UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

_____

IMPERATIVE CARE, INC.,
Petitioner,

v.

INARI MEDICAL, INC.,
Patent Owner.

_____

Case No. IPR2024-01257
U.S. Patent No. 11,744,691

_____

DECLARATION OF BRIAN BROWN

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1. Garrison discloses an aspiration pump that generates positive pressure in a "first chamber" rather than negative pressure, or a "first chamber" that remains at atmospheric pressure if it is vented. 35

2. Garrison's locking syringe embodiments do not disclose the generation of negative pressure in first and second chambers in a system with an aspiration pump. 47

B. Garrison Does Not Disclose "Wherein Upon User Actuation to Open the Valve with the Negative Pressure Having Been Generated in the First and Second Chambers, Fluid Flow at Least Partially from the Second Chamber into the First Chamber Causes Rapid Aspiration into the Second Chamber" as Recited in Claim 1 48

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I, **Brian Brown,** declare as follows:

I. INTRODUCTION

1. My name is Brian Brown. I have been retained by counsel for Patent Owner Inari Medical, Inc., ("Patent Owner" or "Inari") as an independent expert consultant in this *inter partes* review (IPR) proceeding, IPR 2024-01257, concerning U.S. Patent 11,744,691 ("the '691 Patent"; EX1001), pending before the U.S. Patent and Trademark Office, Patent Trial and Appeal Board ("Board").

2. I understand that Imperative Care, Inc. ("Petitioner" or "Imperative") has filed a petition for *inter partes review* before the Board asserting:

> Ground 1: Claims 1-2, 5-6, 10-11, and 13 of the '691 Patent are unpatentable under 35 U.S.C. § 102 as anticipated by U.S. Patent Application Publication No. 2015/0173782 to Garrison et al. (EX1006; "Garrison");
>
> Ground 2: Claims 1-2, 4-6, 9-20, and 28-30 of the '691 Patent are unpatentable under 35 U.S.C. § 103 as obvious over Garrison alone;
>
> Ground 3: Claims 3, 23, and 25-27 of the '691 Patent are unpatentable under 35 U.S.C. § 103 as obvious over Garrison in combination with U.S. Patent Application Publication No. 2003/0116731 to Hartley (EX1008; "Hartley");

Ground 4: Claims 4, 9, 11-12, 14-20, and 28-30 of the '691 Patent are unpatentable under 35 U.S.C. § 103 as obvious over Garrison in combination with WIPO Publication No. WO2006/124307 to Goff et al. (EX1007; "Goff");

Ground 5: Claims 7-8, 21-22, and 31 of the '691 Patent are unpatentable under 35 U.S.C. § 103 as obvious over Garrison in combination with U.S. Patent No. 8,734,374 to Aklog et al. (EX1005; "Aklog");

Ground 6: Claim 24 of the '691 Patent is unpatentable under 35 U.S.C. § 103 as obvious over Garrison in combination with Aklog and Hartley;

Ground 7: Claims 21-22 and 31 of the '691 Patent are unpatentable under 35 U.S.C. § 103 as obvious over Garrison in combination with Aklog and Goff; and

Ground 8: Claims 25-26 of the '691 Patent are unpatentable under 35 U.S.C. § 103 as obvious over Garrison in combination with Hartley and Goff.

I have been asked by counsel for Patent Owner to opine on the patentability of the Claims of the '691 Patent.

3. Along with my years of education, research, and experience, my opinions are based on investigation and study of relevant materials. The materials that I

evaluated in support of this Declaration include all exhibits cited in this Declaration and in the petition.

4. I may rely upon these materials, my knowledge and experience, and/or additional materials to rebut arguments raised by Petitioner. Further, I may also consider additional documents and information in forming any necessary opinions, including documents that may not yet have been provided to me.

5. My analysis of the materials produced in this matter is ongoing, and I will continue to review any new material as it is provided. This Declaration represents only those opinions I have formed to date. I reserve the right to revise, supplement, and/or amend my opinions stated herein based on new information and on my continuing analysis of the materials already provided.

6. My work in this case is being billed at my normal hourly consulting rate, with reimbursement for actual expenses. My compensation is not related to the outcome of this proceeding. I have no personal interest in the outcome of the case.

II. BACKGROUND AND QUALIFICATIONS

7. My qualifications for forming the opinions set forth in this Declaration are summarized here and explained in more detail in my curriculum vitae, which I provide as a first attachment to my Declaration.

8. I received a Bachelor of Science in Mechanical Engineering from North Dakota State University, with an emphasis on electromechanical automation. As part of my studies, I took classes covering many different engineering areas including chemistry, physics, advanced mathematics, statistics, software engineering and architecture, statics, dynamics, thermodynamics, robotics, technical writing, material science, fluid dynamics and engineering design. After my studies, I joined Hutchinson Technology as a machine design engineer. After a few years at Hutchinson, I joined Boston Scientific/SciMED in 1990 and began working with their medical device product lines, including stents and cardiovascular implants.

9. Beginning with my time at SciMED, I have over 30 years of research and development experience working in the cardiovascular and medical device industries across a wide variety of application areas including development of neurovascular, cardiovascular, peripheral vascular, and pulmonary aspiration thrombectomy devices.

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.

11. Starting in 1991, in collaboration with Possis Medical and SciMED Life Systems, I designed and developed a drive unit to supply high pressure water jet and aspiration to a thrombectomy catheter. From 1992 to 1993, as part of my work, I developed and patented several thrombus removal catheters designed for aspiration, irrigation, and mechanical interaction with thrombi.

12. I also held various leadership roles at medical device and diagnostics companies, including Chief Technology Officer at OvaGene Oncology and Vice President of R&D and Operations at both Cogentix Medical, Inc. and Sunshine Heart, Inc, focused on advancing the medical device and diagnostics industries.

13. For the past 6 years, I have served as a technical consultant for various early-stage medical device companies as the founder and President of Brown-Tech, LLC, including QXMedical, Peytant Solutions, and CardioMech. I am also one of the founding partners for Northern Nitinol, LLC, which is a company that focuses on nitinol design and prototyping for medical device components.

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 a mentor to students enrolled in the University of Minnesota Design of Medical Device program.

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.

16. During my career, I developed a range of medical devices from low profile neurovascular catheters for the treatment of neurovascular disease and embolic stroke to large profile catheters for the treatment of peripheral vascular disease (PVD), deep vein thrombosis (DVT), pulmonary embolism (PE), and structural heart disease (SHD). Larger profile catheters were used for the treatment of PVD, DVT, PE, and SHD to accommodate the delivery of larger

therapeutic devices (balloons, stents, valves) to the large diameter vessels. Many of the catheter systems I developed included hemostasis valves, of various designs, on the proximal end to facilitate the introduction of ancillary devices (guidewires, snares, ultrasound, etc.) and the coaxial introduction of a catheter within a catheter to cross challenging anatomy or to extend to distal treatment sites.

III. BASES OF MY OPINION

A. Materials Considered

17. The opinions included in this Declaration are based on the documents I reviewed, my professional judgment, and my education and experience.

18. In forming the opinions expressed in this Declaration, I reviewed all the materials listed in the second attachment I have provided to my Declaration, and any other material I refer to in this Declaration in support of my opinions.

B. Relevant Legal Principles

19. I am not an attorney but, in preparing and forming my opinions, I have been informed of certain legal principles. I have applied my understanding of those principles and taken them into account when forming the opinions I describe. My understanding of the relevant legal principles is summarized below.

20. I understand that claim terms are generally given their ordinary and customary meaning as understood by a person of ordinary skill in the art at the time of the invention when read in the context of the specification and prosecution

history, unless a patentee sets out a different definition or clearly disavows claim scope.

21. I further understand that extrinsic evidence such as expert and inventor testimony, dictionaries, and learned treatises can help determine the meaning of claim terms, although that evidence is less significant than the claims, specification, and prosecution history.

22. I have been informed that Petitioner bears the burden of proving unpatentability by a preponderance of evidence. I have been told that this means that Petitioner must prove that more likely than not that the Claims of the ’691 Patent are anticipated by Garrison, obvious over Garrison alone, or obvious over the combination of Garrison and one or more of Hartley, Goff, and Aklog.

23. I understand that my opinions regarding patentability are from the viewpoint of a person having ordinary skill in the field of the technology of the patent as of the time of the invention. For the purposes of this Declaration, I have assumed that date is the earliest priority date of the ’691 Patent, August 13, 2018. Petitioner also applied August 13, 2018, as the priority date for the ’691 Patent. Paper 2, p.20.

24. I understand that for a patent claim to be anticipated, each claim limitation must be present in a single piece of prior art. It is my understanding from

counsel that a prior art reference anticipates a claimed invention if the prior art reference disclosed each of the claimed limitations of the invention either expressly or inherently.

25. I understand that if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains, the claimed invention is obvious.

26. I understand there are four fact-based inquiries involved in determining patent obviousness. These include: (1) the scope and content of the prior art; (2) the differences between the claimed invention and the prior art; (3) the level of ordinary skill in the art; and (4) objective indicia of non-obviousness. I have been informed that examples of objective indicia include unexpected results, commercial success of the invention, whether the invention satisfied a long felt need in the industry, failure of others to find a solution to the problem at hand, commercial acquiescence via licensing, professional approval, unexpected results, and copying and praise by infringers.

27. I understand that even if all limitations of a claimed invention are disclosed by the prior art combination, the patent challenger must demonstrate an apparent reason to combine the known elements in the fashion of the patent

claim at issue and that a person of ordinary skill in the art would have reasonable expectation of success in pursuing that combination.

28. I understand that a prior art reference teaches away from a proposed modification when a person of ordinary skill in the art would be discouraged from following the path set out in the reference or would be led in a direction divergent from the path followed by and claimed in the patent.

IV. SUMMARY OF OPINIONS

29. For the reasons I discuss below, I believe that the Claims of the ’691 Patent are not anticipated by Garrison, rendered obvious by Garrison alone, or rendered obvious by any combination of the prior art asserted in the Petition.

V. THE ’691 PATENT

A. Overview

30. Thrombi and emboli are blood clots that cause blockages (also called occlusions) of blood vessels or arteries. Blocking blood flow results in oxygen deprivation of tissues that results in tissue death. Clot blockages can cause many very serious health conditions if the clot is located in a critical blood vessel, including stroke (blocking blood flow to or from the brain), pulmonary embolism (blocking the flow of deoxygenated blood to the lungs), heart attacks (blocking blood flow to the heart), and other serious conditions. Venous thromboembolism and the related health conditions are a huge problem, affecting approximately 900,000 people in the United States every year. (*See*

https://www.cdc.gov/blood-clots/data-research/factsstats/index.html.) Venous thromboembolism is, in fact, a leading cause of preventable hospital deaths in the United States and worldwide, causing 60,000-100,000 deaths per year in the United States alone. (*See* https://www.cdc.gov/blood-clots/data-research/factsstats/index.html.)

31. A blood clot is essentially a living polymer, comprising a matrix of intertwined and cross-linked strands within which are situated red and white blood cells, platelets and numerous other proteins and components. The mechanical properties of a clot are influenced by the relative percentages of other materials and red blood cells, and clots that are highly fibrous (and highly organized) and have lower red blood cell content tend to be firmer and more cohesive than clots of a higher red cell content. Such clots have also been found to have a higher coefficient of friction, or in other words to be "stickier." These firm and sticky clots can be challenging to remove from a vessel. Clots that are less organized and with a high red cell content have been found to be less cohesive, more friable (i.e., more easily crumbled) and to have a lower coefficient of friction than the more organized and stickier clots previously described. Fresher (younger) clots are typically characterized as more friable, softer and less organized, whereas older (mature) clots are characterized as more

organized, firmer, and stickier. These properties mean that fresher and softer clots may be easier to dislodge from the site of occlusion.

32. Venous thromboembolism ("VTE") is a disease caused by blood clot formation in the veins of the body, and is, unfortunately, a leading cause of both hospital preventable death and disease worldwide. Pulmonary embolism ("PE") and deep vein thrombosis ("DVT") are common types of VTE.

33. Deep vein thrombosis ("DVT") is a type of blood clot (thrombus) that typically forms in the deep veins of a limb, such as the leg. EX1001, 1:46-51. Thromboembolism occurs when part or all of a thrombus breaks away from the blood vessel wall. This blood clot (now called an embolus) is then carried in the direction of blood flow. When the embolus travels from the vein towards the heart and then lungs, a pulmonary embolism ("PE") may result if such embolus lodges in an artery or branch thereof of the lungs. *Id*. at 1:57-67. Because of their location and how they are formed DVT and PE clots tend to be larger, older, more highly organized, and more fibrous than arterial clots, such as clots in the cerebral vasculature that cause strokes.

34. Treatment of PE and DVT has long been a challenge, with the existing methods of treatment failing to significantly improve patient mortality rates over the last five decades. For example, PE and DVT have traditionally been treated with drugs, e.g., anticoagulants (also called blood thinners),

streptokinase (also called SK manufactured by pharmaceutical makers including GSK and BBT Biotech GmbH), urokinase (also called Abbokinase or Kinlytic, manufactured by companies including Abbott Laboratories), or other drugs in a class of agents called "thrombolytics" (or just "lytics") that break down and dissolve the clot over hours or days, but do not physically remove the clot material from the body. EX1001, 2:26-32. Doctors can treat patients with lytics by introducing the drugs through an IV line or, more preferably for many cases, applying the lytics at the site of the clot using a perfusion catheter placed at the clot. To this day, the use of either anticoagulants or lytics (particularly for certain types of more acute cases) are the most common and recommended treatments for PE and DVT in guidelines by medical organizations such as the American College of Chest Physicians, European Society of Cardiology, American Heart Association, and the Society of Interventional Radiology.

35. Lytics have many disadvantages. First, they can take many hours to work. EX1001, 2:28-32. Second, because the clots are not actually removed from the body, portions of the clot can break off and travel to a different location within the body rather than being eliminated entirely. Additionally, using lytics can cause hemorrhages and serious risks of death, necessitating ICU stays for treatments and monitoring. *Id*. Lytic treatments also are very expensive,

as they require longer hospital stays, and they cannot be used for many patients because of conditions related to increased risk of bleeding (e.g., active bleeding, recent brain bleed/hemorrhage, recent brain or spine surgery, severe hypertension, severe kidney disease, etc.).

36. Anticoagulant drugs also have many disadvantages. The side effects include bleeding risk and loss of bone density. Anticoagulants also are not effective against existing clots, merely preventing clots from forming or continuing to form (to some degree).

37. The ’691 Patent is directed to systems for rapidly aspirating clot material from a patient’s blood vessel that offer significant benefits over such conventional treatments. EX1001, 4:17-19. For example, the ’691 Patent describes various aspiration systems that generate (pre-charge or store) negative (vacuum) pressure in chambers before applying the vacuum to an aspiration catheter positioned near clot material (e.g., PE or DVT) in a patient’s blood vessel to generate large suction forces (and corresponding fluid flow velocities) needed to effectively aspirate and remove the clot material from the patient. *Id*. at 4:34-50. The generated suction forces and corresponding fluid flow velocities are greater than conventional systems allowing the aspiration system to more effectively remove the clot material, even when the clot material is strongly lodged or attached within the blood vessel in the instance of, for example,

chronic PE or chronic DVT. *Id*. at 4:42-47 & 10:14-27. Even today, most commercially available treatment systems do not use the type of rapid aspiration described in the '691 Patent, instead employing a multitude of alternative solutions that have varying advantages and disadvantages.

38. The '691 Patent discloses an aspiration system with accelerated response including (a) an aspiration pump in communication with a first chamber, (b) an aspiration catheter in fluid communication with the first chamber via an aspiration tube, and (c) a second chamber between the aspiration pump and the aspiration catheter. EX1001, cl.1. The system further has a user-actuatable valve (e.g., such as a stopcock) between the second chamber and the aspiration catheter to connect or disconnect negative pressure, allowing pressure to build up (i.e., be pre-charged) in the first and second chambers before connecting negative pressure to the aspiration catheter to aspirate clot material. *Id*. When the user-actuatable valve is opened with the negative pressure having been generated in the first and second chambers, the pre-charged negative pressure is applied all at once to the aspiration catheter to generate rapid aspiration and high flow rates that are needed to effectively remove and treat clot material.

39. Figure 1 of the '691 Patent shows an aspiration system with a pressure source in fluid communication with an aspiration catheter via a user-actuatable valve:

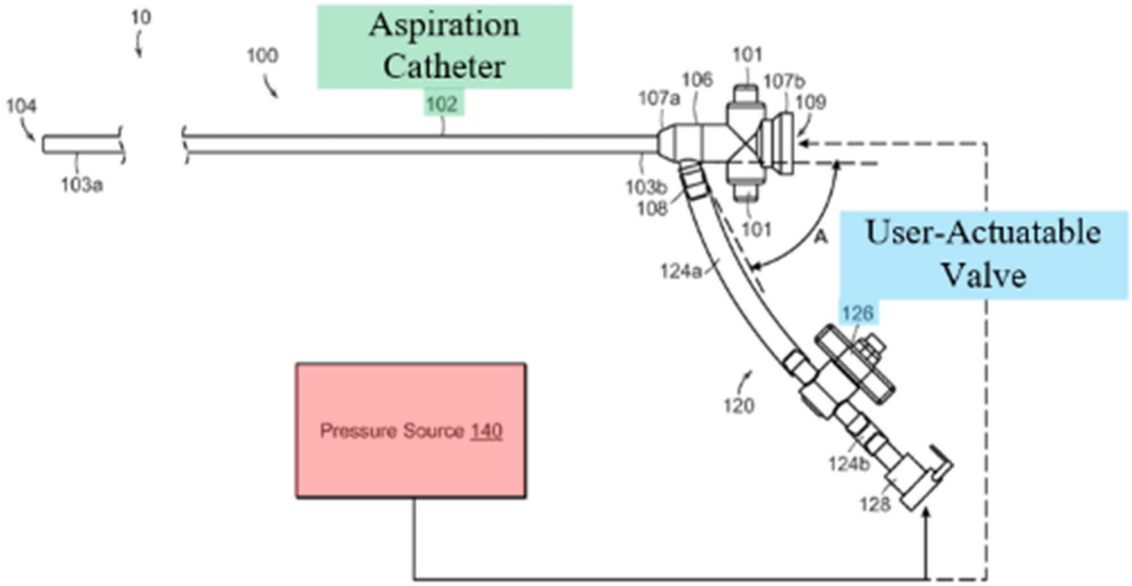
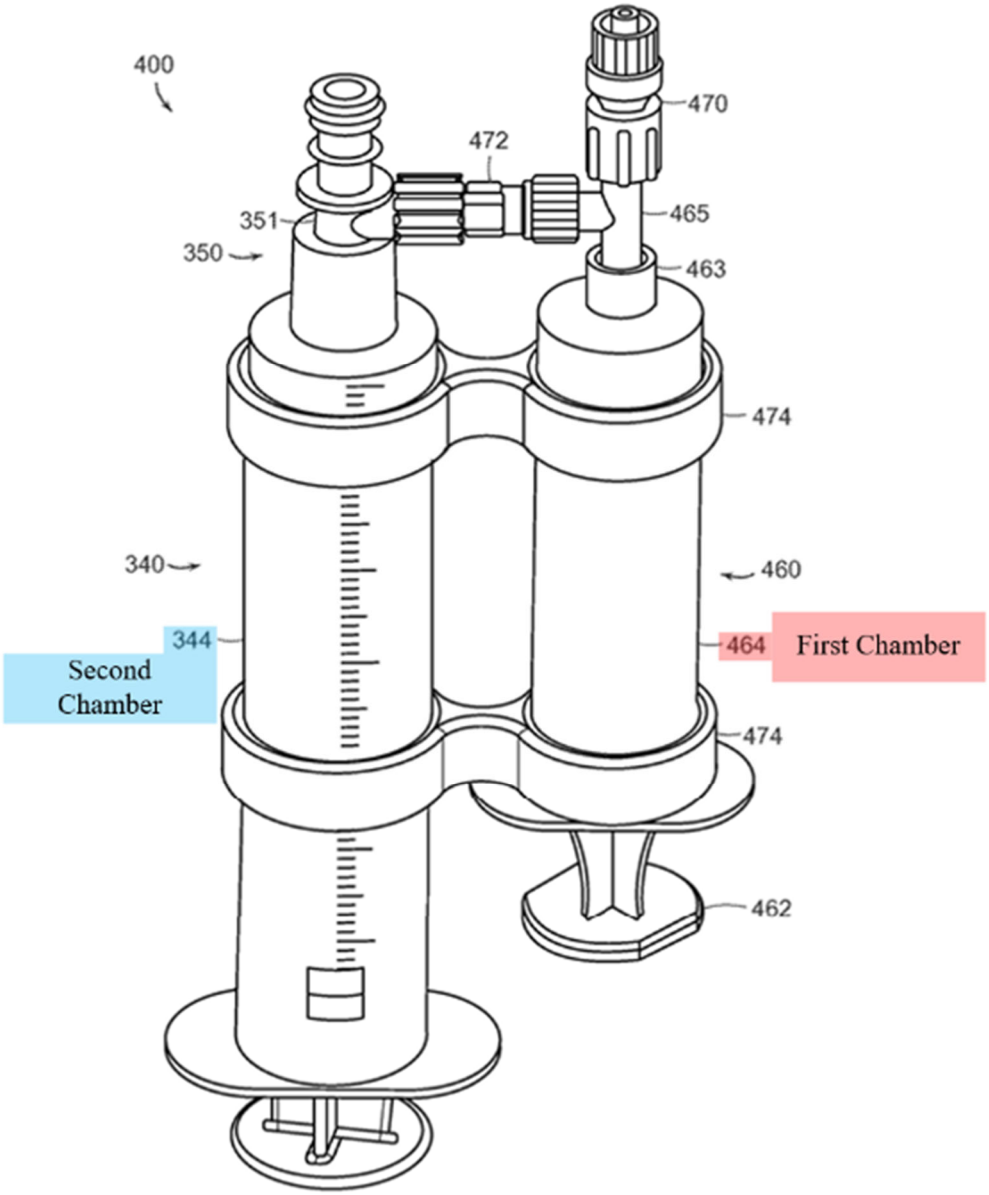


FIG. 1

40. The ’691 Patent explains that either a pump, or alternatively a different pressure source, such as a syringe can be used: “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 … to generate and store a vacuum therein.” EX1001, 7:33-38. Thus, in different embodiments of the ’691 Patent, the pressure source is either a pump or a syringe.

41. Figure 4 of the ’691 Patent shows one example of the pressure source that includes a first chamber and a second chamber in fluid communication with one another:

FIG. 4A



42. The first chamber 464 is shown as a syringe in Figure 4, but the ’691 Patent discloses that “the secondary syringe 460 can comprise a pump or vacuum source other than a syringe.” EX1001, 12:46-48. A POSITA would understand that secondary syringe 460 could be replaced with an aspiration pump.

For example, the syringe 460 could be replaced by an electric pump and vacuum chamber. *Id*. at 7:33-38.

43. In the structure using a pump, the pump operates to generate negative pressure in the first and second chambers when the valve is closed such that the pressure is built up or charged in the chambers. *Id*. at 6:60-64. This happens when the "user-actuatable valve" is closed so that the first and second chambers are fluidly disconnected from the aspiration catheter as, if the valve were open, the negative pressure would be applied to the aspiration catheter as it is generated such that it is not built-up or stored within the chambers. *Id*. at 6:66-7:1. When the valve is subsequently opened after the vacuum pressure is built up, the first and second chambers are fluidly connected to the aspiration catheter. *Id*. at 7:1-7:10. Fluid (e.g., clot and blood) is then rapidly aspirated into the second chamber by the built-up negative pressure in the second chamber. *Id*. at 7:1-22. The '691 Patent provides several examples of numerical flow rates/aspiration times measuring the rapidity of aspiration, which typically happens in less than a second after opening the valve (e.g., the pressure within the system equalizes in less than one second). *Id*. at 10:1-13 & 18:52-55. When the magnitude of negative pressure decreases as the pressure begins to equalize after opening the valve, a pressure differential between the first and

second chambers causes fluid to flow from the second chamber to the first chamber to aid in rapid aspiration.

B. Claims

44. The independent Claims of the ’691 Patent include the limitations of an “aspiration system” comprising at least “an aspiration pump in communication with a first chamber,” “a second chamber,” and a “valve [] configured to be closed while negative pressure is generated in the first and second chambers.” For example, independent Claim 1 reads in its entirety:

> An **aspiration system** with accelerated response, comprising:
>
> an **aspiration pump in communication with a first chamber**;
>
> a coupled assembly including:
>
> > an aspiration catheter configured for placement into fluid communication with the first chamber by way of an aspiration tube;
> >
> > **a second chamber in between the aspiration pump and the aspiration catheter**; and
> >
> > a hemostasis valve; and
>
> a user-actuatable valve between the second chamber and the aspiration catheter, wherein **the valve is configured to be closed while negative pressure is generated in the first and second chambers**, and wherein the valve is configured to be opened

after the negative pressure is generated in the first and second chambers;

wherein upon user actuation to open the valve with the negative pressure having been generated in the first and second chambers, fluid flow at least partially from the second chamber into the first chamber causes rapid aspiration into the second chamber.

45. Similarly, independent Claims 14, 23, and 28 each recite those same limitations as Claim 1 (as well as some different limitations), as follows:

[14./23./28.] An **aspiration system** with accelerated response, comprising:

an aspiration pump in communication with a first chamber;

***

an aspiration catheter configured for placement into fluid communication with the first chamber by way of an aspiration tube;

a second chamber in between the aspiration pump and the aspiration catheter

***

a user-actuatable valve between the second chamber and the aspiration catheter, wherein **the valve is configured to be closed while negative pressure is generated in the first and second chambers**, and wherein the valve is configured to be opened after the negative pressure is generated in the first and second chambers;

> wherein upon user actuation to open the valve with the negative pressure having been generated in the first and second chambers, fluid flow at least partially from the second chamber into the first chamber causes … .

C. Prosecution History

46. I have reviewed the prosecution history of the ’691 Patent, including the Office Action mailed June 21, 2023 (EX1002, pp.256-270), the Amendments and Response to the Office Action mailed July 3, 2024 (*Id*. at pp.244-254), and the Notice of Allowance mailed July 18, 2023 (*Id*. at pp.46-53).

47. I understand that the Examiner rejected the pending independent claims (then numbered 1 and 15) in the only Office Action both for nonstatutory double patenting over parent U.S. Patent No. 11,642,209 (“the ’209 Patent”) and under 35 U.S.C. § 103 over a combination of Heaton (EX1011) and Lockwood (EX1012). EX1002, pp.258-265. The Examiner found dependent claims 6-10, 12, 17, and 18 allowable, and specifically that the prior art did not teach a coupled assembly including the second chamber, the aspiration catheter, and a hemostasis valve or wherein the second chamber is removably coupled between the aspiration pump and the catheter. *Id*. at pp.268-269. I agree with the Examiner that those claims are patentable over Heaton and Lockwood. I also understand that, in response, Patent Owner canceled independent claims 1 and 15, and rewrote dependent claims 6, 10, 17, and 18 in independent form to put

the application in condition for allowance. *Id*. at pp.245-253 & 51-52. Those claims issued as independent Claims 1, 14, 23, and 28 of the '691 Patent, respectively.

48. I further understand that the '691 Patent is a continuation of U.S. Patent Application No. 17/865,315 ("the '315 Application"; EX1001) which matured into the '209 Patent, and that the '691 Patent was filed the same day (March 7, 2023) that a response to a final Office Action was filed in the '315 Application. I reviewed the prosecution history of the '209 Patent (EX2002) and note that prior to the amendment, the then pending claim in the '315 Application was substantially similar to the originally-filed Claim 1 in the application that became the '691 Patent:

Pending Claim 1 of the Parent '315 Application at Time of 2/10/2023 Final Office Action	**Originally-Filed Claim 1 of the '691 Patent**
An aspiration system with accelerated response, comprising:	An aspiration system with accelerated response, comprising:
an aspiration pump in communication with a first chamber;	an aspiration pump in communication with a first chamber;
an aspiration catheter configured for placement into fluid communication with the first chamber by way of an aspiration tube;	an aspiration catheter configured for placement into fluid communication with the first chamber by way of an aspiration tube;
a second chamber in between the aspiration pump and the catheter; and	a second chamber in between the aspiration pump and the catheter; and
a valve between the second chamber and the aspiration catheter, **wherein the valve is configured to be closed while negative pressure is generated in the first and second**	a user-actuatable valve between the second chamber and the aspiration catheter, wherein the valve is configured to be closed while negative pressure is generated in the first and second

chambers, and wherein the valve is configured to be opened after the negative pressure is generated in the first and second chambers;	chambers, and wherein the valve is configured to be opened after the negative pressure is generated in the first and second chambers;
wherein upon opening of the valve with the negative pressure in the first and second chambers, fluid flow at least partially from the second chamber into the first chamber causes rapid aspiration into the second chamber.	wherein upon user actuation to open the valve with the negative pressure having been generated in the first and second chambers, fluid flow at least partially from the second chamber into the first chamber causes rapid aspiration into the second chamber.

EX1002, p.567. The two claims differ only in minor ways in the portions underlined above.

49. I understand that during prosecution of the ’315 Application the Examiner expressly considered the Garrison ’788 publication (EX2003) and, as I explain below in §VIII, the Garrison ’788 publication has substantively the same or cumulative disclosure and figures as the portions of Garrison relied on in the Petition. I also understand that during prosecution of the ’315 Application the Examiner mooted a rejection of Claim 1 over the Garrison ’788 publication in response to an amendment adding the limitation “the valve is configured to be closed while negative pressure is generated in the first and second chambers, and wherein the valve is configured to be opened after the negative pressure is generated in the first and second chambers” (as indicated in bold above). EX2002, pp.64-70. I agree that the Garrison ’788 publication does not

disclose this feature, and recognize that those same limitations are also recited in each of the independent Claims 1, 14, 23, and 28 of the '691 Patent.

D. Garrison and the Garrison '788 Publication

50. As I explain below in §VII., Garrison is substantially the same as U.S. Patent Application Publication No. 2013/0281788 (EX2003; "the Garrison '788 publication"), and contains the same material from Garrison that is cited in the Petition. The following summarizes the disclosure found in both references. Garrison generally discloses systems for treating acute ischemic stroke caused by small clots in the cerebral arterial (rather than venous) vasculature. EX1006, ¶[0002]; EX2003, ¶[0002]. Specifically, Garrison discloses systems for accessing the cerebral arterial vasculature though the common carotid artery (CCA). EX1006, ¶[0050]; EX2003, ¶[0045]. The systems can include an aspiration source that generates vacuum in a catheter. EX1006, ¶[0130]; EX2003, ¶[0084].

51. Figure 32 of Garrison discloses an arterial access device connected to a delivery location, such as a receptacle, via a flow line. EX1006, ¶[0131]; EX2003, ¶[0085]. A source of aspiration, a filter, and a check valve are positioned sequentially along the flow line:

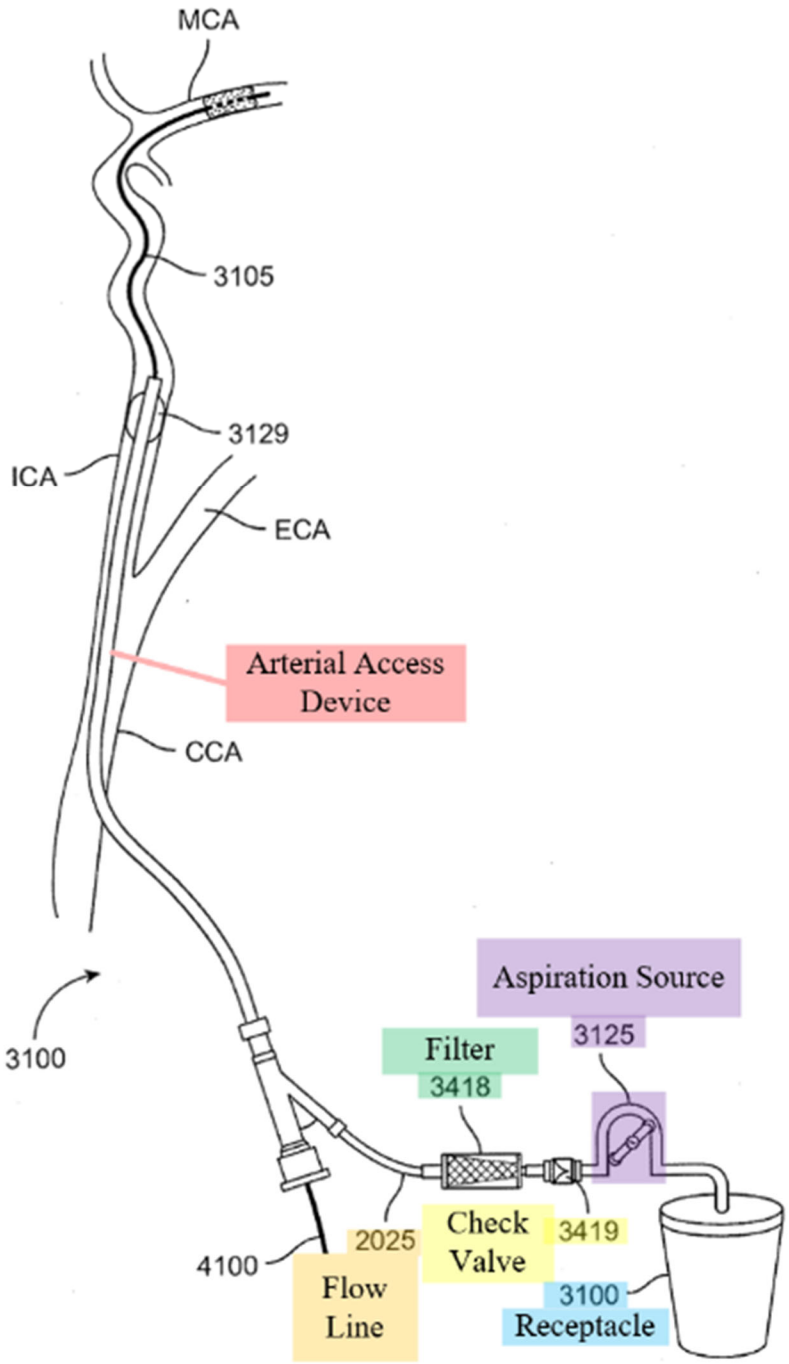


FIG. 32

EX1006, ¶[0131]; EX2003, ¶[0085].

52. A POSITA would recognize the aspiration source 3125 as a peristaltic pump based on its depiction including compressible tubing and a rotatable shaft

connected to a rotor that carries multiple rollers for compressing the tubing as I have labeled in the enlargement to Figure 32 below:

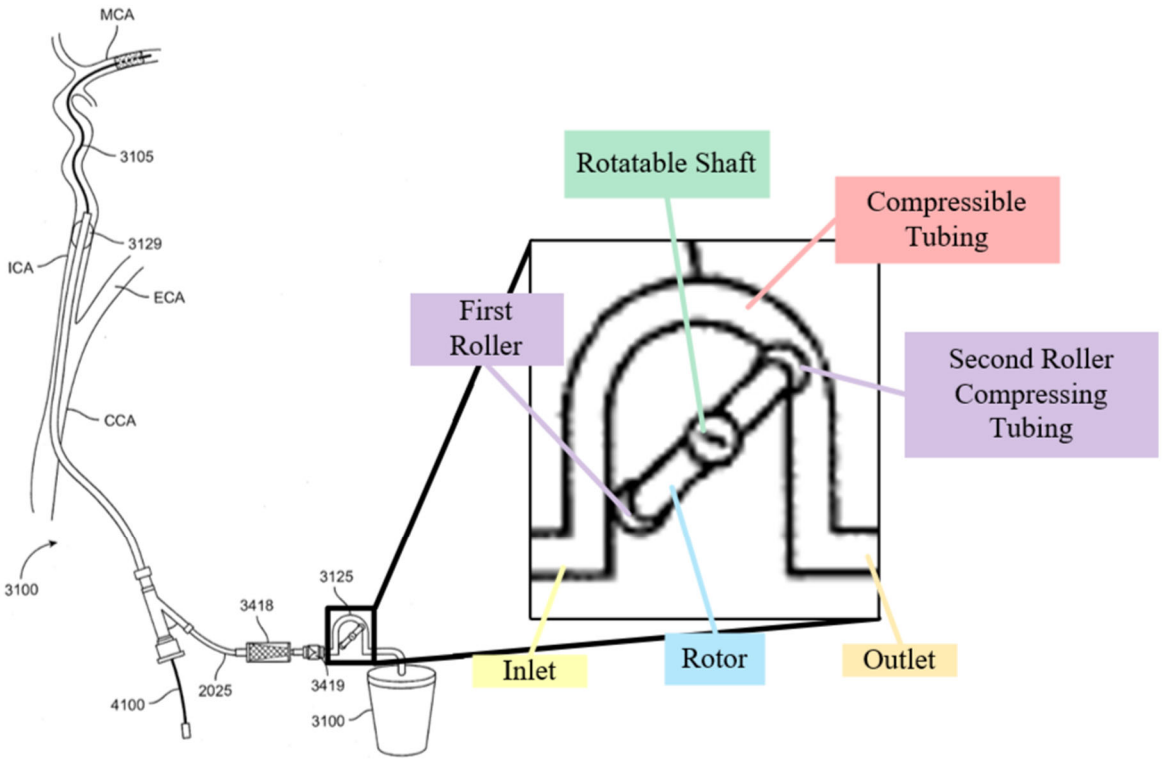


FIG. 32

A POSITA would understand that the peristaltic pump is a positive displacement pump that operates by rotating the shaft to rotate the rotor such that the rollers compress and seal the tubing during passes along the length of the tubing, alternating the compression and relaxation of the tubing, and drawing content in and propelling product away from the pump to: (1) generate negative pressure to draw fluid through the flow line 2025 through the inlet of the pump, (2) transport the fluid through the pump, and (3) expel the fluid through the outlet of the pump for delivery to the receptacle 3100. As a result, negative

pressure is only generated on the inlet side of the pump (e.g., toward the catheter) and positive pressure is generated on the outlet side of the pump (e.g., toward the receptacle). The pump cannot generate negative pressure downstream of its outlet, such as in the receptacle. Instead, the pump would generate positive pressure in the receptacle if sealed, or the receptacle would remain at atmospheric pressure if the receptacle were vented. Put another way, without any connection of the inlet of the pump to the receptacle, a POSITA would understand that there is no way for the pump to evacuate pressure from the receptacle.

53. A POSITA would further understand that peristaltic pumps advantageously contain blood entirely within the tubing as it moves through the peristaltic pump such that the blood does not directly contact any of the pump parts. This permits the pump to be reused in subsequent medical procedures because the tubing (which is the only portion contaminated by blood) can be easily removed from the pump and discarded after the procedure. For example, the blood does not contact an impeller or other movable part as in other types of pumps, such as a centrifugal pump. The pump can then be reused with new tubing.

54. Figure 33 of Garrison shows a similar system to Figure 32 but further includes a second and smaller catheter (e.g., an interventional or treatment catheter)

inserted through the arterial access device/sheath and containing similar flow connections to a second separate peristaltic pump and downstream receptacle via a separate flow line:

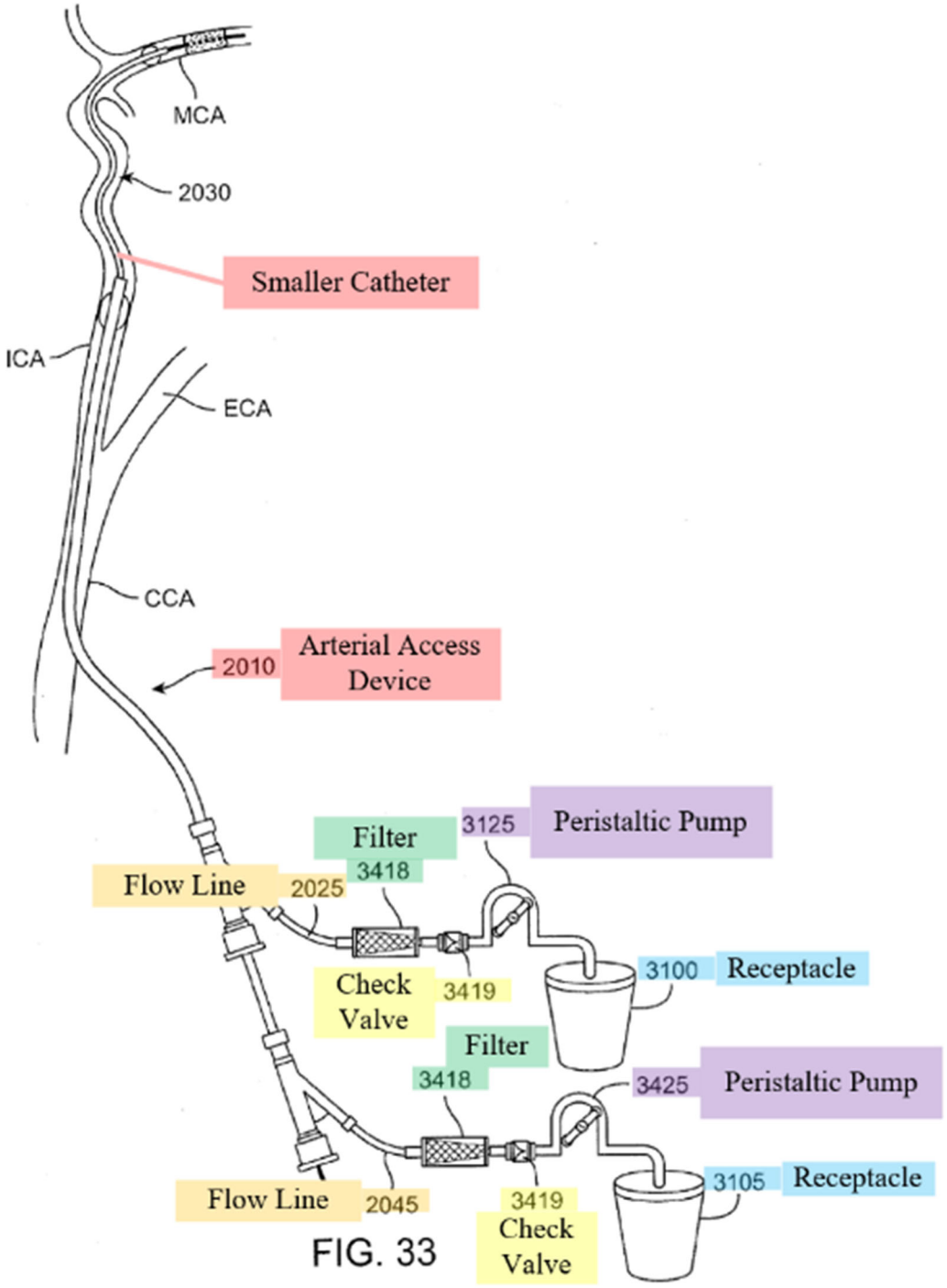


FIG. 33

EX1006, ¶[0131]; EX2003, ¶[0085].

55. Figure 34 of Garrison shows the connection of the flow lines from the arterial access device and smaller catheter to the peristaltic pump and downstream receptacle via a valve:

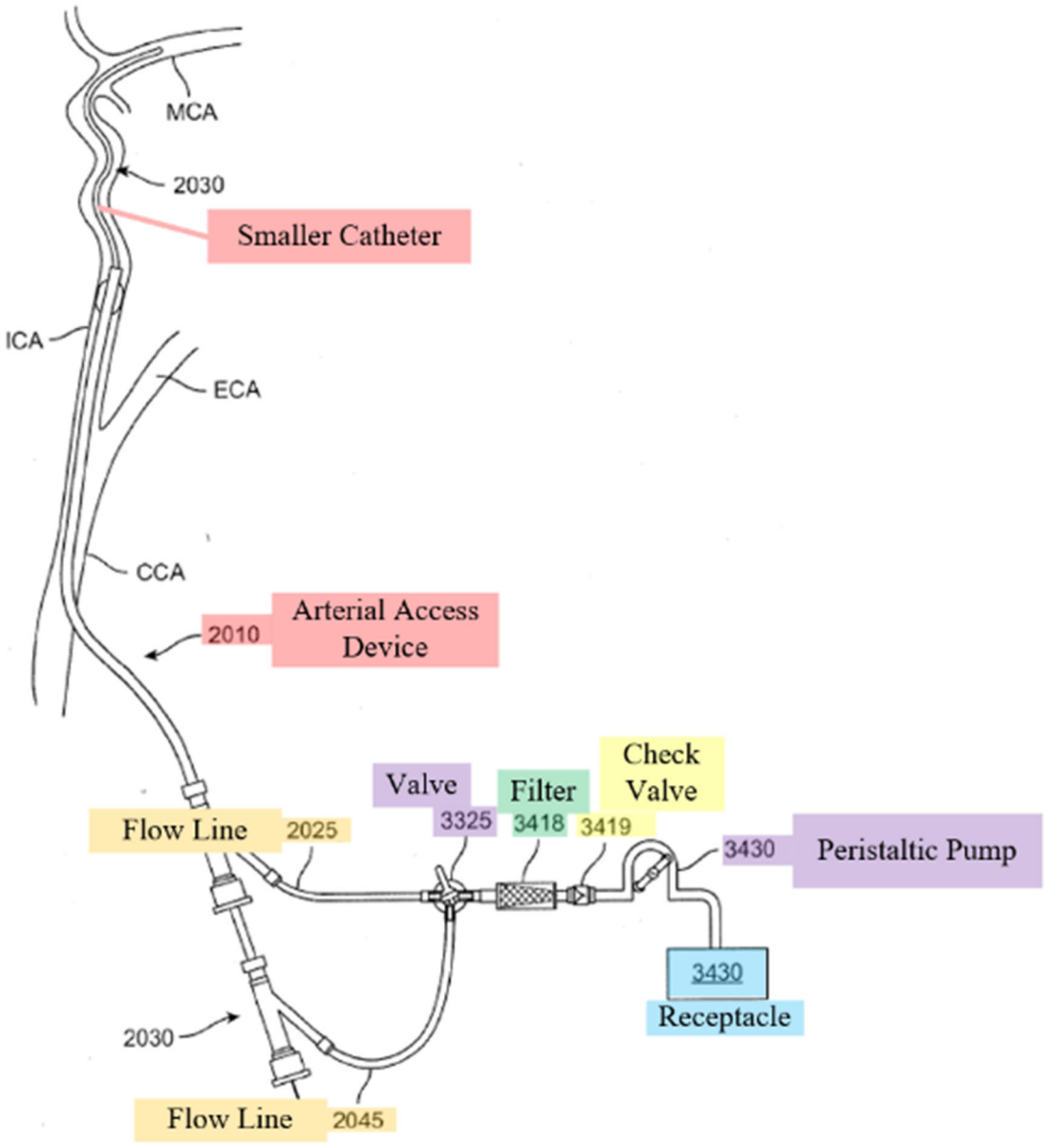


FIG. 34

EX1006, ¶[0132]; EX2003, ¶[0086]. The valve controls which of the devices—the arterial access device or smaller catheter—is connected to the aspiration source. EX1006, ¶[0132]; EX2003, ¶[0086]. "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." EX1006, ¶[0132]; EX2003, ¶[0086].

56. Garrison discloses that "[t]he receptacle 3100 and source of aspiration 3125 may be separate or may be combined into a single device such as a syringe." EX1006, ¶[0131]; EX2003, ¶[0085]. A syringe is the only example Garrison provides of a combined receptacle and source of aspiration. Garrison distinguishes an aspiration pump as a distinct alternative to a syringe by disclosing that the "active source of aspiration may be an aspiration pump, a regular or locking syringe, a hand-held aspirator, hospital suction, **or** the like." EX1006, ¶[0134] (emphasis added); EX2003, ¶[0088] (emphasis added); *see also*, EX1006, ¶[0071] ("aspiration source such as a pump or a syringe").

57. Figure 36 of Garrison discloses a pump device 3250 that is an alternative to the depicted peristaltic pump that is configured to return blood to the central venous system in real time. EX1006, ¶¶[0136]-[0137]; EX2003, ¶¶[0090]-[0091]. The pump device is connected to either or both of the flow lines of the

arterial access device or smaller inner catheter and includes a housing that encloses a chamber that is not fluidically connected to the catheter:

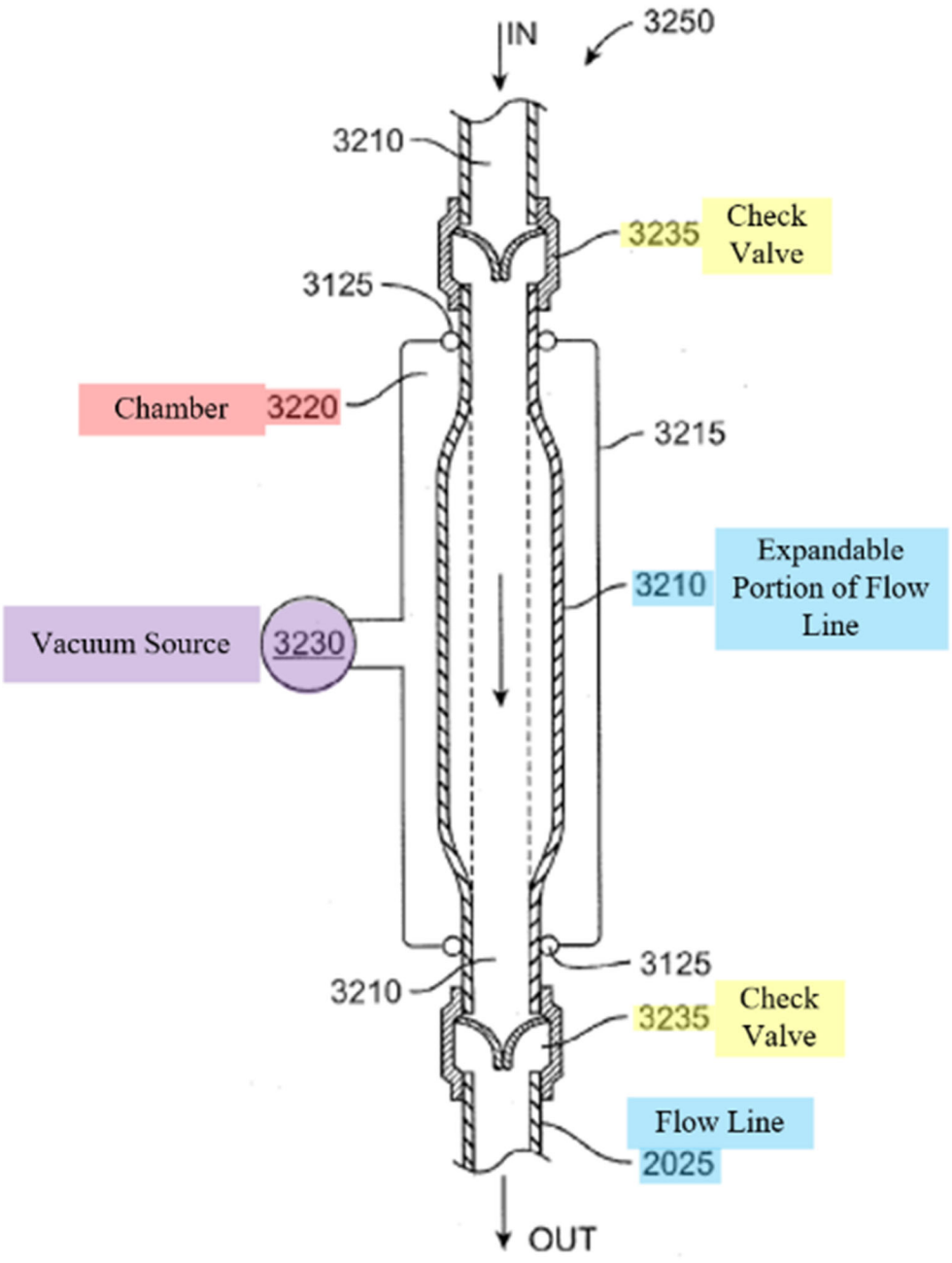


FIG. 36

EX1006, ¶[0136]; EX2003, ¶[0090].

58. The chamber 3220 is connected to a vacuum source 3230, which is configured to generate (1) negative pressure in the chamber 3220 to cause the expandable portion 3210 of the flow line 2025 to expand to draw blood into the expandable portion 3210 through the upstream one-way check valve 3235 and (2) subsequent normalized pressure in the chamber 3220 to permit the expandable portion 3210 to contract to expel blood from the expandable portion 3210 through the downstream one-way check valve 3235. EX1006, ¶¶[0136]-[0137]; EX2003, ¶¶[0090]-[0091]. So, like a peristaltic pump or a centrifugal pump, the pump device 3250 operates to pull blood through an inlet and subsequently expel blood through an outlet. The pump device is "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" by operating the vacuum source so as to oscillate the expandable portion between the expanded and retracted states to, together with the one-way check valves, thereby drive fluid through the flow line. EX1006, ¶¶[0136]-[0137]; EX2003, ¶¶[0090]-[0091]. Thus, a POSITA would understand that the pump device 3250 is designed to continuously operate to shuttle blood into the inlet and out of the outlet without delay. If a user-actuatable valve were incorporated into the system distal of the pump inlet (between the pump and the catheter), the valve would prevent the continuous operation of the pump device 3250 to move

blood therethrough when the valve is closed to disconnect the pump device 3250 from the catheter.

59. In contrast to the illustrated embodiments with an aspiration pump, such as a peristaltic pump or the pump device of Figure 36, Garrison discloses that:

> 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.

EX1006, ¶[0134]; EX2003, ¶[0088]. In this embodiment, the locking syringe is actuated with the connection to the flow line closed such that vacuum is generated in the syringe. Garrison (but not the Garrison '788 publication) provides data for the measured aspiration rates through various-sized catheters using this syringe methodology in paragraph [0129] and Figures 56-57.

E. Person of Ordinary Skill in the Art

60. My opinion on the level of ordinary skill in the art is based upon my personal knowledge and experience as well as my consideration of such things as the education and experience level of persons of skill working in the field. I disagree that a POSITA would have had only "an undergraduate degree in mechanical engineering or a related engineering discipline and 2-4 years of catheter design experience." Paper 2, p.20. Nevertheless, I apply Petitioner's

standard throughout my declaration as, even under this standard, a POSITA would have understood the Claims of '691 Patent to be patentable over the prior art references cited in Grounds 1–8. I was also at least a person of ordinary skill in the art as of the priority date of the '691 Patent according to this standard.

VI. GROUND 1: GARRISON DOES NOT ANTICIPATE CLAIMS 1-2, 5-6, 10-11, AND 13

61. I understand that Petitioner and its expert, Mr. Thornton, allege that Garrison discloses each and every feature of Claims 1-2, 5-6, 10-11, and 13 of the '691 Patent and therefore anticipates these claims. I disagree.

62. A POSITA would understand that Garrison does not anticipate Claim 1 because it does not disclose the aspiration system of Claim 1 including "an aspiration pump in communication with a first chamber" wherein (1) "the valve is configured to be closed while negative pressure is generated in the first and second chambers, and wherein the valve is configured to be opened after the negative pressure is generated in the first and second chambers" [limitation [1D] identified by Petitioner] or wherein (2) "upon user actuation to open the valve with the negative pressure having been generated in the first and second chambers, fluid flow at least partially from the second chamber into the first chamber causes rapid aspiration into the second chamber" [limitation [1E] identified by Petitioner], as recited in Claim 1. Because Claims 2, 5-6, 10-11,

and 13 depend from Claim 1 and include all the limitations from Claim 1, those claims are also not anticipated by Garrison.

63. As I explained above, for a patent claim to be anticipated, each claim limitation must be present in a single piece of prior art. It is my understanding from counsel that a prior art reference can anticipate a claimed invention if the prior art reference disclosed each of the claimed limitations of the invention either expressly or inherently.

A. Garrison Does Not Disclose "Wherein the Valve Is Configured to be Closed While Negative Pressure Is Generated in the First and Second Chambers, and Wherein the Valve Is Configured to be Opened After the Negative Pressure Is Generated in the First and Second Chambers" as Recited in Claim 1

1. Garrison discloses an aspiration pump that generates positive pressure in a "first chamber" rather than negative pressure, or a "first chamber" that remains at atmospheric pressure if it is vented.

64. Petitioner points to embodiments shown in and described with reference to Figures 32-36 of Garrison to support its assertion that Garrison anticipates Claim 1. Paper 2, pp.24-29. However, where Garrison discloses an aspiration pump in the embodiments identified by Petitioner—whether a peristaltic pump as shown in Figures 32-34, a centrifugal pump, or the pump device 3250 shown in Figure 36—the pump is positioned to draw fluid through an inlet and to expel the fluid out of an outlet via positive pressure to a downstream delivery location such as a receptacle or blood return line. A POSITA would

understand that such a pump would not and could not generate negative pressure in the downstream delivery location—and therefore would not generate negative pressure in a "first chamber" identified by Petitioner. A POSITA would further understand that Garrison's arrangement with an aspiration pump allows the blood to be easily discarded from the system via the receptacle or reintroduced into the patient from the receptacle without disconnecting the aspiration source, and that it would not be desirable to modify the system so that the receptacle has a negative pressure.

65. First, with reference to Figures 32-33 of Garrison, Petitioner argues that the source of aspiration 3125/3425 and the receptacle 3100/3105 disclose an "aspiration source" and a "first chamber," respectively. Paper 2, p.28. However, a POSITA would understand that the receptacle 3100/3105 cannot be the "first chamber" because when the source of aspiration 3125/3425 is a pump, the pump is a peristaltic pump (commonly referred to as a roller pump) positioned upstream of the receptacle 3100/3105 that delivers fluid to the receptacle 3100 via positive pressure:

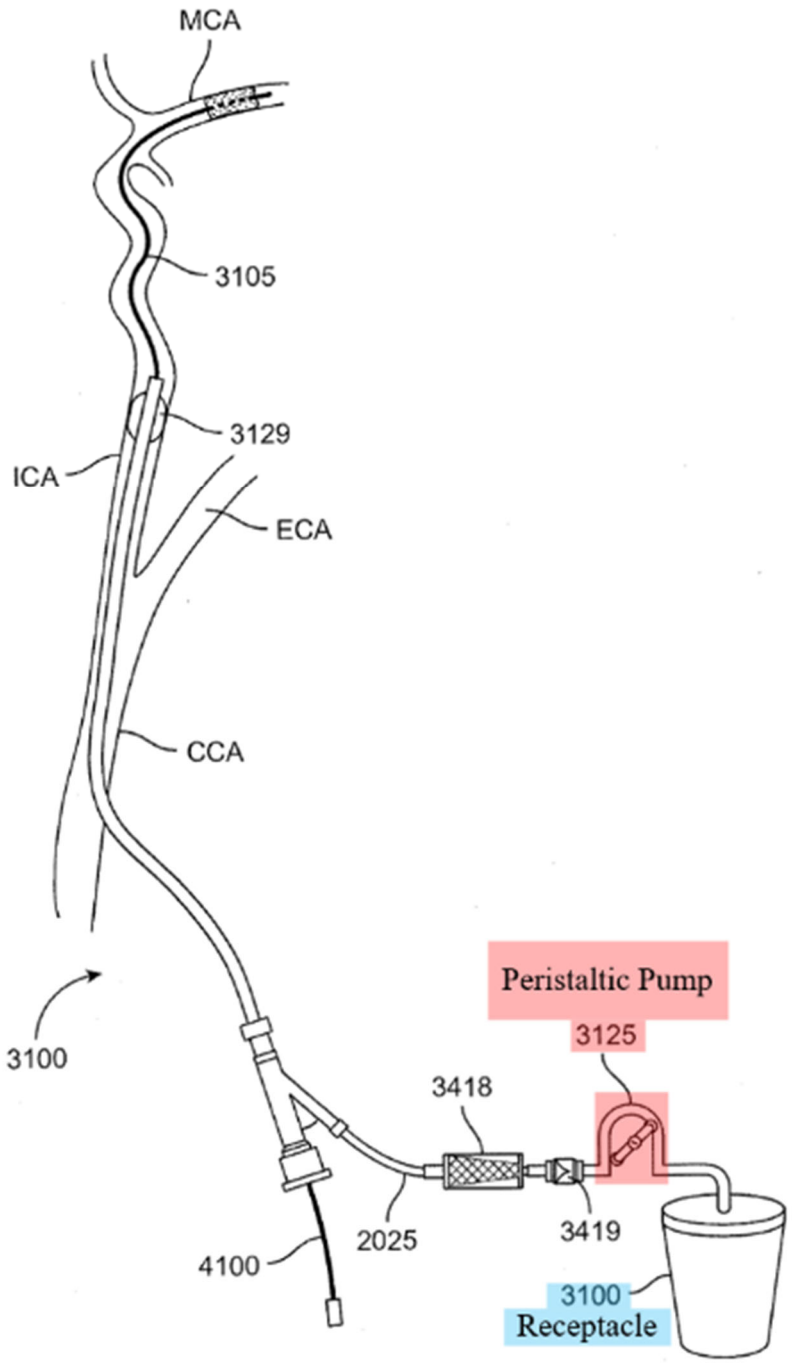

MCA
3105
3129
ICA
ECA
CCA
3100
Peristaltic Pump
3125
3418
3419
2025
4100
3100
Receptacle

FIG. 32

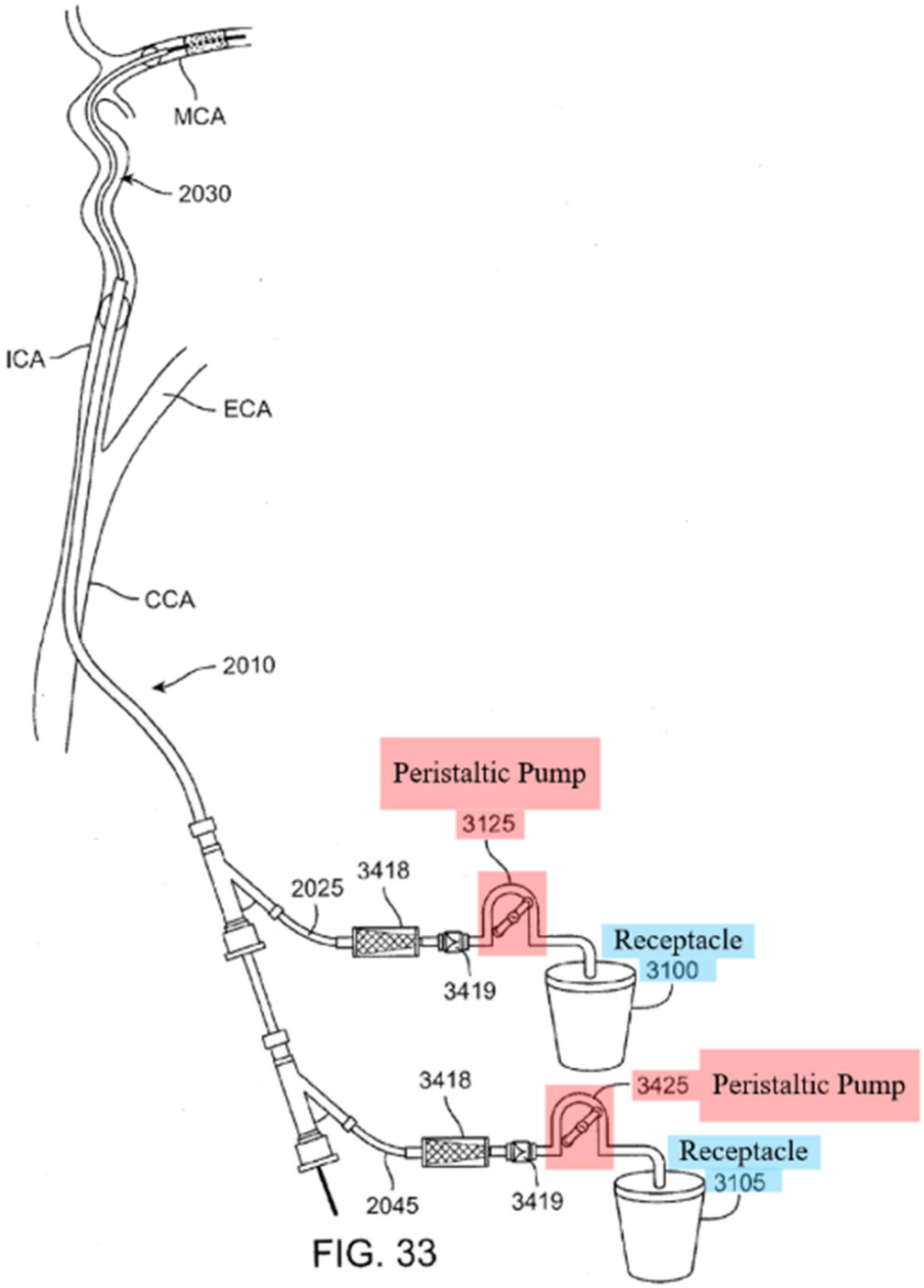


FIG. 33

66. As I explained in §V.D. above, a POSITA would recognize the aspiration source 3125/3425 as a peristaltic pump based on its depiction including

compressible tubing and a rotatable shaft connected to a rotor that carries multiple rollers for compressing the tubing:

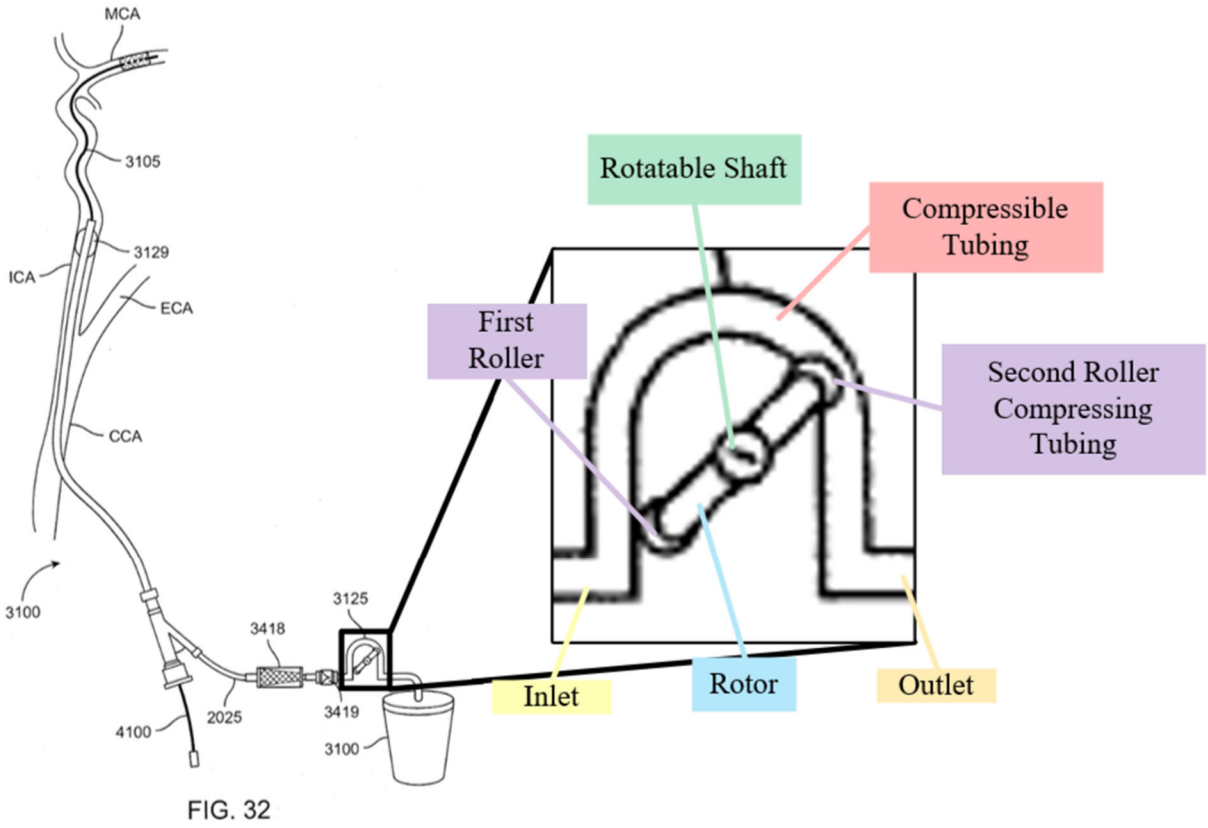


FIG. 32

67. A POSITA would further understand the peristaltic pump to operate by rotating the shaft to rotate the rotor such that the rollers compress the tubing to: (1) generate negative pressure to draw fluid through the flow line 2025 through the inlet of the pump (labeled above), (2) transport the fluid through the pump, and (3) expel the fluid through the outlet of the pump (labeled above) for delivery to the receptacle 3100/3105. As a result, negative pressure is only generated on the inlet side of the pump (e.g., toward the catheter) and positive

pressure is generated on the outlet side of the pump (e.g., toward the receptacle).

68. A POSITA would understand that with this arrangement, the pump cannot generate negative pressure downstream of the outlet, such as in the receptacle. Instead, the pump would generate positive pressure in the receptacle if it were sealed, or the receptacle would remain at atmospheric pressure if the receptacle were vented. So, even if a valve (e.g., the valve 3325 of Figure 34 of Garrison) was incorporated into the embodiments of Figures 32-33, the peristaltic pump 3125/3425 would prevent negative pressure from being built up in the receptacle 3100/3105 when the valve was closed and would instead (1) build up positive pressure in the receptacle via its fluid connection to the positive pressure outlet of the pump if the receptacle was sealed or (2) maintain atmospheric pressure in the receptacle if the receptacle was vented. That is, with the peristaltic pump positioned upstream of the receptacle, positive pressure rather than negative pressure is generated in the receptacle. Or, the receptacle remains, at most, at atmospheric pressure if vented to atmosphere.

69. While Garrison discloses that the "receptacle 3100 and source of aspiration 3125 may be separate or may be combined into a single device such as a syringe," the syringe is the only example of such a combined device. EX1006, ¶[0131]. As I explained above in §V.A., nowhere does Garrison disclose a

combination of the receptacle 3100/3105 and the aspiration pump 3125/3145 in which the aspiration pump is positioned to somehow generate negative rather than positive pressure or atmospheric pressure in the receptacle.

70. A POSITA would understand that Garrison's disclosure that the "receptacle 3100 and source of aspiration 3125 may be separate or may be combined into a single device such as a syringe," (EX1006, ¶[0131]), means the receptacle and the source of aspiration can be combined in a single device. A POSITA would not understand it to mean that when the source of aspiration is an aspiration pump, the receptacle and aspiration pump are combined and reconfigured such that negative pressure is generated in the receptacle in contrast to the disclosed embodiments of an aspiration pump in Garrison. That is, even if one were to combine the receptacle with the aspiration pump, there is no suggestion in Garrison to change the order of these components.

71. Second, with reference to Figure 34 of Garrison, Petitioner argues that the aspiration source 3430 discloses an "aspiration source" and a "first chamber." Paper 2, p.27. But, for the same reasons I discussed above for Figures 32 and 33, a POSITA would understand that when the source of aspiration is a pump, it is positioned upstream of the receptacle to deliver fluid to the receptacle via positive pressure such that negative pressure is not generated in the receptacle, and the pump cannot generate negative pressure in that chamber:

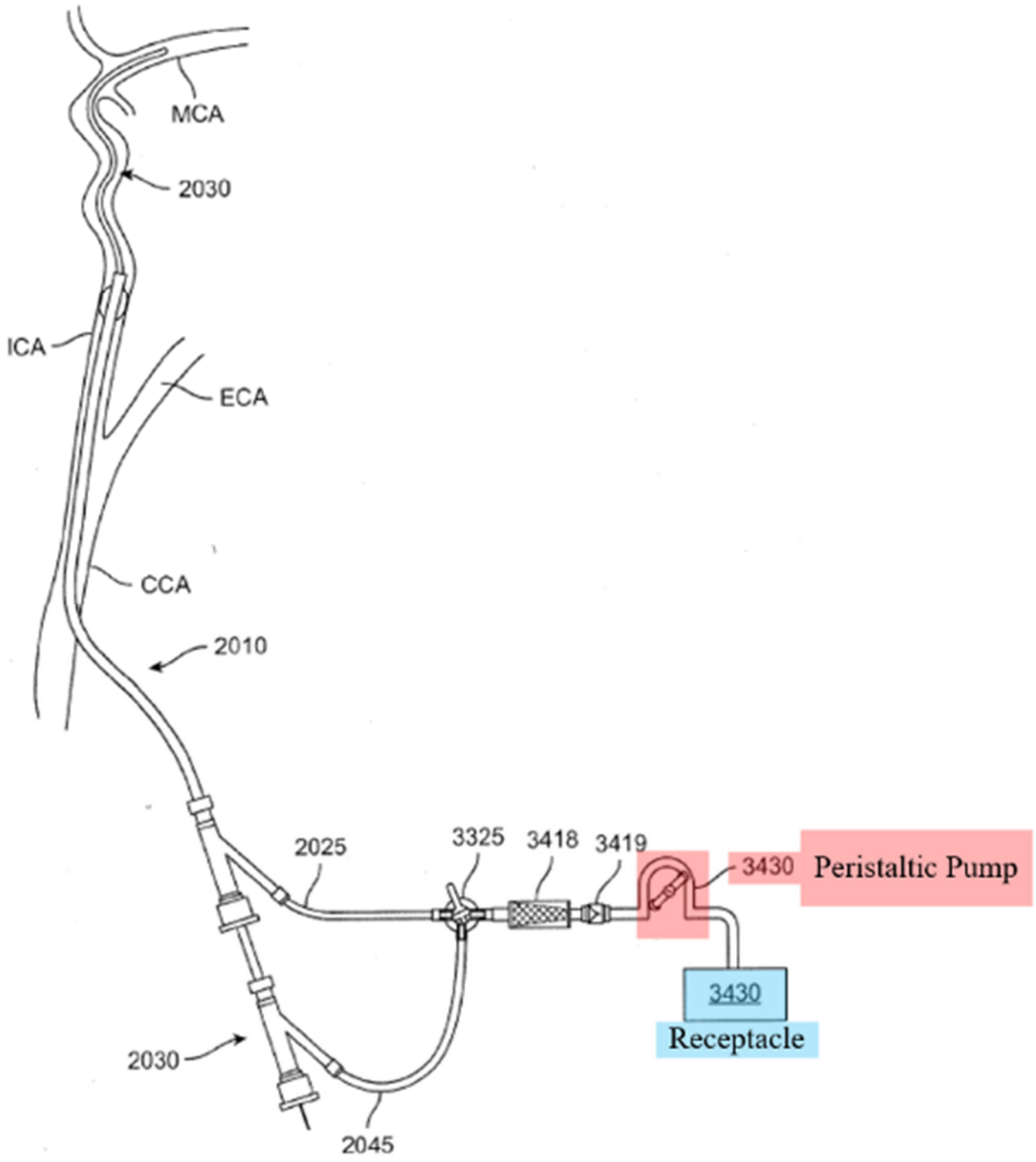


FIG. 34

72. Third, Garrison explains that "pumps such as centrifugal or peristaltic pumps are known to cause damage to blood cells" before disclosing an aspiration pump device 3250 in Figure 36 that "is configured not to harm blood cells." EX1006, ¶¶[0135]-[0136]. A POSITA would understand based on this disclosure that the pump shown in Figures 32-34 of Garrison could be the illustrated

peristaltic pump, a centrifugal pump, or the pump shown in Figure 36, as each of these pumps operates similarly to draw fluid into an inlet and expel the fluid out of an outlet.

73. For example, centrifugal pumps operate to draw fluid into an outlet and push the fluid out of an outlet by the rotation of an impeller. A POSITA would understand that using a centrifugal pump instead of the peristaltic pump shown in Figures 32-34 would have the same result of generating positive pressure rather than negative pressure in the downstream receptacle (or maintaining atmospheric pressure if the receptacle were vented) because the centrifugal pump pushes fluid from the outlet to the receptacle via the connection between those components. In other words, the centrifugal pump would provide the same overall functionality as the peristaltic pump for pressure generation in Garrison's system.

74. A POSITA would also understand that the pump device 3250 illustrated in Figure 36 of Garrison would operate to pressurize Garrison's system in the same manner as the peristaltic pump and centrifugal pump. For example, the pump device 3250 would generate positive pressure in the downstream receptacle (or no pressure if the receptacle were vented) in Garrison's system if it were substituted for the peristaltic pump shown in Figures 32-34. Namely, the pump device 3250 operates to cause "blood to be pulled into the expandable

portion 3210 from the sheath side of the flow line, shown by the 'in' arrow, as controlled by the check valves 3235 … [and t]he check valves 3235 cause[] the blood within the previously-expanded region of the flow line 2025 to be expelled towards location 3120, as shown by the 'out' arrow in FIG. 36." EX1006, ¶[0137]. Thus, like a peristaltic pump and a centrifugal pump, the pump device 3250 operates to pull blood through an inlet and subsequently expel the blood out of an outlet in a manner that would pressurize a down-stream receptacle rather than generate negative pressure therein.

75. I understand that Petitioner further argues that the chamber 3220 of the pump device 3250 is the "first chamber" recited in Claim 1. Paper 2, p.29. A POSITA would understand that this cannot be the case, however, because the chamber 3220 is not "configured for placement into fluid communication with [the aspiration catheter] by way of an aspiration tube," as required by Claim 1. Instead, a POSITA would understand that the chamber 3220 cannot be in fluid communication with the catheter 2030 so that pressure changes in the chamber 3220 cause the expandable portion 3210 to expand and retract. Namely, with the chamber 3220 out of fluid communication with the flow line 2025 (which is in fluid communication with the arterial access device or the smaller inner catheter): (1) negative pressure in the chamber 3220 acts exter-nal to the expandable portion 3210 to cause the expandable portion 3210 of

the flow line 2025 to expand to draw blood into the expandable portion 3210 and (2) equalized pressure in the chamber 3210 acts external to the expandable portion 3210 to permit the expandable portion 3210 to contract to expel blood from the expandable portion 3210:

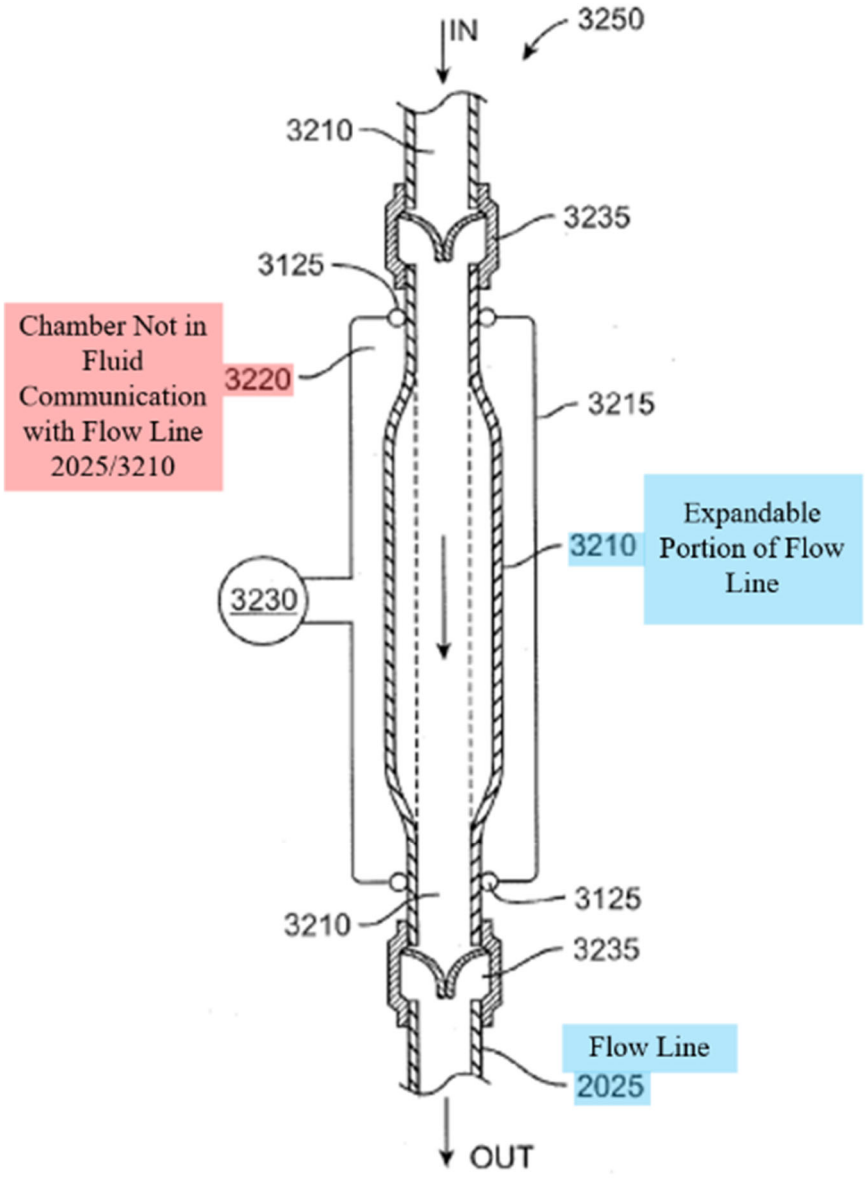


FIG. 36

EX1006, ¶[0137]. If the chamber 3220 were in fluid communication with the arterial access device or smaller inner catheter, the chamber 3220 would apply these pressure changes to the lumen of the catheter itself and not external to the flow line. This would prevent the expandable portion of the flow line from either expanding or retracting.

76. It is therefore my opinion that a POSITA would understand that whenever Garrison discloses a pump—whether a peristaltic pump as shown in Figures 32-34, a centrifugal pump, or the pump device 3250 shown in Figure 36—the pump is positioned to draw fluid through an inlet and expel the fluid out of an outlet via positive pressure to a downstream delivery location, such as a receptacle. That configuration would not generate negative pressure in a downstream receptacle and would instead generate positive pressure if the receptacle were sealed or generate no pressure change if the receptacle were vented. In my opinion, Garrison does not disclose the aspiration system of Claim 1 including "an aspiration pump in communication with a first chamber" and "the valve is configured to be closed while negative pressure is generated in the first and second chambers, and wherein the valve is configured to be opened after the negative pressure is generated in the first and second chambers."

2. Garrison's locking syringe embodiments do not disclose the generation of negative pressure in first and second chambers in a system with an aspiration pump.

77. A POSITA would understand that the syringe-related embodiments cited by Petitioner (Paper 2, pp.45-47) do not demonstrate that Garrison discloses a system with an aspiration pump in which negative pressure is generated in first and second chambers when a valve is closed. First, as I explained above in §V.A., a POSITA would understand that Garrison discloses a syringe as a distinct alternative to an aspiration pump. EX1006, ¶[0134].

78. Second, that the aspiration source could be an aspiration pump rather than a syringe does not indicate to a POSITA that negative pressure would be generated in any of Garrison's first chambers (e.g., receptacles 3100/3105, 3430, 3220) when an aspiration pump is used. As I explained in §VI.A.1. above, while Garrison discloses that the pump could be replaced with a syringe, Garrison discloses that when a pump is used the pump is positioned to draw fluid through an inlet and expel the fluid out of an outlet to a downstream receptacle via positive pressure. The pump would not generate vacuum pressure in the receptacle in this arrangement.

79. Garrison also identifies that a drawback of using a syringe is that the syringe needs to be "disconnect[ed]" and "remove[d] and empt[ied]" in contrast to when the system includes a "continuous source of aspiration" and a

downstream "collection receptacle such as [a] blood-collection bag." EX1006, ¶[0134]. That is, having the downstream receptacle advantageously permits blood to be continuously aspirated and delivered to the receptacle without the need to disconnect the aspiration pump. This is the case for the peristaltic pump embodiments and the embodiments using the pump device 3250 of Figure 36.

80. And, although Garrison discloses that the pump and receptacle could be combined, a POSITA would understand that Garrison only discloses embodiments in which the pumps are upstream of the various receptacles (e.g., numbered as 3100/3104/3220/3430 in Figures 32-34). The alleged first chambers are not disclosed as upstream of the aspiration source or otherwise configured to have negative pressure.

B. Garrison Does Not Disclose "Wherein Upon User Actuation to Open the Valve with the Negative Pressure Having Been Generated in the First and Second Chambers, Fluid Flow at Least Partially from the Second Chamber into the First Chamber Causes Rapid Aspiration into the Second Chamber" as Recited in Claim 1

81. As I explained above in §VI.A., Garrison does not disclose a system including an aspiration pump in which negative pressure is generated in first and second chambers with a valve closed. Because Garrison does not disclose this limitation of Claim 1, a POSITA would understand that Garrison also does not disclose "wherein upon user actuation to open the valve with the negative

pressure having been generated in the first and second chambers, fluid flow at least partially from the second chamber into the first chamber causes rapid aspiration into the second chamber" as recited in Claim 1.

82. I understand that Petitioner asserts that "[o]nce the user generates the negative pressure and positions the tip of the aspiration catheter near the occlusion, 'the user may open the connection to the aspiration syringe' **or other negative pressure source**," citing paragraph [0134] of Garrison. Paper 2, p.37. However, Garrison does not disclose opening the connection to an "other negative pressure source" with vacuum pressure having been generated in first and second chambers. Instead, Garrison discloses that "the user may open the connection to the **aspiration syringe**." EX1006, ¶[0134] (emphasis added). That is, Garrison discloses opening a connection between a syringe that is under pressure and a catheter and not the connection between any other negative pressure source and the catheter.

83. Finally, a POSITA would understand that Petitioner's annotations to Figure 34 of Garrison to purportedly show the claimed rapid aspiration and fluid flow when the valve is opened ignore the placement of the peristaltic pump shown in Figure 34 that would prevent negative pressure from being generated in the receptacle:

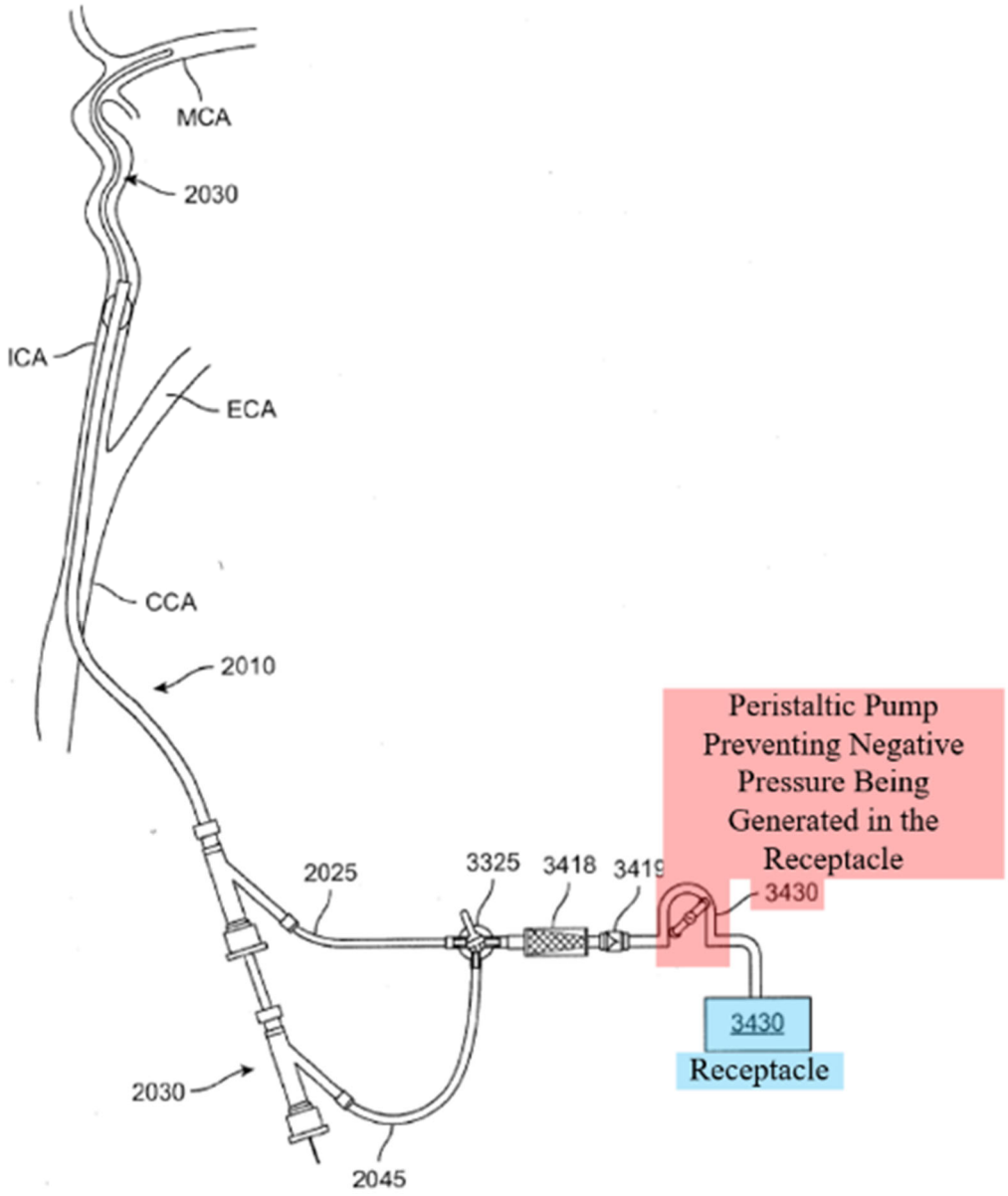


FIG. 34

VII. GROUND 2: CLAIMS 1-2, 4-6, 9-20, AND 28-30 ARE NOT OBVIOUS OVER GARRISON ALONE

84. I understand that Petitioner and its expert, Mr. Thornton, allege that Garrison alone renders obvious Claims 1-2, 4-6, 9-20, and 28-30 of the '691 Patent (Ground 2). I disagree.

85. I understand that the only assertion in the petition that Garrison renders Claim 1 is that Garrison anticipates Claim 1. Paper 2, p.24. However, as I explained above in §VI., Garrison does not anticipate Claim 1 because it does not disclose "an aspiration pump in communication with a first chamber" wherein (1) "the valve is configured to be closed while negative pressure is generated in the first and second chambers, and wherein the valve is configured to be opened after the negative pressure is generated in the first and second chambers" and wherein (2) "upon user actuation to open the valve with the negative pressure having been generated in the first and second chambers…." Therefore, Garrison does not render Claim 1 (and its dependent claims) obvious because it does not anticipate Claim 1.

86. Independent Claims 14 and 28 include those same limitations of Claim 1 discussed above. I understand that Petitioner relies on the same arguments for Garrison disclosing those limitations as for Claim 1. Paper 2, pp.79-80 & 86. Therefore, for the same reason that Garrison does not anticipate these claims, Garrison does not render obvious independent Claims 14 and 28 (and their dependent claims).

87. Nevertheless, it is my opinion that Garrison alone does not render these claims obvious because a POSITA would not have modified any of the various embodiments of Garrison to arrive at the claimed features. For a patent claim to

be rendered obvious, I understand that the differences between the claimed invention and the prior art must be such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. And, for a patent claim to be rendered obvious over a single reference (as is the case here for Petitioner's arguments relating to Garrison for all independent claims related to the limitations at issue), there must be a motivation to combine multiple embodiments in the single reference and a reasonable expectation that the combination would be successful, otherwise a POSITA would not have been motivated to arrive at the claimed combination. A prior art reference teaches away from a modification of a prior art reference when a person of ordinary skill in the art would be discouraged from following the path set out in the reference or would be led in a direction divergent from the path followed by and claimed in the patent.

88. A POSITA would not have modified Garrison's peristaltic pump embodiments (Figures 32-34) to arrive at the claimed features. For example, a POSITA would not have found it obvious to switch the order of the pump and the receptacle, such that the receptacle has negative pressure, even if the pump and receptacle were combined in a single device. Specifically, a POSITA would understand that Garrison positions its peristaltic pump upstream of the

receptacle so that the peristaltic pump effectively delivers aspirated blood to the "delivery location" of the receptacle. EX1006, ¶[0131]. In other words, the peristaltic pump is positioned to push blood to the receptacle. The blood delivered to the receptacle can then be returned to the patient or discarded without disconnecting the aspiration source. *Id*. at ¶¶[0134]-[0135]. A POSITA would understand that if the receptacle were upstream from the aspiration source in order to generate negative pressure in the receptacle, it would not be possible to discard or return the blood in the receptacle without disconnecting the aspiration source contrary to Garrison. Additionally, a POSITA would understand the peristaltic pump to be well suited for delivering blood to the downstream receptacle because the blood remains entirely within the tubing as it moves through the peristaltic pump and does not directly contact any of the pump parts. This specific property of a peristaltic pump would allow the pump to be easily reused in subsequent medical procedures because the tubing could be discarded while all the functional components of the pump (e.g., shaft, rotor, rollers, motor, etc.) could be retained for reuse without exposure to blood for another medical procedure.

89. A POSITA would also not have modified Garrison's embodiment in Figure 36 including the pump device 3250 to arrive at the claimed features. Instead, a POSITA would understand Garrison to teach away from using the pump

device 3250 in a manner that would cause negative pressure to form in a first chamber and a second chamber while a valve is closed. For example, Garrison discloses that the pump device 3250 is "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." EX1006, ¶[0136]. To achieve this, the vacuum source 3230 is "operated so as to oscillate the expandable portion 3210 between the expanded and retracted state and together with the one-way check valves 3235 thereby drive fluid through the flow line lumen 3210." *Id*. at ¶[0137]. If the pump device 3250 were incorporated into a system including a user-actuatable valve, at least some blood would remain static within the system when the valve is closed and cuts off fluid flow. Additionally, a POSITA would understand that it would be untenable to open and close the user-actuatable valve between individual oscillations of the expandable portion 3210. That would require user input to open/close the valve at each oscillation, greatly slowing the procedure and hindering or eliminating the "real time" aspect of the intended system in which the vacuum source oscillates the expandable portion such that no blood remains static within the system.

90. In paragraph 91, I understand that Mr. Thornton alleges that a POSITA would have expected success in combining various components of Garrison and specifies, for example, "where Garrison specifically discloses an exemplary

system that uses a syringe, a person of ordinary skill in the art would have recognized that other pressure sources could be used including, for example, an aspiration pump." EX1003, ¶91 (citing EX1006, ¶[0175]). As I explain in §VI.B. above, that the aspiration source could be an aspiration pump rather than a syringe does not demonstrate to a POSITA that negative pressure would or could be generated in a first chamber with the vacuum pump. Garrison discloses several systems with a pump, but in each one the pump is positioned to draw fluid through an inlet and expel the fluid out of an outlet to a downstream receptacle (the alleged "first chamber") via positive pressure such that the pump would not and could not generate vacuum pressure in the receptacle.

91. Mr. Thornton does not provide any motivation as to why a POSITA would modify Garrison to arrive at the features of Claim 1, nor does Mr. Thornton explain how or why a POSITA could or would modify the embodiments of Garrison to include a system with an aspiration pump in which negative pressure is generated in a "first chamber" contrary to the disclosure of Garrison. A POSITA would not have been so motivated for the reasons I explain above to, for example, maintain the ability of the system to deliver blood to a receptacle for subsequent return to the patient or discard without disconnecting the aspiration source and/or to return blood in real time to the patient.

VIII. GROUNDS 3-8: CLAIMS 3, 4, 7-9, 11-12, 14-31 ARE NOT OBVIOUS OVER GARRISON IN VIEW OF HARTLEY (GROUND 3),

GARRISON IN VIEW OF GOFF (GROUND 4), GARRISON IN VIEW OF AKLOG (GROUND 5), GARRISON IN VIEW OF AKLOG AND HARTLEY (GROUND 6), GARRISON IN VIEW OF AKLOG AND GOFF (GROUND 7), OR GARRISON IN VIEW OF HARTLEY AND GOFF (GROUND 8)

92. As I explained above in § VII., independent Claims 14 and 28 include the same key limitations found in Claim 1, and Petitioner relies on the same arguments of Garrison disclosing those limitations as for Claim 1. Paper 2, pp.79-80 & 86. Independent Claim 23 includes those same key limitations, and Petitioner likewise relies on their same arguments as for Claim 1 for this claim. *Id*. at p.83.

93. Therefore, for the same reason that Garrison does not anticipate these claims (Petitioner's only argument for the obviousness of the key limitations), Garrison does not render obvious independent Claims 1, 14, 23, and 28 (and their dependent claims).

94. Because of the deficiencies of Garrison, I do not analyze the details of the other applied references Hartley, Aklog, and Goff. Nevertheless, I reserve my right to further review and assess any independent reasons of patentability for the claims in view of these references.

IX. THE DISCLOSURE OF GARRISON RELIED ON IN THE PETITION IS IDENTICAL AND CUMULATIVE TO THE DISCLOSURE IN

THE GARRISON ’788 PUBLICATION.

95. I understand that the Patent Office considered U.S. Patent Application Publication No. 2013/0281788 (EX2003; “the Garrison ’788 publication”) during prosecution of U.S. Patent Application No. 17/865,315 (“the ’315 Application”), which is a parent of the ’691 Patent. EX2002, pp. 64-70, 102. Below, I provide a side-by-side comparison of (a) the portions of Garrison cited in the petition with reference to independent Claims 1, 14, 23, and 28 with (b) the corresponding disclosure of the Garrison ’788 publication. As shown in the comparison, there is substantial overlap in subject matter.

96. The disclosure of Garrison cited by Petitioner is substantively the same as and cumulative of the disclosure in the Garrison ’788 publication. Notably, Figures 32-36 and paragraphs [0131]-[0136] are the primary portions of Garrison (EX1006) relied on by Petitioner for allegedly disclosing the features of Claim 1 as I discuss in detail above in §VI. (e.g., an aspiration system including “an aspiration pump in communication with a first chamber” wherein “the valve is configured to be closed while negative pressure is generated in the first and

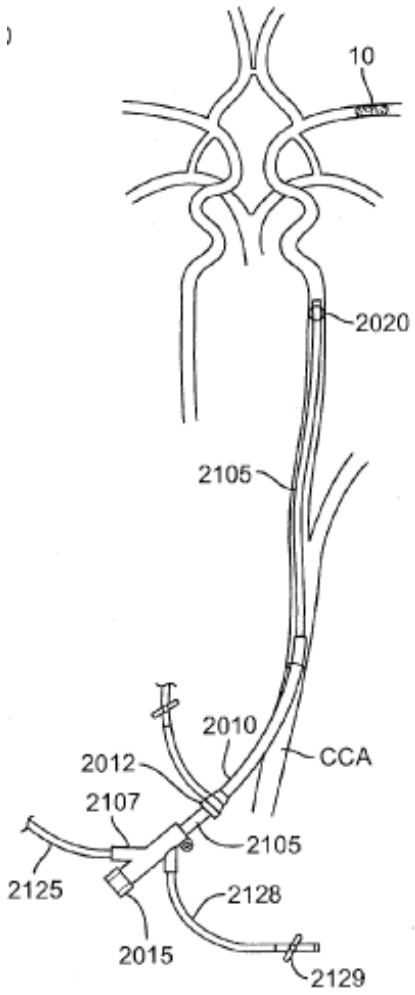
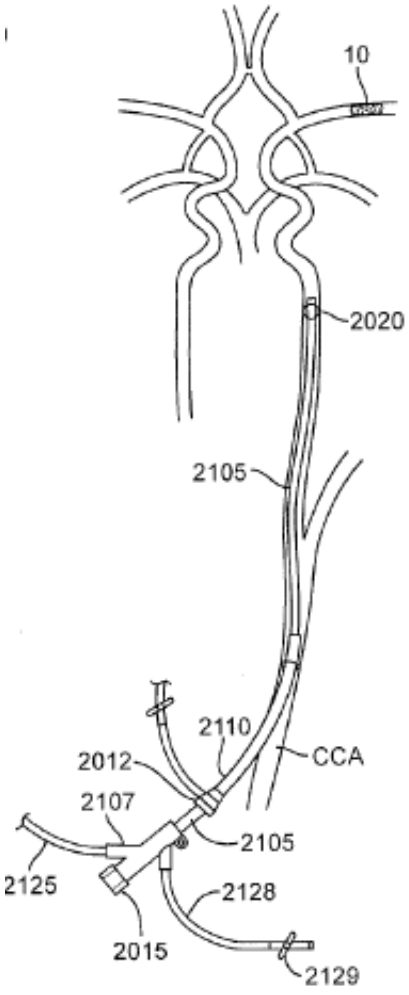
second chambers), and are exactly reproduced in the Garrison '788 (EX2003) publication as Figures 15-19 and paragraphs [0085]-[0090].[1]

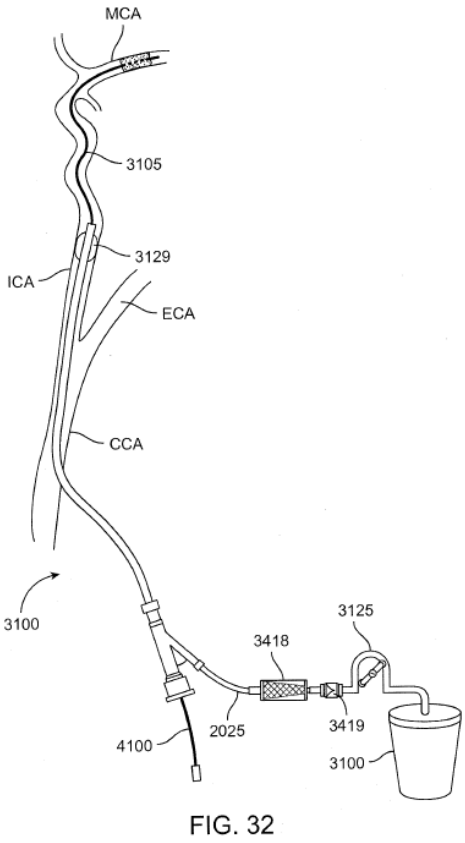
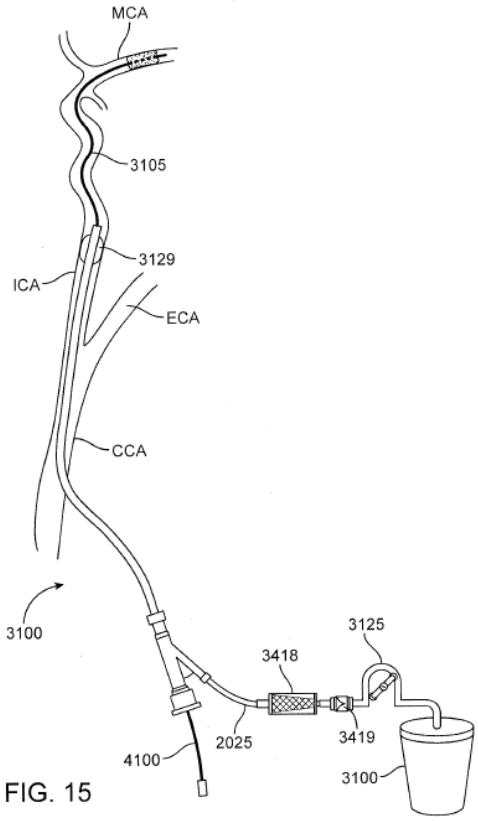
97. While paragraph [0129] of Garrison is not directly found in the Garrison '788 publication, that paragraph does not recite any prior art components, structure, or functions different than what is found in paragraph [0134] of Garrison (and which is identical to paragraph [0088] of the Garrison '788 publication). Rather, paragraph [0129] of Garrison discloses a description of testing the flow rates of systems with different catheter sizes to determine aspiration rates using the locking syringe methodology described in paragraph [0134] of Garrison. It provides no discussion of pump embodiments, and no additional discussion of the first chamber (the receptacle) at all, much less any motivation to modify the system illogically to generate negative pressure in the receptacle. This discussion is superfluous to the arguments in the petition, particularly for the first and second chamber limitations. As such, this paragraph does not provide any non-cumulative disclosure of prior art components, structures, or

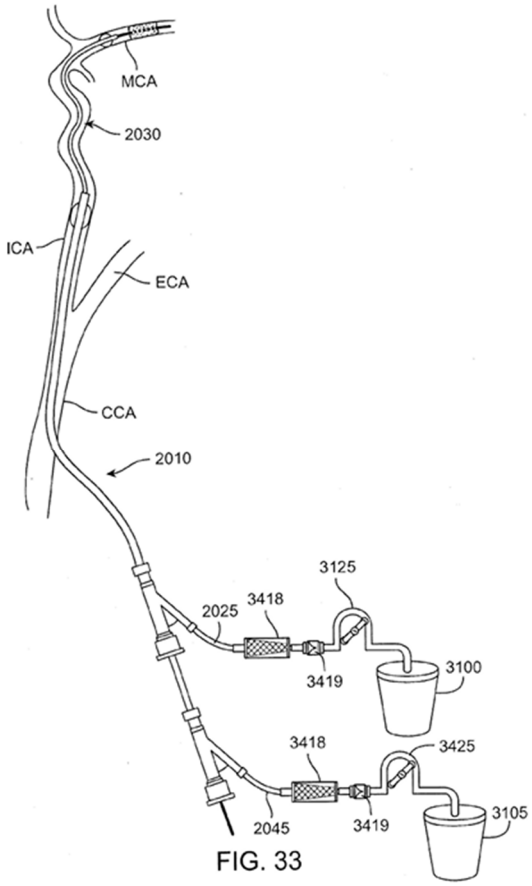
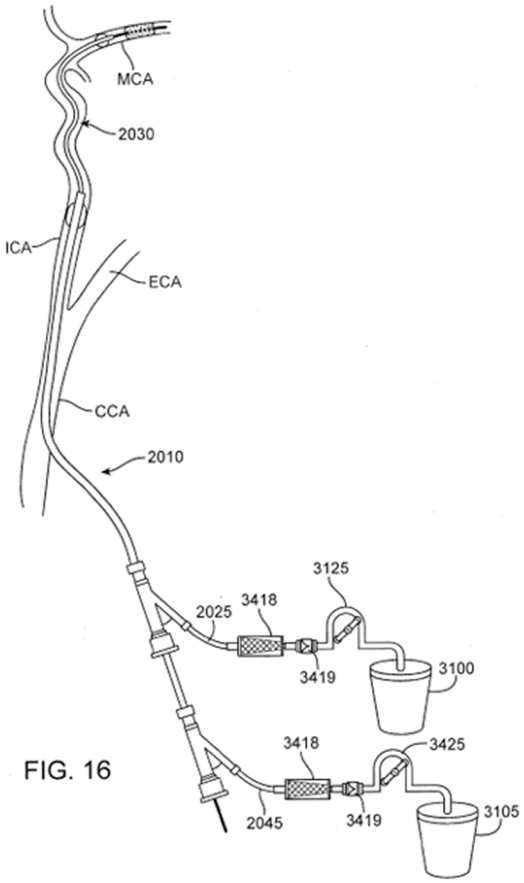
[1] The differences are the references to the different figure numbers, and the correction of a minor typographical error in paragraph [0085] of Garrison (changing "may coupled" to "may <u>also be</u> coupled").

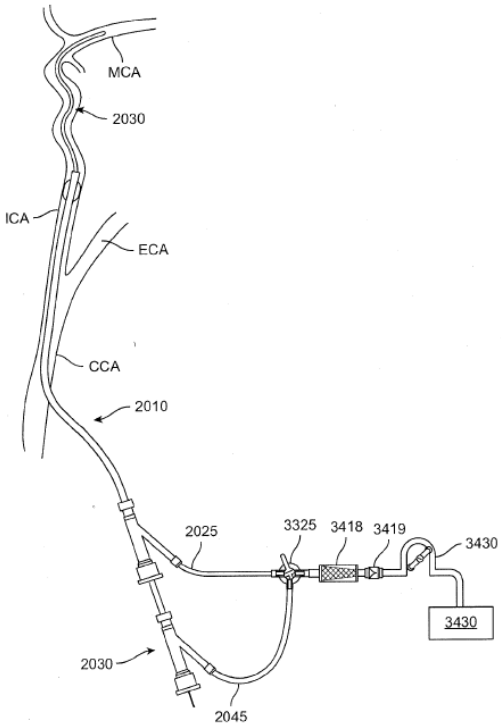
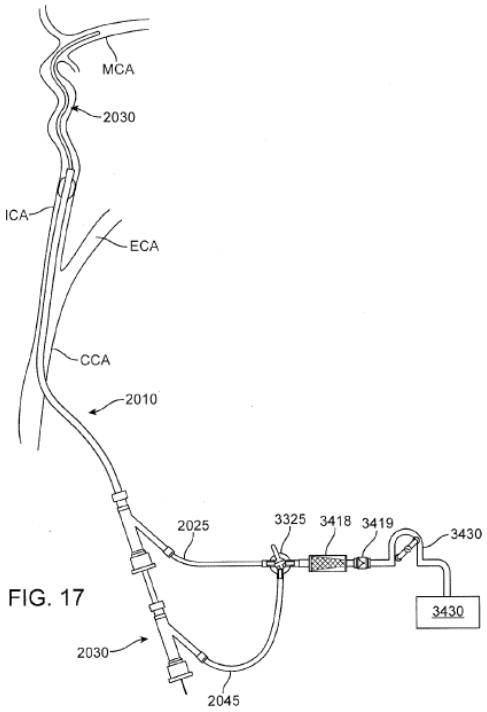
functions over paragraph [0134] of Garrison which describes the same methodology, just not the tested aspiration rates using that methodology.

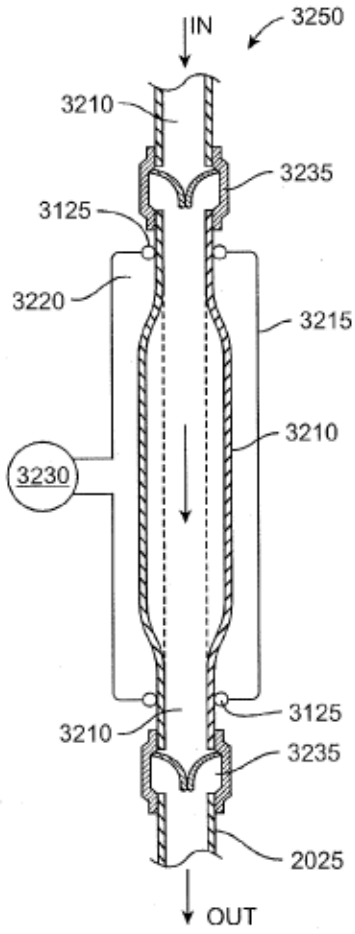
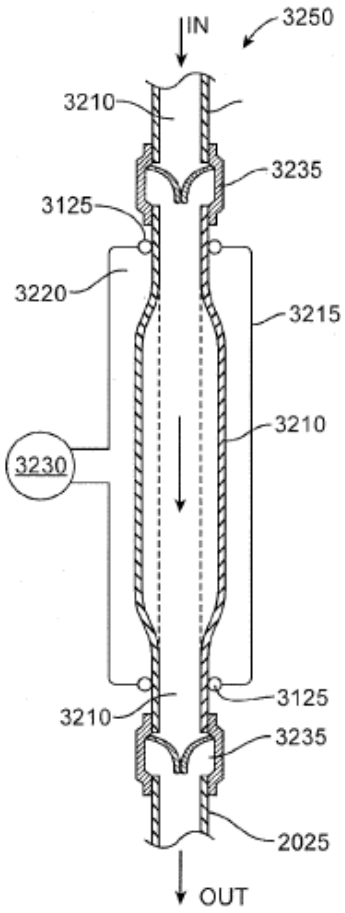
98. The table below provides a side-by-side comparison between (a) the portions of Garrison cited in the petition with reference to independent Claims 1, 14, 23, and 28 and (b) the corresponding disclosure of the Garrison ’788 publication that demonstrates that they are substantively the same in relevant part:

Disclosure of Garrison (EX1006) Relied on By Petitioner for Claims 1, 14, 23, and 28	Corresponding Disclosure of the Garrison '788 Publication (EX2003)
 FIG. 3	 FIG. 2
See, e.g., Paper 2, p.33.	EX2003, fig.2.

Disclosure of Garrison (EX1006) Relied on By Petitioner for Claims 1, 14, 23, and 28	Corresponding Disclosure of the Garrison '788 Publication (EX2003)
 FIG. 32 *See, e.g.*, Paper 2, p.28.	 FIG. 15 EX2003, fig.15.

Disclosure of Garrison (EX1006) Relied on By Petitioner for Claims 1, 14, 23, and 28	Corresponding Disclosure of the Garrison '788 Publication (EX2003)
 FIG. 33	 FIG. 16
See, e.g., Paper 2, p.28.	EX2003, fig.16.

Disclosure of Garrison (EX1006) Relied on By Petitioner for Claims 1, 14, 23, and 28	Corresponding Disclosure of the Garrison '788 Publication (EX2003)
 FIG. 34 *See, e.g.*, Paper 2, p.27.	 FIG. 17 EX2003, fig.17.

Disclosure of Garrison (EX1006) Relied on By Petitioner for Claims 1, 14, 23, and 28	Corresponding Disclosure of the Garrison '788 Publication (EX2003)
 FIG. 36 *See, e.g.*, Paper 2, p.29.	 FIG. 19 EX2003, fig.36.
[0007] Disclosed are methods and devices that enable safe, rapid and relatively short transcarotid access to the cerebral and intracranial arteries to treat acute ischemic stroke. The methods and devices include one or more transcarotid access devices, catheters, and thrombectomy devices to remove the occlusion. Methods and devices are also included to provide	[0010] Disclosed are methods and devices that enable safe, rapid and relatively short and straight transcervical access to the cerebral arteries to treat acute ischemic stroke. The methods and devices include distal catheters and devices to remove the occlusion. Methods and devices are also included to provide aspiration and passive flow reversal for the purpose of

Disclosure of Garrison (EX1006) Relied on By Petitioner for Claims 1, 14, 23, and 28	Corresponding Disclosure of the Garrison '788 Publication (EX2003)
aspiration and passive flow reversal for the purpose of facilitating removal of the occlusion as well as minimizing distal emboli. The system offers the user a degree of flow control so as to address the specific hemodynamic requirements of the cerebral vasculature. The disclosed methods and devices also include methods and devices to protect the cerebral penumbra during the procedure to minimize injury to brain. In addition, the disclosed methods and devices provide a way to securely close the access site in the carotid artery to avoid the potentially devastating consequences of a transcarotid hematoma. *See, e.g.*, Paper 2, p.29.	facilitating removal of the occlusion as well as minimizing distal emboli. The system offers the user a degree of flow control so as to address the specific hemodynamic requirements of the cerebral vasculature. The disclosed methods and devices also include methods and devices to protect the cerebral penumbra during the procedure to minimize injury to brain. In addition, the disclosed methods and devices provide a way to securely close the access site in the carotid artery to avoid the potentially devastating consequences of a transcervical hematoma. EX2003, ¶[0010].
[0050] FIG. 1 shows a system of devices for accessing the common carotid artery (CCA) via a transcarotid approach and for delivering devices to the cerebral vasculature, for example an occlusion 10 in the cerebral artery. The system includes an arterial access device 2010 (sometimes referred to herein as an arterial access sheath) having an internal lumen and a port 2015. The arterial access device 2010 is sized and shaped to be inserted into the common carotid artery via a transcarotid incision or puncture and deployed into a position that provides access to the cerebral vasculature, for	[0045] FIG. 1 shows a system of devices for accessing the common carotid artery CCA via a transcervical approach and for delivering devices to the cerebral vasculature. The system includes an arterial access device 2010 (sometimes referred to as an arterial access sheath), such as a sheath, having an internal lumen and a port 2015. The arterial access device 2010 is sized and shaped to be inserted into the common carotid artery via a transcervical incision or puncture and deployed into a position that provides access to the cerebral vasculature, for example the common or internal carotid artery. The

Disclosure of Garrison (EX1006) Relied on By Petitioner for Claims 1, 14, 23, and 28	Corresponding Disclosure of the Garrison '788 Publication (EX2003)
example the common or internal carotid artery. The port 2015 provides access to the arterial access device's internal lumen, which is configured for introducing additional devices into the cerebral vasculature via the arterial access device 2010. *See, e.g.*, Paper 2, p.33.	port 2015 provides access to the arterial access device's internal lumen, which is configured for introducing additional devices into the cerebral vasculature via the arterial access device 2010. EX2003, ¶[0045].
[0051] FIG. 2 shows an alternate system embodiment, in which the arterial access device has an occlusion balloon 2020 that occludes the artery at the position of the sheath distal tip. As shown, the sheath is long enough to reach the distal cervical ICA from the transcarotid access site, but other embodiments may be shorter such that the occlusion balloon 2020 positioned in the CCA. *See, e.g.*, Paper 2, p.33	[0053] The arterial access device 2010 as shown in FIG. 1 is configured to be directly inserted into the common carotid artery CCA without use of a separate introducer sheath. In this configuration, the entry or distal tip of the device is tapered and includes a tapered dilator so as to allow smooth introduction of the device over a guide wire into the artery. The device 2010 may include an occlusion balloon 2020 which is configured to occlude the artery when inflated … EX2003, ¶[0053].
[0052] In an embodiment, transcarotid access to the common carotid artery directly with the arterial access device 2010 is achieved percutaneously via an incision or puncture in the skin. In an alternate embodiment, the arterial access device 2010 accesses the common carotid artery CCA via a direct surgical cut down to the carotid artery. In another embodiment, the arterial access device provides access to the basilar artery BA or posterior cerebral arteries PCA via a cut down	[0046] In an embodiment, transcervical access to the common carotid artery directly with the arterial access device 2010 is achieved percutaneously via an incision or puncture in the skin. In an alternate embodiment, the arterial access device 2010 accesses the common carotid artery CCA via a direct surgical cut down to the carotid artery. In another embodiment, the arterial access device provides access to the basilar artery BA or posterior cerebral arteries PCA via a cut down

Disclosure of Garrison (EX1006) Relied on By Petitioner for Claims 1, 14, 23, and 28	Corresponding Disclosure of the Garrison '788 Publication (EX2003)
incision in the vertebral artery or a percutaneous puncture of the vertebral artery for access to occlusions in the posterior cerebral vasculature such as the posterior cerebral artery or basilar artery. For entry into the common carotid artery, the arterial access device can be inserted into an opening directly in the common carotid artery, the opening being positioned above the patient's clavicle and below a bifurcation location where the patient's common carotid artery bifurcates into an internal carotid artery and external carotid artery. For example, the opening may be located at a distance of around 3 cm to 7 cm below a bifurcation location where the patient's common carotid artery bifurcates into an internal carotid artery and external carotid artery. *See, e.g.*, Paper 2, p.33.	incision to in the vertebral artery or a percutaneous puncture of the vertebral artery for access to occlusions in the posterior cerebral vasculature such as the posterior cerebral artery or basilar artery. The arterial access device may include an occlusion balloon, to block antegrade flow. For entry into the common carotid artery, the arterial access device is inserted into an opening directly in the common carotid artery, the opening being positioned above the patient's clavicle and below a bifurcation location where the patient's common carotid artery bifurcates into an internal carotid artery and external carotid artery. For example, the opening may be located at distance of around 5 cm to 7 cm below a bifurcation location where the patient's common carotid artery bifurcates into an internal carotid artery and external carotid artery. EX2003, ¶[0046].
[0053] The system may also include an intermediate guide catheter. FIG. 3 shows a guide catheter 2105 that is inserted through an arterial access sheath 2010 via the access device proximal hemostasis valve 2012. The guide catheter 2105 includes a proximal adaptor having a proximal port 2015 with a hemostasis valve to allow introduction of devices while preventing or minimizing blood loss during the procedure. The guide catheter 2105 may also include an	[0056] In an embodiment as shown in FIG. 2, the arterial access device is a guide catheter 2105 which is inserted through the proximal hemostasis valve 2012 of a separate introducer sheath 2110 into the CCA. The arterial access device also includes a proximal adaptor. This proximal adaptor includes a proximal port 2015 with a hemostasis valve, to allow introduction of devices while preventing or minimizing blood loss during the procedure. The guide

Disclosure of Garrison (EX1006) Relied on By Petitioner for Claims 1, 14, 23, and 28	Corresponding Disclosure of the Garrison '788 Publication (EX2003)
occlusion balloon 2020 at the distal region. *See, e.g.*, Paper 2, p.33.	catheter 2105 may include a lumen for balloon inflation. EX2003, ¶[0056].
[0059] In an alternate embodiment, the arterial access device 2010 may be configured for access to the common carotid artery CCA from a femoral artery access site, also without the use of a separate introducer sheath. As above, the access device includes a proximal adaptor with a proximal port 2015 with a hemostasis valve and a connection to a flow line 2025 (or shunt) which may be connected to means for passive or active reverse flow. The flow line 2025 has an internal lumen that communicates with an internal lumen of the arterial access device 2010 for shunting blood from the arterial access device. In both transfemoral and transcarotid embodiments, the connection to the flow line is optimized for aspiration of thrombus with flow lumens at least as large as the ID of the arterial access device 2010. *See, e.g.*, Paper 2, p.33.	[0053] In an alternate embodiment, this valve is an adjustable-opening valve such as a Tuohy-Borst or rotating hemostasis valve (RHV). The hemostasis valve may be integral to the proximal adaptor, or may be attached separately to the proximal end of the adaptor via a Luer connection. The arterial access device 2010 may also include a connection to a flow line 2025 (or shunt) which may be connected to means for passive or active reverse flow. The flow line 2025 has an internal lumen that communicates with an internal lumen of the arterial access device 2010 for shunting blood from the arterial access device. In an embodiment, the flow line 2025 is a side arm or Y-arm 2027 that is attached to and extends from the arterial access device 2010 at a location between the distal and proximal ends of the arterial access device 2010. EX2003, ¶[0053].
[0062] The arterial access sheath systems described herein can include a distal portion configured to be inserted in the vessel and a proximal portion configured to extend outward from the access site when the distal portion of the arterial access sheath is positioned in the arterial pathway. For example	[0053] The arterial access device 2010 as shown in FIG. 1 is configured to be directly inserted into the common carotid artery CCA without use of a separate introducer sheath. In this configuration, the entry or distal tip of the device is tapered and includes a tapered dilator so as to allow smooth

Disclosure of Garrison (EX1006) Relied on By Petitioner for Claims 1, 14, 23, and 28	Corresponding Disclosure of the Garrison '788 Publication (EX2003)
with reference to FIG. 5, the arterial access sheath 220 has an elongated sheath body 222 sized and shaped such that at least a portion of the sheath body 222 is insertable into the artery during a procedure while the proximal portion remains outside the body. The elongated sheath body 222 is the portion of the arterial access sheath 220 that is sized and shaped to be inserted into the artery and wherein at least a portion of the elongated sheath body is actually inserted into the artery during a procedure. A proximal adaptor 224 can be positioned near a proximal end of an elongated sheath body 222 (see also, e.g. port 2015 of FIG. 1). The proximal adaptor 224 is configured to remain outside the body when at least a portion of the sheath body 222 is inserted into the artery. The proximal adaptor 224 can have a hemostasis valve 226 that communicates with the internal lumen of the sheath body 222. The hemostasis valve 226 that communicates with the internal lumen of the sheath body 222 allow for the introduction of devices therein while preventing or minimizing blood loss via the internal lumen during the procedure. The hemostasis valve 226 can be a static seal-type passive valve, or an adjustable-opening valve such as a Tuohy-Borst valve 227 or rotating hemostasis valve (RHV) (see FIG. 6). The hemostasis valve may be integral to the proximal adaptor 224, or the access sheath 220 may terminate on	introduction of the device over a guide wire into the artery. … The arterial access device also includes a proximal adaptor. This proximal adaptor includes a proximal port 2015 with a hemostasis valve, to allow introduction of devices while preventing or minimizing blood loss during the procedure. In an embodiment, this valve is a static seal-type passive valve. In an alternate embodiment, this valve is an adjustable-opening valve such as a Tuohy-Borst or rotating hemostasis valve (RHV). The hemostasis valve may be integral to the proximal adaptor, or may be attached separately to the proximal end of the adaptor via a Luer connection. The arterial access device 2010 may also include a connection to a flow line 2025 (or shunt) which may be connected to means for passive or active reverse flow. The flow line 2025 has an internal lumen that communicates with an internal lumen of the arterial access device 2010 for shunting blood from the arterial access device. In an embodiment, the flow line 2025 is a side arm or Y-arm 2027 that is attached to and extends from the arterial access device 2010 at a location between the distal and proximal ends of the arterial access device 2010. As shown in FIG. 1, the flow line 2025 is located distal of the location where devices enter the proximal port 2015 of the arterial access device. In an alternate embodiment, the flow line

Disclosure of Garrison (EX1006) Relied on By Petitioner for Claims 1, 14, 23, and 28	Corresponding Disclosure of the Garrison '788 Publication (EX2003)
the proximal end in a female Luer adaptor to which a separate hemostasis valve component, such as a passive seal valve, a Tuohy-Borst valve or rotating hemostasis valve, may be attached. Further, one or more features can be positioned near the proximal end of the access sheath 220 to aid in securement of the sheath during the procedure. For example, the access sheath 220 may have a suture eyelet 234 or one or more ribs 236 molded into or otherwise attached to the adaptor 224, which would allow the operator to suture tie the sheath hub to the patient. *See, e.g.*, Paper 2, p.33.	2025 is attached to the Y-arm of a separately attached Tuohy Borst valve. EX2003, ¶[0053].
[0071] In some instances it may be desirable to connect the access sheath to a flow line, for example for the purposes of passive or active aspiration to reduce the risk of distal emboli during the procedure. In an embodiment shown in FIG. 11, the arterial access sheath 220 has a low resistance (large bore) flow line or shunt connected to the access sheath. The low resistance flow line 905 can be connected to an internal lumen of the sheath body 222 via a Y-arm 915 of the connector 815. The flow line 905 may be connected to a lower pressure return site such as a venous return site or a reservoir. The flow line 905 may also be connected to an aspiration source such as a pump or a syringe. As shown in FIG. 11, the flow line 905 can be	[0053] The arterial access device 2010 may also include a connection to a flow line 2025 (or shunt) which may be connected to means for passive or active reverse flow. The flow line 2025 has an internal lumen that communicates with an internal lumen of the arterial access device 2010 for shunting blood from the arterial access device. In an embodiment, the flow line 2025 is a side arm or Y-arm 2027 that is attached to and extends from the arterial access device 2010 at a location between the distal and proximal ends of the arterial access device 2010. As shown in FIG. 1, the flow line 2025 is located distal of the location where devices enter the proximal port 2015 of the arterial access device. In an alternate embodiment, the flow line

Disclosure of Garrison (EX1006) Relied on By Petitioner for Claims 1, 14, 23, and 28	Corresponding Disclosure of the Garrison '788 Publication (EX2003)
located distal of the location where devices enter the proximal port 226 of the arterial access sheath 220. In an alternate embodiment, the flow line 905 is attached to the Y-arm of a separately attached Tuohy Borst valve. *See, e.g.*, Paper 2, p.27.	2025 is attached to the Y-arm of a separately attached Tuohy Borst valve. EX2003, ¶[0053].
[0098] As described above, FIGS. 1, 2 and 3 illustrates embodiments of a catheter 2030 that is configured to be inserted through an arterial access device 2010 into the common carotid artery (CCA), and from there advanced to a target treatment area in the internal carotid artery or cerebral artery. 22 shows a schematic view of an exemplary catheter 105. The catheter 105 has an external dimension that is sized and shaped for insertion into a blood vessel. A proximal hub 2065 has a female Luer configuration for attachment of a syringe during prep and attachment of other components. For example a separate hemostasis valve may be attached to proximal hub 2065, to allow introduction of devices such as a microcatheter, guide wire, or thrombectomy device while preventing or minimizing blood loss during the procedure. Alternately, the hemostasis valve may be integral to the catheter proximal adaptor. In an embodiment, this valve is an adjustable-opening valve such as a Tuohy-Borst or rotating hemostasis valve (RHV). In another	[0065] With reference again to FIG. 1, the distal catheter 2030 is configured to be inserted through the arterial access device distal to the ICA and cerebral vessels, to a location as far as the thrombotic occlusion 10. The distal catheter 2030 has a length longer than the length of the arterial access device such that the distal catheter's distal end can protrude from the distal opening of the arterial access device by about 15-30 cm. The distal catheter is also more flexible than the arterial access device, due to the anatomy of the distal vasculature. A proximal port 2035 with a hemostasis valve may be situated on the proximal end of distal catheter 2030, to allow introduction of devices such as a microcatheter, guide wire, or thrombectomy device while preventing or minimizing blood loss during the procedure. In an embodiment, this valve is an adjustable-opening valve such as a Tuohy-Borst or rotating hemostasis valve (RHV). The hemostasis valve may be integral to the catheter proximal adaptor, or may be attached separately to the proximal end of the catheter via a Luer connection.

Disclosure of Garrison (EX1006) Relied on By Petitioner for Claims 1, 14, 23, and 28	Corresponding Disclosure of the Garrison '788 Publication (EX2003)
embodiment, the valve is a passive seal hemostasis valve. *See, e.g.*, Paper 2, pp.32-33.	EX2003, ¶[0065].
[0129] When different catheter systems are tested for actual aspiration rates this benefit is diminished somewhat as compared to the theoretical aspiration rates, especially at higher flow rates. This is reflective of the fact that at the higher flow rates, the flow is less and less laminar, and thus lower than the theoretical flow as predicted by Poiseuille's law. However, the shorter and larger ID catheters do show a relative benefit. In an exemplary test method, the catheters are tested for aspiration rates with a 40% glycerin mixture to simulate the viscosity of blood using the following method: each catheter was connected to a stopcock and thence to a 30 cc locking syringe. The tip of the catheter was positioned in a container of the glycerin mixture. The catheter and syringe were purged of air, the syringe was emptied, and then the stopcock was closed. The locking syringe was then pulled back the full 30 cc volume and locked in place. A timer was started when the stopcock was opened, and the time was noted at 5 cc, 10 cc, 15 cc and 20 cc of extracted solution in the syringe. The overall average extraction rate was calculated based on the slope of the data points and was roughly linear over the 20 cc volume, indicating a constant vacuum	[As discussed above this has no bearing on the first and second chamber with negative pressure limitations of the independent claims. Particularly for a pump system.]

Disclosure of Garrison (EX1006) Relied on By Petitioner for Claims 1, 14, 23, and 28	Corresponding Disclosure of the Garrison '788 Publication (EX2003)
level using this method. Results and their relative improvements over the baseline Navien Catheters are provided in the tables in FIGS. 56 and 57. *See, e.g.*, Paper 2, p.26.	
[0131] In FIG. 32, the flow line 2025 of the arterial access device 2010 is connected to a delivery location, such as a receptacle 3100. A source of aspiration 3125 may be coupled to the flow line 2025. The receptacle 3100 and source of aspiration 3125 may be separate or may be combined into a single device such as a syringe. A filter 3418 and/or a check valve 3419 may be coupled with flow line 2025. In FIG. 33, the flow line 2045 of the catheter 2030 is additionally or alternately connected to a separate aspiration source 3425 and delivery location, such as receptacle 3105. The aspiration source 3425 and delivery location may be combined into a single device such as a syringe. A filter 3418 and/or a check valve 3419 may <u>also be</u> coupled with the flow line 2045. *See, e.g.*, Paper 2, p.25.	[0085] In FIG. 15, the flow line 2025 of the arterial access device 2010 is connected to a delivery location, such as a receptacle 3100. A source of aspiration 3125 may be coupled to the flow line 2025. The receptacle 3100 and source of aspiration 3125 may be separate or may be combined into a single device such as a syringe. A filter 3418 and/or a check valve 3419 may be coupled with flow line 2025. In FIG. 16, the flow line 2045 of the distal catheter 2030 is additionally or alternately connected to a separate aspiration source 3425 and delivery location, such as receptacle 3105. The aspiration source 3425 and delivery location may be combined into a single device such as a syringe. A filter 3418 and/or a check valve 3419 may coupled with the flow line 2045. EX2003, ¶[0085].
[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	[0086] FIG. 17 shows a system whereby both the arterial access device 2010 and distal 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

Disclosure of Garrison (EX1006) Relied on By Petitioner for Claims 1, 14, 23, and 28	Corresponding Disclosure of the Garrison '788 Publication (EX2003)
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. *See, e.g.*, Paper 2, p.25.	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. EX2003, ¶[0086].
[0133] In an embodiment, a flow controller may facilitate control of multiple mechanisms of aspiration through multiple devices in a single unit. This configuration may facilitate use of the system by a single operator. The flow controller may include one or more control interfaces that a user may actuate to regulate which device is being aspirated, for example the arterial access device, the catheter, both, or neither. FIG. 35 shows an embodiment of a system that utilizes such a flow controller 3400. The flow controller 3400 is connected to the flow line 2025 of the arterial access device 2010 as well as to the flow line 2045 of the catheter 2030. In this manner, the flow lines 2025 and 2045 permit fluid to flow from the arterial access device 2010 and the catheter 2030, respectively, to the flow controller 3400. The controller 3400 may be connected to either or both a passive source of aspiration 3410 and an active source of aspiration 3420. The flow controller housing 3429 contains	[0087] In an embodiment, a flow controller may facilitate control of multiple means of aspiration through multiple devices in a single unit. This configuration may facilitate use of the system by a single operator. The flow controller may include one or more control interfaces that a user may actuate to regulate which device is being aspirated, for example the arterial access device, the distal catheter, both, or neither. FIG. 18 shows an embodiment of a system that utilizes such a flow controller 3400. The flow controller 3400 is connected to the flow line 2025 of the arterial access device 2010 as well as to the flow line 2045 of the distal catheter 2030. In this manner, the flow lines 2025 and 2045 permit fluid to flow from the arterial access device 2010 and the catheter 2030, respectively, to the flow controller 3400. The controller 3400 may be connected to either or both a passive source of aspiration 3410 and an active source of aspiration 3420. The flow controller housing 3429 contains

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control mechanisms to determine how and when each device is connected to each source of aspiration. The control mechanisms may also control the level of aspiration from each source. In addition, the controller may include a control that permits a pulsatile aspiration mode which may facilitate the breaking up and aspiration of the cerebral occlusion. The flow controller may have an interface for switching between continuous and pulsatile aspiration modes. The control mechanisms may be designed to be operable using one hand. For example, the control mechanisms may be toggle switches, push button switches, slider buttons, or the like. In an embodiment, the flow controller 3400 has an interface that can enable the user to restore immediate antegrade flow to the cerebral circulation, for example with a single button or switch that simultaneously deflates the occlusion balloon on the arterial access device and stops aspiration. *See, e.g.*, Paper 2, p.25.	control mechanisms to determine how and when each device is connected to each source of aspiration. The control mechanisms may also control the level of aspiration from each source. In addition, the controller may include a control that permits a pulsatile aspiration mode which may facilitate the breaking up and aspiration of the cerebral occlusion. The flow controller may have an interface for switching between continuous and pulsatile aspiration modes. The control mechanisms may be designed to be operable using one hand. For example, the control mechanisms may be toggle switches, push button switches, slider buttons, or the like. In an embodiment, the flow controller 3400 has an interface that can enable the user to restore immediate antegrade flow to the cerebral circulation, for example with a single button or switch that simultaneously deflates the occlusion balloon on the arterial access device and stops aspiration. EX2003, ¶[0087].
[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	[0088] 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

Disclosure of Garrison (EX1006) Relied on By Petitioner for Claims 1, 14, 23, and 28	Corresponding Disclosure of the Garrison '788 Publication (EX2003)
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 embodiment, the aspiration source is a hand-held aspirator which is configured to be able to aspirate and refill without disconnecting the aspiration device. In an example of this embodiment, the hand-held aspirator contains a chamber with a plunger that is moved up and down with a single-handed actuator. The chamber includes input and output valves, such that when the plunger is moved up and down there is a continuous source of aspiration into and out of the chamber without the need to remove and empty the chamber as would be needed with a syringe. The chamber input is connected to the catheter, and the chamber output is connected to a collection receptacle such as blood-collection bag. In an embodiment, this aspiration source is configured to be used with one hand only. *See, e.g.*, Paper 2, p.25.	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 distal 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 embodiment, the aspiration source is a hand-held aspirator which is configured to be able to aspirate and refill without disconnecting the aspiration device. In an example of this embodiment, the hand-held aspirator contains a chamber with a plunger that is moved up and down with a single-handed actuator. The chamber includes input and output valves, such that when the plunger is moved up and down there is a continuous source of aspiration into and out of the chamber without the need to remove and empty the chamber as would be needed with a syringe. The chamber input is connected to the catheter, and the chamber output is connected to a collection receptacle such as blood-collection bag. In an embodiment, this aspiration source is configured to be used with one hand only. EX2003, ¶[0088].

Disclosure of Garrison (EX1006) Relied on By Petitioner for Claims 1, 14, 23, and 28	Corresponding Disclosure of the Garrison '788 Publication (EX2003)
[0136] FIG. 36 shows a cross-sectional view of an exemplary 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. The pump 3250 may be connected to either or both the arterial access device 2010 and catheter 2030. The pump device 3250 includes a housing 3215 that encloses a chamber 3220 in which is contained a portion of the flow line 2025. An expandable portion 3210 of the flow line 2025 contained within the chamber 3220 is formed of an elastic material that is at a reduced diameter in its natural state (shown in phantom lines in FIG. 36) but may be configured to change to an expanded diameter (shown in solid lines in FIG. 36). One or more seals 3125, such as O-rings, seal the interface between the chamber 3220 and the flow line 2025. A vacuum source 3230 is coupled to the chamber 3220 and is configured to be operated to vary the pressure within the chamber 3220. Two one-way check valves 3235 are located in the flow line 2025 on either side of the expandable portion 3210. *See, e.g.*, Paper 2, p.25.	[0090] FIG. 19 shows a cross-sectional view of an exemplary 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. The pump 3250 may be connected to either or both the arterial access device 2010 and distal catheter 2030. The pump device 3250 includes a housing 3215 that encloses a chamber 3220 in which is contained a portion of the flow line 2025. An expandable portion 3210 of the flow line 2025 contained within the chamber 3220 is formed of an elastic material that is at a reduced diameter in its natural state (shown in phantom lines in FIG. 19) but may be configured to change to an expanded diameter (shown in solid lines in FIG. 19). One or more seals 3125, such as O-rings, seal the interface between the chamber 3220 and the flow line 2025. A vacuum source 3230 is coupled to the chamber 3220 and is configured to be operated to vary the pressure within the chamber 3220. Two one-way check valves 3235 are located in the flow line 2025 on either side of the expandable portion 3210. EX2003, ¶[0090].
[0172] … Aspiration may be via a syringe, a pump, or other means as disclosed above …	[0088] The active source of aspiration may be an aspiration pump, a regular or

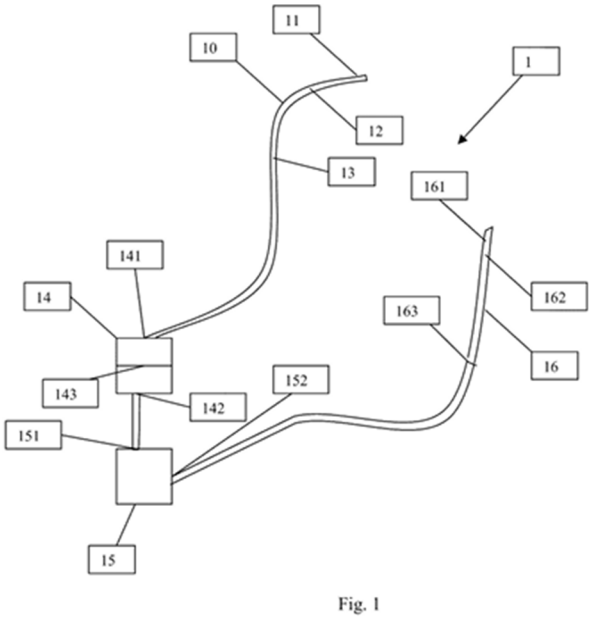
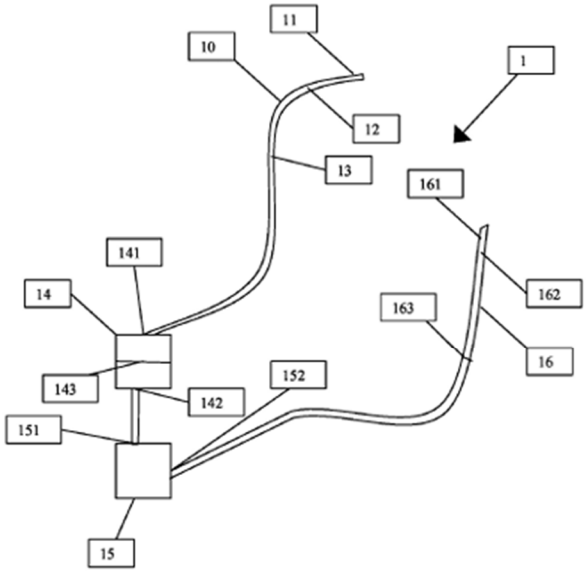
Disclosure of Garrison (EX1006) Relied on By Petitioner for Claims 1, 14, 23, and 28	Corresponding Disclosure of the Garrison '788 Publication (EX2003)
See, e.g., Paper 2, p.27.	locking syringe, a hand-held aspirator, hospital suction, or the like … EX2003, ¶[00088].

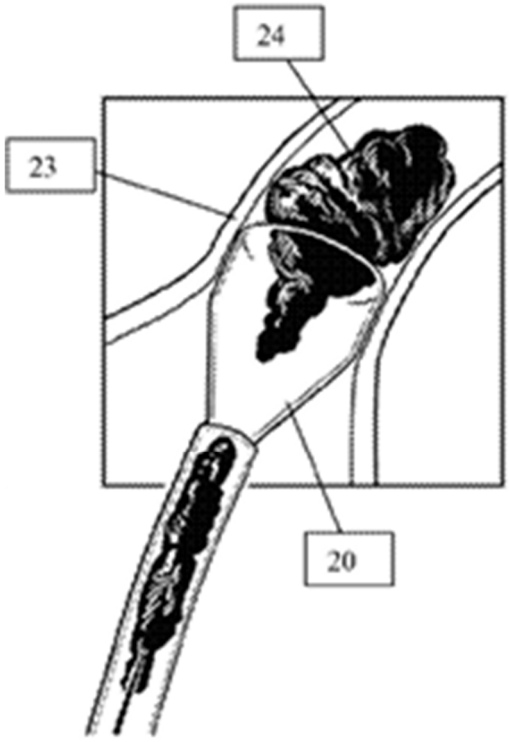
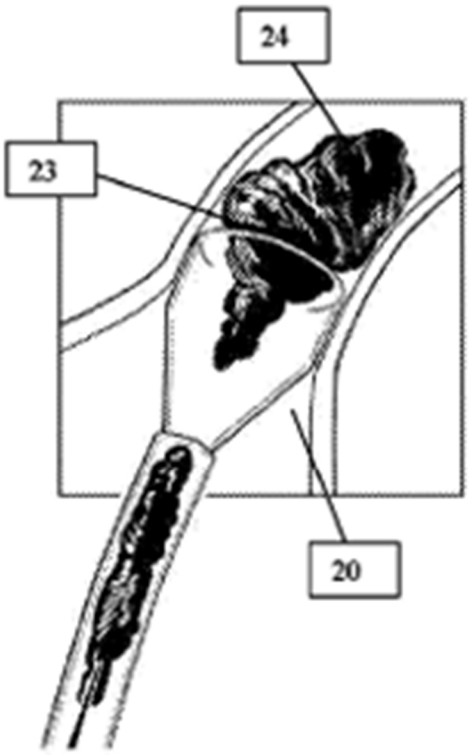
X. THE DISCLOSURE OF AKLOG RELIED ON IN THE PETITION IS THE SAME AS AND CUMULATIVE TO THE DISCLOSURE IN AKLOG'S PARENT

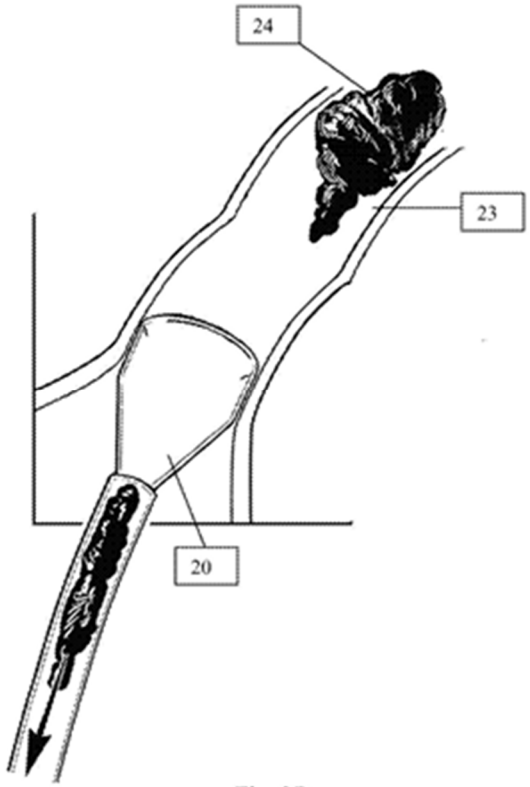
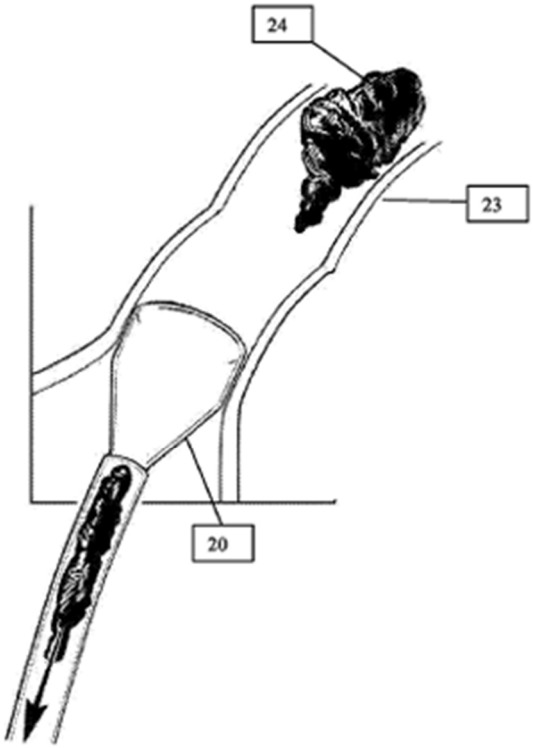
99. I understand that Aklog (EX1005), which is cited for Grounds 5-7 of the petition, was not cited during prosecution of the '691 Patent but Aklog's parent U.S. Patent No. 8,075,510 (EX1019) was cited in an information disclosure statement during prosecution. Paper 2, p.87. Below, I provide a side-by-side comparison of (a) the portions of Aklog cited in the petition with (b) the corresponding disclosure of the Aklog's parent. As shown in the comparison that I provide below, the disclosure is the same.

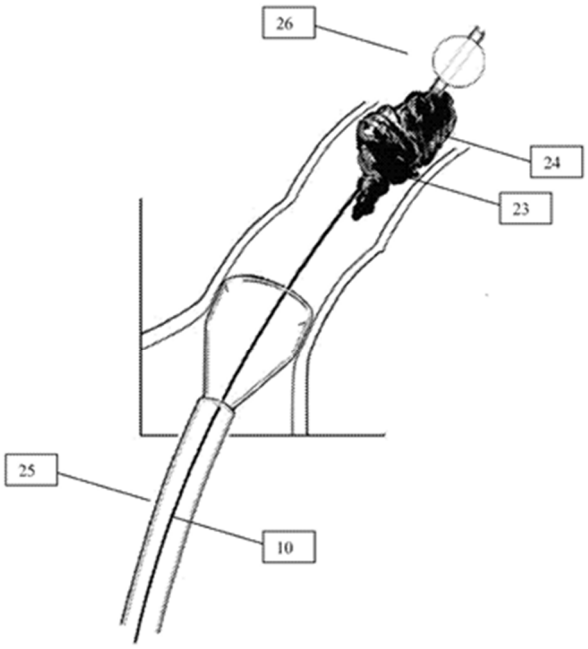
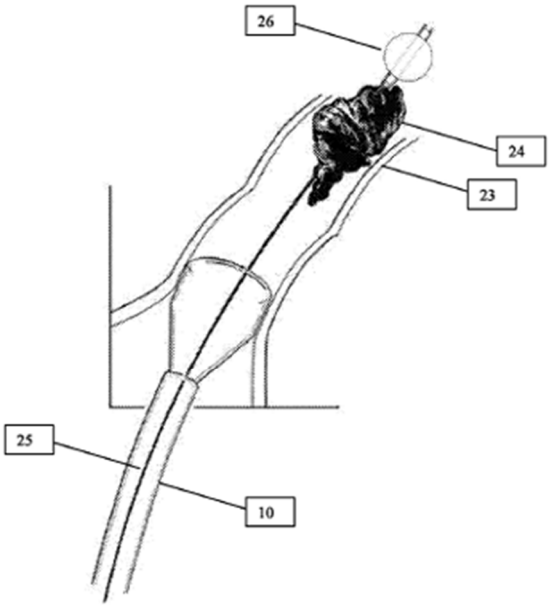
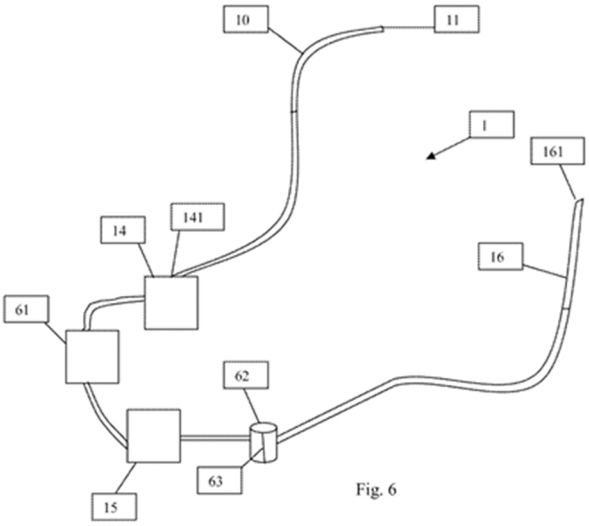
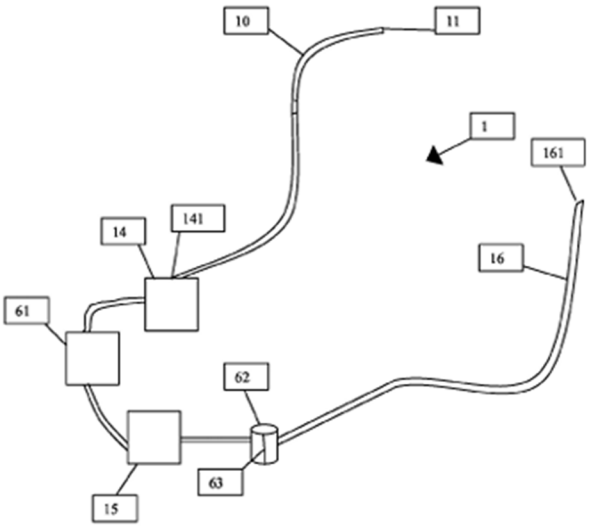
100. The only additional disclosure in Aklog over Aklog's parent is found in column 18, line 56 to column 20, line 27 of Aklog. This portion of Aklog describes using the system already disclosed in Aklog's parent to capture vegetative growths disrupted during another procedure, such as the removal of a pacemaker lead. This is not related to the Claims of the '691 Patent.

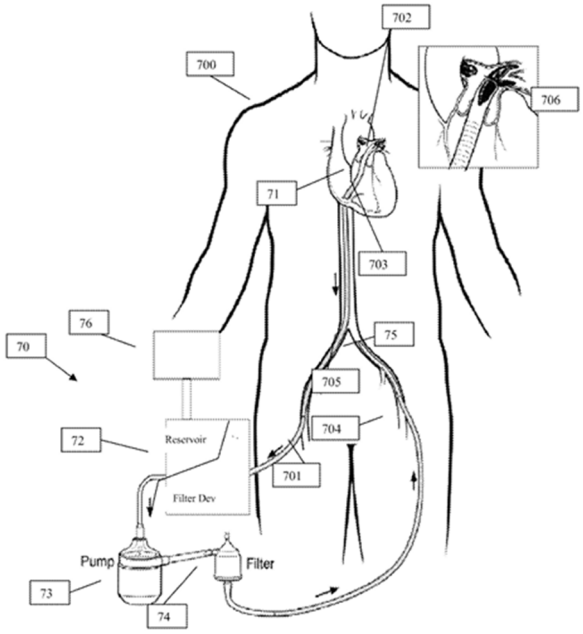
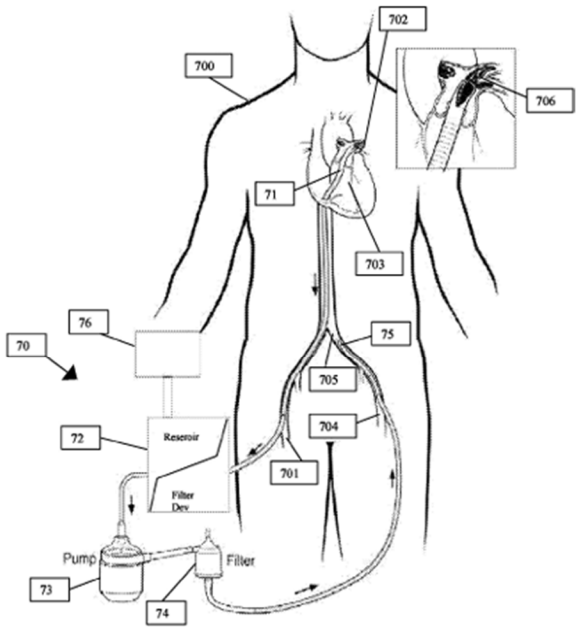
101. The table below provides a side-by-side comparison between (a) the portions of Aklog cited in the petition and (b) the identical disclosure of Aklog's parent:

Disclosure of Aklog (EX1005) Relied on By Petitioner	Identical Disclosure of the Aklog's Parent (EX1019)
 Fig. 1 *See, e.g.*, Paper 2, p.59.	 Fig. 1 EX1019, fig.1.

Disclosure of Aklog (EX1005) Relied on By Petitioner	Identical Disclosure of the Aklog's Parent (EX1019)
 Fig. 2C *See, e.g.*, Paper 2, p.60.	 Fig. 2C EX1019, fig.2C.

Disclosure of Aklog (EX1005) Relied on By Petitioner	Identical Disclosure of the Aklog's Parent (EX1019)
 Fig. 2D *See, e.g.*, Paper 2, p.60.	 Fig. 2D EX1019, fig.2D.

Disclosure of Aklog (EX1005) Relied on By Petitioner	Identical Disclosure of the Aklog's Parent (EX1019)
 Fig. 2H *See, e.g.*, Paper 2, p.60.	 Fig. 2H EX1019, fig.2H.
 Fig. 6 *See, e.g.*, Paper 2, p.59.	 Fig. 6 EX1019, fig.6.

Disclosure of Aklog (EX1005) Relied on By Petitioner	Identical Disclosure of the Aklog's Parent (EX1019)
 Fig. 7 *See, e.g.*, Paper 2, p.59.	 Fig. 7 EX1019, fig.7.
1:17-24: The present invention relates to systems and methods for removing undesirable materials from a site of interest within the circulatory system. More particularly, the present invention relates to systems and methods for removing substantially en bloc clots, thrombi, and emboli, among others, from within heart chambers, as well as medium to large vessels, while reinfusing fluid removed from the site of interest back into the patient to minimize fluid loss. *See, e.g.*, Paper 2, p.59.	1:13-20: The present invention relates to systems and methods for removing undesirable materials from a site of interest within the circulatory system. More particularly, the present invention relates to systems and methods for removing substantially en bloc clots, thrombi, and emboli, among others, from within heart chambers, as well as medium to large vessels, while reinfusing fluid removed from the site of interest back into the patient to minimize fluid loss.
2:7-32:	2:3-28:

Disclosure of Aklog (EX1005) Relied on By Petitioner	Identical Disclosure of the Aklog's Parent (EX1019)
In the systemic venous circulation, undesirable material can also cause serious harm. Blood clots can develop in the large veins of the legs and pelvis, a common condition known as deep venous thrombosis (DVT). DVT arises most commonly when there is a propensity for stagnated blood (long-haul air travel, immobility) and clotting (cancer, recent surgery, especially orthopedic surgery). DVT causes harm by (1) obstructing drainage of venous blood from the legs leading to swelling, ulcers, pain and infection and (2) serving as a reservoir for blood clot to travel to other parts of the body including the heart, lungs (pulmonary embolism) and across a opening between the chambers of the heart (patent foramen ovale) to the brain (stroke), abdominal organs or extremities. In the pulmonary circulation, the undesirable material can cause harm by obstructing pulmonary arteries, a condition known as pulmonary embolism. If the obstruction is upstream, in the main or large branch pulmonary arteries, it can severely compromise total blood flow within the lungs and therefore the entire body, resulting in low blood pressure and shock. If the obstruction is downstream, in large to medium pulmonary artery branches, it can prevent a significant portion of the lung from participating in the exchange of gases to the blood	In the systemic venous circulation, undesirable material can also cause serious harm. Blood clots can develop in the large veins of the legs and pelvis, a common condition known as deep venous thrombosis (DVT). DVT arises most commonly when there is a propensity for stagnated blood (long-haul air travel, immobility) and clotting (cancer, recent surgery, especially orthopedic surgery). DVT causes harm by (1) obstructing drainage of venous blood from the legs leading to swelling, ulcers, pain and infection and (2) serving as a reservoir for blood clot to travel to other parts of the body including the heart, lungs (pulmonary embolism) and across a opening between the chambers of the heart (patent foramen ovale) to the brain (stroke), abdominal organs or extremities. In the pulmonary circulation, the undesirable material can cause harm by obstructing pulmonary arteries, a condition known as pulmonary embolism. If the obstruction is upstream, in the main or large branch pulmonary arteries, it can severely compromise total blood flow within the lungs and therefore the entire body, resulting in low blood pressure and shock. If the obstruction is downstream, in large to medium pulmonary artery branches, it can prevent a significant portion of the lung from participating in the exchange of gases to the blood

Disclosure of Aklog (EX1005) Relied on By Petitioner	Identical Disclosure of the Aklog's Parent (EX1019)
resulting low blood oxygen and build up of blood carbon dioxide. If the obstruction is further downstream, it can cut off the blood flow to a smaller portion of the lung, resulting in death of lung tissue or pulmonary infarction *See*, *e.g.*, Paper 2, p.6.	resulting low blood oxygen and build up of blood carbon dioxide. If the obstruction is further downstream, it can cut off the blood flow to a smaller portion of the lung, resulting in death of lung tissue or pulmonary infarction.
5:11-41: The present invention relates generally to systems and methods for removing undesirable material residing in vessels, such as blood vessels, or within chambers of the heart. More specifically, the subject invention relates to systems and methods for using a cannula to remove substantially en bloc, from a site of obstruction or interest, an undesirable material, such as blood clots, embolisms and thromboembolisms, without significant fragmentation and without excessive fluid 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 may be particularly useful, but may not be limited to, the removal of blood clots, tumors, infective vegetations and foreign bodies from medium to large blood vessels and heart chambers.	5:6-36: The present invention relates generally to systems and methods for removing undesirable material residing in vessels, such as blood vessels, or within chambers of the heart. More specifically, the subject invention relates to systems and methods for using a cannula to remove substantially en bloc, from a site of obstruction or interest, an undesirable material, such as blood clots, embolisms and thromboembolisms, without significant fragmentation and without excessive fluid 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 may be particularly useful, but may not be limited to, the removal of blood clots, tumors, infective vegetations and foreign bodies from medium to large blood vessels and heart chambers.

Disclosure of Aklog (EX1005) Relied on By Petitioner	Identical Disclosure of the Aklog's Parent (EX1019)
In one embodiment, a system for removing an undesirable material from within a vessel is provided. The system includes a first cannula having a distal end and an opposing proximal end. The distal end of the first cannula, in an embodiment, may include or may be deployable to a diameter relatively larger than that of the proximal end. The first cannula may be designed for maneuvering within the vessel to a site of interest, such that an undesirable material can be captured substantially en bloc through the distal end and removed along the first cannula away from the site. The system may also include a pump, in fluid communication with the proximal end of the first cannula, so as to provide a sufficient suction force for removing the undesirable material from the site of interest. *See, e.g.*, Paper 2, pp.59-60.	In one embodiment, a system for removing an undesirable material from within a vessel is provided. The system includes a first cannula having a distal end and an opposing proximal end. The distal end of the first cannula, in an embodiment, may include or may be deployable to a diameter relatively larger than that of the proximal end. The first cannula may be designed for maneuvering within the vessel to a site of interest, such that an undesirable material can be captured substantially en bloc through the distal end and removed along the first cannula away from the site. The system may also include a pump, in fluid communication with the proximal end of the first cannula, so as to provide a sufficient suction force for removing the undesirable material from the site of interest.
7:23-52: 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. 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	7:16-45: 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. 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

Disclosure of Aklog (EX1005) Relied on By Petitioner	Identical Disclosure of the Aklog's Parent (EX1019)
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, in the left heart (e.g., the left ventricular apex and left atrial appendage), right heart (e.g., right atrium and right ventricle), or on its valves. The present invention can also act to remove tumors, infective vegetations and other foreign bodies. Although reference is made to medium and large vessels, it should be appreciated that the systems and methods, hereinafter disclosed, can be scaled and adapted for use within smaller vessels within the body, if desired. Referring now to FIG. 1, there is illustrated a system 1 for removing an undesirable material, substantially en bloc, from an obstruction site or site of interest within the vasculature, and for reinfusion of fluid removed (i.e., suctioned or aspirated) from the site of	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, in the left heart (e.g., the left ventricular apex and left atrial appendage), right heart (e.g., right atrium and right ventricle), or on its valves. The present invention can also act to remove tumors, infective vegetations and other foreign. Although reference is made to medium and large vessels, it should be appreciated that the systems and methods, hereinafter disclosed, can be scaled and adapted for use within smaller vessels within the body, if desired. Referring now to FIG. 1, there is illustrated a system 1 for removing an undesirable material, substantially en bloc, from an obstruction site or site of interest within the vasculature, and for reinfusion of fluid removed (i.e., suctioned or aspirated) from the site of

Disclosure of Aklog (EX1005) Relied on By Petitioner	Identical Disclosure of the Aklog's Parent (EX1019)
interest back into a patient, in order to minimize fluid loss within the patient. *See*, *e.g.*, Paper 2, p.6 & p.63.	interest back into a patient, in order to minimize fluid loss within the patient.
11:33-40: … filter device 14 may further include a permeable sheet 143 positioned within the fluid flow between the inlet 141 and the outlet 142. Permeable sheet 143, in an embodiment, may include a plurality of pores sufficiently sized, so as to permit fluid from the site of interest to flow therethrough, while preventing any undesirable material captured from the site of interest from moving downstream of system 1. *See*, *e.g.*, Paper 2, pp.71-72.	11:26-33: … filter device 14 may further include a permeable sheet 143 positioned within the fluid flow between the inlet 141 and the outlet 142. Permeable sheet 143, in an embodiment, may include a plurality of pores sufficiently sized, so as to permit fluid from the site of interest to flow therethrough, while preventing any undesirable material captured from the site of interest from moving downstream of system 1.
11:62-65: Still looking at FIG. 1, system 1 may also be provided with a pump 15 designed to generate negative pressure, so as to create a necessary suction force through cannula 10 to pull any undesirable material from the site of interest. *See*, *e.g.*, Paper 2, p.60.	11:55-58: Still looking at FIG. 1, system 1 may also be provided with a pump 15 designed to generate negative pressure, so as to create a necessary suction force through cannula 10 to pull any undesirable material from the site of interest.
13:64-14:2: With reference now to FIG. 6, system 1 may also include a reservoir 61. Reservoir 61, in one embodiment, may be situated in fluid communication	13:57-62: With reference now to FIG. 6, system 1 may also include a reservoir 61. Reservoir 61, in one embodiment, may be situated in fluid communication

Disclosure of Aklog (EX1005) Relied on By Petitioner	Identical Disclosure of the Aklog's Parent (EX1019)
between filter device 14 and pump 15, and may act to transiently collect fluid filtered from the site of interest, prior to the filtered fluid being directed into reinfusion cannula 16. *See*, *e.g.*, Paper 2, p.60.	between filter device 14 and pump 15, and may act to transiently collect fluid filtered from the site of interest, prior to the filtered fluid being directed into reinfusion cannula 16.
15:30-34: The first blood vessel through which suction cannula 71 may be inserted into patient 700 can be, in an embodiment, any blood vessel that can be accessed percutaneously or by surgical dissection such as femoral vein, femoral artery or jugular vein. *See, e.g.*, Paper 2, p.59.	15:22-26: The first blood vessel through which suction cannula 71 may be inserted into patient 700 can be, in an embodiment, any blood vessel that can be accessed percutaneously or by surgical dissection such as femoral vein, femoral artery or jugular vein.

102. As shown in the table above, the portions of Aklog cited by Petitioner are the same as to those disclosed in Aklog's parent.

XI. SECONDARY CONSIDERATIONS

103. I have not rendered any opinions on secondary considerations of non-obviousness at this time, but reserve the right to do so.

XII. CONCLUSION

104. For all the above reasons, I find that Petitioner has not met its burden of demonstrating the unpatentability of any challenged claim. Accordingly, I understand that Patent Owner requests the Board confirm the patentability of Claims 1–31.

I, Brian Brown, declare that all statements made herein of my knowledge are true, and that all statements made on information and belief are believed to be true, and that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Respectfully submitted,

Dated: 27 Nov 2024 By: _____
Brian Brown

Brian J. Brown

C (763) 458-8551 bb.browntech@gmail.com

Professional Experience

Brown-Tech , LLC. Hanover, MN **Sept 2017-Present**
President

- Technical Consultant for early stage medical device companies in the areas of product design and intellectual property development (clients: Peytant Solutions, QXMedical, CardioMech)
- Subject Matter Expert for Medical Device patent cases ranging from litigation to Inter Partes Reviews. Responsible for case document reviews, product testing, testing reports, POSA declarations, depositions and testimony.

Brown-Tech , LLC. (Nitinol) Maple Plain, MN **Mar 2018-July 2020**
President

- Specialized contract Nitinol design and prototyping for small to large nitinol projects.
- Expertise in the areas of design, laser cutting, shape setting, grit blasting, electro-polishing, passivation and testing.
- Over 25 years of expertise with nitinol stents, guidewires, structural heart, heart failure and misc. components.

Cogentix Medical Inc. Minnetonka, MN **Nov 2016 – June 2017**
VP of R&D and Operations

Pelvic Health medical device company developing and commercializing neurostimulators, endoscopes and sphincter bulking agents.

- Responsible for production, R&D, supply chain, planning, QC and Customer Care in MN, NY, and MA
- Owned cross functional leadership of New Business Development and Strategic Growth activities
- Provided oversight of Corporate intellectual property portfolio, outside counsel activities, and patents

OvaGene Oncology Irvine CA and Edina, MN **2016**
Chief Technology Officer

A Point of Care (POC) molecular diagnostic company focused on developing and commercializing a diagnostic (Dx) microfluidic chip capable of running self-contained, protein based diagnostic assays.

- Developed a commercial version of a research lab POC Dx prototype
- Sr. Staff member responsible for R&D, Intellectual Property, Operations, Quality, Regulatory, Facilities, and IT.

Sunshine Heart, Inc Eden Prairie, MN **June 2014 – Jan 2016**
Sr. Vice President Technology and Operations

An early-stage, publicly traded medical device company focused on developing, manufacturing and commercializing the C-Pulse System for the treatment of Class III and ambulatory Class IV heart failure.

- Sr. Staff member responsible for R&D, Operations, Facilities, and IT.
- Led the organizational development /optimization of electromechanical, mechanical, sensor and software components for a Class III permanent implant supported by an external controller.
- Led the portfolio planning and technology roadmap efforts for strategic planning
- Provided oversight of Corporate intellectual property portfolio, outside counsel activities, and patents

Boston Scientific Corporation / SciMED, Maple Grove, MN **Feb 1990 – Jan 2014**
R&D, Vice President, Cardiovascular (2004-2014)
Directed worldwide Cardiovascular research and development activities for accelerated launches of implantable stents, drug delivery technologies, structural heart devices, disposable catheters and adjunctive products.

- Developed, sustained, and optimized a $200M/yr. international R&D organization to bring the right new technologies / products to the market
- Aligned company's technology development, M&A activities, and IP portfolio
- Initiated Bio Design partnerships with regional / global research institutions to identify / develop disruptive technologies to fuel future growth.

R&D, Sr. Director, Stents
Created R&D stent and drug elution centers of excellence in MN and Ireland (2001- 2004)

- Championed / built a stent organization bringing BSC's first internally developed nitinol and stainless steel stents to the market.
- Constructed / maintained a world class dual site drug elution organization capturing 70% of the global market launching the Taxus and Promus portfolio of stent products.
- Identified / engaged the technical assessment of business opportunities and integration of new licenses / acquisitions.

Prior History

Previously at Boston Scientific / SciMED held positions of R&D Director Catheters, R&D Director / Manager Stents, Operations Manager Guidewires, Sr. Process Development Engineer, and Sr. Machine Design Engineer. Highlights included developing BSC's core competency in nitinol, stent design, laser cutting, electropolishing, crimping, and fatigue testing. Many ground breaking design, clinical and regulatory competencies were developed to support Boston Scientific's first cardiovascular permanent implants.
Hutchinson Technology (Sep 1984-Jan 1990) as Machine Design Engineer / Supervisor responsible for building and leading equipment / process automation for a rapidly growing company. Examples include automated passivation lines, plating lines, photochemical etching lines, and laser equipment.

Education / Affiliations

North Dakota State University, Fargo, ND
Bachelor of Science, Mechanical Engineering with an emphasis on electro-mechanical automation.

Notable Achievements

- **~60 issued US Patents** in stent geometries, nitinol, balloon catheters, thrombectomy catheters, infusion catheters, and ePTFE processing.
- **Boston Scientific Patent of the Year award, two-time winner**
- **Recognized as one of Minnesota's leading inventors** by the Twin Cities Business Magazine (Jan 13)
- **Developed Boston Scientific's first product development process and design control tools.**
- **Elected to College of Fellows,** American Institute for Medical and Biological Engineering
- **Advisor to University of MN Office of Technology Commercialization** to advance the commercialization of university developed ideas
- **Mentor** for students enrolled in the University of MN Design of Medical Device program.

USA PATENT NUMBER	TITLE	Listed Inventor	GRANT DATE
5358493	VASCULAR ACCESS CATHETER AND METHODS FOR MANUFACTURE THEREOF	Brian J Brown	25-Oct-94
5417703	THROMBECTOMY DEVICES AND METHODS OF USING SAME	Brian J Brown	23-May-95
5419774	THROMBUS EXTRACTION DEVICE	Brian J Brown	30-May-95
5507995	PROCESS FOR MAKING A CATHETER	Brian J Brown	16-Apr-96
5800517	STENT DELIVERY SYSTEM WITH STORAGE SLEEVE	Brian J Brown	1-Sep-98
6013091	STENT CONFIGURATIONS	Brian J Brown	11-Jan-00
6059810	ENDOVASCULAR STENT AND METHOD	Brian J Brown	9-May-00
6096056	FUGITIVE STENT SECUREMENT MEANS	Brian J Brown	1-Aug-00
6123720	STENT DELIVERY SYSTEM WITH STORAGE SLEEVE	Brian J Brown	26-Sep-00
6261319	STENT	Brian J Brown	17-Jul-01
6348060	FUGITIVE STENT SECUREMENT MEANS	Brian J Brown	19-Feb-02
6348065	LONGITUDINALLY FLEXIBLE EXPANDABLE STENT	Brian J Brown	19-Feb-02
6409753	FLEXIBLE STENT	Brian J Brown	25-Jun-02
6416538	STENT CONFIGURATIONS	Brian J Brown	9-Jul-02
6428569	MICRO STRUCTURE STENT CONFIGURATIONS	Brian J Brown	6-Aug-02
6451052	TISSUE SUPPORTING DEVICES	Brian J Brown	17-Sep-02
6471672	SELECTIVE HIGH PRESSURE DILATION BALLOON	Brian J Brown	29-Oct-02
6478816	STENT	Brian J Brown	12-Nov-02
6551351	SPIRAL WOUND STENT	Brian J Brown	22-Apr-03
6582461	IMPROVED TISSUE SUPPORTING DEVICES	Brian J Brown	24-Jun-03
6602226	LOW-PROFILE STENT DELIVERY SYSTEM AND APPARATUS	Brian J Brown	5-Aug-03
6638468	METHOD OF REDUCING THE WALL THICKNESS OF A PTFE TUBE	Brian J Brown	28-Oct-03
6702843	STENT DELIVERY DEVICE WITH BALLOONS	Brian J Brown	9-Mar-04
6776793	LONGITUDINALLY FLEXIBLE EXPANDABLE STENT	Brian J Brown	17-Aug-04
6818014	IMPROVED LONGITUDINALLY FLEXIBLE EXPANDABLE STENT	Brian J Brown	16-Nov-04
6852123	MICRO STRUCTURE STENT CONFIGURATIONS	Brian J Brown	8-Feb-05
6911038	MATCHED BALLOON TO STENT SHORTENING	Brian J Brown	28-Jun-05
6913619	IMPROVED LONGITUDINALLY FLEXIBLE EXPANDABLE STENT	Brian J Brown	5-Jul-05
6939119	METHOD OF REDUCING THE WALL THICKNESS OF A PTFE TUBE AND PRODUCT FORMED THEREBY	Brian J Brown	6-Sep-05
6945993	STENT	Brian J Brown	20-Sep-05
6962603	IMPROVED LONGITUDINALLY FLEXIBLE EXPANDABLE STENT	Brian J Brown	8-Nov-05
6970734	FLEXIBLE MARKER BANDS	Brian J Brown	29-Nov-05
6981985	STENT BUMPER STRUTS	Brian J Brown	3-Jan-06
6981986	IMPROVED LONGITUDINALLY FLEXIBLE EXPANDABLE STENT	Brian J Brown	3-Jan-06
7060089	MULTI-LAYER STENT	Brian J Brown	13-Jun-06
7204848	LONGITUDINALLY FLEXIBLE EXPANDABLE STENT	Brian J Brown	17-Apr-07
7229470	FLEXIBLE STENT	Brian J Brown	12-Jun-07
7318836	COVERED STENT	Brian J Brown	15-Jan-08
7326243	AN IMPROVED STENT	Brian J Brown	5-Feb-08
7331986	INTRALUMINAL MEDICAL DEVICE HAVING IMPROVED VISIBILITY	Brian J Brown	19-Feb-08
7335225	[IMPROVED] STENT CONFIGURATIONS	Brian J Brown	26-Feb-08
7488343	MEDICAL DEVICES	Brian J Brown	10-Feb-09
7491225	SYSTEM AND METHOD FOR DEPLOYING A DRUG-ELUTING EXTERNAL BODY AND TISSUE SCAFFOLD	Brian J Brown	17-Feb-09

USA PATENT NUMBER	TITLE	Listed Inventor	GRANT DATE
7637938	FLEXIBLE STENT	Brian J Brown	29-Dec-09
7731746	AN IMPROVED STENT	Brian J Brown	8-Jun-10
7879082	MICRO STRUCTURE STENT CONFIGURATIONS	Brian J Brown	1-Feb-11
7914570	NON-SHORTENING HELICAL STENT	Brian J Brown	29-Mar-11
7951187	[IMPROVED] STENT CONFIGURATIONS	Brian J Brown	31-May-11
7988717	LONGITUDINALLY FLEXIBLE EXPANDABLE STENT	Brian J Brown	2-Aug-11
7988720	LONGITUDINALLY FLEXIBLE EXPANDABLE STENT	Brian J Brown	2-Aug-11
8038705	INTRALUMINAL MEDICAL DEVICE HAVING IMPROVED VISIBILITY	Brian J Brown	18-Oct-11
8043366	OVERLAPPING STENT	Brian J Brown	25-Oct-11
8114146	LONGITUDINALLY FLEXIBLE EXPANDABLE STENT	Brian J Brown	14-Feb-12
8147538	COVERED STENT	Brian J Brown	3-Apr-12
8206432	STENT	Brian J Brown	26-Jun-12
8221491	IMPROVED TISSUE SUPPORTING DEVICES	Brian J Brown	17-Jul-12
8348992	IMPROVED LONGITUDINALLY FLEXIBLE EXPANDABLE STENT	Brian J Brown	8-Jan-13
8377111	MEDICAL DEVICES	Brian J Brown	19-Feb-13
8449597	LONGITUDINALLY FLEXIBLE EXPANDABLE STENT	Brian J Brown	28-May-13
8668731	STENT	Brian J Brown	11-Mar-14
8685053	TETHER EQUIPPED CATHETER	Brian J Brown	1-Apr-14
8728147	LONGITUDINALLY FLEXIBLE EXPANDABLE STENT	Brian J Brown	20-May-14

MATERIALS CONSIDERED

EXHIBIT/PAPER NO.	DESCRIPTION
1001	U.S. Patent No. 11,744,691 ("the '691 Patent")
1002	'691 Patent Prosecution History
1003	Expert Declaration of Troy Thornton
1004	Resume of Troy Thornton
1005	U.S. Patent No. 8,734,374 B2 to Aklog et al. ("Aklog")
1006	U.S. Patent Publication No. 2015/0173782 A1 to Garrison et al. ("Garrison")
1007	WIPO Publication No. WO 2006/124307 A2 to Goff et al. ("Goff")
1008	U.S. Patent Publication No. 2003/0116731 A1 to Hartley ("Hartley")
1009	U.S. Patent No. 6,776,770 B2 to Treretola ("Treretola")
1010	U.S. Patent Publication No. 2010/0042118 A1 to Garrison et al.
1011	U.S. Patent No. 8,535,283 B2 to Heaton et al. ("Heaton")
1012	U.S. Patent Publication No. 2005/0004534 A1 to Lockwood et al. ("Lockwood")
1013	U.S. Patent Publication No. 2015/0352325 A1 to Quick et al. ("Quick")
1014	U.S. Patent No. 5,938,645 to Gordon ("Gordon")
1015	U.S. Patent Publication No. 2014/0296868 A1 to Garrison et al.
1016	U.S. Patent No. 7,998,104 B2 to Chang ("Chang")
1017	U.S. Patent No. 8,157,760 B2 to Criado et al. ("Criado")
1018	U.S. Patent No. 6,481,439 B1 to Lewis et al. ("Lewis")

EXHIBIT/PAPER NO.	DESCRIPTION
1019	U.S. Patent No. 8,075,510 B2 to Aklog et al.
1020	WIPO Publication No. WO 2018/019829 A1 to Brady et al. ("Brady")
1021	U.S. Patent Application No. 16/117,519 (the "519 application")
1022	Expert Declaration of Dr. Aquilla S. Turk, III, DO
1023	Resume of Dr. Aquilla Turk, III, D.O.
1024	Shani, Jacob M.D., et al., Mechanical Manipulation of Thrombus: Coronary Thrombectomy, Intracoronary Clot Displacement, and Transcatheter Aspiration, 72 Am. J. Cardiol. 116G-118G (1993)
1025	Bose, A et al., The Penumbra System: A Mechanical Device for the Treatment of Acute Stroke due to Thromboembolism, 29 Am. J. Neuroradiol. 1409-1413 (Aug. 2008)
1026	Turk, Aquilla S. et al., Initial clinical experience with the ADAPT technique: A direct aspiration first pass technique for stroke thrombectomy, 6 J. NeuroIntervent. Surg. 231-237 (2014)
1027	Turk, Aquilla S. et al., ADAPT FAST study: a direct aspiration first pass technique for acute stroke thrombectomy, 6 J. NeuroIntervent. Surg. 260-264 (2014)
1028	April 24, 2024 Letter from Inari to Imperative Care
1029	Turk, Aquilla S. et al., Aspiration thrombectomy versus stent retriever thrombectomy as first-line approach for large vessel occlusion (COMPASS): a multicentre, randomized, open label, blinded outcome, non-inferiority trial, 393 Lancet 998-1008 (March 2019)

EXHIBIT/PAPER NO.	DESCRIPTION
1030	Save, Jeffrey L., Time is Brain – Quantified, American Heart Association Journals, available at http://www.stokeaha.org (2005).
Paper 2	Petition for *Inter Partes* Review
2002	Prosecution History of U.S. Patent No. 11,642,209
2003	U.S. Patent Publication No. 2013/0281788 to Garrison ("Garrison '788 publication")
2004	U.S. Patent Application No. 2016/0220741 to Garrison et al. ("Garrison '741")
2005	Prosecution History of U.S. Patent No. 11,554,005

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), I certify that on November 29, 2024, a copy of **CORRECTED EXHIBIT 2001** was served upon the below-listed counsel by electronic mail:

Joshua J. Stowell
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Dated: November 29, 2024 By: */ Kate Rose /*
Kate Rose