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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 IPR2024-01257
Patent No. 11,744,691

**PETITION FOR *INTER PARTES* REVIEW OF
U.S. PATENT NO. 11,744,691**

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LIST OF EXHIBITS

Exhibit No.	Description
1001	U.S. Patent No. 11,744,691 (“the ’691 patent”)
1002	’691 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 Treretola (“Treretola”)
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. 2005/0004534 A1 to Lockwood et al. (“Lockwood”)
1013	U.S Patent Publication No. 2015/0352325 A1 to Quick et al. (“Quick”)
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. (“Lewis”)

Exhibit No.	Description
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”)
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).

Petitioner Imperative Care, Inc. (“Petitioner”) requests *inter partes* review (“IPR”) of Claims 1-31 of U.S. Patent No. 11,744,691 (“the ’691 patent,” Ex.1001), which is assigned to Inari Medical, Inc. (“Patent Owner” or “PO”).

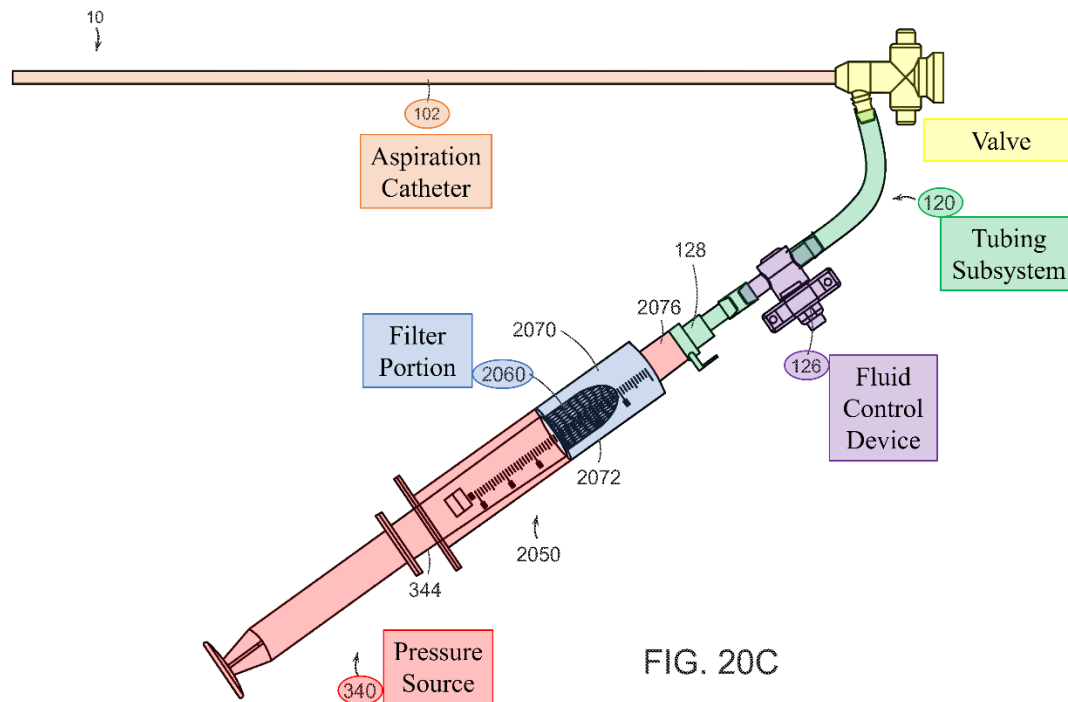
I. INTRODUCTION

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 ’691 patent claims such an aspiration 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 ’691 patent does not explain how the claimed system addresses these alleged shortcomings.

Instead, the claims merely recite conventional aspiration components, including a negative pressure source (e.g., pump or syringe) [red], an aspiration

catheter [orange], a filter [blue], a fluid control device [purple], and a hemostasis valve [yellow]:



(*Id.*, Fig. 9C.) As shown below, aspiration catheters having these conventional components were known and used before August 2018, the earliest claimed priority date of the '691 patent.

The '691 patent claims also recite that (1) the fluid control device (referred to as a “user-actuable valve” in the claims) may be closed “while a negative pressure is generated” and (2) opened “after the negative pressure is generated” to cause “rapid aspiration.” (*Id.*, 6:55-22.) The '691 patent speculates that “pre-charging or storing the vacuum before applying the vacuum to the lumen 104 of the catheter 102 is expected to generate greater suction forces (and corresponding fluid flow

velocities) at and/or near the distal portion 103a of the catheter 102 compared to simply activating the pressure source 140.” (*Id.*) However, as shown below, aspiration catheters that could release a stored vacuum to create rapid aspiration were not new.

Garrison, a prior art patent application published in June 2015, describes an aspiration system for removing unwanted material from a patient’s vasculature. As illustrated below, Garrison’s aspiration system includes the exact same components as Claim 1 of the ’691 patent: a negative pressure source (e.g., pump or syringe) [red], an aspiration catheter [orange], a filter [blue], hemostasis valves [yellow], and a user-actuable valve [purple] that is closed while negative pressure is generated by the pressure source and opened after the negative pressure is generated to cause rapid aspiration through the catheter.

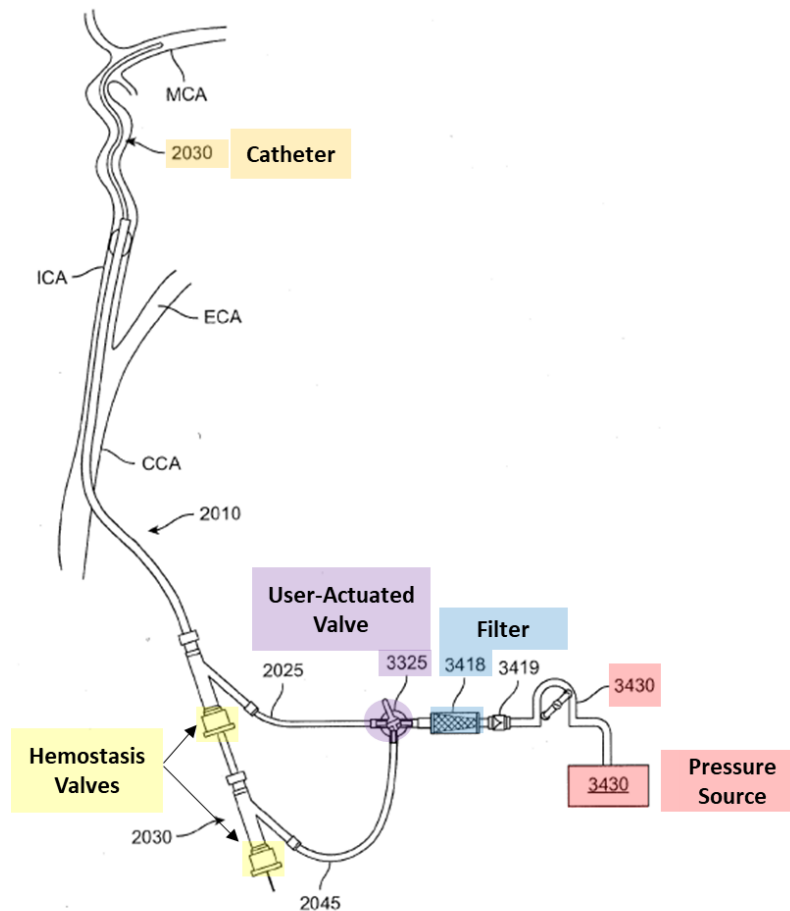


FIG. 34

(Ex. 1006, Fig. 34.) Garrison explains that opening the valve after generating the negative pressure enables “the maximum level of aspiration in a *rapid fashion* with one user, something that is not currently possible with existing technologies.” (*Id.*, [0134] (emphasis added).) As explained herein, Garrison anticipates or renders obvious the ’691 patent claims.

While Garrison was listed in an Invention Disclosure Statement (“IDS”) during prosecution, it was buried among hundreds of other prior art references. The Examiner obviously overlooked and failed to apply the teachings of Garrison to the ’691 patent claims.

In addition to the conventional components discussed above, some of the challenged claims recite additional limitations that also fail to distinguish the challenged claims from the prior art. **First**, dependent Claims 7 and 8, among others, require that the aspiration catheter’s “distal end portion” is “configured to be positioned proximate to clot material” wherein “the clot material comprises a pulmonary embolism” (hereinafter, “PE”) or “a deep vein thrombosis” (hereinafter, “DVT”). Garrison discloses using its aspiration system to remove cerebral occlusions but does not specifically mention PE or DVT.

However, as shown herein, Garrison’s catheter is “configured to be positioned” proximate these types of clots because it has the correct size and flexibility. Additionally, if the Board determines the claims require more, a person of ordinary skill in the art (“POSITA”) would have found it obvious to use and/or adapt Garrison’s cerebral aspiration system to aspirate PE or DVT. Each procedure involves the identical process of advancing a catheter through an artery or vein to reach an embolism and activating a vacuum through the catheter to aspirate the emboli. Unsurprisingly, catheter designers knew well before 2018 how to size catheters to fit the desired vessel.

The use and/or adaptation of Garrison’s system to treat PE and DVT is particularly obvious in view of **Aklog**, a prior art patent issued in May 2014. Aklog discloses an aspiration system for removing undesirable materials, including PE and

DVT, from blood vessels. (Ex. 1005, 2:7-32, 7:27-42.) Aklog also acknowledges that a POSITA could simply adapt aspiration catheters for use in other parts of the vasculature, stating “Although reference is made to medium and large vessels, it should be appreciated that the systems and methods, herein disclosed, can be scaled and adapted for use within smaller vessels within the body, if desired.” (*Id.*, 7:43-46.)

Notably, the ’691 patent also expressly reinforces the interchangeability of aspiration catheters for different parts of the vasculature by alleging the described catheters are useful for “treating a pulmonary embolism,” “intravascular procedures other than the treatment of emboli, intravascular procedures for treating ***cerebral embolism***, intravascular procedures for treating deep vein thrombosis (DVT), etc.” (Ex. 1001, 4:51-58 (emphasis added).)

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

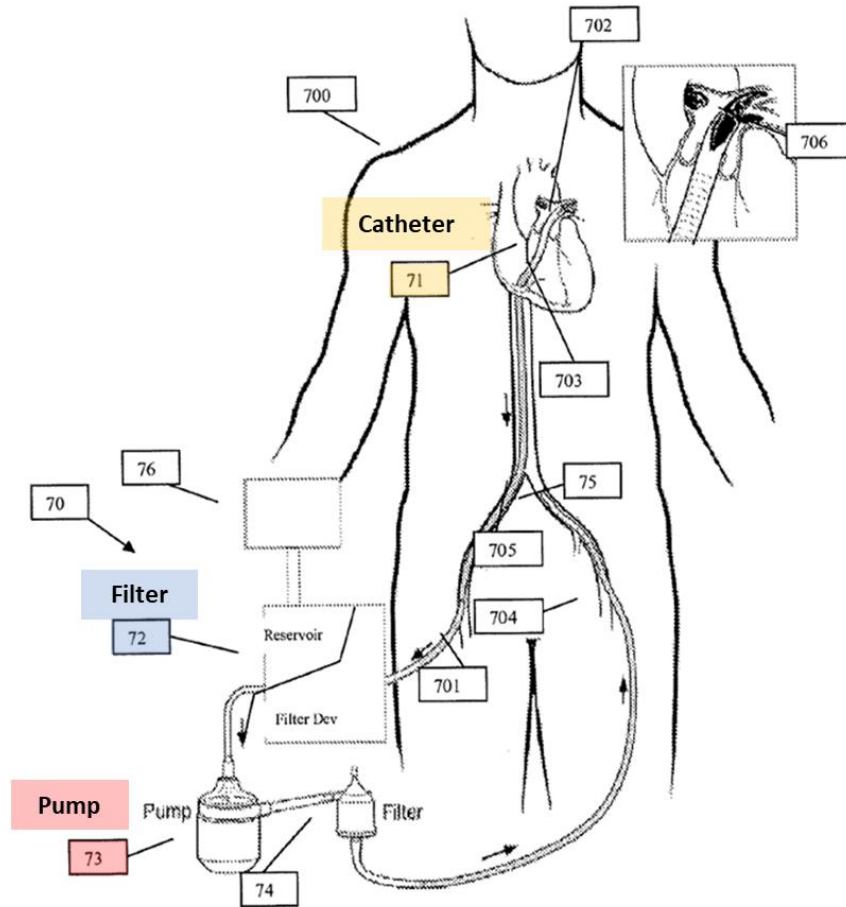


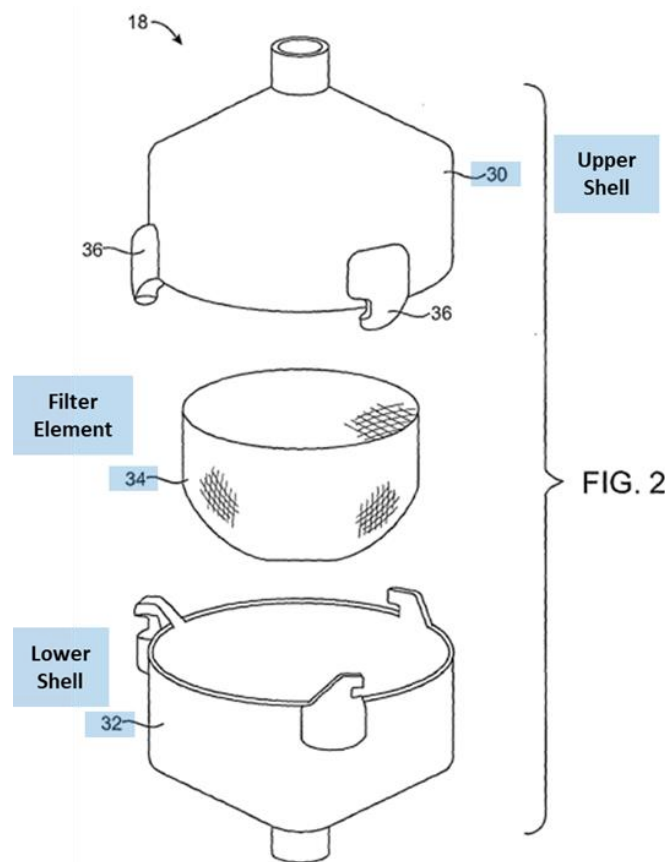
Fig. 7

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

Second, dependent Claims 4 and 9 of the '691 patent, among others, require “the second chamber is removably carried by the assembly” and “the second

chamber is removably coupled between the aspiration pump and the aspiration catheter.” Similarly, dependent Claim 12 requires that “the filter is removable from within the second chamber.” Garrison and Aklog both disclose second chambers that contain a filter and are between the aspiration pump and catheter. However, the references do not expressly disclose whether the second chamber or filter are removable. But aspiration systems having removable chambers and filters were well known by August 2018 simply because the clot may plug the filter or exceed the capacity of the filter chamber. Such clogging would bring an abrupt halt to this time sensitive procedure if the chamber could not be opened to empty the captured clot.

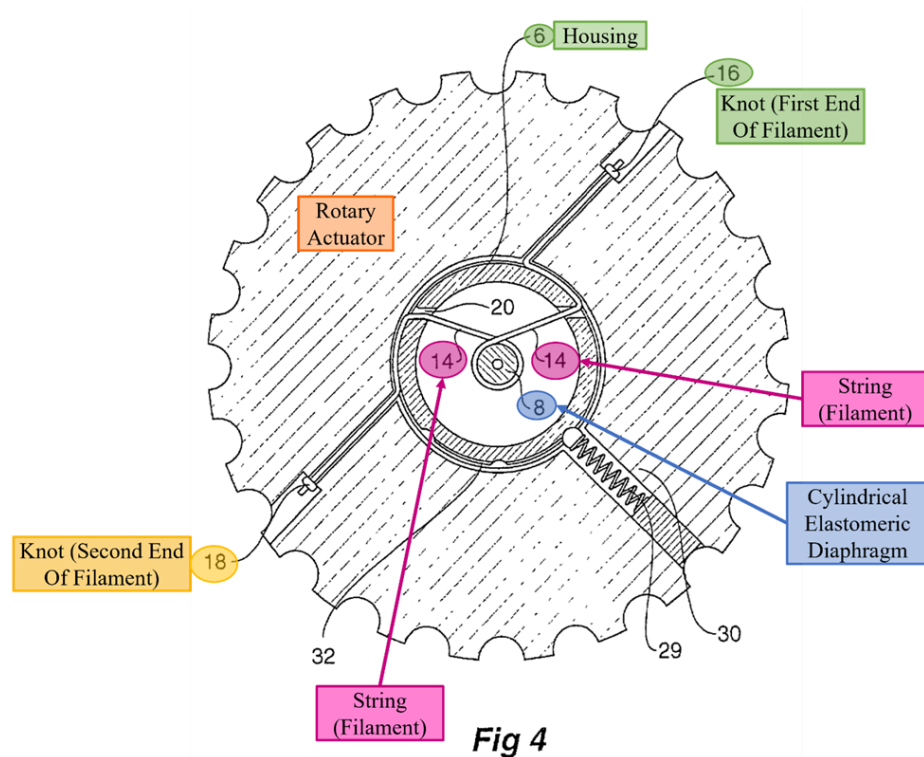
Goff, a PCT application published in November 2006, discloses an aspiration system having a filter housing 18 to “remove solid materials from the aspirate.” (Ex. 1007, [0011].) The “filter housing has an upper shell and a lower shell which may be taken apart to permit introduction, **removal**, and replacement of the filter element in the interior of the housing.” (*Id.*, [0015] (emphasis added).)



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

Third, dependent Claim 3 of the ’691 patent, among others, requires a specific type of hemostasis valve having a “tubular member” and a “filament extending at least partially around the tubular member.” Garrison discloses several different

hemostasis valves that can be interchangeably used with its aspiration system including, for example, a “rotating hemostasis valve.” However, Garrison does not expressly describe the valve structures. **Hartley**, a patent application published in 2003, discloses the structure for a rotating hemostasis valve that includes a filament extending around a tubular member to restrict the member and close the valve:



As shown herein, POSITAs would have found it obvious to combine Hartley’s rotating hemostasis valve with Garrison’s aspiration system.

The challenged claims merely recite known aspiration systems or combine known aspiration systems with prior art components according to their known functions to yield predictable results. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007). The prior art grounds identified in this Petition show a reasonable

likelihood that one or more claims of the '691 patent are unpatentable. Thus, Petitioner requests that the Board institute this IPR to reconsider the patentability of the '691 patent.

II. THE '691 PATENT

A. Overview

The '691 patent describes an aspiration system for intravascular removal of clot material. (Ex. 1001, 4:17-4:33.) The '691 patent alleges that the system can treat various clots including PE, cerebral embolism, and DVT. (*Id.*, 4:51-4:58.) The aspiration system comprises an aspiration “assembly 10” including “catheter subsystem 100”, “pressure source 140,” and “tubing subsystem 120.” (*Id.*, 5:27-5:28.)

The catheter subsystem may include an aspiration catheter 102 [orange] “comprising an elongated shaft defining a lumen 104,” and a “valve 106” [yellow] with a “lumen 109 extending therethrough.” (*Id.*, 5:23-5:48.) The valve “is configured to maintain hemostasis during a clot removal procedure by preventing fluid [blood] flow in the proximal direction through the valve 106” when other components are inserted, such as “other aspiration catheters.” (*Id.*)

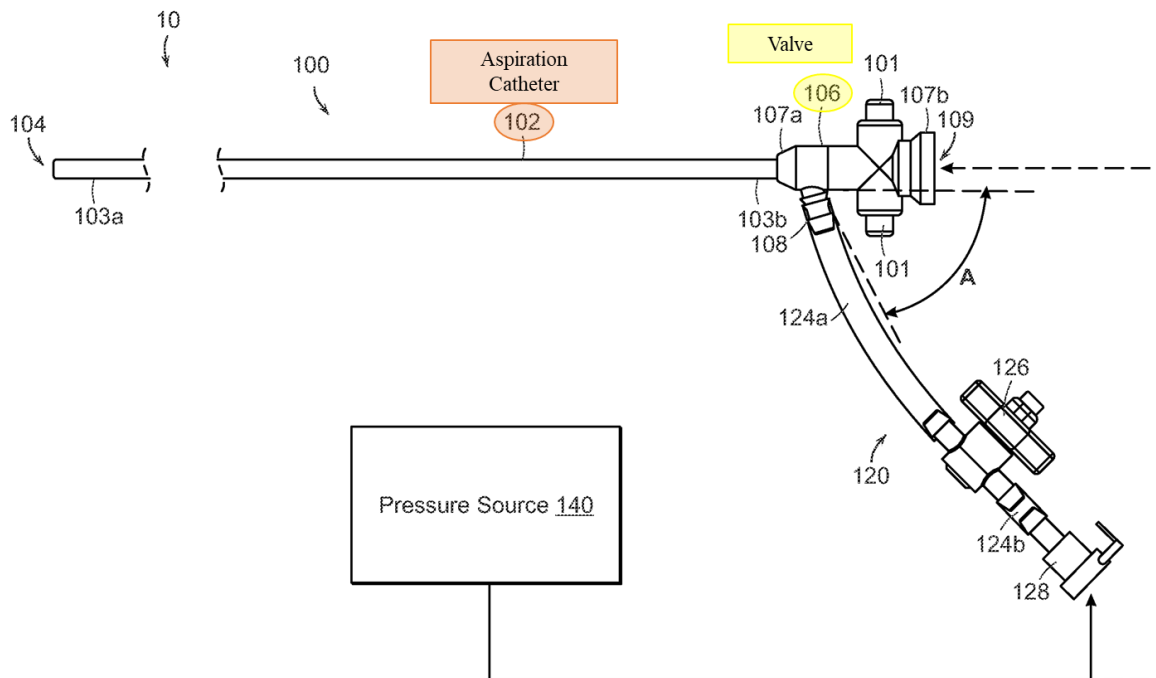


FIG. 1

The pressure source [red, below] 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 application to the catheter subsystem 100.” (*Id.*, 6:55-6:58.) “[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.*, 7:33-7:38.)

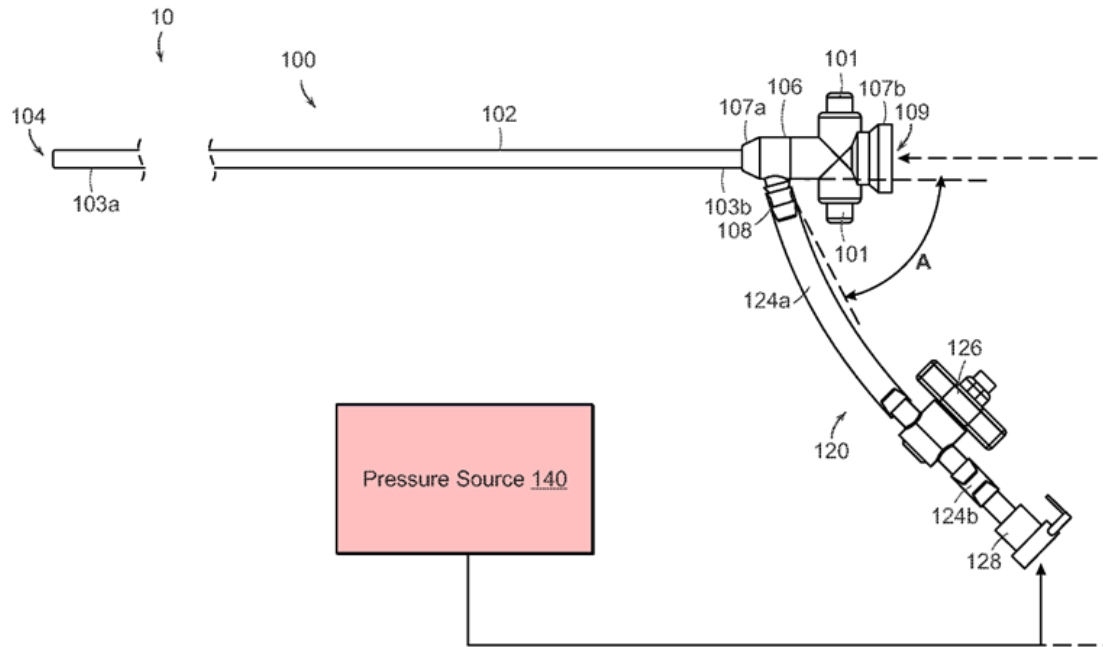


FIG. 1

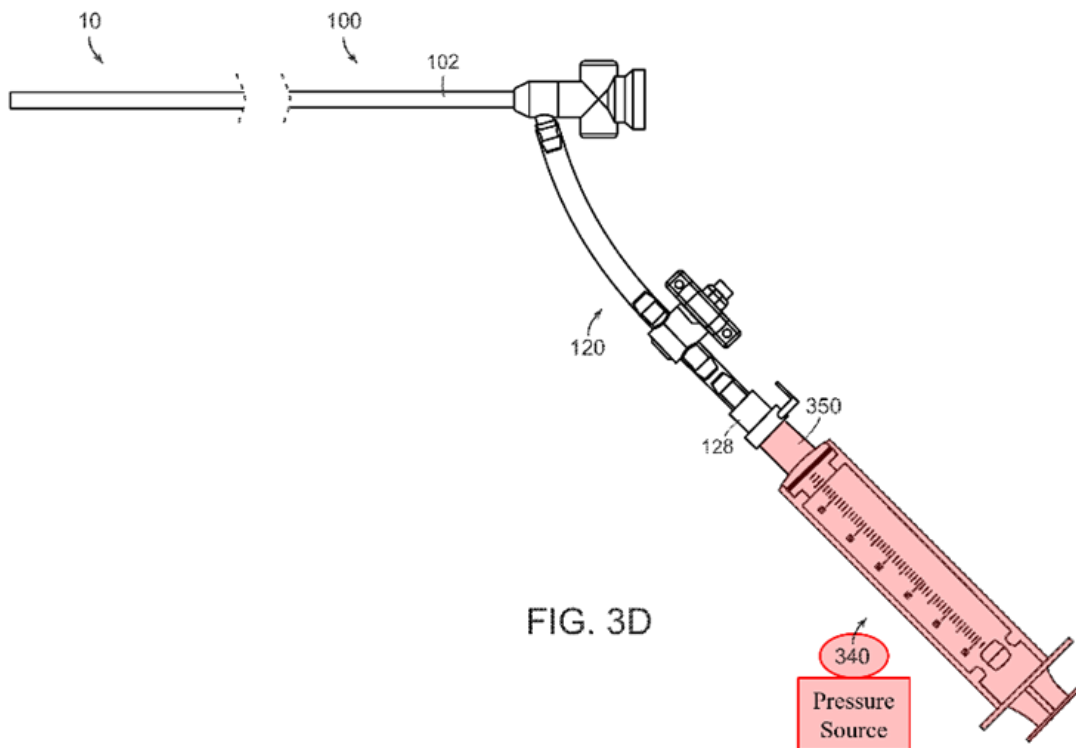


FIG. 3D

The tubing subsystem “fluidly couples the catheter subsystem 100 to the pressure source 140.” (*Id.*, 6:4-6:5.) The tubing subsystem can include “one or more tubing sections 124,” at least one “fluid control device 126” such 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.*, 6:4-6:21.)

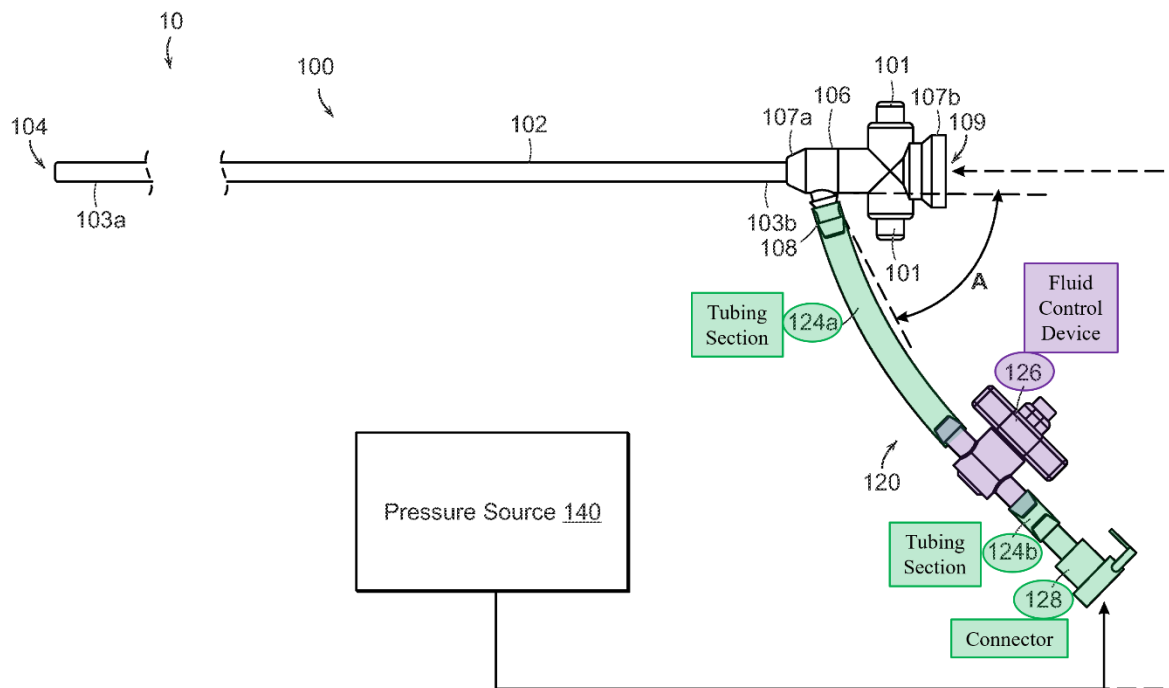
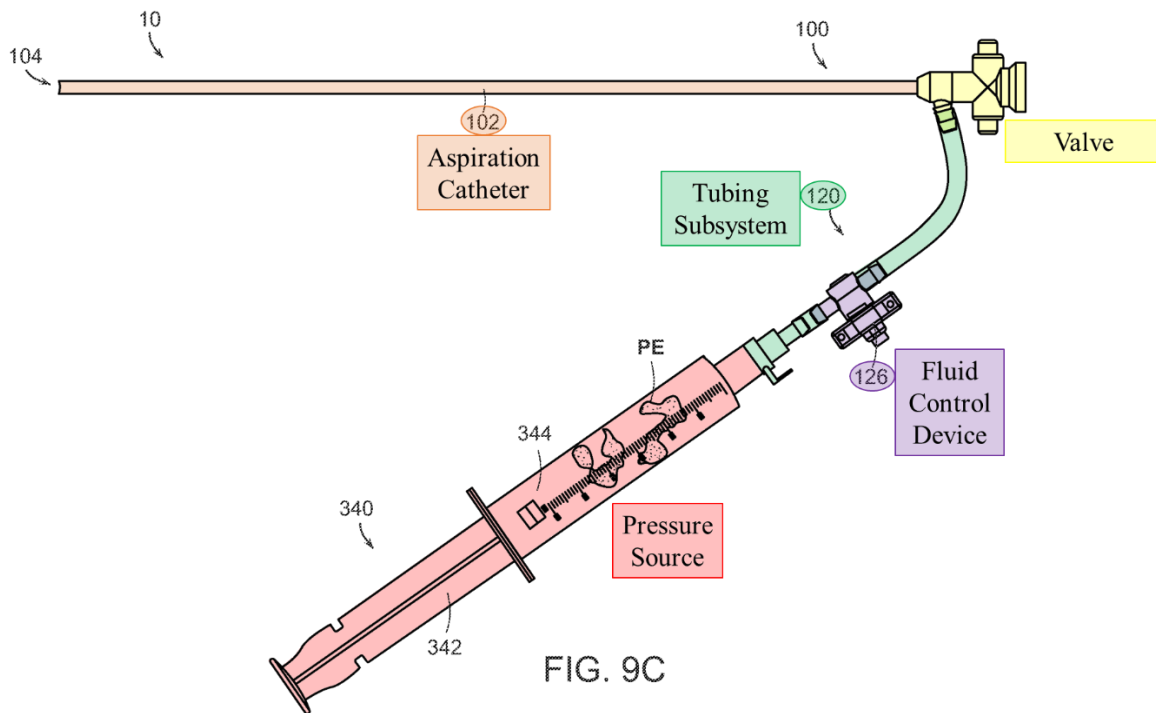


FIG. 1

During operation, 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.*, 6:60-6:64.) 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.*, 18:41-18:45.) 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.*, 7:1-7:6.)



The ‘691 patent further alleges 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.*, 7:6-7:10.)

The ‘691 patent also describes modifications to the aspiration system. For example, the patent describes embodiments having a “pressure source 1900” with a “secondary syringe 460” and a “canister 1940.” (*Id.*, 31:1-19, Fig. 19.) The “canister 1940 further includes a filter 1942.” (*Id.*, 31:20.)

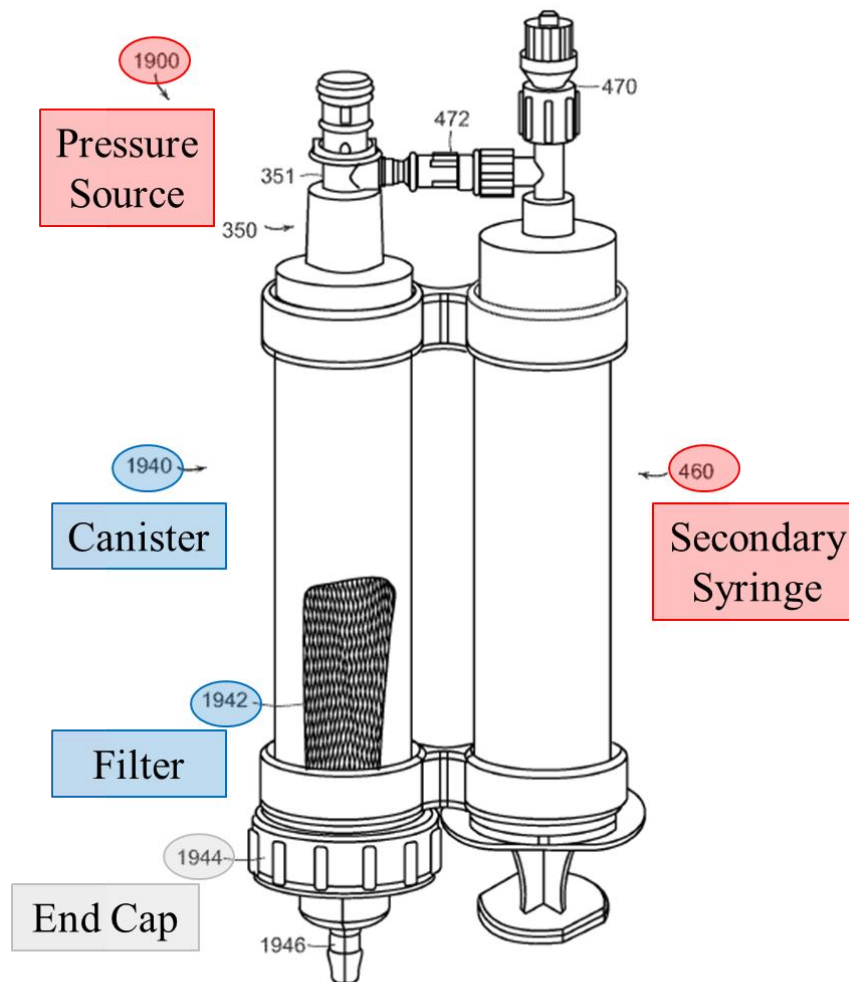


FIG. 19

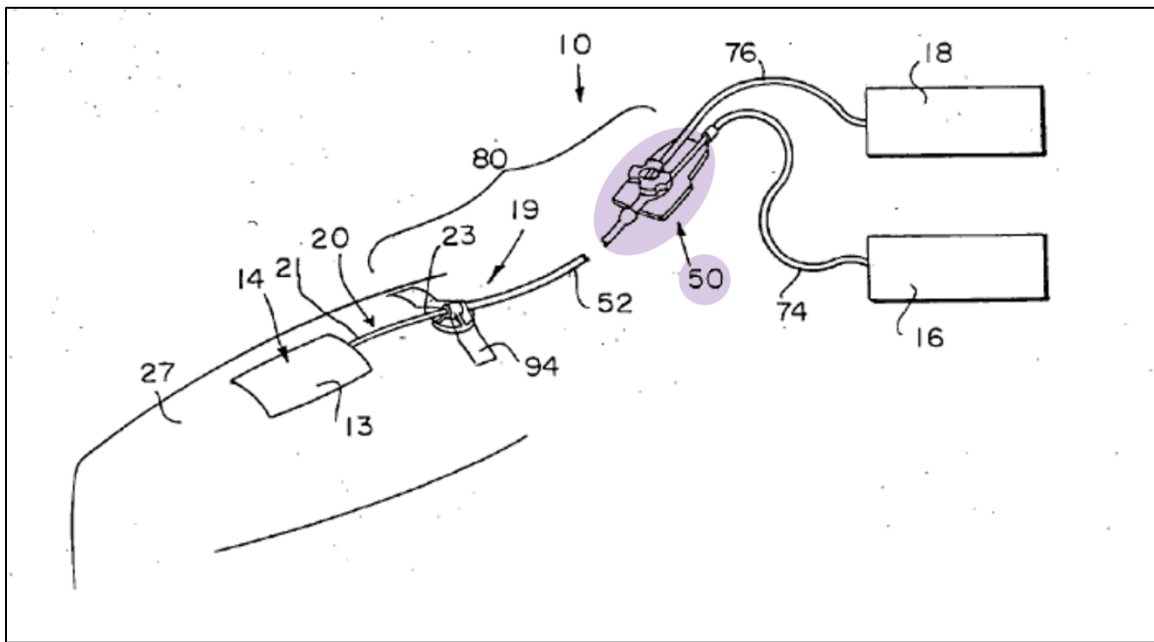
(*Id.*, Fig. 19.) The canister 1940 also includes an end cap 1944 that can be unscrewed to access the filter. (*Id.*, 31:20-42.)

B. Prosecution History

Inari filed the application that became the ‘691 patent on March 8, 2023. The Examiner rejected the independent claims under 35 U.S.C. §103 over U.S. Patent 8,535,283 (Ex. 1011, “Heaton”) in view of U.S. Patent Publication 2005/0004534 (Ex. 1012, “Lockwood”). Both Heaton and Lockwood describe devices for treating

wounds on the skin surface. (See *e.g.*, Ex. 1011, 1:13-15 (“The present invention relates generally to the field of tissue treatment”); Ex. 1012, [0001] (“The present disclosure relates to vacuum therapy wound treatment systems”).)

The Examiner found that Heaton disclosed all the elements of Claim 1 except “a [sic] aspiration system comprising a user-actuatable valve.” (Ex. 1002, 262.) However, the Examiner found that Lockwood discloses “a user-actuatable valve (stopcock or switch valve (50) [purple]) coupled to the single lumen tube (52).” (*Id.*)



(Ex. 1012, Fig. 1.) The Examiner further found that it “would have been obvious to a person having ordinary skill in the art before the effective filing date of the invention to modify the valve of the reduce pressure system of Heaton and replace it with the user actuatable stopcock or switch valve, as taught by Lockwood.” (Ex.

1002, 262.) The Examiner found many other claims obvious over Heaton and Lockwood in addition to Claim 1.

The Examiner also found several dependent claims unpatentable over Heaton modified by Lockwood in further view of US 20150352325 A1 (Ex. 1013, “Quick”). (Ex. 1002, 265-268.) These additional claims required an aspiration catheter “configured to be intravascularly positioned within a blood vessel of a patient” proximate a PE or DVT. (*Id.*) The Examiner found that Quick disclosed catheters for treating PE or DVT and that it would have been obvious to modify the catheters in the wound treatment devices “to enable intravascular delivery of an interventional device to a treatment site in a blood vessel, as taught by Quick.” (*Id.*)

The Examiner also found a few dependent claims allowable. These claims required “a coupled assembly including: the second chamber; the aspiration catheter; and a hemostasis valve” or “a second chamber is removably coupled between the aspiration pump and the catheter.” (*Id.*, 268-269.) The Examiner found that Heaton lacked the “coupled assembly” because Heaton’s second chamber “is configured to be part of the first chamber” so “having the second chamber be part of another assembly that includes the aspiration catheter and a hemostasis valve would destroy the function of how Heaton operates.” (*Id.*) Similarly, the Examiner found that Heaton’s second chamber could not be “removably coupled between the aspiration

pump and the catheter” because it was part of the pump. (*Id.*) The Examiner also found that Heaton did not mention a hemostasis valve. (*Id.*)

In response, Inari withdrew the rejected claims and rewrote the allowable dependent claims in independent form. (*Id.*, 244-254.)

6. (Currently Amended) ~~The~~ An aspiration system of claim 1 with accelerated response, further comprising:
an aspiration pump in communication with a first chamber;
a coupled assembly including:
the second chamber;
~~the~~ an aspiration catheter configured for placement into fluid communication with
the first chamber by way of an aspiration tube; and
a second chamber in between the aspiration pump and the aspiration catheter; and
a hemostasis valve; and
a user-actuatable valve between the second chamber and the aspiration catheter, wherein
the valve is configured to be closed while negative pressure is generated in the first
and second chambers, and wherein the valve is configured to be opened after the
negative pressure is generated in the first and second chambers;
wherein upon user actuation to open the valve with the negative pressure having been
generated in the first and second chambers, fluid flow at least partially from the
second chamber into the first chamber causes rapid aspiration into the second
chamber.

Inari also added new Claims 21-33. (*Id.*)

The Examiner subsequently allowed the rewritten and new claims. In allowing the claims, the Examiner repeated that Heaton does not disclose “a coupled assembly including: the second chamber; the aspiration catheter; and a hemostasis valve.” (*Id.*, 51-52.) The Examiner also repeated that Heaton does not disclose a

second chamber “wherein the second chamber is removably coupled between the aspiration pump and the catheter.” (*Id.*)

The prior art discussed below discloses each of the limitations allegedly missing from the prior art.

C. Earliest Possible Priority Date

The '691 patent claims priority to two provisional applications 62/554,931 and 62/718,269, both filed August 13, 2018. (Ex. 1001.) Accordingly, the earliest possible priority date for the '691 patent is August 13, 2018. Petitioner applies this earliest priority date in this Petition; however, Petitioner reserves its right to challenge the priority date of the '691 patent 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. (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.

Claims 3 and 23 of the '691 patent require a hemostasis valve having “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 a 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.” (Ex. 1001, Claims 3, 23 (emphasis added).) As shown, the claim language does not provide a POSITA with guidance on the meaning of “filament,” other than reciting that the filament extends “at least partially around the tubular member.”

Further, the '691 patent specification does not describe a hemostasis valve having a filament. In fact, the word “filament” does not appear in the '691 patent (other than in Claims 3 and 23). If this limitation has support in the '691 patent, the support must be incorporated by reference from another patent application describing a filament.¹ (See Ex. 1001, 5:54-59 (purporting to incorporate by reference “U.S. patent application Ser. No. 16/117,519 ... titled ‘HEMOSTASIS VALVES AND METHODS OF USE’”) (hereinafter, the “’519 application”, Ex. 1021.)

¹ Petitioner reserves its right to challenge in future proceedings whether PO has effectively incorporated the material into the '691 patent.

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 patent 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 FIGS. 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, ¶¶51-59.)

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	Reference(s)	35 U.S.C.	Challenged Claims
1	Garrison	§102	1-2, 5-6, 10-11, 13
2	Garrison	§103	1-2, 4-6, 9-20, 28-30
3	Garrison + Hartley	§103	3, 23, 25-27
4	Garrison + Goff	§103	4, 9, 11-12, 14-20, 28-30
5	Garrison + Aklog	§103	7-8, 21-22, 31
6	Garrison + Aklog + Hartley	§103	24
7	Garrison + Aklog + Goff	§103	21-22, 31
8	Garrison + Hartley + Goff	§103	25-26

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) Garrison (Ex. 1006) published June 25, 2015;
- (3) Goff (Ex. 1007) published November 23, 2006; and
- (4) Hartley (Ex. 1008) published June 26, 2003.

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 '691 patent, e.g., devices for aspirating unwanted material from a patient. (Ex. 1003, ¶26; *see also* Ex. 1002, 260-268 (the Examiner found aspiration devices for tissue wounds to be analogous art and PO did not object).) 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. (Ex. 1003, ¶26; *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 1-8: GARRISON ALONE OR COMBINED WITH AKLOG, HARTLEY, AND/OR GOFF RENDERS CLAIMS 1-31 UNPATENTABLE

A. Independent Claim 1

Claim 1 is anticipated or rendered obvious by Garrison.² (Ex. 1003, ¶¶66-91.)

² "It is well settled that a 'disclosure that anticipates under §102 also renders the claim invalid under §103, for anticipation is the epitome of obviousness.'" *Realtime Data, LLC v. Iancu*, 912 F.3d 1368, 1373 (Fed. Cir. 2019).

1. **Preamble [1]: “An aspiration system with accelerated response, comprising”**

If the preamble is limiting, Garrison discloses this limitation. (Ex. 1003, ¶¶67-69.) Garrison discloses an aspiration system “to provide aspiration and passive flow reversal for the purpose of facilitating removal of the occlusion as well as minimizing distal emboli.” (Ex. 1006, [0007].) Garrison’s system includes an aspiration catheter [orange], an aspiration source (e.g., aspiration pump) having a first chamber [red], a second chamber having a filter [blue], and at least one hemostasis valve [yellow]:

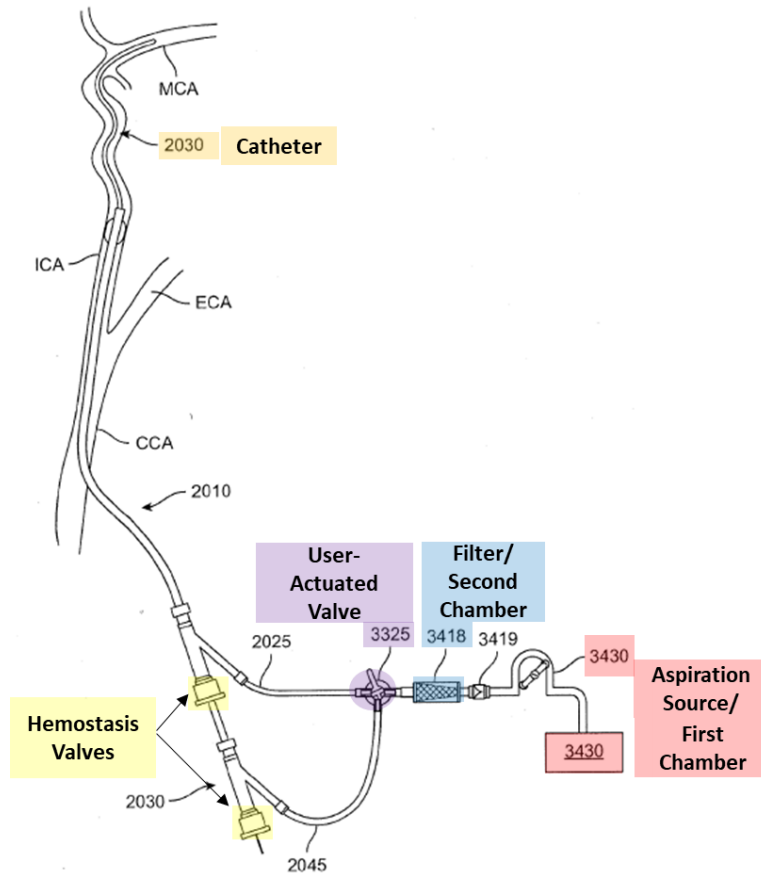


FIG. 34

(*Id.*, Fig. 34, [0131]-[0134] (describing Figure 34 and related figures).)

Garrison also discloses aspiration with an accelerated response. Garrison’s system includes a user-actuated valve [purple]. (*Id.*) Garrison discloses generating a negative pressure “while the connection [e.g., user-actuated valve] to the flow line is closed prior to the thrombectomy step of the procedure.” (*Id.*, [0134].) “During the procedure when the tip of the aspiration device ... is near or at the face of the occlusion, the user may open the connection to the aspiration syringe.” (*Id.*) Garrison discloses that opening the user-actuated valve after generating the negative pressure “would enable the maximum level of aspiration in a **rapid** fashion with one user, something that is currently not possible with existing technologies.” (*Id.* (emphasis added).) Thus, Garrison discloses an aspiration system with accelerated response. (Ex 1003, ¶69; *see also* Ex. 1006, [0129] (disclosing testing results for accelerated response).)

2. **Limitation [1A]: “an aspiration pump in communication with a first chamber”**

Garrison discloses this limitation. (Ex. 1003, ¶¶70-74.) Garrison’s aspiration system includes an aspiration source 3430 [red]:

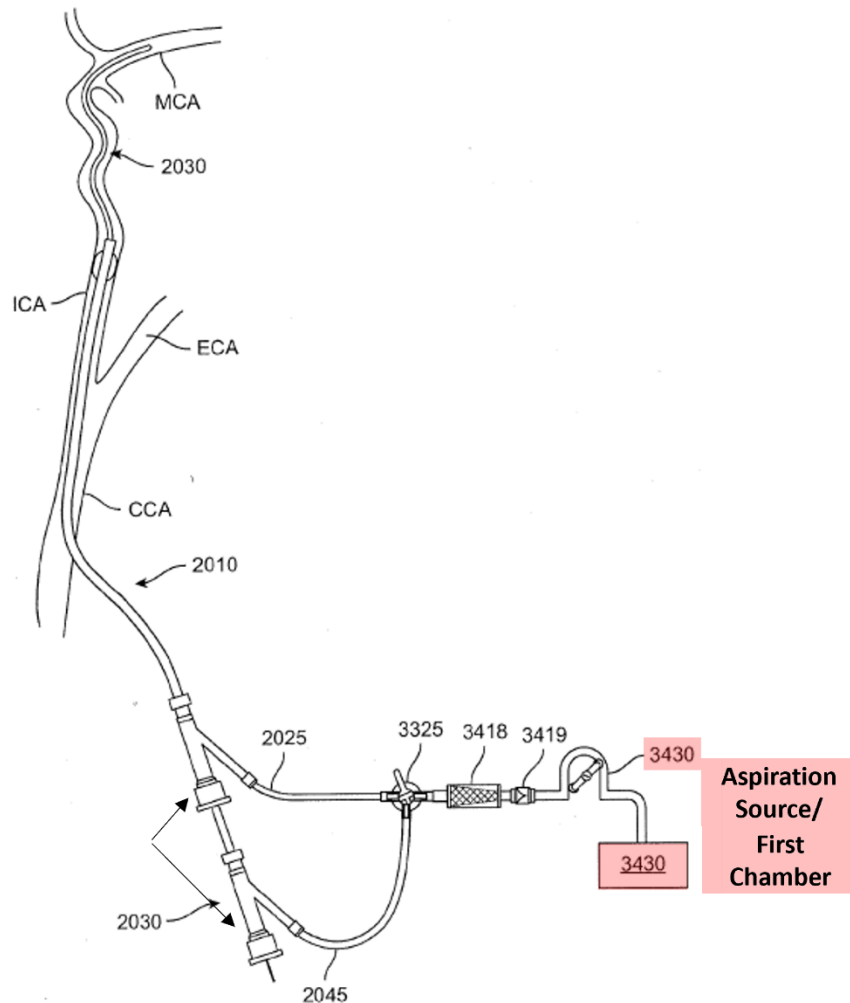
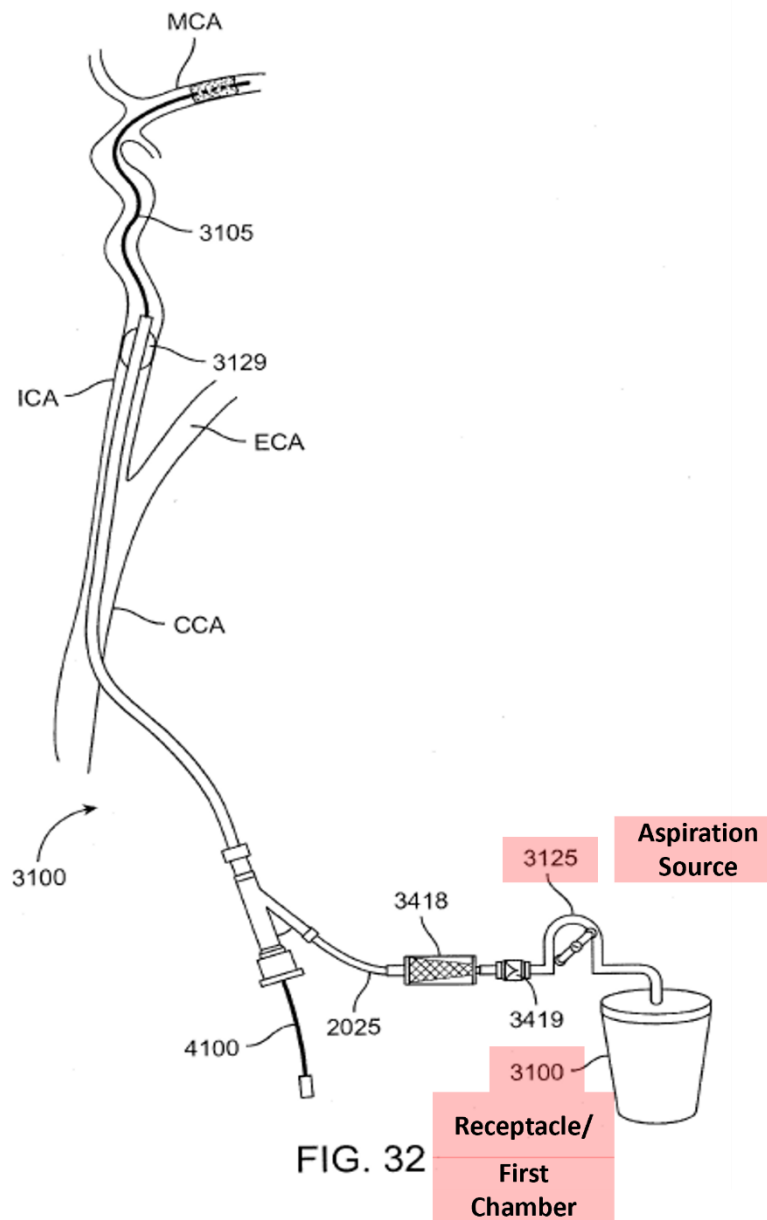


FIG. 34

(Ex. 1006, [0132], FIG. 34.) Garrison states, “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] (emphasis added); *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.”).)

Garrison also discloses that the catheter assembly may include a receptacle (i.e., first chamber) to collect the aspirated blood and an aspiration source that “may be separate or may be combined into a single device such as a syringe.” (*Id.*, [0131], Figs. 32-33; *see also id.*, [0131] (“The aspiration source 3425 and delivery location may be combined into a single device such as a syringe.”).)



As a further example, Garrison discloses an “aspiration pump device 3250” that may be connected to either or both the arterial access device 2010 and catheter 2030.” (*Id.*, [0136].) The pump device includes an “expandable portion 3210” to collect blood within “chamber 3220” before expelling the blood into a return line:

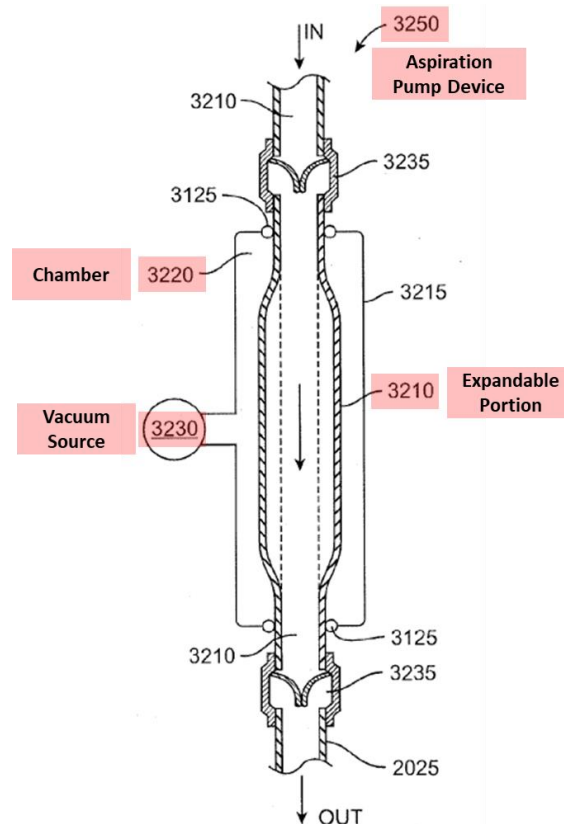


FIG. 36

(*Id.*, [0136], Fig. 36; *see also id.*, [0134] (describing hand-held aspirator that “contains a chamber with a plunger that is moved up and down with a single-handed actuator.”).)

As illustrated above, regardless of whether the receptacle/chamber is “separate” from the pump, or “combined into a single device” with the pump, the

receptacle/chamber is “in communication” with the aspiration pump. (Ex. 1003, ¶¶71-74.)

3. **Limitation [1B]: “a coupled assembly including: an aspiration catheter configured for placement into fluid communication with the first chamber by way of an aspiration tube; a second chamber in between the aspiration pump and the aspiration catheter; and a hemostasis valve”**

Garrison discloses this limitation. (Ex. 1003, ¶¶75-80.) Garrison discloses a coupled assembly including an aspiration catheter [orange] configured for placement into fluid communication with a first chamber [red] by way of a flow line (i.e. aspiration tube) [green]:

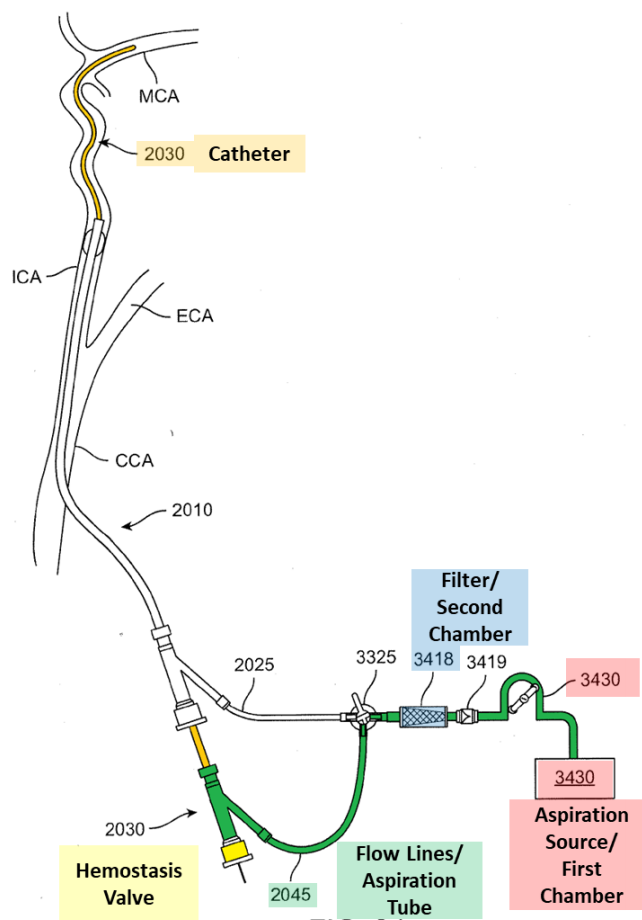
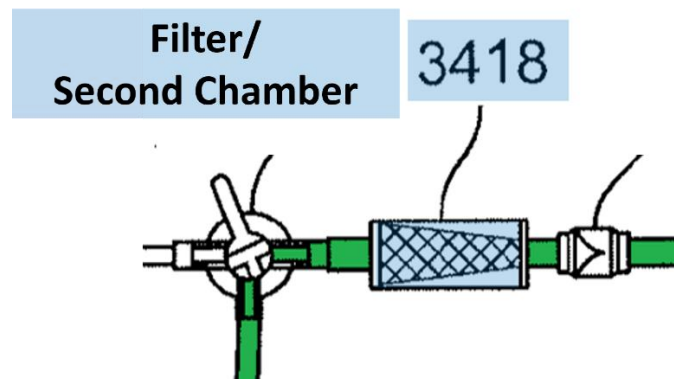


FIG. 34

(Ex. 1006, Fig. 34; *see also id.*, [0132] (“both the arterial access device 2010 and catheter 2030 are connected to the same aspiration source via flow lines 2024 and 2045, respectively”), Fig. 32.)

Garrison’s coupled assembly includes a second chamber having a filter [blue] between the aspiration pump [red] and the aspiration catheter [orange]. (*Id.*, Fig. 34; *see also id.*, [0131] (“A filter 3418 and/or a check valve 3419 may also be coupled with the flow line 2045.”).) As shown in Figure 34 (below), the second chamber [blue] is coupled to the aspiration pump and catheter by the flow lines [green] and surrounds the filter. (*Id.*) The flow lines are an aspiration tube. (Ex. 1003, ¶77.)



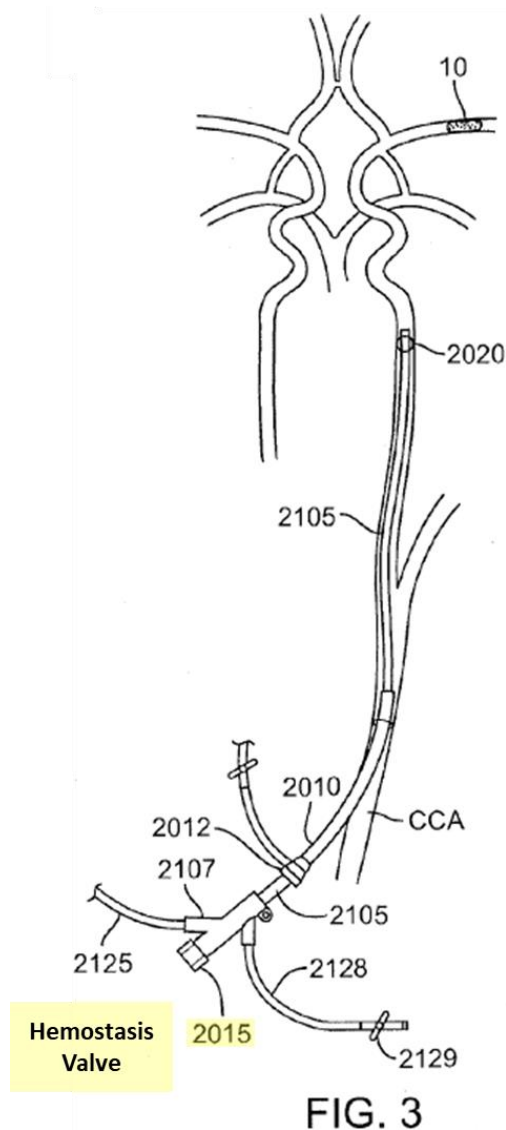
(Ex. 1006, Fig. 34 (excerpt).) The chamber that surrounds the filter is necessary to prevent the blood from leaking out of the system and to maintain pressure across the aspiration system. (Ex. 1003, ¶78.)

Garrison also discloses that catheter 2030 [orange] can include a hemostasis valve [yellow] in its proximal hub 2065 (item 2065 not pictured in Figure 34). (Ex. 1006, [0098].) “[T]he hemostasis valve may be integral to the catheter proximal

adaptor” and, therefore, is part of the coupled assembly. (*Id.*; Ex. 1003, ¶¶79-80.)

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.” (Ex. 1006, [0098].)

Figure 34 does not expressly label the proximal adaptor and hemostasis valve, but other, related figures do. For example, Figure 3 identifies 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.*, [0050]-[0053], [0059], [0062], Figs. 1-3, 6 (describing hemostasis valve 2012 in arterial access device).) A POSITA would have understood that catheter 2030's hemostasis valve in Figure 34 is located at the end of the proximal adaptor as in Figure 3. (Ex. 1003, ¶¶79-80.)

4. **Limitation [1C]: “a user-actuatable valve between the second chamber and the aspiration catheter”**

Garrison discloses this limitation. (Ex. 1003, ¶¶81-82.) Garrison includes a “valve 3325” between the second chamber and aspiration catheter:

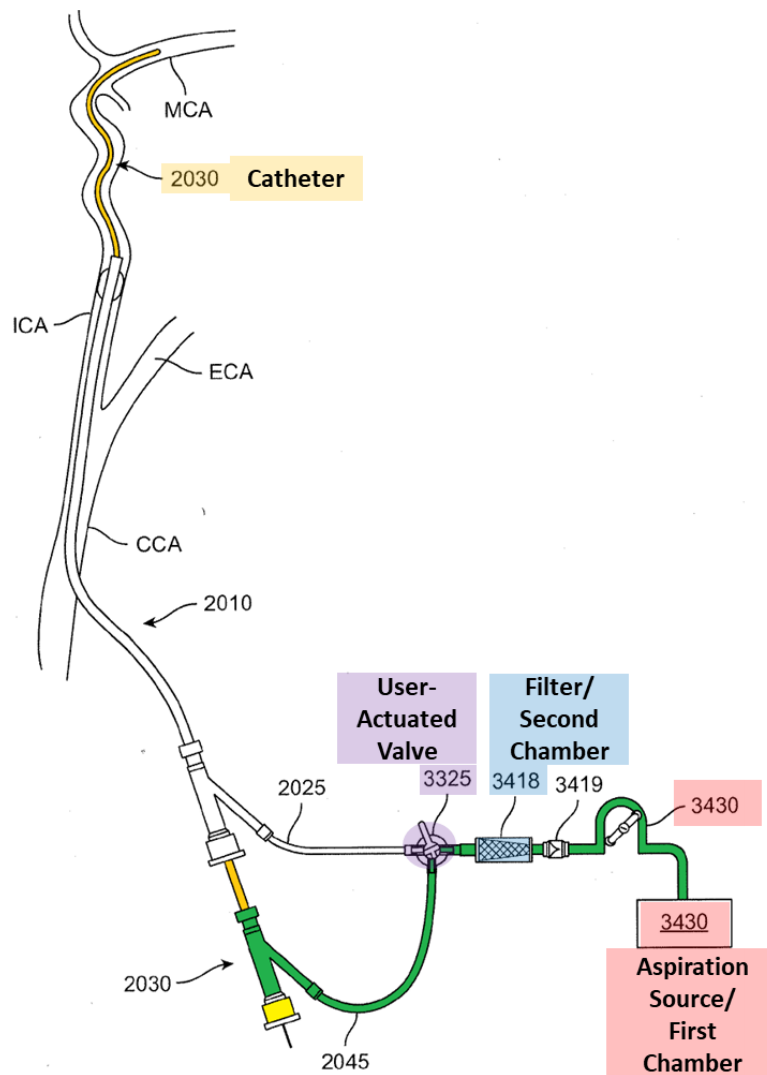


FIG. 34

(Ex. 1006, [00132], Fig. 34.) Garrison discloses that the “valve 3325 controls which device is connected to the aspiration source 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 user-actuatable valves. (Ex. 1003, ¶82; *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”).)

5. **Limitation [1D]: “wherein the valve is configured to be closed while negative pressure is generated in the first and second chambers, and wherein the valve is configured to be opened after the negative pressure is generated in the first and second chambers”**

Garrison discloses this limitation. (Ex. 1003, ¶¶83-86.) 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]; *see also* Ex. 1022, ¶23 (describing the 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] (emphasis added).) Because the valve (e.g., stopcock 3325) is distal to the first and second chambers, the negative pressure is generated in both the first and second chambers. (*Id.*, Fig. 34; Ex. 1003, ¶84.) While this embodiment specifically

includes 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, ¶85.)

Garrison also discusses testing different catheters by generating a negative pressure in a chamber and then releasing the negative 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 they syringe.

(*Id.* (emphasis added).) As described, the valve was closed while negative pressure was generated in the first chamber (i.e., syringe), and opened after negative pressure was generated. (Ex. 1003, ¶86.) Thus, Garrison includes multiple disclosures of closing a valve to generate negative pressure and opening the valve after the negative pressure is generated.

6. **Limitation [1E]: “wherein upon user actuation to open the valve with the negative pressure having been generated in the first and second chambers, fluid flow at least partially from the second chamber into the first chamber causes rapid aspiration into the second chamber”**

Garrison discloses this limitation. (Ex. 1003, ¶¶87-91.) As explained above, Garrison describes generating a negative pressure in the first and second chambers by closing the user-actuated valve (e.g., stopcock or flow controller). (*Supra* Limitation [1D].) Once the user generates the negative pressure and positions the tip of the aspiration catheter near the occlusion, “the user may open the connection to the aspiration syringe” or other negative pressure source. (Ex. 1006, [0134], Fig. 34.) Garrison discloses, “[t]his would enable the maximum level of aspiration in a **rapid** fashion with one user, something that is not currently possible with existing technologies.” (*Id.*, (emphasis added).)

As illustrated in Figure 34, the blood aspirated through the catheter [orange] flows through the flow line 2045 [green] and into the second chamber housing the filter [blue]:

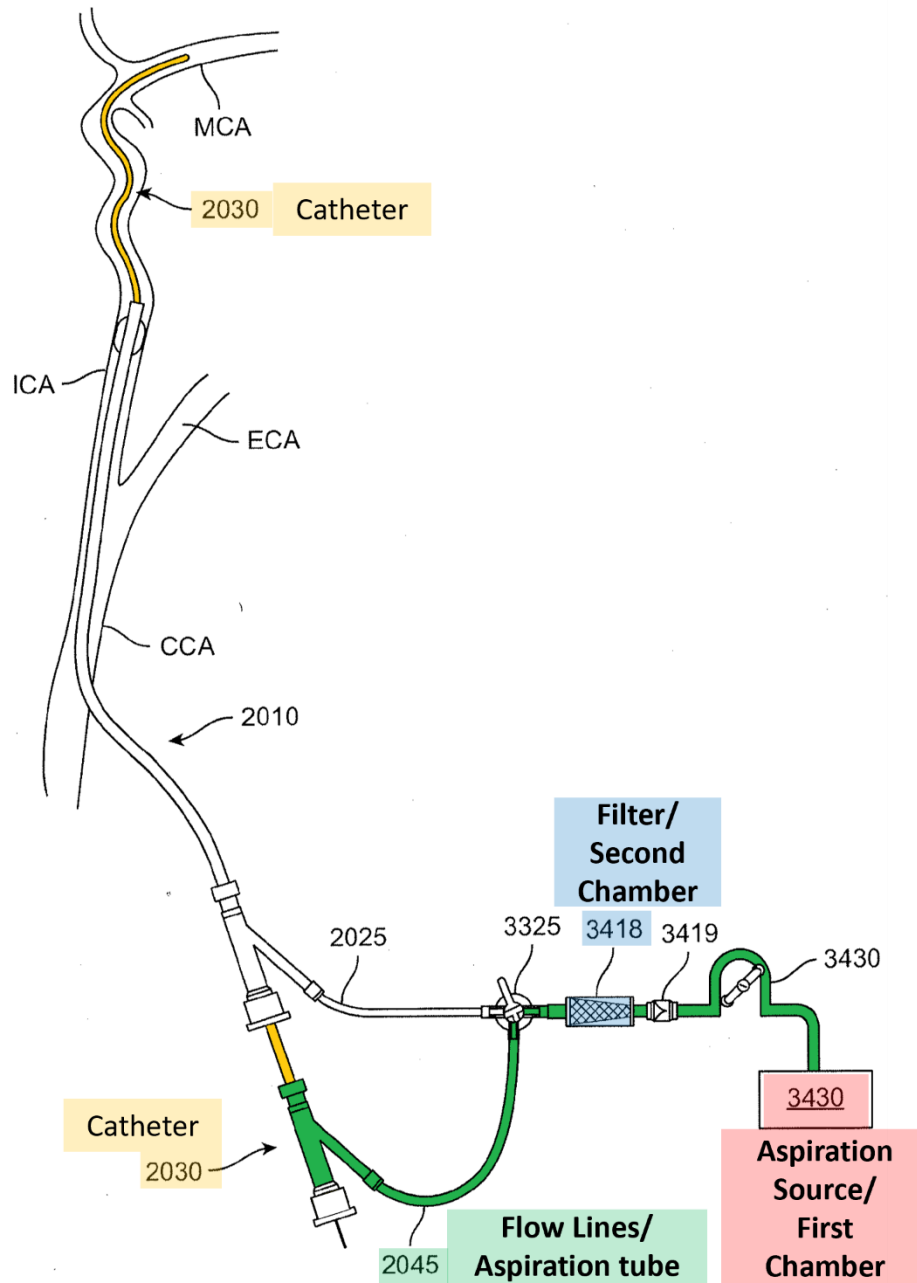


FIG. 34

(*Id.*, Fig. 34; Ex. 1003, ¶89; *see also* Ex. 1006, [0132] (“arterial access device 2010 and catheter 2030 are connected to the same aspiration source 3430 via flow lines 2025 and 2045, respectively”).) The blood then passes through the remainder of the flow line to the first chamber [red]. (Ex. 1003, ¶89.) Consequently, fluid flow at

least partially from the second chamber into the first chamber causes rapid aspiration into the second chamber. (*Id.*, ¶¶89-91.)

B. Claim 2

Claim 2 depends from Claim 1 and recites: “wherein the hemostasis valve is configured to receive a second catheter and direct the second catheter through the aspiration catheter.” Garrison discloses this limitation. (Ex. 1003, ¶¶92-94.)

Garrison discloses a catheter 2030 [orange] having a hemostasis valve [yellow]:

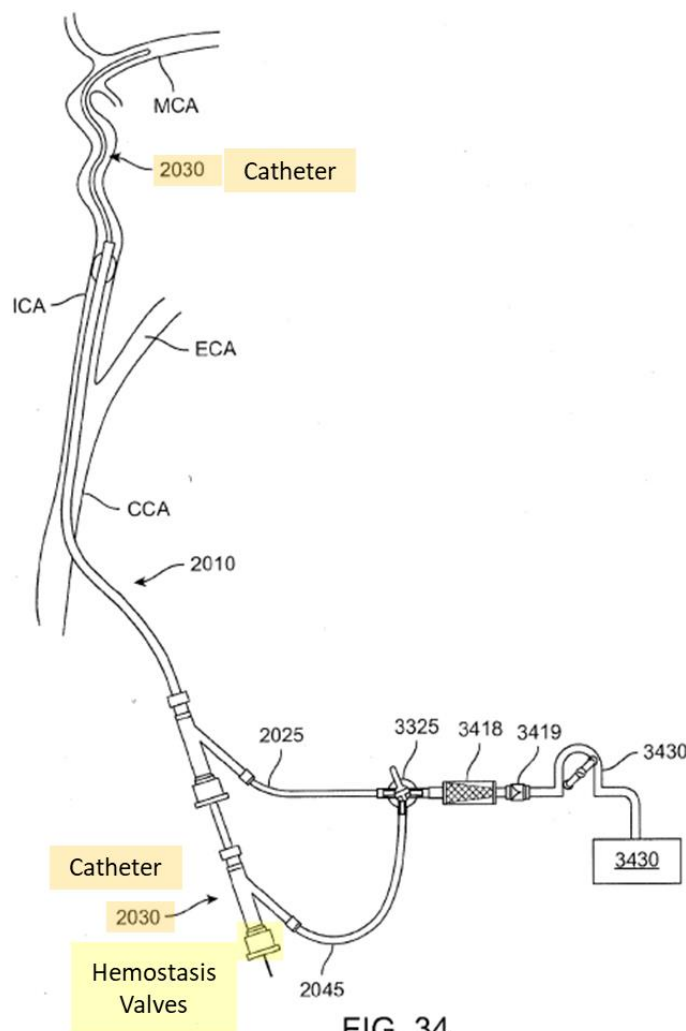


FIG. 34

(*Supra* Limitation [1B]; Ex. 1006, Fig. 34.)

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].) Garrison expressly discloses that a “second, smaller diameter catheter ***may be inserted through the first catheter***” (*Id.* (emphasis added).) The physician would insert the second, smaller diameter catheter through the hemostasis valve attached to the first catheter because that is the purpose of the hemostasis valve – to seal the lumen when other devices are inserted. (Ex. 1003, ¶94; *see also* Ex. 1006, [0053] (explaining that the catheter has “a hemostasis valve to allow introduction of devices while preventing or minimizing blood loss during the procedure”).) Thus, the hemostasis valve directs the second catheter through the first catheter.

C. Claim 3

Claim 3 depends from Claim 2 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 a 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 combined with Hartley renders Claim 3 obvious. (Ex. 1003, ¶¶95-103.)

Garrison discloses a catheter 2030 having a hemostasis valve. (*Supra* Limitation [1B].) 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 filament loop around a collapsible-tube-type structure of the hemostasis valves, instead presuming that POSITAs would have been familiar with such valves.

Hartley discloses a type of rotating hemostasis valve with a filament loop around a collapsible tube. Hartley’s valve “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’s valve includes a “cylindrical housing 6 into which is received a cylindrical elastomeric diaphragm 8 ... [that] defines a cylindrical aperture 3 therethrough”:

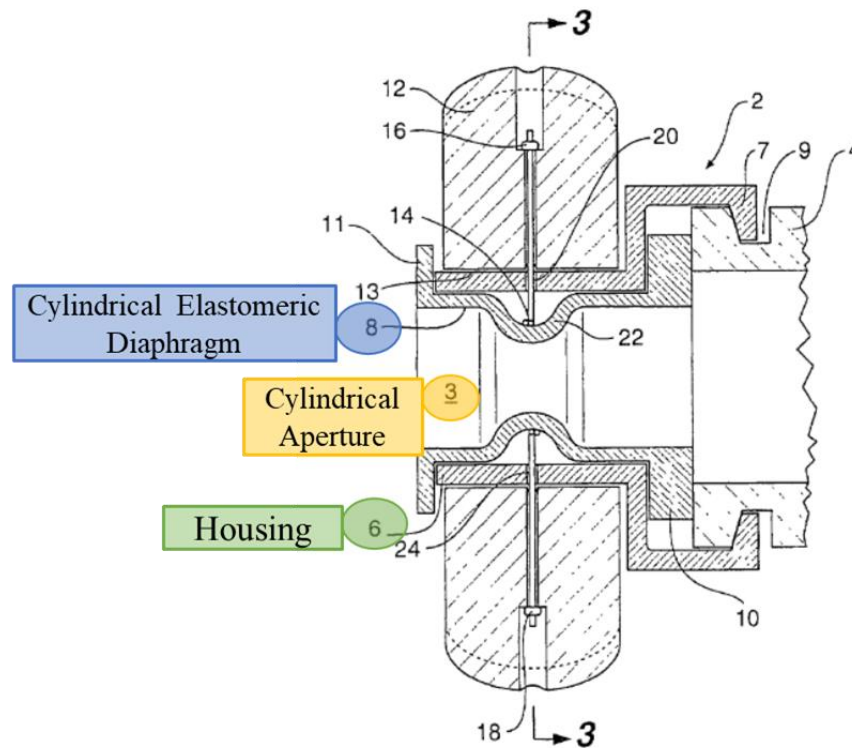
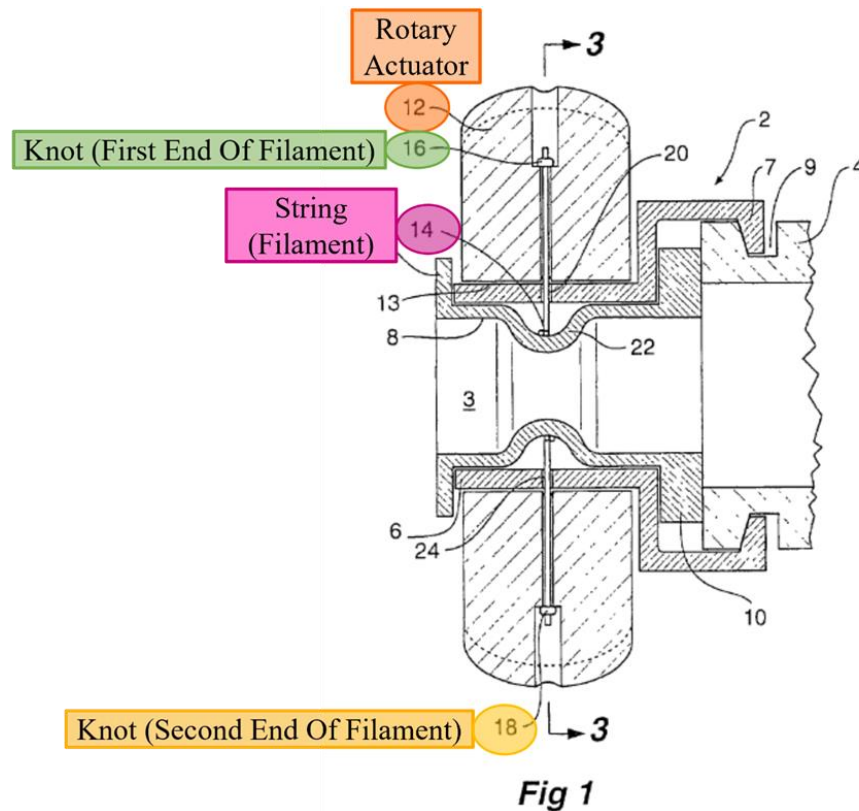


Fig 1

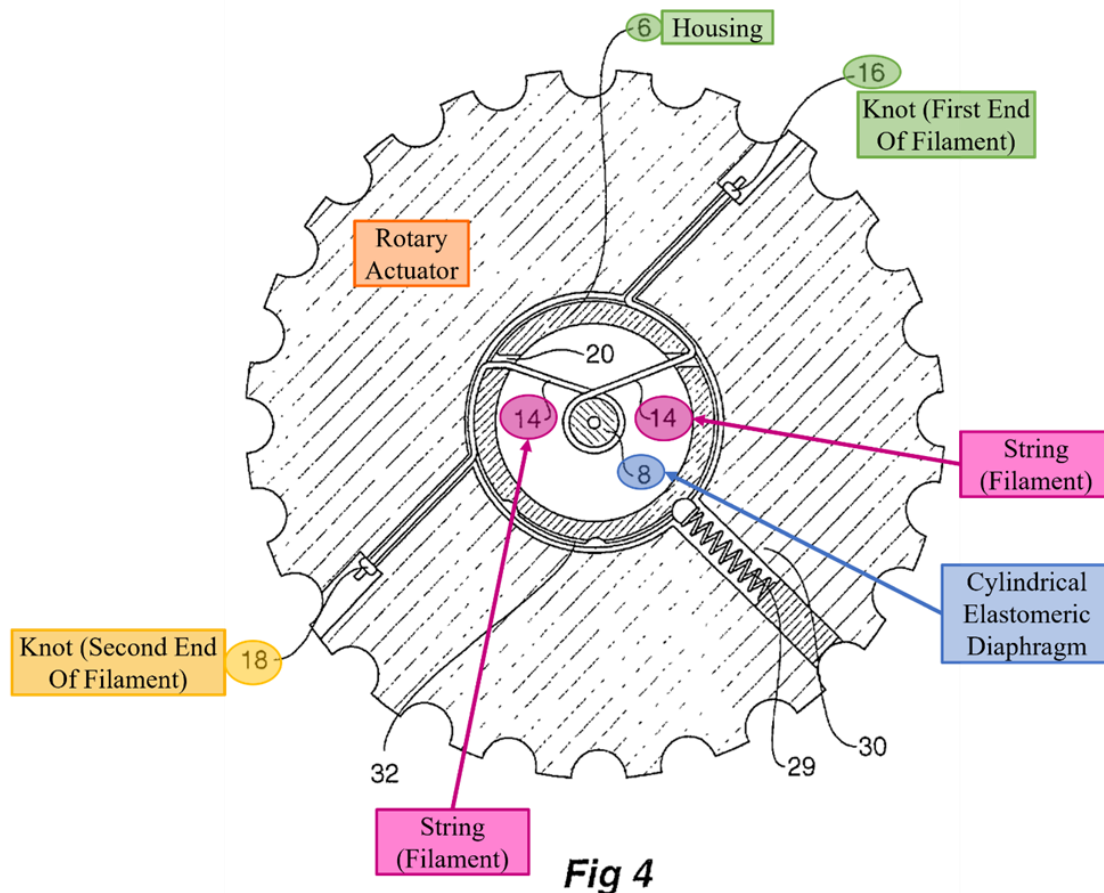
(*Id.*, [0031], Fig. 1.) Hartley’s “cylindrical diaphragm can be completely constricted to prevent fluid flow through the valve or can be constricted to the extent that it closes around an instrument, for instance a catheter, passed through the valve.” (*Id.*, [0006].) Accordingly, Hartley’s cylindrical diaphragm is “a tubular member defining a lumen configured to slidably receive the second catheter.” (Ex. 1003, ¶97.)

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



(Ex. 1008, [0031], Fig. 1.) Hartley’s string 14 is a filament because it includes, for example, one or more threads. (Ex. 1003, ¶98; *supra* §IV (Claim Construction).)

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.) In this configuration, the filament is in a first position wherein the filament circumferentially constricts a lumen to create a seal around the second catheter. (Ex. 1003, ¶99.)

Hartley further 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”:

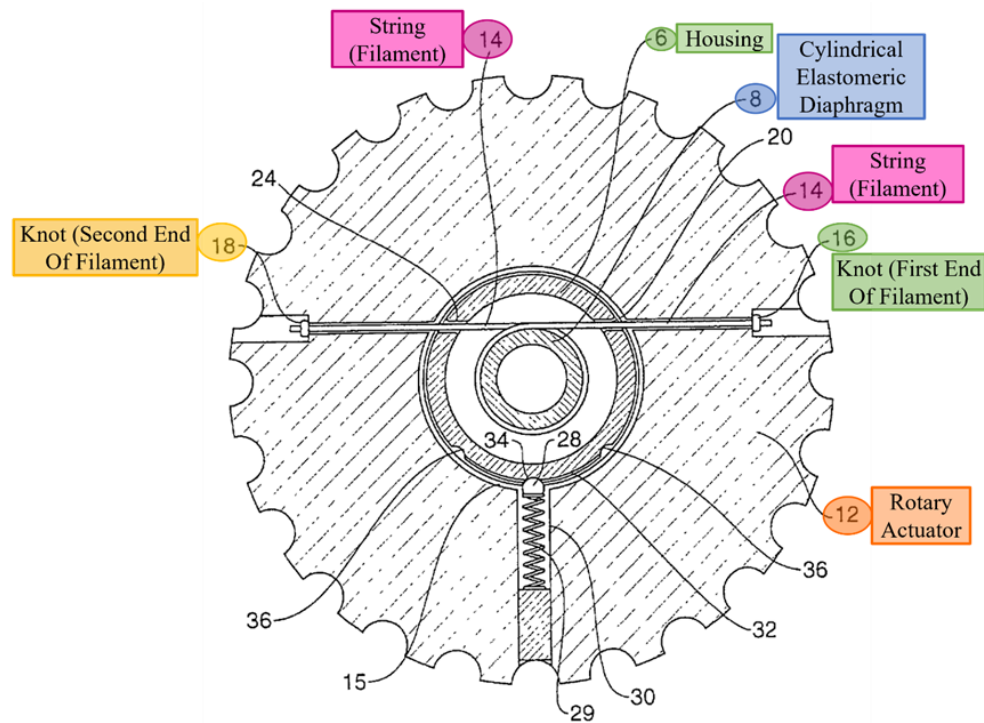


Fig 3

(Ex. 1008, [0034], Fig. 3.) In this configuration, the filament is in a second position wherein the filament is moved to at least partially open the lumen. (Ex. 1003, ¶100.)

A POSITA would have been motivated to combine Hartley’s filament-loop-type hemostasis valve with Garrison’s catheter 2030 for several reasons and reasonably expected success in doing so. (*Id.*, ¶¶101-103.) First, Garrison expressly suggests combining Garrison’s catheter 2030 with a “rotating hemostasis valve.” (Ex. 1006, [0098].) Hartley discloses a rotating hemostasis valve and, therefore, a POSITA would have been motivated to combine, and reasonably expected success in combining, Hartley’s valve with Garrison. (Ex. 1003, ¶101.)

Second, combining Hartley’s valve with catheter 2030 would have merely entailed the combination of known elements (Hartley’s hemostasis valve and Garrison’s catheter 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; (Ex. 1006, [0098], Ex. 1003, ¶102.)

Third, POSITA’s in August 2018 had a finite number of predictable hemostasis valves to choose, including an “adjustable-opening valve such as a Tuohy-Borst or rotating hemostasis valve (RHV)” like Hartley’s valve, or “a passive seal hemostasis valve.” (Ex. 1003, ¶103.) A POSITA would have found it obvious to try any of these hemostasis valves in combination with catheter 2030. (*Id.*); *KSR*, 550 U.S. at 417. Moreover, the known valves, including Hartley’s rotating hemostasis valve, were simple mechanical structures that operate in a predictable way. (Ex. 1003, ¶103.) For this additional reason, POSITAs would have reasonably expected success in combining any of the known valves with Garrison. (*Id.*)

D. Claim 4

Claim 4 depends from Claim 1 and recites: “wherein the second chamber is removably carried by the assembly.” Garrison renders this claim obvious alone or in combination with Goff. (Ex. 1003, ¶¶104-116.)

1. **Garrison**

Garrison discloses a second chamber that houses a filter 3418 [blue]:

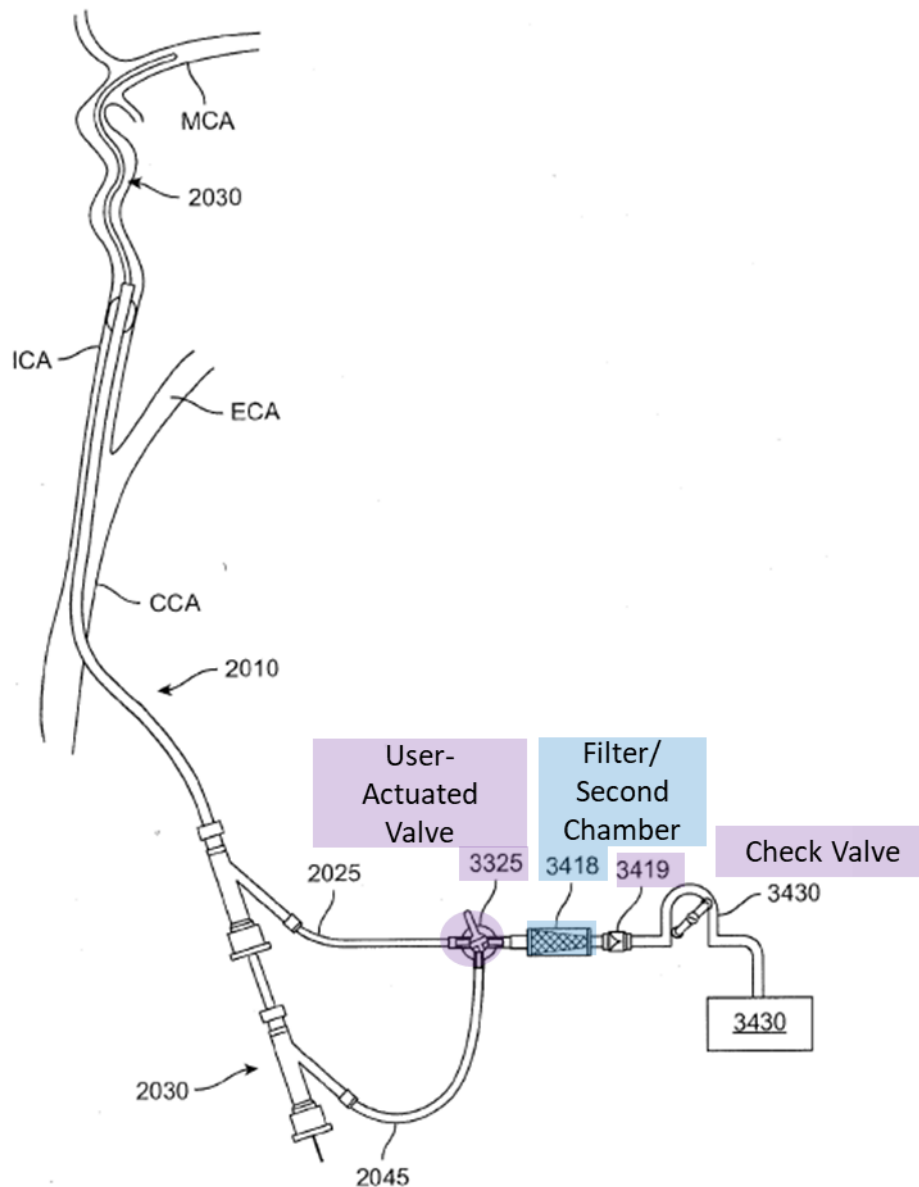


FIG. 34

(*Supra* Limitation [1B].) The filter/second chamber is positioned between the user-actuated valve 3325 (e.g., stopcock) and a check valve 3419. (*Id.*) Garrison describes the stopcock, filter 3418, and check valve 3419 as optional components

the user can add or remove depending on the procedure. (See *e.g.*, Ex. 1006, [0131] (“A filter 3418 and/or a check valve 3419 *may* be coupled with flow line 2025.” (emphasis added)).)

Garrison does not expressly describe how its filter is coupled to the tubing. However, in August 2018, a POSITA would have found it obvious to couple the filter to the tubing using conventional, removable connectors, such as Luer-type connectors (*e.g.*, Luer slip and Luer lock) and barb connectors. (Ex. 1003, ¶106; *see also* Ex. 1006, [0062], [0065], Fig. 11 (illustrating stopcock with standard female connector); Ex. 1009, 4:29-40 (describing the use of Luer type connectors for aspiration catheters); Ex. 1001, 7:61 (describing a “standard luer connector”), 33:24 (describing a “standard Luer or large bore connector”).) In fact, Garrison incorporates by reference patents and publications that describe attaching catheter components using “a conventional luer fitting” or improvements to such fittings. (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”).) Moreover, the ’691 patent acknowledges that Luer type and large bore connectors were known in the art. (Ex. 1001, 7:58-67 (referencing “a standard luer connector”; 33:24 (referencing “*e.g.*, a standard Luer or large bore connector”); 34:25-28 (referencing “*e.g.*, a standard Luer or large bore connector”).)

A POSITA would have been motivated to use conventional, removable connectors, such as Luer type connectors, to removably connect Garrison's filter to the system for several reasons. First, conventional connectors, such as Luer type connectors, allowed physicians to add off-the-shelf tubing and related components simply and quickly. (Ex. 1003, ¶107.) Physicians preferred this flexibility because different procedures and patient conditions may require fewer or additional components, as suggested by the many configurations disclosed in Garrison. (*Id.*) Physicians would have been motivated to avoid using unnecessary components due to the additional cost and complexity and would have preferred components that could be easily attached and removed. (*Id.*)

Second, the conventional connectors came in standard sizes that made them compatible with other catheter-based medical components, such as tubing and valves. (*Id.*, ¶108.) Physicians preferred this compatibility because it increased the options available to the physician during a procedure and, thus, POSITAs were motivated to include these connectors with medical devices. (*Id.*)

Third, physicians were familiar with the conventional connectors. (*Id.*, ¶109.) This familiarity meant physicians preferred the standard connectors, such as Luer type connectors, because they reduced the risk of complications and increased the speed for assembling the systems. (*Id.*) The user preference would have motivated POSITAs to use conventional connectors. Moreover, POSITAs would have

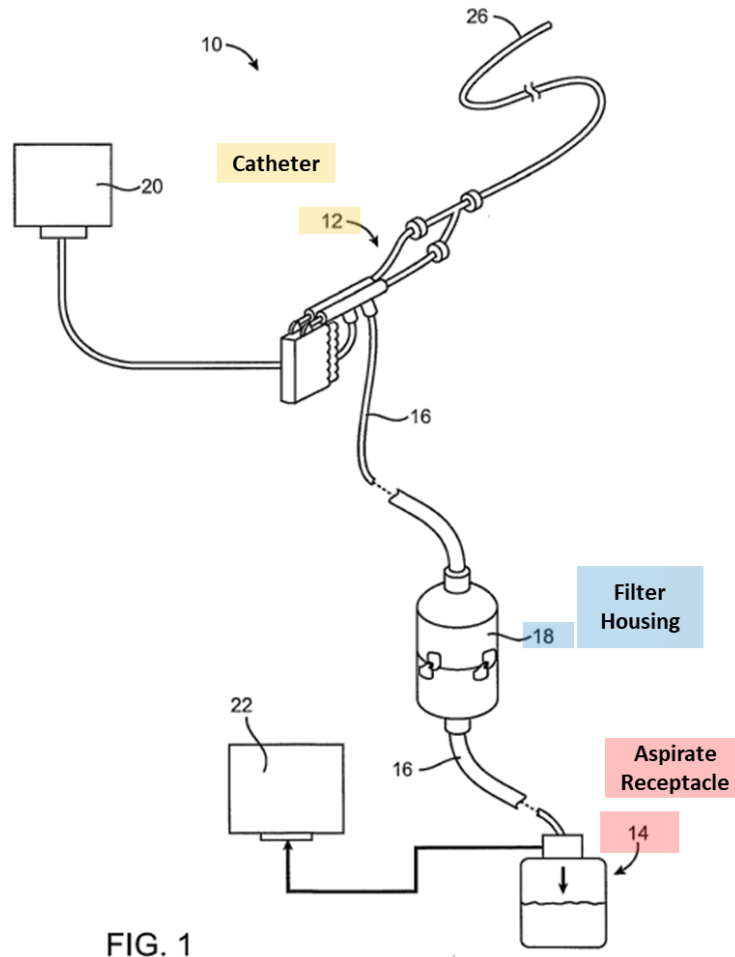
reasonably expected success in using these conventional, removable connectors, such as Luer-type connectors, with Garrison’s optional filter because the connectors were simple, widely used, and predictable. (*Id.*) If Garrison’s filter included these conventional connectors, then the second chamber would be removably carried by the assembly. (*Id.*)

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

Additionally, a POSITA would have been motivated to include a removable filter chamber in Garrison’s system so that the physician could empty the chamber and clean the filter. (Ex. 1003, ¶111.) Garrison discloses a process for the physician to remove multiple occlusions with Garrison’s aspiration system. (*See e.g.*, Ex. 1006, [0166] (“if a second more distal treatment site needs to be reached after removal of a first occlusion, a second, smaller diameter catheter may be inserted through the first catheter”).) A POSITA would have recognized that multiple occlusions could clog the filter or fill the chamber, thereby motivating a POSITA to removably couple the chamber to the system so that the chamber and filter could be cleaned and replaced. (Ex. 1003, ¶111.)

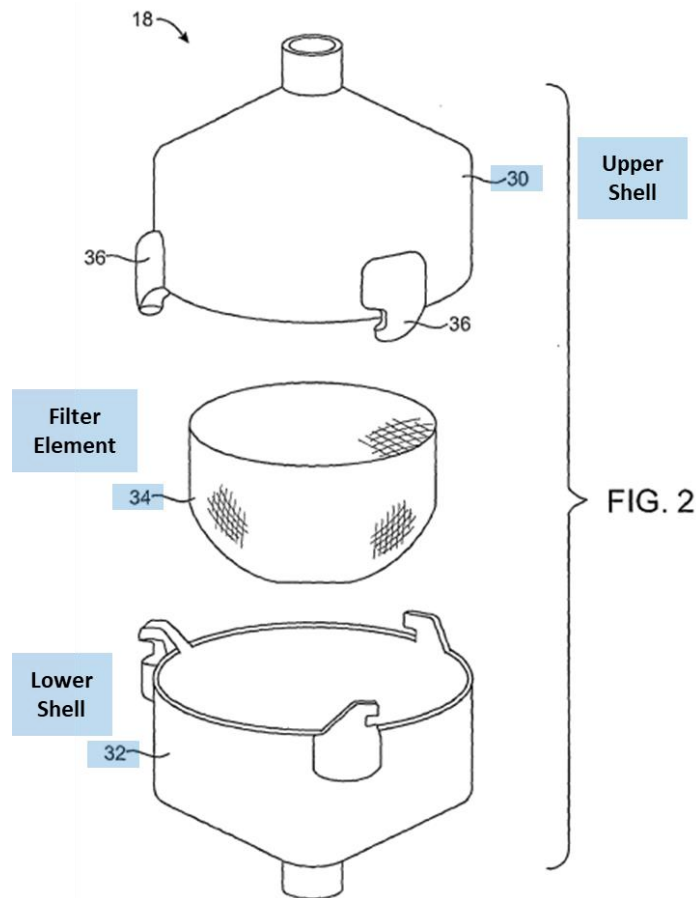
2. Garrison and Goff

Goff discloses “methods and systems for filtering aspirated material.” (Ex. 1007, Title.) Goff’s aspiration system includes a “filter housing 18 ... between the aspiration catheter 12 and the aspirate receptacle 14”:



(*Id.*, [0025], Fig. 1.)

Goff’s “filter assembly 18 typically comprises an upper shell 30, a lower shell 32, and a filter element 34 which may be disposed within the interior of the shells”:



(*Id.*, [0025], Fig. 2; *see also id.*, [0015] (“the filter housing has an upper shell and a lower shell which may be taken apart to permit introduction, removal, and replacement of the filter element in the interior of the housing”).)

Goff discloses, “The housing will further have **conventional connectors** to permit connection at an upper end to the aspiration catheter and at a lower end to the aspirate receptacle.” (*Id.*, [0015] (emphasis added).) As discussed above, conventional connectors in August 2018 included removable connectors, such as Luer-type connectors and barb connectors. (Ex. 1003, ¶114.) Moreover, Goff discloses that its filter forms a structure where “the separated solid materials be in a

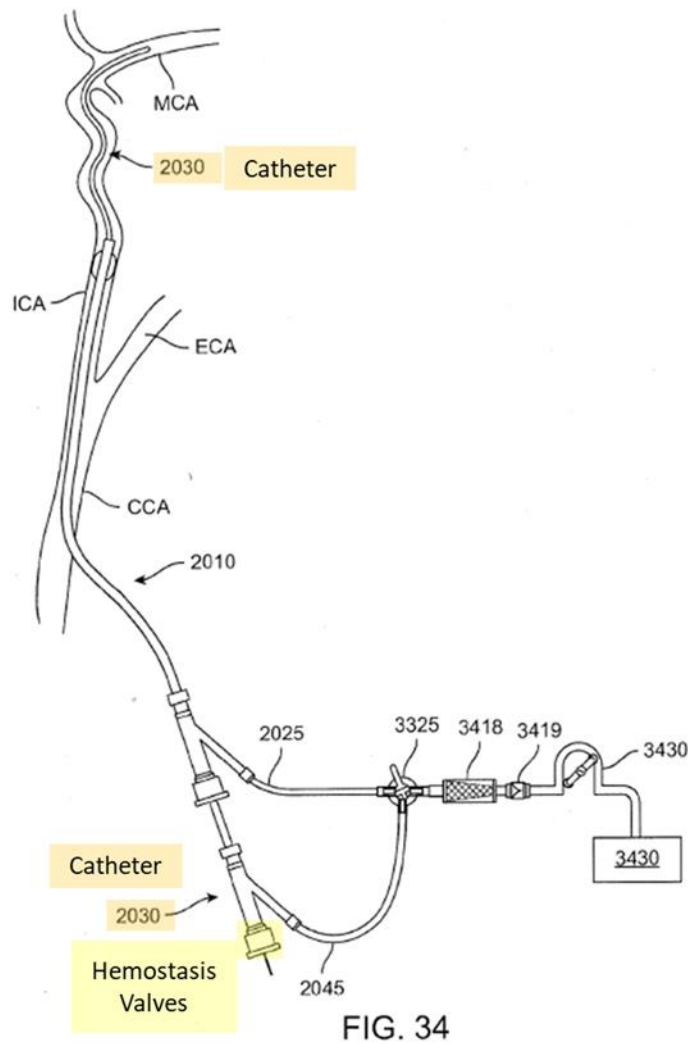
convenient structure or assembly to permit easy **removal** and observation.” (Ex. 1007, [0005].) Thus, Goff would have further motivated POSITAs to removably couple Garrison’s filter to its system with removable connectors so that the filter could be removed, and the clot material removed and/or observed. (Ex. 1003, ¶114.)

Alternatively, a POSITA would have been motivated to use Goff’s removable filter in Garrison’s aspiration system. (Ex. 1003, ¶115.) Goff’s filter is used for the same purpose as Garrison’s filter – filtering clots from aspirated blood. (Ex. 1007, [0001].) Goff’s filter is also positioned between the aspiration catheter and first chamber/pressure source. (*Id.*, [0025].) Thus, combining Goff’s filter with Garrison’s system would have merely entailed the combination of known elements (filter and Garrison’s aspiration system) according to known methods (conventional connectors) to yield the predictable result of filtering aspirated blood. *KSR*, 550 U.S. at 416; (Ex. 1003, ¶115.) Moreover, the similarities between the Goff and Garrison filters would have given a POSITA a reasonable expectation of success for incorporating Goff’s filter into Garrison’s aspiration system. (Ex. 1003, ¶116.) For example, Goff discloses that its “filter element will have a pore size or screen size selected to separate solid particles at a desired particle size cutoff,” the same requirement for Garrison’s filter. (Ex. 1007, [0011].)

E. Claim 5

Claim 5 depends from Claim 1 and recites: “wherein the aspiration catheter is configured to be intravascularly positioned within a blood vessel of a patient.” Garrison discloses this limitation. (Ex. 1003, ¶¶117-118.)

Garrison discloses a catheter that “has an external dimension that is sized and shaped for insertion into a blood vessel.” (Ex. 1006, [0098].) Garrison also discloses that “the catheter may be used to aspirate an occlusion in the blood vessel.” (*Id.*, [0109].) Garrison illustrates aspiration catheters [orange] positioned intravascularly within the blood vessel of a patient, for example in Figure 34.

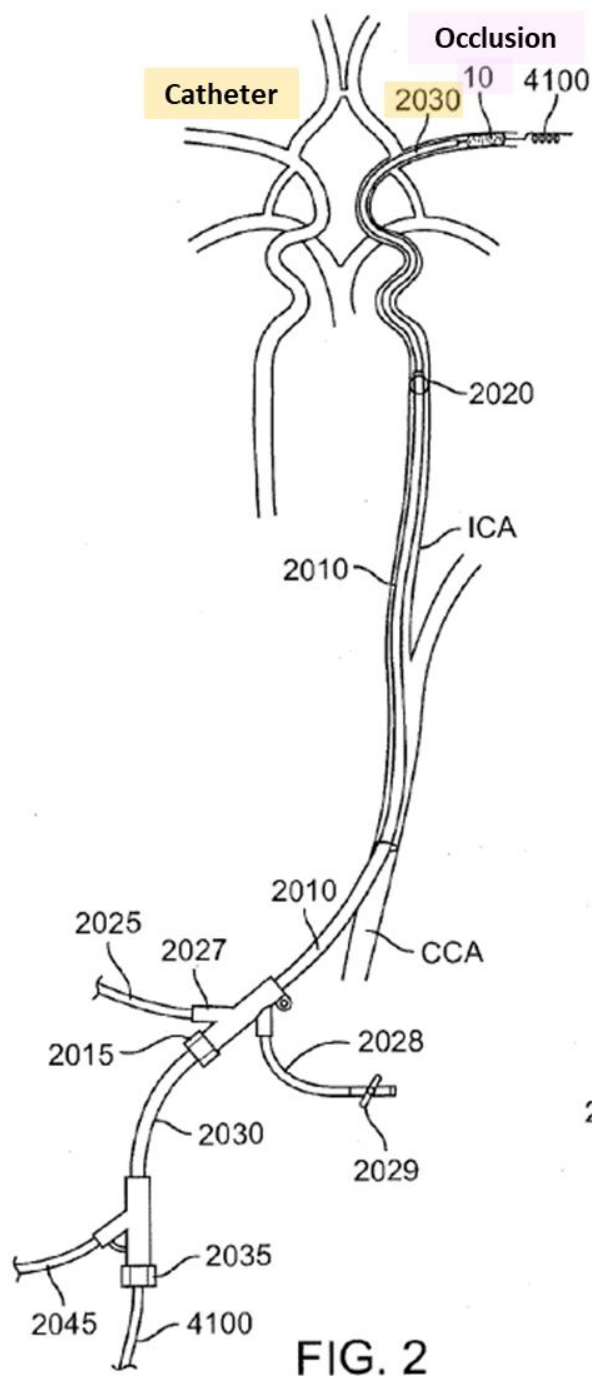


(*Id.*, Fig. 1.)

F. Claim 6

Claim 6 depends from Claim 5 and recites: “wherein the aspiration catheter has a distal end portion configured to be positioned proximate to clot material within the blood vessel of the patient.” Even if one assumes this claim limits the device of Claim 5, Garrison still discloses this claim. (Ex. 1003, ¶¶119-121.)

In Figure 2, Garrison shows an aspiration catheter (catheter 2030, orange) with a distal end portion positioned proximate to clot material (thrombus 10, pink) within the blood vessel of the patient:



(Ex. 1006, Fig. 2, [0050]-[0051].) 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 force on the occlusion located near the tip.” (*Id.*) Thus, Garrison repeatedly discloses positioning the distal portion of the catheter proximate the clot material. (Ex. 1003, ¶¶120-121.)

G. Claim 7

Claim 7 depends from Claim 6 and recites: “wherein the clot material comprises a pulmonary embolism.” Even if one assumes this claim is directed to some attribute of the claimed device of Claim 6, Garrison anticipates this claim or renders the claim obvious combined with Aklog. (Ex. 1003, ¶¶122-136.)

1. Garrison

As discussed above, Garrison’s aspiration catheter includes a distal end portion configured to be positioned proximate to clot material. (*Supra* Claim 6.) While Garrison focuses on the “treatment of cerebral occlusions,” the distal end of Garrison’s catheter is **configured to be** positioned proximate other types of clots, including pulmonary embolisms and deep vein thrombosis. (Ex. 1006, [0002]; Ex. 1003, ¶123.) Garrison explains that cerebral occlusions are more difficult to treat than occlusions in larger vessels (e.g., pulmonary embolisms and DVT) due to “special access challenges.” (Ex. 1006, [0042]; *see also* Ex. 1022, ¶¶33-37

(explaining why treating cerebral occlusions is more difficult than treating PE or DVT).) 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.” (Ex. 1006, [0042].) Additionally, “the cerebral vessels are usually more delicate and prone to perforation than coronary or other peripheral vasculature.” (*Id.*; Ex. 1022, ¶ 36.) To address these challenges, Garrison describes catheter 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”).) Thus, while an aspiration catheter designed to treat pulmonary embolisms or DVT may not be configured to be positioned proximate a cerebral embolism due to its size or stiffness, a catheter designed to treat cerebral emboli *is* configured to be positioned proximate emboli in other parts of the vasculature, including pulmonary embolisms and DVT. (Ex. 1003, ¶123; Ex. 1022, ¶¶30-41.)

Moreover, Garrison discloses the insertion techniques and locations necessary to position a catheter proximate a pulmonary embolism or DVT. (Ex. 1003, ¶124.) For example, Garrison discloses using transfemoral access approaches to reach the targeted emboli. (Ex. 1006, [0048].) Similar access sites, and methods of access, can be used to reach a pulmonary embolism or DVT. (*See e.g.*, Ex. 1001, 17:7-8

(“Access to the pulmonary vessels can be achieved through the patient’s vasculature, for example, via the femoral vein.”); Ex. 1005, 15:30-34 (“The first blood vessel through which suction cannula 71 may be inserted into patient 700 can be, in an embodiment, any blood vessel that can be accessed percutaneously or by surgical dissection such as femoral vein, femoral artery or jugular vein.”); Ex. 1003, ¶124.)

2. **Garrison and Aklog**

Claim 7 is an apparatus claim that merely requires the distal end portion of the catheter be “configured to be positioned proximate” a pulmonary embolism – the claim does not recite a method of treating a pulmonary embolism. Thus, Garrison anticipates the claim. *Supra* Claim 7 [Garrison]. However, if additional limitations are imported into the claim and the Board finds that Garrison does not anticipate, a POSITA would have found it obvious to position the distal end of Garrison’s aspiration system proximate a PE within the blood vessel of the patient based on Aklog and the knowledge of a POSITA. (Ex. 1003, ¶¶125-136.)

Aklog discloses an aspiration system for removing clot material from different parts of the vasculature, including “the pulmonary circulation (e.g., pulmonary arteries), systemic venous circulation (e.g., vena cavae, pelvic veins, leg veins, neck and arm veins) or arterial circulation (e.g., aorta or its large and medium branches).” (Ex. 1005, 7:32-37; *see also id.*, 1:17-24, 5:11-19, 5:28-41, Figs. 1, 6-7.) Aklog

discloses that an obstruction of the pulmonary arteries is “known as pulmonary embolism,” a condition treated by Aklog’s aspiration system. (*Id.*, 2:20-32.)

A POSITA would have been motivated to position the distal end of Garrison’s aspiration catheter proximate a PE and, to the extent necessary, adapt Garrison’s aspiration system to treat PE. (Ex. 1003, ¶¶125-136.) Garrison’s system is already designed to aspirate clots and Aklog explains that PE is a harmful type of clot that can block blood flow to the lungs and cause death. (*Id.*, 2:20-32.) Thus, a POSITA would have been motivated to adapt Garrison’s existing and proven aspiration technology to treat similar conditions in other parts of the vasculature. (Ex. 1003, ¶126.)

A POSITA would have been further motivated to adapt Garrison’s system to be positioned proximate a PE and, if necessary, to treat PE because Aklog discloses that aspiration can effectively remove the PE. (*See e.g.*, Ex. 1005, 5:11-27 (describing invention).) Moreover, the systems in Garrison and Aklog are similarly configured. Like Garrison, Aklog’s aspiration system includes a suction cannula 10 [orange] that is inserted into a patient’s artery or vein until the end of the cannula is proximate the clot material, such as a PE. (*Id.*, 5:28-41, 11:62-65, 13:64-14:2; *see also id.*, Figs. 2C, 2D, 2H (illustrating cannula proximate a clot).)

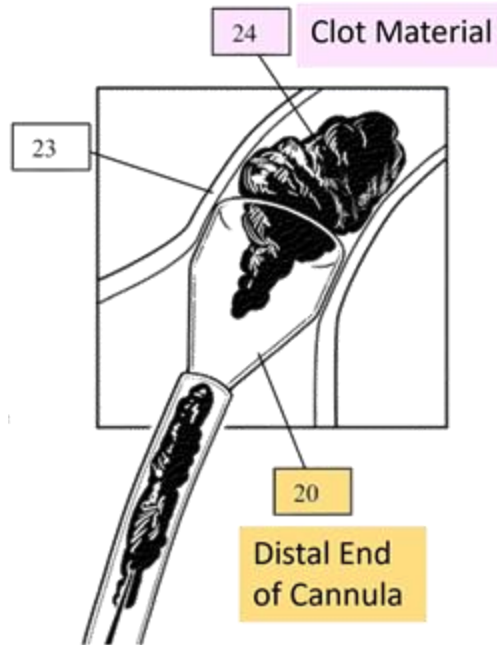


Fig. 2C

(*Id.*, Fig. 2C.)

Also, like Garrison, the suction cannula is connected to a filter 14 [blue], a reservoir 61 [green], and a pump 15 [red] that provides “a sufficient suction force for removing the undesirable material from the site of interest.” (*Id.*, 5:37-41.)

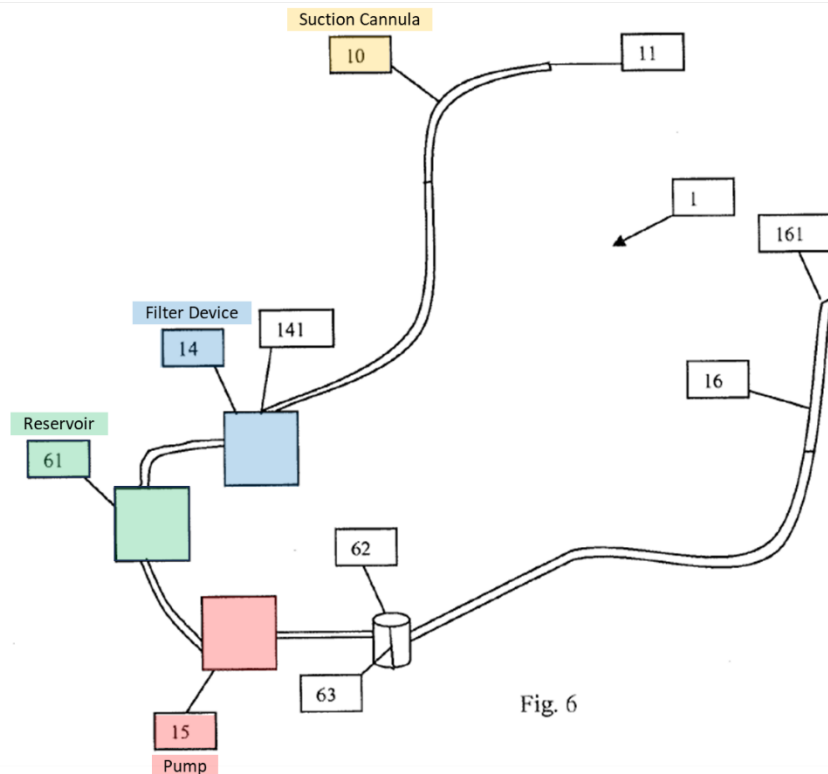


Fig. 6

(*Id.*, Fig. 6; *see also id.*, Fig. 7.) Additionally, the systems are inserted into the patient in the same way (e.g., through the femoral artery). (*Id.*, 15:30-34 (describing insertion through “femoral vein, femoral artery or jugular vein); Ex. 1006, [0048] (“Disclosed also are methods and devices that optimize clot aspiration through either transfemoral or transcarotid access approaches.”).) A POSITA would have reasonably expected success in adapting Garrison’s system to treat the conditions described in Aklog, including PE, based on the similar system configurations, insert locations, and methods of treatment. (Ex. 1003, ¶127.)

A POSITA would have recognized that adapting Garrison’s system to treat PE would have benefitted by simple modifications, such as increasing the size of the

aspiration catheter (and related components) and potentially adjusting the aspiration force. (*Id.*, ¶128.) Aklog discloses that POSITAs possessed the requisite knowledge to make such adjustments. For example, while Aklog primarily describes treatments for medium and large vessels, Aklog discloses “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 modifications. (See Ex. 1003, ¶128 (explaining that POSITA’s routinely make such modifications); Ex. 1022, ¶¶30-37 (describing real-world upsizing of neuro catheters for PE and DVT).) Similarly, Garrison discloses a range of possible sheath and catheter sizes for its system and presumes that a POSITA would have possessed the necessary knowledge to select the correct size. (See, e.g., Ex. 1006, [0063] (describing 6 and 8 French size sheaths); [0070] (describing 10 French size sheaths).)

Aklog also describes one topic POSITAs addressed in 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 discloses 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 also addresses aspirating excessive blood. (Ex. 1006, [0135].) Garrison describes 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.” (*Id.*, [0136]; *see also id.*, [0140], Fig. 38 (describing additional blood return systems).) Because Garrison already addresses the primary challenge a POSITA would have encountered in adapting Garrison’s aspiration system to treat PE, a POSITA would have reasonably expected success in enlarging Garrisons’ catheters to treat PE. (Ex. 1003, ¶130; *see also* Ex. 1022, ¶41 (describing real-world solutions for addressing blood loss).)

A POSITA would have also found it obvious to adapt Garrison’s aspiration system to remove the clot materials identified in Aklog, including PE, because the adaption would have been the predictable use of prior art elements (Garrison’s system) according to their established functions (aspiration of clot material). *KSR*, 550 U.S. at 417; (Ex. 1003, ¶131.) POSITAs developing catheter-based medical devices before and in August 2018 regularly adapted innovations developed for one portion of the vasculature to treat another. (Ex. 1003, ¶131; Ex. 1022, ¶¶21-41.) This was particularly true with respect to treating emboli and clots because the various conditions (e.g., pulmonary embolism, deep vein thrombosis (“DVT”), cerebral embolisms) were related. (Ex. 1022, ¶¶21-41.) 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, POSITAs working on treating clots in one part of the body consulted innovations for treating clots in other parts of the body. (Ex. 1003, ¶131; Ex. 1022, ¶¶25-31 (identifying real-world examples of adapting aspiration catheters for one part of the vasculature for another).)

In fact, Garrison suggests adapting its aspiration system with features described for use in other parts of the vasculature. For example, Garrison states that “it may be desirable to incorporate features on the arterial access sheath in order to minimize flow resistance through the insertable portion of the access sheath.” (Ex. 1006, [0070].) Garrison incorporates by reference two patents for this purpose: (1) Chang (Ex. 1016), which describes “a method for treating lesions in the carotid artery of a mammalian body (*id.*, abstract), and (2) Craido (Ex. 1017), which describes “[a] system for use in accessing and treating a carotid artery” (*id.*, abstract).

Garrison also incorporates by reference several patents describing thrombectomy devices having aspiration catheters to remove thrombus. (Ex. 1006, [0144].) Many of these patents describe the use of the aspiration catheters for parts

of the vasculature outside of cerebral applications. For example, Garrison incorporates U.S. Patent No. 6,481,439, which describes methods of treating blocked or occluded blood vessels. (Ex. 1018, 3:15-17.) While the reference primarily focuses on the treatment of a “catastrophic blockage of a cerebral artery,” the patent states that the “present invention, however, will also be useful for treating acute blockages in other portions of the vasculature as well as for treating chronic occlusions in the cerebral, cardiac, peripheral, mesenteric, and other vasculature.” (*Id.*, 3:28-39.; *see also* Ex. 1014, 1:17-20 (Garrison incorporates U.S. Patent No. 5,938,645, which discloses “a device adapted to break up and extract clots or thrombi which may form within the coronary artery comprising an improved percutaneous aspiration thrombectomy catheter system”).)

The patents incorporated into Garrison are not isolated examples. Other prior art patents disclose aspiration systems intended for use across all portions of the vasculature. For example, Brady, a PCT patent application published in February 2018, describes “devices intended for removing acute blockages from blood vessels.” (Ex. 1020, [0001], [0011].) Brady states, “The invention is particularly suited to removing clot from cerebral arteries in patients suffering acute ischemic stroke (AIS), from coronary native or graft vessels in patients suffering from myocardial infarction (MY), and from pulmonary arteries in patients suffering from

pulmonary embolism (PE) and from other peripheral arterial and venous vessels in which clot is causing an occlusion.” (*Id.*, [0001].)

In fact, ***even the challenged ’691 Patent*** acknowledges that POSITAs would have understood that aspiration systems for one part of the vasculature could be adapted for other portions of the vasculature. For example, the ’691 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, 4:41-58 (emphasis added).) The ’691 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. Rather, the ’691 patent admits a “person of ordinary skill in the art, therefore, will accordingly understand that the technology can have other embodiments with additional elements, or the technology can have other embodiments without several of the features shown and described below with reference to FIGS. 1-25.” (*Id.*, 2:2-7.)

For these reasons, a POSITA would have found it obvious to adapt Garrison’s aspiration system, with any necessary modifications, to treat PE based on Aklog and the knowledge of a POSITA. (Ex. 1003, ¶¶125-136.)

H. Claim 8

Claim 8 depends from Claim 6 and recites: “wherein the clot material comprises a deep vein thrombus.” Even though this claim is not directed to any attribute of the device of Claim 6, Garrison anticipates this claim or renders it obvious combined with Aklog and the knowledge of a POSITA. (Ex. 1003, ¶¶137-140; *see also* Ex. 1022, ¶¶21-41 (describing adaption of aspiration catheters for other parts of vasculature).)

As explained in connection with Claim 7, the distal end portion of Garrison’s aspiration catheter is configured to be placed proximate cerebral occlusions, as well as other types of clot material including PE and DVT. (*Supra* Claim 7 [Garrison].) Thus, Garrison anticipates this claim for the same reasons it anticipates Claim 7.

Moreover, Claim 8, like Claim 7, is an apparatus claim that merely requires the distal end portion of the claimed catheter be “configured to be positioned proximate” a DVT – the claim does not recite a method of treating a DVT. Thus, Garrison anticipates the claim. However, if additional limitations are imported into the claim and the Board finds that Garrison does not anticipate, a POSITA would have found it obvious to position the distal end of Garrison’s aspiration system

proximate a DVT within the blood vessel of the patient based on Aklog and the knowledge of a POSITA. (Ex. 1003, ¶139.)

As explained in connection with Claim 7, Aklog discloses an aspiration system for removing clot material from different parts of the vasculature, including “the pulmonary circulation (e.g., pulmonary arteries), systemic venous circulation (e.g., vena cavae, **pelvic veins**, **leg veins**, neck and arm veins) or arterial circulation (e.g., aorta or its large and medium branches).” (Ex. 1005, 7:32-37 (emphasis added).) Aklog discloses that blood clots in the large veins of the legs and pelvis are “known as deep venous thrombosis (DVT),” a condition treated by Aklog’s aspiration system. (*Id.*, 2:7-19.) A POSITA would have been motivated to position the distal end portion of Garrison’s catheter proximate a DVT, and to the extent necessary adapt Garrison’s system to treat DVT. (Ex. 1003, ¶140.) Garrison’s system is already designed to aspirate clots and Aklog explains that DVT causes “swelling, ulcers, pain and infection” and leads to embolisms in other parts of the body. (Ex. 1005, 2:20-32.) Thus, a POSITA would have been motivated to adapt Garrison’s existing and proven aspiration technology to treat similar conditions in other parts of the vasculature. (Ex. 1003, ¶140.)

Moreover, a POSITA would have been motivated to adapt Garrison’s system to treat DVT, and would have reasonably expected success in doing so, for the additional reasons described in Claim 7. (Ex. 1003, ¶140.)

I. Claim 9

Claim 9 depends from Claim 1 and recites: “wherein the second chamber is removably coupled between the aspiration pump and the aspiration catheter.” Garrison renders this claim obvious alone or in combination with Goff. (Ex. 1003, ¶¶141-143.)

Garrison discloses a second chamber between the aspiration pump and aspiration catheter. (*Supra* Limitation [1B], Claim 4.) For the reasons provided in connection with Claim 4, a POSITA would have found it obvious to removably couple Garrison’s second chamber (i.e., filter 3418) to the flow lines 2025/2045 and related components. (*Supra* Claim 4 [Garrison].).

Additionally, a POSITA would have found it obvious to modify Garrison’s second chamber/filter to be removably coupled, or to use the removable chamber in Goff, for the reasons provided in connection with Claim 4. (*Supra* Claim 4 [Garrison and Goff].)

J. Claim 10

Claim 10 depends from Claim 1 and recites: “further comprising a filter in the second chamber.” Garrison discloses this claim. (Ex. 1003, ¶¶144-145.)

Garrison discloses a filter 3418, which may be coupled to the assembly with flow line 2025 and/or flow line 2045. (Ex. 1006, [0131].) As shown in Figure 34, the filter 3418 is enclosed in a second chamber. (*Supra* Limitation [1B].)

K. Claim 11

Claim 11 depends from Claim 10 and recites: “wherein the filter includes a plurality of pores sized to inhibit clot material from flowing therethrough and to permit blood to flow therethrough.” Garrison anticipates this claim or renders it obvious alone or in combination with Goff. (Ex. 1003, ¶¶146-152.)

1. Garrison

Garrison discloses a filter 3418. (Ex. 1006, [0131].) However, Garrison does not expressly describe the filter construction and instead presumes a POSITA would have possessed the knowledge to select an appropriate filter. A POSITA would have recognized that the filter must necessarily have a plurality of pores to inhibit clot material from flowing through the valve. (Ex. 1003, ¶147.) Afterall, the purpose of Garrison’s filter is to remove clot material from the blood. (*Id.*)

Further, even if Garrison’s filter does not inherently disclose this limitation, it renders the limitation obvious in combination with the knowledge of a POSITA. (*Id.*, ¶148.) Conventional filters included pores sized to inhibit certain diameters of material from flowing through the filter. (*Id.*) For example, Aklog describes a filter for its aspiration system having a “permeable sheet 143 positioned with the fluid flow” that “may include a **plurality of pores** sufficiently sized, so as to permit fluid from the site of interest to flow therethrough, while preventing undesirable material captured from the site of interest from moving downstream” (Ex. 1005, 11:33-

40.) A POSITA implementing Garrison’s aspiration system would have found it obvious to select pore sizes to remove clot material, as reflected by, for example, Aklog. (Ex. 1003, ¶148.)

Moreover, a POSITA would have reasonably expected success in implementing a filter having a plurality of pores sized to inhibit clot material from flowing therethrough because that is the purpose of Garrison’s filter, and, generally, any filter. (See Ex. 1006 at 12:35-37 (“filtered fluid can be reinfused back into the body.”).) Further, filters were commonly used in medical devices in August 2018 and would have been well understood by POSITAs such that they would have produced predictable results. (Ex. 1003, ¶149.)

2. Garrison and Goff

Goff also describes a filter that meets the claim limitations. Goff confirms that POSITAs would have been familiar with filters, stating the “filter element may be any conventional filter element, such as paper, polymer, a woven filter membrane, a screen, or other porous member, or the like.” (Ex. 1007, [0011].) Goff further explains, “The filter element will have a pore size or screen size selected to separate solid particles at a desired particle size cutoff.” (*Id.*) Goff provides examples of suitable pore sizes (e.g., “1 μm to 1000 μm ”). (*Id.*)

A POSITA would have been motivated to use Goff’s pore sizes for Garrison’s filter, or use Goff’s filter in Garrison, because Goff’s pore sizes are suitable to

“separate solid particles at a desired particle size cutoff” and “will allow the separated solid materials to collect on an exposed surface so that the solid materials will be easily removed and/or absorbed.” (*Id.*; Ex. 1003, ¶151.) Further, combining Goff’s filter with Garrison’s aspiration system would have merely entailed the combination of known elements (Goff’s filter and Garrison’s system) according to known methods (positioning the filter within a chamber in line with the system) to yield the predictable result of removing unwanted particles from the aspirated blood. *KSR*, 550 U.S. at 416; (Ex. 1003, ¶151.)

A POSITA would have reasonably expected success in incorporating Goff’s pore sizes, or Goff’s filter, into Garrison because Goff’s filter is used to filter blood and filters are simple, predictable devices that both Goff and Garrison acknowledge were well understood in the art. (Ex. 1003, ¶152.)

L. Claim 12

Claim 12 depends from Claim 10 and recites: “wherein the filter is removable from within the second chamber.” Garrison alone or in combination with Goff renders this claim obvious. (Ex. 1003, ¶¶153-157.)

1. Garrison

Garrison discloses a filter 3418 within a second chamber but does not expressly state whether the filter is removable from the second chamber. (Ex. 1006, [0131], Fig. 34; *supra* Limitation [1B].)

A POSITA would have found it obvious to configure the second chamber so that the filter is removable. (Ex. 1003, ¶¶155.) POSITAs would have been motivated to make Garrison's filter removable so that the filter could be easily replaced or cleaned then reinserted. (*Id.*) As mentioned previously, Garrison discloses that a physician can use the system to remove multiple clots. (Ex. 1006, [0166].) A POSITA would have recognized that multiple clots could clog the system and require cleaning or replacement of the filter. (Ex. 1003, ¶155.) Thus, POSITAs would have been motivated to configure the filter chamber so that it could be opened to permit removal or cleaning of the filter. (*Id.*) As shown by the examples below, filter chambers that could be unscrewed (left) or unclamped (right) were well known:

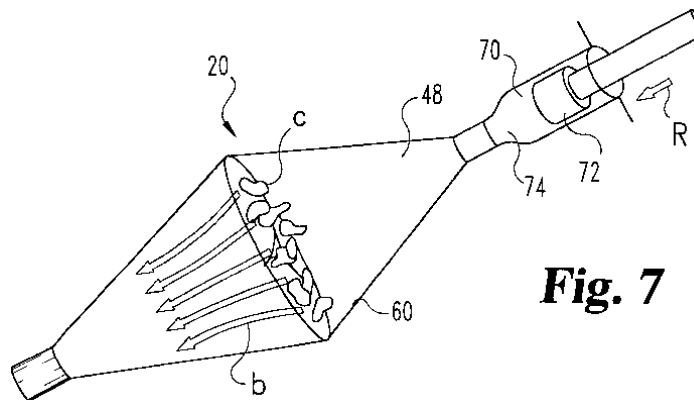
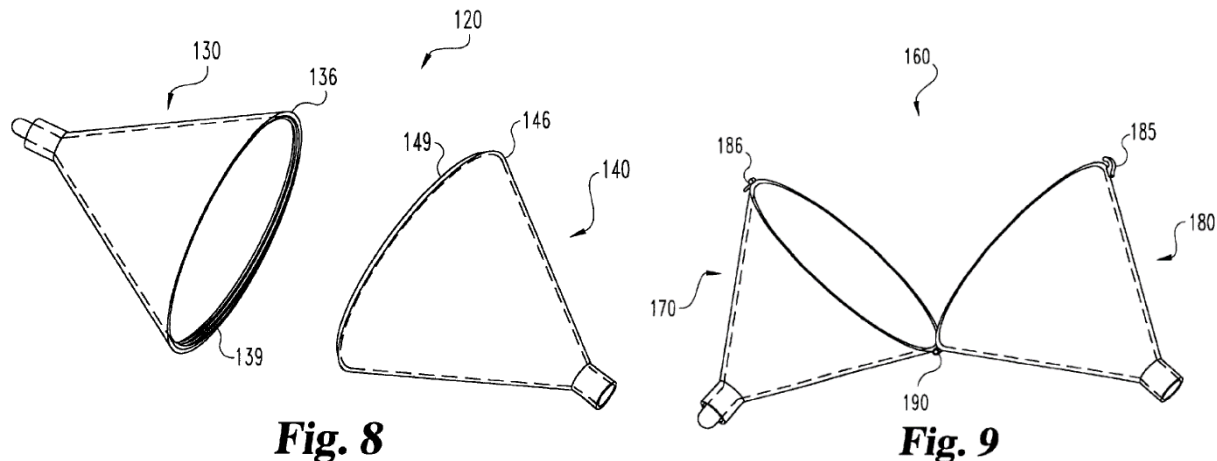


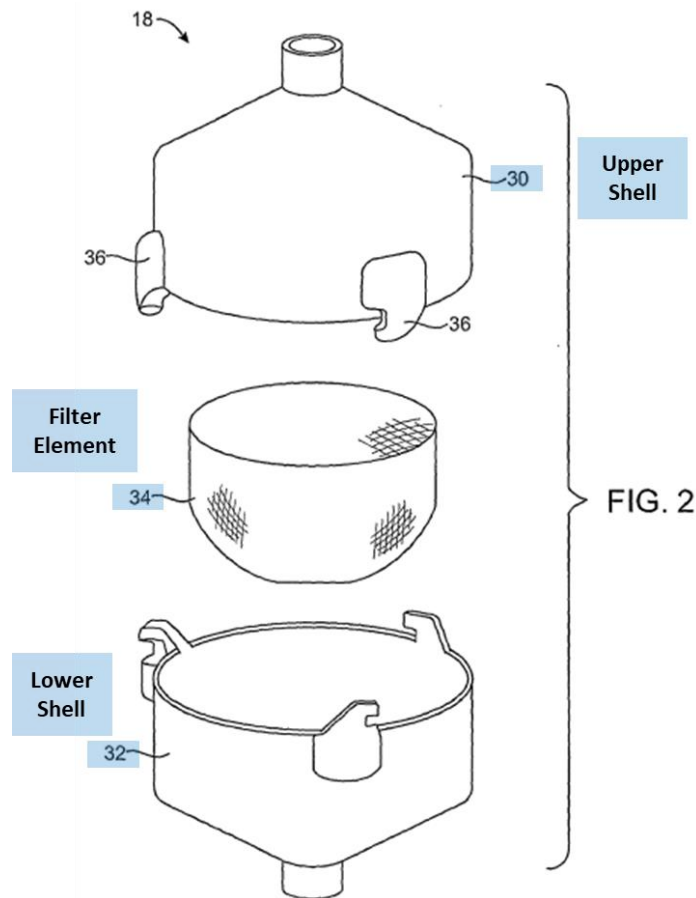
Fig. 7



(Ex. 1009, 5:65-6:10, Figs. 7-9; *see also* Ex. 1007, [0025] (describing filter chamber that can be separated to remove the filter).) A POSITA would have reasonably expected success in incorporating such chambers into Garrison because the chambers involve simple and predictable mechanical parts (e.g., hinge, clip, interlocking tabs, or screw threads) that would have been well understood by POSITAs. (Ex. 1003, ¶155.)

2. Garrison and Goff

If Garrison does not render this claim obvious, Garrison in combination with Goff does. (Ex. 1003, ¶¶156-157.) Goff’s “filter assembly 18 typically comprises an upper shell 30, a lower shell 32, and a filter element 34 which may be disposed within the interior of the shells”:



(Ex. 1007, [0025], Fig. 2.) Goff further discloses “the filter housing has an upper shell and a lower shell which may be taken apart to permit introduction, **removal**, and replacement of the filter element in the interior of the housing.” (*Id.*, [0015] (emphasis added).) A POSITA would have been motivated to use Goff’s filter in Garrison’s aspiration system because it would have permitted to physician to clean or replace a clogged filter. (Ex. 1003, ¶156; *supra* Claim 4 [Garrison and Goff] (describing motivation to combine Garrison and Goff).) Additionally, Goff explains, “The filter element will have a pore size or screen size selected to separate solid particles at a desired particle size cutoff,” which POSITAs would have

recognized would be useful in Garrison’s system. (Ex. 1007, [0011]; Ex. 1003, ¶156.) Further, combining Goff’s filter with Garrison’s aspiration system would have merely entailed the combination of known elements (Goff’s filter and Garrison’s system) according to known methods (positioning the filter within a chamber in line with the system) to yield the predictable result of removing unwanted particles from the aspirated blood. *KSR*, 550 U.S. at 416; (Ex. 1003, ¶156.)

A POSITA would have reasonably expected success in incorporating Goff’s removable filter into Garrison because Goff’s filter is used to filter blood and filters are simple, predictable devices that both Goff and Garrison acknowledge were well understood in the art. (Ex. 1003, ¶157.)

M. Claim 13

Claim 13 depends from Claim 1 and recites: “wherein the first chamber is fluidically coupled in serial to the second chamber.” Garrison discloses this limitation. (Ex. 1003, ¶¶158-159.)

Garrison discloses a second chamber that houses filter 3418, which is fluidically coupled in serial to the first chamber in the aspiration source with flow line 2025 and/or flow line 2045 [green]:

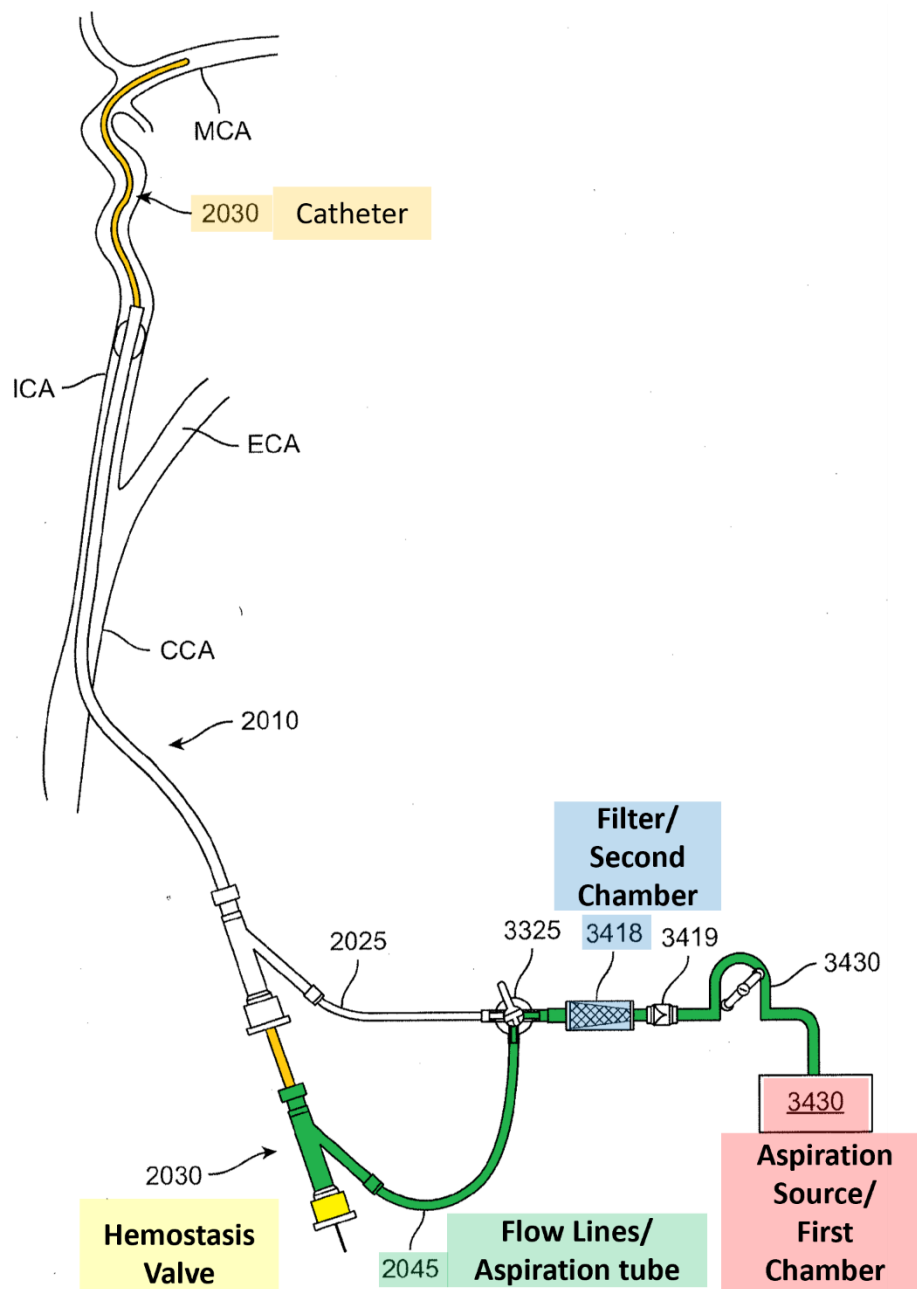


FIG. 34

(Ex. 1006, [0131], Fig. 34; see also Fig. 32 (showing receptacle fluidly coupled in serial with second chamber).)

N. Independent Claim 14

Claim 14 combines the limitations of Claim 1 and Claim 9 (*see* Limitation [14C] below). Thus, Claim 14 is rendered obvious by Garrison alone or in combination with Goff. (Ex. 1003, ¶¶160-167.)

1. Preamble [14]: “An aspiration system with accelerated response, comprising”

The preamble also appears in Claim 1. If the preamble is limiting, Garrison discloses this limitation for the reasons provided in Claim 1. (*Supra* Preamble [1].)

2. Limitation [14A]: “an aspiration pump in communication with a first chamber”

This limitation also appears in Claim 1. Garrison discloses this limitation for the reasons provided in Claim 1. (*Supra* Limitation [1A].)

3. Limitation [14B]: “an aspiration catheter configured for placement into fluid communication with the first chamber by way of an aspiration tube;”

This limitation also appears in Claim 1. Garrison discloses this limitation for the reasons provide in Claim 1. (*Supra* Limitation [1B].)

4. Limitation [14C]: “a second chamber in between the aspiration pump and the aspiration catheter, wherein the second chamber is removably coupled between the aspiration pump and the aspiration catheter”

This limitation combines limitations from Claim 1 and Claim 9. Garrison renders this limitation obvious alone or in combination with Goff for the reasons provided in Claims 1 and 9. (*Supra* Limitation [1B], Claims 4, 9.)

5. **Limitation [14D]: “a user-actuatable valve between the second chamber and the aspiration catheter”**

This limitation appears in Claim 1. Garrison discloses this limitation for the reasons provide in Claim 1. (*Supra* Limitation [1C].)

6. **Limitation [14E]: “wherein the valve is configured to be closed while negative pressure is generated in the first and second chambers, and wherein the valve is configured to be opened after the negative pressure is generated in the first and second chambers”**

This limitation appears in Claim 1. Garrison discloses this limitation for the reasons provide in Claim 1. (*Supra* Limitation [1D].)

7. **Limitation [14F]: “wherein upon user actuation to open the valve with the negative pressure having been generated in the first and second chambers, fluid flow at least partially from the second chamber into the first chamber causes rapid aspiration into the second chamber”**

This limitation appears in Claim 1. Garrison discloses this limitation for the reasons provided in Claim 1. (*Supra* Limitation [1E].)

O. **Claim 15**

Claim 15 depends from Claim 14 and recites: “further comprising a filter in the second chamber.” This limitation appears in Claim 10, and Garrison discloses the limitation for the reasons provided in Claim 10. (*Supra* Claim 10.)

P. **Claim 16**

Claim 16 depends from Claim 15 and recites: “wherein the filter includes a plurality of pores sized to inhibit clot material from flowing therethrough and to

permit blood to flow therethrough.” This limitation appears in Claim 11, and Garrison discloses the limitation or renders the limitation obvious alone or in combination with Goff for the reasons provided in Claim 11. (*Supra* Claim 11.)

Q. Claim 17

Claim 17 depends from Claim 15 and recites: “wherein the filter is removable from within the second chamber.” This limitation appears in Claim 12, and Garrison renders the limitation obvious alone or in combination with Goff for the reasons provided in Claim 12. (*Supra* Claim 12.)

R. Claim 18

Claim 18 depends from Claim 14 and recites: “wherein the first chamber is fluidically coupled in serial to the second chamber.” This limitation appears in Claim 13, and Garrison discloses the limitation for the reasons provided in Claim 13. (*Supra* Claim 13.)

S. Claim 19

Claim 19 depends from Claim 14 and recites: “wherein the aspiration catheter is configured to be intravascularly positioned within a blood vessel of a patient.” This limitation appears in Claim 5, and Garrison discloses the limitation for the reasons provided in Claim 5. (*Supra* Claim 5.)

T. Claim 20

Claim 20 depends from Claim 19 and recites: “wherein the aspiration catheter has a distal end portion configured to be positioned proximate to clot material within

the blood vessel of the patient.” This limitation appears in Claim 6, and, even if one assumes this claim limits the device of Claim 19, Garrison discloses the limitation for the reasons provided in Claim 6. (*Supra* Claim 6.)

U. Claim 21

Claim 21 depends from Claim 20 and recites: “wherein the clot material comprises a pulmonary embolism.” This limitation appears in Claim 7. Even if one assumes Claim 21 describes an attribute of the claimed device of Claim 20, Garrison anticipates this claim or renders the claim obvious in combination with Aklog for the reasons provided in Claim 7. (*Supra* Claim 7.)

Further, the modification of Garrison’s system to include Goff’s removable filter chamber and/or removable filter would not impact the positioning of Garrison’s catheter proximate a PE or DVT, or Garrison’s further adaptation to treat PE or DVT. (Ex. 1003, ¶175.) Goff discloses that its removable filter is appropriate for filtering unwanted material from different parts of the body. (*See* Ex. 1007, [0008] (“The fluid may be aspirated from a variety of hollow body organs and other structures”).) Likewise, Goff discloses that the filter can have a range of pore sizes depending on the application and can filter aspirated blood. (*Id.*, [0008], [0011].) Thus, Goff would be appropriate for treating clots removed from all portions of the vasculature, including PE and DVT. (Ex. 1003, ¶175.)

V. Claim 22

Claim 22 depends from Claim 20 and recites: “wherein the clot material comprises a deep vein thrombus.” This limitation appears in Claim 8. Even though this claim is not directed to any attribute of the device of Claim 22, Garrison anticipates this claim or renders the claim obvious in combination with Aklog for the reasons provided in Claim 8. (*Supra* Claim 8.)

W. Independent Claim 23

Independent Claim 23 combines the limitations of Claims 1-3 with one modification. Claim 23 requires “fluid flow at least partially from the second chamber into the first chamber causes rapid decrease in pressure in the aspiration catheter,” which is different from the limitation in Claim 1 (“fluid flow at least partially from the second chamber into the first chamber causes rapid aspiration into the second chamber”). However, this change does not meaningfully differentiate Claims 1 and 23. (Ex. 1003, ¶177.) When a physician opens the user-actuated valve after building up negative pressure in the first and second chambers, the system causes a rapid decrease in pressure in the aspiration catheter because the material in the catheter is being suctioned into the first and second chambers. (*Id.*) This rapid decrease in pressure causes the rapid aspiration of clot material through the catheter. (*Id.*) Thus, Garrison combined with Hartley renders Claim 23 obvious for the reasons provided in Claims 1-3. (*Supra* Claims 1-3.)

X. Claim 24

Claim 24 depends from Claim 23 and recites: “wherein the aspiration catheter is configured to be intravascularly positioned within a blood vessel of a patient, wherein the aspiration catheter has a distal end portion configured to be positioned proximate to clot material within the blood vessel of the patient, and wherein the clot material comprises a pulmonary embolism or deep vein thrombus.” Claim 24 combines the limitations of Claims 5-6 and 7 or 8. Even assuming these are limitations to the device of Claim 23, Garrison anticipates this claim or renders the claim obvious in combination with Aklog for the reasons provided previously. (*Supra* Claims 5-8.)

Further, the modification of Garrison’s system to include Hartley’s hemostasis valve would not impact positioning Garrison’s catheter proximate a PE or DVT or treating those clots. (Ex. 1003, ¶179.) Hartley generally describes a hemostasis valve for use with “medical devices” to “prevent loss of blood or other fluid.” (Ex. 1008, [0002]-[0003].) Hartley is not limited to medical devices for use in a particular part of the anatomy. (Ex. 1003, ¶179.) Thus, Hartley would be appropriate for aspiration catheters for use in all portions of the vasculature, including PE and DVT. (*Id.*)

Y. Claim 25

Claim 25 depends from Claim 23 and recites: “wherein the second chamber is removably coupled between the aspiration pump and the aspiration catheter.” This limitation appears Claim 9, and Garrison renders this limitation obvious alone or in combination with Goff for the reasons provided in Claim 9. (*Supra* Claims 4, 9.)

Further, it would have been obvious for a POSITA to have used Goff’s removable filter with Hartley’s hemostasis valve in an aspiration catheter. (Ex. 1003, ¶181.) As explained above, Goff and Hartley both describe devices for use in a range of medical procedures and across all portions of the vasculature. (*Supra* §§VI.C, VI.D.2.) Thus, Hartley would be appropriate for aspiration systems that also incorporate Goff’s removable filter. (Ex. 1003, ¶181.)

Z. Claim 26

Claim 26 depends from Claim 23 and recites: “further comprising a filter in the second chamber, wherein the filter is removable from within the second chamber.” This claim combines limitations from Claims 10 and 12, and Garrison alone or in combination with Goff renders this claim obvious for the reasons provided in Claims 10 and 12. (*Supra* Claims 10, 12.)

AA. Claim 27

Claim 27 depends from Claim 23 and recites: “wherein the first chamber is fluidically coupled in serial to the second chamber.” This limitation also appears in

Claim 13, and Garrison discloses this limitation for the reasons provided in Claim 13. (*Supra* Claim 13.)

BB. Independent Claim 28

Claim 28 combines the limitations of Claims 1 and 9, as well as the last limitation of Claim 23 requiring “fluid flow at least partially from the second chamber into the first chamber causes rapid decrease in pressure in the aspiration catheter.” Claim 28 is rendered obvious by Garrison alone or in combination with Goff for the reasons provided in Claims 1, 9, and 23. (*Supra* Claims 1, 9, and 23.)

CC. Claim 29

Claim 29 depends from Claim 28 and recites: “further comprising a filter in the second chamber, wherein the filter is removable from the second chamber.” This claim combines the limitations of Claims 10 and 12, and Garrison alone or in combination with Goff renders this claim obvious for the reasons provided in Claims 10 and 12. (*Supra* Claims 10, 12.)

DD. Claim 30

Claim 30 depends from Claim 28 and recites: “wherein the first chamber is fluidically coupled in serial to the second chamber.” This limitation also appears in Claim 13, and Garrison discloses this limitation for the reasons provided in Claim 13. (*Supra* Claim 13.)

EE. Claim 31

Claim 31 depends from Claim 28 and recites: “wherein the aspiration catheter is configured to be intravascularly positioned within a blood vessel of a patient, wherein the aspiration catheter has a distal end portion configured to be positioned proximate to clot material within the blood vessel of the patient, and wherein the clot material comprises a pulmonary embolism or deep vein thrombus.” Claim 31 combines the limitations of Claims 5-6 and 7 or 8. Even assuming Claim 31 includes limitations to the device of Claim 28, Garrison anticipates this claim or renders the claim obvious in combination with Aklog for the reasons provided in Claims 5-6 and 7 or 8. (*Supra* Claims 5-8.)

VII. SECONDARY CONSIDERATIONS

Petitioner is not aware of any evidence of secondary considerations. (Ex. 1003, ¶¶188-189.) If PO identifies evidence of secondary considerations, Petitioner respectfully requests an opportunity to respond.

VIII. THE BOARD SHOULD NOT DENY INSTITUTION UNDER §325(d)

Aklog, which forms the basis for Grounds 5-7 herein, was not cited during prosecution of the '691 patent. Aklog's parent, U.S. Patent No. 8,075,510, was cited in an IDS during prosecution, but was never applied. (Ex. 1002, 340.) However, Aklog is a “continuation-in-part” of its parent and includes additional disclosure. (Ex. 1005, 1:8-9.) Specifically, Aklog's parent did not include the description of

Aklog’s Figure 7, which describes the implementation of Aklog’s device to capture emboli and reinfuse aspirated blood during the procedure. (*Compare* Ex. 1005 with Ex. 1018.) Thus, because Aklog’s full disclosure was not before the Examiner, and because the Examiner never applied even Aklog’s parent, the Board should not exercise its discretion to deny institution under §325(d).

The other references identified in this Petition, Garrison, Hartley, and Goff, were listed on IDS’s during prosecution of the ’691 patent among hundreds of other references. (Ex. 1002, 348, 358, 364.) However, none of the references were cited by the Examiner, used in a rejection, or substantively discussed during prosecution. Nor were the arguments presented in this Petition presented to the Patent Office. *See Becton, Dickinson & Co. v. Braun Melsungen AG*, IPR2017-01586, Paper 8 (PTAB Dec. 15, 2017) (establishing factors for §325(d) analysis); *Advanced Bionics, LLC v. MED-EL Elektromedizinische Gerate GmbH*, IPR2019-01469, Paper 6 (Feb. 13, 2020) (clarifying standards under §325(d)).

Further, during prosecution, the Patent Examiner primarily relied on prior art for treating wounds on the skin surface. (*Supra* §II.B (Prosecution Histor).) The Examiner found that this prior art did not “teach a coupled assembly including: the second chamber; aspiration catheter; and a hemostasis valve.” (Ex. 1002, 51-52.) The Examiner further found that the second chamber in the wound treatment reference could not “be part of another assembly that includes the aspiration catheter

and a hemostasis valve” because that “would destroy the function” of how the wound treatment reference operates. (*Id.*) The Examiner also found that “there is no hemostasis valve mentioned” in the wound treatment reference. (*Id.*) On these grounds, the Examiner allowed the challenged claims.

However, as demonstrated above, the prior art relied upon in this Petition, which is all related to aspiration catheters, discloses a coupled assembly including: the second chamber; aspiration catheter; and a hemostasis valve. Thus, the prior art rebuts the alleged points of novelty identified by the Examiner.

As a result, the Examiner materially erred in allowing the challenged claims over Garrison, Hartley, and Goff (and even Aklog’s parent). The Examiner never addressed any combinations of these references, or any combinations with Aklog’s parent. Accordingly, the Board should not deny institution based on the citation of Garrison, Hartley, and Goff in the dense IDSs because, as shown above, the references render the challenged claims unpatentable and the Examiner never applied them. (Ex. 1002); *see e.g., Comcast Cable Commc’ns LLC v. Promptu Sys. Corp.*, IPR2018-00342, Paper 13 (PTAB July 19, 2018) (declining to deny institution under §325(d) because prior art was not applied).

**IX. 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 party in interest for Petitioner.

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

PO recently filed suit alleging that Petitioner’s Symphony system infringes the ’691 patent, as well as U.S. Patent Nos. 11,974,910; 11,969,333; 11,554,005; 11,844,921; 11,697,011; 11,697,012; and 11,865,291. *Inari Medical, Inc. v. Imperative Care, Inc.*, No. 24-cv-3117 (N.D. Cal., filed May 22, 2024) (the “Litigation”). The court has not set a schedule or a trial date in the litigation.

Petitioner also filed a Petition for Inter Partes Review of U.S. Patent No. 11,697,011 assigned to PO, which is IPR2024-01157. Some of the arguments relating to the hemostasis valve made in this Petition overlap with arguments made in IPR2024-01157.

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 BoxImperative691@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 BoxImperative691@knobbe.com.

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

Petitioner certifies that the '691 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.

X. 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: August 12, 2024

By: /Joshua J. Stowell/

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

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

Brian C. Barnes (Reg. No. 75,805)

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. 11,744,691 contains 13,906 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: August 12, 2024 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. 11,744,691, PETITIONER’S POWER OF ATTORNEY, AND EXHIBITS 1001-1030, were served via Priority Mail Express on the Patent Owner at the correspondence address of record for the subject patent as follows:

PERKINS COIE LLP
P.O. BOX 1247
PATENT PROCUREMENT
SEATTLE, WA 98111-1247

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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Dated: August 12, 2024

By: /Joshua J. Stowell/

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