

The Patent Trial and Appeal Board

Imperative Care, Inc.,

Petitioner,

v.

Inari Medical Inc.,

Patent Owner.

Case Nos. IPR2025-01021 (US11,969,333), 2025-01025 (US11,974,910)

Patent Owner Demonstratives

INARI-2022

Imperative Care, Inc. v. Inari Medical, Inc., IPR2025-01025

US11,974,910('910 Patent): Grounds and Unchallenged claims

Ground 1: Garrison + Laub

Ground 4: (+Hartley)

Ground 7: (+Pasha)

Ground 2: Garrison + Aklog

Ground 5: (+Hartley)

Ground 8: (+Pasha)

Ground 3: Garrison + Laub + Aklog

Ground 6: (+Hartley)

Ground 9: (+Pasha)

Claims 9-10 and 16-17 are not challenged in Petition.

'910 Patent Claims: Garrison/Aklog/Laub fail to disclose

Claims 1 (system claims):

“treating clot material comprising a pulmonary embolism”

“a first fluid control device” and “a second fluid control device” (claim 1)

“wherein the [first/second] pressure source is configured to generate vacuum pressure while the [first/second] fluid control device is in the first position” and

“upon movement of the [first/second] fluid control device from the first position to the second position, the vacuum pressure is applied to the [first/second] catheter to generate suction at a distal portion of the [first second catheter]”

“the second catheter has a size of 16 French or greater”

US11,969,333 ('333 Patent): Grounds and Unchallenged Claims

Ground 1A : Laub + Garrison

Ground 1B: (+Goff)

Ground 1C: (+Schaffer)

Ground 1D: (+Schaffer + Hartley)

Ground 3A: Garrison + Laub

Ground 1B: (+Goff)

Ground 1C: (+Schaffer)

Ground 1D: (+Schaffer + Hartley)

Ground 2A: Aklog + Garrison

Ground 1B: (+Goff)

Ground 1C: (+Schaffer)

Ground 1D: (+Schaffer + Hartley)

Ground 4: Garrison + Aklog

Ground 1B: (+Goff)

Ground 1C: (+Schaffer)

Ground 1D: (+Schaffer + Hartley)

Claims 13 and 32 are not challenged in Petition.

'333 Patent Claims: Garrison/Aklog/Laub fail to disclose

Claims 1, 20 (method claims):

“treating a pulmonary embolism (claim 1)” / “treating a **deep vein thrombosis**(claim 20)”

“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,”

Dependent claims:

“catheter having a size of 16 French or greater (claims 2, 21, 37)” / “20 French or greater (claims 3, 22)”

'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

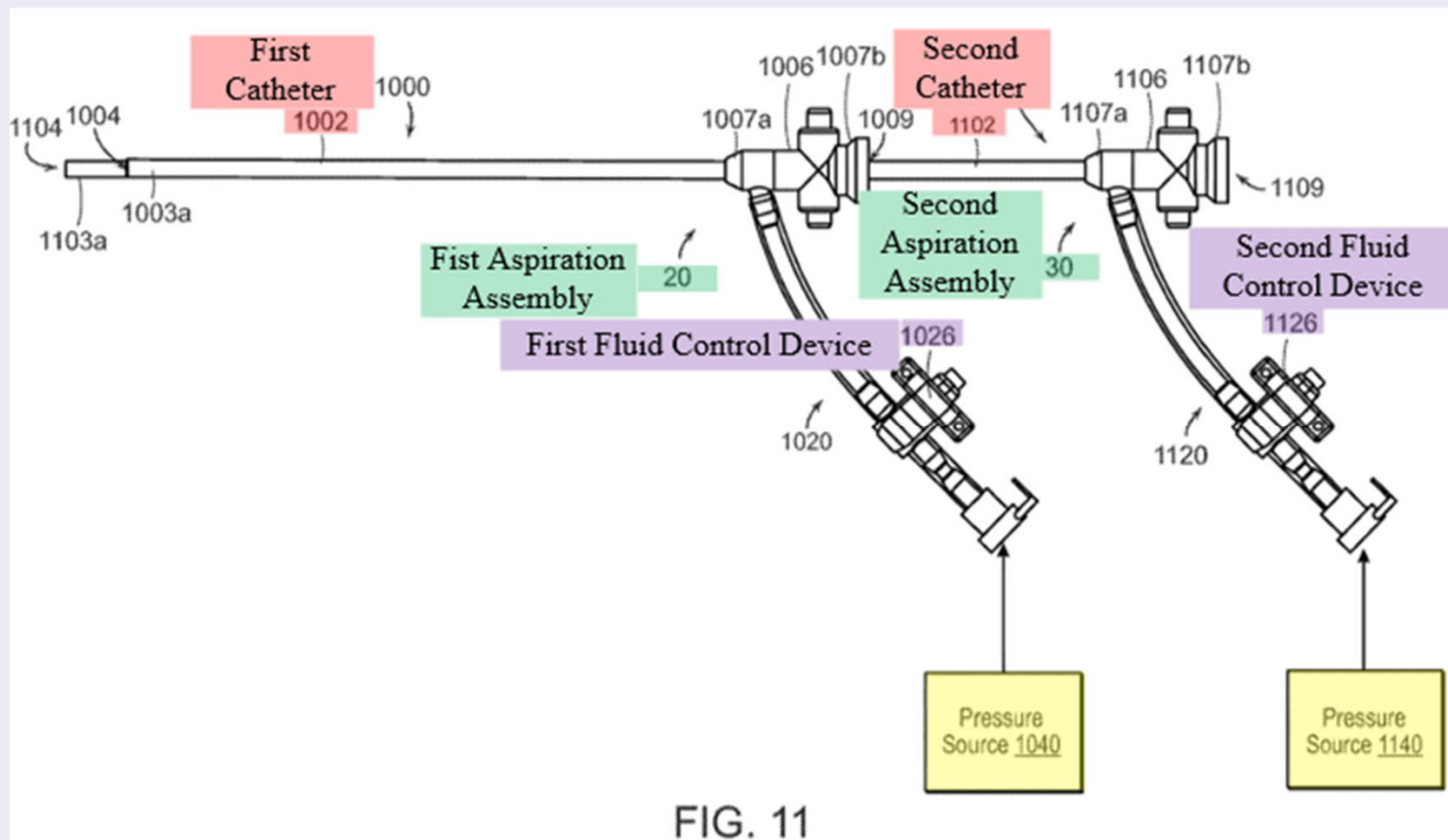
a second clot aspiration assembly, including:

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.

'910 Patent, Fig 11



EX1001 ('910 Patent).

'910 Patent, Fig 13A

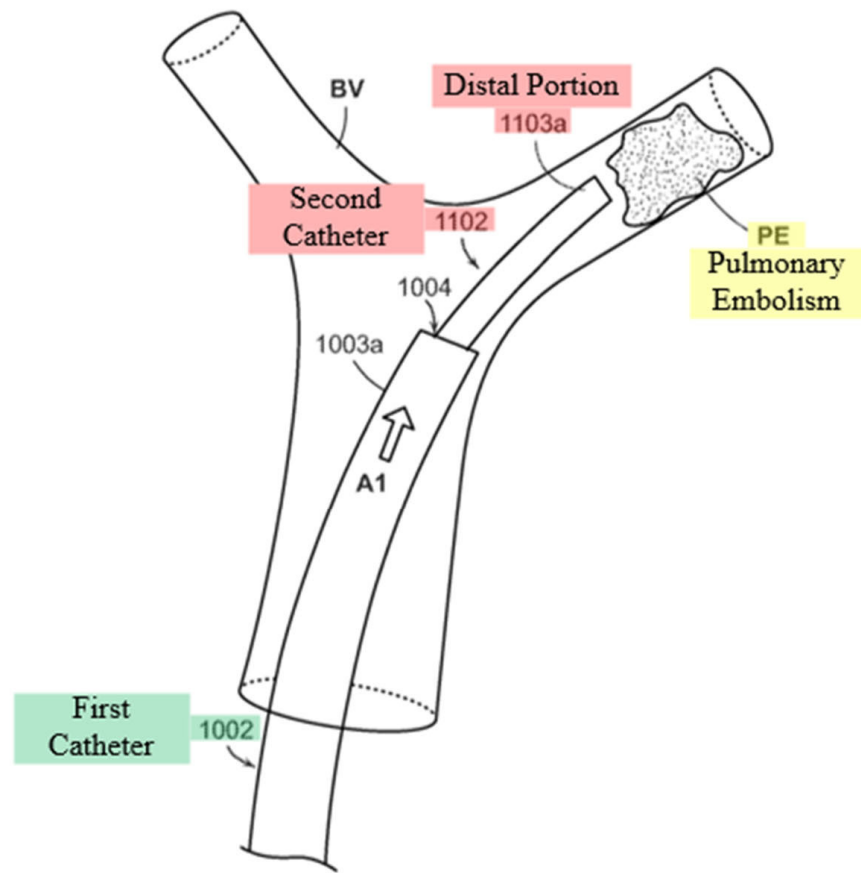


FIG. 13A

EX1001 ('910 Patent).

POR, 15.

Technical Field of the Invention

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

EX1001 ('910 Patent), 1:23-26;

EX1001 ('333 Patent), 1:23-26.

Q And what is the field of the invention?

A As I state in the '910 declaration, on page 8, the references are from the same field as the '910 patent. That is, devices for aspirating unwanted material from a patient.

Q What does that mean, aspirating unwanted material from a patient?

A Aspirating means providing a vacuum, and this patent talks about the unwanted material being blood clots or emboli that are in the vasculature.

EX2013 (Thornton Tr.), 22:3-12.

Q Do you see the first sentence, under technical field?

A Yes.

Q Would you agree that that's a reasonable description of the technical field of the '910 patent?

A Yes.

Q And is that the same in substance to your statement on page 8 of your declaration with respect to the '910 patent devices for aspirating unwanted material from a patient?

A I think they're quite similar, yes.

EX2013 (Thornton Tr.), 23:2-12.

Q So then is it fair to say that the field of the invention of the '910 patent and the field of the invention of the '333 patent are the same?

A I believe so.

EX2013 (Thornton Tr.), 26:10-13.

POSA

Patent Owner's POSA:

“Bachelor of Science degree in engineering or an equivalent field, with

two to four years of academic or industry experience in the **mechanical thrombectomy industry or comparable industry experience**

who would, where necessary or desired, work or consult with others including a physician to develop thrombectomy devices;

or (2) an interventional radiologist or pulmonologist with at least three years of experience developing and/or using medical devices in thrombectomy procedures, and who would, where necessary, work or consult with others including an engineer to develop such a medical device.” EX2008, ¶47;

¹⁰ EX2016, ¶45.

Petitioner's POSA:

“[A]n undergraduate degree in mechanical engineering or a related engineering discipline and

2-4 years of **catheter design experience**

and, where necessary, would have consulted with a physician regarding the methods of treatment.” Pet., 18.

POR, 19.

Thrombectomy Experience is Required

THE WITNESS: Yes, they would need to know what the device is trying to treat. They need to know the physiology of getting to that location, the potential damage or risk they could do to the patient by doing this treatment. They would need to understand the disease state that they are trying to treat.

You keep asking me about questions to design the catheter, but designing the catheter is almost secondary to understanding the disease state because if we don't understand the disease state, you can't design the catheter to treat the disease state.

EX1063 (Brown Tr.), 78:17-79:3.

Q. Let's assume that the person of ordinary skill in the art understands the disease state. Is there any more information that they would need in order to design a catheter of a specific size that can be used to treat that disease state?

[Objections omitted.]

THE WITNESS: They would need to know the performance requirements or expectations of the physician. They would need to know the benefit/risk requirements, meaning what the benefits are of treating the disease versus the risk that the device may cause to the patient. What are the limitations of those risks. They would need know what materials are available to them, what technologies are available to them.

EX1063 (Brown Tr.), 79:18-80:9.

Thrombectomy Experience is Required

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.

EX1065 (Morris Tr.), 205:17-206:21.

PO's expert, Mr. Brown, has extensive Thrombectomy Experience

10. For 24 years, I served in various roles at SciMED Life Systems and Boston Scientific, including multiple research and development engineering positions in various application areas including catheters, stents, guidewires, thrombectomy systems, and cardiovascular implants. For my final 10 years at Boston Scientific, I served as the global vice president of R&D Interventional Cardiology, where I was tasked to direct worldwide cardiovascular research and development activities for accelerated launches of implantable stents, drug delivery technologies, structural heart devices, disposable catheters, and adjunctive products.

EX2008 (Brown Supp. Decl.), ¶10).

PO's expert, Mr. Brown, has extensive Thrombectomy Experience

14. I was the two-time recipient of the Boston Scientific Patent of the Year award, recognized as one of Minnesota's leading inventors by Twin City Business Magazine in 2013, elected to College of Fellows, American Institute for Medical and Biological Engineering, and served as an Advisor to the University of Minnesota Office of Technology Commercialization. I also served as

EX2008 (Brown Supp. Decl.), ¶14).

PO's expert, Mr. Brown, has extensive Thrombectomy Experience

15. I am a named inventor on approximately sixty issued U.S. medical device patents covering a wide variety of technologies, including two aspiration thrombectomy patents and several others on stent geometries, nitinol, balloon catheters, infusion catheters, and ePTFE processing. I am an inventor of U.S. Patent No. 5,419,774 on a thrombus extraction device for quickly removing thrombus from a saphenous vein graft, and U.S. Patent No. 5,417,703 on an intravascular device for removing vascular occlusion material.

EX2008 (Brown Supp. Decl.), ¶14).

PO's expert, Dr. Morris, has extensive Thrombectomy Experience

9. I am currently a professor emeritus of radiology at the University of Vermont and an adjunct professor of radiology at the University of Utah. I have been performing thrombosis procedures, including mechanical thrombectomy and pharmacologic thrombolysis since the late 1980s and have extensive experience treating arterial, venous, and pulmonary embolism thrombosis using a wide range of devices, including Inari Medical's catheter devices as well as products as/from Pronto, AngioJet, Trellis, Penumbra and EKOS. In my clinical practice, I frequently manage cases involving deep vein thrombosis and pulmonary embolism. I also have experience with peripheral vascular arterial and cerebral (stroke) thromboembolism treatments, including mechanical thrombectomy.

PO's expert, Dr. Morris, has extensive Thrombectomy Experience

16. Throughout my career, in addition to teaching and research, I have practiced as a clinician treating venous thrombosis, including treating pulmonary embolisms and deep vein thromboses using a wide range of devices, techniques and procedures. During that time I performed and observed thousands of such procedures, including teaching how to perform such procedures.
18. I have coauthored more than 50 peer-reviewed publications in the field of Radiology and frequently present and speak on various topics in the field of Radiology to various industry and academic organizations both nationally and internationally.

EX2016 (Morris Decl.), ¶¶16, 18).

Mr. Thornton has no Thrombectomy Experience

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

A No.

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

A I'll answer no again.

EX2013 (Thornton Tr.), 50:5-10.

Q Do you have any experience designing aspiration catheters?

A No. My experience has been designing

EX2013 (Thornton Tr.), 47:13-15.

Q. So does that mean reducing the formation of a thrombus clot or emboli?

A. Well, certainly thrombus -- the goal was to prevent accumulative cells which would cause a thrombus. A thrombus which releases into the patient is generally termed an emboli.

Q. Does that phrase relate to removing or treating an already formed thrombus emboli or clot?

A. No. It's discussing preventing a thrombus from forming in or on a device.

EX2018 (Thornton Tr.), 47:2-12.

POR, 21-23; PO Sur-Reply, 5-6.

Dr. Turk is a Biased Witness with no Relevant Testimony

Q. When you were preparing this declaration, did you review the patents at issue in the IPRs?

A. I don't know, but I seriously doubt it. I don't typically review patents, it's not my -- my area of strength.

Q. Do you know whether you reviewed U.S. Patent Number 11,969,333?

A. I'm sure I did not.

Q. Do you know whether you reviewed U.S. Patent Number 12,016,580?

A. Again, I seriously doubt it.

Q. Same answer for U.S. Patent 11,974,910?

A. Yes.

Q. Is it fair to say since you didn't read the patents, you didn't analyze or read the claims of those patents?

A. Correct.

EX2015 (Turk Tr.), 33:12-34:6.

Q. Turning back just for a moment to the table of exhibits on -- look on the first page.

Did you, in preparing your declaration, read Exhibit Numbers 1005, 1006, or 1012?

A. No.

EX2015 (Turk Tr.), 69:7-11.

Q. Were you informed of what legal standards you should be adhering to in providing your opinions?

A. No, I don't -- I think it was just -- as far as I know, I don't know that there are legal standards that I get arrested if I say this or don't say that. As far as I know, I'm just giving my expert opinion on strokes, thrombectomies, aspiration, those topics.

EX2015 (Turk Tr.), 36:15-37:1.

Dr. Turk is a Biased Witness with no Relevant Testimony

Q. Do you have experience in treating deep vein thrombosis or pulmonary embolisms?

A. No.

EX2015 (Turk Tr.), 23:14-16.

Q. Would you consider yourself an expert in treating deep vein thrombosis or pulmonary embolisms?

A. No.

EX2015 (Turk Tr.), 24:6-9.

Q. How much are you compensated as the chief medical officer of Imperative?

A. \$250,000 a year.

Q. Do you own equity in Imperative?

A. Yes.

Q. How much?

A. A lot.

EX2015 (Turk Tr.), 15:3-9.

Garrison (EX1006)

(54) METHODS AND SYSTEMS FOR TREATMENT OF ACUTE ISCHEMIC STROKE

[0002] The present disclosure relates generally to medical methods and devices for the treatment of acute ischemic stroke. More particularly, the present disclosure relates to methods and systems for transcarotid access of the cerebral arterial vasculature and treatment of cerebral occlusions.

EX1006 (Garrison), ¶[002].

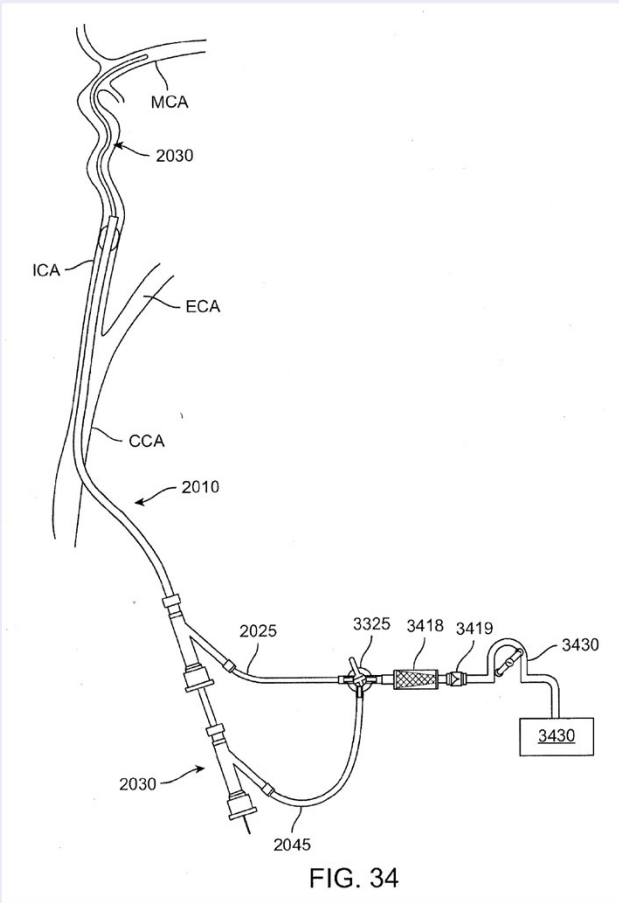
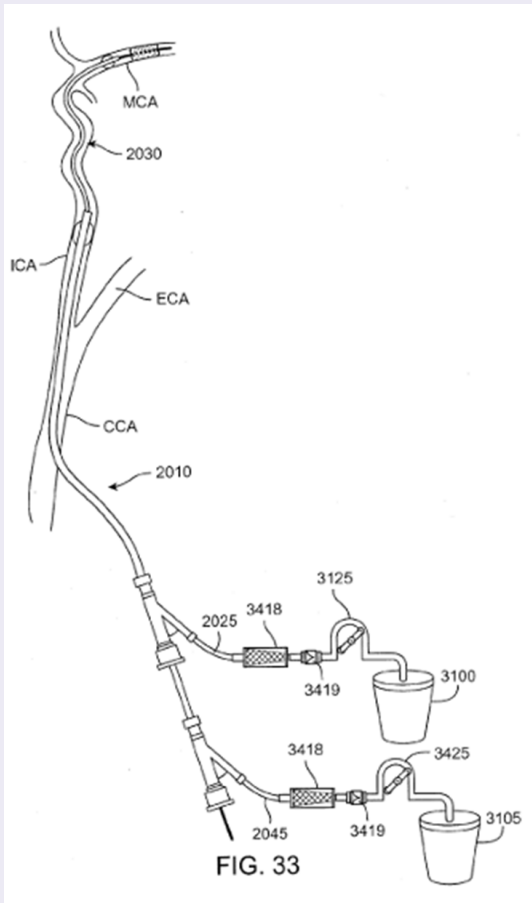
procedure. In patients with tortuous anatomy, access to the occlusion may be difficult or impossible with existing catheters and devices. In addition, the cerebral vessels are usually more delicate and prone to perforation than coronary or other peripheral vasculature. Many neurovascular interventional procedures remain either more difficult or impossible because of device access challenges.

EX1006 (Garrison), ¶[0042].

[0063] In an embodiment, the sheath body 222 can have an inner diameter of about 0.087" and an outer diameter of about 0.104", corresponding to a 6 French sheath size. In another embodiment, the sheath body 222 has an inner diameter of about 0.113" and an outer diameter of about 0.136", corresponding to an 8 French sheath size. In an embodiment, the sheath length is between 10 and 12 cm. In another embodiment, the sheath length is between 15 and 30 cm. The diameter and length most suitable to a particular embodiment is dependent on the location of the target site and nature of the devices and flow requirements through the lumen of the access device 200.

EX1006 (Garrison), ¶[0063].

Garrison (EX1006)



Garrison (EX1006)

[0135] One disadvantage of current sources of aspiration is that the aspirated blood is received into an external reservoir or syringe. This blood is generally discarded at the end of the procedure, and as such represents blood loss from the patient. In addition, pumps such as centrifugal or peristaltic pumps are known to cause damage to blood cells. Although it is possible to return blood from the external reservoir to the patient, the blood has been exposed to air or has been static for a period of time, and there is risk of thrombus formation or damage to the blood cells. Usually, aspirated blood is not returned to the patient to avoid risk of thromboembolism.

EX1006 (Garrison), ¶[0135].

Aklog (EX1005)

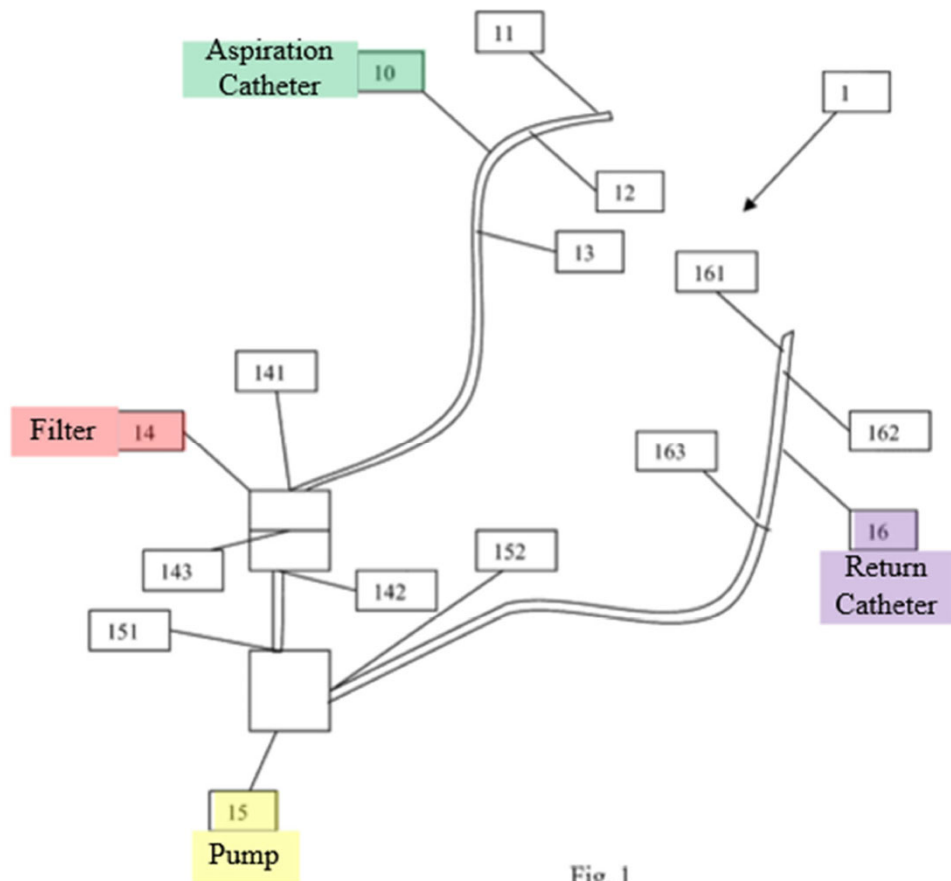


Fig. 1

EX1005 (Aklog) (annotations added).

Aklog (EX1005)

downstream obstruction. If the catheter is enlarged to accommodate the larger structure and material, such a catheter may aspirate an unacceptable volume of blood, resulting in excessive fluid loss and/or shock in the patient.

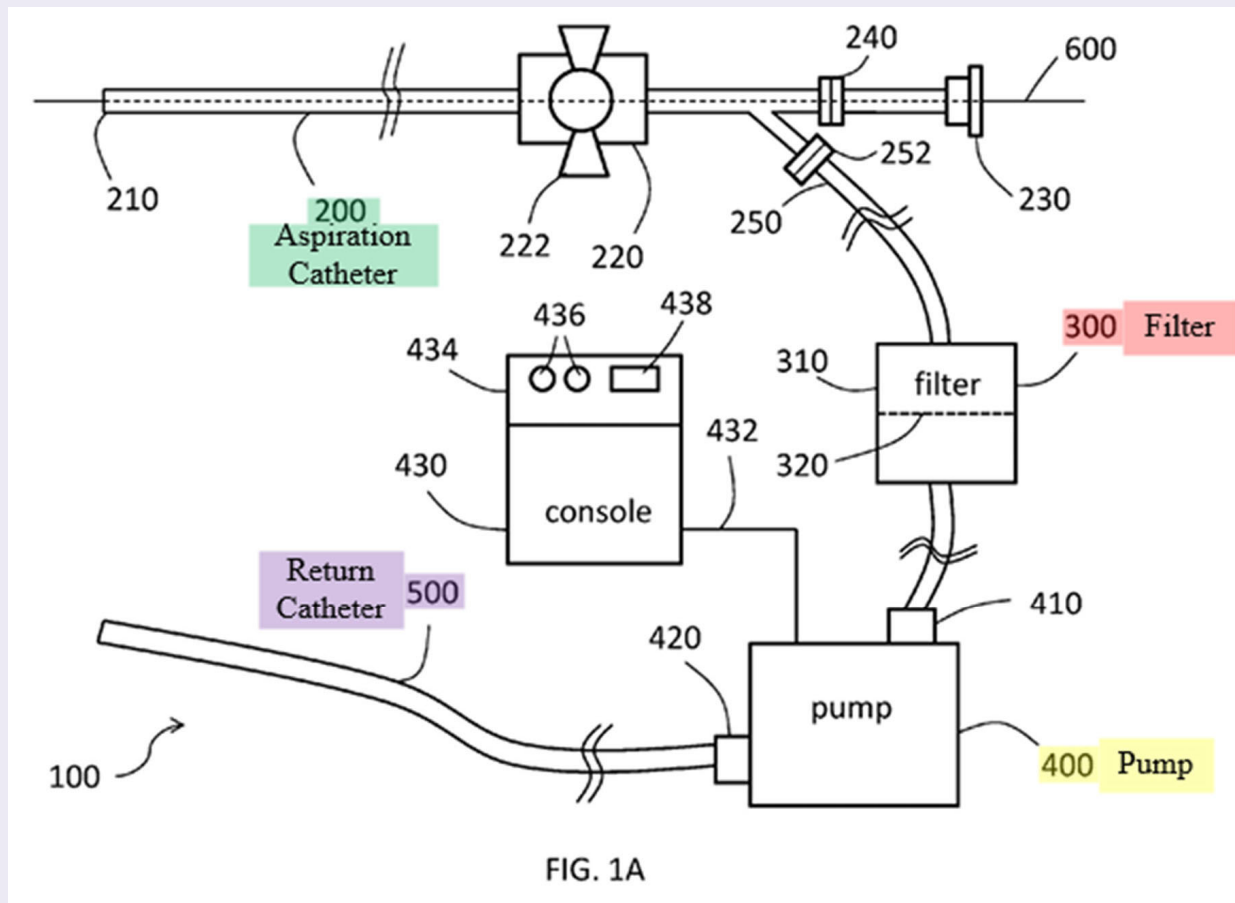
EX1005 (Aklog), 7:23-26.

eter. On the other hand, techniques which depend on aspiration of undesirable material will result in excessive blood loss as the size of the catheter increases.

A need therefore exists for a system and method to endovascularly remove undesirable material residing in medium to large blood vessels and heart chambers with minimal fragmentation and without excessive blood loss.

EX1005 (Aklog), 5:1-7.

Laub (EX1012)



Laub (EX1012)

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

EX1012 (Laub), [0045].

Catheter size/Flow rate

could damage the MCA. Put another way, upsizing Garrison's catheter from 8 French or smaller to 16 French or greater would massively increase the cross-sectional area of the catheter by four times.

EX2008 (Brown Supp. Decl.), ¶116.

theory by Poiseuille's law ($Q=(\pi \times r^4 \times \Delta P)/(8 \times n \times L)$, where Q =flow rate, r =radius of the tube, P =pressure, n =viscosity, and L =length): "[a]ccording to Poiseuille's law for laminar flow in a tube ... flow rate drops by increases in length and drops proportionally by decreases in radius to the fourth power." EX1006, ¶[0127]. Because the radius of the catheters disclosed in Garrison

EX2016 (Morris Decl.), ¶54.

Petition's discussion of blood return

Finally, Garrison already accounts for one challenge POSITAs encountered when moving from smaller to larger aspiration catheters – a larger catheter “may aspirate an unacceptable volume of blood, resulting in excessive fluid loss and/or shock in the patient.” (Ex. 1005, 7:23-26.) Aklog explains that the solution to using larger catheters is to reinfuse the “fluid removed (i.e., suctioned or aspirated) from the site of interest back into a patient, in order to minimize fluid loss within the patient.” (*Id.*, 7:47-52.) Garrison addresses this challenge by including an

Pet., 33.

Petition's discussion of blood return

patient.” (*Id.*, 7:47-52.) Garrison addresses this challenge by including an “aspiration pump device 3250 which is configured not to harm blood cells and which may be configured to return blood to the central venous system in real time during the procedure, so there is no reservoir in which the blood remains static.” (Ex. 1006, [0135]; *id.* at [0136]; *see also id.* at [0140], Fig. 38 (describing blood return variations). This blood return solution would have reinforced a POSITA's

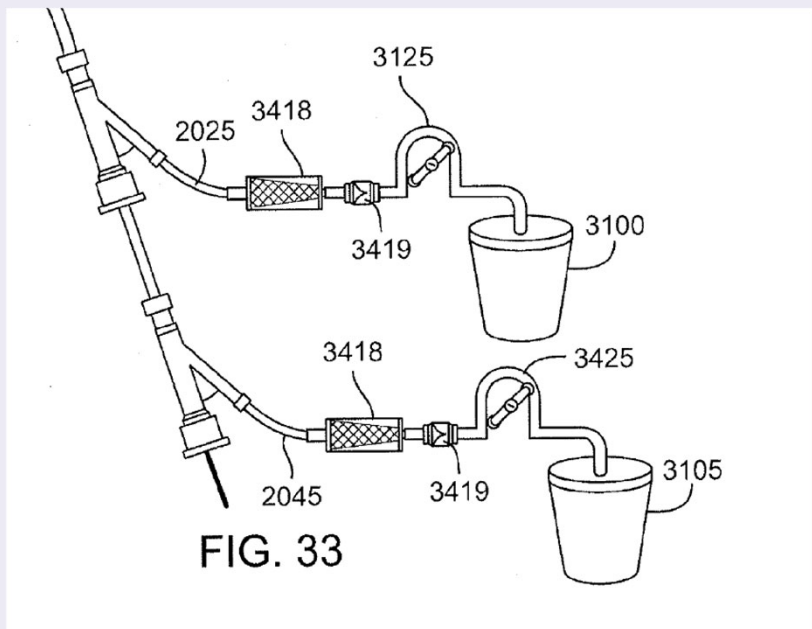
Pet., 33.

Garrison blood return embodiments

sion when blood is returned to the patient. A POSITA would understand such systems to be incompatible with the challenged Claims including the treatment of PE, a “16 French or greater” inner catheter, and the “fluid control device[s]” that enable vacuum pressure to be generated “while the ... fluid control device is in the first position” inhibiting fluid flow therethrough because the fluid control device would prevent continuous reinfusion and aspiration.

EX2008 (Brown Supp. Decl.), ¶1110.

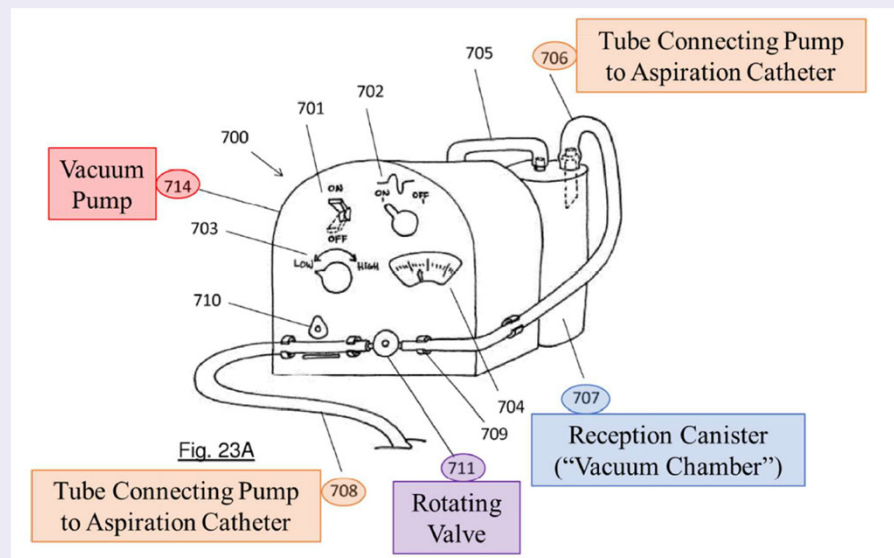
Petitioner's new pumps/arguments



EX1006 (Garrison).

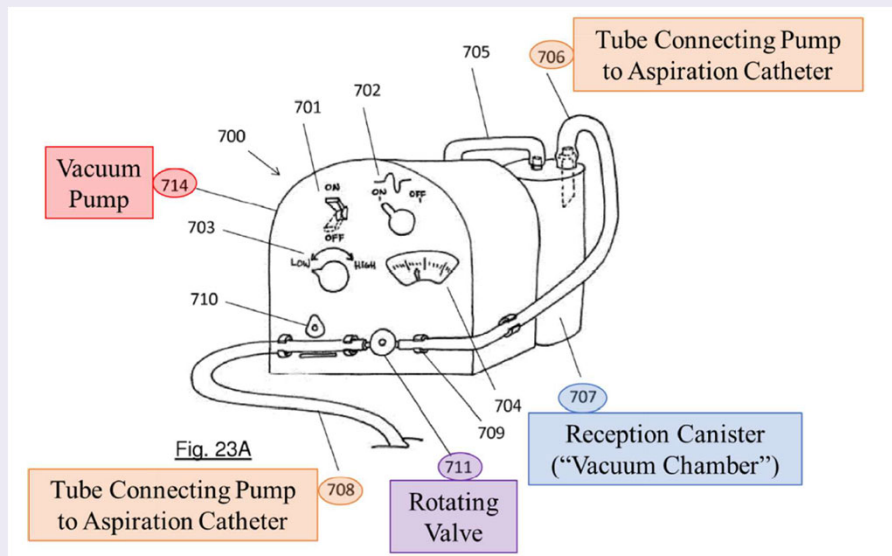
pump, or a peristaltic pump, or other means of generating a negative pressure differential. This vacuum pump is connected by tube 705 to a reception canister 707, which is configured to receive aspirated blood or material. A safety valve may be provided within the canister to

EX1020 (Brady), 21:19-21.



Reply, 12, (citing EX1020 (Brady)).

Petitioner's new pumps/arguments



Reply, 12, (citing EX1020 (Brady)).

Q. So for this reception canister, how is a vacuum created in that reception canister?

A. By the vacuum pump.

Q. And is that via this tube labeled 705?

A. I would have to look at the patent to see how they labeled 705. I didn't label it in here. That does appear to be the means of connection to the vacuum pump into the canister -- the means of connection between the pump and the canister.

Q. Is canister 707 sealed?

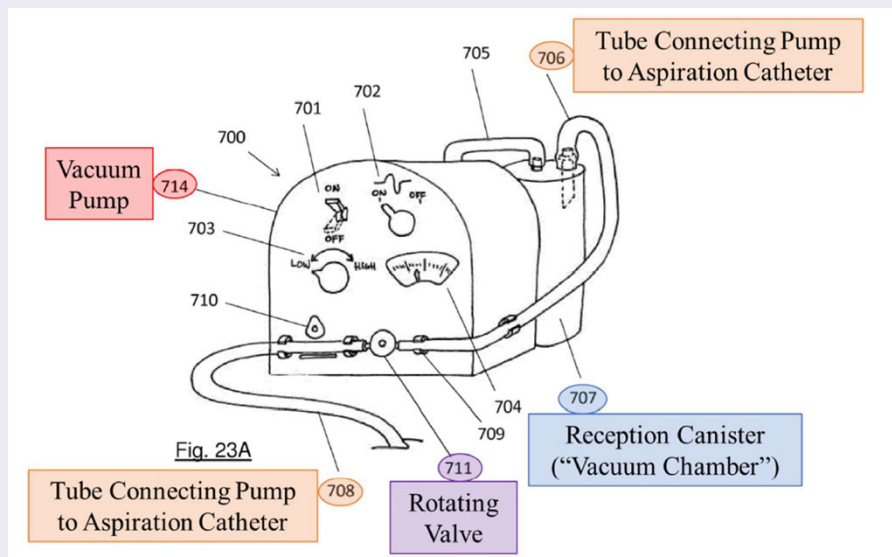
A. Yes.

EX2018 (Thornton Tr.), 59:13-23.

A. It is because if it were not sealed, you wouldn't be able to create a vacuum within the canister.

EX2018 (Thornton Tr.), 60:2-4.

Petitioner's new pumps/arguments



Reply, 12, (citing EX1020 (Brady)).

Q. So then would it be a fair summary to say that the pump shown here on page 15 generally operates by having a sealed vacuum chamber?

A. Certainly if it weren't sealed, you wouldn't be able to create a significant vacuum that the physician wants to use -- wants in order to perform a thrombectomy procedure.

EX2018 (Thornton Tr.), 61:24-62:5.

We have got a couple different pumps here. So you got another one on page 19. Does that pump operate by the same principle of a sealed vacuum chamber?

A. Yes, I believe the pumps that we show from Pons, Penumbra, and Medela all function similarly in creating a vacuum in a chamber in order to perform a thrombectomy.

EX2018 (Thornton Tr.), 63:5-12.

Petitioner's new pumps/arguments

We have got a couple different pumps here.

So you got another one on page 19. Does that pump operate by the same principle of a sealed vacuum chamber?

A. Yes, I believe the pumps that we show from Pons, Penumbra, and Medela all function similarly in creating a vacuum in a chamber in order to perform a thrombectomy.

EX2018 (Thornton Tr.), 63:5-12.

Penumbra Pump MAX

Indication For Use

The Penumbra Pump MAX is indicated as a vacuum source for Penumbra Aspiration Systems.

Contraindications

There are no known contraindications.

Warnings/Precautions

- The canister/tubing is intended for single use only. Do not reuse. Reuse may result in the inability to aspirate.
- Do not block bottom or back air vents. Unit may overheat and shut off or fail to restart if run for extended periods without airflow.
- To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
- Do not position the pump so that it is difficult to operate the power cord disconnection device.
- Remove and service the pump if liquids or solids have been drawn into the vacuum pump.
- Do not use in the presence of flammable anaesthetic mixture with air or nitrous oxide.
- Do not use in oxygen rich environment.
- To prevent fire or shock hazard, use replacement fuses of equal size and rating.
- To prevent fire or shock hazard, use a replacement power cord of equal rating.
- Do not re-infuse blood or fluid from the canister back into the patient.
- Do not use petroleum base compounds, acids, caustics, or chlorinated solvents to clean or lubricate any parts. It will reduce service life of the pump. Use only water-base solvents for cleaning.
- Federal law (USA) restricts this device to sale by or on the order of a physician.
- No modification of this equipment is allowed.

EX1084 (Penumbra Max Pump), 5.

INDICATIONS FOR USE

AXS Universal Liner Set and Aspiration Tubing is suitable for the safe collection and disposal of suctioned fluids. It is only for allowed to use only by medically trained staff, which is aware of the in-house hygienic regulations. Medela can only guarantee the safe function if used in combination with Medela components.

EX1039 (Medela Pump), 1.

Pulmonary Embolisms

was only capable of removing that easier-to-remove clot. Instead, a POSA would design the device and methods to remove the primary clots encountered when treating PE, which are often chronic, tortuous, large, and difficult to remove and which pose the greatest risk to a patient.

EX2016 (Morris Decl.), ¶73.

The benefit of removing such a clot with mechanical aspiration is minimal because of the redundancy in the vessels of the lungs. Conversely, the risk from such a procedure is great, particularly damage to the vessels, minimizing the need for a POSA to design a device to treat those issues. Instead, a POSA designing a treatment for PE would by necessity design the device to treat blockages in the largest and most central vessels which pose the greatest risk to a patient.

EX2016 (Morris Decl.), ¶74.

No Reasonable Expectation of Success

Second, a POSA would not have any expectation that a catheter of smaller size could be used to aspirate PE due to the difficult nature of removing those clots with a small diameter catheter. More particularly, a POSA would have understood that a catheter of size 10 French or less, could not generate a sufficiently rapid pressure equalization or “whoosh” to treat a PE. As such a POSA would not have been motivated to include a stop valve or similar to pre-charge the vacuum, particularly in view of the desire to include continuous blood return in Aklog and Laub.

EX2016 (Morris Decl.), ¶177.

Fragmentation

Current efforts to apply existing catheter embolectomy technologies to medium to large blood vessels and heart chambers encounter at least two obstacles: fragmentation and excessive blood loss. Techniques which depend on fragmentation of the material tend to be inefficient and ineffective in medium to large blood vessels and heart chambers because the flow of blood will carry a significant portion of the fragmented material away before it can be captured in the catheter. On the other hand, techniques which depend on aspiration of undesirable material will result in excessive blood loss as the size of the catheter increases.

EX1005 (Aklog), 4:60-5:3.

Unexpected Results confirm patentability

84. And, upon 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, often times removing the clot intact. A POSA would not have expected such a result due to the difficulty in mechanically removing clot material when treating a PE. And more specifically, a POSA would not have expected a quick burst of pre-charged vacuum as provided by the current claims could so effectively remove the clot material, particularly in view of the difficulty in mechanically removing clot material using other methods and systems including the AngioVac system. In summary, a POSA would not have expected any meaningful improvement in clot removal for treating PE using a pre-charged vacuum as set forth the claims of the '910 patent compared with the expected result for the closest prior art.

Unexpected Results confirm patentability

85. To the extent a POSA would have expected any improvement using the claimed method by combining aspects of Garrison, Aklog and/or Laub (one would not have expected any improvement as explained above), the ability to remove a clot when treating PE (particularly with catheters of 16 French or greater) greatly exceeded any expectation of POSA and thus was surprising and unexpected.

EX2016 (Morris Decl.), ¶85.

Unexpected Results confirm patentability

78. I am familiar with and have personally used the Inari Flowtriever systems to treat pulmonary emboli, including both the Trierer 16, Trierer 20, and Trierer 24.

81. I first note that, as I explain above, a POSA would not have combined Garrison, Aklog and/or Laub in the manner claimed in claims 1 and 11. I also note that the AngioVac system by Angiotech, now Angiodynamics, is similar to the Aklog reference (EX1005) relied upon in the Petition. I have personally used and witnessed the use of that AngioVac system.

EX2016 (Morris Decl.), ¶¶78, 81.

Unexpected Results confirm patentability

9. I am currently a professor emeritus of radiology at the University of Vermont and an adjunct professor of radiology at the University of Utah. I have been performing thrombosis procedures, including mechanical thrombectomy and pharmacologic thrombolysis since the late 1980s and have extensive experience treating arterial, venous, and pulmonary embolism thrombosis using a wide range of devices, including Inari Medical's catheter devices as well as products as/from Pronto, AngioJet, Trellis, Penumbra and EKOS. In my clinical practice, I frequently manage cases involving deep vein thrombosis and pulmonary embolism. I also have experience with peripheral vascular arterial and cerebral (stroke) thromboembolism treatments, including mechanical thrombectomy.

Unexpected Results confirm patentability ('910 Patent)

79. I understand that Inari's Flowtriever systems include "a [] fluid control device between the [] catheter and the [] pressure source, wherein the [] fluid control device is movable between (a) a first position in which the [] pressure source is fluidly disconnected from the [] catheter and (b) a second position in which the [] pressure source is fluidly connected to the [] catheter, wherein the [] pressure source is configured to generate vacuum pressure while the [] fluid control device is in the first position, and wherein, upon movement of the [] fluid control device from the first position to the second position, the vacuum pressure is applied to the [] catheter to generate suction at the distal portion of the [] catheter to aspirate blood and at least a portion of the pulmonary embolism into the [] catheter." as recited in claims 1 and 11 of the '910 Patent.

EX2016 (Morris Decl.), ¶79.

Unexpected Results confirm patentability

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.

EX2016 (Morris Tr.), 192:12-22.

Unexpected Results confirm patentability

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.

EX1001 ('910 patent), claim 1.

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

EX1001 ('333 patent), claim 1.

Unexpected Results confirm patentability

104 of the catheter 102. Opening 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. In particular, the suction is applied at the distal

EX1001 ('910 patent), 7:8-12.

'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.

'333 Patent, Claim 20

20. A method of treating a deep vein thrombosis 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 deep vein thrombosis, 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 deep vein thrombosis 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 deep vein thrombosis.

'333 Patent, dependent claims (16/20 French or greater)

2. The method of claim 1 wherein advancing the aspiration catheter comprises inserting a catheter having a size of 16 French or greater through the vasculature.

3. The method of claim 1 wherein advancing the aspiration catheter comprises inserting a catheter having a size of 20 French or greater through the vasculature.

18. The method of claim 1 wherein advancing the aspiration catheter comprises inserting through the vasculature an aspiration catheter having a size of 16 French or greater and an inner diameter, and wherein the fluid path from the aspiration catheter through the valve to the clot canister has a diameter that is the same as or greater than the inner diameter.

21. The method of claim 20 wherein advancing the aspiration catheter comprises inserting a catheter having a size of 16 French or greater through the vasculature.

22. The method of claim 20 wherein advancing the aspiration catheter comprises inserting a catheter having a size of 20 French or greater through the vasculature.

37. The method of claim 20 wherein advancing the aspiration catheter comprises inserting through the vasculature an aspiration catheter having a size of 16 French or greater and an inner diameter, and wherein the fluid path from the aspiration catheter through the valve to the clot canister has a diameter that is the same as or greater than the inner diameter.

EX1001 ('333 Patent).

'333 Patent

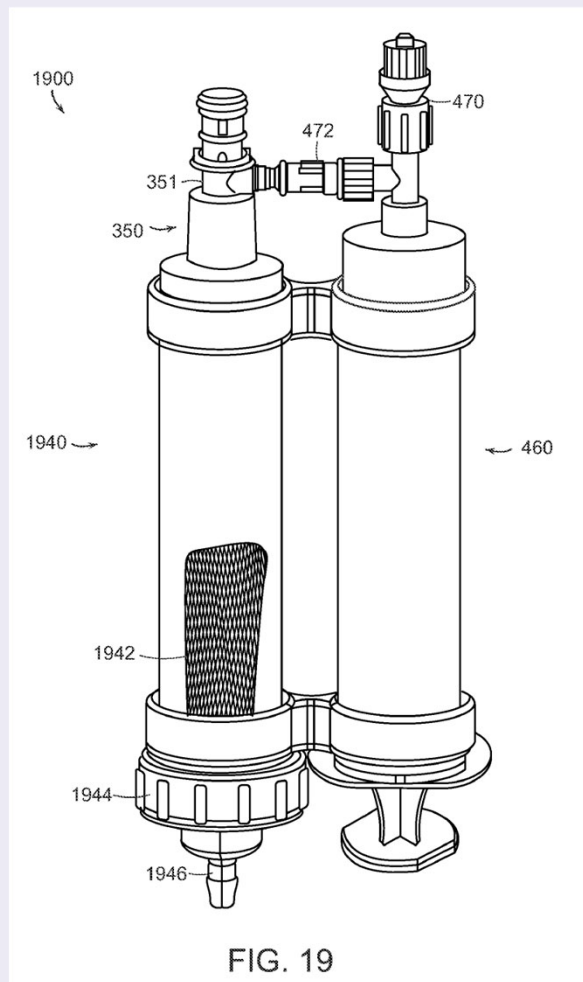


FIG. 19

EX1001 ('333 Patent).

Unexpected Results confirm patentability ('333 Patent)

78. I understand that Inari's Flowtriever systems include the ability "to generat[e] vacuum pressure" using an "aspiration source" where "a valve" is in a "first position that inhibits fluid flow along [a] fluid path from the lumen of the aspiration catheter" and "mov[e] the valve from the first position to a second position thereby applying the vacuum pressure to the lumen of the aspiration catheter" where "in the second position the valve permits fluid flow along the fluid path from the lumen of the aspiration catheter" as recited in claims 1 and 20 of the '333 Patent.

EX2016 (Morris Decl.), ¶19.