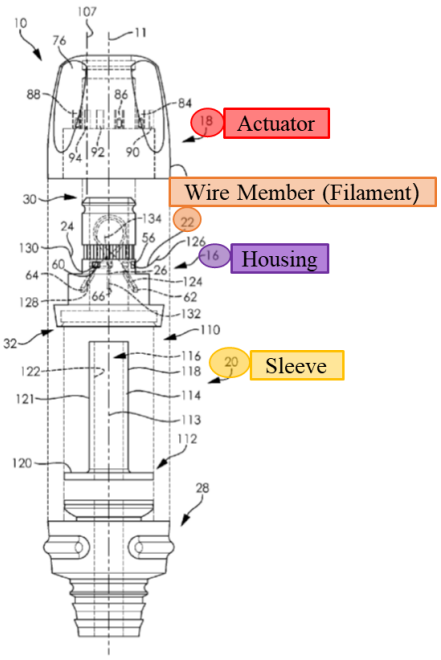


FIG. 2

(Eller, 5:1-12, Fig. 2.)

To the extent Schaffer's actuating members do not comprise "filaments," a POSITA would have found it obvious to replace Schaffer's actuating members with the filaments in Hartley or Eller for the same reasons discussed in connection with the '012 Patent and '921 Patent, above. Thus, for at least the reasons discussed above, claims 1-8, 12-17, and 19 of the '291 Patent are obvious over Schaffer, alone or in combination with Hartley and/or Eller.

In addition, claims 1-8, 12-17, and 19 of the '291 Patent are obvious over Hartley, in combination with Eller. During prosecution of the '291 patent, the Examiner did not issue any office actions or make any prior-art based rejections. However, in the Notice of Allowance, the Examiner found that Hartley taught each limitation of the '291 patent's independent claims except the "biasing member." (Aug. 9, 2023, Notice of Allowance, 2-3.) Eller was listed in an Invention Disclosure Statement ("IDS") during prosecution but was not discussed or applied by the Examiner. Thus, the Examiner never addressed whether a POSITA would have found it obvious to incorporate a biasing

mechanism, such as that disclosed in Eller, into Hartley.

Eller combines a torsion spring with a rotational actuator to bias the valve toward the closed position. (Eller, 19:22-30.) A POSITA would have found it obvious to combine Eller's torsion spring with Hartley's rotatable hemostasis valve. Eller was listed in an Information Disclosure Statement ("IDS") during prosecution but was not discussed or applied by the Examiner, and the Examiner never particularly address the combination of Eller's torsion spring with Hartley's valve.

IX. INVALIDITY OF THE '333 PATENT

As set forth below, claims 1-4, 6-12, 14-23, 25-31, and 33-38 of the '333 Patent are invalid at least because they are rendered obvious under 35 U.S.C. § 103 at least by Garrison in combination with Aklog, Goff, Laub, Schaffer, Hartley, and/or Eller. In addition to the invalidity arguments described below, an exemplary claim chart is also attached hereto as Appendix F, which identifies additional prior art references and disclosures that, when combined with other prior art references identified therein, renders the Asserted Claims of the '333 Patent obvious.

Imperative Care may rely on cited or uncited portions of the prior art, other documents, and expert testimony to establish (1) the state of the relevant art and (2) the general knowledge of one of skill in the art. Furthermore, to the extent similar claim limitations occur in one or more claims, the disclosures below applied to a given claim should be read to apply to all similar claim limitations, as should the prior art descriptions above.

A. <u>Claims 1-4, 6-12, 14-23, 25-31, and 33-38 of the '333 Patent are Obvious over Garrison in combination with Aklog, Goff, Laub, Schaffer, Hartley and/or Eller</u>

Claims 1-4, 6-12, 14-23, 25-31, and 33-38 of the '333 Patent are directed to methods of treating either pulmonary embolisms (independent claim 1 and

dependent claims 2-4, 6-12, and 14-19) or deep vein thrombosis (independent claim 20 and dependent claims 21-23, 25-31, and 33-38. The claimed methods recite positioning "an aspiration catheter" proximal to a treatment site in fluid communication with a clot canister and an aspiration source. ('333 Patent, Claims 1, 20.) The claimed methods recite generating vacuum pressure "within the clot canister via the aspiration source" while using a valve to inhibit fluid flow through the aspiration catheter. (*Id.*) The claimed methods then recite opening the valve to apply vacuum pressure to the lumen of the catheter and thereby aspirate clot from the treatment site. (*Id.*) The asserted dependent claims further specify: the size of the aspiration catheter (claims 2, 3, 18, 21, 22, 37); the location of the treatment site (claims 4, 23); additional method steps involving the clot canister and filter (claims 6-8, 25-27); the structure of the valve (claims 9, 28); the use of a hemostasis valve (claims 10-12, 29-31); the use of additional treatment devices (claims 14, 33); the structure and operation of the aspiration source and/or clot canister (claims 15-17, 19, 34-36, 38). Except for references to treating pulmonary embolisms or deep vein thromboses, independent claim 1 and its dependent claims are identical to independent claim 20 and its corresponding dependent claims.

Garrison, in combination with Aklog, Goff, Laub, Schaffer, Hartley, and/or Eller render claims 1-4, 6-12, 14-23, 25-31, and 33-38 of the '333 Patent obvious. Garrison discloses an aspiration system for removing unwanted material from a patient's vasculature. As illustrated below, Garrison's aspiration system includes the same components required to practice the methods recited in claims 1 and 20 (and corresponding dependent claims) of the '333 patent: an aspiration source (e.g., pump or syringe) [red], an aspiration catheter [orange], a clot cannister with a filter [blue], hemostasis valves [yellow], and a user-actuatable valve [purple] that is closed while vacuum pressure is generated by the aspiration source and opened after the vacuum

pressure is generated to cause rapid aspiration through the catheter.

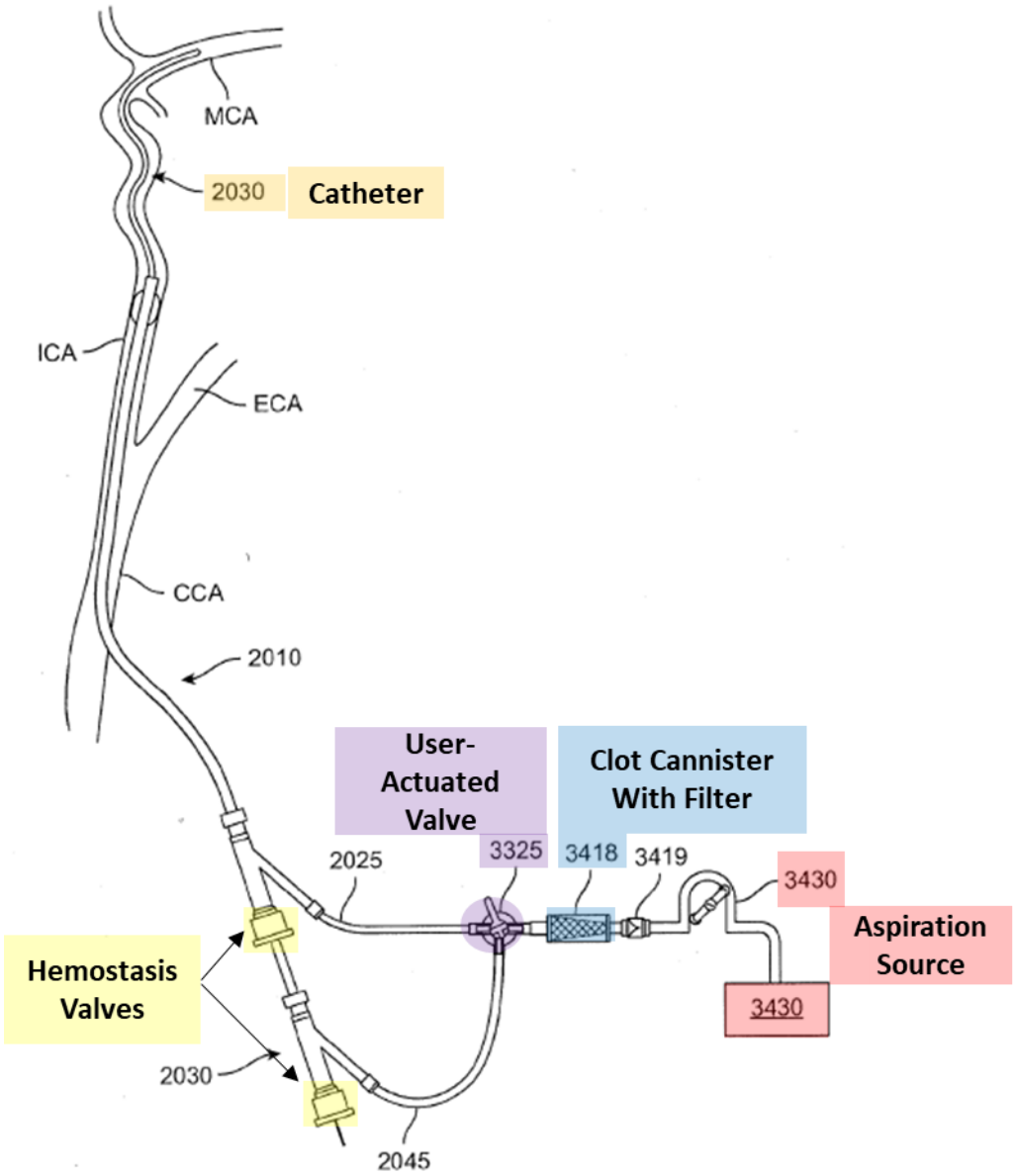


FIG. 34

(Garrison, Fig. 34.) Garrison explains that opening the valve after generating the vacuum pressure enables "the maximum level of aspiration in a ***rapid fashion*** with one user, something that is not currently possible with existing technologies." (*Id.*, [0134] (emphasis added).)

As noted above, the claims of the '333 patent are directed to methods of treating a PE or DVT. Garrison discloses using its aspiration system to remove

cerebral occlusions but does not specifically mention PE or DVT. However, Garrison's catheter is configured to be positioned proximate these types of clots because it has the correct size and flexibility. Additionally, a POSITA would have found it obvious to use and/or adapt Garrison's cerebral aspiration system to aspirate PE or DVT. Each procedure involves the identical process of advancing a catheter through an artery or vein to reach an embolism and activating a vacuum through the catheter to aspirate the emboli. Unsurprisingly, catheter designers knew well before 2018 how to size catheters to fit the desired vessel.

The use and/or adaptation of Garrison's system to treat PE and DVT is particularly obvious in view of Aklog and Laub. Aklog discloses an aspiration system for removing undesirable materials, including PE and DVT, from blood vessels. (Aklog, 2:7-32, 7:27-42.) Aklog also acknowledges that a POSITA could simply adapt aspiration catheters for use in other parts of the vasculature, stating: "Although reference is made to medium and large vessels, it should be appreciated that the systems and methods, herein disclosed, can be scaled and adapted for use within smaller vessels within the body, if desired." (*Id.*, 7:43-46.)

Moreover, Aklog's system has similar components to Garrison's system, including an aspiration source (e.g., pump or syringe) [red], an aspiration catheter [orange], a clot cannister with a filter [blue], and a hemostasis valve (described, but not illustrated below).

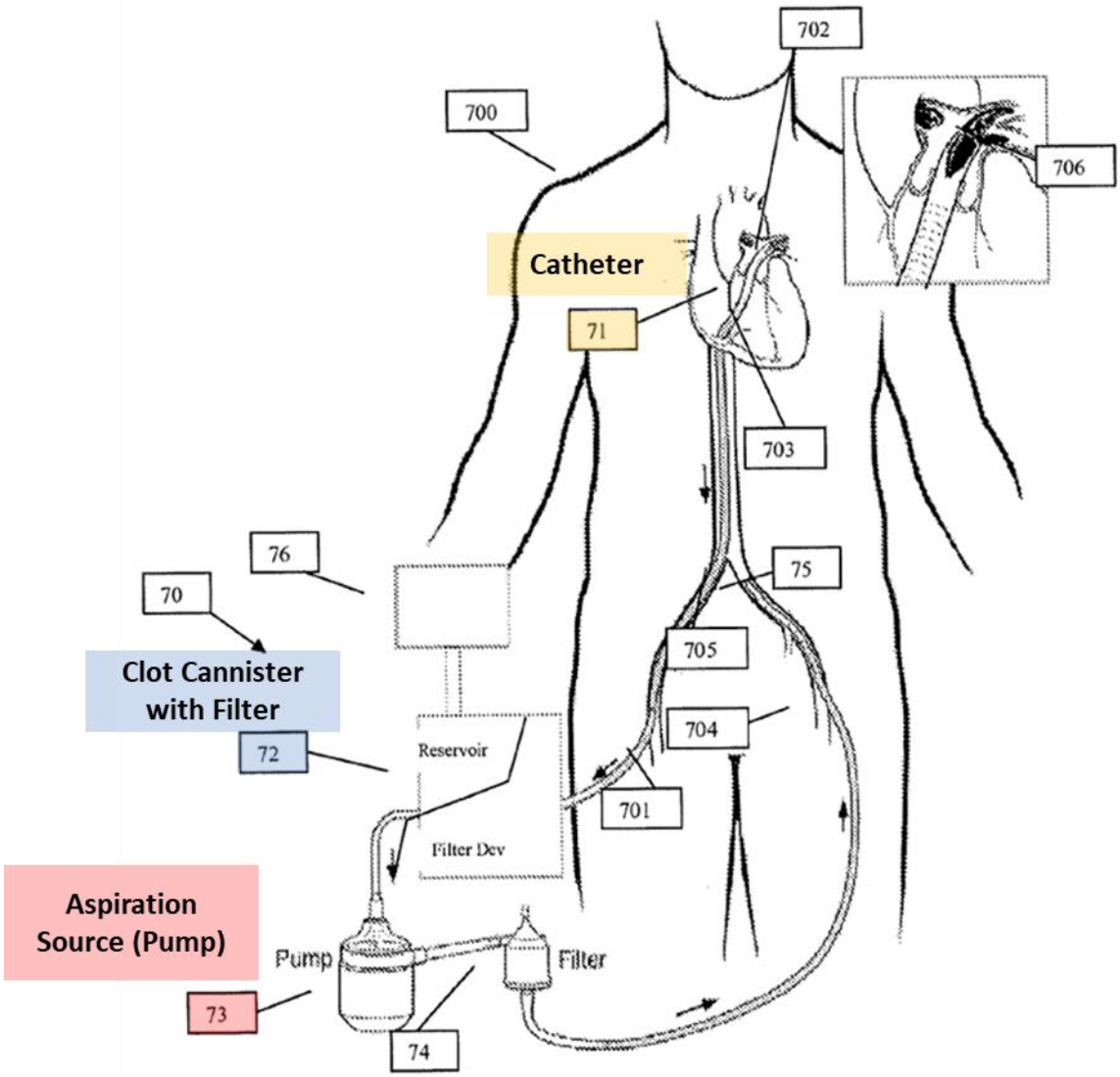


Fig. 7

(*Id.*, Fig. 7.) Aklog also discloses ways to optimize aspiration systems to treat PE and DVT, including, for example, returning the aspirated blood to the patient to reduce blood loss. (*Id.*, 1:17-24.) Garrison also describes this blood-return procedure and, thus, contains the components Aklog identifies as important for treating PE and DVT. (Aklog, [0136]-[0142].)

Similarly, Laub discloses an aspiration system for removing "unwanted material such as emboli, thrombi, tumors, or debris" from a patient's vasculature. (Laub, [0002].) Laub discloses that "[s]ystems according to

certain embodiments of the present invention may be used, for example, to remove clots from patients suffering from or at risk of ***pulmonary embolisms***." (*Id*., [0005] (emphasis added).)

Like Garrison, Laub's clot treatment system includes an aspiration catheter connected to a pump (i.e., pressure source):

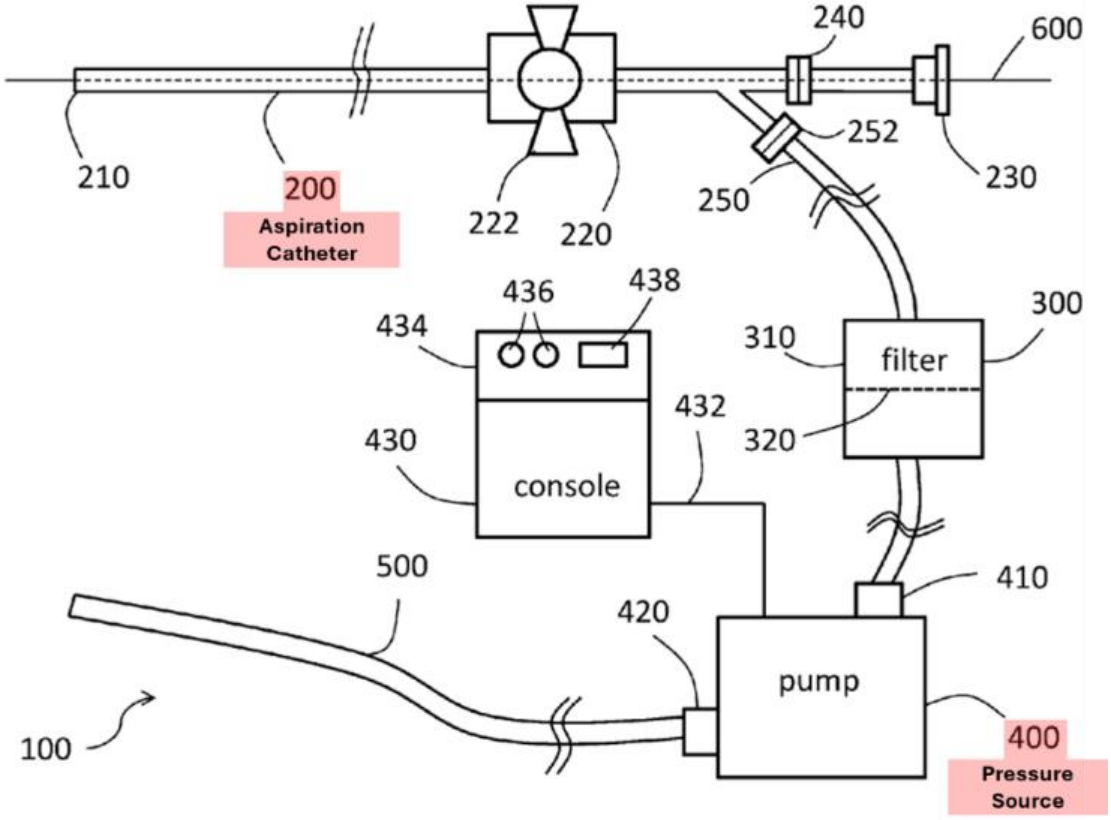


FIG. 1A

(*Id.* at ¶ [0024], Fig. 1A.) Laub also discloses catheters having a diameter ranging from 5 French to 20 French and Laub specifically states, "[i]n some embodiments, aspiration catheter 200 has a French ***size of at least 16 Fr.***" (*Id.* at ¶ [0028] (emphasis added).) Thus, Garrison, in view of Laub, also renders obvious claims 2, 3, 21, and 22 of the ''333 Patent, which recite aspiration catheters having a size of "16 French or greater" or "20 French of greater."

A POSITA would have found it obvious to adapt Garrison's aspiration system to use catheters of 16 French, 20 French, or greater to treat PE or DVT, as claimed in the '333 Patent. First, the '333 patent confirms the

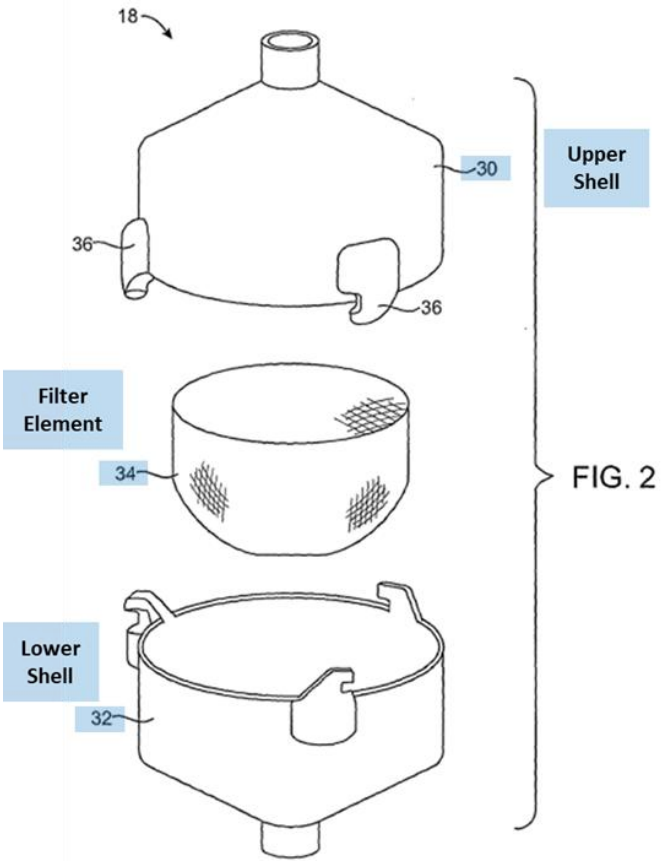
interchangeability of aspiration catheters for different parts of the vasculature by alleging the described catheters are useful for "treating a pulmonary embolism," "intravascular procedures other than the treatment of emboli, intravascular procedures for treating ***cerebral embolism***, intravascular procedures for treating deep vein thrombosis (DVT), etc." ('333 Patent, 4:51-61 (emphasis added).) Thus, POSITAs working on treating clots in one part of the body naturally relied upon innovations for treating clots in other parts of the body.

Garrison also suggests adapting its aspiration systems with components for use in other parts of the vasculature. (Garrison, [0070], [0144] (incorporating by reference patents addressing other parts of the vasculature).) Further, Garrison is not alone in presuming that a POSITA would have found it obvious to adapt aspiration catheters designed for one part of the vasculature for another. Other prior art patents disclose aspiration systems intended for use across all portions of the vasculature. For example, Brady describes catheters capable of removing clots "from the cerebral arteries" and the "pulmonary arteries." (Brady, [0001].) For at least these reasons, a POSITA would have found it obvious to adapt Garrison's aspiration system to use catheters having a size of 16 French or greater to treat PE based on Aklog, Laub, and the knowledge of a POSITA.

Dependent Claims 6-7 and 25-26 of the '333 patent require "removing the filter from the clot cannister." Garrison and Aklog both disclose clot cannisters that contain a filter. However, the references do not expressly disclose whether the filters are removable. But aspiration systems having removable filters were well known by August 2018 simply because the clot may plug the filter or exceed the capacity of the filter chamber. Such clogging would bring an abrupt halt to this time sensitive procedure if the chamber could not be opened to empty the captured clot.

Goff discloses an aspiration system having a filter housing 18 to "remove

solid materials from the aspirate." (Goff, [0011].) 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." (*Id.*, [0015] (emphasis added).)

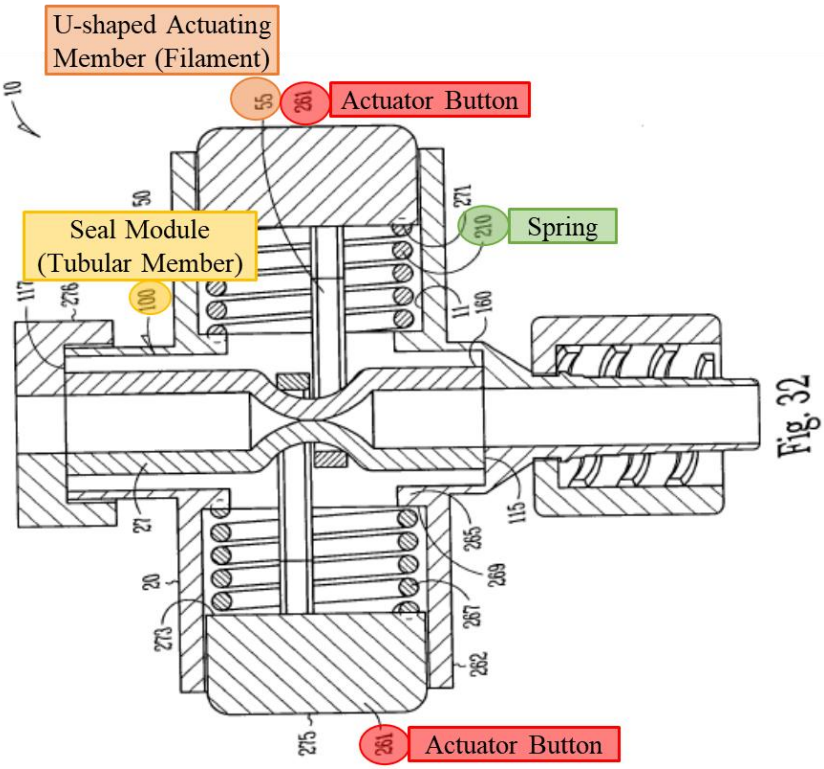


Goff further discloses that the "housing will further have conventional connectors to permit connection at an upper end to the aspiration catheter and at a lower end to the aspirate receptacle." (*Id.*) The use of conventional connectors, such as Luer-type connectors, means that the housing is removable. As shown herein, a POSITA would have found it obvious to incorporate Goff's filter device into Garrison's system or modify Garrison's existing filter to make the filter and housing removable as taught in Goff.

Dependent Claims 11-12 and 30-31 of the '333 patent require opening and closing the hemostasis valve by decreasing and increasing "tension on a filament of the hemostasis valve." Garrison discloses several different

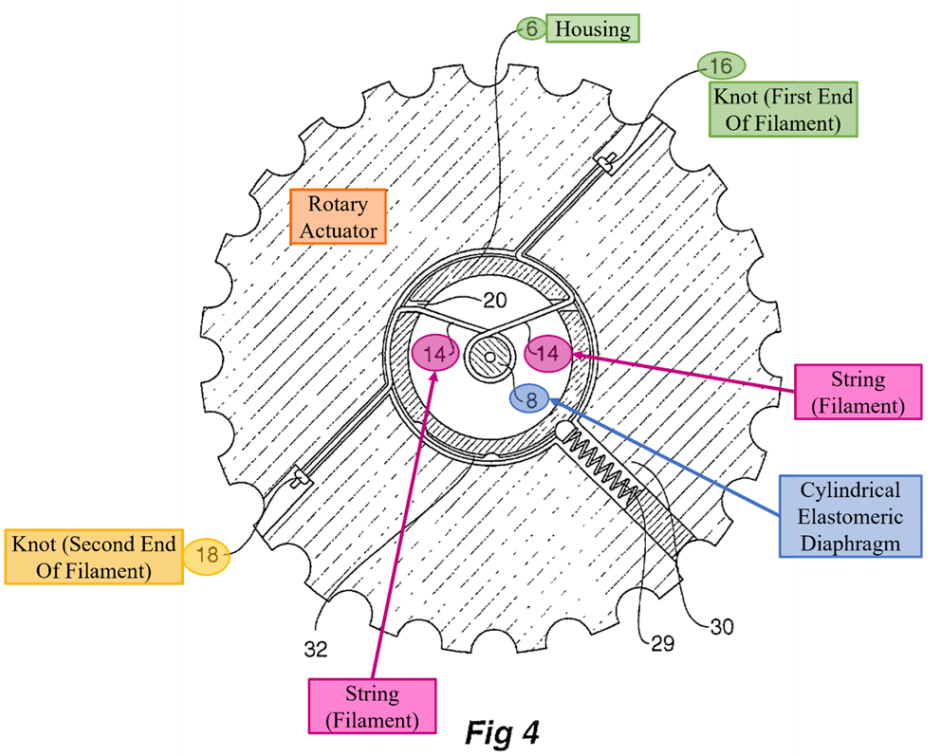
hemostasis valves that can be interchangeably used with its aspiration system including, for example, an "adjustable-opening valve" or a "rotating hemostasis valve." Garrison presumes a person of ordinary skill in the art would have been familiar with the available hemostasis valves and, therefore, does not describe their structures. However, other prior art references do.

For example, Schaffer discloses an adjustable-opening hemostasis valve for use during minimally invasive intravascular procedures. (Schaffer, [0002], [0008].) Schaffer's valve includes a tubular member that can slidably receive a second catheter, a constricting mechanism including a filament, an actuator coupled to the filament, and a biasing system (e.g., spring):



(*Id.*, Fig. 32.)

Hartley discloses the structure for a rotating hemostasis valve that includes a filament extending around a tubular member to restrict the member and close the valve:



(Hartley, Fig. 4.)

Eller discloses a rotatable hemostasis valve like the valve disclosed in Hartley. Eller's hemostasis valve includes a filament that constricts an elongate member to seal the valve:

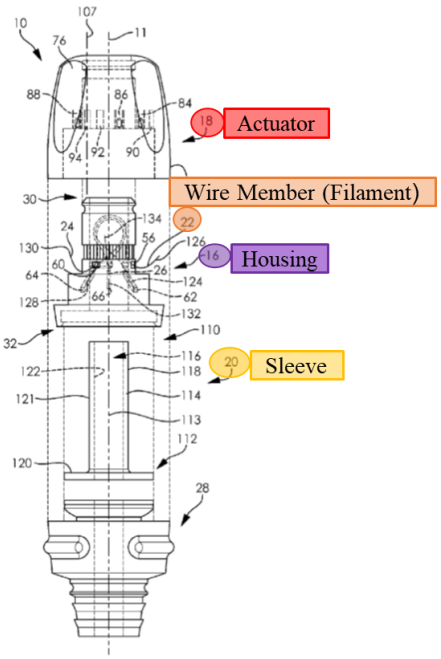


FIG. 2

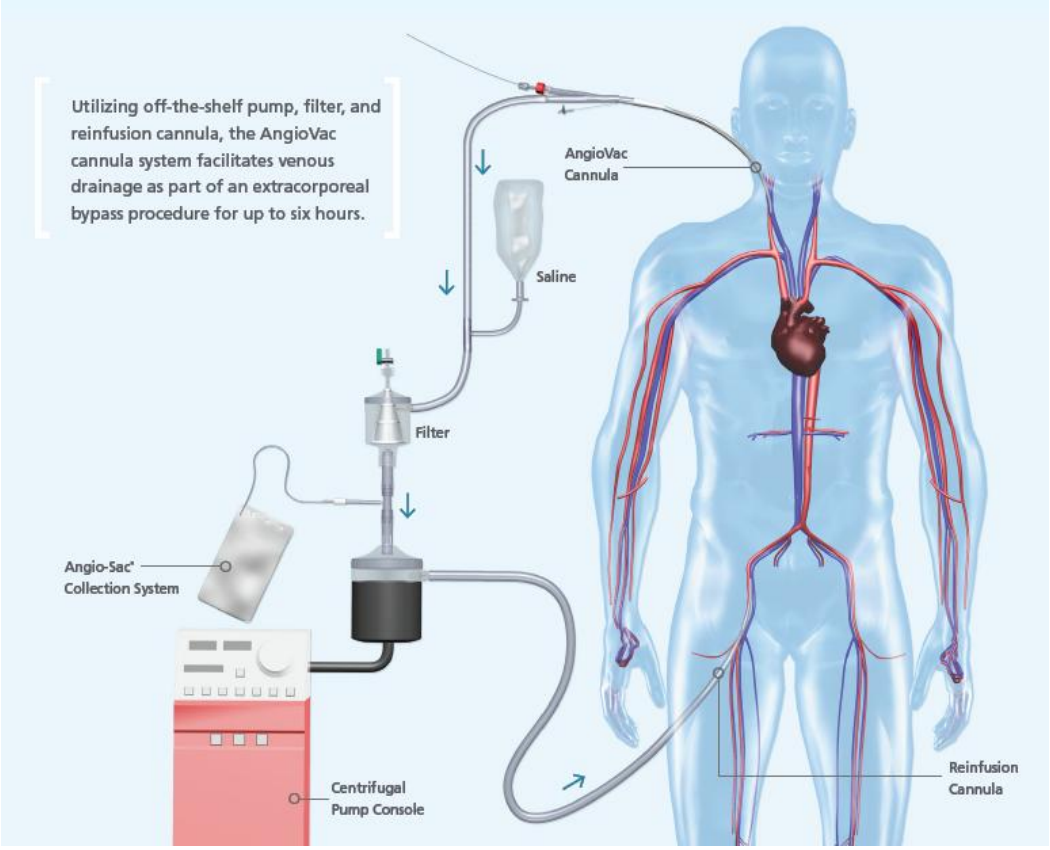
(Eller, 5:1-12, Fig. 2.) To the extent Schaffer's actuating members do not comprise "filaments," a POSITA would have found it obvious to replace Schaffer's actuating members with the filaments in Hartley or Eller for the same reasons discussed in connection with the '012, '921, and '291 Patents, above. Likewise, a POSITA would have found it obvious to include a hemostasis valve, such as that disclosed in Schaffer, Hartley, and/or Eller for the same reasons discussed in connection with the '005 Patent above.

Thus, for at least the reasons discussed above, claims 1-4, 6-12, 14-23, 25-31, and 33-38 of the '333 Patent are obvious over Garrison, in combination with Aklog, Goff, Laub, Schaffer, Hartley, and/or Eller.

B. <u>Alternative Obviousness Combinations that Render Claims 1-4, 6-12, 14-23, 25-31, and 33-38 of the '333 Patent Obvious</u>

The exemplary obviousness combination discussed above relies on Garrison's disclosure of a method of aspirating clot material from a patient, comprising "advancing an aspiration catheter" that is "fluidly coupled to a clot canister" and "an aspiration source," "generating vacuum pressure within the clot canister" using "a valve" between the aspiration catheter and clot canister," and "moving the valve" to apply the vacuum pressure to the aspiration catheter," as recited in claim 1 of the '333 Patent. However, the prior art is replete with examples of vacuum aspiration systems with similar method steps and containing similar elements. Thus, to the extent Inari contends Garrison does not disclose one or more of these steps or elements, it would have been obvious to a person of ordinary skill in the art to combine other prior art aspiration systems with Garrison to achieve the claimed invention.

For example, Aklog discloses "systems and methods for removing substantially en bloc clots, thrombi, and emboli, among others, from within heart chambers, as well as medium to large vessels." (Aklog, 1:17-24.) The Aklog system, commercially released as the AngioVac system, shown below:



(AngioVac Brochure.)

Likewise, Laub discloses "a system for removing thrombi and other unwanted material from the body of a patient, particularly from the patient's vasculature." (Laub, [0005].) An embodiment of Laub is shown in the figure below:

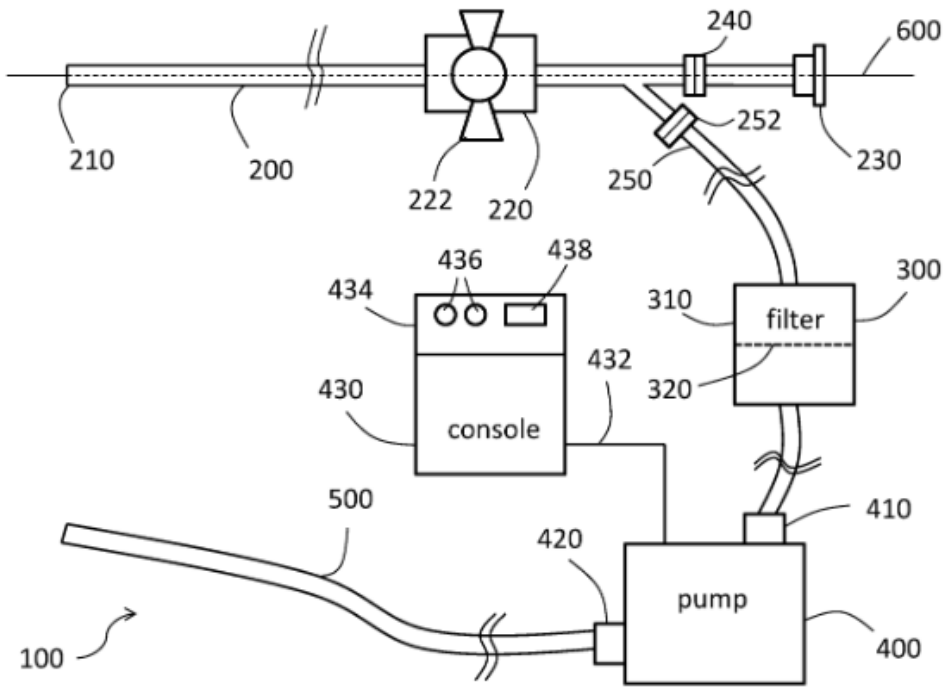
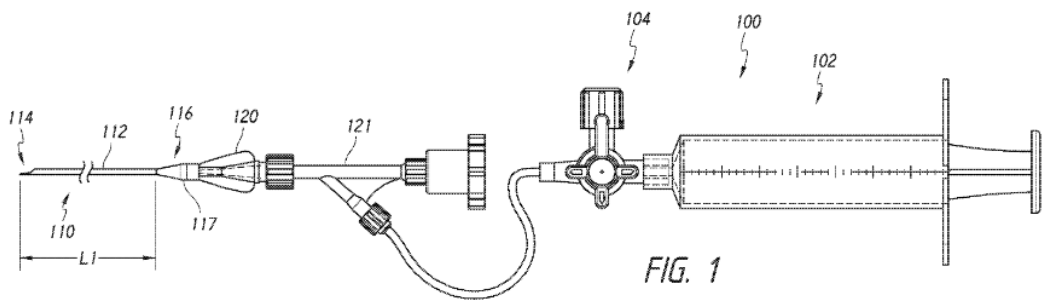


FIG. 1A

(Laub, Fig. 1A.) "In some embodiments … fluid path 250 may optionally connect with aspiration catheter 200 via a separate connector (e.g., connector 252) which may allow detachment of fluid path 250 from aspiration catheter 200." (Laub, [0039].)

In addition, Mogi discloses "an embodiment of an assistive jet aspiration catheter system 100 having a suction source 102 (which can be a Vaclok 30 cc syringe, a pump system such as a Penumbra™ pump, or otherwise), a stopcock or valve 104 to control the suction and flow of fluid through the system 100, and an assistive jet aspiration catheter 110 (also referred to herein as a assistive jet catheter and just an aspiration catheter)." (Mogi, [0154].) This embodiment is shown in the figure below:



(Mogi, Fig. 1.)

Moreover, several aspiration systems were being sold well before the priority date of the ’333 Patent, including AngioDynamic’s AngioVac system (discussed above), Penumbra’s Indigo Aspiration System, Medtronic’s Export Aspiration Catheter, and even Inari’s own FlowTriever and ClotTriever systems.

In addition to Garrison, other prior art references disclose other claimed elements, such as the “clot canister” with a “filter” fluidly coupled to the “aspiration catheter.” Aklog discloses a filter having a “permeable sheet 143 positioned with the fluid flow” that “may include a plurality of pores sufficiently sized, so as to permit fluid from the site of interest to flow therethrough, while preventing undesirable material captured from the site of interest from moving downstream ….” (Aklog, 11:33-40.) Goff discloses the use of a “filter element” to “separate solid particles at a desired particle size cutoff.” (Goff, [0011].) Laub discloses “filter 300 is configured to trap solid material received through aspiration catheter 200 from the body of the patient during use. For example, filter 300 is configured to trap thrombi, emboli, tumor tissue, debris, or other materials aspirated from the patient’s body using system 100.” (Laub, [0040].)

Other references disclose the claimed “valve” that can be closed to generate a vacuum and opened to release the vacuum. For example, Mogi discloses “stopcock or valve 104 to control the suction and flow of fluid through

the system 100." (Mogi, [0154].) Teigen discloses the use of valves to create a "pressure differential between the vacuum source and the catheter," which "results in a pressure pulse." (Tiegen, 18:34-37.) Michelson discloses: "The AngioVac suction is initiated by the perfusionist removing the clamp from the inflow and venous line and opening the clamp to the bubble trap. This clamp placement provides a closed circuit allowing the centrifugal pump to provide the necessary suction for thrombus removal without the use of additional vacuum." (Michelson, 300.)

In addition to Garrison, other prior art references disclose the use of valves, such as hemostasis valves, to facilitate the insertion of treatment devices into the system while minimizing blood loss. For example, Laub discloses "working port 230 is configured to provide a fluid tight seal around stylet 700 or other device inserted through working port 230, for example, so as to prevent leakage of blood out of working port 230 during use." (Laub, [0036].) For the same reasons discussed above in connection with Garrison, in view of these disclosures, a person of ordinary skill in the art would have been motivated to combine the above-referenced aspiration systems with the hemostasis valves of Schaffer, Hartley, and/or Eller to achieve the claimed invention.

In view of this additional prior art, and the other prior art references identified in Appendix F, the asserted claims of the '333 Patent would have been obvious to a person of ordinary skill in the art.

X. INVALIDITY OF THE '910 PATENT

As set forth below, claims 1-8, 11-5, and 18-20 of the '910 Patent are invalid at least because they are rendered obvious under 35 U.S.C. § 103 at least by Garrison in combination with Aklog, Laub, Schaffer, Hartley, and/or Eller. In addition to the invalidity arguments described below, an exemplary claim chart is also attached hereto as Appendix G, which identifies additional prior art references and disclosures that, when combined with other prior art references

identified therein, renders the Asserted Claims of the ’910 Patent obvious.

Imperative Care may rely on cited or uncited portions of the prior art, other documents, and expert testimony to establish (1) the state of the relevant art and (2) the general knowledge of one of skill in the art. Furthermore, to the extent similar claim limitations occur in one or more claims, the disclosures below applied to a given claim should be read to apply to all similar claim limitations, as should the prior art descriptions above.

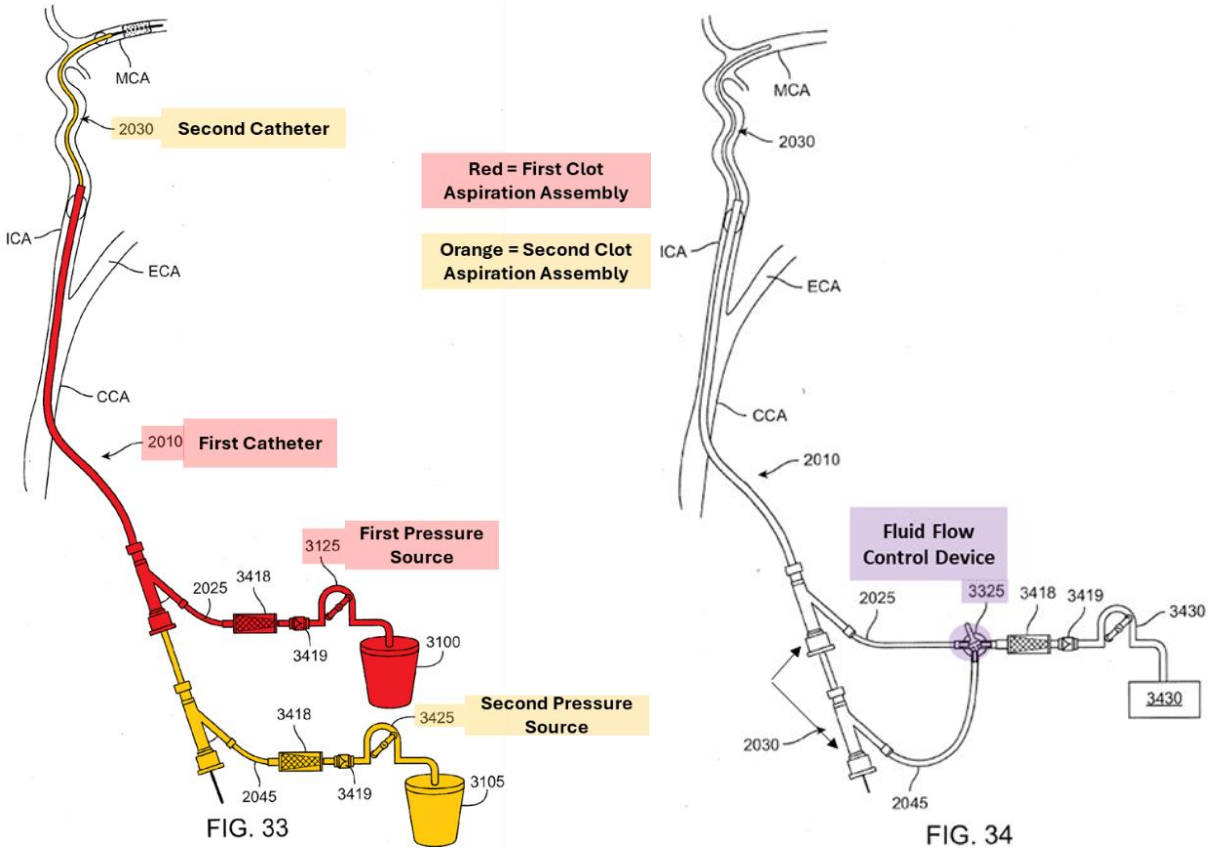
Imperative Care has also addressed the invalidity of the claims of the ’910 Patent in the preliminary injunction proceedings pending before the Court. Imperative Care incorporates those arguments as if set forth in full herein.

A. <u>Claims 1-8, 11-15, and 18-20 of the ’910 Patent are Obvious over Garrison in combination with Aklog, Laub, Schaffer, Hartley, and/or Eller</u>

Independent claims 1 and 11 of the ’910 Patent are directed to the embodiment described in connection with Figure 11 shown above, that is, a system comprising a first aspiration assembly and a second aspiration assembly that can inserted and advanced through the first aspiration assembly. The claimed systems are also directed to “treating clot material comprising a pulmonary embolism in a vasculature of a patient.” (’910 Patent, Claims 1, 11.) The asserted dependent claims are directed to: specific sizes of the first and second catheters (Claims 2, 3, 12, 18); the configuration of the pressure sources (Claims 4, 5, 13, 14, 19, 20); and a hemostasis valve (Claims 6, 7, 16, 17). Garrison, in combination with Aklog, Laub, Schaffer, Hartley, and/or Eller renders claims 1-8, 11-15, and 18-20 of the ’910 Patent obvious.

Garrison describes aspiration systems for removing clots from patients. (Garrison, [0007].) Garrison provides many examples of these clot treatment systems, including systems having (1) a first clot aspiration assembly with a first catheter and first pressure source, and (2) a second clot aspiration assembly

with a second catheter and a second pressure source:



(*Id.* at Figs. 33-34.) As shown in Figure 33 above, Garrison discloses embodiments wherein a second aspiration assembly [yellow, above] is advanced through a second aspiration assembly [red, above] to a treatment site. In related examples, Garrison also discloses using a valve (i.e., fluid control device) to control when the pressure source is connected to the catheter(s). (*Id.* at [0132].) A POSITA would have found it obvious to use a fluid flow control device with each of the clot aspiration assemblies shown in Figure 33.

Garrison also describes the purpose of the fluid flow control device is to enable a physician to close the fluid flow control device to generate vacuum pressure in the portions of the system between the pressure source and the valve prior to treating the patient. (*Id.*, [0134].) Garrison explains that the physician can open the valve to release the built-up pressure. (*Id.*) Garrison explains this method "would enable the maximum level of aspiration in a rapid fashion with

one user …." (*Id.*)

As noted above, the claims of the '910 patent are directed to systems of treating a ***pulmonary embolism***. Garrison discloses using its aspiration system to remove cerebral occlusions, but does not specifically mention pulmonary embolism. However, Garrison's catheter is configured to be positioned proximate these types of clots because it has the correct size and flexibility. Additionally, a POSITA would have found it obvious to use and/or adapt Garrison's cerebral aspiration system to aspirate pulmonary embolisms. Each procedure involves the identical process of advancing a catheter through an artery or vein to reach an embolism and activating a vacuum through the catheter to aspirate the emboli.

The use and/or adaptation of Garrison's system to treat pulmonary embolism is particularly obvious in view of Aklog and Laub. Aklog discloses an aspiration system for removing undesirable materials, including pulmonary embolism, from blood vessels. (Aklog, 2:7-32, 7:27-42.) Aklog also acknowledges that a POSITA could simply adapt aspiration catheters for use in other parts of the vasculature, stating: "Although reference is made to medium and large vessels, it should be appreciated that the systems and methods, herein disclosed, can be scaled and adapted for use within smaller vessels within the body, if desired." (*Id.*, 7:43-46.)

Moreover, Aklog's system has similar components to Garrison's system, including an aspiration source (e.g., pump or syringe) [red], an aspiration catheter [orange], and a hemostasis valve (described, but not illustrated below).

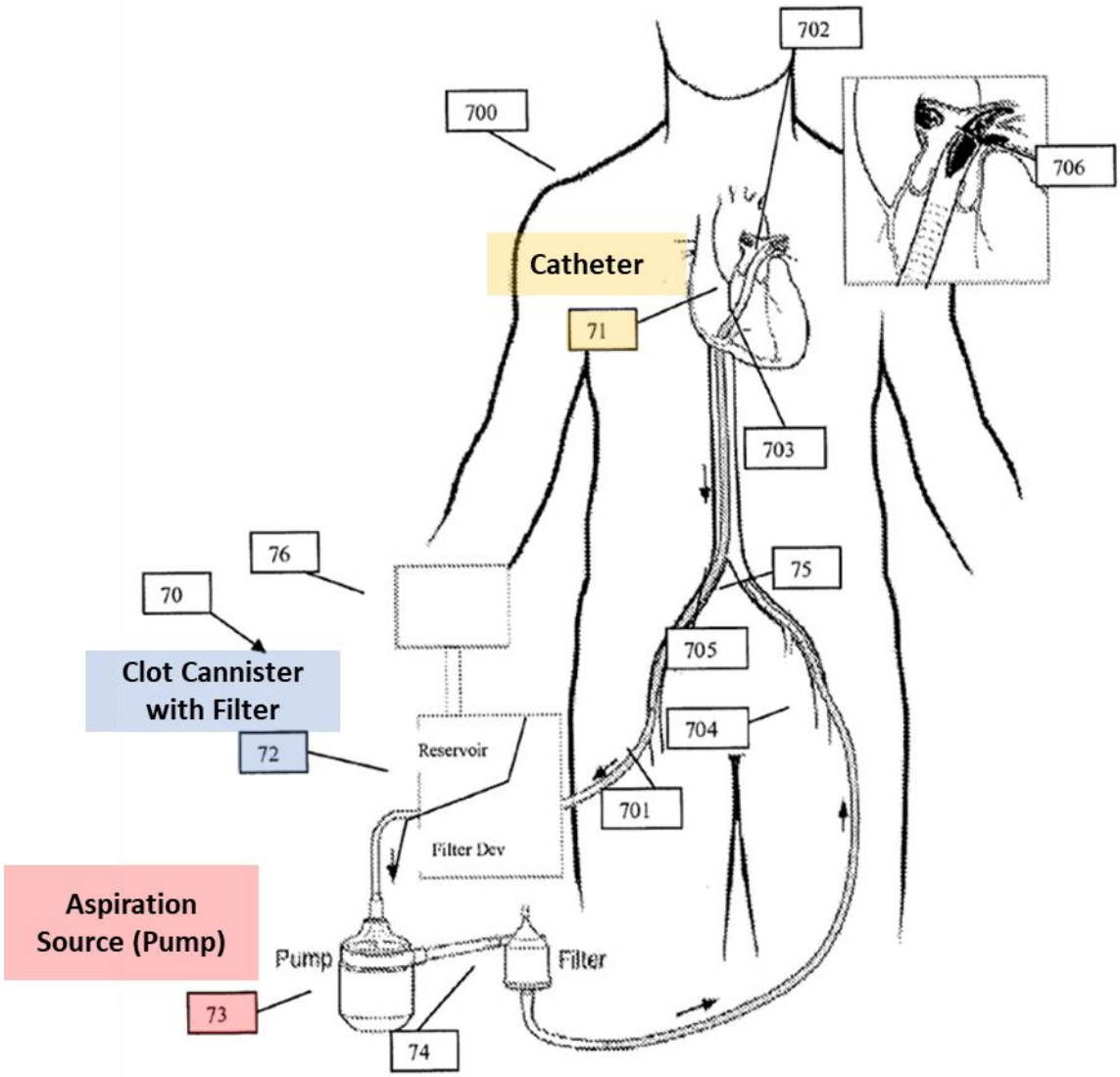


Fig. 7

(*Id.*, Fig. 7.) Aklog also discloses ways to optimize aspiration systems to treat pulmonary embolism, including, for example, returning the aspirated blood to the patient to reduce blood loss. (*Id.*, 1:17-24.) Garrison also describes this blood-return procedure and, thus, contains the components Aklog identifies as important for treating pulmonary embolism. (Aklog, [0136]-[0142].)

Similarly, Laub discloses an aspiration system for removing "unwanted material such as emboli, thrombi, tumors, or debris" from a patient's vasculature. (Laub, [0002].) Laub discloses that "[s]ystems according to

certain embodiments of the present invention may be used, for example, to remove clots from patients suffering from or at risk of ***pulmonary embolisms***." (*Id*., [0005] (emphasis added).)

Like Garrison, Laub's clot treatment system includes an aspiration catheter connected to a pump (i.e., pressure source):

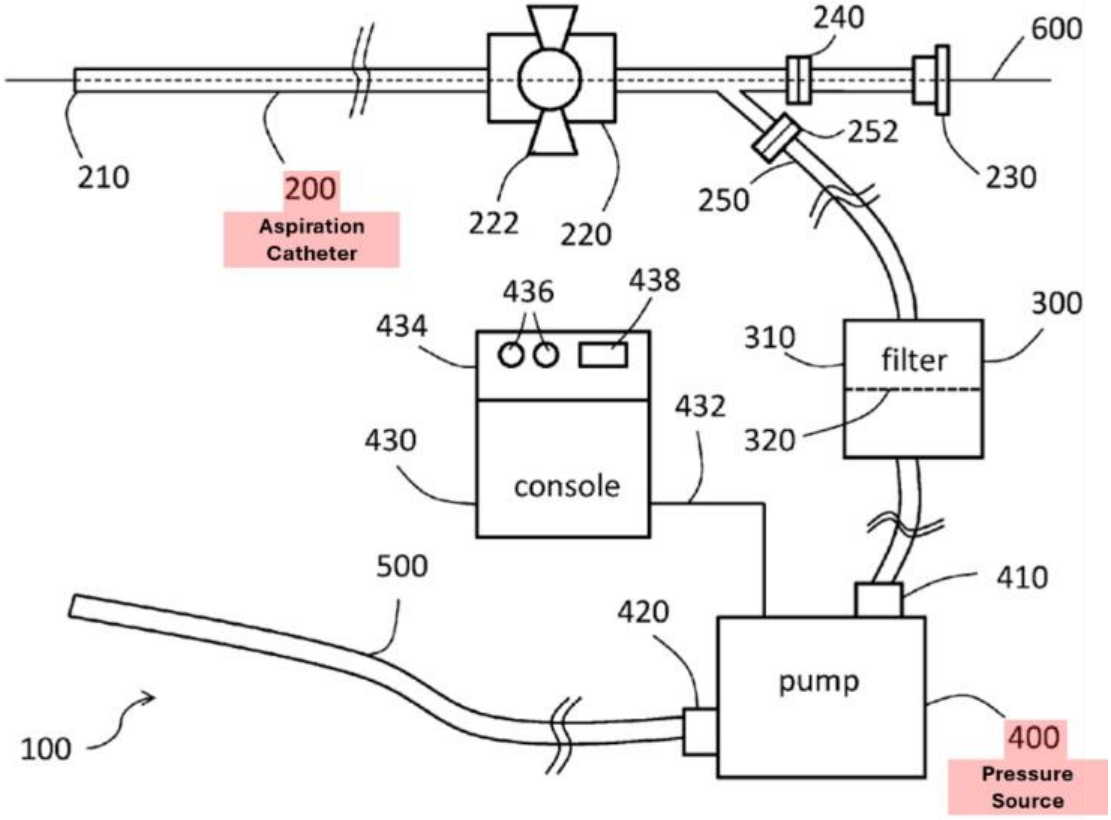


FIG. 1A

(*Id.* at ¶ [0024], Fig. 1A.) Laub also discloses catheters having a diameter ranging from 5 French to 20 French and Laub specifically states, "[i]n some embodiments, aspiration catheter 200 has a French ***size of at least 16 Fr.***" (*Id.* at ¶ [0028] (emphasis added).) Thus, Garrison, in view of Laub, also renders obvious the claims of the '910 Patent requiring catheter sizes equal to or greater than 16 French.

A POSITA would have found it obvious to adapt Garrison's aspiration system to use catheters of 16 French, 20 French, or greater to treat pulmonary embolism, as claimed in the '910 Patent. First, the '910 patent confirms the

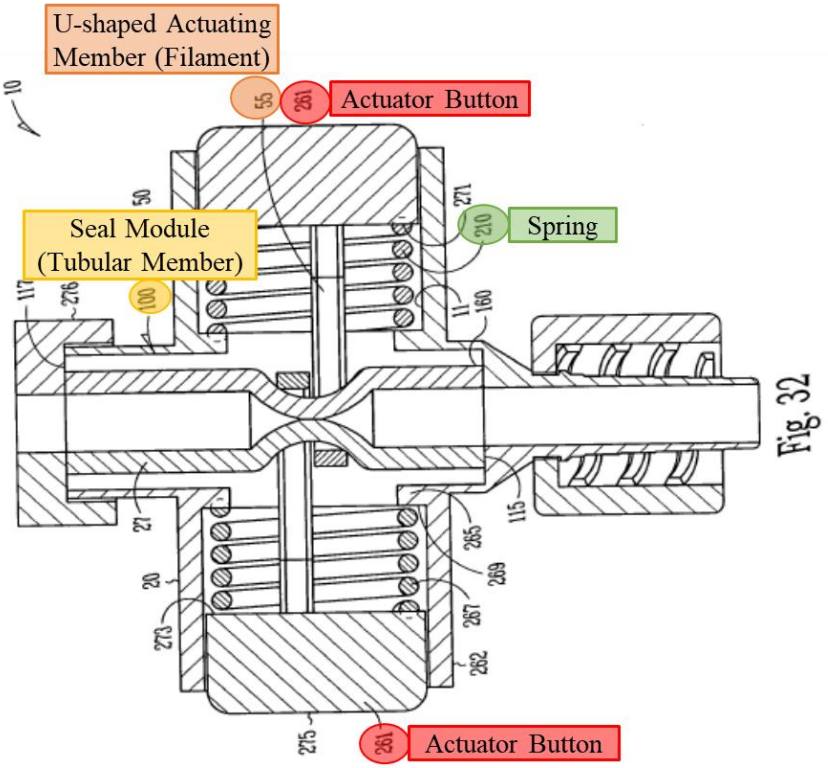
interchangeability of aspiration catheters for different parts of the vasculature by alleging the described catheters are useful for "treating a pulmonary embolism," "intravascular procedures other than the treatment of emboli, intravascular procedures for treating ***cerebral embolism***, intravascular procedures for treating deep vein thrombosis (DVT), etc." ('910 Patent, 4:51-61 (emphasis added).) Thus, POSITAs working on treating clots in one part of the body naturally relied upon innovations for treating clots in other parts of the body.

Garrison also suggests adapting its aspiration systems with components for use in other parts of the vasculature. (Garrison, [0070], [0144] (incorporating by reference patents addressing other parts of the vasculature).) Further, Garrison is not alone in presuming that a POSITA would have found it obvious to adapt aspiration catheters designed for one part of the vasculature for another. Other prior art patents disclose aspiration systems intended for use across all portions of the vasculature. For example, Brady describes catheters capable of removing clots "from the cerebral arteries" and the "pulmonary arteries." (Brady, [0001].) For at least these reasons, a POSITA would have found it obvious to adapt Garrison's aspiration system to use catheters having a size of 16 French or greater to treat pulmonary embolism based on Aklog, Laub, and the knowledge of a POSITA.

As noted above, several dependent claims include an additional hemostasis valve component on one or both of the claimed aspiration assemblies. Garrison discloses several different hemostasis valves that can be interchangeably used with its aspiration system including, for example, an "adjustable-opening valve" or a "rotating hemostasis valve." Garrison presumes a person of ordinary skill in the art would have been familiar with the available hemostasis valves and, therefore, does not describe their structures. However, other prior art references do.

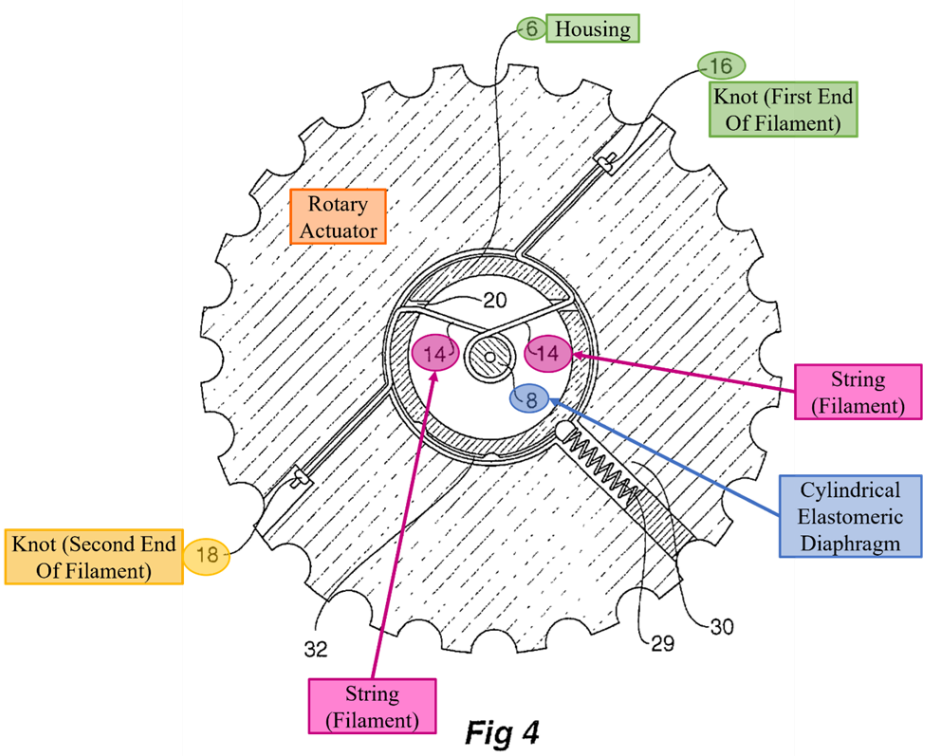
For example, Schaffer discloses an adjustable-opening hemostasis valve

for use during minimally invasive intravascular procedures. (Schaffer, [0002], [0008].) Schaffer's valve includes a tubular member that can slidably receive a second catheter, a constricting mechanism including a filament, an actuator coupled to the filament, and a biasing system (e.g., spring):



(*Id.*, Fig. 32.)

Hartley discloses the structure for a rotating hemostasis valve that includes a filament extending around a tubular member to restrict the member and close the valve:



(Hartley, Fig. 4.)

Eller discloses a rotatable hemostasis valve like the valve disclosed in Hartley. Eller's hemostasis valve includes a filament that constricts an elongate member to seal the valve:

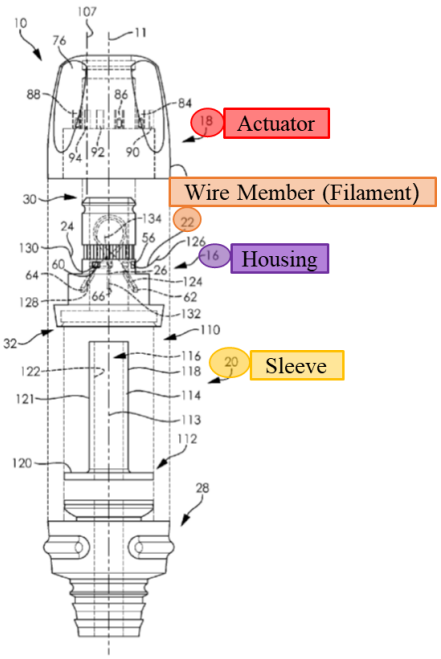


FIG. 2

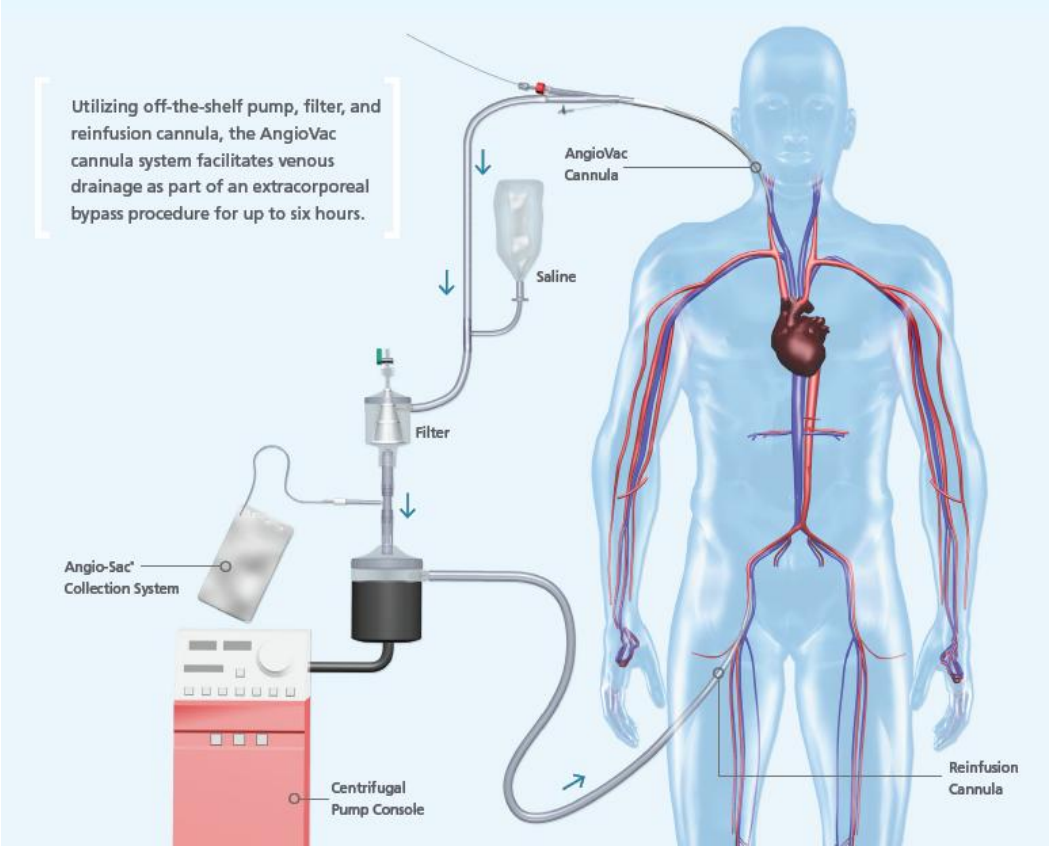
(Eller, 5:1-12, Fig. 2.) To the extent Schaffer's actuating members do not comprise "filaments," a POSITA would have found it obvious to replace Schaffer's actuating members with the filaments in Hartley or Eller for the same reasons discussed in connection with the '012, '921,'291, and '333 Patents, above. Likewise, a POSITA would have found it obvious to include a hemostasis valve, such as that disclosed in Schaffer, Hartley, and/or Eller for the same reasons discussed in connection with the '005 and '333 Patents above.

Thus, for at least the reasons discussed above, claims 1-8, 11-15, and 18-20 of the '910 Patent are obvious over Garrison, in combination with Aklog, Laub, Schaffer, Hartley, and/or Eller.

B. <u>Alternative Obviousness Combinations that Render Claims 1-8, 11-15, and 18-20 of the '910 Patent Obvious</u>

The exemplary obviousness combination discussed above relies on Garrison's disclosure of a clot treatment system comprising "a first clot aspiration assembly" and "a second clot aspiration assembly," each having a separate "catheter," "pressure source," and "fluid control device," wherein the second assembly may be telescoped through the first assembly as recited in claim 1 of the '910 Patent. However, the prior art is replete with examples of clot treatment systems with similar components and configurations. Thus, to the extent Inari contends Garrison does not disclose one or more of these steps or elements, it would have been obvious to a person of ordinary skill in the art to combine other prior art aspiration systems with Garrison to achieve the claimed invention.

For example, Aklog discloses "systems and methods for removing substantially en bloc clots, thrombi, and emboli, among others, from within heart chambers, as well as medium to large vessels." (Aklog, 1:17-24.) The Aklog system, commercially released as the AngioVac system, shown below:



(AngioVac Brochure.)

Likewise, Laub discloses "a system for removing thrombi and other unwanted material from the body of a patient, particularly from the patient's vasculature." (Laub, [0005].) An embodiment of Laub is shown in the figure below:

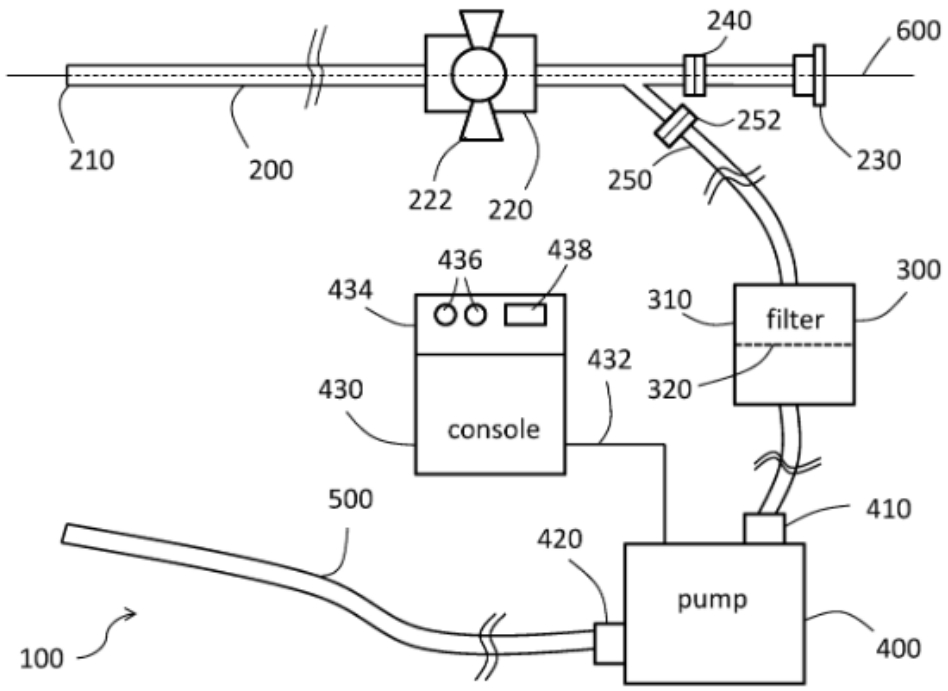
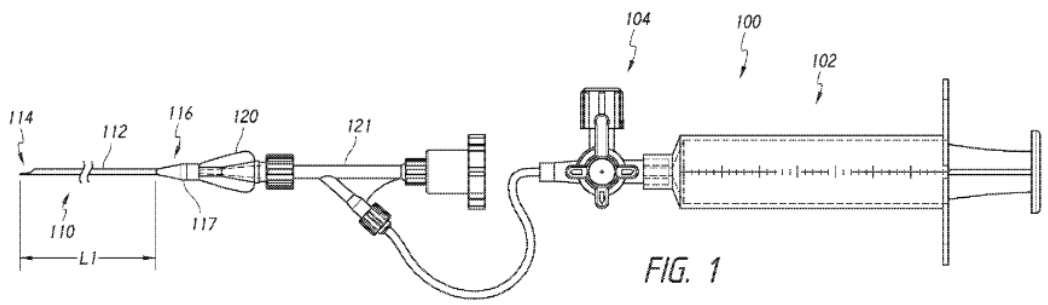


FIG. 1A

(Laub, Fig. 1A.) "In some embodiments … fluid path 250 may optionally connect with aspiration catheter 200 via a separate connector (e.g., connector 252) which may allow detachment of fluid path 250 from aspiration catheter 200." (Laub, [0039].)

In addition, Mogi discloses "an embodiment of an assistive jet aspiration catheter system 100 having a suction source 102 (which can be a Vaclok 30 cc syringe, a pump system such as a Penumbra™ pump, or otherwise), a stopcock or valve 104 to control the suction and flow of fluid through the system 100, and an assistive jet aspiration catheter 110 (also referred to herein as a assistive jet catheter and just an aspiration catheter)." (Mogi, [0154].) This embodiment is shown in the figure below:



(Mogi, Fig. 1.)

In addition to Garrison, other prior art references disclose other claimed elements, such as "an electric pump" (claims 5, 14, 18). For example, Teigen discloses: "The base unit will typically be configured to be mounted directly on or near a vacuum pump or console and will usually include a connecting cable in order to receive power from the vacuum console or line and optionally exchange information with the controller and vacuum console." (Tiegen, 5:54-59.) Laub discloses: "Pump 400, according to certain embodiments, is configured to create a suction force to drive system 100 during use… pump 400 may be a rotary pump, peristaltic pump, roller pump, or other form of pump known in the art." (Laub, [0041].)

Other references disclose the claimed "fluid control device" that can be closed to generate a vacuum and opened to release the vacuum. For example, Mogi discloses "stopcock or valve 104 to control the suction and flow of fluid through the system 100." (Mogi, [0154].) Teigen discloses the use of valves to create a "pressure differential between the vacuum source and the catheter," which "results in a pressure pulse." (Tiegen, 18:34-37.) Michelson discloses: "The AngioVac suction is initiated by the perfusionist removing the clamp from the inflow and venous line and opening the clamp to the bubble trap. This clamp placement provides a closed circuit allowing the centrifugal pump to provide the necessary suction for thrombus removal without the use of additional vacuum." (Michelson, 300.)

Moreover, several aspiration systems with similar components, including telescoping catheters, fluid control valves, and electric pumps, were being sold well before the priority date of the ’910 Patent, including AngioDynamic’s AngioVac system (discussed above), Penumbra’s Indigo Aspiration System, Medtronic’s Export Aspiration Catheter, and even Inari’s own FlowTriever and ClotTriever systems.

In addition to Garrison, other prior art references disclose the use of valves, such as hemostasis valves, to facilitate the insertion of treatment devices into the system while minimizing blood loss. For example, Laub discloses “working port 230 is configured to provide a fluid tight seal around stylet 700 or other device inserted through working port 230, for example, so as to prevent leakage of blood out of working port 230 during use.” (Laub, [0036].) For the same reasons discussed above in connection with Garrison, in view of these disclosures, a person of ordinary skill in the art would have been motivated to combine the above-referenced aspiration systems with the hemostasis valves of Schaffer, Hartley, and/or Eller to achieve the claimed invention.

In view of this additional prior art, and the other prior art references identified in Appendix G, the asserted claims of the ’910 Patent would have been obvious to a person of ordinary skill in the art.

XI. INVALIDITY OF THE ’580 PATENT

As set forth below, claims 1, 5, 6, 9-30, and 33-34 of the ’580 Patent are invalid at least because they are rendered obvious under 35 U.S.C. § 103 at ;east by Garrison in combination with Aklog, Laub, Schaffer, Hartley, and/or Eller. In addition to the invalidity arguments described below, an exemplary claim chart is also attached hereto as Appendix H, which identifies additional prior art references and disclosures that, when combined with other prior art references identified therein, renders the Asserted Claims of the ’580 Patent obvious.

Imperative Care may rely on cited or uncited portions of the prior art,

other documents, and expert testimony to establish (1) the state of the relevant art and (2) the general knowledge of one of skill in the art. Furthermore, to the extent similar claim limitations occur in one or more claims, the disclosures below applied to a given claim should be read to apply to all similar claim limitations, as should the prior art descriptions above.

A. Claims 1, 5, 6, 9-30, and 33-34 of the ’580 Patent are Obvious over Garrison in combination with Aklog, Laub, Goff, Schaffer, Hartley, and/or Eller

Claims 1, 5, 6, 9-30, and 33-34 of the ’580 Patent are directed to methods or the intravascular treatment of clot material within a blood vessel. The claimed methods recite, *inter alia*, “positioning a distal portion of an elongated shaft” proximal to a treatment site, “pre-charging a vacuum in a pressure source,” fluidly connecting the pressure source to the elongate shaft to “aspirate” clot material into the elongate shaft, “advancing an interventional device” through the shaft, and “engaging the interventional device” with additional clot material within the blood vessel. (’580 Patent, Claim 1.) The asserted dependent claims further specify: the use of a hemostasis valve to seal/unseal the claimed “attachment member” (e.g. claims 5, 6, 14-17, 22, 23, 28, 29); the use of a fluid control device and/or connecting tubes to control the application of vacuum within the system (e.g. claims 9, 11-13, 27); the use of a filter chamber (e.g. claims 18-21, 24-26); and additional method steps (e.g. claims 33, 34).

Garrison, in combination with Aklog, Goff, Laub, Schaffer, Hartley, and/or Eller render claims 1, 5, 6, 9-30, and 33-34 of the ’580 Patent obvious. Garrison discloses an aspiration system for removing unwanted material from a patient’s vasculature. As illustrated below, Garrison’s aspiration system includes the same components required to practice the methods recited in claim 1 (and corresponding dependent claims) of the ’580 patent: a pressure source

(e.g., pump or syringe) [red], an elongate member (e.g. an aspiration catheter) [orange], a filter chamber [blue], hemostasis valves [yellow], and a fluid control device (e.g. a valve) [purple] that is closed while vacuum pressure is generated by the pressure source and opened after the vacuum pressure is pre-charged to cause rapid aspiration through the catheter.

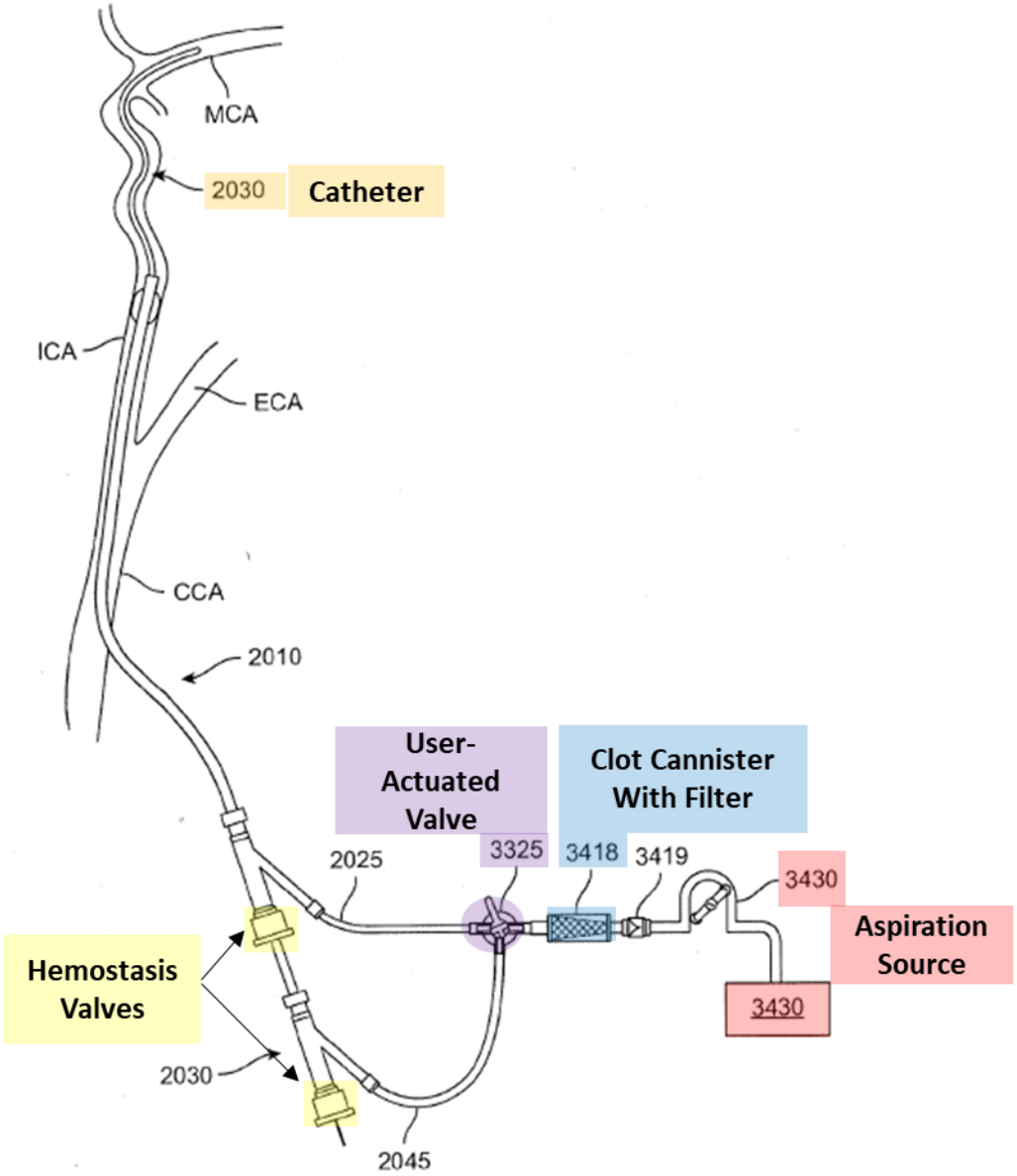


FIG. 34

(Garrison, Fig. 34.) Garrison explains that opening the valve after pre-charging the vacuum pressure enables "the maximum level of aspiration in a ***rapid***

fashion with one user, something that is not currently possible with existing technologies." (*Id*., [0134] (emphasis added).)

Dependent claim 10 of the '580 Patent recites "the method of claim wherein the blood vessel is a pulmonary blood vessel." ('580 Patent, Claim 10.) Garrison discloses using its aspiration system to remove cerebral occlusions, but does not specifically mention pulmonary blood vessels. However, Garrison's catheter is configured to be positioned proximate clots in such vessels because it has the correct size and flexibility. Additionally, a POSITA would have found it obvious to use and/or adapt Garrison's cerebral aspiration system to aspirate clots in the pulmonary vasculature. Each procedure involves the identical process of advancing a catheter through an artery or vein to reach an embolism and activating a vacuum through the catheter to aspirate the emboli. Unsurprisingly, catheter designers knew well before 2018 how to size catheters to fit the desired vessel.

The use and/or adaptation of Garrison's system to treat pulmonary vessels is particularly obvious in view of Aklog and Laub. Aklog discloses an aspiration system for removing undesirable materials, including from pulmonary blood vessels. (Aklog, 2:7-32, 7:27-42.) Aklog also acknowledges that a POSITA could simply adapt aspiration catheters for use in other parts of the vasculature, stating: "Although reference is made to medium and large vessels, it should be appreciated that the systems and methods, herein disclosed, can be scaled and adapted for use within smaller vessels within the body, if desired." (*Id*., 7:43-46.)

Moreover, Aklog's system has similar components to Garrison's system, including an aspiration source (e.g., pump or syringe) [red], an aspiration catheter [orange], a filter chamber [blue], and a hemostasis valve (described, but not illustrated below).

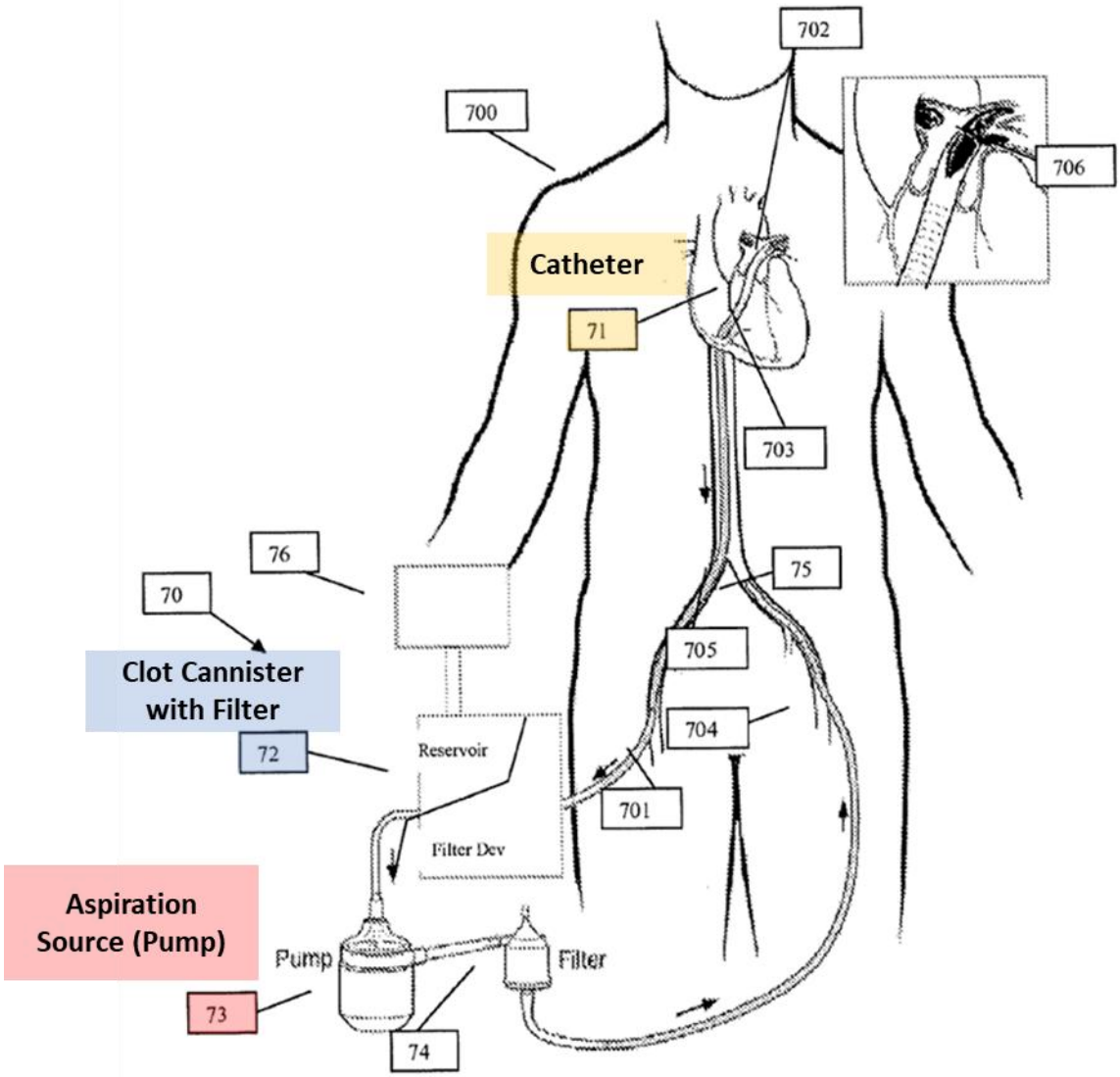


Fig. 7

(*Id.*, Fig. 7.) Aklog also discloses ways to optimize aspiration systems to treat clots in the pulmonary vessels, including, for example, returning the aspirated blood to the patient to reduce blood loss. (*Id.*, 1:17-24.) Garrison also describes this blood-return procedure and, thus, contains the components Aklog identifies as important for treating clots in the pulmonary vessels. (Aklog, [0136]-[0142].)

Similarly, Laub discloses an aspiration system for removing "unwanted material such as emboli, thrombi, tumors, or debris" from a patient's

vasculature. (Laub, [0002].) Laub discloses that "[s]ystems according to certain embodiments of the present invention may be used, for example, to remove clots from patients suffering from or at risk of ***pulmonary embolisms***." (*Id*., [0005] (emphasis added).)

Like Garrison, Laub's clot treatment system includes an aspiration catheter connected to a pump (i.e., pressure source):

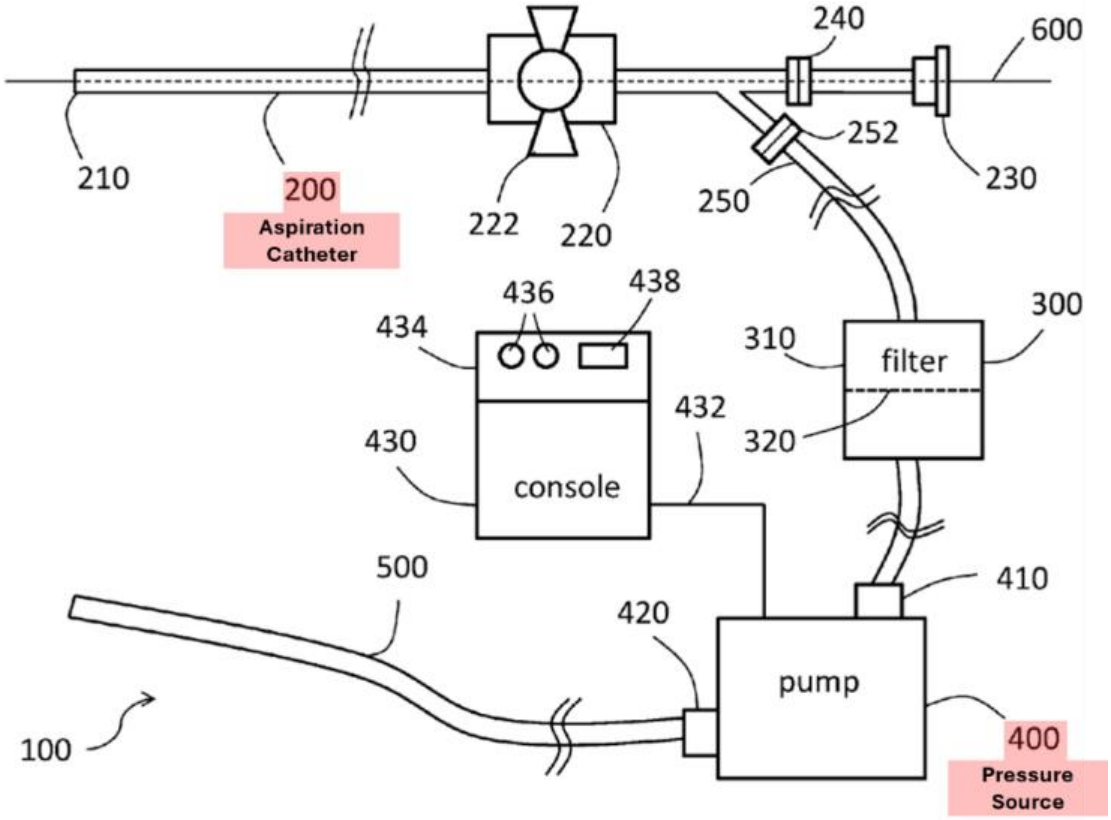


FIG. 1A

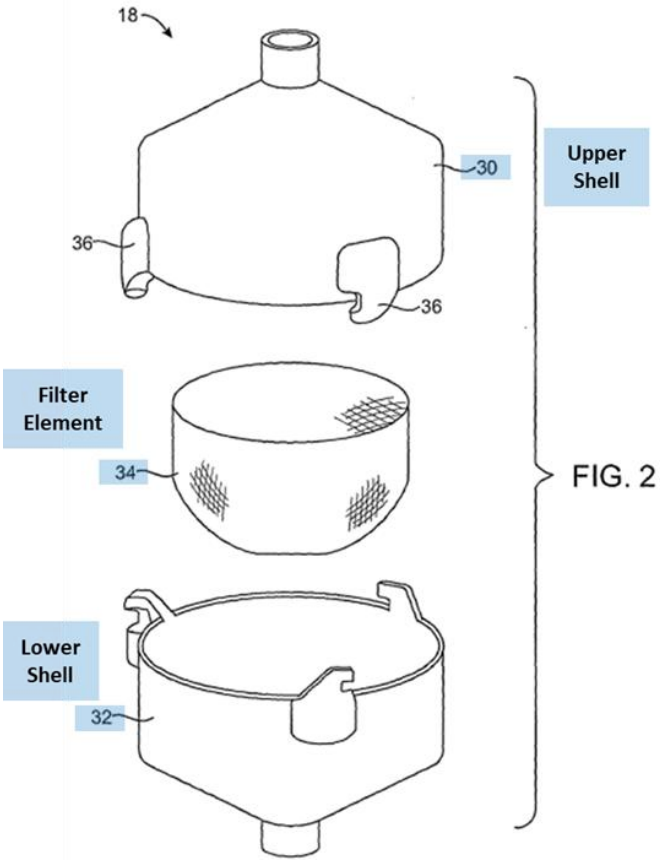
(*Id.* at ¶ [0024], Fig. 1A.)

A POSITA would have found it obvious to adapt Garrison's aspiration system to aspirate clot material from pulmonary vessels, as claimed in the '580 Patent. First, the '580 patent confirms the interchangeability of aspiration catheters for different parts of the vasculature by alleging the described catheters are useful for "treating a pulmonary embolism," "intravascular procedures other than the treatment of emboli, intravascular procedures for treating ***cerebral embolism***, intravascular procedures for treating deep vein thrombosis (DVT),

etc." ('333 Patent, 4:51-61 (emphasis added).) Thus, POSITAs working on treating clots in one part of the body naturally relied upon innovations for treating clots in other parts of the body.

Garrison also suggests adapting its aspiration systems with components for use in other parts of the vasculature. (Garrison, [0070], [0144] (incorporating by reference patents addressing other parts of the vasculature).) Further, Garrison is not alone in presuming that a POSITA would have found it obvious to adapt aspiration catheters designed for one part of the vasculature for another. Other prior art patents disclose aspiration systems intended for use across all portions of the vasculature. For example, Brady describes catheters capable of removing clots "from the cerebral arteries" and the "pulmonary arteries." (Brady, [0001].) For at least these reasons, a POSITA would have found it obvious to adapt Garrison's aspiration system to aspirate clot material from pulmonary vessels based on Aklog, Laub, and the knowledge of a POSITA.

The dependent claims of the '580 Patent that recite the use of a "filter chamber" are also obvious over the prior art. For example, Garrison and Aklog both disclose clot cannisters that contain a filter. Although these references do not expressly disclose removable filters (as recites in some of the dependent claims), aspiration systems having removable filters were well known by August 2018 simply because the clot may plug the filter or exceed the capacity of the filter chamber. Such clogging would bring an abrupt halt to this time sensitive procedure if the chamber could not be opened to empty the captured clot. Moreover, Goff discloses an aspiration system having a filter housing 18 to "remove solid materials from the aspirate." (Goff, [0011].) 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." (*Id.*, [0015] (emphasis added).)

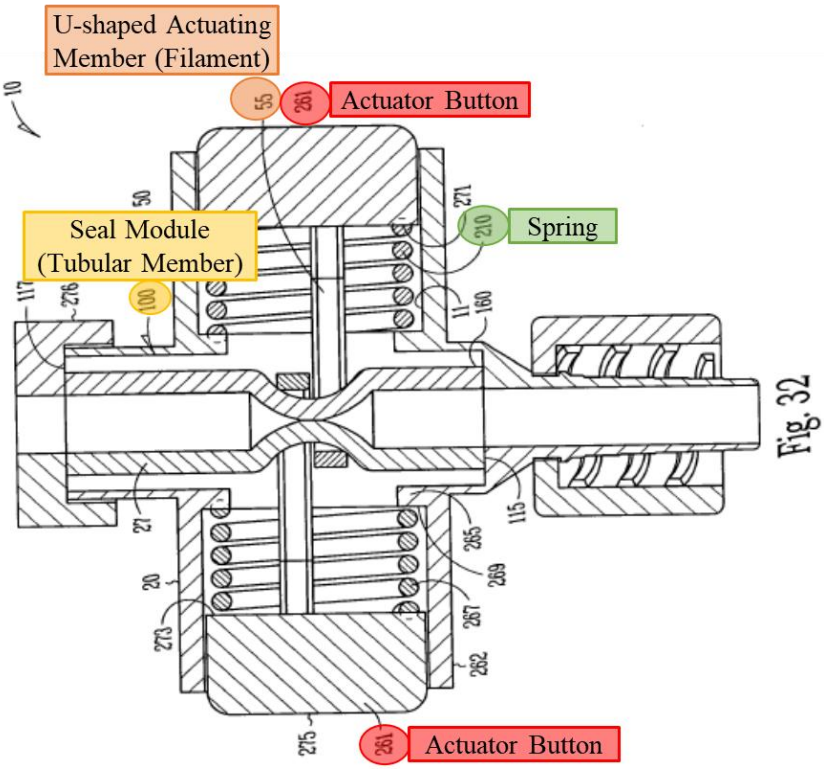


Goff further discloses that the "housing will further have conventional connectors to permit connection at an upper end to the aspiration catheter and at a lower end to the aspirate receptacle." (*Id.*) The use of conventional connectors, such as Luer-type connectors, means that the housing is removable. As shown herein, a POSITA would have found it obvious to incorporate Goff's filter device into Garrison's system or modify Garrison's existing filter to make the filter and housing removable as taught in Goff.

The dependent claims of the '580 Patent that recite the use of a hemostasis valve are also obvious over Garrison in combination with other prior art. Garrison discloses several different hemostasis valves that can be interchangeably used with its aspiration system including, for example, an "adjustable-opening valve" or a "rotating hemostasis valve." Garrison presumes a person of ordinary skill in the art would have been familiar with the available hemostasis valves and, therefore, does not describe their structures. However,

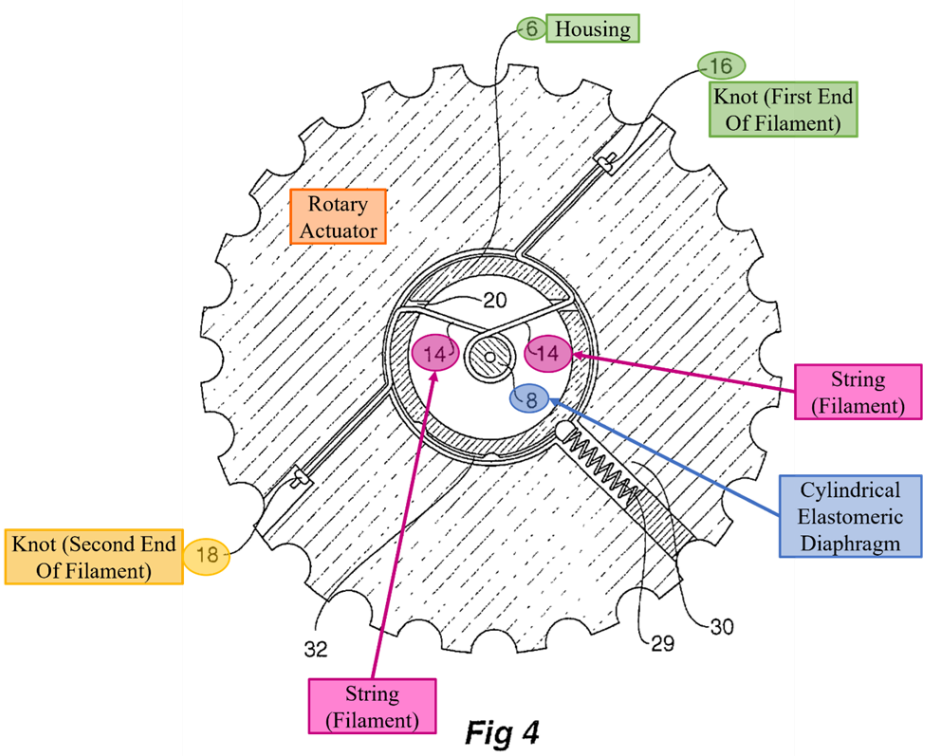
other prior art references do.

For example, Schaffer discloses an adjustable-opening hemostasis valve for use during minimally invasive intravascular procedures. (Schaffer, [0002], [0008].) Schaffer's valve includes a tubular member that can slidably receive a second catheter, a constricting mechanism including a filament, an actuator coupled to the filament, and a biasing system (e.g., spring):



(*Id.*, Fig. 32.)

Hartley discloses the structure for a rotating hemostasis valve that includes a filament extending around a tubular member to restrict the member and close the valve:



(Hartley, Fig. 4.)

Eller discloses a rotatable hemostasis valve like the valve disclosed in Hartley. Eller's hemostasis valve includes a filament that constricts an elongate member to seal the valve:

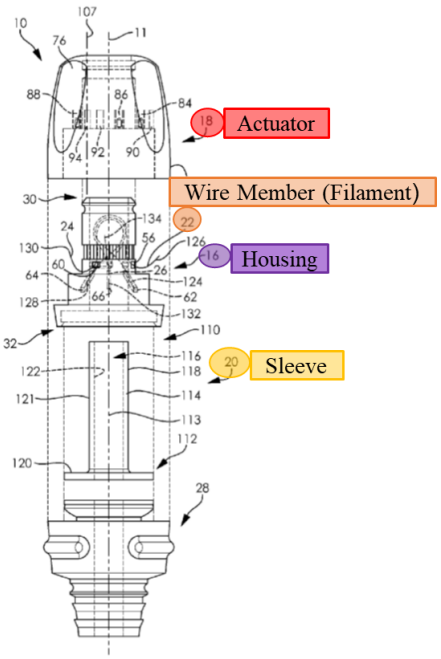


FIG. 2

(Eller, 5:1-12, Fig. 2.) To the extent Schaffer's actuating members do not comprise "filaments," a POSITA would have found it obvious to replace Schaffer's actuating members with the filaments in Hartley or Eller for the same reasons discussed in connection with the '012, '921, and '291 Patents, above. Likewise, a POSITA would have found it obvious to include a hemostasis valve, such as that disclosed in Schaffer, Hartley, and/or Eller for the same reasons discussed in connection with the '005 Patent above.

The dependent claims of the '580 Patent that recite the use of a interventional device are also obvious over Garrison, in combination with other prior art. For example, Garrison discloses the use of a hemostasis valve "to allow introduction of devices such as a microcatheter, guide wire, or ***thrombectomy device*** while preventing or minimizing blood loss during the procedure." (Garrison, [0098].) Similarly, Laub discloses embodiments wherein a "working port" (i.e. a hemostasis valve) "allows insertion of instruments into and/or through the lumen of aspiration catheter … ." (Laub, [0035].)

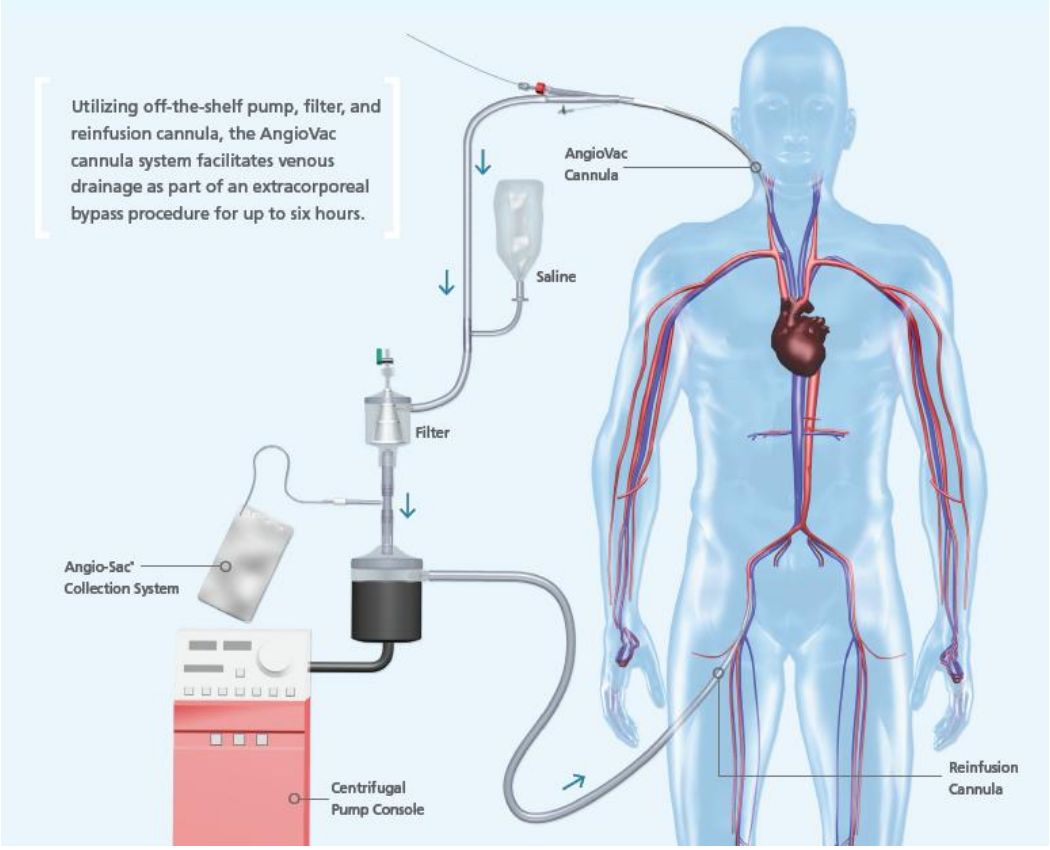
Thus, for at least the reasons discussed above, claims 1, 5, 6, 9-30, and 33-34 of the '580 Patent are obvious over Garrison, in combination with Aklog, Goff, Laub, Schaffer, Hartley, and/or Eller.

B. <u>Alternative Obviousness Combinations that Render Claims 1, 5, 6, 9-30, and 33-34 of the '580 Patent Obvious</u>

The exemplary obviousness combination discussed above relies on Garrison's disclosure of a method for the intravascular treatment of clot material, comprising "positioning" an aspiration catheter proximate the clot, "pre-charging a vacuum in a pressure source," "fluidly connecting" the pressure source and the aspiration catheter "to aspirate" the clot material, "advancing an interventional device" through the aspiration catheter, and "engaging the interventional device" with remaining clot material, as recited in claim 1 of the

’580 Patent. However, the prior art is replete with examples of clot treatment systems with similar components and methods. Thus, to the extent Inari contends Garrison does not disclose one or more of these steps or elements, it would have been obvious to a person of ordinary skill in the art to combine other prior art aspiration systems with Garrison to achieve the claimed invention.

For example, Aklog discloses “systems and methods for removing substantially en bloc clots, thrombi, and emboli, among others, from within heart chambers, as well as medium to large vessels.” (Aklog, 1:17-24.) The Aklog system, commercially released as the AngioVac system, shown below:



(AngioVac Brochure.)

Likewise, Laub discloses “a system for removing thrombi and other unwanted material from the body of a patient, particularly from the patient’s vasculature.” (Laub, [0005].) An embodiment of Laub is shown in the figure

below:

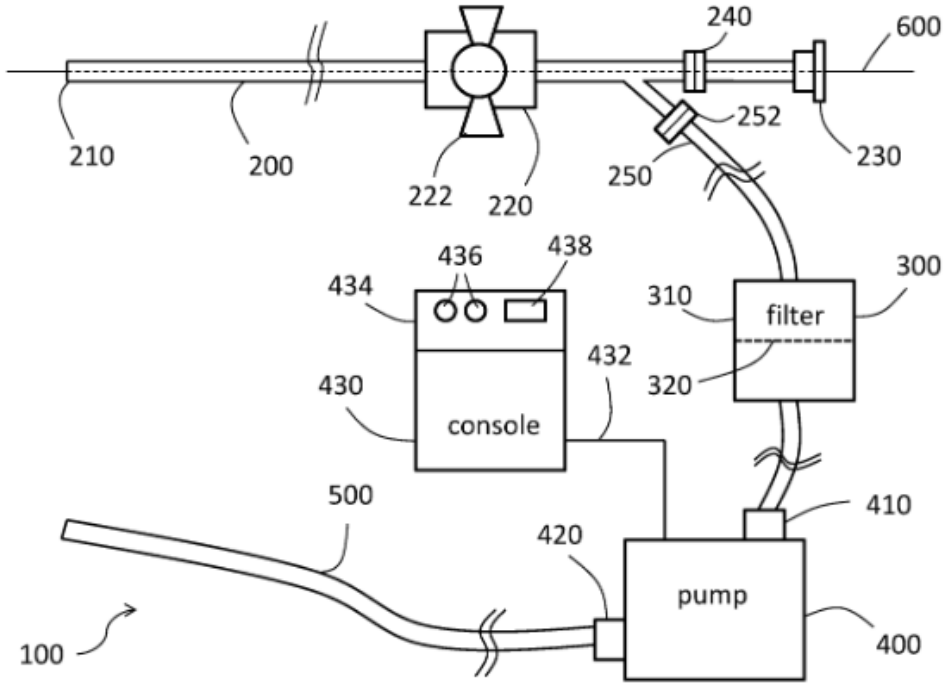
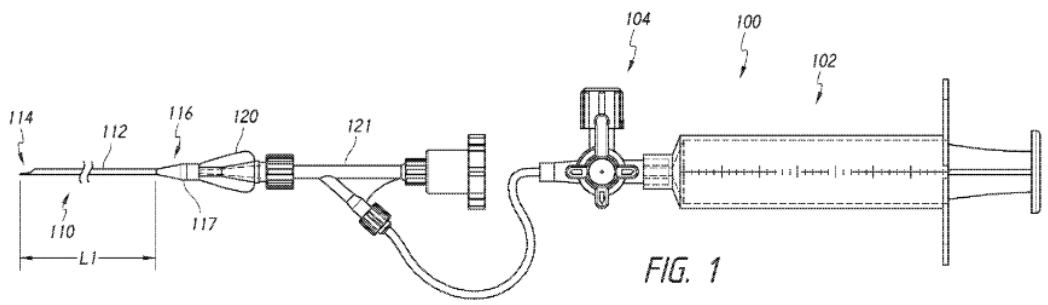


FIG. 1A

(Laub, Fig. 1A.) "In some embodiments … fluid path 250 may optionally connect with aspiration catheter 200 via a separate connector (e.g., connector 252) which may allow detachment of fluid path 250 from aspiration catheter 200." (Laub, [0039].)

In addition, Mogi discloses "an embodiment of an assistive jet aspiration catheter system 100 having a suction source 102 (which can be a Vaclok 30 cc syringe, a pump system such as a Penumbra™ pump, or otherwise), a stopcock or valve 104 to control the suction and flow of fluid through the system 100, and an assistive jet aspiration catheter 110 (also referred to herein as a assistive jet catheter and just an aspiration catheter)." (Mogi, [0154].) This embodiment is shown in the figure below:



(Mogi, Fig. 1.)

Moreover, several aspiration systems with similar components and employing similar methods, including the use of interventional devices in connection with aspiration-based thrombectomy procedures, were being sold well before the priority date of the ’580 Patent, including AngioDynamic’s AngioVac system (discussed above), Penumbra’s Indigo Aspiration System, Medtronic’s Export Aspiration Catheter, and even Inari’s own FlowTriever and ClotTriever systems.

In addition to Garrison, other references disclose the claimed “fluid control device” that can be closed to pre-charge a vacuum and opened to release the vacuum and aspirate the clot. For example, Mogi discloses “stopcock or valve 104 to control the suction and flow of fluid through the system 100.” (Mogi, [0154].) Teigen discloses the use of valves to create a “pressure differential between the vacuum source and the catheter,” which “results in a pressure pulse.” (Tiegen, 18:34-37.) Michelson discloses: “The AngioVac suction is initiated by the perfusionist removing the clamp from the inflow and venous line and opening the clamp to the bubble trap. This clamp placement provides a closed circuit allowing the centrifugal pump to provide the necessary suction for thrombus removal without the use of additional vacuum.” (Michelson, 300.)

In addition to Garrison, other prior art references disclose the use of valves, such as hemostasis valves, to facilitate the insertion of treatment devices

into the system while minimizing blood loss. For example, Laub discloses "working port 230 is configured to provide a fluid tight seal around stylet 700 or other device inserted through working port 230, for example, so as to prevent leakage of blood out of working port 230 during use." (Laub, [0036].) For the same reasons discussed above in connection with Garrison, in view of these disclosures, a person of ordinary skill in the art would have been motivated to combine the above-referenced aspiration systems with the hemostasis valves of Schaffer, Hartley, and/or Eller to achieve the claimed invention.

In view of this additional prior art, and the other prior art references identified in Appendix H, the asserted claims of the '580 Patent would have been obvious to a person of ordinary skill in the art.

XII. INVALIDITY BASED ON OTHER GROUNDS (PLR 3-3(D))

Many of the Asserted Claims are invalid under 35 U.S.C. § 112 for failure to particularly point out and distinctly claim the subject matter of the inventions and for failure to provide an adequate written description. Other Asserted Claims are invalid for obviousness-type double patenting. Those grounds are discussed below.

A. <u>Indefiniteness Under 35 U.S.C. 112(b)</u>

As set forth in 35 U.S.C. § 112, the "specification must conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention." To satisfy the definiteness requirement, the "claims, when read in light of the specification and the prosecution history, must provide objective boundaries for those of skill in the art." *Interval Licensing LLC* v. *AOL, Inc.*, 766 F.3d 1364, 1371 (Fed. Cir. 2014) (citing *Nautilus, Inc.* v. *Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2130 (2014)). Claims are invalid as indefinite where they fail this test. *See id.; Allen Eng'g Corp. v. Bartell Indus., Inc.,* 299 F.3d 1336, 1349 (Fed. Cir. 2002) (concluding that the term "perpendicular" is indefinite when it should be

read to mean "parallel"), cited with approval by *Trs. of Columbia Univ. v. Symantec Corp.*, 811 F.3d 1359, 1366 (Fed. Cir. 2016).

The following Asserted Claims are indefinite for failing to provide objective boundaries for those of skill in the art:

- '012 Patent – Claims 1-7, 9 - "collapsible tubular sidewall" – The '012 Patent specification does not use or define the term "collapsible tubular sidewall." Nor does the specification describe a structure that a person of ordinary skill in the art would understand to fall within this claim term. Further, neither the specification nor the claims provide objective boundaries for those skilled in the art regarding what would constitute a "collapsible tubular sidewall." Consequently, the claims fail to inform with reasonable certainty those skilled in the art about the scope of the invention and do not afford clear notice of what is claimed. Thus, the claims are indefinite and invalid.
- '012 Patent – Claims 1-7, 9 - "a collapsible tubular sidewall defining a valve lumen in communication with the central lumen" – The'012 Patent specification does not use or define the term "collapsible tubular sidewall." Nor does the specification describe a structure that a person of ordinary skill in the art would understand to fall within this claim term. Further, neither the specification nor the claims provide objective boundaries for those skilled in the art regarding what would constitute a "collapsible tubular sidewall." Additionally, the description of Claim 1 conflicts with Claim 2. Consequently, the claims fail to inform with reasonable certainty those skilled in the art about the scope of the invention and do not afford clear notice of what is claimed. Thus, the claims are indefinite and invalid.
- '012 Patent – Claims 1-7, 9 – "the proximal end of the catheter" – Claim 1 does not provide antecedent basis for "the proximal end of the

catheter." The only "proximal end" previously mentioned in the claim is associated with "an elongate, flexible tubular body." Consequently, the claims fail to inform with reasonable certainty those skilled in the art about the scope of the invention and do not afford clear notice of what is claimed. Thus, the claims are indefinite and invalid.

- '012 Patent – Claim 5 – "a first volume" and "a second volume" - The'012 Patent specification does not use or define the term "first volume" or "second volume." Nor does the specification describe a structure or area that a person of ordinary skill in the art would understand to fall within this claim term. Further, neither the specification nor the claims provide objective boundaries for those skilled in the art regarding what would constitute a "first volume" or "second volume." Consequently, the claims fail to inform with reasonable certainty those skilled in the art about the scope of the invention and do not afford clear notice of what is claimed. Thus, the claims are indefinite and invalid.
- '012 Patent – Claim 6 – "a volume" - The'012 Patent specification does not use or define the term "a volume." Nor does the specification describe a structure or area that a person of ordinary skill in the art would understand to fall within this claim term. Further, neither the specification nor the claims provide objective boundaries for those skilled in the art regarding what would constitute "a volume." Consequently, the claims fail to inform with reasonable certainty those skilled in the art about the scope of the invention and do not afford clear notice of what is claimed. Thus, the claims are indefinite and invalid.
- '921 Patent – Claim 5 - "a first volume" and "a second volume" - The'921 Patent specification does not use or define the term "first

volume" or "second volume." Nor does the specification describe a structure or area that a person of ordinary skill in the art would understand to fall within this claim term. Further, neither the specification nor the claims provide objective boundaries for those skilled in the art regarding what would constitute a "first volume" or "second volume." Consequently, the claims fail to inform with reasonable certainty those skilled in the art about the scope of the invention and do not afford clear notice of what is claimed. Thus, the claims are indefinite and invalid.

- '921 Patent – Claim 6 - "a volume" - The'921 Patent specification does not use or define the term "a volume." Nor does the specification describe a structure or area that a person of ordinary skill in the art would understand to fall within this claim term. Further, neither the specification nor the claims provide objective boundaries for those skilled in the art regarding what would constitute "a volume." Consequently, the claims fail to inform with reasonable certainty those skilled in the art about the scope of the invention and do not afford clear notice of what is claimed. Thus, the claims are indefinite and invalid.
- '291 Patent – Claims 1-8, 12-17, 19 – "a support" – The '291 Patent specification does not use or define the term "support." Nor does the specification describe a structure that a person of ordinary skill in the art would understand to fall within this claim term. Further, neither the specification nor the claims provide objective boundaries for those skilled in the art regarding what would constitute a "support." Consequently, the claims fail to inform with reasonable certainty those skilled in the art about the scope of the invention and do not afford clear notice of what is claimed. Thus, the claims are indefinite and

invalid.

- ’291 Patent – Claims 1-8, 12-17, 19 – “collapsible tubular sidewall” - The ’291 Patent specification does not use or define the term “collapsible tubular sidewall.” Nor does the specification describe a structure that a person of ordinary skill in the art would understand to fall within this claim term. Further, neither the specification nor the claims provide objective boundaries for those skilled in the art regarding what would constitute a “collapsible tubular sidewall.” Consequently, the claims fail to inform with reasonable certainty those skilled in the art about the scope of the invention and do not afford clear notice of what is claimed. Thus, the claims are indefinite and invalid.
- ’291 Patent – Claim 5 – “a device extending through the lumen” – The claim is unclear regarding whether “a device extending through the lumen” is required. Consequently, the claims fail to inform with reasonable certainty those skilled in the art about the scope of the invention and do not afford clear notice of what is claimed. Thus, the claims are indefinite and invalid.
- ’005 Patent – Claims 10-15 - “a support” – The ’005 Patent specification does not use or define the term “support.” Nor does the specification describe a structure that a person of ordinary skill in the art would understand to fall within this claim term. Further, neither the specification nor the claims provide objective boundaries for those skilled in the art regarding what would constitute a “support.” Consequently, the claims fail to inform with reasonable certainty those skilled in the art about the scope of the invention and do not afford clear notice of what is claimed. Thus, the claims are indefinite and invalid.

- ’005 Patent – Claims 10-15 - “collapsible tubular sidewall” - The ’005 Patent specification does not use or define the term “collapsible tubular sidewall.” Nor does the specification describe a structure that a person of ordinary skill in the art would understand to fall within this claim term. Further, neither the specification nor the claims provide objective boundaries for those skilled in the art regarding what would constitute a “collapsible tubular sidewall.” Consequently, the claims fail to inform with reasonable certainty those skilled in the art about the scope of the invention and do not afford clear notice of what is claimed. Thus, the claims are indefinite and invalid.
- ’005 Patent – Claim 5 - “a first volume” and “a second volume” - The’005 Patent specification does not use or define the term “first volume” or “second volume.” Nor does the specification describe a structure or area that a person of ordinary skill in the art would understand to fall within this claim term. Further, neither the specification nor the claims provide objective boundaries for those skilled in the art regarding what would constitute a “first volume” or “second volume.” Consequently, the claims fail to inform with reasonable certainty those skilled in the art about the scope of the invention and do not afford clear notice of what is claimed. Thus, the claims are indefinite and invalid.
- ’005 Patent – Claim 6 - “a volume” - The’005 Patent specification does not use or define the term “a volume.” Nor does the specification describe a structure or area that a person of ordinary skill in the art would understand to fall within this claim term. Further, neither the specification nor the claims provide objective boundaries for those skilled in the art regarding what would constitute “a volume.” Consequently, the claims fail to inform with reasonable certainty those

skilled in the art about the scope of the invention and do not afford clear notice of what is claimed. Thus, the claims are indefinite and invalid.

- ’910 Patent – Claims 1-8, 11-15, 18-20 - “the second catheter is shaped to be intravascularly advanced through the vasculature of the patient such that the distal portion of the second catheter is positioned proximate to the pulmonary embolism” - The ’910 Patent specification does not use or define the term “…shaped to be intravascularly advanced….” Nor does the specification describe a structure that a person of ordinary skill in the art would understand to fall within this claim term. Further, neither the specification nor the claims provide objective boundaries for those skilled in the art regarding what would constitute a catheter “…shaped to be intravascularly advanced….” Consequently, the claims fail to inform with reasonable certainty those skilled in the art about the scope of the invention and do not afford clear notice of what is claimed. Thus, the claims are indefinite and invalid.

To the extent Imperative Care asserts, in the alternative, invalidity arguments based upon a construction of the above-identified claim terms, it does so without waiver of its position that these terms are indefinite. Imperative Care reserves the right to identify additional claim limitations as indefinite as the case proceeds and as Inari clarifies its Infringement Contentions.

B. <u>Lack of Written Description Under 35 U.S.C. § 112(a)</u>

35 U.S.C. §112(a) states:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the

> best mode contemplated by the inventor or joint inventor of carrying out the invention.

35 U.S.C. §112(a). Written description and enablement are separate and distinct requirements.

To satisfy the written description requirement of 35 U.S.C. § 112, the specification of a patent must describe the full scope of the claimed invention in sufficient detail so "that one skilled in the art can clearly conclude that the inventor invented the claimed invention as of the filing date sought." *Lockwood* v. *Am. Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997); *see also LizardTech, Inc.* v. *Earth Resource Mapping, Inc.*, 424 F.3d 1336, 1344–45 (Fed. Cir. 2005); *Gentry Gallery, Inc.* v. *Berkline Corp.*, 134 F.3d 1473, 1479 (Fed. Cir. 1998); *Eiselstein* v. *Frank*, 52 F.3d 1035, 1039 (Fed. Cir. 1995). "Such description need not recite the claimed invention in haec verba but must do more than merely disclose that which would render the claimed invention obvious." *ICU Med., Inc.* v. *Alaris Med. Sys., Inc.*, 558 F.3d 1368, 1377 (Fed. Cir. 2009).

Notably, Inari has admitted that it has not developed a product that is covered by many of the Asserted Claims. Inari's failure to develop such a device is evidence that Inari did not possess the claimed aspiration systems and/or valves as of the earliest claimed priority date of the Asserted Patents.

The test for enablement is whether, upon reading the specification and in view of information known in the art, a person of ordinary skill in the art could make or use the invention without undue experimentation. *See Callicrate v. Wadsworth Mfg., Inc.*, 427 F.3d 1361, 1374 (Fed. Cir. 2005); *see also In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988) (providing non-exhaustive list of factors to be considered in the enablement analysis).

The following Asserted Claims fail the written description requirement for at least the following reasons:

- ’012 Patent – Claims 1-7, 9 - “collapsible tubular sidewall” – The ’012 Patent specification does not use the term “collapsible tubular sidewall.” Nor does the specification describe a structure that a person of ordinary skill in the art would understand to fall within this claim term. Consequently, the specification does not reasonably convey to those skilled in the art that the inventor had possession of a valve having the “collapsible tubular sidewall” as of the earliest claimed priority date. Thus, the claims lack written description and are invalid.
- ’012 Patent – Claims 1-7, 9 - “a collapsible tubular sidewall defining a valve lumen in communication with the central lumen” - The ’012 Patent specification does not use the term “collapsible tubular sidewall.” Nor does the specification describe a structure that a person of ordinary skill in the art would understand to fall within this claim term. Consequently, the specification does not reasonably convey to those skilled in the art that the inventor had possession of a valve having the “collapsible tubular sidewall” as of the earliest claimed priority date. Thus, the claims lack written description and are invalid.
- ’291 Patent – Claims 1-8, 12-17, 19 – “a support” – The ’291 Patent specification does not use the term “support.” Nor does the specification describe a structure that a person of ordinary skill in the art would understand to fall within this claim term. Consequently, the specification does not reasonably convey to those skilled in the art that the inventor had possession of a valve having the “support” as of the earliest claimed priority date. Thus, the claims lack written description and are invalid.
- ’291 Patent – Claims 1-8, 12-17, 19 – “collapsible tubular sidewall” - The ’291 Patent specification does not use the term “collapsible tubular sidewall.” Nor does the specification describe a structure that a person of ordinary skill in the art would understand to fall within this claim term.

Consequently, the specification does not reasonably convey to those skilled in the art that the inventor had possession of a valve having the "collapsible tubular sidewall" as of the earliest claimed priority date. Thus, the claims lack written description and are invalid.

- '005 Patent – Claims 1-7, 9-15 – "a housing" and "a clot cannister" – The '005 Patent specification does not use the term "clot cannister" and does not use the term "housing" consistent with the claim. Nor does the specification describe a vacuum aspiration system having a "housing" and a "clot cannister" as described in the claims. Consequently, the specification does not reasonably convey to those skilled in the art that the inventor had possession of a vacuum aspiration system having the "housing" and "clot cannister" as of the earliest claimed priority date. Thus, the claims lack written description and are invalid.
- '005 Patent – Claims 1-7, 9-15 – "hemostasis valve in the housing" – The '005 Patent does not use the term "housing" consistent with the claim. Nor does the specification describe a vacuum aspiration system having a "housing" and a "hemostasis valve" as described in the claims. Consequently, the specification does not reasonably convey to those skilled in the art that the inventor had possession of a vacuum aspiration system having a "hemostasis valve in the housing" as of the earliest claimed priority date. Thus, the claims lack written description and are invalid.
- '005 Patent – Claims 1-7, 9-15 – "hemostasis valve" having the features recited in the claims including a "tubular member," "a collapsible tubular sidewall," "a filament," "an actuator," "a biasing system," and a "spring" - The '005 Patent does not use the terms "tubular member," "a collapsible tubular sidewall," "a filament," "an actuator," "a biasing system," and a "spring" as they are used in the claim. Nor does the specification

describe a vacuum aspiration system having a "hemostasis valve" with the claimed features. To the extent Inari argues that any disclosure related to the hemostasis valve has been incorporated by reference from another reference, the incorporation is ineffective. Consequently, the specification does not reasonably convey to those skilled in the art that the inventor had possession of a vacuum aspiration system having a "hemostasis valve" with the described features as of the earliest claimed priority date. Thus, the claims lack written description and are invalid.

- '005 Patent – Claims 10-15 – "a support" – The '005 Patent specification does not use the term "support." Nor does the specification describe a structure that a person of ordinary skill in the art would understand to fall within this claim term. Consequently, the specification does not reasonably convey to those skilled in the art that the inventor had possession of a valve having the "support" as of the earliest claimed priority date. Thus, the claims lack written description and are invalid.
- '005 Patent – Claims 10-15 – "collapsible tubular sidewall" - The '005 Patent specification does not use the term "collapsible tubular sidewall." Nor does the specification describe a structure that a person of ordinary skill in the art would understand to fall within this claim term. Consequently, the specification does not reasonably convey to those skilled in the art that the inventor had possession of a valve having the "collapsible tubular sidewall" as of the earliest claimed priority date. Thus, the claims lack written description and are invalid.
- '691 Patent – Claims 14-22 – "an aspiration pump in communication with a first chamber" - The '691 Patent specification does not use the term "aspiration pump." Nor does the specification describe a structure that a person of ordinary skill in the art would understand to fall within this claim term. Consequently, the specification does not reasonably convey

to those skilled in the art that the inventor had possession of an aspiration system having "an aspiration pump in communication with a first chamber" as of the earliest claimed priority date. Thus, the claims lack written description and are invalid.

- '691 Patent – Claims 14-22 – "a first chamber," "a second chamber," "wherein the second chamber is removably coupled between the aspiration pump and the aspiration catheter" – The '691 patent specification does not use the terms "aspiration pump," "first chamber," or "second chamber." Nor does the specification describe a structure having "a first chamber," "a second chamber" and "wherein the second chamber is removably coupled between the aspiration pump and the aspiration catheter." Consequently, the specification does not reasonably convey to those skilled in the art that the inventor had possession of an aspiration system having the claimed features as of the earliest claimed priority date. Thus, the claims lack written description and are invalid.
- '691 Patent – Claims 14-22 – "wherein the valve is configured to be closed while negative pressure is generated in the first and second chambers" - The '691 patent specification does not use the terms "first chamber" or "second chamber." Nor does the specification describe a structure "wherein the valve is configured to be closed while negative pressure is generated in the first and second chambers." Consequently, the specification does not reasonably convey to those skilled in the art that the inventor had possession of an aspiration system having the claimed features as of the earliest claimed priority date. Thus, the claims lack written description and are invalid.
- '333 Patent – Claims 2 and 21 - "a catheter having a size of 16 French or greater" – The '333 Patent specification does not describe "a catheter having a size of 16 French or greater" as required by the claim.

Consequently, the specification does not reasonably convey to those skilled in the art that the inventor had possession of a method of treating a pulmonary embolism or deep vein thrombosis having the claimed steps as of the earliest claimed priority date. Thus, the claims lack written description and are invalid.

- ’333 Patent – Claims 11-12, and 30-31 - “decreasing tension on a filament” - The ’333 patent specification does not use the term “filament.” Nor does the specification describe a structure, or method of using a structure, that permits “decreasing tension on a filament.” Consequently, the specification does not reasonably convey to those skilled in the art that the inventor had possession of a method of treating a pulmonary embolism or deep vein thrombosis having the claimed steps as of the earliest claimed priority date. Thus, the claims lack written description and are invalid.
- ’333 Patent – Claims 18 and 37 - “an aspiration catheter having a size of 16 French or greater” – The ’333 Patent specification does not describe “an aspiration catheter having a size of 16 French or greater” as required by the claim. Consequently, the specification does not reasonably convey to those skilled in the art that the inventor had possession of a method of treating a pulmonary embolism or deep vein thrombosis having the claimed steps as of the earliest claimed priority date. Thus, the claims lack written description and are invalid.
- ’910 Patent – Claims 1-8, 11-15, 18-20 - “the second catheter has a size of 16 French or greater” - The ’910 Patent specification does not describe “a second catheter having a size of 16 French or greater” as required by the claim. Consequently, the specification does not reasonably convey to those skilled in the art that the inventor had possession of a clot treatment system having the claimed features as of the earliest claimed priority date.

Thus, the claims lack written description and are invalid.

- ’910 Patent – Claims 3, 12, 18 - “the first catheter has a size of 24 French, and wherein the size of the second catheter has [sic] is 16 French” - The ’910 Patent specification does not describe “the first catheter has a size of 24 French, and wherein the size of the second catheter has [sic] is 16 French.” Consequently, the specification does not reasonably convey to those skilled in the art that the inventor had possession of a clot treatment system having the claimed features as of the earliest claimed priority date. Thus, the claims lack written description and are invalid.
- ’910 Patent – Claims 4, 13, 19, and 20 - “the first pressure source is the same as the second pressure source” - The ’910 Patent specification does not describe a system where “the first pressure source is the same as the second pressure source.” Consequently, the specification does not reasonably convey to those skilled in the art that the inventor had possession of a clot treatment system having the claimed features as of the earliest claimed priority date. Thus, the claims lack written description and are invalid.
- ’910 Patent – Claims 5, 14, and 18 - “wherein the first pressure source and the second pressure source comprise an electric pump” - The ’910 Patent specification does not describe a system “wherein the first pressure source and the second pressure source comprise an electric pump.” Consequently, the specification does not reasonably convey to those skilled in the art that the inventor had possession of a clot treatment system having the claimed features as of the earliest claimed priority date. Thus, the claims lack written description and are invalid.
- ’910 Patent – Claim 7 – “hemostasis valve” having “a tubular member” and “filament” – The ’910 Patent specification does not use the terms “tubular member” and “filament.” Fruther, the ’910 Patent specification

does not describe a "hemostasis valve" having "a tubular member" and "filament." Consequently, the specification does not reasonably convey to those skilled in the art that the inventor had possession of a clot treatment system having the claimed features as of the earliest claimed priority date. Thus, the claims lack written description and are invalid.

C. <u>Improper Dependent Claim Under 35 U.S.C. § 112(d)</u>

35 U.S.C. § 112(d) requires:

> Subject to subsection (e), a claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed. A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers.

"A dependent claim that contradicts, rather than narrows, the claim from which it depends is invalid." *Multlayer Stretch Cling Film Holdings, Inc. v. Berry Plastics Corp.*, 831 F.3d 1350, 1362, (Fed. Cir. 2016).

The following Asserted Claims are improper dependent claims for at least the following reasons:

- '910 Patent – Claims 4, 13, 19, 20 - "the first pressure source is the same as the second pressure source" – These claims do not specify a further limitation and contradict the claims from which they depend because those claims require "a first pressure source" and a "second pressure source." Thus, the dependent claims are improper and invalid.
- '910 Patent – Claims 4, 13, 19, 20 - "wherein the first pressure source and the second pressure source comprise an electric pump" – These claims do not specify a further limitation and contradict the claims from which they depend because those claims require "a first pressure source" and a "second pressure source." Thus, the dependent claims are improper and invalid.
- '691 Patent – Claims 21– "wherein the clot material comprises a

pulmonary embolism" - This claim does not specify a further limitation of the claims from which it depends. Thus, the dependent claim is improper and invalid.

- '691 Patent – Claim 22 – "wherein the clot material comprises a deep vein thrombosis" - This claim does not specify a further limitation of the claims from which it depends. Thus, the dependent claim is improper and invalid.

D. <u>Improper Double Patenting by Inari</u>

Many of Inari's Asserted Claims are invalid for obviousness-type double patenting ("ODP"). The below table identifies the Asserted Claims that are invalid for double patenting and the reference(s) that render those claims invalid.

ODP Reference	Asserted Patent	Asserted Claims
11,697,012	11,554,005	1-7, 9-15
12,156,669	11,554,005	1-7, 9-15
11,697,012 + aspiration system reference (Garrison, Aklog, Laub, Mogi, etc.)	11,554,005	1-7, 9-15
11,865,291 + aspiration system reference (Garrison, Aklog, Laub, Mogi, etc.)	11,554,005	1-7, 9-15
11,849,963	11,554,005	1-7, 9-15
12,156,669	11,744,691	14-22
11,849,963	11,744,691	14-22
12,016,580	11,969,333	1-4, 6-12, 14-23, 25-31, 33-38

XIII. OBJECTIVE INDICIA OF NON-OBVIOUSNESS

Objective indicia of non-obviousness, also known as secondary considerations of non-obviousness, may be considered in an obviousness analysis, but do not control the ultimate conclusion of obviousness. *See Newell Cos., Inc. v. Kenney Mfg. Co.*, 864 F.2d 757, 768 (Fed. Cir. 1988). Where a strong showing of *prima facie* obviousness has been made, as is the case here (*see supra*, Sections V-XI), the Federal Circuit has repeatedly held that even relevant objective indicia supported by substantial evidence are insufficient to overcome obviousness. *See, e.g., Leapfrog*, 485 F.3d at 1162.

Secondary considerations of non-obviousness must be attributable to the claimed invention, and must be apart from what is unclaimed or in the prior art. *See In re Huai-Hung Kao*, 639 F.3d 1057, 1068 (Fed. Cir. 2011); *see also, e.g., Ormco Corp. v. Align Tech., Inc.*, 463 F.3d 1299, 1312 (Fed. Cir. 2006). Additionally, secondary considerations are relevant only where the patentee can establish a "nexus" between the secondary consideration and the claimed invention. *See, e.g., In re GPAC Inc.*, 57 F.3d 1573, 1580 (Fed. Cir. 1995). Moreover, "[e]vidence of secondary considerations must be reasonably commensurate with the scope of the claims." *Huai-Hung Kao*, 639 F.3d at 1068.

Discovery in this case is in its early stages. Imperative Care reserves the right to amend, supplement, and/or modify these Preliminary Invalidity Contentions—or to proffer expert reports—to respond to Inari's purported evidence of objective indicia of non-obviousness as fact and expert discovery proceeds in this case.

A. <u>No Nexus</u>

Imperative Care is not aware of any alleged secondary consideration with a nexus to any of the Asserted Claims, that could support a finding of non-obviousness. Imperative Care reserves the right to respond to any contention by Inari of any such nexus.

B. No Unexpected Results

Imperative Care is not aware of any evidence of unexpected results that could support a finding of non-obviousness. Imperative Care reserves the right to respond to any contention by Inari of any such unexpected results.

C. No Commercial Success

Imperative Care is not aware of any evidence of commercial success that could support a finding of non-obviousness. Imperative Care reserves the right to respond to any contention by Inari of any such commercial success.

D. No Long-Felt but Unmet Need

Imperative Care is not aware of any evidence of long-felt but unmet need that could support a finding of non-obviousness. Imperative Care reserves the right to respond to any contention by Inari of any such long-felt but unmet need.

E. No Industry Praise or Skepticism

Imperative Care is not aware of any evidence of industry praise or skepticism that could support a finding of non-obviousness. Imperative Care reserves the right to respond to any contention by Inari of any such industry praise or skepticism.

F. No Copying

Imperative Care is not aware of any evidence of copying that could support a finding of non-obviousness. Imperative Care reserves the right to respond to any contention by Inari of any such copying.

G. No Failure by Others

Imperative Care is not aware of any evidence of failure of others that could support a finding of non-obviousness. Imperative Care reserves the right to respond to any contention by Inari of any such failure of others.

XIV. IMPERATIVE'S DOCUMENT PRODUCTION ACCOMPANYING ITS INVALIDITY CONTENTIONS (PLR 3-4)

- **PLR 3-4(a): "Source code, specifications, schematics, flow charts, artwork, formulas, or other documentation sufficient to show the operation of any aspects or elements of an Accused Instrumentality identified by the patent claimant in its Patent L.R. 3-1(c) chart."**

Documents providing the information required by Patent Local Rule 3-4(a) can be found at IC_00000001-IC_00004727. However, in identifying this bates range, Imperative Care does not mean to represent, and does not represent, that each document in the range is responsive to this Patent Local Rule.

- **PLR 3-4(b): "A copy or sample of the prior art identified pursuant to Patent L.R. 3-3(a) which does not appear in the file history of the patent(s) at issue. To the extent any such item is not in English, an English translation of the portion(s) relied upon shall be produced."**

Documents providing the information required by Patent Local Rule 3-4(b) can be found at IC_00005028-IC_00006768. However, in identifying this bates range, Imperative Care does not mean to represent, and does not represent, that each document in the range is responsive to this Patent Local Rule.

- **PLR 3-4(c): "All agreements that may be related to the accused instrumentality or may be comparable to a license that would result from a hypothetical reasonable royalty negotiation."**

Documents providing the information required by Patent Local Rule 3-4(c) can be found at IC_00004728-IC_00005027. However, in identifying this bates range, Imperative Care does not mean to represent, and does not represent, that each document in the range is responsive to this Patent Local Rule.

- **PLR 3-4(d): "Documents sufficient to show the sales, revenue, cost, and profits for accused instrumentalities identified pursuant to Patent L.R. 3-1(b) for any period of alleged infringement."**

Documents providing the information required by Patent Local Rule 3-4(d) can be found at IC_00006769.

- **PLR 3-4(e): "All agreements that may be used to support the party denying infringement's damages case."**

Documents providing the information required by Patent Local Rule 3-4(e) can be found at IC_00004728-IC_00005027. However, in identifying this bates range, Imperative Care does not mean to represent, and does not represent, that each document in the range is responsive to this Patent Local Rule.

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: February 27, 2025 By: */s/Joshua J. Stowell*
Joseph R. Re
Joshua J. Stowell
Nicholas A. Belair

Attorneys for Defendant
Imperative Care, Inc.

CERTIFICATE OF SERVICE

I am a citizen of the United States of America and I am employed in Irvine, California. I am over the age of 18 and not a party to the within action. My business address is 2040 Main Street, Fourteenth Floor, Irvine, California.

On February 27, 2025, I served the foregoing: **IMPERATIVE CARE, INC,'S PRELIMINARY INVALIDITY CONTENTIONS AND DOCUMENT PRODUCTION ACCOMPANYING INVALIDITY CONTENTIONS PURSUANT TO PATENT LOCAL RULES 3-3 AND 3-4** on the parties or their counsel shown below, by transmitting it electronically to the addresses as follows:

VIA ELECTRONIC MAIL:

Amanda Tessar Perkins Coie LLP 1900 Sixteenth Street Suite 1400 Denver, CO 80202 303-291-2357 Email: atessar@perkinscoie.com	Ramsey M. Al-Salam Perkins Coie LLP 1201 Third Avenue Suite 4000 Seattle, WA 98101-3099 206-359-8000 Email: ralsalam@perkinscoie.com
Daniel T. Keese DKeese@perkinscoie.com Perkins Coie LLP 1120 NW Couch Street, 10th Floor Portland, Oregon 97209-4128 Telephone: 503.757.2000	Kendrick R. Tyler RKendrick@perkinscoie.com 1201 Third Avenue Suite 4900 Seattle, WA 98101-3099
Trevor Bervik 1900 Sixteenth Street Suite 1400 Denver, CO 80202 TBervik@perkinscoie.com	Inari-Imperative@perkinscoie.com

I declare that I am employed in the office of a member of the bar of this Court at whose direction the service was made.

Executed on February 27, 2025, at Irvine, California.

/s/Chloe Lee
Chloe Lee
Litigation Paralegal