

Filed May 20, 2025

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

IMPERATIVE CARE, INC.,
Petitioner,

v.

INARI MEDICAL, INC.,
Patent Owner.

Case No. IPR2025-01025
Patent No. 11,974,910

**PETITION FOR *INTER PARTES* REVIEW OF
U.S. PATENT NO. 11,974,910**

TABLE OF CONTENTS

	Page No.
I. INTRODUCTION	1
II. THE '910 PATENT	8
A. Overview	8
B. Prosecution History	15
C. Earliest Possible Priority Date.....	18
III. LEVEL OF ORDINARY SKILL.....	18
IV. CLAIM CONSTRUCTION	19
V. STATEMENT OF RELIEF REQUESTED	21
A. IPR Grounds	21
B. The Asserted References Are Prior Art	21
C. The Asserted References Are Analogous Art	22
VI. GROUNDS 1-3: GARRISON COMBINED WITH LAUB AND/OR AKLOG RENDERS CLAIMS 1-6, 8, 11-15, 18-20 UNPATENTABLE.....	22
A. Independent Claim 1	22
1. Preamble.....	23
2. A First Clot Assembly	34
3. First Fluid Control Device	35
4. The First Pressure Source is Configured to Generate Vacuum Pressure.....	37
5. Second Clot Aspiration Assembly	39

TABLE OF CONTENTS
(cont'd)

	Page No.
a. Laub	42
b. Aklog	43
c. Garrison and Laub or Aklog.....	45
6. Second Pressure Source	48
7. Second Fluid Control Device.....	49
8. The Second Pressure Source is Configured to Generate Vacuum Pressure	54
9. The Vacuum Pressure is Applied.....	56
B. Claim 2	57
C. Claim 3	59
D. Claim 4	62
E. Claim 5	65
F. Claim 6	67
G. Claim 8	70
H. Independent Claim 11	71
I. Claim 12	73
J. Claim 13	73
K. Claim 14	73
L. Claim 15	74
M. Claim 18	74

TABLE OF CONTENTS
(cont'd)

	Page No.
N. Claim 19	74
O. Claim 20	75
VII. GROUNDS 4-6: GARRISON COMBINED WITH LAUB, AKLOG, AND/OR HARTLEY RENDERS CLAIMS 6-7, 20 UNPATENTABLE.....	75
A. Claim 6	75
B. Claim 7	75
C. Claim 20	82
VIII. GROUNDS 7-9: GARRISON COMBINED WITH LAUB AND/OR AKLOG AND PASHA	83
A. Claim 3	83
B. Claims 12 and 18.....	85
IX. SECONDARY CONSIDERATIONS	85
X. <i>SOTERA</i> STIPULATION.....	85
XI. MANDATORY NOTICES, GROUNDS FOR STANDING, AND FEE PAYMENT	85
A. Real Parties-In-Interest (37 C.F.R. §42.8(b)(1)).....	85
B. Related Matters (37 C.F.R. §42.8(b)(2)).....	86
C. Lead and Backup Counsel (37 C.F.R. §42.8(b)(3)).....	87
D. Service Information (37 C.F.R. §42.8(b)(4))	88
E. Grounds for Standing (37 C.F.R. §42.104).....	88

TABLE OF CONTENTS
(cont'd)

	Page No.
F. Payment of Fees (37 C.F.R. §42.15(a))	88
XII. CONCLUSION.....	89

TABLE OF AUTHORITIES

Page No(s).

<i>Apple v. Fintiv</i> , IPR2020-00019, Paper 11 (PTAB Mar. 20, 2020)	85
<i>KSR Int’l Co. v. Teleflex Inc.</i> , 550 U.S. 398 (2007).....	<i>passim</i>
<i>In re Nilssen</i> , 851 F.2d 1401 (Fed. Cir. 1988)	22
<i>Phillips v. AWH Corp.</i> , 415 F.3d 1303 (Fed. Cir. 2005)	19
<i>Unwired Planet, LLC v. Google Inc.</i> , 841 F.3d 995 (Fed. Cir. 2016)	22
<i>Vitronics Corp. v. Conceptronic, Inc.</i> , 90 F.3d 1576 (Fed. Cir. 1996)	19

OTHER AUTHORITIES

35 U.S.C. §102.....	21
35 U.S.C. §103.....	23
35 U.S.C. §112.....	62
37 C.F.R. §42.8	85,86, 87
37 C.F.R. §42.15	88
37 C.F.R. §42.100	19
37 C.F.R. §42.104	88

LIST OF EXHIBITS

Exhibit No.	Description
1001	U.S. Patent No. 11,974,910 (“the ’910 patent”)
1002	’910 Patent Prosecution History
1003	Expert Declaration of Troy Thornton
1004	Resume of Troy Thornton
1005	U.S. Patent No. 8,734,374 B2 to Aklog et al. (“Aklog”)
1006	U.S. Patent Publication No. 2015/0173782 A1 to Garrison et al. (“Garrison”)
1007	WIPO Publication No. WO 2006/124307 A2 to Goff et al. (“Goff”)
1008	U.S. Patent Publication No. 2003/0116731 A1 to Hartley (“Hartley”)
1009	U.S. Patent No. 6,776,770 B2 to Trerotola (“Trerotola”)
1010	U.S. Patent Publication No. 2010/0042118 A1 to Garrison et al.
1011	U.S. Patent No. 8,535,283 B2 to Heaton et al. (“Heaton”)
1012	U.S. Patent Publication No. 2017/0043066 A1 to Laub (“Laub”)
1013	U.S. Patent Publication US 2003/0225379 A1 to Schaffer et al. (“Schaffer”)
1014	U.S. Patent No. 5,938,645 to Gordon (“Gordon”)
1015	U.S. Patent Publication No. 2014/0296868 A1 to Garrison et al.
1016	U.S. Patent No. 7,998,104 B2 to Chang (“Chang”)
1017	U.S. Patent No. 8,157,760 B2 to Criado et al. (“Criado”)
1018	U.S. Patent No. 6,481,439 B1 to Lewis et al.
1019	U.S. Patent No. 8,075,510 B2 to Aklog et al.
1020	WIPO Publication No. WO 2018/019829 A1 to Brady et al. (“Brady”)

Exhibit No.	Description
1021	U.S. Patent Application No. 16/117,519 (the “519 application”)
1022	Expert Declaration of Dr. Aquilla S. Turk, III, DO
1023	Resume of Dr. Aquilla Turk, III, D.O.
1024	Shani, Jacob M.D., et al., Mechanical Manipulation of Thrombus: Coronary Thrombectomy, Intracoronary Clot Displacement, and Transcatheter Aspiration, 72 Am. J. Cardiol. 116G-118G (1993)
1025	Bose, A et al., The Penumbra System: A Mechanical Device for the Treatment of Acute Stroke due to Thromboembolism, 29 Am. J. Neuroradiol. 1409-1413 (Aug. 2008)
1026	Turk, Aquilla S. et al., Initial clinical experience with the ADAPT technique: A direct aspiration first pass technique for stroke thrombectomy, 6 J. NeuroIntervent. Surg. 231-237 (2014)
1027	Turk, Aquilla S. et al., ADAPT FAST study: a direct aspiration first pass technique for acute stroke thrombectomy, 6 J. NeuroIntervent. Surg. 260-264 (2014)
1028	April 24, 2024 Letter from Inari to Imperative Care
1029	Turk, Aquilla S. et al., Aspiration thrombectomy versus stent retriever thrombectomy as first-line approach for large vessel occlusion (COMPASS): a multicentre, randomized, open label, blinded outcome, non-inferiority trial, 393 Lancet 998-1008 (March 2019)
1030	Save, Jeffrey L., Time is Brain – Quantified, American Heart Association Journals, available at http://www.stokeaha.org (2005).
1031	U.S. Patent No. 9,980,813 B1 to Eller (“Eller”)
1032	US 2018/0064453 A1 (“Garrison II”)
1033	US 2005/0054995 A1 (“Barzell”)
1034	Decision Granting Institution of <i>Inter Partes</i> Review for U.S. Patent No. 11,697,011 (Paper 7) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2024-01157 (P.T.A.B. Jan. 23, 2025)

Exhibit No.	Description
1035	Decision Granting Institution of <i>Inter Partes</i> Review for U.S. Patent No. 11,697,012 (Paper 6) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-00156 (P.T.A.B. Apr. 22, 2025)
1036	U.S. Patent No. 12,109,384 B2 to Merritt et al.
1037	Patent Owner’s Exhibit 2002 filed in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-00289 (P.T.A.B.)
1038	Indigo Aspiration System-Penumbra Engine Pump and Canister, 510(k) No. K180105 (Mar. 8, 2018) (“Indigo Aspiration System”)
1039	AXS Universal Aspiration Set Brochure (2017)
1040	VacLok Negative Pressure Syringe Brochure
1041	O. Nikoubashman et al., Under Pressure: Comparison of Aspiration Techniques for Endovascular Mechanical Thrombectomy, 39 Am. J. Neuroradiol. 905-909 (May 2018) (“Nikoubashman”)
1042	Inari’s Supplemental Infringement Contentions (without claim charts) from <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , No. 24-cv-3117 (N.D. Cal.) (served February 7, 2025)
1043	Inari’s Notice of Motion and Motion for Leave to File Third Amended Complaint (Dkt. #88) in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 24-cv-03117-EKL (N.D. Cal.) (filed March 5, 2025)
1044	Case Management & Scheduling Order (Dkt. #54) in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 24-cv-03117-EKL (N.D. Cal.) (issued December 19, 2024)
1045	Decision Denying Institution of <i>Inter Partes</i> Review for U.S. Patent No. 11,744,691 (Paper 10) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2024-01257 (P.T.A.B. Feb. 7, 2025)
1046	U.S. Patent No. 7,984,730 B2 to Ziv et al.
1047	Imperative Care’s Opposition to Inari’s Motion for Leave to File Third Amended Complaint (Dkt. #98) in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 24-cv-03117-EKL (N.D. Cal.) (filed March 26, 2025)

Exhibit No.	Description
1048	Imperative Care’s Notice of Motion and Motion to Stay Pending <i>Inter Partes</i> Review (Dkt. #100) in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 24-cv-03117-EKL (N.D. Cal.) (filed April 2, 2025)
1049	Ahmed Pasha et al., Successful Management of Acute Massive Pulmonary Embolism Using Angiovac Suction Catheter Technique in a Hemodynamically Unstable Patient, 15 <i>Cardiovasc. Revasc. Med.</i> 240-243 (2014)
1050	Certified File History of U.S. Patent Application 10/371,190 (Schaffer File History)
1051	Maureen Kohi, Catheter Directed Interventions for Acute Deep Vein Thrombosis, 6 <i>Cardiovasc. Diagn. Ther.</i> 599-611 (2016)
1052	Interview Summary from U.S. Patent Application No. 18/329,450 dated January 31, 2024
1053	Claim Construction Expert Report of Troy Thornton in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 24-cv-03117-EKL (N.D. Cal.)

Petitioner Imperative Care, Inc. (“Petitioner”) requests *inter partes* review (“IPR”) of claims 1-8, 11-15, and 18-20 (“the challenged claims”) of U.S. Patent No. 11,974,910 (“the ’910 patent,” Ex.1001), which is assigned to Inari Medical, Inc. (“Patent Owner” or “PO”).

I. INTRODUCTION

Patent Owner has asserted claims 1-8, 11-15, and 18-20 against Petitioner in the co-pending district court litigation (the “Litigation”). *See* Ex. 1042 (PO’s infringement contentions). The Litigation is in its early stages and no trial date has been set. (*See* Ex. 1043 at 2 (representing to Court that “discovery is at an early stage”); Ex. 1044 (setting case schedule to claim construction).) Therefore, Petitioner challenges the patentability of the asserted claims in this IPR.

The accumulation of unwanted material, such as blood clots, in a patient’s vasculature can cause serious conditions, including stroke and death. Over the last several decades, medical device companies have developed devices to remove such undesirable material from the vasculature, including catheter-based systems that aspirate (i.e., suction) the material from the blood vessel.

The ’910 patent claims such a clot treatment system. However, the patent provides little description regarding what is new and nonobvious about the claimed system. The patent generically states, “there exists a need for improved systems and methods for embolic extraction” and argues that prior art systems were “highly

complex,” “cause trauma to the treatment vessel,” and “may not completely capture and/or collect all of the clot material.” (Ex. 1001, 2:33-46.) However, the ’910 patent does not explain how the claimed system addresses these alleged shortcomings.

Instead, the claims describe a clot treatment system comprised of two clot aspiration assemblies having conventional aspiration components, including first and second catheters [orange], first and second pressure sources [red], two valves [yellow], and first and second fluid control devices [purple] to fluidly connect and disconnect the pressure source from the catheter:

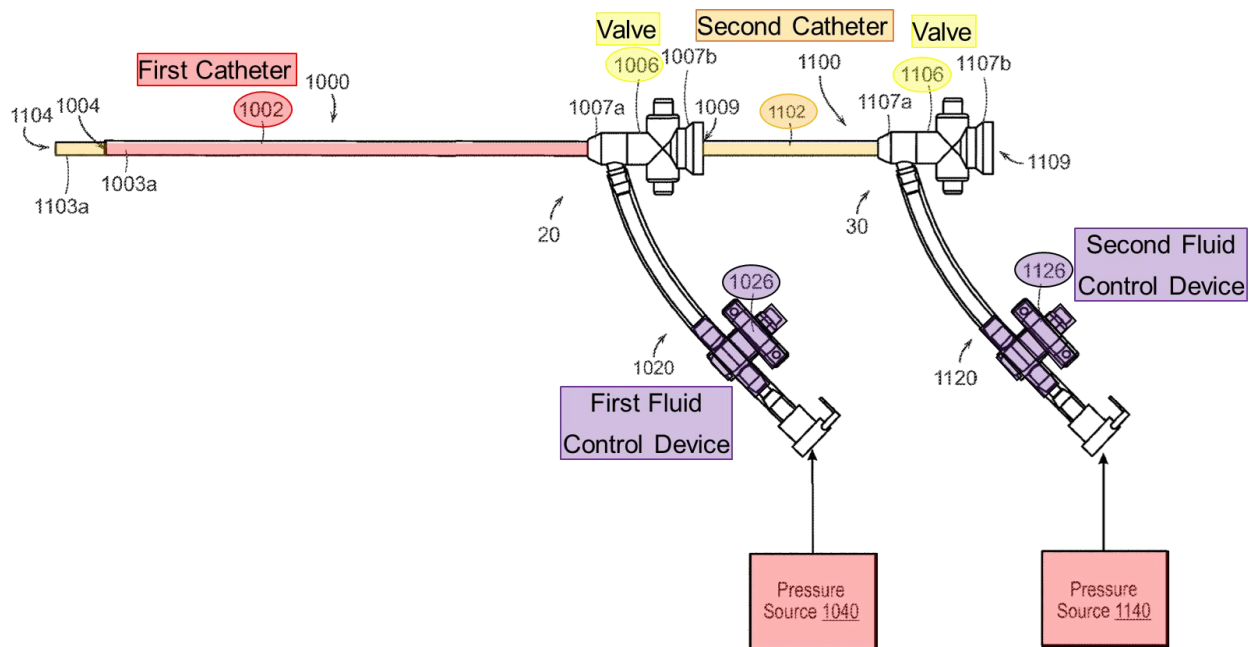
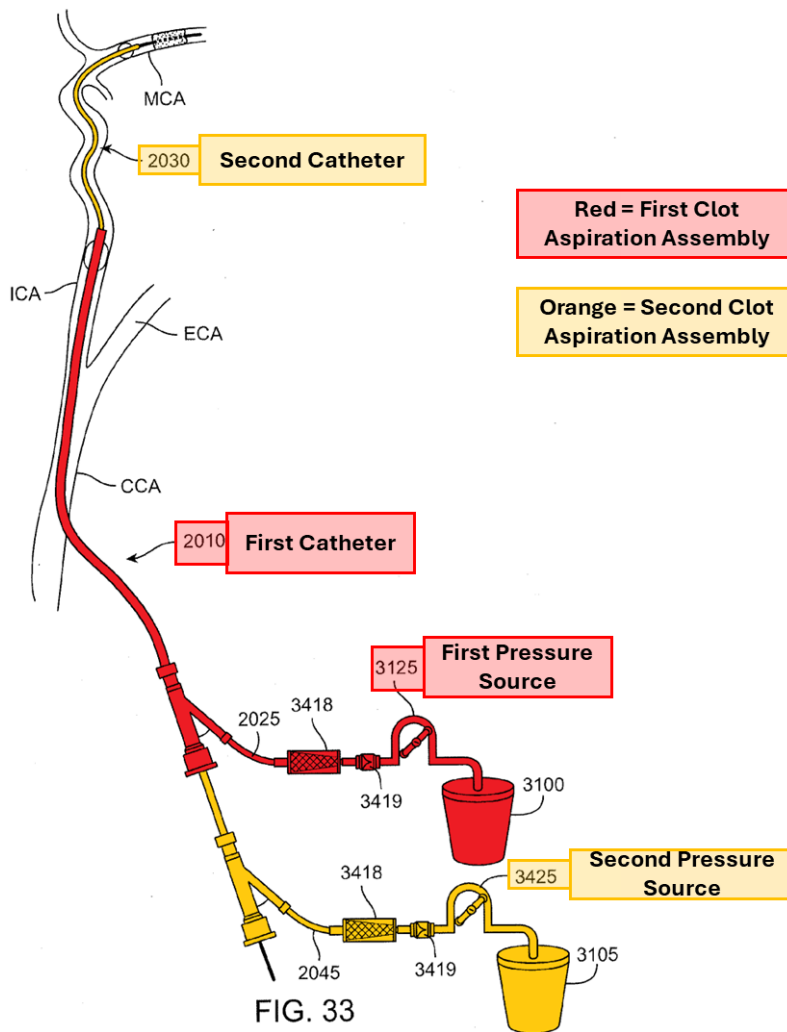


FIG. 11

(*Id.*, Fig. 11.) As demonstrated below, clot treatment systems having these conventional components were known and used before August 2018, the earliest claimed priority date of the ’910 patent.

Garrison, a prior art patent application published in June 2015, describes clot treatment systems for removing clots from patients. In one embodiment, Garrison describes an aspiration system having (1) a first clot aspiration assembly with a first catheter and first pressure source [red] and (2) a second clot aspiration assembly with a second catheter and a second pressure source [orange]:



(Ex. 1006, [0131]-[0134], Fig. 33). In related embodiments, Garrison incorporates a valve 3325 (i.e., fluid control device) to fluidly connect and disconnect the pressure source from the catheter(s):

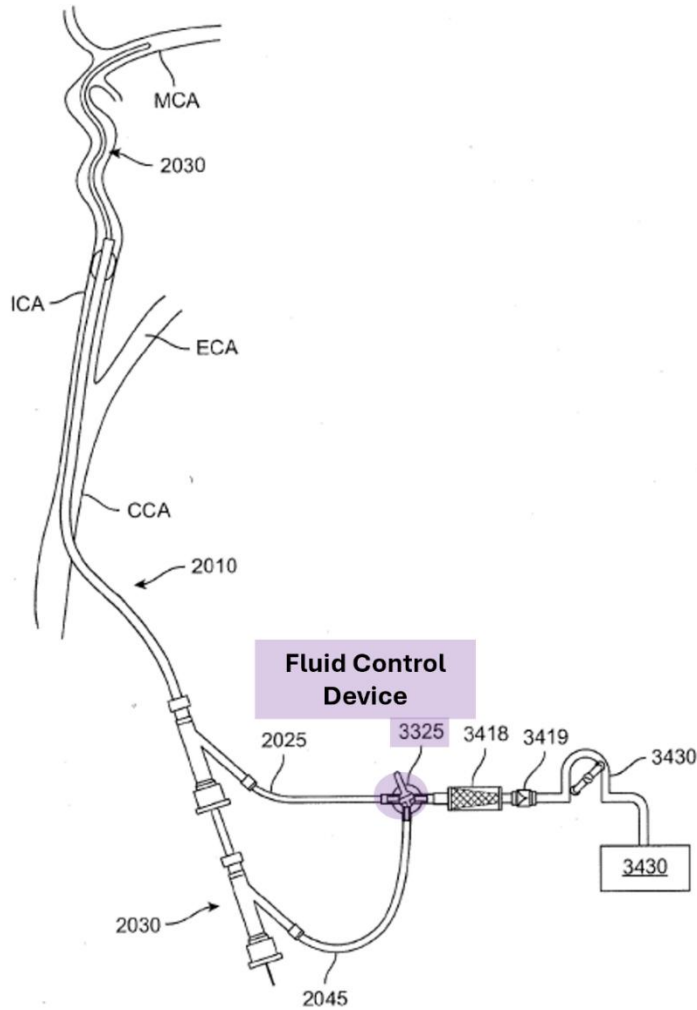


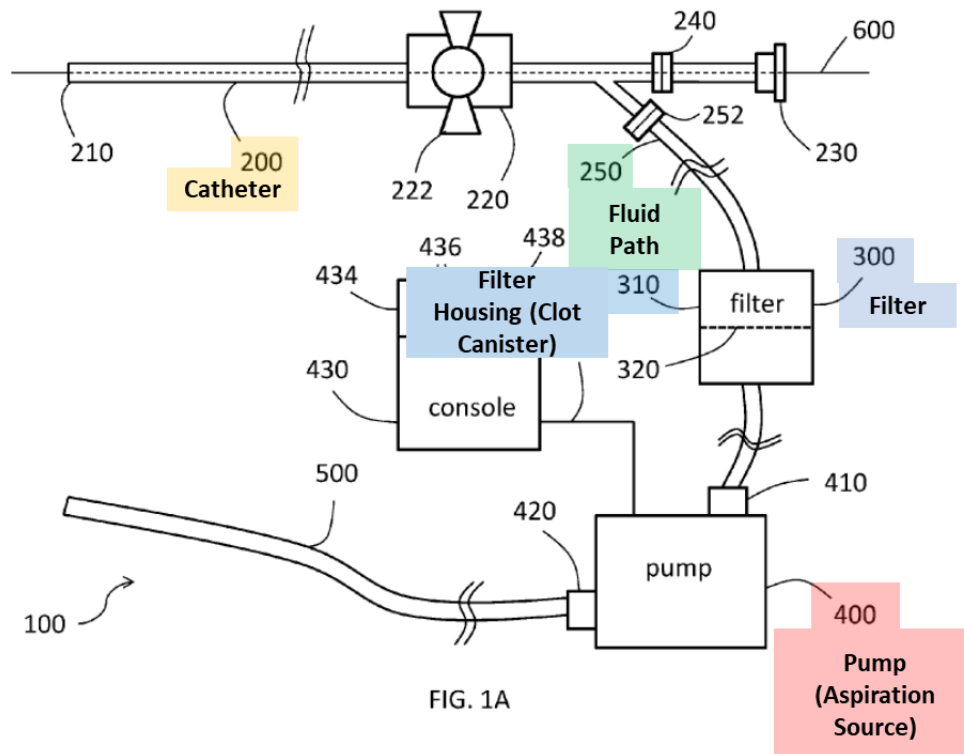
FIG. 34

(*Id.*, [0132], Fig. 34.)

During prosecution of the '910 patent, the Examiner found that Garrison disclosed almost every limitation of claim 1. (Ex. 1002, 43-51.) The only limitations the Examiner did not find in Garrison were a description of using Garrison's system to treat a *pulmonary embolism* ("PE") and a second catheter having a size of **16 French or greater**.

Garrison describes using its clot treatment system to remove cerebral clots but does not expressly mention PEs. (Ex. 1006, [0002].) Garrison discloses removing the clots with varying sizes of catheter, which generally range from 5 French to 10 French. (*See e.g., id.*, [0063], [0066], [0082], [0124].) The Examiner mistakenly allowed the '910 patent over Garrison based on an interview with one of the named inventors in which the Examiner was convinced that “[i]t would be unreasonable to modify the clot treatment device of Garrison to be used for pulmonary embolisms.” (Ex. 1002, 43-51.) As shown herein, this is not true.

Treating PEs with a catheter size 16 French or greater was not new. **Laub**, a prior art patent application published in February 2017, discloses a clot treatment “system for removing thrombi and other unwanted material from the body of a patient, particularly from the patient’s vasculature.” (Ex. 1007, [0005].) Laub was *not* before the Examiner. Laub expressly describes using aspiration catheters having a size of 16 French or greater to treat PE, the very limitations that were allegedly missing from the prior art. (*Id.; see also id.*, [0028].) Like Garrison, Laub’s clot treatment system includes an aspiration catheter connected to a pump (i.e., pressure source) and a filter:



(*Id.*, [0024], [0039]-[0040], Fig. 1A.) Laub discloses using catheters ranging from 5 French to 20 French and specifically describes, “[i]n some embodiments, aspiration catheter 200 has a French *size of at least 16 Fr.*” (*Id.*, [0028] (emphasis added).)

Aklog, a prior art patent issued in May 2014, also discloses a clot treatment system for removing PEs from blood vessels. (Ex. 1005, 2:7-32, 7:27-42.) Aklog also was *not* before the Examiner. Like Garrison and Laub, Aklog’s system includes an aspiration catheter [orange] coupled to a pump (i.e., pressure source) [red], and a filter device [blue].

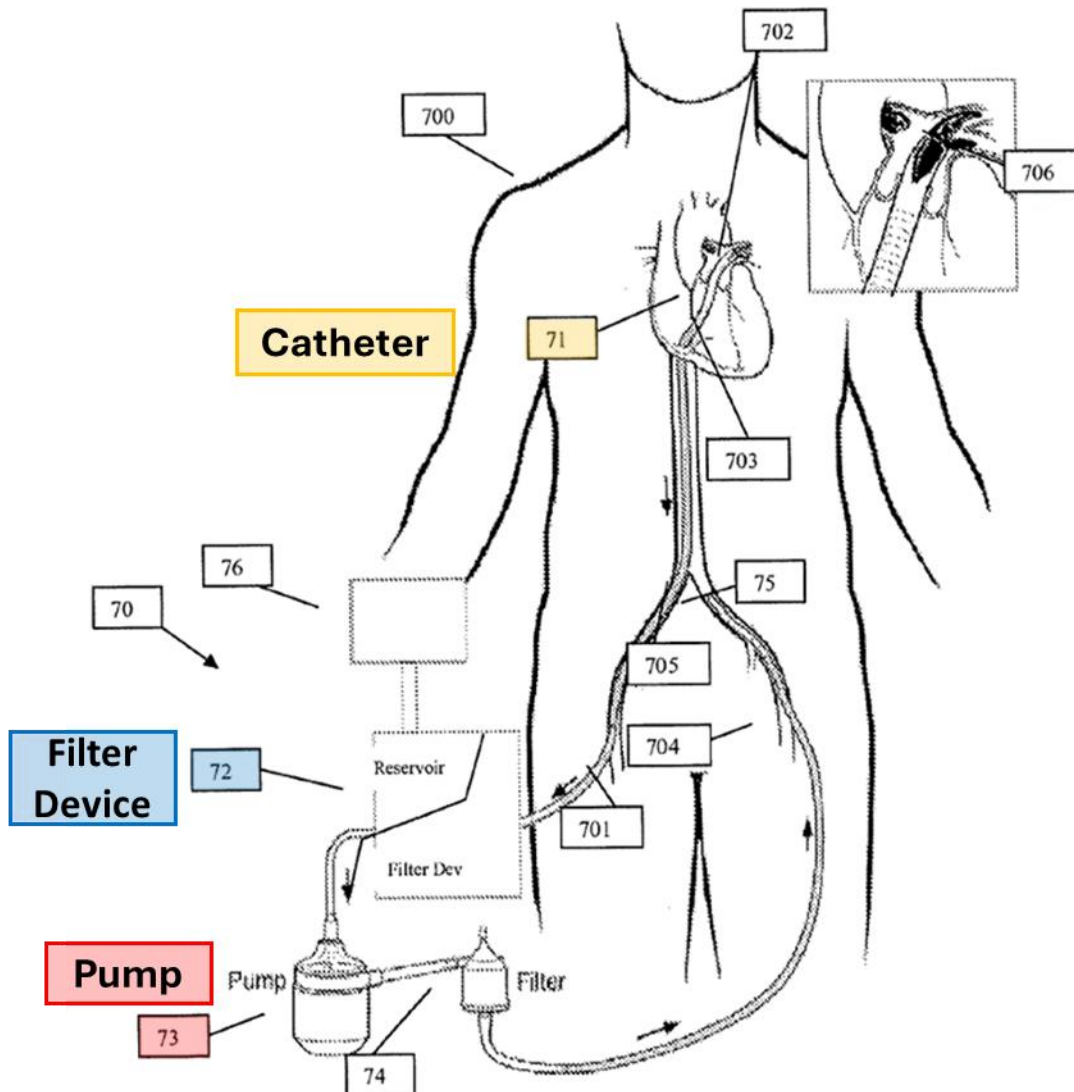


Fig. 7

(*Id.*, Fig. 7.) Aklog discloses that the catheter “may be of any sufficient size, so long as it can be accommodated within a predetermined vessel, such as a medium to large size blood vessel.” (*Id.*, 11:12-15.) Aklog specifically discloses use of its catheters in the “pulmonary circulation (e.g., pulmonary arteries).” (*Id.*, 5:34-35.)

As demonstrated below, a person of ordinary skill in the art (“POSITA”) would have found it obvious to use Garrison’s clot treatment system to treat PE *and*

to upsize one or more of Garrison’s catheters to 16 French or larger based on Laub and Aklog. The challenged claims merely recite using known clot treatment systems and prior art catheter components according to their known functions to predictably aspirate known clots (i.e., PE). *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007). Thus, the prior art grounds identified in this Petition show a reasonable likelihood that one or more claims of the ’910 patent are unpatentable. Accordingly, Petitioner requests that the Board institute this IPR to reconsider the patentability of the ’910 patent.

II. THE ’910 PATENT

A. Overview

The ’910 patent describes an aspiration system for intravascular removal of clot material and alleges that the system can treat various clots including PE, cerebral embolism, and DVT. (Ex. 1001, 4:17-58.) The aspiration system includes an “assembly 10” having a “catheter subsystem 100,” “pressure source 140,” and “tubing subsystem 120.” (*Id.*, 5:25-30.) The catheter subsystem also has a catheter 102 [orange below] “comprising an elongated shaft defining a lumen 104,” and a “valve 106” [yellow below] with a “lumen 109 extending therethrough.” (*Id.*, 5:30-40.)

The ’910 patent discloses the pressure source [red] is “configured to generate (e.g., form, create, charge, build-up, etc.) a vacuum (e.g., negative relative pressure)

and store the vacuum for subsequent applications to the catheter subsystem 100.”
(*Id.*, 6:57-60.) “[T]he pressure source can be a pump (e.g., an electric pump coupled to a vacuum chamber) while, in other embodiments, the pressure source can include one or more syringes that can be actuated or otherwise activated by a user of the assembly 10 to generate and store a vacuum therein.” (*Id.*, 7:36-41.)

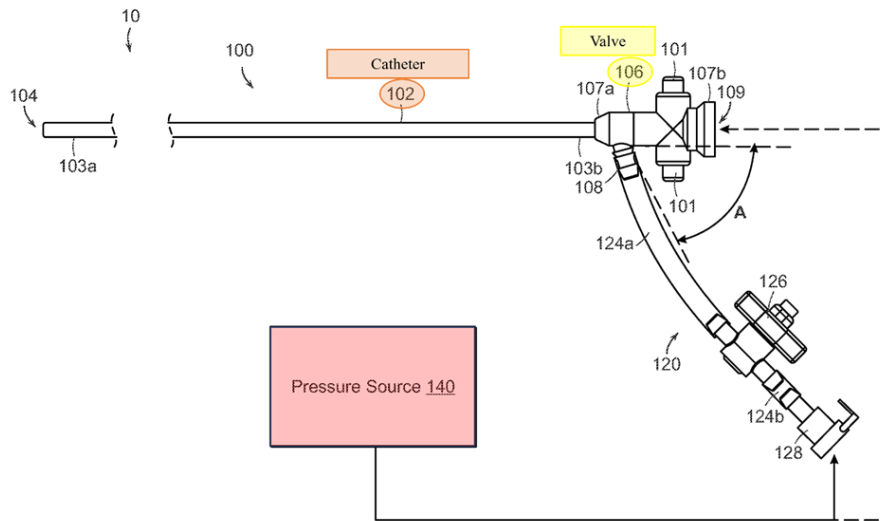


FIG. 1

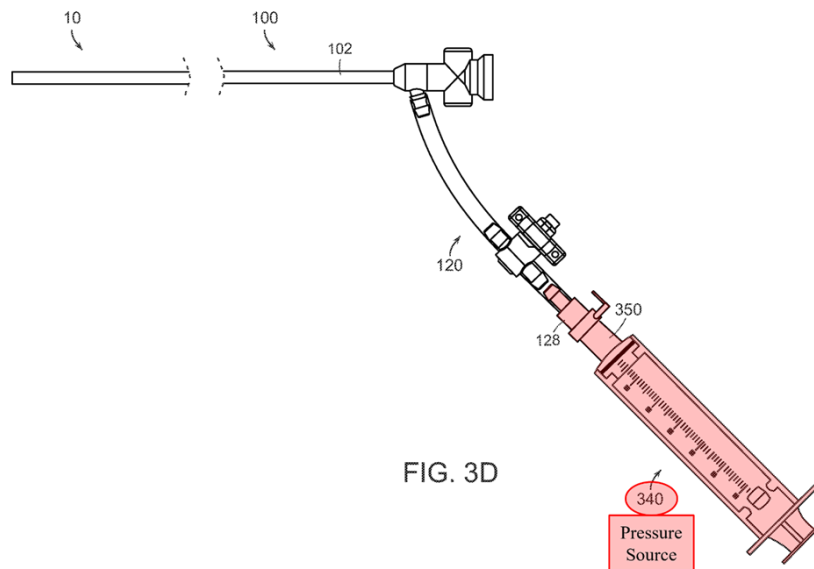


FIG. 3D

(*Id.*, Figs. 1, 3D.)

The '910 patent explains that the tubing subsystem “fluidly couples the catheter subsystem 100 to the pressure source 140.” (*Id.*, 6:6-7.) The tubing subsystem can include “one or more tubing sections 124” [green], at least one “fluid control device 126” [purple] such as a stopcock, and at least one “connector 128 for fluidly coupling the tubing subsystem 120 to the pressure source 140 and/or other suitable components.” (*Id.* 6:6-24.)

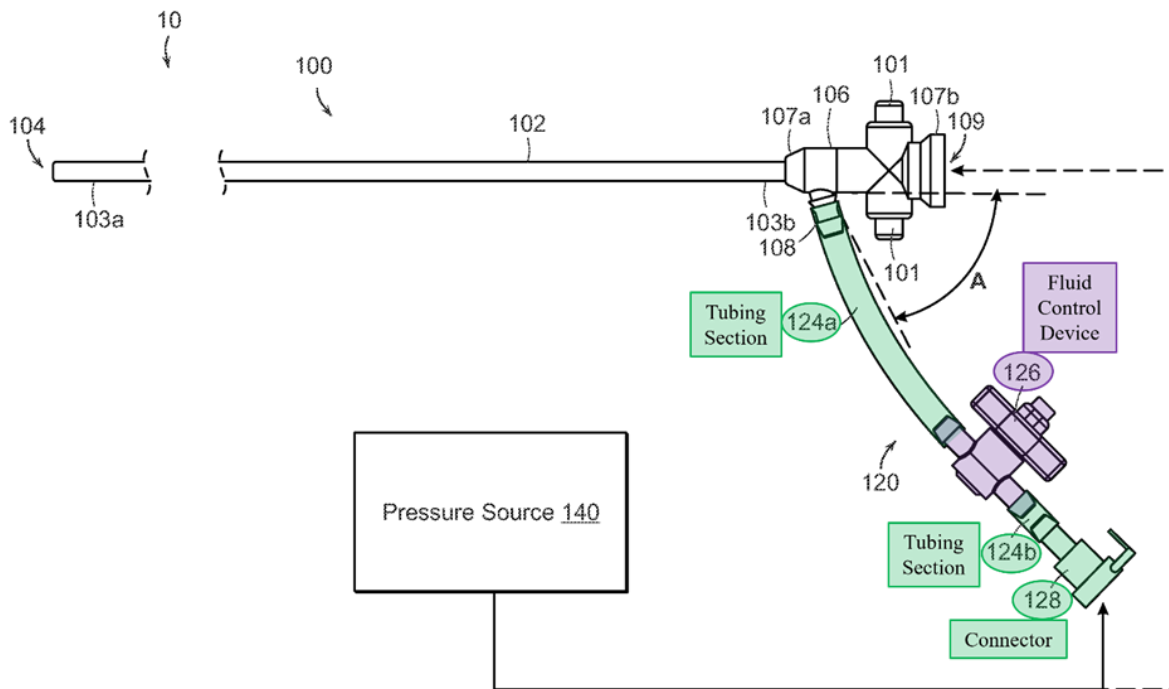
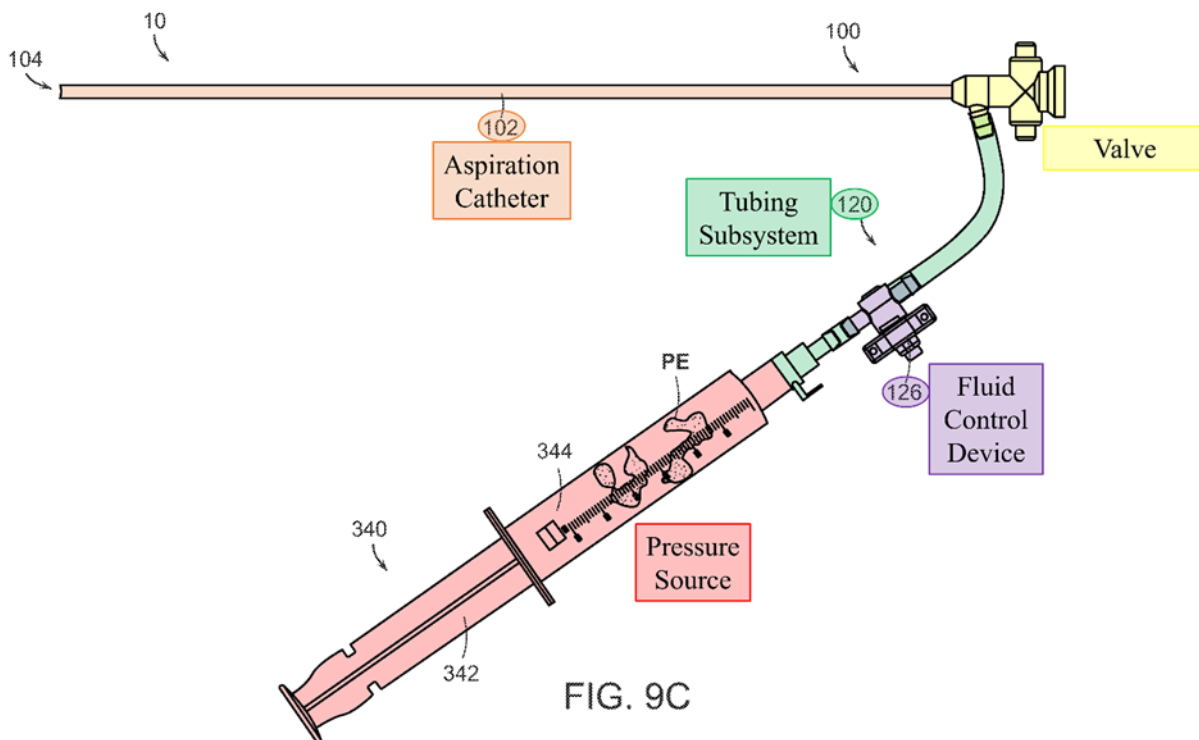


FIG. 1

(*Id.*, Fig. 1.)

The '910 patent explains that a user “can first close the fluid control device 126 before activating the pressure source 140 to build up vacuum pressure within the pressure source 140 (e.g., a vacuum chamber of the pressure source 140).” (*Id.*,

6:62-66.) After pressure is generated, “the user can actuate (e.g., twist a handle of) the fluid control device 126 to open the fluid control device 126.” (*Id.*, 18:44-48.) Opening the fluid control device 126 will “fluidly connect the pressure source 140 to the catheter subsystem 100 and thereby apply or release the vacuum stored in the pressure source 140 to the lumen 104 of the catheter 102.” (*Id.*, 7:3-8.)



(*Id.*, Fig. 9C.) The '910 patent also explains that “[o]pening of the fluid control device 126 instantaneously or nearly instantaneously applies the stored vacuum pressure to the tubing subsystem 120 and the catheter 102, thereby generating suction throughout the catheter 102.” (*Id.*, 7:8-12.)

The '910 patent describes variations of the aspiration system described above. For example, the '910 patent describes a variation with “a first aspiration assembly

20 and a second aspiration assembly 30.” (*Id.*, 20:60-62.) The ’910 patent explains that “the first and second aspiration assemblies 20, 30 (“assemblies 20, 30”) include some features generally similar to the features of the aspiration assembly 10 described in detail above with reference to FIGS. 1-10B.” (*Id.*, 20:62-66.) For example, the ’910 patent explains that the aspiration system includes a first aspiration assembly 20 having a “first catheter subsystem 1000,” “first pressure source 1040,” and “first tubing subsystem 1020.” (*Id.*, 20:65-21:5.) Similarly, the aspiration system includes a second aspiration assembly 30 having a “second catheter subsystem 1100,” “second pressure source 1140,” and “second tubing subsystem 1120.” (*Id.*, 21:5-12.)

The ’910 patent explains that the first tubing subsystem fluidly couples the first catheter subsystem 1000 to the first pressure source 1040 [red], and the second tubing subsystem fluidly couples the second catheter subsystem 1100 to the second pressure source 1140 [red]. (*Id.*, 20:65-21:12.) The first catheter subsystem also has a first catheter 1002 [red] “comprising an elongated shaft defining a lumen 1004,” a “valve 1006” [yellow] with a “lumen 1009... extending therethrough”, and a “first fluid control device 1026” [purple]. (*Id.*, 21:13-23.) The second catheter subsystem has a “second catheter... 1102” [orange] defining a “lumen... 1104,” and a “second valve... 1106” [yellow] with a “lumen... 1109 extending therethrough,” and a “second fluid control device 1126” [purple]. (*Id.*) The first fluid control device 1026

is configured to “regulate or control fluid flow between (e.g., fluidly connect or disconnect) the first pressure source 1040 and the first catheter subsystem 1000”. (*Id.*, 21:20-23.) Likewise, the second fluid control device 1126 is configured to “regulate or control fluid flow between (e.g., fluidly connect or disconnect) the second pressure source 1140 and the second catheter subsystem 1100”:

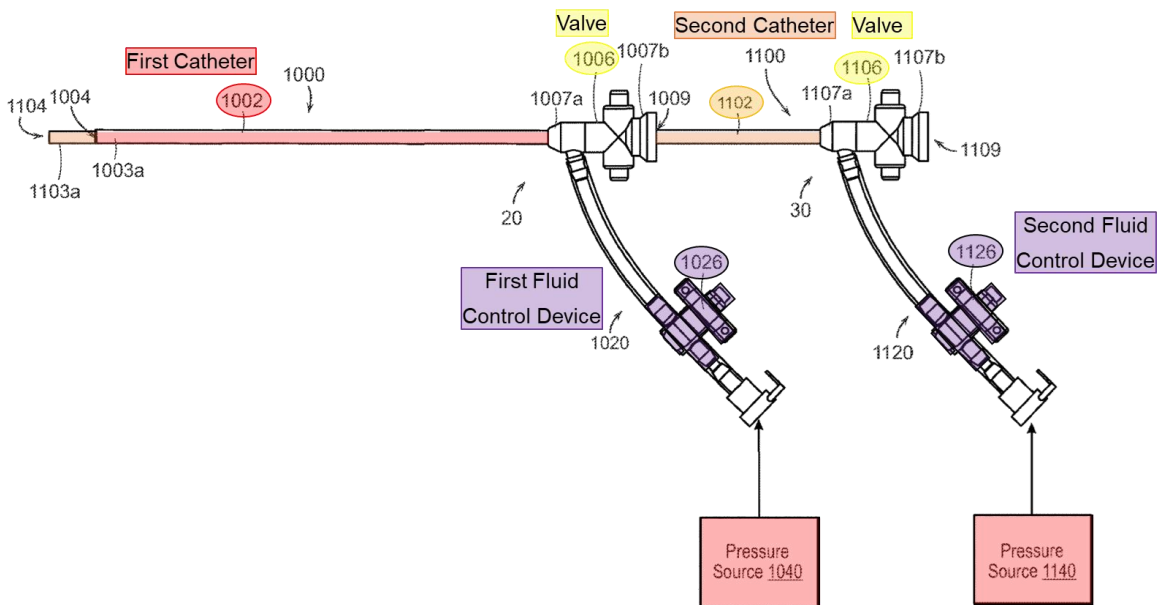


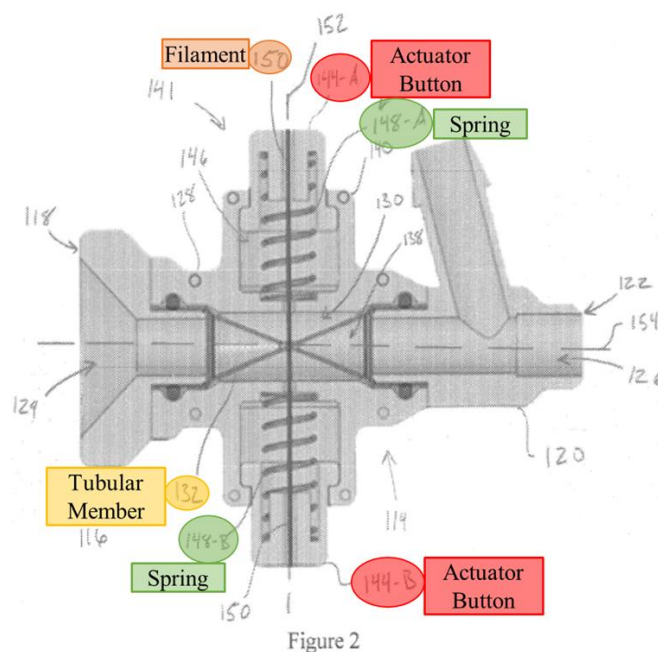
FIG. 11

(*Id.*, 21:23-27, Figure 11.)

The '910 patent explains that the second catheter 1102 can be inserted through the “first valve 1006” and “can be telescoped through the lumen 1004 of the first catheter 1002”. (*Id.*, 21:28-36.) The second catheter 1102 can “have a size of 16 French or smaller” and the first catheter 1102 can “have a size of 20 French or greater.” (*Id.*, 21:36-40.) The '910 patent further explains that the first pressure source and second pressure source can “be activated to generate and store a vacuum”

for subsequent application. (*Id.*, 23:26-29.) The first fluid control device 1026 can be opened “to generate suction at the distal portion 1003a of the first catheter 1002.” (*Id.*, 23:48-52.) Similarly, the second fluid control device 1126 can be opened “to apply the vacuum stored in second pressure source 1140 to the lumen 1104 of the second catheter 1102.” (*Id.*, 23:30-33.)

The '910 patent does not describe the structure of any hemostasis valve. However, the '910 patent purports to incorporate by reference “U.S. patent application Ser. No. 16/117,519” (the “'519 application” (Ex. 1017)). (*Id.*, 5:56-61.) The '519 application describes a valve having an “elongate member 132” that extends through the valve. (Ex. 1021, [0039].) The elongate member has a “thin-walled compliant tubular structure” that facilitates “the uniform collapse of the elongate member 132 and the sealing of the elongate member 132”:

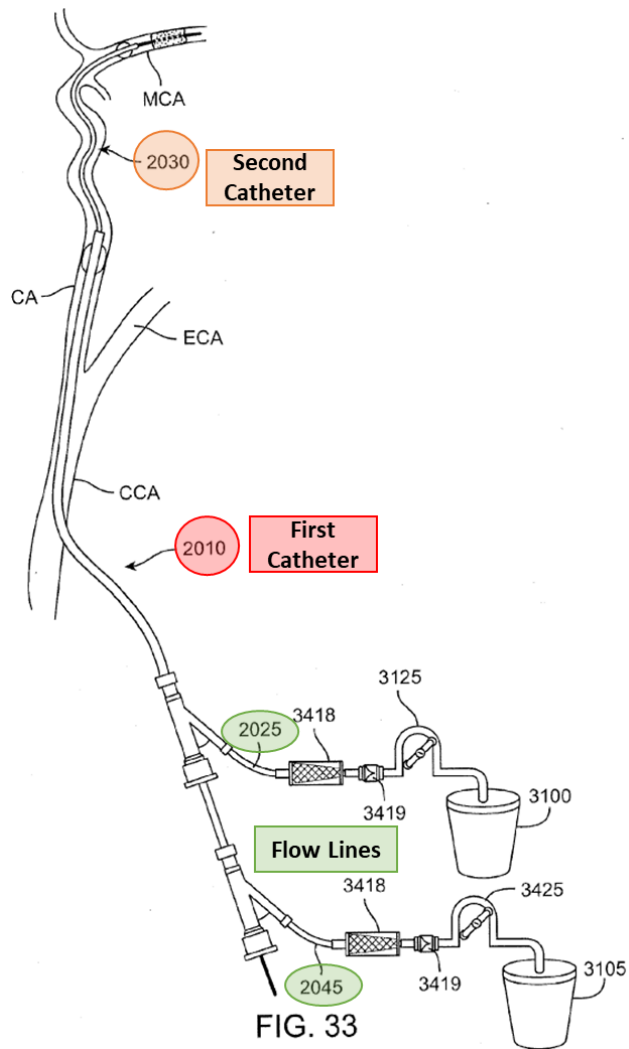


(*Id.*, [0039], Fig. 2.)

The valve also includes a “constricting mechanism 141” that can “collapse and seal the elongate member 132 via compression and/or constriction, and specifically via constriction with at least one filament 150.” (*Id.*, [0042-0043], Fig. 2.) The constricting mechanism includes “an actuator 142 which can be a manual actuator such as one or several buttons 144; and the at least one filament 150 that can extend at least partially around the elongate member 132.” (*Id.*) The “filament 150 can be coupled to the actuator 142 such that the filament 150 selectively constricts, collapses, and/or seals the elongate member 132 ... based on the movement and/or position of the actuator 142.” (*Id.*, [0048].)

B. Prosecution History

The Examiner issued a single non-final rejection during prosecution. In the rejection, the Examiner found original claim 18 anticipated by Garrison. (Ex. 1002, 373-382.) The Examiner also found that Garrison disclosed all the limitations of the other claims except “a second catheter advanceable through the first catheter.” (*Id.*) The Examiner stated, “The second catheter (2045) does not advance through first catheter (2025), as shown in Figure 33.” (*Id.*) The Examiner continued, “There is no reason to advance the second catheter through the first catheter of Garrison.” (*Id.*) Clearly, the Examiner was confused about Garrison because items 2025 and 2045 are not catheters, but “flow lines”:



(Ex. 1006, [0131], Fig. 33.) Garrison’s catheter 2030 is clearly advanced through catheter 2010. (*Id.*)

PO subsequently cancelled rejected claim 18 and amended the remaining claims to require a system “for treating clot material comprising a pulmonary embolism in the vasculature of a patient” and to specify that the second catheter in the system has a “size of 16 French or greater.” (Ex. 1002, 141-149.) PO argued that the amended claims “are further patentable over Garrison at least for the reasons

discussed during the January 25th videoconference interview with the Examiner and his supervisor in the related U.S. Patent Application No. 18/329,450 (‘the ’450 application’), and specifically the Examiner’s comments in the Applicant-Initiated Interview Summary mailed January 31, 2024 that ‘Attorney and Examiner agree that incorporating more structural claim language, i.e. diameter of the catheter, would make the claim 1 allowable over the prior art of Garrison.’” (*Id.*)

The Summary was not made of record in the ’910 patent prosecution history. However, the Summary has been included as an exhibit here and it does not specifically state why the Attorney and Examiner reached their agreement. (Ex. 1052.) The Summary merely adds that “Attorney and Examiner agree that the newly added method claims would be allowable for reciting the specific use in pulmonary embolism applications” and that “Dr. Tu [a named inventor on the ’910 Patent] discussed the differences between catheters used in cerebral occlusions vs. pulmonary embolisms and deep vein thrombosis.” (*Id.*) Notably, the ’910 patent does not include “method claims,” adding further ambiguity to the role the interview played during the ’910 patent prosecution.

The Examiner subsequently allowed the claims of the ’910 Patent. (Ex. 1002, 43-51.) The Examiner found that Garrison teaches all the limitations of the claims except “a clot treatment system for treating clot material comprising a pulmonary embolism in the vasculature of a patient” and “wherein the second catheter has a size

of 16 French or greater.” (*Id.*) The Examiner alleged that the “clot treatment device of Garrison is configured for a neurovascular application and not for larger vasculature such as pulmonary embolism” and that “[i]t would be unreasonable to modify the clot treatment device of Garrison to be used for pulmonary embolisms.” (*Id.*) The Examiner did not cite any evidence to support this conclusion but apparently relied on the unsupported arguments made by the named inventor during prosecution of the ’450 application. (*Id.*)

C. Earliest Possible Priority Date

The ’910 patent claims priority to two provisional applications 62/554,931 and 62/718,269, both filed August 13, 2018, which is the earliest possible priority date for the ’910 patent. (Ex. 1001.) Petitioner applies this earliest priority date in this Petition; however, Petitioner reserves its right to challenge the priority date in subsequent proceedings.

III. LEVEL OF ORDINARY SKILL

A POSITA in August 2018 would have had an undergraduate degree in mechanical engineering or a related engineering discipline and 2-4 years of catheter design experience and, where necessary, would have consulted with a physician regarding the methods of treatment. (Ex. 1003, ¶¶35-36.)

IV. CLAIM CONSTRUCTION

The claim terms should receive their ordinary and customary meaning as understood by a POSITA at the time of filing and in accordance with the specification and the prosecution history. 37 C.F.R. §42.100(b); *see Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005). However, “the specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess [and i]n such cases, the inventor's lexicography governs.” *Id.* at 1316.

Claim 7 requires a hemostasis valve having a “filament.” A POSITA would have understood the term “filament” to mean at least “one or more threads, lines, cords, ropes, ribbons, flat wires, sheets, or tapes” based on the intrinsic record. (Ex. 1003, ¶¶55-63.)

Claim construction generally begins with the claim language. *Vitronics Corp. v. Conception, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). Here, however, the claims provide little information regarding the “filament.” For example, claim 7 describes the “filament” as “extending at least partially around the tubular member,” wherein the filament is moveable between a first and second position. This claim language does not provide a POSITA with guidance on the “filament” structure.

Further, the '910 patent specification does not describe a hemostasis valve having a filament. In fact, the word “filament” does not appear in the '910 patent

(other than in the claim 7). If this limitation has support in the '910 patent, the support must be incorporated by reference from the '519 application.¹ (*See* Ex. 1001, 5:56-61 (citing, Ex. 1021.))

The '519 application identifies examples of “filaments” that expand the meaning of “filament” beyond the plain and ordinary meaning. The '519 application states, “the filament 150 can comprise one or several threads, lines, cords, rope, ribbon, flat wire, sheet, or tape.” (Ex. 1021, [0047].) The application also states, “the filament can be made from a variety of materials including, for example, a polymer, a synthetic, and/or a metal.” (*Id.*) The application further states, “the filament can comprise a single strand such as, for example, a monofilament, [or] the filament can comprise a plurality of strands that can be, for example, twisted, woven, grouped, and/or fused to form the filament.” (*Id.*) Additionally, the '519 application explains that “the filament 150 can comprise multiple filaments and specifically, as shown in Figures 7 through 9, the filament 150 can comprise a first filament 150-A and a second filament 150-B.” (*Id.*, [0065].)

Given the above descriptions, a POSITA would have understood the claim term “filament” to mean at least “one or more threads, lines, cords, ropes, ribbons, flat wires, sheets, or tapes.” (Ex. 1003, ¶¶55-63.)

¹ Petitioner reserves its right to challenge written description and the incorporation by reference in future proceedings.

Petitioner does not believe any other terms in the challenged claims require construction to resolve the patentability issues herein.

V. STATEMENT OF RELIEF REQUESTED

A. IPR Grounds

Petitioner asserts the following grounds of unpatentability:

Ground	Challenged Claims	35 U.S.C.	Reference(s)
1	1-6, 8, 11-15, 18-20	§103	Garrison + Laub
2	1-6, 8, 11-15, 18-20	§103	Garrison + Aklog
3	1-6, 8, 11-15, 18-20	§103	Garrison + Laub + Aklog
4	6-7, 20	§103	Garrison + Laub + Hartley
5	6-7, 20	§103	Garrison + Aklog+ Hartley
6	6-7, 20	§103	Garrison + Laub + Aklog + Hartley
7	3, 12, 18	§103	Garrison + Laub + Pasha
8	3, 12, 18	§103	Garrison + Aklog + Pasha
9	3, 12, 18	§103	Garrison + Laub + Aklog + Pasha

The Petition is supported by the expert declaration of Troy Thornton. (Ex. 1003.)

B. The Asserted References Are Prior Art

The following references are prior art under at least 35 U.S.C. §102(a)(1):

- (1) Aklog (Ex. 1005) issued May 27, 2014;
- (2) Laub (Ex. 1007) published on February 16, 2017;
- (3) Garrison (Ex. 1006) published June 25, 2015;
- (4) Schaffer (Ex. 1008) published on December 4, 2003; and
- (5) Pasha (Ex. 1049) published on May 31, 2014.

C. The Asserted References Are Analogous Art

The asserted references are analogous art that is usable in an obviousness combination. *Unwired Planet, LLC v. Google Inc.*, 841 F.3d 995, 1000 (Fed. Cir. 2016). The references are from the same field as the '910 patent, e.g., devices for aspirating unwanted material from a patient. (Ex. 1003, ¶26.) The references are also pertinent to the problem the inventor was focused on, e.g., removing clots, emboli, and thrombi from a patient's blood vessel. (*Id.*; *see also* Ex. 1001, 2:45-46 (“there exists a need for improved systems and methods for embolic extraction”).) Accordingly, a POSITA is presumed to have been aware of these references and the teachings may be combined to support an obviousness rejection. *In re Nilssen*, 851 F.2d 1401, 1403 (Fed. Cir. 1988).

VI. GROUNDS 1-3: GARRISON COMBINED WITH LAUB AND/OR AKLOG RENDERS CLAIMS 1-6, 8, 11-15, 18-20 UNPATENTABLE

A. Independent Claim 1

Claim 1 is rendered obvious by Garrison in view of Laub and/or Aklog. (Ex. 1003, ¶¶65-123.)

1. Preamble

If the preamble is limiting, Garrison in view of Laub and/or Aklog renders obvious “a clot treatment system for treating clot material comprising a pulmonary embolism in a vasculature of a patient.” (Ex. 1003, ¶¶66-86.)

Garrison discloses systems to aspirate (i.e., suction) clots from the vasculature of a patient. (Ex. 1006, abstract, [0007].) Figure 34 (below) illustrates one embodiment that includes two clot aspiration assemblies having two aspiration catheters [orange] coupled to a pressure source (e.g., aspiration pump) [red], and a fluid control device [purple]:

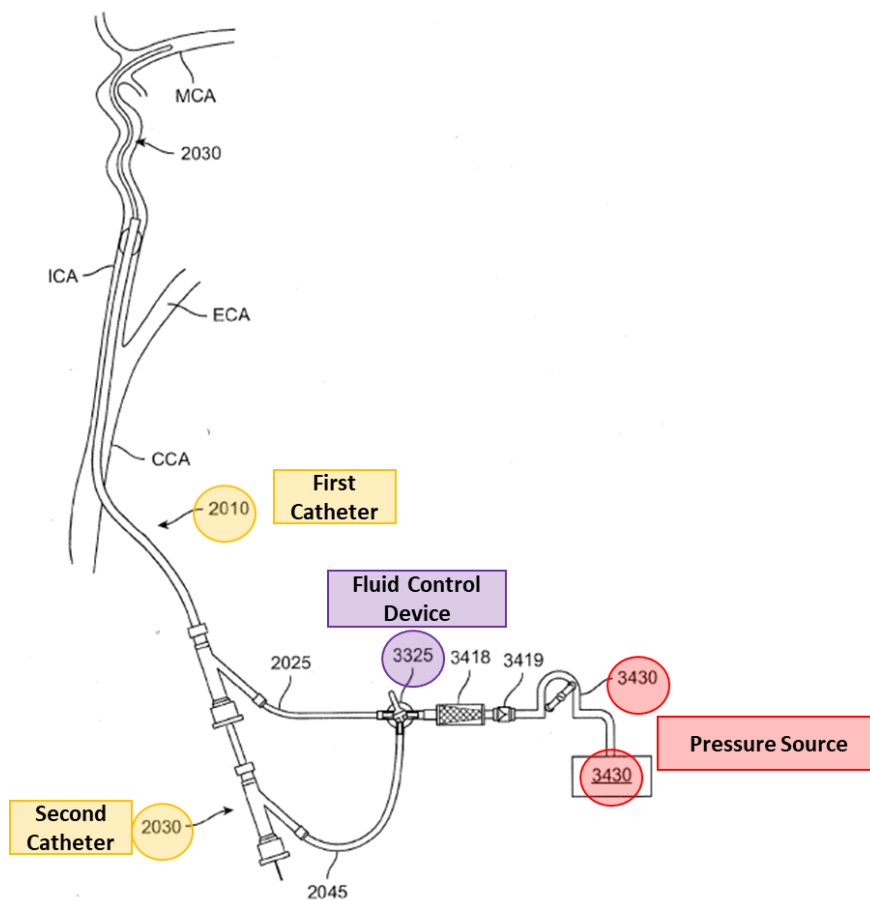
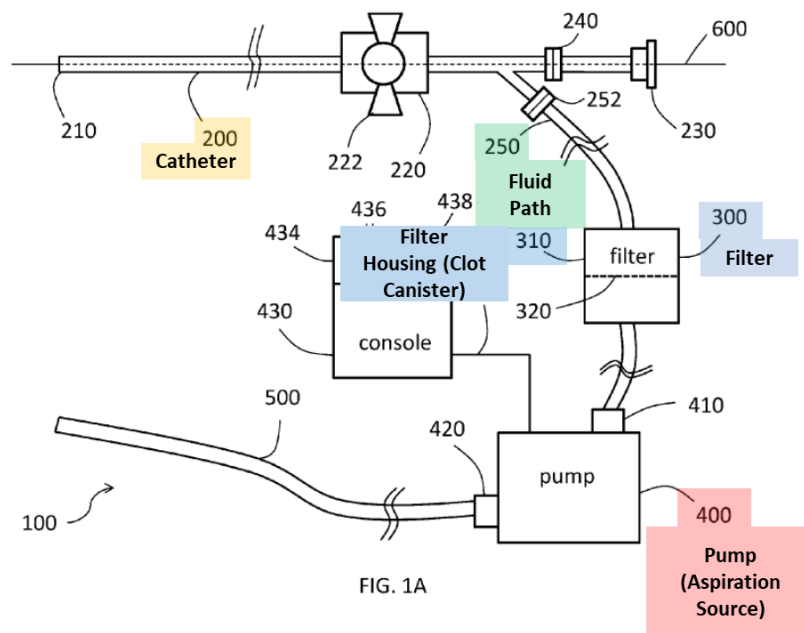


FIG. 34

(*Id.*, Fig. 34; *see also id.*, [0131]-[0134].) While Garrison focuses on the “treatment of cerebral occlusions,” a POSITA would have found it obvious to use and optimize Garrison’s clot treatment system to treat PE based on Laub or Aklog. (Ex. 1006, [0002]; Ex. 1003, ¶¶68-86.)

Like Garrison, Laub discloses “a system for removing thrombi and other unwanted material from the body of a patient, particularly from the patient’s vasculature.” (Ex. 1012, [0005].) Laub specifically discloses that its system may be used “to remove clots from patients suffering from or at risk of pulmonary embolisms.” (*Id.*)



(*Id.*, Fig. 1A.)

Similarly, Aklog discloses systems and methods for removing clot material from “the pulmonary circulation (e.g., pulmonary arteries), systemic venous

1022, ¶21; Ex. 1003, ¶¶69-86.) “Generally, a physician inserts an aspiration catheter into the patient’s vasculature through a small incision in the skin.” (Ex. 1022, ¶21.) Garrison, Laub, and Aklog, for example, all disclose inserting the catheter system through a small incision in the leg to access the transfemoral vein or artery. (See Ex. 1006, [0048] (describing delivery through the “transfemoral or transcarotid access approaches”); Ex. 1012, [0024]-[0026] (describing inserting catheter “from a patient’s vein (e.g., right common femoral vein) during use”); Ex. 1005, 15:30-34 (describing percutaneously accessing the patient’s “femoral vein, femoral artery or jugular vein); see also Ex. 1001, 17:7-8 (“Access to the pulmonary vessels can be achieved through the patient’s vasculature, for example, via the femoral vein.”)).

The physician then initiates aspiration (i.e., suction) by withdrawing a syringe or turning on an electric pump to aspirate the clot. (Ex. 1022, ¶22.) Garrison, Laub, and Aklog all disclose using a pump, in addition to other suction devices, to generate the necessary suction. (Ex. 1005, 5:37-41; Ex. 1006, [0134]; Ex. 1012, abstract.) These references also confirm that aspiration systems for the brain and other parts of the vasculature, including the lungs (PE), use the same general components. In each reference, the aspiration system includes a pressure source connected by medical tubing to a filter, which is then connected to an aspiration catheter. (Ex. 1005, Figs. 6-7; Ex. 1006, Figs. 33-34; Ex. 1012, Fig. 1A; Ex. 1022, ¶24.)

The similarities between the systems would have further motivated a POSITA to use Garrison’s system to treat clots in other parts of the vasculature, including PEs, and given the POSITA a reasonable expectation of success. (Ex. 1003, ¶¶70, 81.) In fact, using Garrison’s system to treat PEs would have been nothing more than the predictable use of prior art elements according to their established functions. *KSR*, 550 U.S. at 416.

Not surprisingly, POSITAs routinely used aspiration catheters designed for one part of the vasculature to treat different parts of the vasculature. (*See* Ex. 1022, ¶25 (describing use of peripheral systems for cerebral applications).) And the prior art patents confirm that using the same aspiration catheter system across many parts of the vasculature was common practice. (*See* Ex. 1003, ¶¶74-78, 84-86 (citing Ex. 1020, describing catheters for cerebral clots and PE).)

Further, prior to 2018, POSITAs routinely upsized catheter systems initially intended for one part of the vasculature for another. (Ex. 1022, ¶¶26-37; Ex. 1003, ¶¶74-78, 84-86.) For example, Penumbra, one of the market leaders in thrombectomy, and Petitioner both adapted their aspiration catheters designed to remove cerebral clots to treat other types of clots, including PE, by simply increasing the size of the catheters and related components and making routine modifications to the catheters such as adjusting flexibility. (Ex. 1022, ¶¶30-32.)

In fact, even the '910 patent acknowledges that aspiration systems could be used across different parts of the vasculature. The '910 patent states, “Although many of the embodiments are described below with respect to devices, systems, and methods for treating *pulmonary embolism*, other applications and other embodiments in addition to those described herein are within the scope of the technology (e.g., intravascular procedures other than the treatment of emboli, *intravascular procedures for treating cerebral embolism*, intravascular procedures for treating deep vein thrombosis (DVT), etc.” (Ex. 1001, 4:51-58 (emphasis added).) The '910 patent does not identify any special reasons why its aspiration catheters can be used interchangeability across different parts of the vasculature while other aspiration catheters could not. Nor does the '910 patent disclose that treating PE can be accomplished *only* with catheters measuring 16 French or greater. To the contrary, the '910 patent discloses that its catheters can be as small as 9 French and still aspirate PEs and other clots. (*Id.*, 9:19-22.) This common and successful practice of using the same aspiration system across the vasculature, and making minor optimizations to catheter size and construction to facilitate enhanced performance depending on the specific use, would have given POSITAs additional comfort that Garrison’s system could be used and optimized to treat PEs. (Ex. 1003, ¶¶74-78, 84-86.)

A POSITA would have also been motivated to use and optimize Garrison’s clot treatment system to treat PEs, and reasonably expected success in doing so, based on the similarities between cerebral clots and clots in other parts of the body like PEs. (Ex. 1022, ¶¶38-41; Ex. 1003, ¶74.) The references cited herein illustrate the close relationship between clots and embolisms across the vasculature.

For example, Aklog explains, “DVT causes harm by (1) obstructing drainage of venous blood from the legs ... and (2) serving as a reservoir for blood clot to travel to other parts of the body including the heart, lungs (*pulmonary embolism*) and across a opening between the chambers of the heart (patent foramen ovale) to the *brain (stroke)*, abdominal organs or extremities.” (Ex. 1005, 2:13-19 (emphasis added).) Thus, a DVT can become a PE or cerebral embolism as it travels through the body. (See also Ex. 1022, ¶¶38-41 (describing similarity of clots).) Consequently, POSITAs developing treatments for clots in one part of the body naturally consulted and borrowed from innovations for treating clots in other parts of the body. Laub and Aklog explain that PEs are harmful clots that can block blood flow to the lungs and cause death. (Ex. 1012, [0004]; Ex. 1005, 2:20-32.) Given the similarity in clots and the known danger of PE, POSITAs would have found it obvious to try using Garrison’s clot treatment system to treat PEs and, to the extent necessary, would have found it obvious to optimize the system to treat PEs by, for

example, including the slightly larger catheters disclosed in Laub and Aklog. (Ex. 1003, ¶¶74, 84.)

Moreover, Garrison’s catheters are appropriately sized to treat PE without modification. Garrison describes catheters ranging from 6-10F. (Ex. 1006 (Garrison) at [0063].) Penumbra, one of the current market leaders in aspiration thrombectomy, sells aspiration catheters of 7F and 12F for removing PEs and DVTs. (Ex. 1022, ¶39.) Likewise, Petitioner sells its Prodigy Thrombectomy system in sizes ranging from 5F-8F to treat the peripheral vasculature. (*Id.*) Finally, the ’910 patent describes catheters of 9F that are purportedly useful for aspiration PEs. (Ex. 1001, 9:19-22.)

Further, Garrison explains that cerebral occlusions are more difficult to treat than clots in larger vessels due to “special access challenges.” (Ex. 1006, [0042]; *see also* Ex. 1022, ¶¶33-37 (describing challenges of treating neurovascular clots).) Garrison explains that the “access route is long, often tortuous and may contain stenosis plaque material in the aortic arch and carotid and brachiocephalic vessel origins, presenting a risk of embolic complications during the access portion of the procedure.” (*Id.*) Additionally, “the cerebral vessels are usually more delicate and prone to perforation than coronary or other peripheral vasculature.” (*Id.*)

To address these challenges, Garrison describes additional catheters with small diameters and enhanced flexibility. (*Id.*; *see also id.*, [0109] (describing a

“very flexible, kink resistant and collapse resistant catheter with a thin wall and large inner diameter”).) Accordingly, while an aspiration catheter designed to treat PEs may not have the size and flexibility to reach a cerebral clot, a catheter designed to treat cerebral clots *can* reach and treat PEs. (Ex. 1022, ¶¶33-37.) For these additional reasons, POSITAs would have been motivated to use, and found it obvious to try, Garrison’s system to treat PEs, and reasonably expected success in doing so. (*Id.*)

Further, if Garrison’s system required some optimization to more effectively treat PEs, POSITAs would have possessed the necessary skills to perform such optimizations. (Ex. 1003, ¶¶71, 74, 82, 85.) These optimizations could have included upsizing Garrison’s aspiration catheters (and related components), such as by using Laub’s catheters measuring 16F or 20F, optimizing the catheter’s flexibility and torque characteristics, and potentially adjusting the suction force. (*Id.*) All of these optimizations were routine tasks a POSITA would perform on any catheter project. (*Id.*)

Aklog confirms that POSITAs possessed the knowledge to make these routine optimizations. While Aklog primarily describes treatments for medium and large vessels, Aklog explains “that the systems and methods, hereinafter disclosed, can be scaled and adapted for use within smaller vessels within the body, if desired.” (Ex.

1005, 7:43-46.) Thus, Aklog presumes that POSITAs possessed the requisite knowledge to make these simple optimizations. (Ex. 1003, ¶¶71, 82.)

Garrison also discloses several sheath and catheter sizes for its system, further demonstrating that optimizing the size of a catheter was routine. (Ex. 1006, [0063] (describing 6 and 8 French sheaths); [0070] (describing 10 French sheaths).) POSITAs would have reasonably expected success in incorporating some of the larger catheters described in Laub and Aklog into Garrison’s system because this type of routine upsizing was common and because Laub and Aklog describe such catheters as being effective for treating PE. (Ex. 1003, ¶¶71-79, 82-86; Ex. 1022, ¶¶30-37 (describing real-world upsizing of neuro catheters for PE).)

Further, Garrison specifically suggests combining its aspiration system with components from aspiration systems for treating other parts of the vasculature. For example, Garrison incorporates by reference components from devices for treating the coronary, cerebral, cardiac, and peripheral vasculature. (Ex. 1006, [0070], [0144] (citing Exs. 1014, 1018); Ex. 1003, ¶¶75-76.) The combination of Garrison’s catheter system with Laub or Aklog’s larger catheter components would have involved the simple substitution of one known element (Garrison’s catheter) for another (Laub’s or Aklog’s catheters) to obtain the predictable result of aspirating blood clots. *KSR*, 550 U.S. at 416. Further, to the extent other components in Garrison’s system would require upsizing, like the valves, such upsizing was routine.

Thus, the specific teachings in Garrison would have further motivated POSITAs to use or optimize Garrison’s system to treat PEs and would have given POSITAs a reasonable expectation of success in doing so. (Ex. 1003, ¶¶75-76, 85-86.)

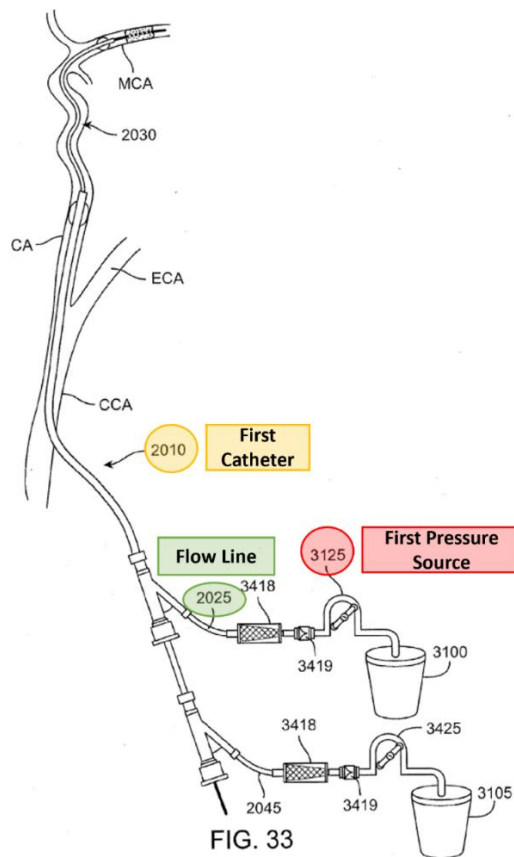
Finally, Garrison already accounts for one challenge POSITAs encountered when moving from smaller to larger aspiration catheters – a larger catheter “may aspirate an unacceptable volume of blood, resulting in excessive fluid loss and/or shock in the patient.” (Ex. 1005, 7:23-26.) Aklog explains that the solution to using larger catheters is to reinfuse the “fluid removed (i.e., suctioned or aspirated) from the site of interest back into a patient, in order to minimize fluid loss within the patient.” (*Id.*, 7:47-52.) Garrison addresses this challenge by including an “aspiration pump device 3250 which is configured not to harm blood cells and which may be configured to return blood to the central venous system in real time during the procedure, so there is no reservoir in which the blood remains static.” (Ex. 1006, [0135]; *id.* at [0136]; *see also id.* at [0140], Fig. 38 (describing blood return variations). This blood return solution would have reinforced a POSITA’s reasonable expectation of success in upsizing Garrisons’ catheters to aspirate PEs. (Ex. 1003, ¶¶72-73, 83; *see also* Ex. 1022, ¶41 (describing real-world blood-loss solutions).)

For all of these reasons, a POSITA would have found it obvious to use, or optimize, Garrison’s aspiration system treat PE based on Laub and/or Aklog and would have reasonably expected success in doing so. (Ex. 1003, ¶¶69-86.)

2. A First Clot Assembly

Claim 1 next recites: “a first clot aspiration assembly, including: a first catheter; a first pressure source.” Garrison discloses this limitation. (Ex. 1003, ¶¶87-89.)

Garrison’s clot treatment system includes a first clot aspiration assembly having a first catheter 2010 [orange] that is fluidly connected to a first pressure source [red] by way of flow line 2025 [green]:



(Ex. 1006, [0131], Fig. 33.) While Garrison refers to catheter 2010 as an “arterial access device,” the device is a catheter because the device 2010 has a lumen that is fluidly coupled to a pressure source and aspirates blood and clot from the patient. (Ex. 1006, [0131]; Ex. 1003, ¶88.)

Garrison also confirms that the “active source of aspiration may be an aspiration pump, a regular or locking syringe, a hand-held aspirator, hospital suction, or the like.” (*Id.*, [0134]; *see also id.*, [0071] (“The flow line 905 may also be connected to an aspiration source such as a pump or a syringe.”); [0172] (“Aspiration may be via a syringe, a pump, or other means as disclosed above.”).) The listed sources of aspiration are all “pressure sources.” (Ex. 1003, ¶89; Ex. 1001, 6:57-60).

3. First Fluid Control Device

Claim 1 next recites: “a first fluid control device between the first catheter and the first pressure source, wherein the first fluid control device is movable between (a) a first position in which the first pressure source is fluidly disconnected from the first catheter and (b) a second position in which the first pressure source is fluidly connected to the first catheter.” Garrison discloses this limitation. (Ex. 1003, ¶¶90-92.)

Garrison’s Figure 34 shows a variation of the system shown in Figure 33 (above) “whereby both the arterial access device 2010 and catheter 2030 are connected to the same aspiration source via flow lines 2025 and 2045, respectively.”

(Ex. 1006, [0132].) This system includes a “valve 3325” between the first catheter and the first pressure source:

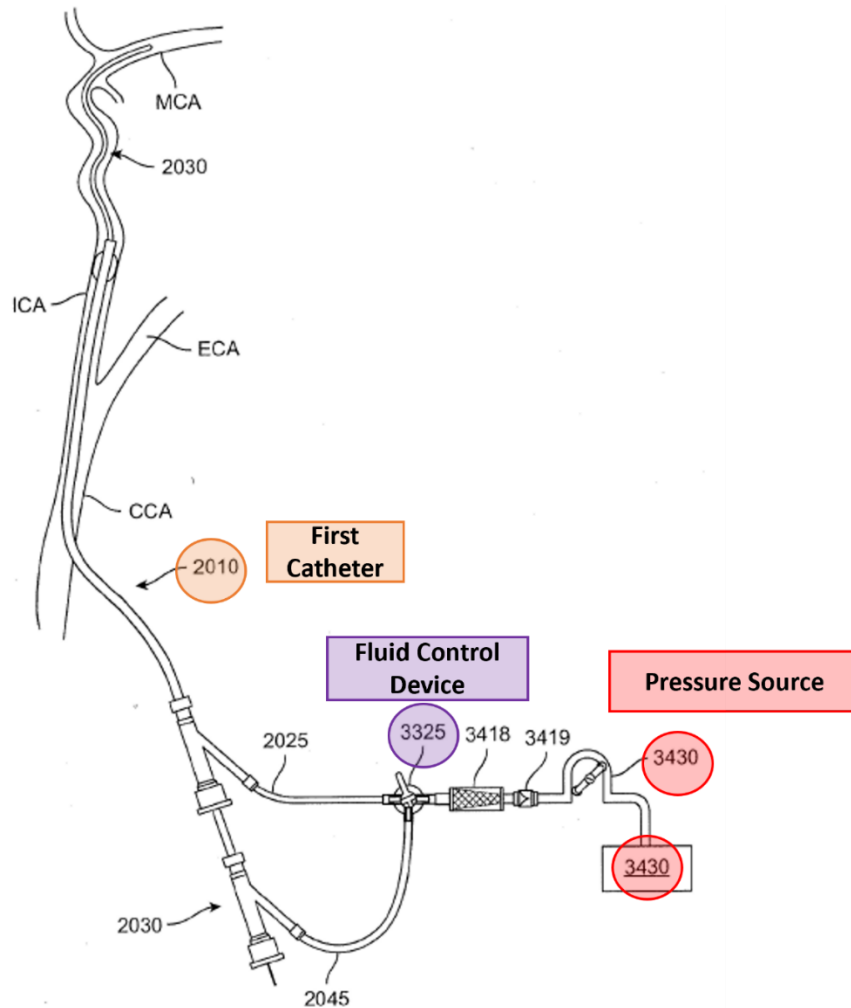


FIG. 34

(Ex. 1006, [00132], Fig. 34.) Garrison discloses that the “valve 3325 controls which device is connected to the aspiration system 3430.” (*Id.*) “The valve may be a 3-way or 4-way stopcock” and “enable one device, the other device, both devices, or neither device to be connected to the aspiration source at any given time.” (*Id.*) The valve can also “be a flow controller with a simple actuation which selects the

configuration as described above.” (*Id.*; *see also id.*, [0133] (describing flow controller).) Both the stopcock and flow controller are fluid control devices because they regulate whether fluid can flow through the flow lines 2025 and 2045 to the pressure source. (Ex. 1003, ¶91; *see also* Ex. 1006, [0133] (“the flow control may include one or more control interfaces that a user may actuate to regulate which device is being aspirated”).) Similarly, a user controls the fluid flow by turning (i.e., moving) the handle of the stopcock valve to open and close the valve. (Ex. 1003, ¶91.)

As explained in Garrison, the valve 3325 has a first position in which the first pressure source is fluidly disconnected from the first catheter and a second position in which the first pressure source is fluidly connected to the first catheter. (Ex. 1006, [00132], Fig. 34; Ex. 1003, ¶¶91-92.)

4. The First Pressure Source is Configured to Generate Vacuum Pressure

Claim 1 next recites: “wherein the first pressure source is configured to generate vacuum pressure while the first fluid control device is in the first position, and wherein, upon movement of the first fluid control device from the first position to the second position, the vacuum pressure is applied to the first catheter to generate suction at a distal portion of the first catheter.” Garrison discloses this limitation. (Ex. 1003, ¶¶93-95.)

Garrison describes an embodiment in which “a locking syringe (for example a VacLok Syringe) is attached to the flow controller and the plunger is pulled back into a locked position by the user *while the connection to the flow line is closed* prior to the thrombectomy step of the procedure.” (Ex. 1006, [0134] (emphasis added); *see also* Ex. 1022, ¶23 (describing use of this procedure since the early 2010s).) Once the catheter is positioned near the thrombus, “the user may open the connection to the aspiration syringe” to “enable the maximum level of aspiration in a rapid fashion.” (Ex. 1006, [0134].) Because the valve (e.g., stopcock 3325) is located between the pressure source and the catheter 2010, the movement of the valve to open and close the valve determines whether vacuum pressure is applied to the first catheter to generate suction at a distal portion of the first catheter. (*Id.*, Fig. 34; Ex. 1003, ¶94.) While this embodiment specifically describes using a flow controller and syringe, Garrison discloses that the valve could be a stopcock (Ex. 1006, [0132]) and the aspiration source could be an aspiration pump (*Id.*, [0134]). (Ex. 1003, ¶94.)

Garrison also discusses testing different catheters by closing a stopcock, generating vacuum pressure in a pressure source, and then releasing the vacuum pressure by opening a stopcock. (Ex. 1006, [0129], Figs. 56-57.) Garrison states:

The catheter and syringe were purged of air, the syringe was emptied, and *then the stopcock was closed*. The *locking syringe was then pulled back* the full 30 cc volume and locked in place. A timer was started

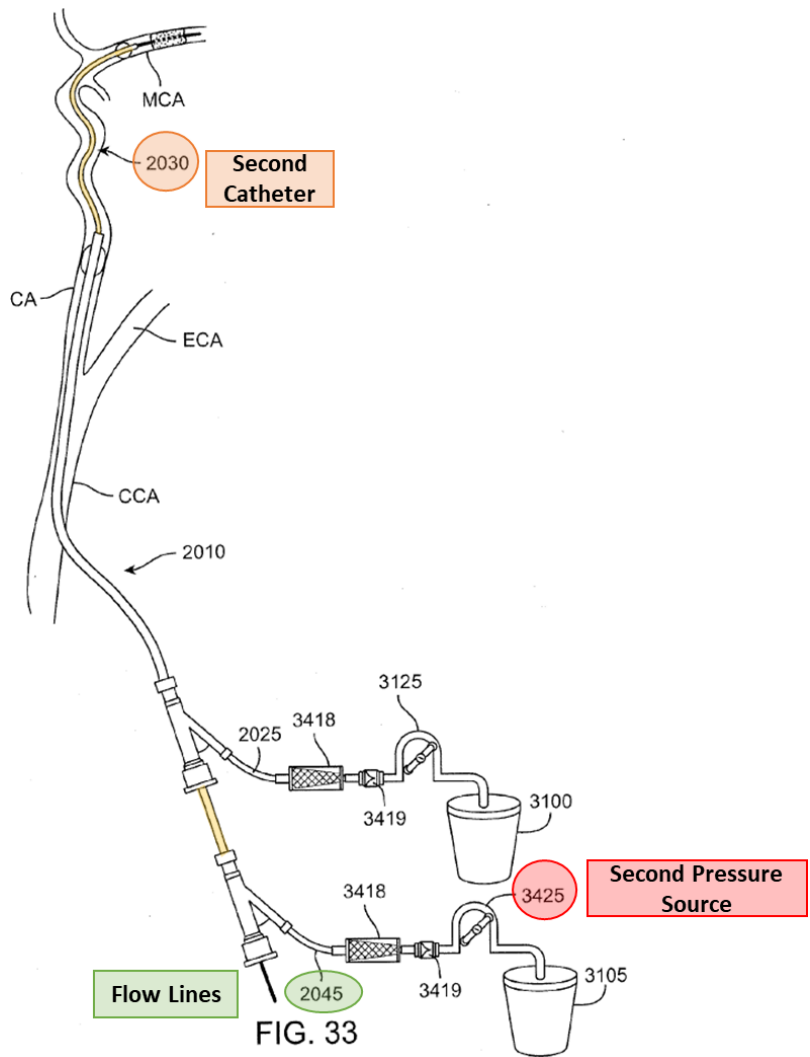
when ***the stopcock was opened***, and the time was noted at 5 cc, 10 cc, 15 cc and 20 cc of extracted solution in the syringe.

(*Id.* (emphasis added).) As described, the valve is closed while vacuum pressure is generated by the pressure source (i.e., syringe), and opened after vacuum pressure is generated. (Ex. 1003, ¶95.) Thus, Garrison includes multiple disclosures of closing a valve to generate vacuum pressure and opening the valve after the vacuum pressure is generated to cause suction at the distal end of a catheter.

5. Second Clot Aspiration Assembly

Claim 1 next recites: “a second clot aspiration assembly, including: a second catheter advanceable through the first catheter, wherein the second catheter has a distal portion, wherein the second catheter has a size of 16 French or greater, and wherein 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.” Garrison in view of Laub and/or Aklog renders this limitation obvious. (Ex. 1003, ¶¶96-109.)

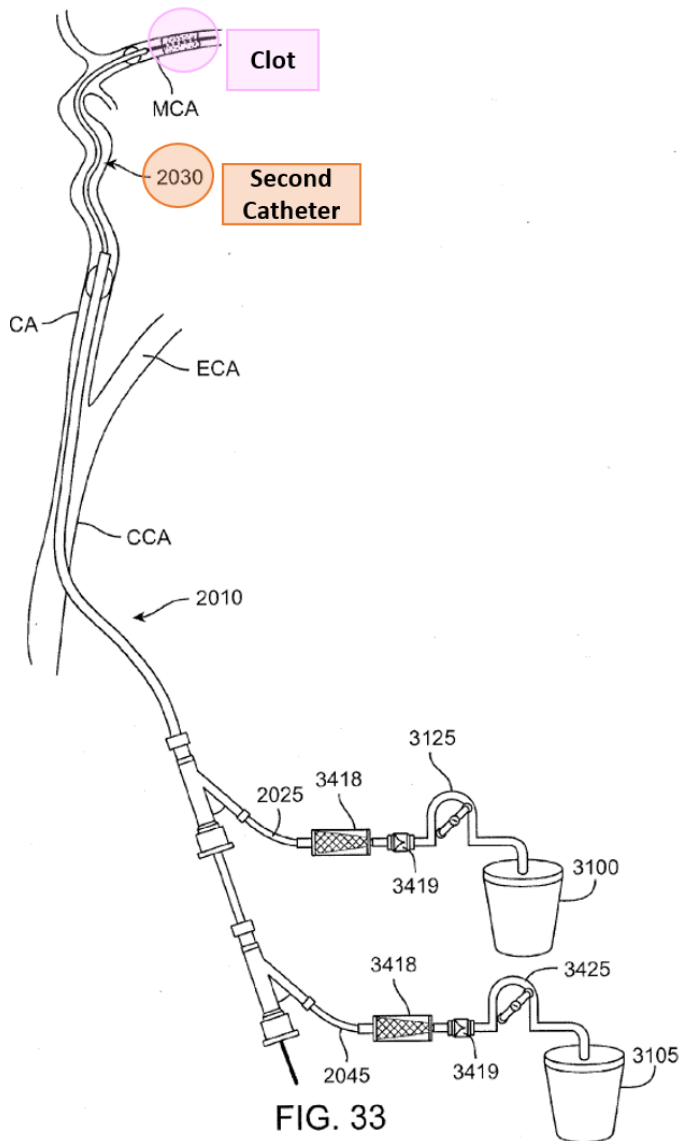
Garrison’s aspiration system includes a second clot assembly including a second aspiration catheter 2030 [orange] configured for placement into fluid communication with a second pressure source 3425 [red] by way of a flow line 2045 [green]:



(Ex. 1006, [0131], Fig. 33.) As shown above, the second catheter 2030 is advanceable through the first catheter 2010. (Ex. 1003, ¶97.)

Garrison’s catheter 2030 may “provide distal access for additional devices, localized fluid or contrast delivery, or localized aspiration at a location distal of the distal-most end of the arterial access device 2010.” (Ex. 1006, [0054].) In Figure 33, for example, Garrison shows the second aspiration catheter (catheter 2030,

orange) with a distal end portion positioned proximate to clot material within the blood vessel of the patient:



(Ex. 1006, Fig. 33, [0050]-[0051]; *see also e.g., id.*, Fig. 2.) Likewise, Garrison discloses variations of the aspiration catheter, such as catheters with an enlarged “distal-most tip or edge,” which may be “used to aspirate a clot in an artery.” (*Id.*, [0111].) Garrison discloses that “the catheter therefore may provide a larger suction

b. Aklog

Aklog discloses that its “[c]annula ... may be of any sufficient size, so long as it can be accommodated within a predetermined vessel, such as a medium to large size blood vessel.” (Ex. 1005, 11:12-14.) Aklog further discloses that the “size of cannula 10 may also be determined by the size of the undesirable material to be removed, so long as the undesirable material can be removed substantially en bloc without significant fragmentation,” and it explains that the cannula may have a sufficient size “to remove at least 10 cm³ of undesirable material substantially en bloc.” *Id.* at 11:15-20. Figure 7 of Aklog also depicts a large diameter catheter aspirating a large clot from the proximal portion of the pulmonary vasculature, which is typically much larger than 16F. As shown, the catheter is roughly the same size as the vasculature:

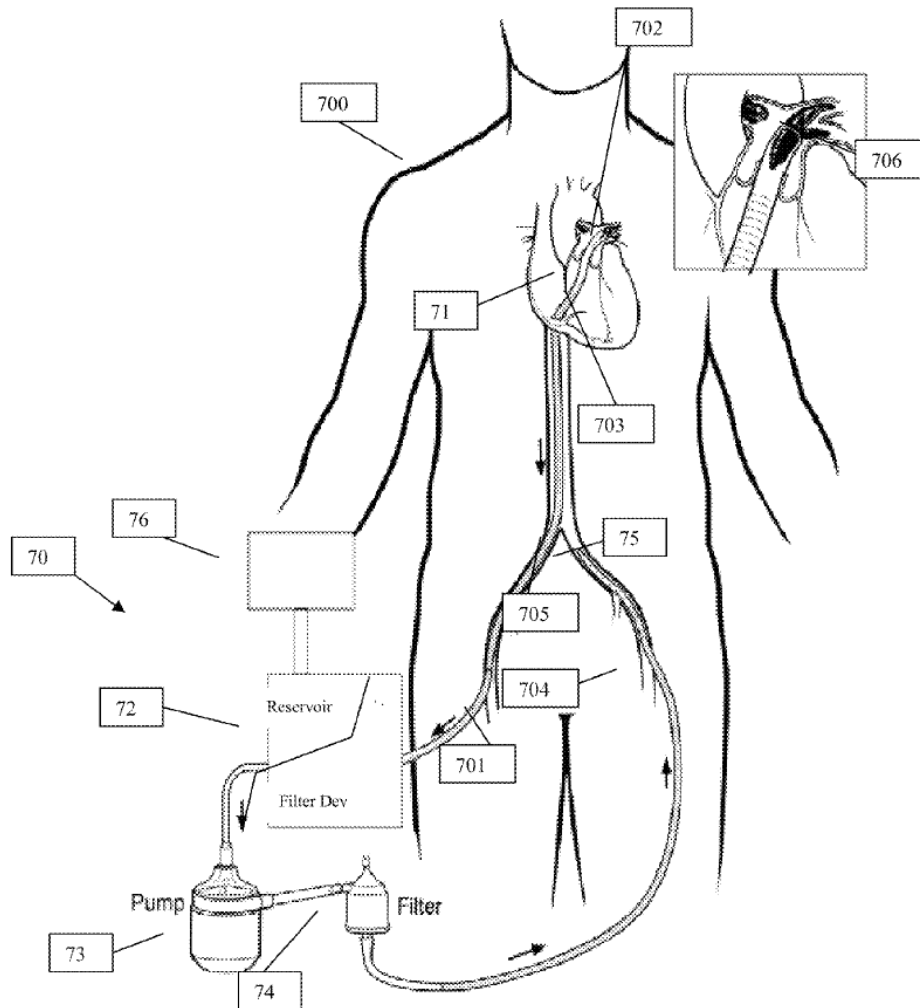


Fig. 7

(*Id.*, Fig. 7; Ex. 1003, ¶103.) Because Aklog explains that the catheter “may be of any sufficient size, so long as it can be accommodated within a predetermined vessel,” a POSITA would have understood Aklog to disclose using catheters of 16F or larger, at least based on Figure 7 and the description in Aklog that the system can be used to treat PEs. (Ex. 1005, 11:12-14; Ex. 1003, ¶103.)

c. Garrison and Laub or Aklog

A POSITA would have been motivated to increase the size of Garrison’s second catheter to 16F or greater based on Laub and Aklog because those references describe the successful use of larger catheters (16F or greater) to treat PE. (Ex. 1003, ¶104.) As discussed in the “Preamble,” a POSITA would have had many motivations and reasonably expected success in using, or optimizing, Garrison’s system to treat PE. (*Supra* §VI.A.1.)

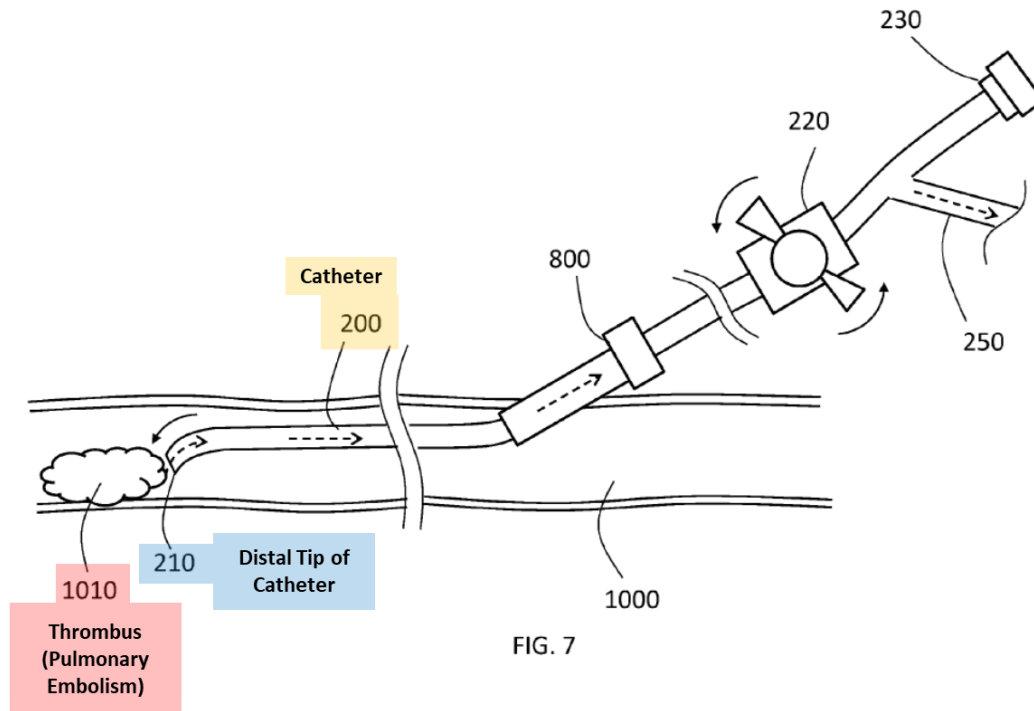
Further, POSITAs would have recognized that optimizing Garrison’s system to treat PE would have required, at most, simple modifications, such as increasing the size of the aspiration catheter (and related components), optimizing the flexibility and torque characteristics of the catheter, and potentially adjusting the suction force or the catheter strength to resist the suction force. (Ex. 1003, ¶105.) These types of catheter modifications, and specifically increasing the size of a catheter, were routine for medical device engineers. (*Id.*; *supra* §VI.A.1.) In fact, Laub acknowledges that POSITAs possessed the requisite knowledge to optimize aspirations systems to use the appropriately sized catheter. For example, Laub discloses embodiments where the “aspiration catheter 200 has a French size of at least 5 Fr”, and embodiments where “aspiration catheter 200 has a French size of at least 20 Fr”. (Ex. 1012, [0028].) Laub presumes that POSITAs possessed the requisite knowledge to select the correct catheter size for the particular application. (Ex. 1003, ¶105.)

Similarly, Garrison discloses a range of possible sheath and catheter sizes for its system and also presumes that POSITAs would have possessed the necessary knowledge to select the correct size for the particular application. (*See, e.g.*, Ex. 1006, [0063] (describing 6 and 8 French sheaths); [0070] (describing 10 French sheaths).) Aklog also presumes that the POSITA would be able to select the appropriately sized catheter, instructing that the catheter “may be of any sufficient size, so long as it can be accommodated within a predetermined vessel, such as a medium to large size blood vessel.” (Ex. 1005, 11:13-15; *see also* Ex. 1003, ¶107 (explaining catheter sizing).)

Further, using aspiration catheters having a size of 16 French or greater to treat PE was well known prior to 2018, as evidenced by Laub above. There were also several commercially available aspiration systems at that time that treated PE and DVT with catheters larger than 16 French. (*See, e.g.*, Ex. 1049, 241 (disclosing 26 Fr. AngioVac catheter used to treat PE); Ex. 1051, 605-607, Table 3 (disclosing 22 Fr. AngioVac catheter used to treat DVT); *see also* Ex. 1003, ¶108 (explaining development of 16F and 24F prior art catheters).) For all of these reasons, a POSITA would have reasonably expected success in upsizing Garrison’s catheters from 8 French or 10 French to 16 French or larger. (Ex. 1003, ¶108.)

Additionally, POSITAs would have found it obvious to position the distal end of Garrison’s aspiration system proximate a PE within the blood vessel based on

Laub and Aklog. (Ex. 1003, ¶109.) Laub includes “a diagram illustrating the positioning of the steerable aspiration catheter proximate a thrombus”:



(Ex. 1012, Fig. 7, [0020]; [0046].) As shown, the distal tip 210 of the catheter 200 is positioned proximate to the thrombus/clot. (*Id.*, [0046].) A POSITA would therefore have been motivated to similarly position Garrison’s catheter proximate the PE in that application. (Ex. 1003, ¶109.)

Aklog also discloses inserting its suction cannula proximate to the clot material:

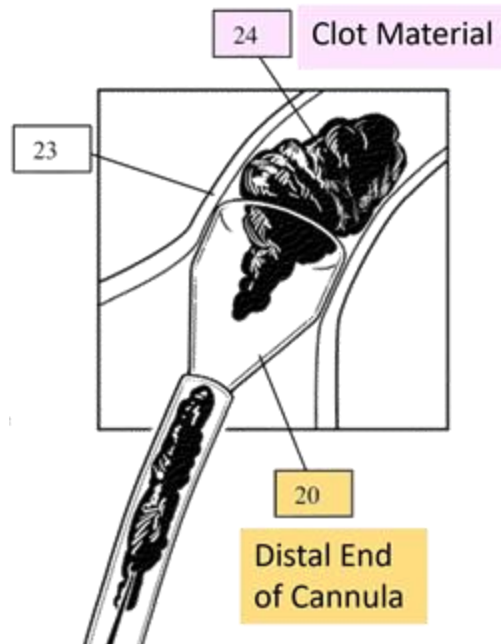
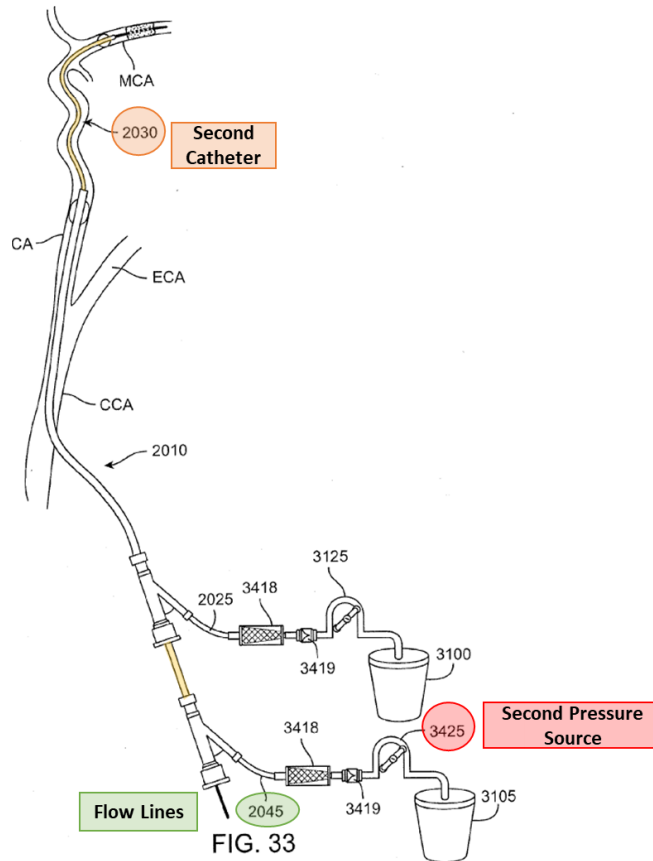


Fig. 2C

(Ex. 1005, 5:28-41, 11:62-65, 13:64-14:2, 16:27-53, 16:66-17:4; *see also id.*, Figs. 2C, 2D, 2H (illustrating cannula proximate a clot).) A POSITA would therefore have found it obvious to similarly position the distal end of Garrison’s aspiration system proximate a PE based on Aklog. (Ex. 1003, ¶109.)

6. Second Pressure Source

Claim 1 next recites: “a second pressure source.” Garrison discloses this limitation. (Ex. 1003, ¶¶110-111.) Garrison describes an embodiment in which the clot treatment system includes a second aspiration source 3425 [red]:



(Ex. 1006, [0131], Fig. 33.) Garrison discloses: “the flow line 2045 of the catheter 2030 is additionally or alternately connected to a separate aspiration source 3425 and delivery location, such as receptacle 3105.” (*Id.*) Garrison further explains that “the aspiration source 3425 and delivery location may be combined into a single device such as a syringe.” (*Id.*)

7. Second Fluid Control Device

Claim 1 next recites: “a second fluid control device between the second catheter and the second pressure source, wherein the second fluid control device is movable between (a) a first position in which the second pressure source is fluidly

disconnected from the second catheter and (b) a second position in which the second pressure source is fluidly connected to the second catheter.” Garrison combined with Laub and/or Aklog renders this limitation obvious. (Ex. 1003, ¶¶112-118.)

Garrison’s aspiration system includes “valve 3325” [purple] between the first catheter and the first pressure source in Figure 34:

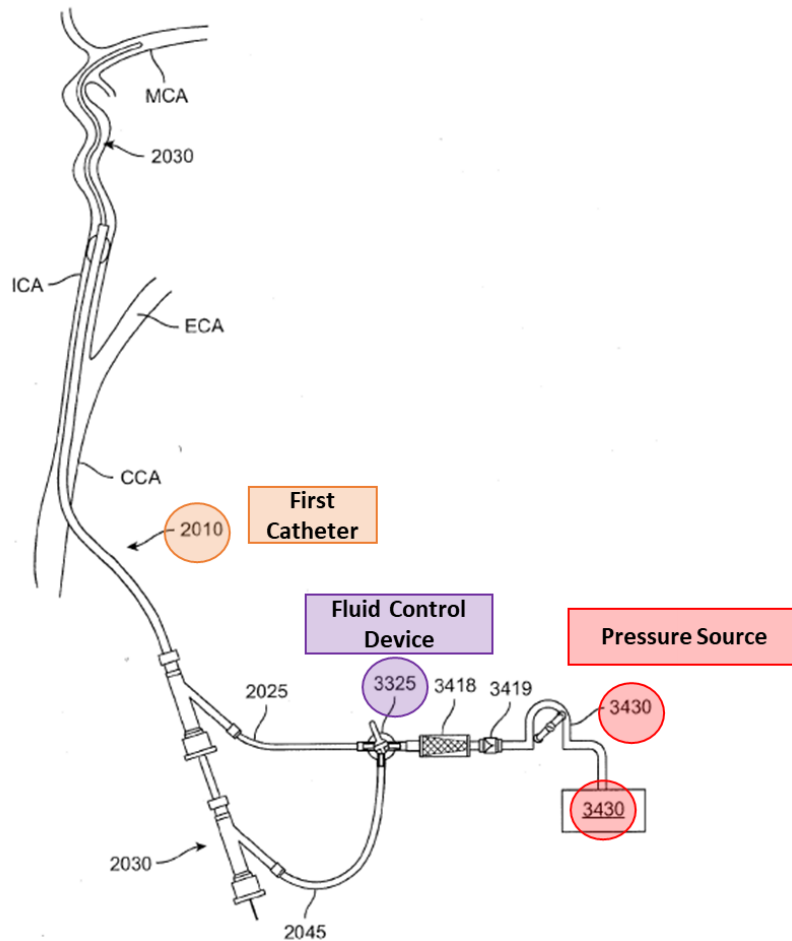
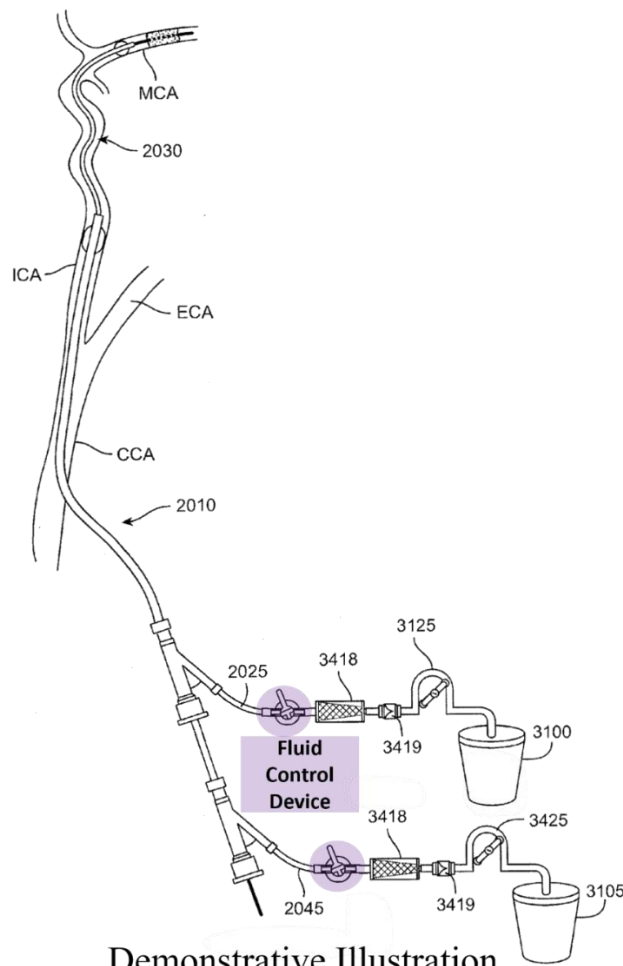


FIG. 34

(*Id.*, [0132], Fig. 34.) The valve is a fluid control device for the reasons previously described. *Supra* §VI.A.3. While Figure 34 illustrates a single fluid control device (stopcock valve 3325) between the pressure source and catheters, Garrison explains

that the flow control elements, such as valve 3325, can be used with **all** the catheters and flow lines. (Ex. 1006, [0130] (“Described herein are aspiration and flow control elements configured to be used with an arterial access device, a guide catheter, and/or a catheter of the disclosed system.”))

A POSITA using the embodiment in Figure 33 would have found it obvious, and been motivated, to add the same valve 3325 (as shown in Figure 34) between each pressure source and catheter so that the user could control the flow of suction to the catheter and achieve “the maximum level of aspiration in a rapid fashion”:



Demonstrative Illustration
Modified FIG. 33

(Ex. 1006, Fig. 33 (Modified); Ex. 1003, ¶114.)² The above demonstrative illustrates the potential location for the fluid control devices. (*Id.*) Notably, the fluid control device is in the same position in modified Figure 33 above (i.e., between the filter and the catheter) as in Figure 34. A POSITA would have been motivated to position the valve at this location based on the description in Figure 34 that positioning the valve here allows the physician to effectively control suction through the catheters. (Ex. 1003, ¶114.) The valve is also close to the portion of the catheter being held by the physician so it would make operation simple. (*Id.*)

Further, incorporating two separate valves into the system with two separate pressure sources would have given physicians more flexibility when using the device. (*Id.*, ¶115.) For example, the pressure sources could be different types of pressure sources, such as a syringe and pump, that could provide different amounts and different types (e.g., continuous vs. short burst) of suction. (*Id.*) The pressure sources could also provide different suction strengths. (*Id.*) By incorporating two fluid control devices (e.g., stopcocks) in the device, the user could control these independent pressure sources separately, and this would have motivated a POSITA to do so. (*Id.*)

² This image reflects a demonstrative prepared by Defendant. All modifications to the figure have been made by Defendant.

A POSITA would have reasonably expected success in connecting two fluid control valves (e.g., stopcocks) to the system, as demonstrated in modified Figure 33 above, because Garrison already discloses that such a valve is useful in controlling the flow of pressure to the catheters and creating the maximum level of aspiration. (*Id.*, ¶116.) Likewise, Garrison discloses that positioning the valve between the filter and catheter provides effective control.

Further, connecting two valves to the tubing shown in Figure 33 would have been a simple modification. (*Id.*, ¶117.) In August 2018, a POSITA would have found it obvious to couple the fluid control devices to the tubing and other components using conventional connectors, such as Luer-type connectors (e.g., Luer slip and Luer lock) and barb connectors. (*Id.*; Ex. 1006, [0062], [0065], Fig. 11 (illustrating stopcock with standard female connector); 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. (Ex. 1010, [0130]; *see also* Ex. 1014, 8:45, 8:63 (describing an “auxiliary Luer port”); Ex. 1015, [0056]-[0059] (describing improvements to the “standardized ... locking Luer taper design”).)

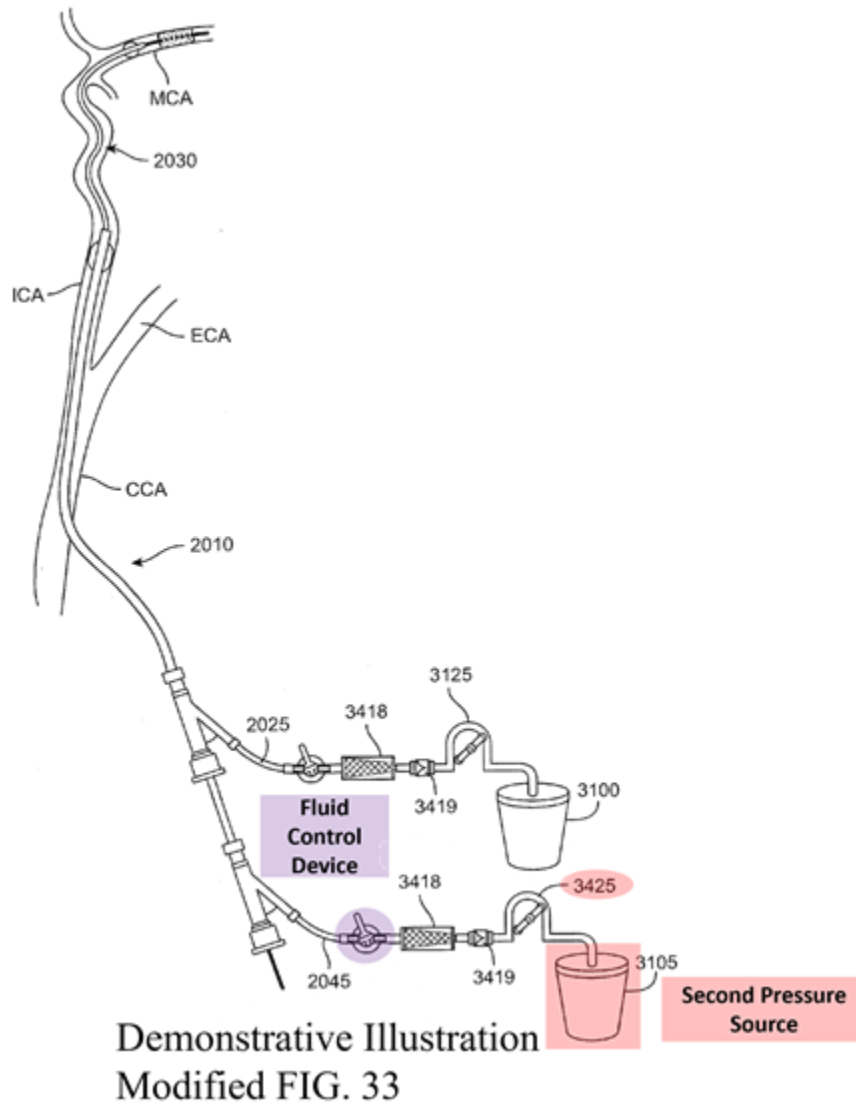
Additionally, if the fluid control device were the same as the device in Figure 34 (e.g., a stopcock), as suggested herein, then the second fluid control device would

be movable between (a) a first position in which the second pressure source is fluidly disconnected from the second catheter and (b) a second position in which the second pressure source is fluidly connected to the second catheter for the same reasons previously provided. (*Supra* §VI.A.3.)

8. The Second Pressure Source is Configured to Generate Vacuum Pressure

Claim 1 next recites: “wherein the second pressure source is configured to generate vacuum pressure while the second fluid control device is in the first position.” Garrison discloses this limitation. (Ex. 1003, ¶¶119-120.)

As explained above, Garrison describes a pressure source that is configured to generate vacuum pressure while a fluid control device is in the first position, most notably with respect to Figure 34. (*Supra* §VI.4.) A POSITA would have found it obvious, and been motivated, to use this same procedure with a second fluid control device:

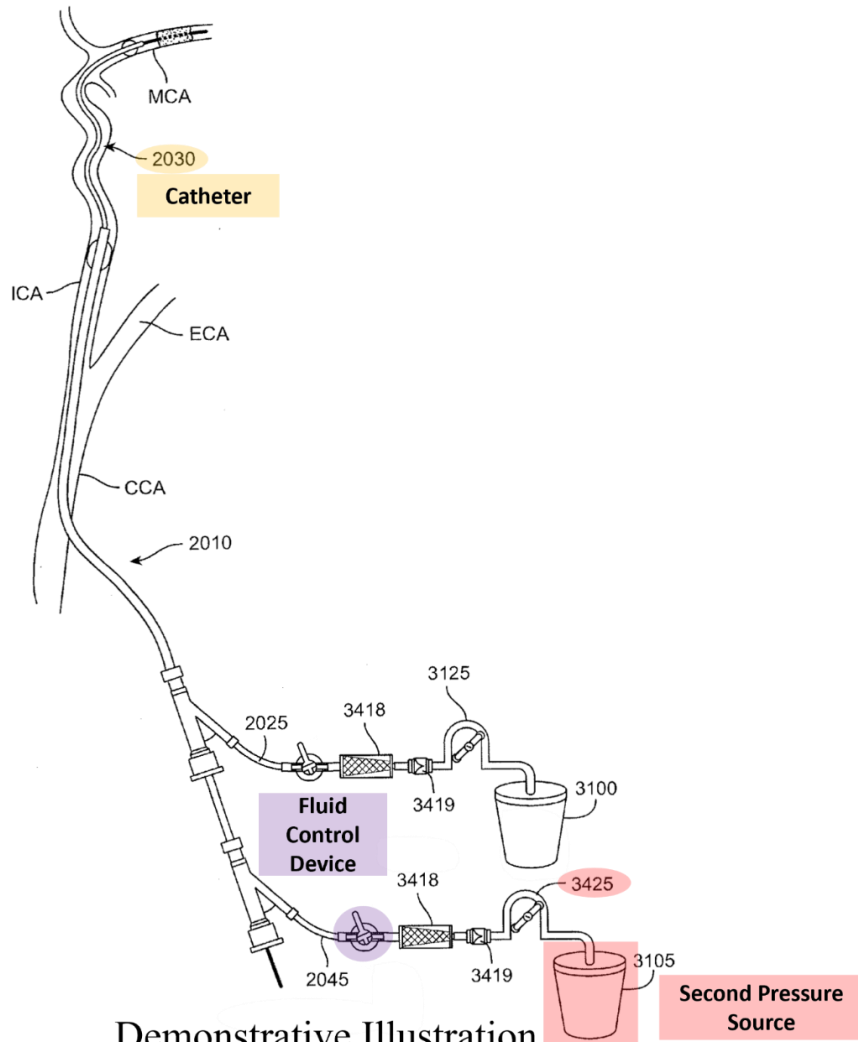


(Ex. 1006, Fig. 33 (Modified); Ex. 1003, ¶120.) Garrison explains that closing the fluid control device while the pressure source generates vacuum and then opening the fluid control device when the catheter is positioned near the clot “would enable the maximum level of aspiration in a rapid fashion with one user[.]” (Ex. 1006, [0134]. Both the fluid control devices shown in modified Figure 33 above are configured to have this capability. (Ex. 1003, ¶120.)

9. The Vacuum Pressure is Applied

Claim 1 next recites: “wherein, upon movement of the second fluid control device from the first position to the second position, the vacuum pressure is applied to the second catheter to generate suction at the distal portion of the second catheter to aspirate blood and at least a portion of the pulmonary embolism into the second catheter.” Garrison in combination with Laub and/or Aklog renders this limitation obvious. (Ex. 1003, ¶¶121-123.)

Garrison discloses a fluid control device that can be moved from a first position to a second position. (*Supra* §§VII. A.3, VI.A.7.) When that happens, the built-up vacuum pressure is applied to the catheter to generate suction at the distal portion of the catheter to aspirate blood and clot. (*Supra* §§VI.A.4, VI.A.8; Ex. 1006, [0134], Figs. 33-34.) If the fluid control device disclosed in Figure 34 were incorporated into both flow lines in the embodiment in Figure 33, moving either of the fluid control devices to the second position would have this same impact:



Demonstrative Illustration
Modified FIG. 33

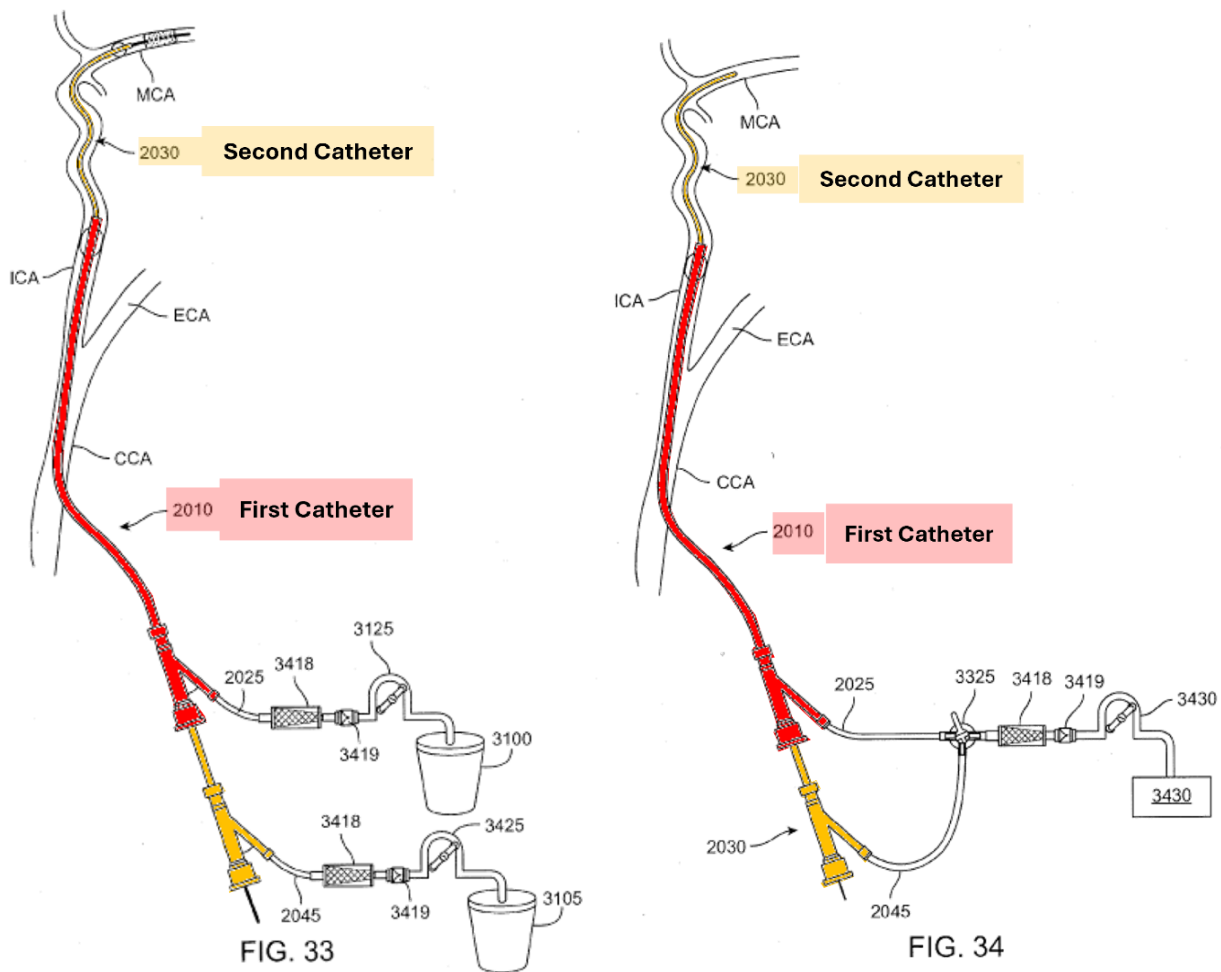
(Ex. 1006, Fig. 33 (Modified); Ex. 1003, ¶122.) And, as discussed above, Garrison’s second catheter includes a distal end portion configured to be positioned proximate to clot material, such as PEs, to aspirate at least a portion of the PE. (*Supra* § VI.A.5; Ex. 1003, ¶123.)

B. Claim 2

Claim 2 depends from Claim 1 and recites: “wherein the first catheter has a first length, and wherein the second catheter has a second length longer than the first

length.” Garrison in view of Laub and/or Aklog renders this claim obvious. (Ex. 1003, ¶¶124-125.)

Garrison discloses that “[if] the catheter is unable to reach the treatment site, or if a secondary 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, and positioned at the distal treatment site.” (Ex. 1006, [0166].) Garrison illustrates a second catheter that has a length longer than the length of the first catheter in multiple embodiments, including the embodiments in Figures 33 and 34:



(*Id.*, Figs. 33-34).

C. Claim 3

Claim 3 depends from Claim 1 and recites: “wherein the first catheter has a size of 24 French, and wherein the size of the the [sic] second catheter has [sic] is 16 French.” Garrison in view of Laub and/or Aklog renders this claim obvious. (Ex. 1003, ¶¶126-131.)

Laub discloses that “[i]n some embodiments, aspiration catheter 200 has a French size of *at least* 20 Fr.” (Ex. 1007, [0028] (emphasis added).) Laub also discloses that “[i]n some embodiments, aspiration catheter 200 has a French size of at least 16 Fr.” (*Id.*)

Aklog discloses that its “[c]annula ... may be of any sufficient size, so long as it can be accommodated within a predetermined vessel, such as a medium to large size blood vessel.” (Ex. 1005, 11:12-14.) Aklog further discloses that the “size of cannula 10 may also be determined by the size of the undesirable material to be removed, so long as the undesirable material can be removed substantially en bloc without significant fragmentation,” and it explains that the cannula may have a sufficient size “to remove at least 10 cm³ of undesirable material substantially en bloc.” (*Id.*, 11:15-20.) Figure 7 of Aklog also depicts a large diameter catheter aspirating a large clot from the proximal portion of the pulmonary vasculature,

extent necessary, Laub's disclosure of catheters measuring 20F or greater. (*Id.*, 11:12-14; Ex. 1003, ¶128).

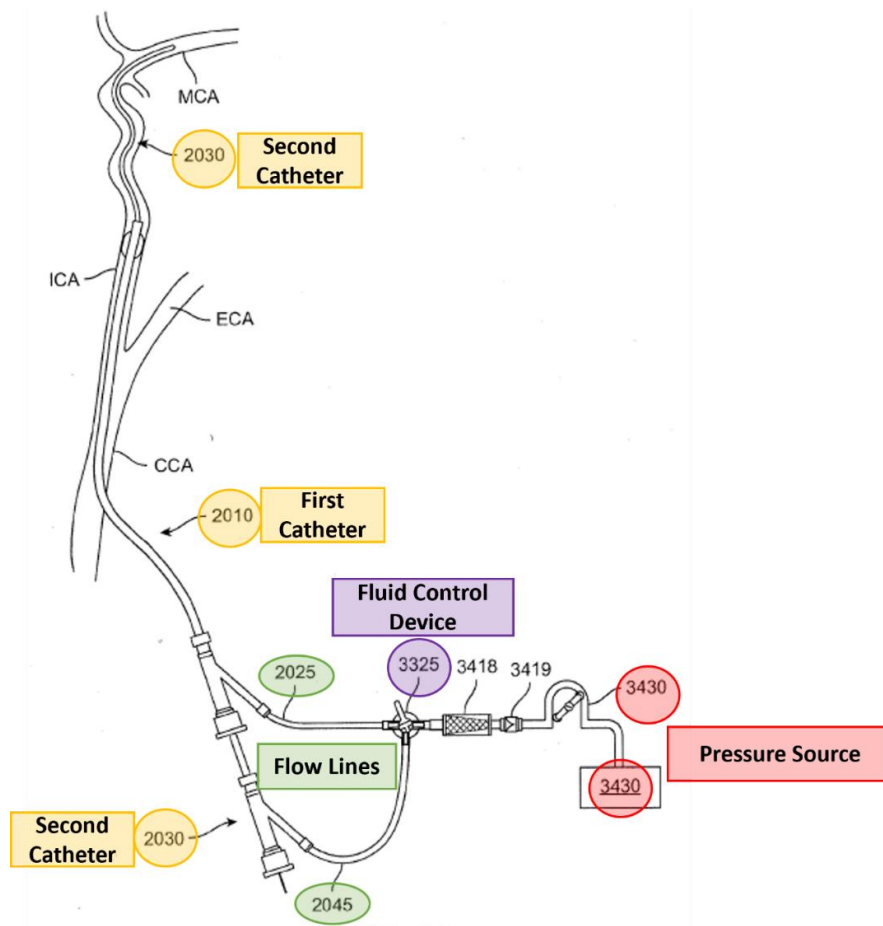
Moreover, using aspiration catheters having a size of 16 or 24 French or greater to treat PE was well known prior to 2018, as evidenced by Laub. (Ex. 1003, ¶129.) There were also several commercially available aspiration systems at that time that were used to treat both PE and DVT that included catheters larger than 16 and even 24 Fr. (*See e.g.*, Ex. 1049, 241 (disclosing 26 Fr. Angiovac catheter used to treat PE); Ex. 1051, 604-607, Table 3 (disclosing 22 Fr. Angiovac catheter used to treat DVT).)

Accordingly, given Laub's or Aklog's disclosures and the knowledge of a POSITA regarding the available systems for treating PE in August 2018, a POSITA would have been motivated to use catheters of at least 16 Fr and 24 Fr in Garrison's system to treat PE. (Ex. 1003, ¶130.) Further, there were only a finite number of large catheter sizes that could be used to aspirate large blood vessels (~16 French to 26 French). A POSITA would have found it obvious to try any of these finite, predictable catheter sizes for treating PE and would have optimized a clot treatment system to use the proper combination of catheter diameter, flexibility, and torque. A POSITA would have reasonably expected success in using 16 French and 24 French catheters because Laub, Aklog, and the other prior art references confirm the effectiveness of these sizes for treating PE. (*Id.*)

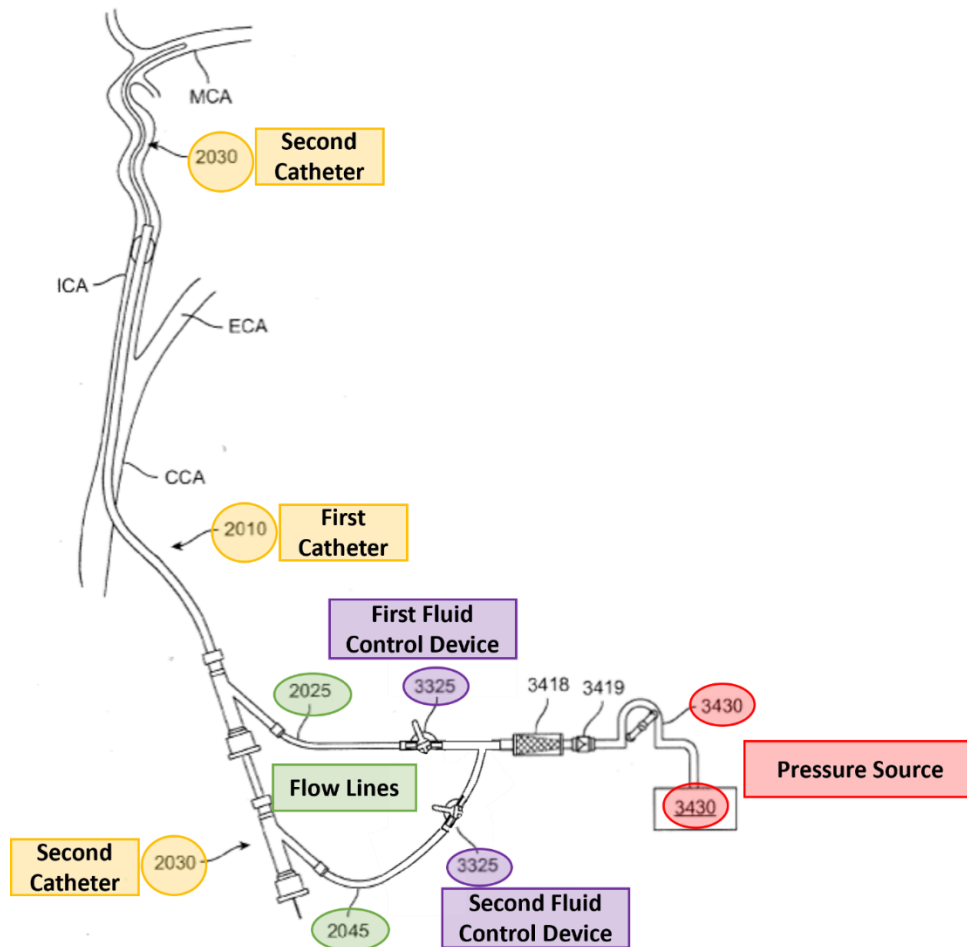
D. Claim 4

Claim 4 depends from Claim 1 and recites: “wherein the first pressure source is the same as the second pressure source.” To the extent claim 4 is a proper dependent claim under 35 U.S.C. §112(d), and two pressure sources can be a single pressure source, Garrison in view of Laub and/or Aklog renders this claim obvious. (Ex. 1003, ¶¶132-135.)

Garrison discloses an embodiment “whereby both the arterial access device 2010 and catheter 2030 are connected to the same aspiration source 3430 via flow lines 2025 and 2045, respectively”:



(Ex. 1006, [0132], Fig. 34.) A POSITA would have found it obvious to use two valves 3325 with the embodiment shown in Fig. 34 so that the physician could separately apply pressure to both catheters:



Demonstrative Illustration
Modified FIG. 34

(*Supra* §V.A.7; Ex. 1006, Fig. 34 (Modified); Ex. 1003, ¶133.)³

³ This image reflects a demonstrative prepared by Imperative Care. All modifications to the figure have been made by Imperative Care.

While Figure 34 already includes a three- or four-way stopcock to allow the physician to separately control the flow of fluid through both flow lines, a POSITA would have been motivated to try using a separate, two-way fluid control device on each individual flow line. (Ex. 1003, ¶134.) While a three- or four-way stopcock is a convenient tool, it increases the risk that the user inadvertently applies pressure to the wrong flow line at the wrong time. (*Id.*) For example, the user may wish to apply negative pressure to only flow line 2025 but accidentally turn the three-way stopcock in the wrong direction resulting in the application of pressure to flow line 2045 (and ultimately the second catheter). (*Id.*) By using individual, two-way stopcocks on each line, the risk of inadvertently applying pressure to the wrong flow line is decreased. (*Id.*)

A POSITA would have expected success in using two fluid control devices (e.g., stopcocks) in the embodiment in Figure 34 for several reasons. (*Id.*, ¶135.) First, Garrison already describes using such a stopcock to maximize fluid flow to the catheter. (*Id.*) Second, stopcocks are simple mechanical structures that were used with many medical devices in 2018. (*Id.*) A POSITA would have been intimately familiar with these devices and would have had experience connecting and disconnecting them from medical tubing, such as flow lines 2025 and 2045. (*Id.*) In fact, Garrison incorporates patents describing standard connectors for stopcocks. (*Supra* §VI.A.6.) Ultimately, the combination of a second fluid control device with

the system in Figure 34 would have been nothing more than the combination of prior art elements (stopcock and tubing) according to known methods (positioning the stopcock between the filter and catheter using standard connectors) to yield predictable results (controlling the application of suction to the catheter). (Ex. 1003, ¶135.)

E. Claim 5

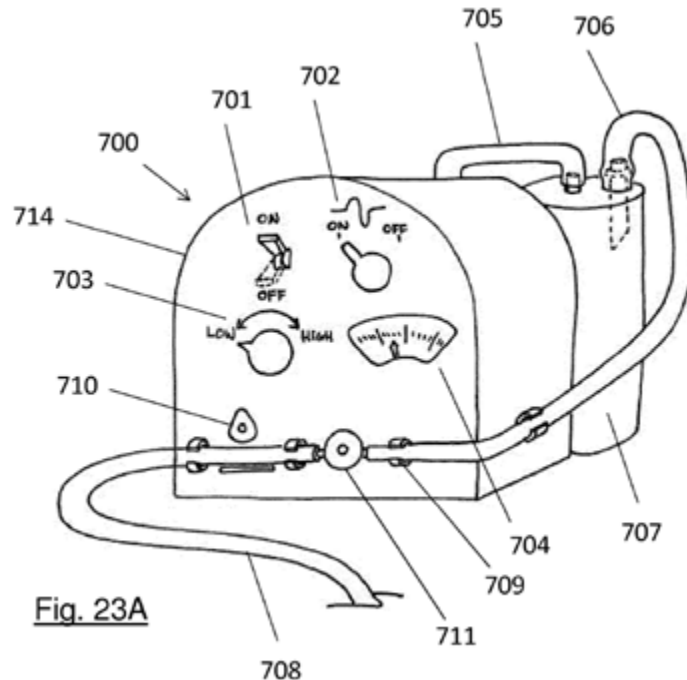
Claim 5 depends from Claim 1 and recites: “wherein the first pressure source and the second pressure source comprise an electric pump.” Garrison in view of Laub and/or Aklog renders this claim obvious. (Ex. 1003, ¶¶136-139.)

Garrison discloses aspiration for its system “may be an aspiration pump, a regular or locking syringe, a hand-held aspirator, hospital suction, or the like.” (Ex. 1006, [00134], *see also id.* at [0165].) Garrison also discloses using “a syringe or other manual aspiration device, or an aspiration pump.” (*Id.*, [0072]; *see also id.*, [0134], [0071] (“an aspiration source such as a pump or a syringe”).) Because Garrison distinguishes between “manual aspiration devices” and “aspiration pumps,” a POSITA would have understood aspiration pumps to mean electric pumps. (Ex. 1003, ¶137.)

Laub’s system also includes a pump 400 which may be a centrifugal pump, a rotary pump, peristaltic pump, roller pump, or other form of pump known in the art. (Ex. 1012, [0041].) The pump 400 “may be controlled by a console” connected to

the pump via either a “hard-wired electrical pathway” or a wireless connection. (*Id.*) Thus, if the Board determines that Garrison does not expressly disclose an electric pump, a POSITA would have found it obvious to use one of Laub’s electric pumps with Garrison to provide continuous suction. (Ex. 1003, ¶138.)

Aklog discloses that its system can include a pump 15 “designed to generate negative pressure ... to create a necessary suction force through cannula 10 to pull any undesirable material from the site of interest.” (Ex. 1005, 11:62-65.) The pump 15 “may be any commercially available pump, including those for medical applications and those capable of pumping fluids, such as blood.” (*Id.*, 11:62-12:14.) There were several commercially available electronic pumps designed and used for clot aspiration systems prior to August 2018. (*See, e.g.*, Ex. 1038; Ex. 1039.) Likewise, many prior art patents and applications described electric pumps for aspiration system, such as Brady:

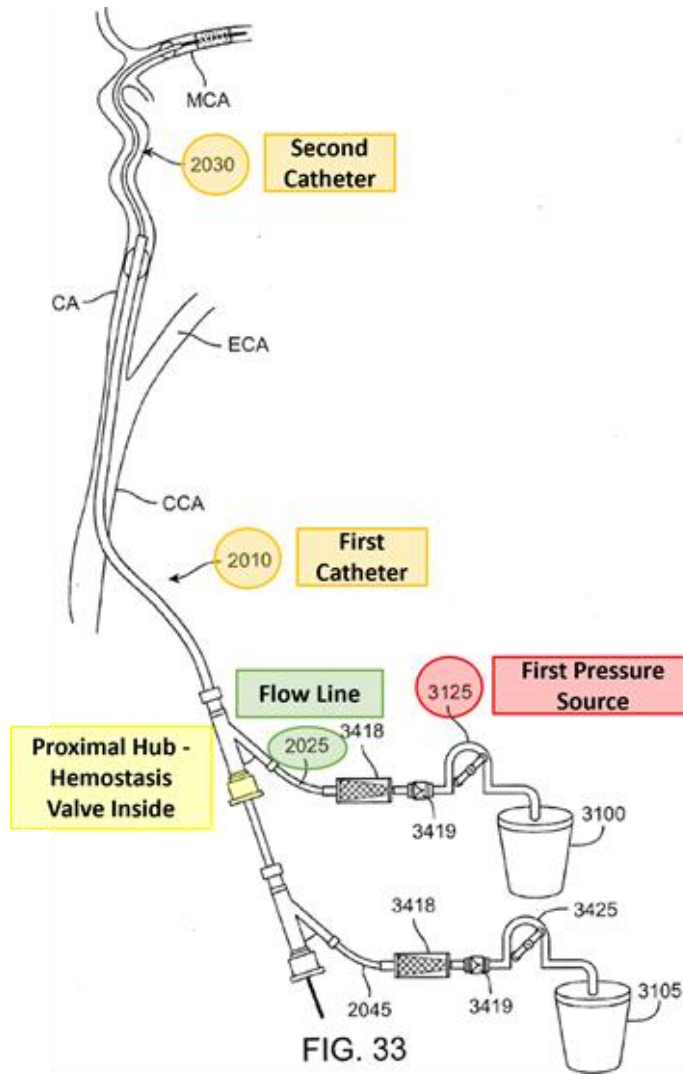


(Ex. 1020, Fig. 23A.) Therefore, if Garrison does not expressly disclose an electric pump, a POSITA would have found it obvious to combine Aklog and a commercially available electric pump with Garrison. (Ex. 1003, ¶139.) The substitution of Laub’s or Aklog’s pumps for Garrison’s pump would have been the simple substitution of one known element for another to obtain predictable results (e.g., suction to aspirate clots). *KSR*, 550 U.S. at 417.

F. Claim 6

Claim 6 depends from Claim 1 and recites: “wherein the first clot aspiration assembly further includes a hemostasis valve configured to receive the second catheter.” Garrison in view of Laub and/or Aklog renders this claim obvious. (Ex. 1003, ¶¶140-142.)

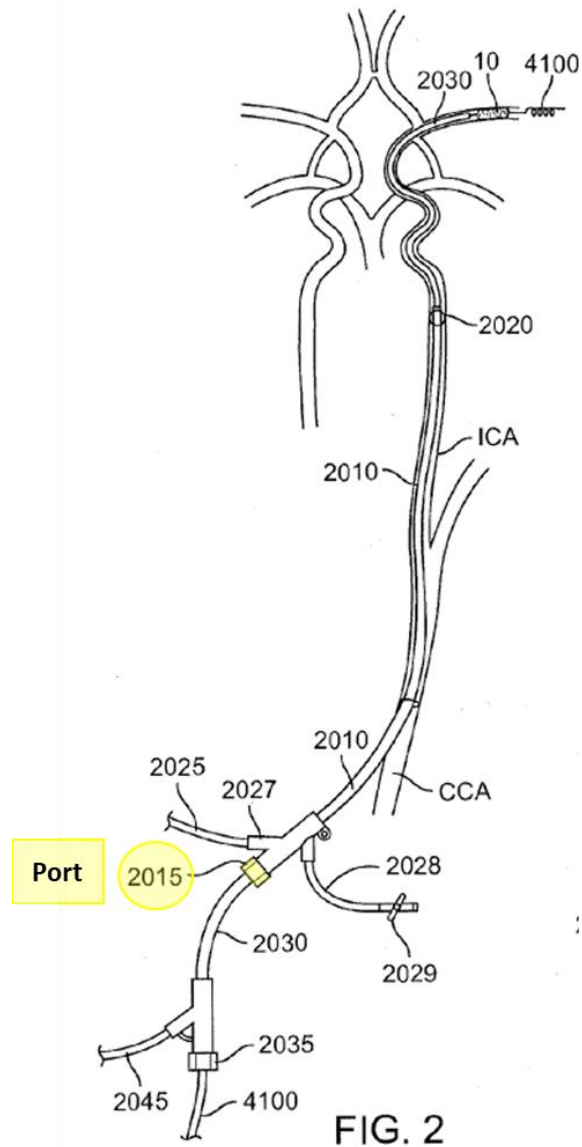
Garrison discloses a first catheter 2010 [orange] having a hemostasis valve [yellow] in its proximal hub 2065 (item 2065 not pictured in Figure 34):



(Ex. 1006, [0098], Fig. 33.) Garrison specifically states that “a separate hemostasis valve may be attached to proximal hub 2065, to allow introduction of devices such as a microcatheter, guide wire, or thrombectomy device while preventing or minimizing blood loss during the procedure.” (*Id.*, [0098].) Garrison also discloses that “the hemostasis valve may be integral to the catheter proximal adaptor.” (*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.” (*Id.*)

Figure 34 (above) does not expressly label the proximal adaptor and hemostasis valve, but other, related figures do. For example, Figures 2 and 3 identify a “proximal adaptor having a proximal port 2015 *with a hemostasis valve* to allow introduction of devices while preventing or minimizing blood loss during the procedure.” (*Id.*, [0053] (emphasis added), Fig. 3; *see also id.* at [0050]-[0053], [0059], [0062], Figs. 1-3, 6 (Garrison also explains that the arterial access device also has a hemostasis valve 2012).) The location of the hemostasis valve in Figure 3 is the customary location for a hemostasis valve on a catheter. (Ex. 1003, ¶142.)



(*Id.*, Fig. 2.) Accordingly, Garrison discloses the additional limitations of Claim 6.
(Ex. 1003, ¶142.)

G. Claim 8

Claim 8 depends from Claim 1 and recites: “wherein the first fluid control device is user actuatable to move between the first position and the second positions of the first fluid control device, and wherein the second fluid control device is user

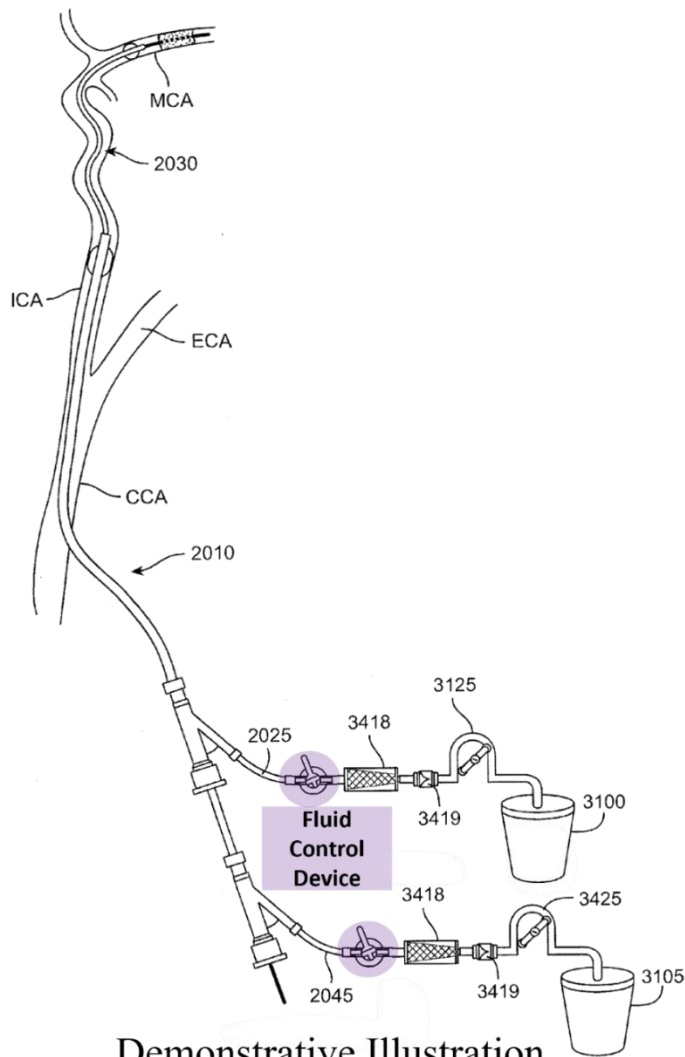
actuatable to move between the first positoin [sic] and the second position of the second fluid control device.” Garrison’s stopcock is a user actuatable type of valve. (Ex. 1003, ¶143.) Thus, Garrison in view of Laub and/or Aklog renders this claim obvious for the reasons explained in Claim 1. (*Supra* §§VI. A.3, VI.A.7.)

H. Independent Claim 11

Claim 11 recites the same limitations as Claim 1 except that claim 11 recites that the first pressure source is configured to be fluidly “coupled” to the first catheter instead of fluidly “connected” to the first catheter, and does not require a first fluid control device between the first catheter and the first pressure source. Because the ’910 patent does not distinguish between coupled and connected, Garrison in view of Laub and/or Aklog renders this claim obvious for the reasons explained in Claim 1. (*Supra* § VI.A; Ex. 1003, ¶¶144-146.)

Garrison’s first pressure source is fluidly connected to the first catheter. (*Supra* §VI.4.) The first pressure source is also fluidly coupled to the first catheter for the same reasons, namely that fluid can flow from the catheter and the flow lines to the first pressure source and the associated receptacle. (Ex. 1003, ¶145.)

As explained in Claim 1, a POSITA would have found it obvious to add the same valve 3325 from Garrison’s Figure 34 to the flow lines (2025, 2045) in the embodiment shown in Garrison’s Fig. 33:



Demonstrative Illustration
Modified FIG. 33

(Ex. 1006, Fig. 33 (Modified); Ex. 1003, ¶146.) The fluid control device would beneficially allow the physician to independently control the flow of pressure to one or both of the catheters, and would have motivated a POSITA to make this modification with a reasonable expectation of success. (*Supra* §VI.A.6; Ex. 1003, ¶146.) For example, the user may want to provide continuous suction through the first catheter, while providing a rapid burst of aspiration through the second catheter,

as described by Garrison. (Ex. 1006, [0134].) Thus, Garrison renders this limitation obvious. (Ex. 1003, ¶¶145-147.)

I. Claim 12

Claim 12 depends from Claim 11 and recites: “wherein the first catheter has a size of 24 French, and wherein the size of the second catheter is 16 French.” This is the same limitation found in Claim 3. Thus, Garrison in view of Laub and/or Aklog renders Claim 12 obvious for the reasons previously provided. (*Supra* § VI.C.)

J. Claim 13

Claim 13 depends from Claim 11 and recites: “wherein the first pressure source is the same as the second pressure source.” This is the same limitation found in Claim 4. Thus, to the extent the claim is proper, Garrison in view of Laub and/or Aklog renders Claim 13 obvious for the reasons previously provided. (*Supra* §VI.D.)

K. Claim 14

Claim 14 depends from Claim 11 and recites: “wherein the first pressure source and the second pressure source comprise an electric pump.” This is the same limitation found in Claim 5. Thus, Garrison in view of Laub and/or Aklog renders Claim 14 obvious for the reasons previously provided. (*Supra* §VI.E.)

L. Claim 15

Claim 15 depends from Claim 11 and recites: “wherein the first clot aspiration assembly further includes a hemostasis valve configured to receive the second catheter.” This is the same limitation found in Claim 6. Thus, Garrison in view of Laub and/or Aklog renders Claim 15 obvious for the reasons previously provided. (*Supra* §VI.F.)

M. Claim 18

Claim 18 depends from Claim 11 and recites: “wherein the first catheter has a size of 24 French, wherein the size of the second catheter is 16 French, and wherein the first pressure source and the second pressure source comprise an electric pump.” This is the same limitation found in Claims 3, 5, 12 and 14. Thus, Garrison in view of Laub and/or Aklog renders Claim 18 obvious for the reasons previously provided. (*Supra* §§ VI.C, VI.E.)

N. Claim 19

Claim 19 depends from Claim 15 and recites: “wherein the first pressure source is the same as the second pressure source.” This is the same limitation found in Claims 4 and 13. Thus, to the extent the claim is proper, Garrison in view of Laub and/or Aklog renders Claim 19 obvious for the reasons previously provided. (*Supra* §VI.D.)

O. Claim 20

Claim 20 depends from Claim 7 and recites: “wherein the first pressure source is the same as the second pressure source.” This is the same limitation found in Claims 4, 13, and 19. Thus, if the claim is proper, Garrison in view of Laub and/or Aklog renders Claim 20 obvious for the reasons previously provided. (*Supra* §VI.D.)

VII. GROUNDS 4-6: GARRISON COMBINED WITH LAUB, AKLOG, AND/OR HARTLEY RENDERS CLAIMS 6-7, 20 UNPATENTABLE

A. Claim 6

Garrison in view of Laub and/or Aklog and Hartley renders this claim obvious. (Ex. 1003, ¶154.) As explained in the next section, POSITAs would have been motivated, and found it obvious, to use Hartley’s hemostasis valve as the hemostasis valve on Garrison’s catheters. (*Infra* §VII.B; Ex. 1003, ¶¶154-164.)

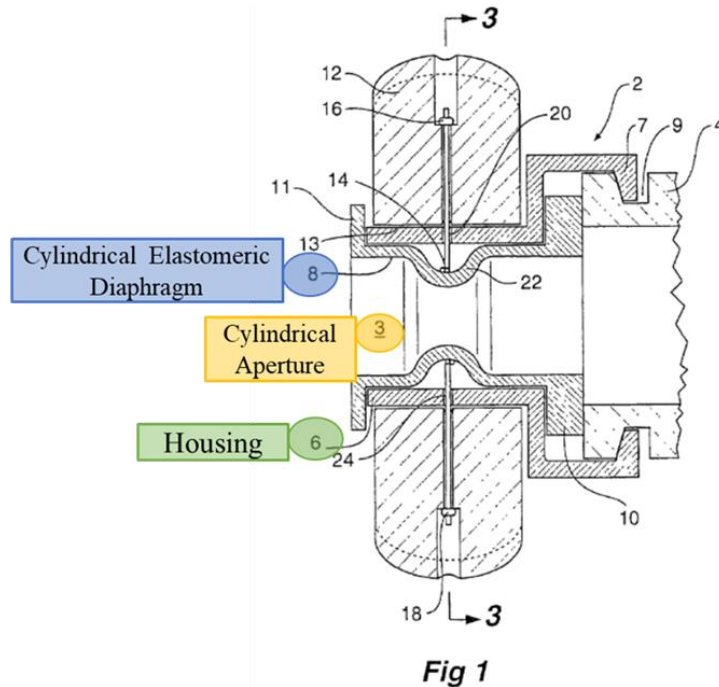
B. Claim 7

Claim 7 depends from Claim 6 and recites: “wherein the hemostasis valve comprises: a tubular member defining a lumen configured to slidably receive the second catheter; and a filament extending at least partially around the tubular member, wherein the filament is moveable between (a) a first position wherein the filament circumferentially constricts the lumen to create a seal around the second catheter and (b) a second position wherein the filament is moved to at least partially

open the lumen.” Garrison in view of Laub and/or Aklog and Hartley renders this claim obvious. (Ex. 1003, ¶¶155-164.)

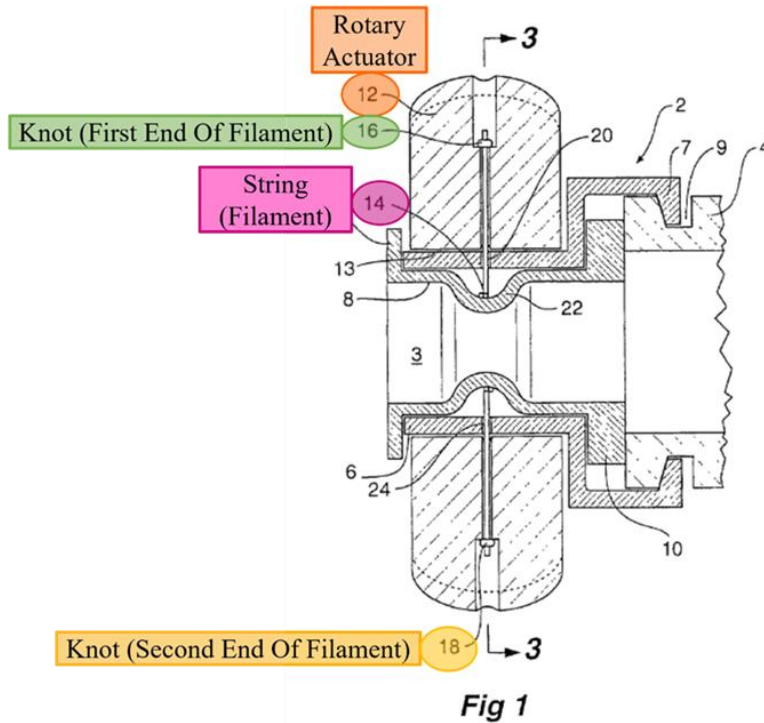
Garrison discloses catheters 2010 and 2030 having a hemostasis valve in the hub or port at the end of the catheter. (*Supra* §VI.F.) Garrison explains that different types of hemostasis valves can be combined with the catheter, including, for example, “an adjustable-opening valve such as a Tuohy-Borst or rotating hemostasis valve (RHV)” or “a passive seal hemostasis valve.” (Ex. 1006, [0098].) However, Garrison does not expressly describe the structure of the hemostasis valves combinable with its system. Yet, hemostasis valves were ubiquitous in the art and POSITAs would have been familiar with such valves. (Ex. 1003, ¶156.) Presumably, Garrison did not expressly describe the structure of the hemostasis valves because POSITAs were already familiar with such structures. (*Id.*)

Hartley discloses a type of rotating hemostasis valve that “can be controlled to vary the size of the aperture through the valve and be flexible so that a seal may be formed against an instrument or other object inserted through the access valve.” (Ex. 1008, [0003].) Hartley explains that the valve includes a “cylindrical housing 6 into which is received a cylindrical elastomeric diaphragm 8 ... [that] defines a cylindrical aperture 3 therethrough”:



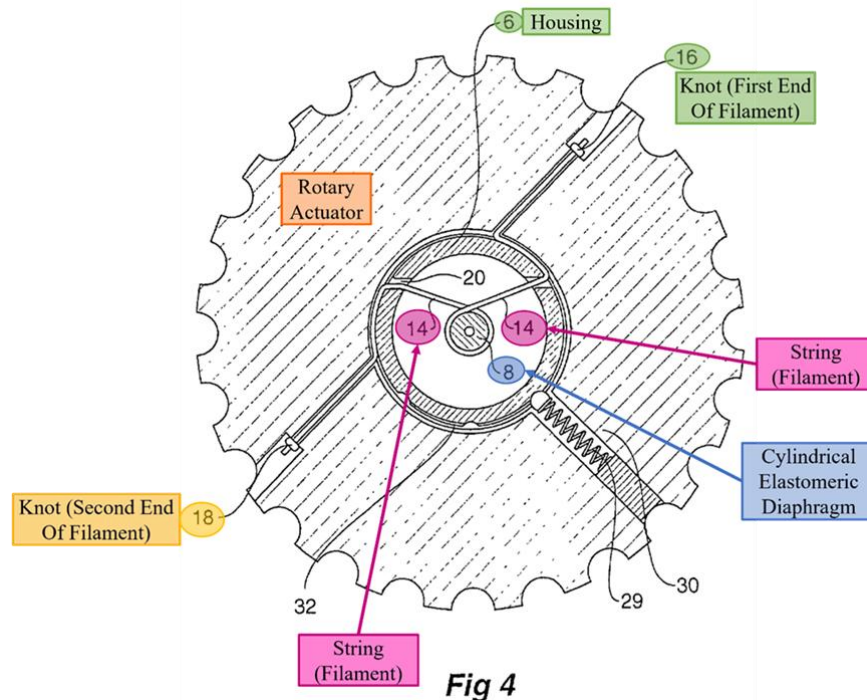
(*Id.*, [0031], Fig. 1.) Hartley also explains that the “cylindrical diaphragm can be completely constricted to prevent fluid flow through the valve or can be constricted to the extent that it closes around an instrument, for instance a catheter, passed through the valve.” (*Id.*, [0006].) Thus, Hartley’s cylindrical diaphragm is “a tubular member defining a lumen configured to slidably receive the second catheter,” as required by Claim 7. (Ex. 1003, ¶157.)

Hartley’s valve also includes a rotatory actuator 12 and a “string 14 ... mounted into the rotary actuator”:



(*Id.*, [0031], Fig. 1.) Hartley’s string 14 is a filament because it includes, for example, one or more threads, lines, cords, ropes, ribbons, flat wires, sheets, or tapes. (Ex. 1003, ¶158; *supra* §IV.)

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”:



(Ex. 1008, [0031], [0034], Fig. 4.) This configuration corresponds to the “first position” required by Claim 7 because the filament circumferentially constricts the lumen (i.e., cylindrical elastomeric diaphragm) to create a seal around the second catheter. (Ex. 1003, ¶159.) Hartley expressly states that the “cylindrical diaphragm can be completely constricted to prevent fluid flow through the valve or can be constricted to the extent that it closes *around an instrument, for instance a catheter*, passed through the valve.” (Ex. 1008, [0006] (emphasis added).)

Hartley also discloses that “[r]otation of the rotary actuator back to the central position where the detent ball 28 is received in depression 34 will cause the sutures to loosen again so that the resilient cylindrical diaphragm will retain its original shape as shown in FIGS. 1 and 3”:

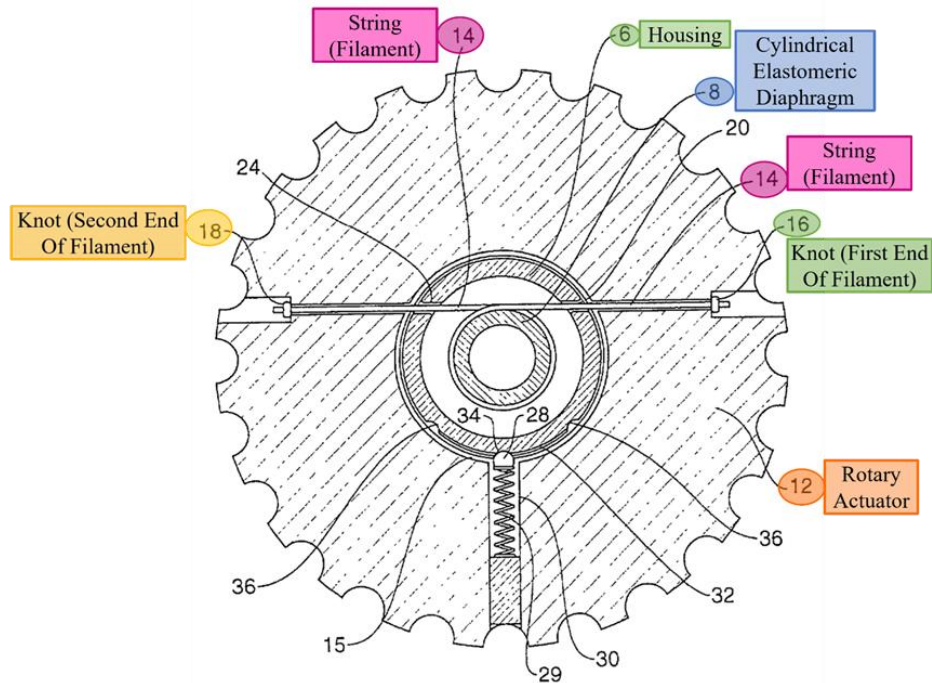


Fig 3

(*Id.*, [0034], Fig. 3.) This configuration corresponds to the “second position” required by Claim 7 because the filament has been moved to at least partially open the lumen. (Ex. 1003, ¶160.)

A POSITA would have been motivated to combine Hartley’s hemostasis valve with Garrison’s catheters 2010 and 2030 for several reasons and would have reasonably expected success in doing so. (Ex. 1003, ¶¶161-164.) First, Garrison expressly discloses that Garrison’s catheters 2010 and 2030 can be combined with a “rotating hemostasis valve.” (Ex. 1006, [0098].) Hartley discloses a type of rotating hemostasis valve and, therefore, a POSITA would have been motivated to combine, and reasonably expected success in combining, Hartley’s valve with Garrison based on this suggestion. (Ex. 1003, ¶161.)

Second, combining Hartley’s valve with Garrison’s catheters 2010 and 2030 would have merely entailed the combination of known elements (Hartley’s hemostasis valve and Garrison’s catheters 2010 and 2030) according to known methods (attaching the valve to a proximal hub on the catheter or forming it integrally with the hub) to yield the predictable result of reducing leakage through the valve. *KSR*, 550 U.S. at 416. Catheters having hemostasis valves were ubiquitous in the art before August 2018, as was the procedure to combine a hemostasis valve with a catheter. (Ex. 1003, ¶162.) A POSITA would have encountered various types of hemostasis valves during their education and career and would have been familiar with how the valves operate. (*Id.*) The valves, like the valve described in Hartley, are simple mechanical structures that operate in a predictable manner and would have been obvious to combine with Garrison’s catheters. (*Id.*)

Third, a POSITA in August 2018 had a finite number of predictable hemostasis valves to select when trying to seal a catheter. (*Id.*, ¶163.) Garrison and Hartley reference some of the known hemostasis valves, including an “adjustable-opening valve such as a Tuohy-Borst or rotating hemostasis valve (RHV),” Hartley’s rotating valve, or “a passive seal hemostasis valve.” (Ex. 1006, [0098].) A POSITA would have found it obvious to try any of these hemostasis valves in combination with Garrison’s catheters 2010 and 2030. (Ex. 1003, ¶163.) Moreover, as discussed

above, the known hemostasis valves, including Hartley’s rotating hemostasis valve, were simple mechanical structures that operate in a predictable way. For this additional reason, a POSITA would have reasonably expected success in combining any of the known valves with Garrison’s catheters 2010 and 2030. (*Id.*)

Lastly, Hartley’s valve would have been appropriate for aspiration catheters for use in all portions of the vasculature, including catheters for treating PE. (*Id.*, ¶164.) Hartley does not restrict its hemostasis valve to any particular size and, therefore, a POSITA would have understood that the hemostasis valve could be used with catheters measuring 16F or 24F. (*Id.*) In fact, Hartley discloses its valve could be used for access ports in laparoscopic catheters (or trocars), which can commonly be 10 or 12mm in diameter (i.e., 30F-36F), well above 24F. (Ex. 1008, [0021]; Ex. 1003, ¶164.)

C. Claim 20

Claim 20 presents the same limitation found in Claims 4, 13, and 19. The use of the Hartley’s valve would not impact whether the system uses two pressure sources or the same pressure source. (Ex. 1003, ¶165.) Thus, Garrison in view of Laub and/or Aklog renders Claim 20 obvious for the reasons previously provided. (*Supra* §VI.D.)

**VIII. GROUNDS 7-9: GARRISON COMBINED WITH LAUB
AND/OR AKLOG AND PASHA**

A. Claim 3

Garrison in view of Laub and/or Aklog and additionally Pasha renders claim 3 obvious. (Ex. 1003, ¶¶166-169.) If Laub and Aklog do not disclose using a first catheter measuring 24F, a POSITA would have found it obvious to optimize Garrison’s system to use a 24F first catheter based on Pasha. (*Id.*, ¶166.)

Pasha is an article published in 2014 that describes the treatment of a patient suffering from a “pulmonary embolus extending into right and left pulmonary arteries as well as lobar arteries.” (Ex. 1049, 240-241.) The physicians determined the patient was not a candidate for thrombolytics or surgery. (*Id.*, 241.) Therefore, the physicians treated the patient’s PE using “a 26-French Angiovac catheter” using suction created by the catheter. (*Id.*) The physicians concluded that “off-label use of Angiovac suction catheter devices provides a novel technique to remove large emboli effectively as an alternative method to other catheter-based devices.” (*Id.*)

The decision by these physicians to use the Angiovac system for this patient confirms that physicians and POSITAs possessed the requisite knowledge to select the appropriately sized catheter for a particular procedure. (Ex. 1003, ¶168.) There is nothing novel or nonobvious about selecting one catheter size over another – such selections are routine. (*Id.*) Pasha discloses the successful use of catheter even larger than 24F to treat PE. This disclosure would have motivated POSITAs to adapt

Garrison's system to use a first catheter of at least 24F to treat PE. (*Id.*) Moreover, the successful results experienced by the physicians in using such a catheter would have given POSITAs a reasonable expectation of success. (*Id.*)

Further, Laub discloses using catheters of 16F to treat PEs, and Aklog also discloses using larger catheters to treat such embolisms. (*Supra* §VI.2.) A POSITA would have found it obvious to use a first catheter measuring 24F and a second catheter measuring 16F that could telescope (i.e., be advanced) through the first catheter. (Ex. 1003, ¶168.) Laub specifically discloses that a catheter measuring 16F can successfully treat PEs. Moreover, Garrison discloses the benefits of using telescoping catheters to treat patients suffering from blood clots. (*See e.g.*, Ex. 1006, [0054].) For example, the larger catheter may initially engage a clot but the second, smaller diameter catheter may be necessary to reach more distal clots. (*Id.*) Thus, the use of a 16F catheter in a telescoping configuration with a 24F catheter would have been nothing more than the combination of prior art elements (two known catheters) according to known methods (telescoping) to yield predictable results (aspirating PEs). *KSR*, 550 U.S. at 417.

Moreover, a POSITA would have been familiar with using catheters ranging from 16F to 24F in a telescoping fashion. (*Supra* §VI.A.5; *see also* Ex. 1003, ¶169 (describing use of such catheters).) The ubiquitousness of telescoping catheters in the medical device field to deliver all manner of devices, including stents and heart

valves, would have given a POSITA a reasonable expectation of success in using telescoping 16F and 24F catheters to treat a PE. (Ex. 1003, ¶169.)

B. Claims 12 and 18

Claims 12 and 18 recite the same limitations found in Claims 3 and 5. Therefore, Garrison in view of Laub and/or Aklog and Pasha renders Claims 12 and 18 obvious for the reasons previously provided. (*Supra* §§ VI.C; VI.E, VIII.A.)

IX. SECONDARY CONSIDERATIONS

Petitioner is not aware of any evidence of secondary considerations. (Ex. 1003, ¶¶171-172.) If PO identifies evidence of secondary considerations, Petitioner respectfully requests an opportunity to respond.

X. SOTERA STIPULATION

Petitioner hereby stipulates that if the Board institutes this IPR based on the grounds and claims raised in the Petition, Petitioner will not pursue in district court the grounds asserted in the IPR Petition or any other ground that could have been reasonably raised in this IPR. Thus, there will be no “overlap between issues raised in the petition and in the parallel proceeding.” *Apple v. Fintiv*, IPR2020-00019, Paper 11 at 6 (PTAB Mar. 20, 2020) (precedential).

**XI. MANDATORY NOTICES, GROUNDS FOR STANDING,
AND FEE PAYMENT**

A. Real Parties-In-Interest (37 C.F.R. §42.8(b)(1))

Imperative Care, Inc. is the real parties in interest for Petitioner.

B. Related Matters (37 C.F.R. §42.8(b)(2))

In the Litigation, PO filed a Second Amended Complaint alleging that Petitioner's Symphony system infringes the '910 patent, as well as U.S. Patent Nos. 11,969,333; 11,554,005; 11,744,691; 11,697,012; 11,844,921, 11,865,291, 12,016,580; 12,109,384; and 12,156,669. *Inari Medical, Inc. v. Imperative Care, Inc.*, No. 24-cv-3117 (N.D. Cal., filed May 22, 2024). In the Second Amended Complaint, Petitioner also dropped its infringement allegations regarding U.S. Patent No. 11,697,011, which is the subject of an instituted IPR. (Ex. 1042.) The court has set a case schedule only through the claim construction hearing, currently set for July 24, 2025. (Ex. 1044.) The court has not set a trial date in the litigation. (*Id.*)

PO has also filed a Motion for Leave to File a Third Amended Complaint, which would add U.S. Patent No. 12,239,333 to the litigation. (Ex. 1043.) Petitioner has opposed the Motion and requested that the Court vacate the case schedule until PO is done asserting additional patents. (Ex. 1047.) The motion is scheduled for hearing on May 28, 2025. Petitioner has also filed a Motion to Stay the Litigation pending resolution of the IPRs. (Ex. 1048.) The motion is schedule for hearing on July 16, 2025.

Petitioner has filed seven IPRs against patents asserted by PO in the Litigation: (1) *Imperative Care, Inc. v. Inari Medical, Inc.*, IPR2024-01157

IPR Petition – Patent 11,974,910
Imperative Care, Inc. v. Inari Medical Inc.

requesting review of U.S. Patent No. 11,697,011 (Filed July 8, 2024); (2) *Imperative Care, Inc. v. Inari Medical, Inc.*, IPR2024-01257 requesting review of U.S. Patent No. 11,744,691 (Filed August 12, 2024); (3) *Imperative Care, Inc. v. Inari Medical, Inc.*, IPR2025-00156 requesting review of U.S. Patent No. 11,697,012 (Filed November 8, 2024); (4) *Imperative Care, Inc. v. Inari Medical, Inc.*, IPR2025-00289 requesting review of U.S. Patent No. 11,554,005 (Filed December 13, 2024); (5) *Imperative Care, Inc. v. Inari Medical, Inc.*, IPR2025-00728 requesting review of U.S. Patent No. 11,844,921 (Filed March 13, 2025); (6) *Imperative Care, Inc. v. Inari Medical, Inc.*, IPR2025-00989 requesting review of U.S. Patent No. 11,865,291 (Filed May 9, 2025); (7) *Imperative Care, Inc. v. Inari Medical, Inc.*, IPR2025-01021 requesting review of U.S. Patent No. 11,969,333 (Filed May 19, 2025). The Board granted institution of the '011 and '012 patent IPRs. The Board denied institution of the '691 patent IPR. The '691 patent shares the same parent as the '910 patent. However, the Board denied institution of the '691 patent IPR based on a claim limitation not present in the '910 patent.

C. Lead and Backup Counsel (37 C.F.R. §42.8(b)(3))

Petitioner provides the following designation of counsel, all of whom are included in Customer No. 20,995 identified in Petitioner's Power of Attorney.

Lead Counsel	Back-up Counsel
Joshua J. Stowell (Reg. No. 64,096) 2jys@knobbe.com BoxImperative910@knobbe.com Knobbe, Martens, Olson, & Bear, LLP <u>Postal and Hand-Delivery Address:</u> 2040 Main St., 14 th Floor Irvine, CA 92614 Telephone: 949-760-0404 Facsimile: 949-760-9502	Joseph R. Re (Reg. No. 31,291) 2jrr@knobbe.com Brian C. Barnes (Reg. No. 75,805) 2bcb@knobbe.com Knobbe, Martens, Olson, & Bear, LLP <u>Postal and Hand-Delivery Address:</u> 2040 Main St., 14 th Floor Irvine, CA 92614 Telephone: 949-760-0404 Facsimile: 949-760-9502

D. Service Information (37 C.F.R. §42.8(b)(4))

Please direct all correspondence to lead counsel and back-up counsel at the addresses shown above. Petitioner also consents to electronic service by email to BoxImperative910@knobbe.com.

E. Grounds for Standing (37 C.F.R. §42.104)

Petitioner certifies that the '910 patent is available for IPR and that Petitioner is not barred or estopped from requesting IPR on the identified grounds. This Petition is being filed within one year of service of the Complaint in the Litigation.

F. Payment of Fees (37 C.F.R. §42.15(a))

The fee for this petition has been paid. Additional fees may be charged to Deposit Account 11-1410.

XII. CONCLUSION

For the reasons above, Petitioner has established a reasonable likelihood of prevailing in showing that at least one or more claims are unpatentable as anticipated or obvious and, therefore, requests that the Board institute an *inter partes* review.

Dated: May 20, 2025

By: /Joshua J. Stowell/

Joshua J. Stowell (Reg. No. 64,096)

Joseph R. Re (Reg. No. 31,291)

Sabing Lee (Reg. No. 43,745)

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KNOBBE MARTENS OLSON & BEAR, LLP

Attorneys for Petitioner Imperative Care, Inc.

CERTIFICATE OF COMPLIANCE

Pursuant to 37 C.F.R. § 42.24(d), the undersigned certifies that this PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 11,974,910 contains 13,564 words according to the word-processing program used to prepare this paper. The foregoing word count complies with the 14,000-word type-volume limit specified by 37 C.F.R. § 42.24(a)(1).

Dated: May 20, 2025

By: /Joshua J. Stowell/

Joshua J. Stowell (Reg. No. 64,096)

KNOBBE MARTENS OLSON & BEAR, LLP

CERTIFICATE OF SERVICE

The undersigned hereby certifies that on the date below a copy of this PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 11,974,910, PETITIONER’S POWER OF ATTORNEY, AND EXHIBITS 1001-1053, were served by Priority Mail Express on the Patent Owner at the correspondence address of record for the subject patent as follows:

25096 - PERKINS COIE LLP - SEA General
PATENT-SEA
P.O. BOX 1247
SEATTLE, WA 98111-1247
UNITED STATES

A courtesy copy has been sent by email on this day to Patent Owner’s counsel of record in the Litigation as follows:

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