

Petitioner Imperative Care's Demonstratives For Consolidated Oral Argument

September 10, 2026

Imperative Care, Inc. v. Inari Medical, Inc.

IPR2025-01021 (Patent 11,969,333)

IPR2025-01025 (Patent 11,974,910)

<i>Imperative Care v. Inari Medical</i> IPR2025-01021 Imperative Care Ex. 1090
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Outline Of Petitioner's Oral Argument

- ⊙ Overview of Proceedings
- ⊙ '333 Patent, Grounds 1A, 2A – Laub or Aklog + Garrison
- ⊙ '333 Patent, Grounds 3A, 4A – Garrison + Laub or Aklog
- ⊙ '910 Patent, Grounds 1-3 – Garrison + Laub and/or Aklog
- ⊙ PO Fails To Prove Unexpected Results
- ⊙ The Board Should Deny PO's Motion To Exclude

Disputed Issues

- ⊙ Does Garrison disclose building up vacuum in a clot canister with the valve closed? ('333 & '910 patents)
- ⊙ Is Garrison's valve and aspiration method compatible with Laub's/Aklog's aspiration systems? ('333 patent)
- ⊙ Is Garrison's valve and aspiration method compatible with blood return? ('333 & '910 patents)
- ⊙ Would a POSITA have been motivated to optimize Garrison's system to treat PE/DVT? ('333 & '910 patents)
- ⊙ Has PO proven unexpected results? ('333 & '910 patents)
- ⊙ Has PO proven that Petitioner's expert testimony should be excluded? ('333 & '910 patents)

Issues Not In Dispute

- ⦿ PO does not raise unique arguments for any dependent claims
- ⦿ PO does not raise arguments regarding Schaffer, Hartley, Goff, or Pasha
- ⦿ No dispute that Petitioner's references qualify as prior art

Overview Of IPR Proceedings

'333 Patent IPR Grounds

Ground		References	Basis	Challenged Claims
1	A	Laub + Garrison	35 U.S.C. § 103	1-10, 13-29, 33-38
	B	Laub + Garrison + Goff	35 U.S.C. § 103	6-8, 17, 25-27, 36
	C	Laub + Garrison + Shaffer	35 U.S.C. § 103	11-12, 30-31
	D	Laub + Garrison + Shaffer + Hartley	35 U.S.C. § 103	11-12, 30-31
2	A	Aklog + Garrison	35 U.S.C. § 103	1-10, 13-29, 33-38
	B	Aklog + Garrison + Goff	35 U.S.C. § 103	6-8, 17, 25-27, 36
	C	Aklog + Garrison + Shaffer	35 U.S.C. § 103	11-12, 30-31
	D	Aklog + Garrison + Shaffer + Hartley	35 U.S.C. § 103	11-12, 30-31
3	A	Garrison + Laub	35 U.S.C. § 103	1-10, 13-29, 33-38
	B	Garrison + Laub + Goff	35 U.S.C. § 103	6-8, 17, 25-27, 36
	C	Garrison + Laub + Shaffer	35 U.S.C. § 103	11-12, 30-31
	D	Garrison + Laub + Shaffer + Hartley	35 U.S.C. § 103	11-12, 30-31
4	A	Garrison + Aklog	35 U.S.C. § 103	1-10, 13-29, 33-38
	B	Garrison + Aklog + Goff	35 U.S.C. § 103	6-8, 17, 25-27, 36
	C	Garrison + Aklog + Shaffer	35 U.S.C. § 103	11-12, 30-31
	D	Garrison + Aklog + Shaffer + Hartley	35 U.S.C. § 103	11-12, 30-31

'910 Patent IPR Grounds

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

District Court's Preliminary Findings Consistent With Institution

- ⦿ Inari asserted '910 Patent (claim 1) in preliminary injunction motion
- ⦿ District Court found Imperative Care raised “substantial question of validity” based on Garrison and Laub
- ⦿ “Imperative Care also persuasively argues that **a person of ordinary skill in the art would be motivated to combine Garrison’s aspiration system for treating cerebral blood clots with Laub’s teaching of an aspiration method for treating PE using larger-sized catheters**, specifically 16F as claimed by the '910 Patent.”

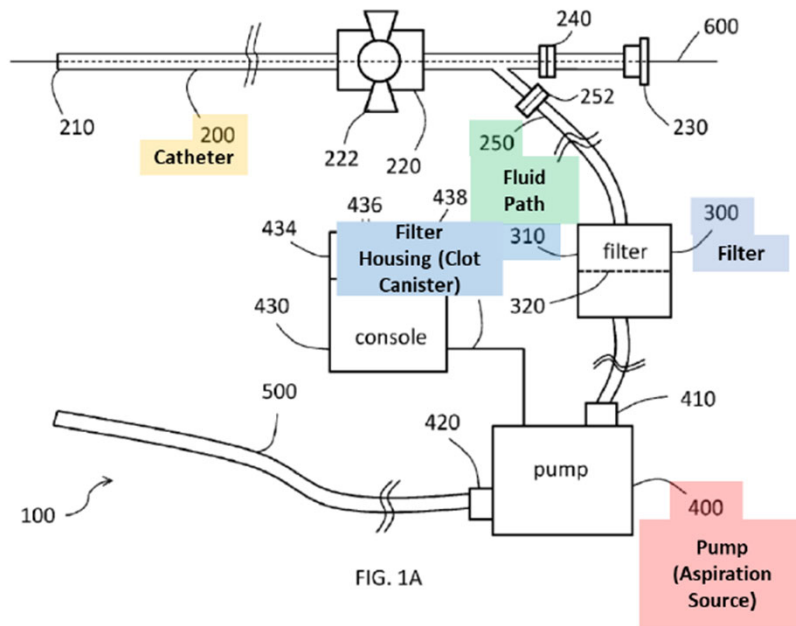
Laub or Aklog + Garrison Render Claims 1-10,
13-29, 33-38 of the '333 Patent Obvious
('333 Patent, Grounds 1A, 2A)

'333 Patent – Claim 1

1. A method of **treating a pulmonary embolism** within a vasculature of a patient, the method comprising:
advancing an aspiration catheter at least partially through the vasculature of the patient such that a distal end portion of the aspiration catheter is positioned proximate to the pulmonary embolism, wherein a lumen of the aspiration catheter is fluidly coupled along a fluid path to a clot canister and an aspiration source proximal to the clot canister;
generating vacuum pressure within the clot canister via the aspiration source while a valve positioned along the fluid path between the aspiration catheter and the clot canister is in a first position that inhibits fluid flow along the fluid path from the lumen of the aspiration catheter to the clot canister; and
moving the valve from the first position to a second position thereby applying the vacuum pressure to the

lumen of the aspiration catheter such that at least a portion of the pulmonary embolism and blood are aspirated into the clot canister, wherein **in the second position the valve permits fluid flow along the fluid path** from the lumen of the aspiration catheter to the clot canister, and wherein the clot canister includes a filter configured to filter the blood from the portion of the pulmonary embolism.

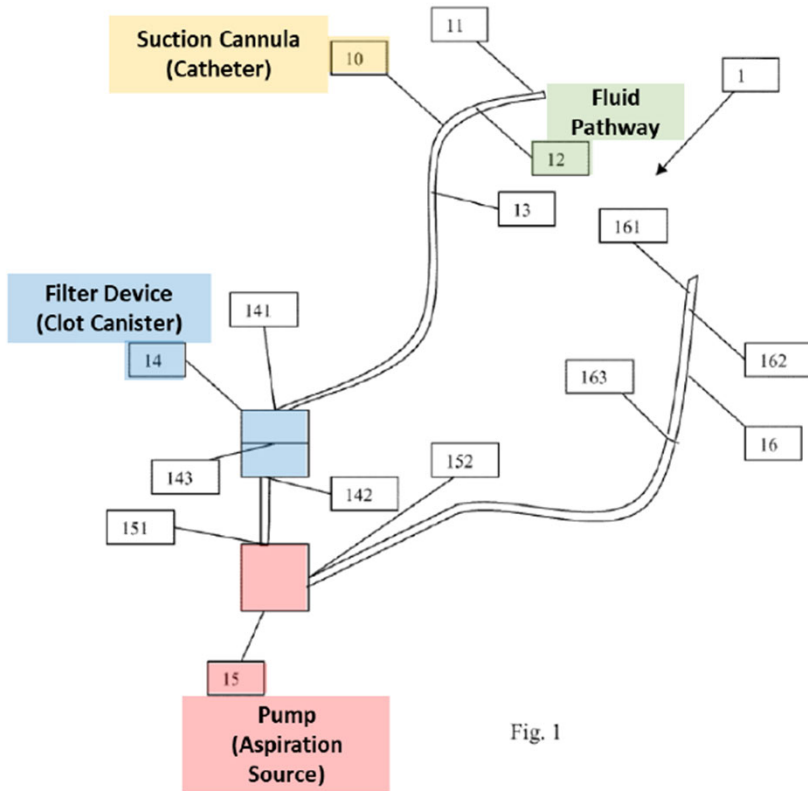
Laub Discloses Aspiration System For Treating PE/DVT



nary patients. In some embodiments, systems according to the present invention may be suited for thrombectomy and/or embolectomy procedures. Systems according to certain embodiments of the present invention may be used, for example, to remove clots from patients suffering from or at risk of pulmonary embolisms. In some embodiments, a system of the present invention is configured to aspirate thrombi and/or other unwanted material from the patient's vasculature. In some further embodiments, a system accord-

For example, in one embodiment, aspiration catheter 200 may be positioned to aspirate blood from a patient's vein (e.g., right common femoral vein) during use while return catheter 500 is inserted in either a vein (e.g., right internal jugular vein) or artery (e.g., right femoral artery) to return the aspirated blood to the patient after being modified by oxygenator 300. Oxygenator 330 may be positioned any-

Aklog Discloses Aspiration System For Treating PE/DVT



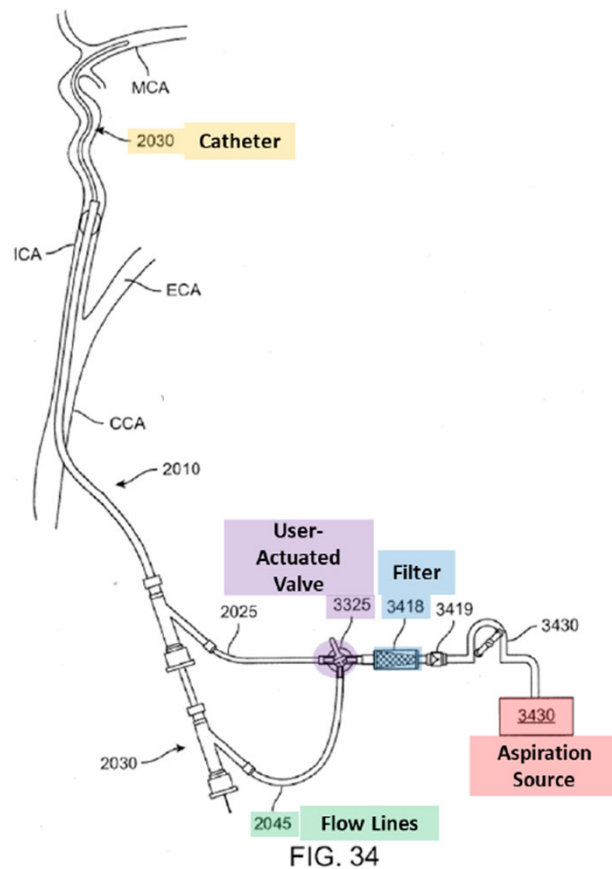
The present invention overcomes the deficiencies of existing devices and techniques and can act to remove substantially en bloc (i.e., wholly or entirely) undesirable material, such as thrombi and emboli, from the vasculature, including medium to large size blood vessels, and from heart chambers. Vessels from which the undesirable material may be removed, in accordance with an embodiment of the present invention, include, for example, those within 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). The heart chambers may be, for example,

Laub And Aklog – Undisputed Disclosures

⦿ PO does **not** dispute that Laub and Aklog each disclose:

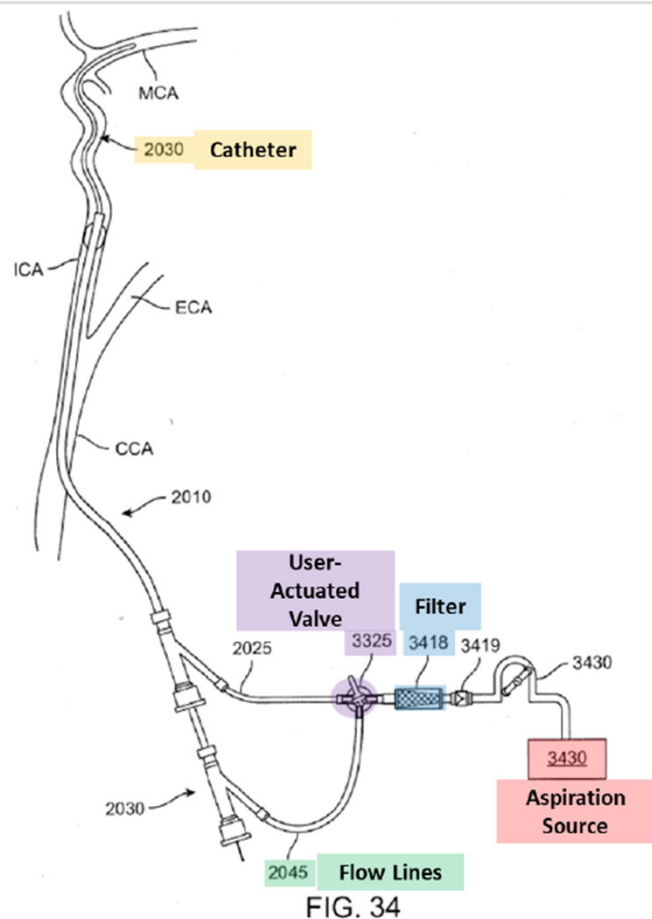
- “A method of treating a pulmonary embolism within a vasculature of a patient”;
- “[A]dvancing an aspiration catheter at least partially through the vasculature of the patient such that a distal end portion of the aspiration catheter is positioned proximate to the pulmonary embolism;
- The “lumen of the aspiration catheter is fluidly coupled along a fluid path to a clot canister and an aspiration source proximal to the clot canister”; and
- The “clot canister includes a filter configured to filter the blood from the portion of the pulmonary embolism”

Garrison Discloses Aspiration System With On/Off Valve



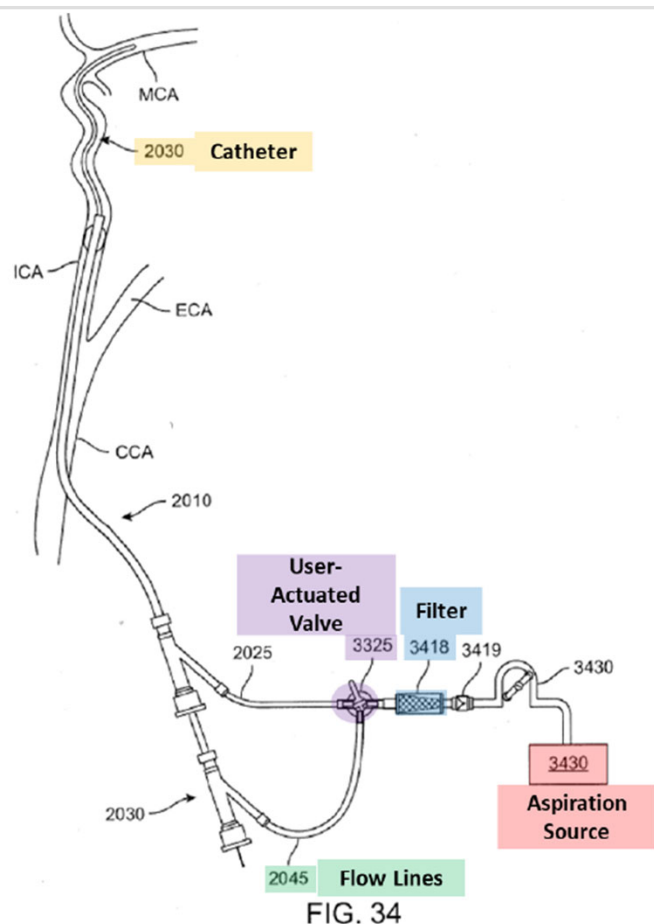
[0132] FIG. 34 shows a system whereby both the arterial access device 2010 and catheter 2030 are connected to the same aspiration source 3430 via flow lines 2025 and 2045, respectively. A valve 3325 controls which device is connected to the aspiration source 3430. The valve may enable one device, the other device, both devices, or neither device to be connected to the aspiration source at any given time. The valve may be a 3-way or 4-way stopcock. Alternately, the valve may be a flow controller with a simple actuation which selects the configuration as described above.

Garrison Discloses Generating Vacuum With Valve Closed To Provide Rapid Burst Of Aspiration



[0134] The active source of aspiration may be an aspiration pump, a regular or locking syringe, a hand-held aspirator, hospital suction, or the like. In one embodiment, 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. During the procedure when the tip of the aspiration device (either the arterial access device or the catheter) is near or at the face of the occlusion, the user may open the connection to the aspiration syringe. This would enable the maximum level of aspiration in a rapid fashion with one user, something that is currently not possible with existing technologies. In another

Garrison's Aspiration Method Applies To System In Figure 34



[0132] FIG. 34 shows a system whereby both the arterial access device 2010 and catheter 2030 are connected to the same aspiration source 3430 via flow lines 2025 and 2045, respectively. A valve 3325 controls which device is connected to the aspiration source 3430. The valve may enable one device, the other device, both devices, or neither device to be connected to the aspiration source at any given time. The valve may be a 3-way or 4-way stopcock. Alternately, the valve may be a flow controller with a simple actuation which selects the configuration as described above.

[0134] The active source of aspiration may be an aspiration pump, a regular or locking syringe, a hand-held aspirator, hospital suction, or the like. In one embodiment, 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. During the procedure when the tip of the aspiration device (either the arterial access device or the catheter) is near or at the face of the occlusion, the user may open the connection to the aspiration syringe. This would enable the maximum level of aspiration in a rapid fashion with one user, something that is currently not possible with existing technologies. In another

PO's Experts Agree That Garrison's Fig. 34 Is Not Limited To A Syringe Or Peristaltic Pump

PO's Expert – Brian Brown

Q: Could **Garrison's Figure 34 use an aspiration pump that is not a peristaltic pump?**

A: For what Garrison is teaching, I believe **there are other pumps that can be used**. Now, which specific pumps would have to be something that is tested. But I believe that **other pumps could be used that would not be limited to just a peristaltic pump**.

PO's Expert – Dr. Christopher Morris

Q: And what different types of aspiration sources can be used with this figure, based on your review of the patent?

A: I'd have to read further to, you know, find the description, but. **I know one of them is a pump. Aspiration pump, a regular or locking syringe, a handheld aspirator, hospital suction or the like.**

Q: Okay. So it's your understanding that **item 3430 could be any one of those types of aspiration sources?**

A: **Yeah.**

PO's Experts Agree That Garrison Discloses Building Up Vacuum In Figure 34 While Valve Is Closed

PO's Expert – Brian Brown

Q: The examiner also concluded that **Garrison discloses “Wherein the first pressure source is configured to generate vacuum pressure while the fluid control device is in the closed position.”** Do you agree with that portion of the examiner's conclusion?

A: **Yeah. For the most part, I -- I do.** It's – it's kind of odd here when it talks about a pressure source. I mean, earlier, I think they defined the pressure source, at least Garrison defined it or the examiner defined it, as 31 -- I guess 3125.

Q: And what do you think is odd about that?

A: I guess I'm just looking at it from the image there of a roller pump. **As I look at it more, I guess I can see where it could generate the vacuum that's being discussed here.**

PO's Experts Agree That Garrison Discloses Building Up Vacuum In Figure 34 While Valve Is Closed

PO's Expert – Dr. Christopher Morris

Q: So if I close valve 3325 so the pressure source is not connected to either catheter, and I turn on my pump, what then happens to the pressure to the right of the valve 3325?

A: It becomes lower.

Q: So we **would generate some negative pressure to the right of valve 3325**, correct?

A: **Yes.**

PO's Expert – Dr. Paul Zalesky

Q: And you would agree that **Garrison discloses a method in which the aspiration is built up while the valve 3325 is in the closed position.** Correct?

A: I didn't address that specific aspect of Garrison, but **it appears to be the case.**

***First* Motivation To Add Garrison's Valve To Laub Or Aklog**

Thornton Declaration

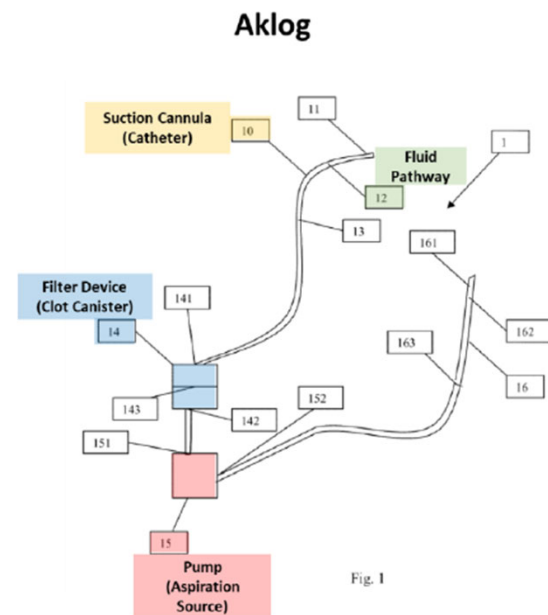
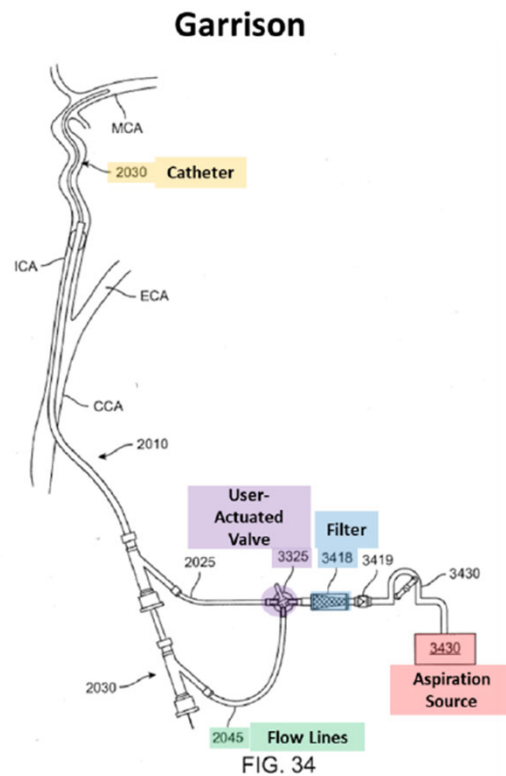
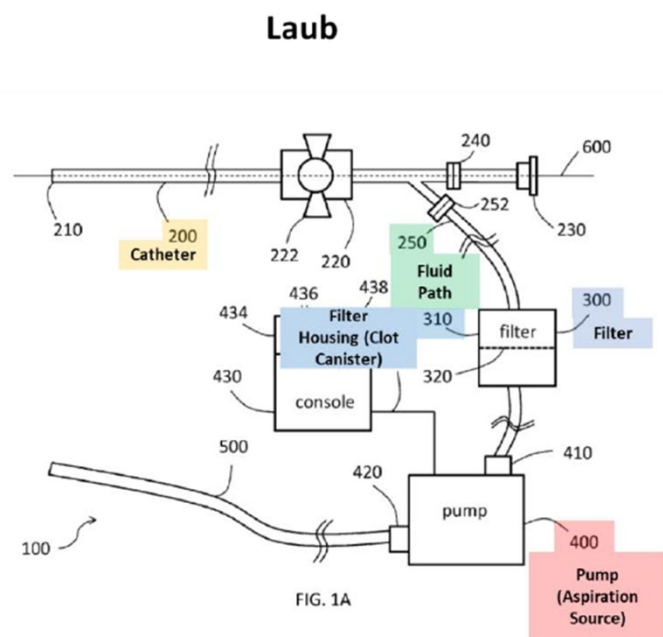
106. A person of ordinary skill in the art would have been motivated to incorporate Garrison's valve 3325 and method of generating pressure while the valve is closed into Laub's aspiration system in order "enable the maximum level of aspiration in a rapid fashion with one user" as taught by Garrison. Ex. 1006 (Garrison) at [0134]. Given Garrison's descriptions of the benefits of its rapid aspiration procedures, a person of ordinary skill in the art would have recognized that Garrison's valve could maximize Laub's aspiration power to aspirate PE's more quickly. This would help Laub's system operate more quickly and effectively.

Second Motivation To Add Garrison's Valve To Laub Or Aklog

Thornton Declaration

In addition, combining Garrison's valve with Laub's aspiration system would have merely entailed combining known elements (Garrison's valve and Laub's system) according to known methods (positioning the valve between the catheter and filter along the flow path) to yield the predictable result of aspirating unwanted material from the patient's vasculature.

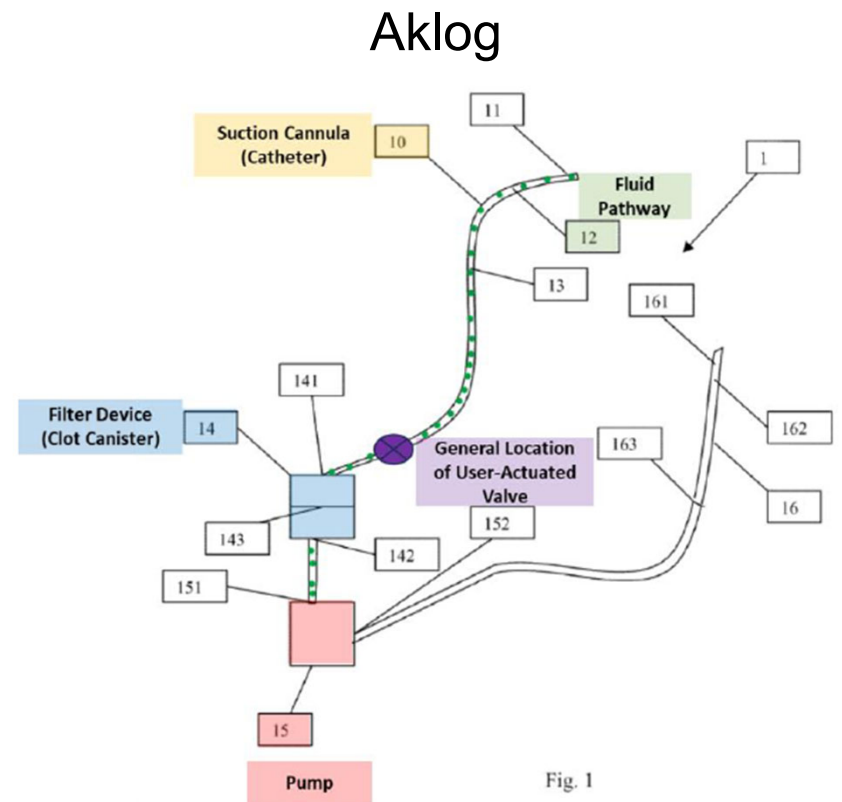
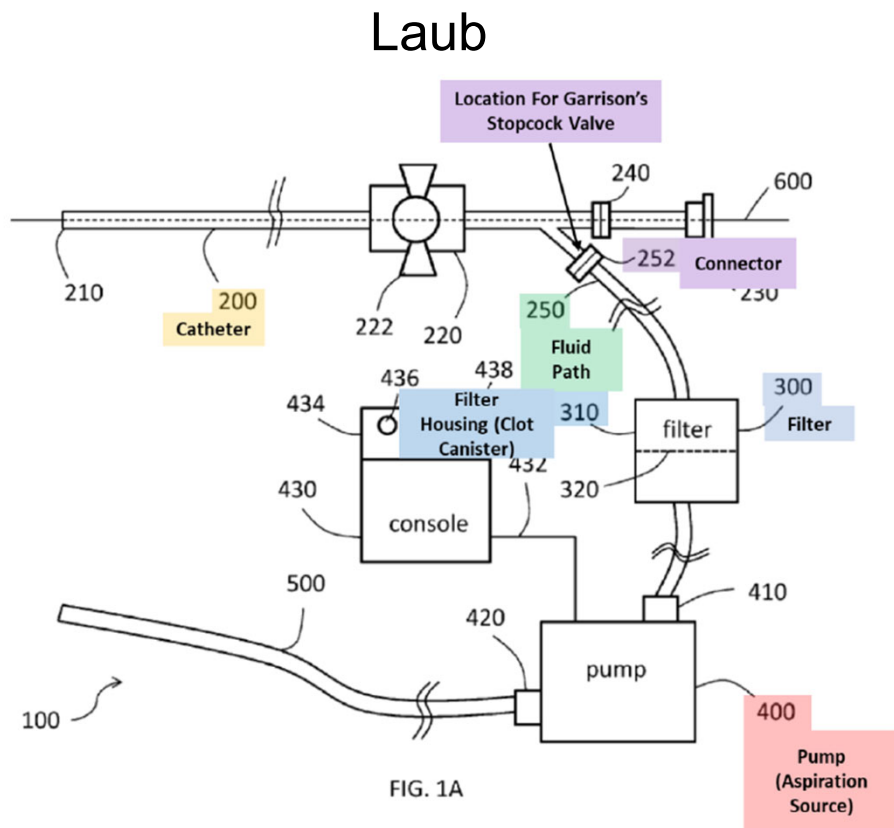
Laub, Aklog, And Garrison Disclose Similar Systems



—'333 Ex. 1003 (Thornton Decl.) at ¶¶ 79, 90; '333 Petition (Paper 1) at 38-41.

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

POSITA Would Have Expected Success Adding Garrison's Valve To Laub Or Aklog



—'333 Ex. 1003 (Thornton Decl.) at ¶¶108, 111; '333 Petition (Paper 1) at 39-41.

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

PO's Counterarguments Lack Support

⦿ PO Disputes:

- Specific types of pumps that could be used with Garrison's valve
 - Pump type is not described or claimed in the '333 patent
 - PO ignores known aspiration pumps that are compatible with Garrison's valve
- Whether Garrison's valve would allow continuous blood return
 - Continuous blood return not required by '333 patent or the prior art
- Whether Garrison's valve would improve the “maximum level of aspiration” of a pump
 - '333 patent does not claim “maximum level of aspiration”
 - No dispute that Garrison's valve would enable rapid burst of aspiration to clot

PO's Pump Arguments Lack Support

PO Response

Even if a POSA would combine Garrison's incompatible disclosures to create a new (undisclosed) method of closing a valve and generating a stored pressure in a clot canister with a filter, then releasing that pressure by opening the valve, a POSA still would not have been motivated to "incorporate Garrison's valve 3325 and method of generating pressure while the valve is closed into Laub's or Aklog's aspiration systems" because such a modification would be incompatible with the centrifugal/positive displacement pumps of Laub and Aklog by for example, potentially damaging those pumps and systems. Petition, pp.38-41; EX2008, ¶¶86-91.

PO Cannot Rely On Pump Types To Distinguish The Prior Art

“[A]n unclaimed and undisclosed feature ... cannot be the basis for finding [a] patent to be non-obvious over the prior art.”

Smith & Nephew, Inc. v. Rea, 721 F.3d 1371, 1380-81 (Fed. Cir. 2013)

'333 Patent

aspirating clot material from within a blood vessel. In general, the pressure source can be any suitable source or combination of sources for generating and/or storing negative pressure. In some embodiments, the 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.

Laub And Aklog Are Not Limited To Centrifugal Or “Positive Displacement” Pumps

Laub

[0041] Pump 400, according to certain embodiments, is configured to create a suction force to drive system 100 during use. In preferred embodiments, pump 400 is a centrifugal pump. In other embodiments, pump 400 may be a rotary pump, peristaltic pump, roller pump, or other form of pump known in the art. In some embodiments, pump 400

Aklog

site of interest back into the body. In an embodiment, the suction force and the drive force may be generated by pump 15 simultaneously and may take place continuously or intermittently for a set duration. Pump 15, as it should be appreciated, may be any commercially available pump, including those for medical applications and those capable of pumping fluids, such as blood. Examples of such a pump includes a kinetic pump, such as a centrifugal pump, and an active displacement pump, such as a rollerhead pump.

PO Fails To Show That Garrison's Valve Is Incompatible With All Centrifugal Or "Positive Displacement" Pumps

Brown Declaration

86. A POSITA would not have been motivated to add Garrison's valve or a like valve to "generat[e] pressure while the valve is closed into Laub's or Aklog's aspiration systems" because a POSITA would understand such a modification to be incompatible with the centrifugal/positive displacement pumps of Laub and Aklog by for example, **potentially** damaging those pumps and systems. Petition, pgs. 38-41.

Brown Deposition

Q: Is there any peristaltic pump that was known prior to 2018 that would generate vacuum in the clot canister while the valve is closed if it was used as the aspiration source in Claim 1 of the '333 patent?

A: **There may have been peristaltic pumps that could generate a vacuum there.** May not have been.

Prior Art Aspiration Pumps Are Compatible With Garrison

Brady

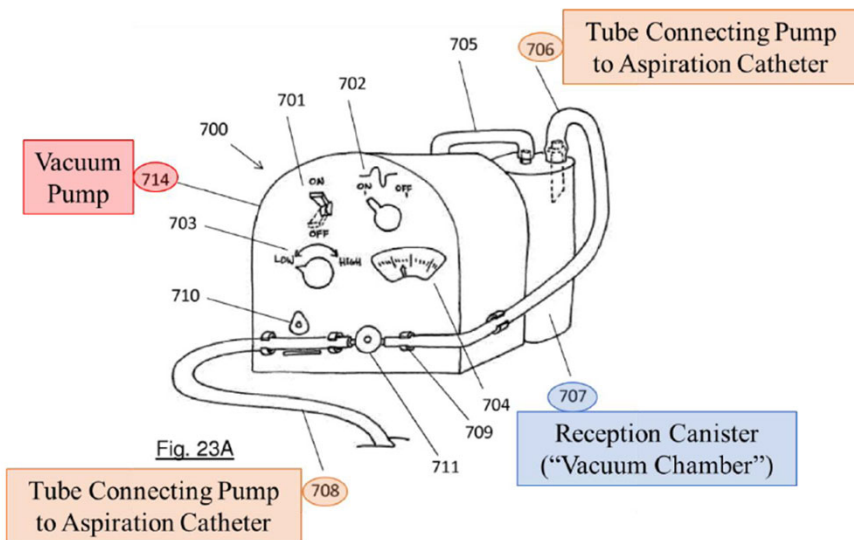


Fig. 23a illustrates an apparatus 700 of this invention, comprising a vacuum pump 714 and a pulse generating system. Fig. 23b shows a more detailed view of the pulse generating components of the system. The vacuum pump 714 may comprise a diaphragm or vane or piston pump, or a peristaltic pump, or other means of generating a negative pressure differential. This vacuum pump is connected by tube 705 to a reception canister 707, which is configured to receive aspirated blood or material. A safety valve may be provided within the canister to

...
rotating element 713. When rotating element 713 covers the mouth of either connector 717 or 716 the valve is closed and tube 708 is no longer exposed to the vacuum within canister 707. Thus by rotating or oscillating element 713 a vacuum pulse may be delivered through tube 708, and this may be beneficial for the retrieval of stubborn clot material as previously described.

Prior Art Aspiration Pumps Are Compatible With Garrison

Brady

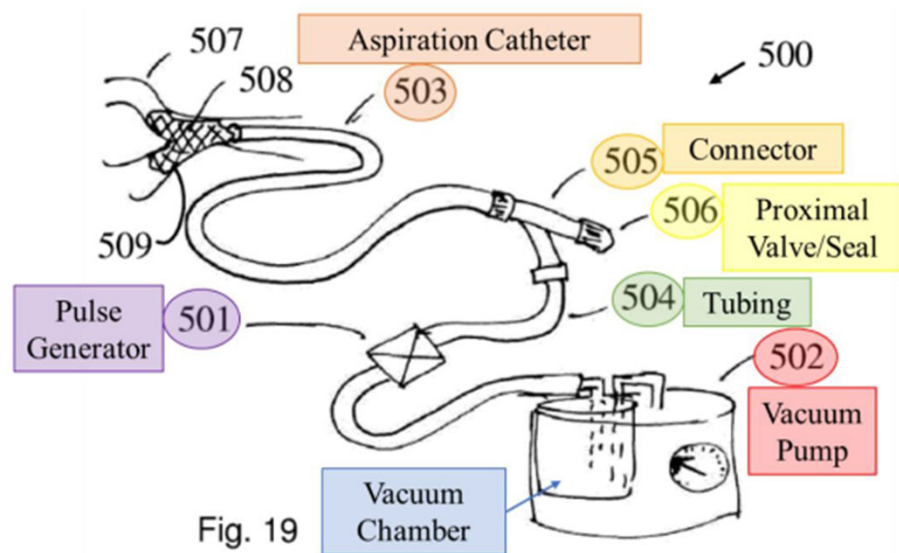
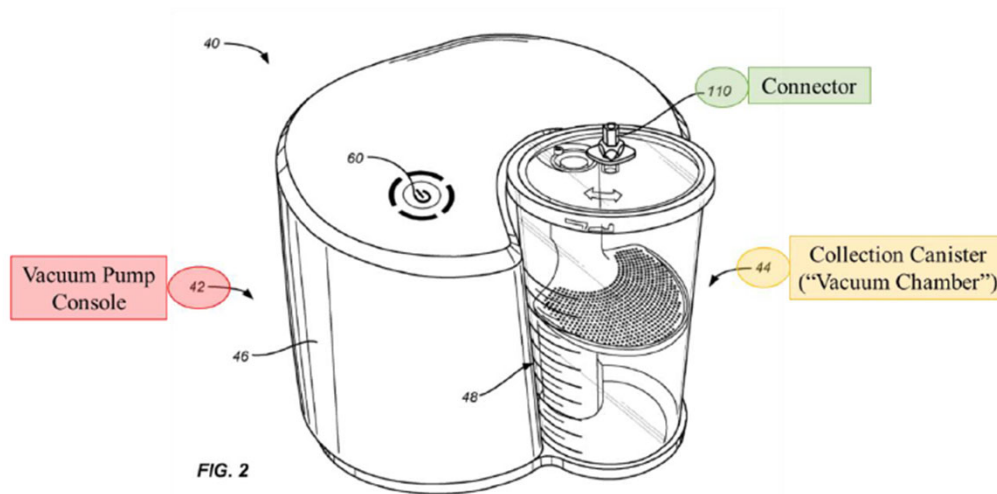


Fig. 19 is an illustration of another configuration 500 of the invention. In this schematic a pulse generator (501) is a separate apparatus to a vacuum pump 502. This pulse generator 501 can produce a pressure differential waveform at the tip of the catheter 503 as described elsewhere in this patent but is non blood contacting. The pulse generator 501 creates the waveform by selective compression of connector tubing 504. This creates the benefit of not having to sterilise part of the apparatus prior to use, as the connector tubing 504 is disposable and single use only. The method of use is the same as that described before with the vacuum pump 502 and pulse generator 501 connected to the proximal end of the catheter 503 at a connector 505 with a proximal valve / seal 506. The catheter 503 is introduced through the vasculature to the target location in a vessel 507 of the clot 508. In this case a stentriever type clot capture device 509 is also shown.

Prior Art Aspiration Pumps Are Compatible With Garrison

Pons



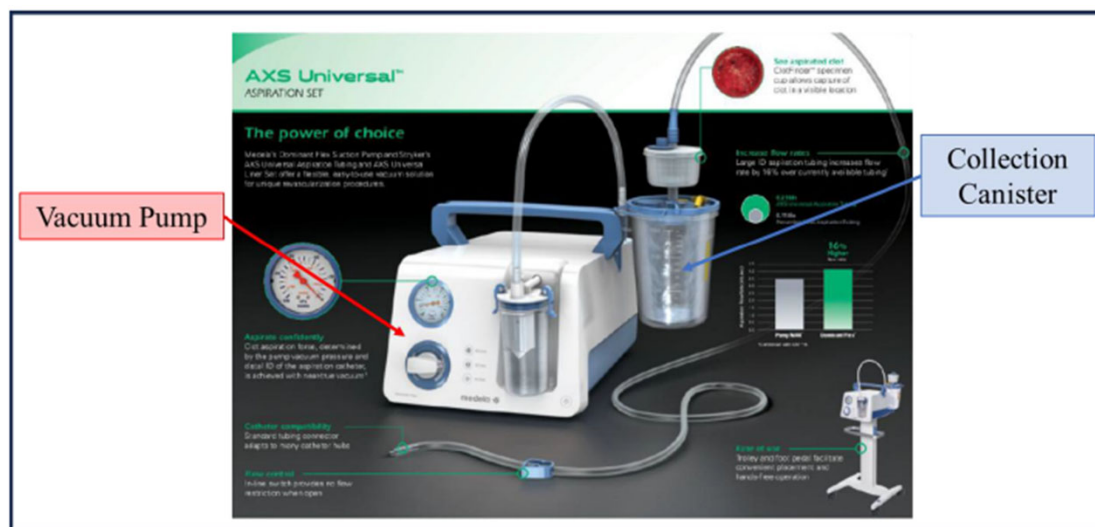
The present invention provides improved vacuum systems including a vacuum console and a collection canister for use with mechanical thrombectomy systems, such as with reperfusion catheters of the type which are used in the Penumbra System®, the Indigo® Aspiration System mechanical thrombectomy system, and other systems used for the therapeutic extraction of clot and/or blood and other fluids. Use of the vacuum console and collection canister of the present invention, however, is not limited to any particular thrombectomy system, and the vacuum systems can find use with any thrombectomy, embolectomy, atherec-tomy, or other catheter or probe system where blood and clot are withdrawn wholly or partially by application of a vacuum to the proximal end of any reperfusion catheter, aspiration catheter or probe for the purpose of clot extrac-tion.

Prior Art Aspiration Pumps Are Compatible With Garrison

Penumbra MAX



Medela Dominant Flex



—Ex. 1068; Ex. 1039; '333 Petition (Paper 1) at 59-60; '333 Petitioner's Reply (Paper 32) at 14-16.

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

32

PO's Cardiopulmonary Bypass Pumps Would Not Have Discouraged A POSITA From Using Garrison's Valve

Medtronic Bio-Pump (Ex. 2009)

2 Indications for use

The Medtronic Bio-Pump centrifugal blood pump is indicated for use only with the Medtronic Bio-Console pump speed controller to pump blood through the extracorporeal bypass circuit for extracorporeal circulatory support for periods appropriate to cardiopulmonary bypass procedures (up to 6 hours).

3 Contraindications

The Medtronic centrifugal blood pumping system is contraindicated as a cardiomy suction device.

Use the device only as indicated.

RF-32 Centrifugal Pump (Ex. 2010)

2 INDICATIONS

The RF-32 centrifugal pump is intended for use in an extracorporeal circulation during a cardiopulmonary bypass within the framework of surgical procedures, or in circulatory support. The RF-32 pumps blood within the flow rate range as described.

3 CONTRAINDICATIONS

Possible side effects include, but are not limited to: mechanical failure, hemolysis and thromboembolic phenomena. These are potential side effects with all extracorporeal blood systems. The centrifugal pump is contraindicated to use as a suction device.

BVP-BP Centrifugal Pump (Ex. 2012)

Range of application and safety precautions

The pumps are intended for liquid handling in laboratory and industry. We take it for granted that the GLP (Good Laboratory Practice) guidelines are observed as well as the recommendations given below.

The pump must not be used:

- **for medical applications on humans**
- **in hazardous (Ex) areas and in the presence of flammable gases and vapours.**

PO's Cardiopulmonary Bypass Pumps Would Not Have Discouraged A POSITA From Using Garrison's Valve

PO's Expert – Brian Brown

Q: And you would agree that none of those three pumps in Exhibits 2009, 2010, and 2012 were indicated for use in thrombectomy procedures, correct?

A: I would agree with that.

...

Q: Were there any aspiration pumps that were available in 2018 that were indicated for use in thrombectomy aspiration procedures?

A: Yes.

POSITA Would Not Use PO's Cardiopulmonary Bypass Pumps For Aspiration

PO's Expert – Brian Brown

Q: You would agree that one of the things that can happen during a thrombectomy procedure is that the aspirated clot material can clog the aspiration catheter, correct?

A: Correct.

...

Q: So if you were using [the Medtronic Bio-pump] in a thrombectomy system, and the aspiration catheter became clogged for more than 30 seconds, what would happen to the pump?

A: It does not say here what could happen. But from an engineering perspective, it could overheat. It could cause damage to the blood. It could change the performance of the device such that when flow does resume, that could be additional damage to the blood.

PO's Blood Return Arguments Lack Support

PO Response

2. Petitioner's modifications to Laub and Aklog adding a valve (not found in either reference) to build up pressure would endanger the patient by compromising blood return.

As set forth in §§III.B-C and §IV.C. above, both Laub and Aklog emphasize the critical nature of blood return to patient health and safety when treating large clots, which PE and DVT are. For example, omitting substantially continuous blood return “could quickly result in exsanguination of the patient” (EX1012, ¶[0045]) and/or lead to “occurrences of fluid loss and/or shock” (EX1005, 5:19-23).

Laub And Aklog Do Not Require Continuous Blood Return

Laub

rate into pump 400 through inlet port 410. As shown in FIG. 1, system 100 may include a return catheter 500 in fluid communication with discharge port 420. In some embodiments, return catheter 500 is configured to carry aspirated blood expelled from discharge port 420 back to the patient. By returning the aspirated blood back to the patient, embodiments of the present system 100 allows for aspiration while minimizing the blood loss of the patient. In certain embodiments, reinfusing the patient's blood continuously during aspiration allows for greater suction pressure and/or flow rates (e.g., 2-4 L/min) which can assist in dislodging and removing larger clots and/or tumors than would otherwise be possible. Without returning the blood back to the patient, such high flow rates could quickly result in exsanguination of the patient. Return catheter 500 in some embodiments is

Aklog

loss. In addition, the systems and methods of the present invention may simultaneously reinfuse aspirated (i.e., removed) and filtered fluid, such as blood, back into the patient on a substantially continuous basis to minimize any occurrences of fluid loss and/or shock. The subject invention

...
end of the first cannula. The suction and reinfusion of blood can occur, in an embodiment, continuously for a desired duration to minimize fluid loss in the patient. Alternatively, the step of suctioning an undesirable material can occur at an intermittent pulse for a desired duration following reinfusion of the removed fluid.

Aspirating PE/DVT Does Not Always Require Blood Return

PO's Expert – Dr. Christopher Morris

Q: And when you used the Penumbra Indigo to treat PE, did you return the blood you withdrew to the patient?

A: No.

Prior Art Aspiration Pumps Are Compatible With Blood Return

Thornton Supplemental Declaration

48. A person of ordinary skill in the art in 2018 would have known of several prior-art aspiration pumps that could be safely used with Garrison's valve and the aspiration systems in Garrison, Laub, and Aklog. *Supra* §II.A.2. A person of ordinary skill in the art would have also understood that blood aspirated with those pumps, including the pumps in Brady, Pons, the Penumbra Max pump, and the Medela pump, could be safely returned to the patient after passing through the filters disclosed in Garrison, Laub, or Aklog.

Blood Collected In A Syringe Or Canister Can Be Reinfused

'333 Patent

reintroduction into the patient. FIGS. 19-20E illustrate various devices for filtering aspirated blood from removed clot material to reintroduce the aspirated blood into the patient without reintroducing a significant amount of clot material.

In one aspect of the present technology, separating the blood from the clot material such that the blood is within the syringe 340 permits the blood to be easily reintroduced to the patient. For example, FIGS. 20D and 20E are side views of the syringe 340 coupled to the tubing subsystem 120 of the assembly 10 for reintroducing blood to a patient. In some embodiments, as shown in FIG. 20D, the syringe 340 can be decoupled from the filter device 2050 and directly coupled to the connector 128. With the fluid control device 126 in an open position, the blood can then be reintroduced to the patient through the assembly 10 by depressing the plunger 342 of the syringe 340. In some embodiments, as shown in

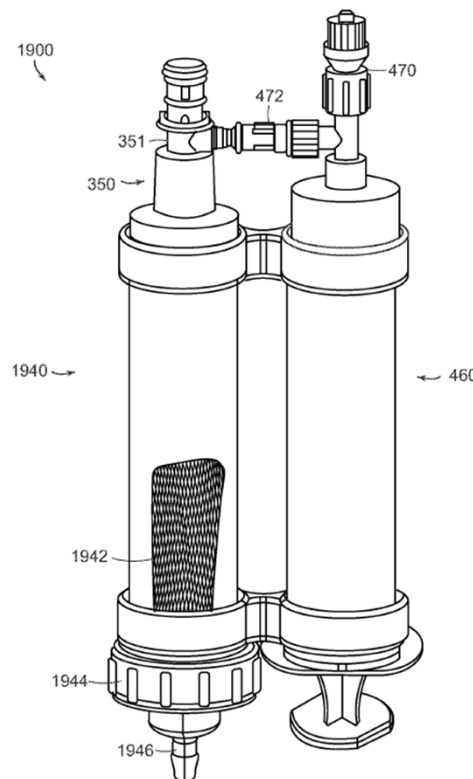


FIG. 19

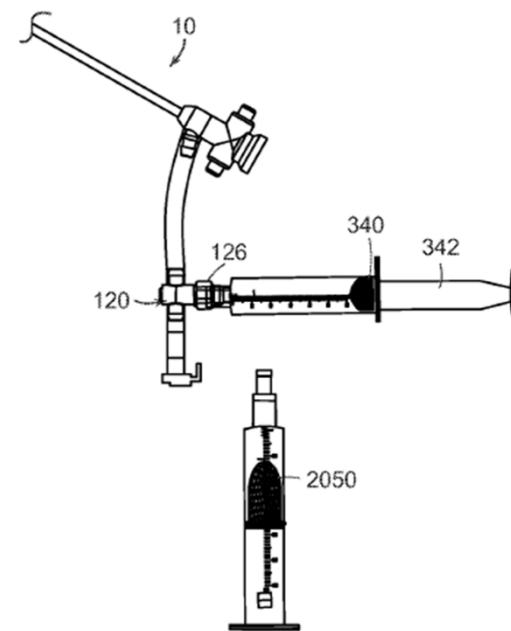


FIG. 20E

Blood Collected In A Syringe Or Canister Can Be Reinfused

PO's Expert – Dr. Christopher Morris

Q: And how is the negative pressure generated or the vacuum generated by the FlowTrievery?

A: A syringe.

. . .

Q: You mentioned blood return. Do you always have to return blood when you're using the Inari FlowTrievery for a PE procedure?

A: I always do.

Garrison's Valve Would Not Prevent Continuous Reinfusion *During* Aspiration

Thornton Supplemental Declaration

57. In addition, a person of ordinary skill in the art would have understood that once Garrison's valve is opened, the aspiration could be applied continuously until the thrombus is removed as disclosed in Laub and Aklog, particularly if the aspiration source is a pump. As a result, temporarily closing the valve to build up vacuum before aspiration begins as Garrison teaches would not prohibit continuous blood return once aspiration is applied as disclosed in Laub and Aklog.

PO's Expert – Brian Brown

Q: What does it mean to reinfuse the patient's blood continuously during aspiration as stated here in Laub?

A: My understanding of what he is referring to here is that the aspirated blood is delivered back to the patient's circulatory system.

Q: Would that reinfusion occur before any aspiration is being applied?

A: Not that I'm aware of.

Q: So the reinfusion would only take place once aspiration has begun to be applied to the occlusion; is that right?

A: The reinfusion is of aspirated blood. So therefore, aspiration must exist in order for reinfusion to exist.

PO's "Maximum Level Of Aspiration" Arguments Lack Support

PO Response

3. Petitioner's modifications would not "enable the maximum level of aspiration."

Petitioner's assertions that a "POSITA would have been motivated to incorporate Garrison's valve 3325 (e.g., multi-way stopcock) and method of generating pressure while the valve is closed into Laub's or Aklog's aspiration systems" to "enable the maximum level of aspiration in a rapid fashion with one user" ignores the fundamental difference between a syringe and a peristaltic pump.

Petition, pp.38-41; EX1006, ¶[0134].

PO's Experts Agree That Garrison Is Not Limited To A Syringe Or Peristaltic Pump

PO's Expert – Brian Brown

Q: Could Garrison's Figure 34 use an aspiration pump that is not a peristaltic pump?

A: For what Garrison is teaching, I believe there are other pumps that can be used. Now, which specific pumps would have to be something that is tested. But I believe that other pumps could be used that would not be limited to just a peristaltic pump.

PO's Expert – Dr. Christopher Morris

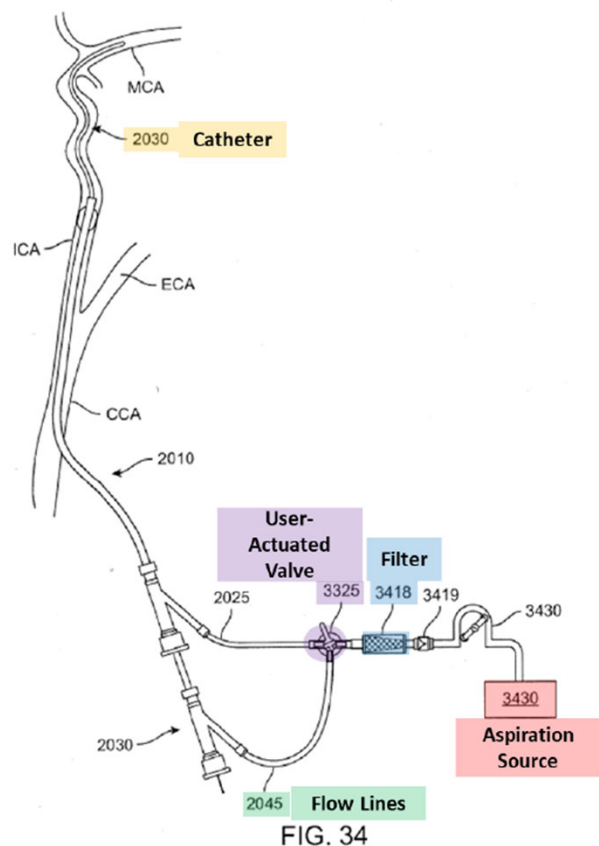
Q: And what different types of aspiration sources can be used with this figure, based on your review of the patent?

A: I'd have to read further to, you know, find the description, but. I know one of them is a pump. Aspiration pump, a regular or locking syringe, a handheld aspirator, hospital suction or the like.

Q: Okay. So it's your understanding that item 3430 could be any one of those types of aspiration sources?

A: Yeah.

Garrison's Aspiration Method Is Not Limited To A Syringe



[0134] The active source of aspiration may be an aspiration pump, a regular or locking syringe, a hand-held aspirator, hospital suction, or the like. In one embodiment, 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. During the procedure when the tip of the aspiration device (either the arterial access device or the catheter) is near or at the face of the occlusion, the user may open the connection to the aspiration syringe. This would enable the maximum level of aspiration in a rapid fashion with one user, something that is currently not possible with existing technologies. In another

Garrison's Valve Would Improve Laub's And Aklog's Temporary Aspiration Power

Thornton Declaration

106. A person of ordinary skill in the art would have been motivated to incorporate Garrison's valve 3325 and method of generating pressure while the valve is closed into Laub's aspiration system in order "enable the maximum level of aspiration in a rapid fashion with one user" as taught by Garrison. Ex. 1006 (Garrison) at [0134]. Given Garrison's descriptions of the benefits of its rapid aspiration procedures, a person of ordinary skill in the art would have recognized that Garrison's valve could maximize Laub's aspiration power to aspirate PE's more quickly. This would help Laub's system operate more quickly and effectively.

Building Up Pressure Before Aspiration Was A Common Prior Art Practice

Turk Declaration

23. One of the techniques my fellow surgeons and I have done since the early 2010s is to place a tube clamp on the tubing running from the aspiration catheter to the syringe or pump. We then pull back the syringe or turn on the pump to create negative pressure in the tubing before removing the tube clamp. This technique increases the suction immediately applied to the clot. The suction caused by the syringe or pump draws the clot into the catheter. The physician

Building Up Pressure Before Aspiration Was A Common Prior Art Practice

PO's Expert – Brian Brown

Q: And in your experience in the field with aspiration-based thrombectomy devices, had you ever had experiences where doctors or other engineers built up pressure in a line before releasing it for aspiration?

A: I have.

Q: And in what circumstances have you seen that before?

A: Many times. The aspiration systems are designed to have a vacuum applied to a catheter. And as part of the system, there is a fluid control valve, which many times is referred to as a stopcock valve, and those are all part of the system that I've seen before.

Q: And when you say systems you've seen before, what time frame are you talking about here?

A: Those systems could date back into the 1990s, into the 2000s. Those systems were systems that were being designed for coronary aspiration, for cerebral aspirations.

Garrison + Laub or Aklog Renders Claims 1-10,
13-29, 33-38 of the '333 Patent Obvious
('333 Patent, Grounds 3A, 4A)

Optimizing Garrison To Treat PE/DVT Would Have Been Obvious

Thornton Declaration

78. Garrison discloses an aspiration system for the “treatment of cerebral occlusions.” Ex. 1006 (Garrison) at [0002]. A person of ordinary skill in the art would have been motivated to use and, to the extent necessary, modify and optimize Garrison’s aspiration system to treat pulmonary embolism. Garrison’s system is already designed to aspirate clots and Aklog explains that pulmonary embolisms are a harmful type of clot that can block blood flow to the lungs and cause death. *Id.* Thus, a person of ordinary skill in the art would have been motivated to use, and to the extent necessary, modify and optimize the existing and proven technology described in Garrison to treat similar conditions in other parts of the vasculature.

PO's Counterarguments Lack Support

⤿ PO repeats arguments that:

- Garrison's aspiration method does not apply to Figure 34
- Garrison's aspiration method would compromise blood return

⤿ PO does **not** dispute:

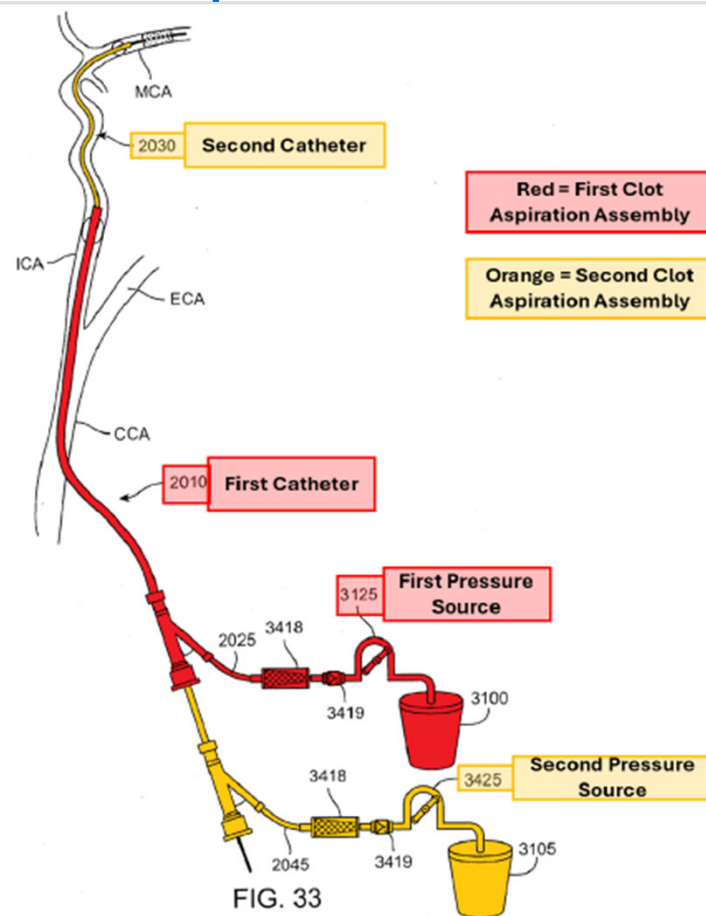
- POSITAs routinely adapted catheter systems for treating other parts of the body
- POSITAs possessed the skills and knowledge to optimize size of catheters for treating PE/DVT

Garrison + Laub and/or Aklog Renders Claims 1-6, 8, 11-15, 18-20 of the '910 Patent Obvious ('910 Patent, Grounds 1-3)

'910 Patent – Claim 1

1. A clot treatment system for treating clot material comprising a pulmonary embolism in a vasculature of a patient, comprising: a first clot aspiration assembly, including: - a first catheter; - a first pressure source; and - a first fluid control device between the first catheter and the first pressure source, wherein the first fluid control device is movable between (a) a first position in which the first pressure source is fluidly disconnected from the first catheter and (b) a second position in which the first pressure source is fluidly connected to the first catheter, wherein the first pressure source is configured to generate vacuum pressure while the first fluid control device is in the first position, and wherein, upon movement of the first fluid control device from the first position to the second position, the vacuum pressure is applied to the first catheter to generate suction at a distal portion of the first catheter; and	a second clot aspiration assembly, including: a second catheter advanceable through the first catheter, wherein the second catheter has a distal portion, wherein the second catheter has a size of 16 French or greater, and wherein the second catheter is shaped to be intravascularly advanced through the vasculature of the patient such that the distal portion of the second catheter is positioned proximate to the pulmonary embolism; - a second pressure source; and - a second fluid control device between the second catheter and the second pressure source, wherein the second fluid control device is movable between (a) a first position in which the second pressure source is fluidly disconnected from the second catheter and (b) a second position in which the second pressure source is fluidly connected to the second catheter, wherein the second pressure source is configured to generate vacuum pressure while the second fluid control device is in the first position, and	wherein, upon movement of the second fluid control device from the first position to the second position, the vacuum pressure is applied to the second catheter to generate suction at the distal portion of the second catheter to aspirate blood and at least a portion of the pulmonary embolism into the second catheter.
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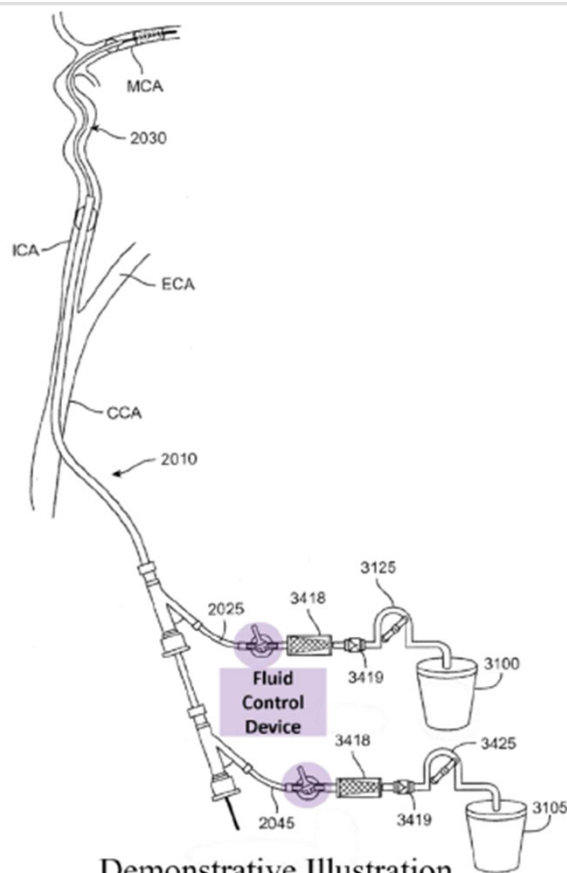
Garrison Discloses Aspiration System With First And Second Clot Aspiration Assemblies



—Ex. 1006 (Garrison) at [0131]-[0134], Fig. 33; '910 Petition (Paper 1) at 3, 34-57.

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

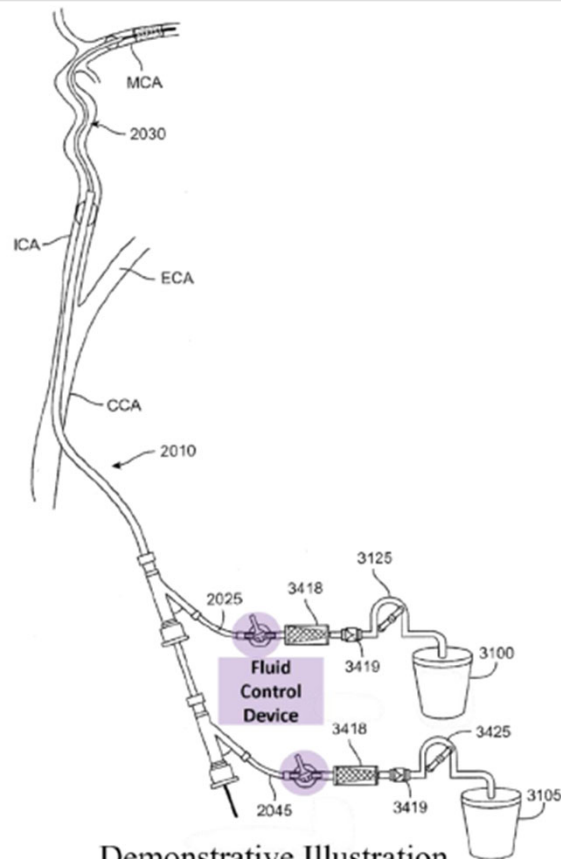
First Motivation To Add Garrison's Valves To Fig. 33



Thornton Declaration

114. A person of ordinary skill in the art using the embodiment in Figure 33 would have found it obvious, and been motivated, to add the same valve 3325 (as shown in Figure 34) between each pressure source and catheter so that the user could control the flow of suction to the catheter and achieve “the maximum level of aspiration in a rapid fashion”:¹

Second Motivation To Add Garrison's Valves To Fig. 33

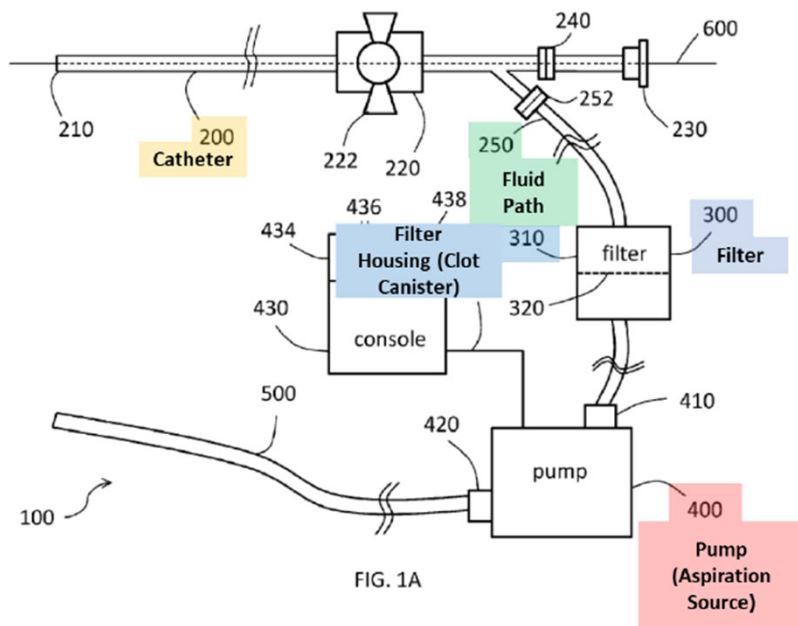


Thornton Declaration

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

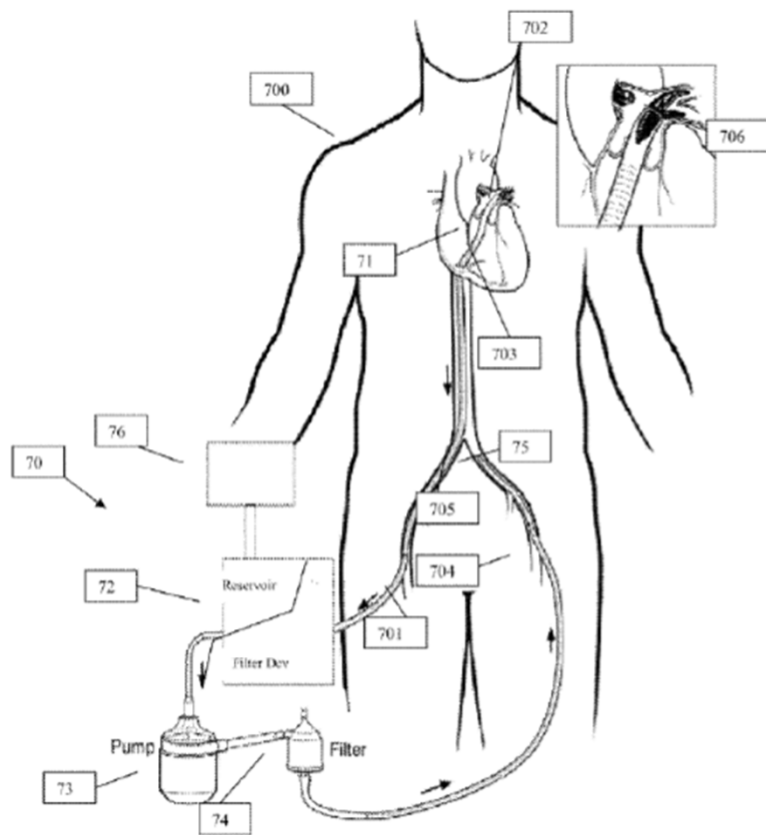
Demonstrative Illustration
Modified FIG. 33

Laub Discloses Aspirating PE/DVT With 16 French Catheter



has a French size of at least 15 Fr. In some embodiments, aspiration catheter 200 has a French size of at least 16 Fr. In some embodiments, aspiration catheter 200 has a French size of at least 17 Fr. In some embodiments, aspiration catheter 200 has a French size of at least 18 Fr. In some embodiments, aspiration catheter 200 has a French size of at least 19 Fr. In some embodiments, aspiration catheter 200 has a French size of at least 20 Fr. In some embodiments, aspiration catheter 200 has a French size of 8 Fr to 12 Fr. In some embodiments, aspiration catheter 200 has a French size of 9 Fr to 11 Fr. In certain preferred embodiments, aspiration catheter has a French size of equal to or greater than 10 Fr to allow for aspiration of large thrombi and/or other solid materials from the patient.

Aklog Discloses Aspirating PE/DVT With Large Diameter Catheters



Cannula 10 of the present invention may be of any sufficient size, so long as it can be accommodated within a predetermined vessel, such as a medium to large size blood vessel. The size of cannula 10 may also be determined by the size of the undesirable material to be removed, so long as the undesirable material can be removed substantially en bloc without significant fragmentation. In one embodiment, suction cannula 10 may be designed to remove at least 10 cm³ of undesirable material substantially en bloc. Of course, cannula

POSITA Would Have Been Motivated To Increase Size Of Garrison's Second Catheter To 16F Or Greater

Thornton Declaration

104. A person of ordinary skill in the art would have been motivated to increase the size of Garrison's second catheter to 16F or greater based on Laub or Aklog because those references describe the successful use of larger catheters (16F or greater) to treat PE. As I explained the section above addressing the claim "Preamble" (*supra* §VI.A.1), a person of ordinary skill in the art would have had many motivations and reasonably expected success in using, or modifying and optimizing, Garrison's system to treat PE.

PO's Counterarguments Lack Support

- ⦿ PO repeats unsupported arguments from '333 IPR:
 - Garrison's aspiration method does not apply to Figures 33 or 34
 - Garrison's valve would not enable “maximum level of aspiration” with a pump
 - Garrison's aspiration method would compromise blood return

- ⦿ PO does **not** dispute:
 - Garrison discloses first and second clot aspiration assemblies
 - Garrison discloses a “second catheter advanceable through the first catheter”
 - POSITA would have possessed skills and knowledge to increase the size of Garrison's catheters

PO Fails To Prove Unexpected Results

PO Fails To Prove Nexus

For objective [evidence of secondary considerations] to be accorded substantial weight, its proponent must establish a nexus between the evidence and the merits of the *claimed invention*.

In re GPAC Inc., 57 F.3d 1573, 1580 (Fed.Cir.1995).

Where the offered secondary consideration actually results from something other than what is both claimed and *novel* in the claim, there is no nexus to the merits of the claimed invention.

In re Kao, 639 F.3d 1057, 1068–69 (Fed. Cir. 2011).

PO Fails To Prove Nexus

- ⌚ No presumption of nexus
 - No argument or evidence that FlowTrievers is coextensive with the claims

- ⌚ No evidence that allegedly unexpected efficacy is direct result of claimed features
 - Claims do not require quickly opening the valve or unconstricted catheter

- ⌚ No nexus to aspect of claims that is not in the prior art
 - Garrison expressly discloses building up vacuum with valve closed and opening valve to release vacuum

PO's Expert Admitted Results Are Due To Unclaimed Features

PO's Expert – Dr. Christopher Morris

- Q: And so these unexpected results that you're talking about, so these are due to, it sounds like, the absence of any constriction in the FlowTrievers catheter system, in addition to the method of abruptly opening the on/off valve, is that correct?
- A: Yes. And both of those together create the synergistic effect, which we call the whoosh, because it's an actual audible phenomenon that occurs during the aspiration of the clot into the catheter. And actually there's a literal vibration that occurs. When the clot is sucked into the catheter, it has a chugging effect. And so everyone's waiting, when this process occurs, for the chug. The catheter chugs, chugs and chugs as the clot is aspirated out. It's -- I never thought that would ever happen. I was actually pretty pessimistic that it was going to work, with all the other devices that we had used, and remarkably surprised at how well it worked. That was the unexpected result.

PO Fails To Provide Factual, Objective Evidence Of Unexpected Results

- ⊙ PO's only evidence – subjective surprise of PO's paid expert
 - Dr. Morris: “[U]pon first use of the Flowtriever systems, **I was personally surprised** that the generation of a quick burst of vacuum and rapid pressure equalization could so effectively remove a clot when treating a PE or DVT, often times removing the clot intact.”

- ⊙ PO does **not** provide
 - Objective data on efficacy of FlowTrievers
 - Testing of FlowTrievers
 - Explanation for Dr. Morris's “surprise[]”
 - Comparison to the prior art, including Garrison

PO Does Not Compare FlowTrieve To Closest Prior Art

⦿ PO's argument:

- FlowTrieve's "quick burst of pre-charged vacuum" was unexpected

⦿ Garrison (closest prior art) expressly discloses:

- Pre-charging vacuum in pressure source (e.g., syringe) while valve is closed
- Releasing built-up vacuum by opening valve
- Release "enable[s] the maximum level of aspiration in a rapid fashion with one user"

The Board Should Deny PO's Motion To Exclude

PO Waived Its Objections To Experts' POSITA Status

⦿ '011 IPR Final Written Decision:

- “Patent Owner waived any evidentiary objection to the testimony in Exhibits 1003 and 1014 based on an allegedly ‘incorrect’ POSA definition.”
- “Although Patent Owner timely objected to Mr. Thornton’s testimony in Exhibits 1003 and 1014, nowhere did Patent Owner reference any issue with the POSA definition as the basis for the objection.”

⦿ PO’s objections to Ex. 1003 (Thornton Declaration) and Ex. 1022 (Turk Declaration) do not reference any issue with POSITA status as the basis for an objection

PO Waived Its Objections To Experts' POSITA Status

PO's Objections

Exhibit 1003

Patent Owner objects to Exhibit 1003 (Expert Declaration of Troy Thornton) under FRE 702 because the testimony is not based upon sufficient facts or data and is not the result of application of reliable principles and methods. Patent Owner further objects under FRE 703 that the facts or data are not of a type reasonably relied upon by experts. Patent Owner further objects to Exhibit 1003 as creating unfair prejudice, confusing the issues, or as a waste of time pursuant to FRE 403 and as not being relevant and therefore being inadmissible under FRE 401 and 402.

Patent Owner further objects to Exhibit 1003 to the extent that any paragraph relies upon an exhibit that is objected to herein for the reasons set forth in those objections. Any paragraph in Exhibit 1003 that relies upon any exhibit not relied upon by the PTAB to institute this proceeding is further objected to as not being relevant and therefore being inadmissible under FRE 401 and 402. Patent Owner likewise objects to any testimony or argument purporting to rely on Petitioner's Exhibit No. 1003.

Exhibit 1022

Patent Owner objects to Exhibit 1022 (Expert Declaration of Dr. Aquilla S. Turk, III, DO) under FRE 702 because the testimony is biased in view of the individuals affiliation with Petitioner and not based upon sufficient facts or data and is not the result of application of reliable principles and methods. Patent Owner further objects under FRE 703 that the facts or data are not of a type reasonably relied upon by experts. For the same reasons, Patent Owner further objects to Exhibit 1022 as creating unfair prejudice, confusing the issues, or as a waste of time pursuant to FRE 403 and as not being relevant and therefore being inadmissible under FRE 401 and 402.

Patent Owner further objects to Exhibit 1022 to the extent that any paragraph relies upon an exhibit that is objected to herein for the reasons set forth in those objections. Any paragraph in Exhibit 1022 that relies upon any exhibit not relied upon by the PTAB to institute this proceeding is further objected to as not being relevant and therefore being inadmissible under FRE 401 and 402. Patent Owner likewise objects to any testimony or argument purporting to rely on Petitioner's Exhibit No. 1022.

Furthermore, Patent Owner objects to paragraphs in the Petition that rely on exhibits objected to in this Patent Owner's Objections to Petitioner's Evidence.

PO Improperly Narrows The Field Of The Invention

'333 & '910 Specification

TECHNICAL FIELD

The present technology relates generally to systems, methods, and devices for the intravascular treatment of emboli and/or thrombi within a blood vessel of a human patient. In particular, some embodiments of the present technology relate to systems for releasing stored vacuum pressure to aspirate clot material from a blood vessel.

BACKGROUND

Thromboembolic events are characterized by an occlusion of a blood vessel. Thromboembolic disorders, such as stroke, pulmonary embolism, heart attack, peripheral thrombosis, atherosclerosis, and the like, affect many people. These disorders are a major cause of morbidity and mortality.

...

There are many existing techniques to reestablish blood flow through an occluded vessel. Embolectomies, for

...

Percutaneous methods are also utilized for reestablishing blood flow. A common percutaneous technique is referred to as balloon angioplasty where a balloon-tipped catheter is introduced to a blood vessel (e.g., typically through an introducing catheter). The balloon-tipped catheter is then advanced to the point of the occlusion and inflated to dilate the stenosis. Balloon angioplasty is appropriate for treating

PO's Expert – POSITA Needs Experience Mitigating Effects Of Clots

PO's Expert – Dr. Christopher Morris

Q: What about, for example, a person of skill in the art -- a person who has a bachelor of science degree in engineering and who has developed stents, and who has worked on ways to minimize coagulation around the stents. Would that person qualify as a person of ordinary skill in the art?

A: I think the common denominator here is clotting, or clot. Does that person have a lot of experience in clots, and mitigating the effects of clots. So stents in and of themselves hopefully aren't associated with clots, except for the stentriever, which is another device used for stroke that competes with a lot of these aspiration catheters. But that's a different type of a stent. I think clot is the key. So if there's experience working actually with clot, that's very paramount in dealing with devices that are used to treat clot. Because there's all different types of clot and sizes of clot, consistencies of clot. Some clot is like jelly, and other clot is like cardboard, essentially. I mean, it's a big spectrum. And someone needs -- who is a POSA has to be familiar with clot. Stents in and by themselves aren't necessarily involved with clot.

Mr. Thornton Is A POSITA In The Relevant Field

- ⦿ Mr. Thornton has more than 35 years of experience designing intravascular medical devices including:
 - Angioplasty catheters
 - Cardiopulmonary bypass blood pump
 - Complex intravascular catheters with a range of sizes and properties

- ⦿ Mr. Thornton has “extensive experience with blood clots and mitigating the effects of blood clots”

- ⦿ Mr. Thornton has first-hand experience with disputed issues in this IPR
 - Mr. Thornton designed a centrifugal cardiopulmonary bypass pump
 - Mr. Thornton has first-hand experience with blood return using pumps and syringes
 - Mr. Thornton has first-hand experience adjusting the size of intravascular catheters

Dr. Turk's Testimony Is Relevant And Credible

- ⊙ The Board credited Dr. Turk's testimony when instituting both '333 and '910 IPRs
- ⊙ Dr. Turk's testimony regarding prior art practice of surgeons pre-charging vacuum with pumps and syringes is relevant
 - PO's expert admitted to witnessing this practice "many times" prior to 2018
- ⊙ Dr. Turk's role as Petitioner's CMO goes to the weight of his testimony, not its admissibility
 - PO's bias arguments are unfounded given the undisputed nature of Dr. Turk's testimony



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