

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

IMPERATIVE CARE, INC.,
Petitioner,

v.

INARI MEDICAL, INC.,
Patent Owner.

Case No. IPR2025-01021
U.S. Patent No. 11,969,333

SUPPLEMENTAL DECLARATION OF BRIAN BROWN

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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, IPR2025-01021, concerning U.S. Patent 11,969,333 (“the ’333 Patent”; EX1001), pending before the U.S. Patent and Trademark Office, Patent Trial and Appeal Board (“Board”).
2. I previously provided a declaration (EX2003) in support of Patent Owner’s Preliminary Response (“Opening Declaration”) which I incorporate by reference. In my Opening Declaration, I addressed certain aspects of the challenged claims and the prior art. This Supplemental Declaration (“Declaration” or “Supplemental Declaration”) is meant to supplement and clarify points in my Opening Declaration, as well as to respond to the Institution Decision and arguments raised in Petitioner’s Reply to Patent Owner’s Preliminary Response. As I explained in my Opening Declaration, I understand that Imperative Care, Inc. (“Petitioner” or “Imperative”) has filed a petition for *inter partes review* before the Board asserting:

Ground 1A: Claims 1-10, 13-29, and 33-38 of the ’333 Patent are unpatentable under 35 U.S.C. § 103 as obvious over U.S. Patent Application Publication No. 2017/0043066 (EX1012; “Laub”) in

combination with U.S. Patent Application Publication No. 2015/0173782 to Garrison et al. (EX1006; “Garrison”);

Ground 1B: Claims 6-8, 17, 25-27, and 36 of the ’333 Patent are unpatentable under 35 U.S.C. § 103 as obvious over Laub in combination with Garrison and WIPO Patent Application Publication No. WO2006/124307 to Goff et al. (EX1007; “Goff”);

Ground 1C: Claims 11-12 and 30-31 of the ’333 Patent are unpatentable under 35 U.S.C. § 103 as obvious over Laub in combination with Garrison and U.S. Patent Application Publication No. 2003/0225379 to Schaffer et al. (EX1013; “Schaffer”);

Ground 1D: Claims 11-12 and 30-31 of the ’333 Patent are unpatentable under 35 U.S.C. § 103 as obvious over Laub in combination with Garrison, Schaffer, and U.S. Patent Application Publication No. 2003/0116731 to Hartley (EX1008; “Hartley”);

Ground 2A: Claims 1-10, 13-29, and 32-38 of the ’333 Patent are unpatentable under 35 U.S.C. § 103 as obvious over U.S. Patent No. 8,734,374 B2 to Aklog et al. (EX1005; “Aklog”) in combination with Garrison;

Ground 2B: Claims 6-8, 17, 25-27, and 36 of the '333 Patent are unpatentable under 35 U.S.C. § 103 as obvious over Aklog in combination with Garrison and Goff;

Ground 2C: Claims 11-12 and 30-31 of the '333 Patent are unpatentable under 35 U.S.C. § 103 as obvious over Aklog in combination with Garrison and Schaffer;

Ground 2D: Claims 11-12 and 30-31 of the '333 Patent are unpatentable under 35 U.S.C. § 103 as obvious over Aklog in combination with Garrison, Schaffer, and Hartley;

Ground 3A: Claims 1-10, 13-29, and 32-38 of the '333 Patent are unpatentable under 35 U.S.C. § 103 as obvious over Garrison in combination with Laub;

Ground 3B: Claims 6-8, 17, 25-27, and 36 of the '333 Patent are unpatentable under 35 U.S.C. § 103 as obvious over Garrison in combination with Laub and Goff;

Ground 3C: Claims 11-12 and 30-31 of the '333 Patent are unpatentable under 35 U.S.C. § 103 as obvious over Garrison in combination with Laub and Schaffer;

Ground 3D: Claims 11-12 and 30-31 of the '333 Patent are unpatentable under 35 U.S.C. § 103 as obvious over Garrison in combination with Laub, Schaffer, and Hartley;

Ground 4A: Claims 1-10, 13-29, and 32-38 of the '333 Patent are unpatentable under 35 U.S.C. § 103 as obvious over Garrison in combination with Aklog;

Ground 4B: Claims 6-8, 17, 25-27, and 36 of the '333 Patent are unpatentable under 35 U.S.C. § 103 as obvious over Garrison in combination with Aklog and Goff;

Ground 4C: Claims 11-12 and 30-31 of the '333 Patent are unpatentable under 35 U.S.C. § 103 as obvious over Garrison in combination with Aklog and Schaffer; and

Ground 3D: Claims 11-12 and 30-31 of the '333 Patent are unpatentable under 35 U.S.C. § 103 as obvious over Garrison in combination with Aklog, Schaffer, and Hartley.

Petition, pg. 16. I have been asked by counsel for Patent Owner to opine on the patentability of the Claims of the '333 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 '333 Patent are obvious over (grounds 1A-1D) Laub in combination with Garrison or Garrison and one or more of Goff, Schaffer, and Hartley, (grounds 2A-2D) Aklog in combination with Garrison or Garrison and one or more of Goff, Schaffer, and Hartley, (grounds 3A-3D) Garrison in combination with Laub or Laub and one or more of Goff, Schaffer, and Hartley, and (grounds 4A-4D) Garrison in combination with Aklog or Aklog and one or more of Goff, Schaffer, and Hartley.
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 '333 Patent, August 13,

2018. Petitioner also applied August 13, 2018, as the priority date for the '333 Patent. Petition, pg. 13.

24. 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.
25. 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.
26. 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.

27. 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

28. For the reasons I discuss below, I believe that the Claims of the '333 Patent are not rendered obvious by any combination of the prior art asserted in the Petition.

V. THE '333 PATENT

A. Overview

29. 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>.)

30. 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.

31. 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.
32. 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.
33. 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.

34. Lytics have many disadvantages. First, they can take many hours to work. EX1001, 2:28-29. 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.* at 2:30-32. 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.).

35. 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).
36. Invasive surgical procedures have also been used to treat VTE. *Id.* at 2:10-12. But those procedures involve exposing a patient to surgery which can cause significant trauma and danger to the patient, particularly for patients that have already exhibited a tendency for dangerous clotting.
37. The '333 Patent is directed to method of treating PE and DVT that offer significant benefits over such conventional treatments. EX1001, 4:17-19. For example, the '333 Patent describes various aspiration systems that generate (pre-charge or store) negative (vacuum) pressure 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.

38. I understand that Patent Owner has come to call their methodology of applying pre-charged vacuum “whoosh,” so named based on the sound the catheter system makes when the pre-charged vacuum is applied to the catheter to aspirate blood and clot material.
39. The ’333 Patent includes two independent claims that recite identical methods but for “treating a pulmonary embolism” (Claim 1) and “treating a deep vein thrombosis” (Claim 20). EX1001, cls.1 & 20. Each method includes “advancing an aspiration catheter at least partially through the vasculature of the patient such that a distal end portion of the aspiration catheter is positioned proximate to the” pulmonary embolism or deep vein thrombosis. *Id.* A “lumen of the aspiration catheter is fluidly coupled along a fluid path to a clot canister and an aspiration source proximal to the clot canister.” *Id.* The claimed methods further include “generating vacuum pressure within the clot canister via the aspiration source while a valve positioned along the fluid path between the aspiration catheter and the clot canister is in a first position that inhibits

fluid flow along the fluid path from the lumen of the aspiration catheter to the clot canister” and “moving the valve from the first position to a second position thereby applying the vacuum pressure to the lumen of the aspiration catheter such that at least a portion of the pulmonary embolism [or deep vein thrombosis] and blood are aspirated into the clot canister, wherein in the second position the valve permits fluid flow along the fluid path from the lumen of the aspiration catheter to the clot canister, and wherein the clot canister includes a filter configured to filter the blood from the portion of the pulmonary embolism [or deep vein thrombosis].” *Id.*

40. Accordingly, the Claims of the '333 Patent recite methods including building up vacuum pressure in a clot canister with an aspiration source when a valve inhibits fluid flow from the aspiration catheter to the aspiration source, and then actuating the valve to apply that built-up vacuum pressure to the aspiration catheter to aspirate PE or DVT and blood therethrough. The clot canister includes a filter to filter the PE or DVT from the blood.
41. Figure 1 of the '333 Patent illustrates one example of a system for carrying out the methods for treating PE/DVT claimed in '333 Patent. In Figure 1, an aspiration assembly 10 comprises an aspiration catheter 102 fluidly coupled to a pressure source 140 via a valve 126 (e.g., a stopcock or other fluid control valve) when the valve is open:

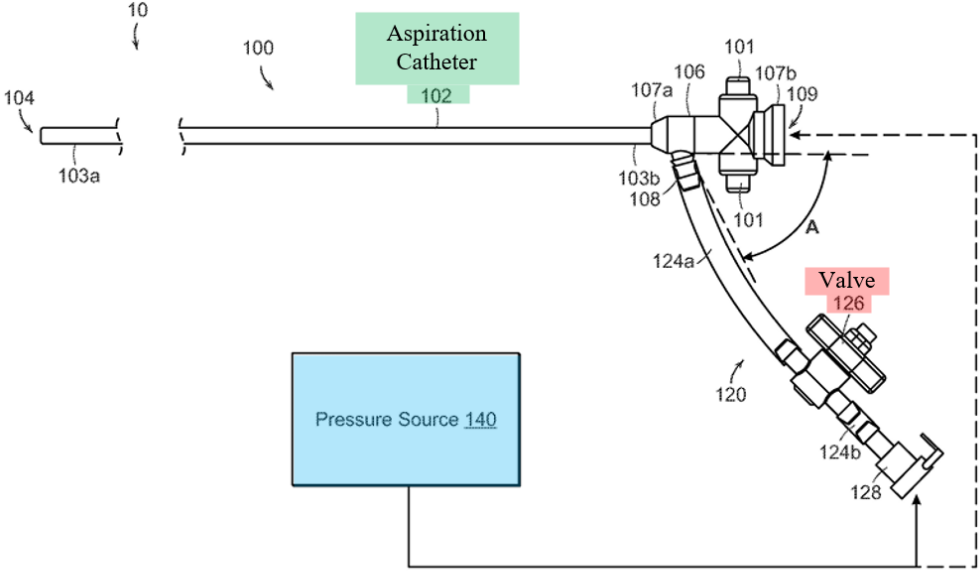


FIG. 1

EX1001, 5:25-7:23. The '333 describes many different configurations of the pressure source including those with a filter positioned in a chamber that build-up vacuum pressure when a valve is closed. For example, in Figure 19 discloses a “a pressure source 1900 for filtering blood from aspirated clot material during a clot removal procedure” including a clot canister 1940 with a filter 1942 and an aspiration source 460 that generates vacuum pressure in the clot canister 1940 when the valve 126 shown in Figure 1 is closed:

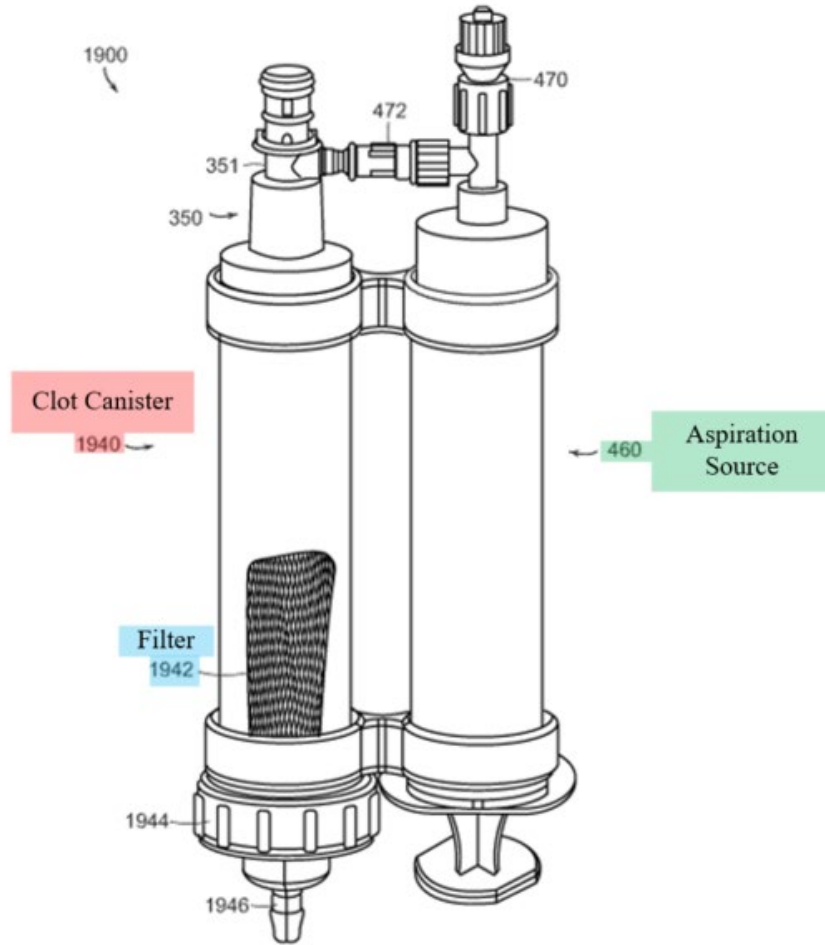
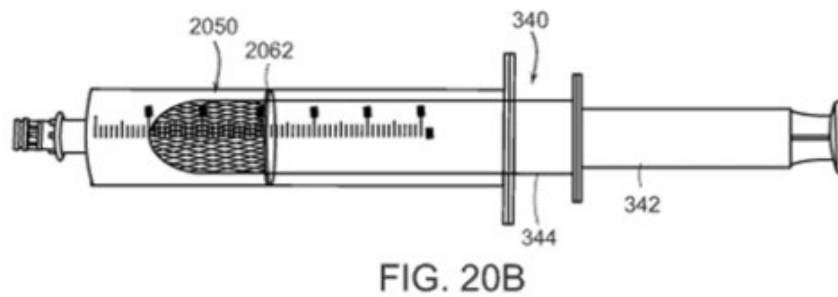
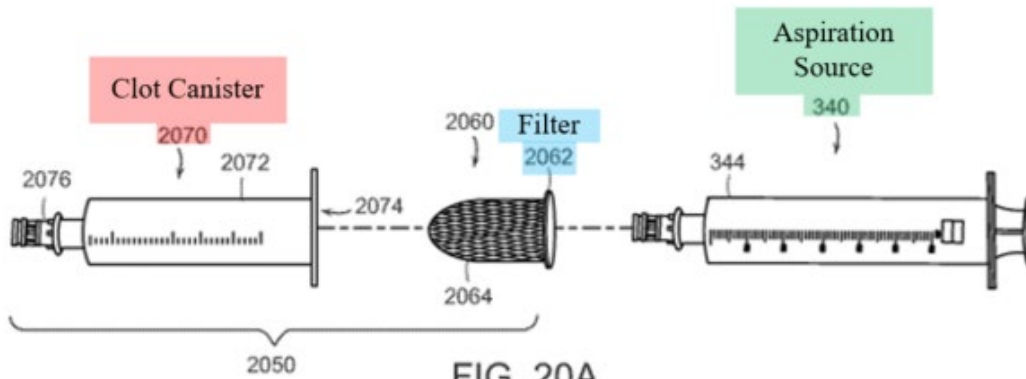


FIG. 19

Id. at 31:9-50. Figures 20A-20E show yet another pressure source that can be utilized in the system of Figure 1 and configured for “filtering blood from aspirated clot material during a clot removal procedure,” including a clot canister 2070 containing a filter 2062 and an aspiration source 340 that generates vacuum pressure in the clot canister 2070 when the valve 126 shown in Figure 1 is closed:



Id. at 31:51-33:6.

42. The '333 Patent explains that the aspiration source can either be a pump, or alternatively a different pressure source such as a syringe: “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.” *Id.* at 7:33-41. Thus, in different embodiments of the '333 Patent, the aspiration source is either a pump or a syringe.
43. Figure 8 of the '333 Patent is a flow chart illustrating the steps of the claimed methods for treating PE/DVT, and some of those steps are shown with respect

to Figures 9A-10B. EX1001, 16:33-56. For example, as shown in Figure 10A a distal portion of the aspiration catheter is advanced through the vasculature such that a distal portion thereof is positioned proximate to a PE or DVT:

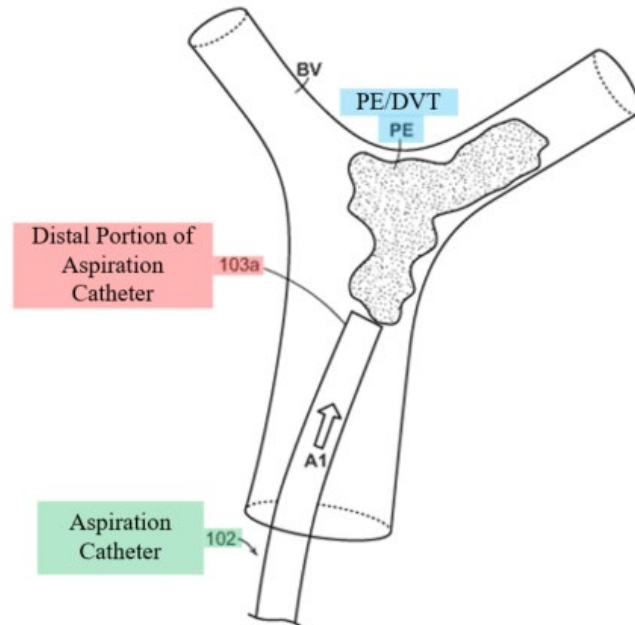
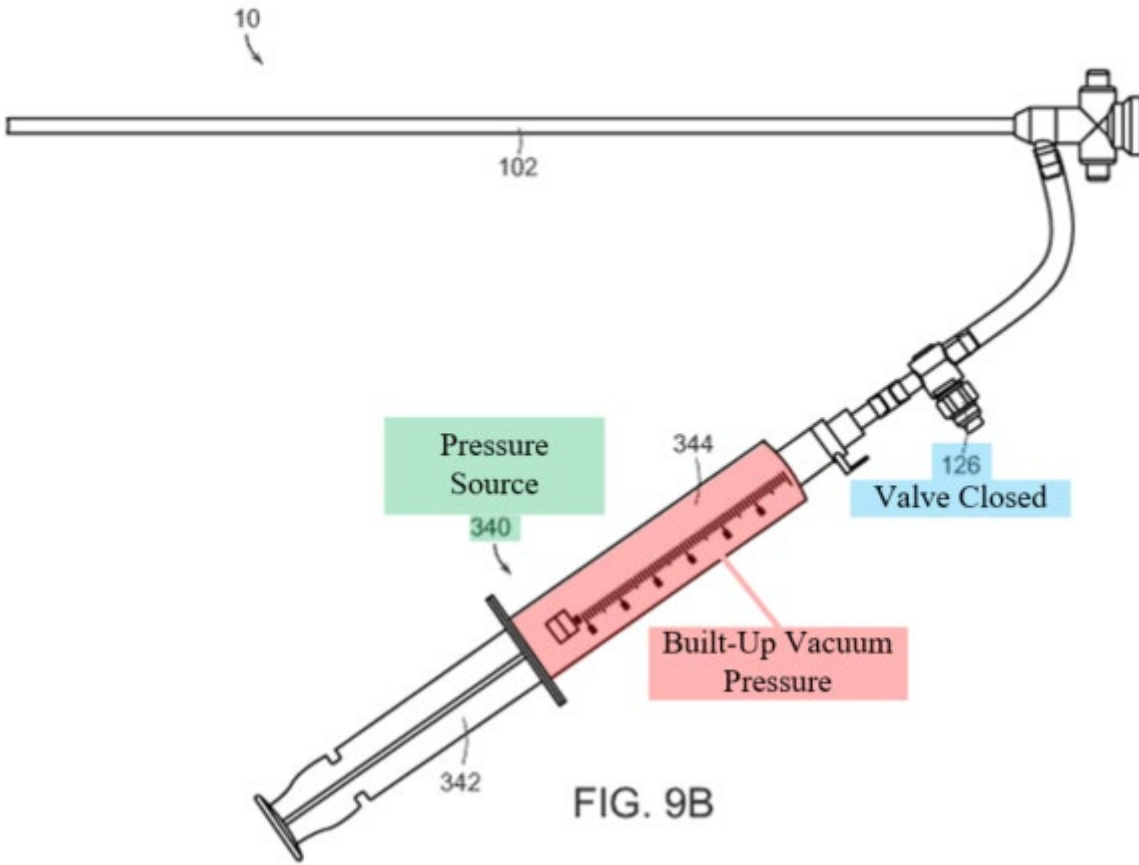


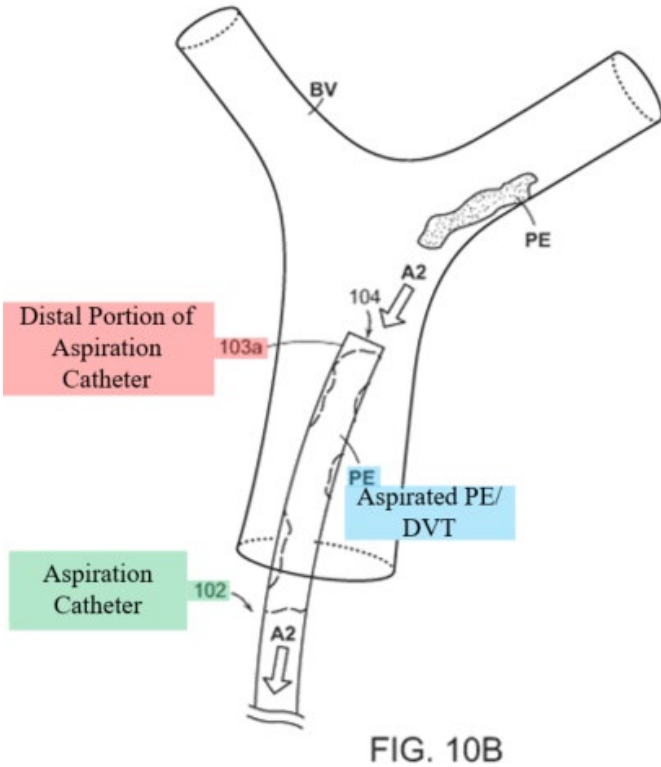
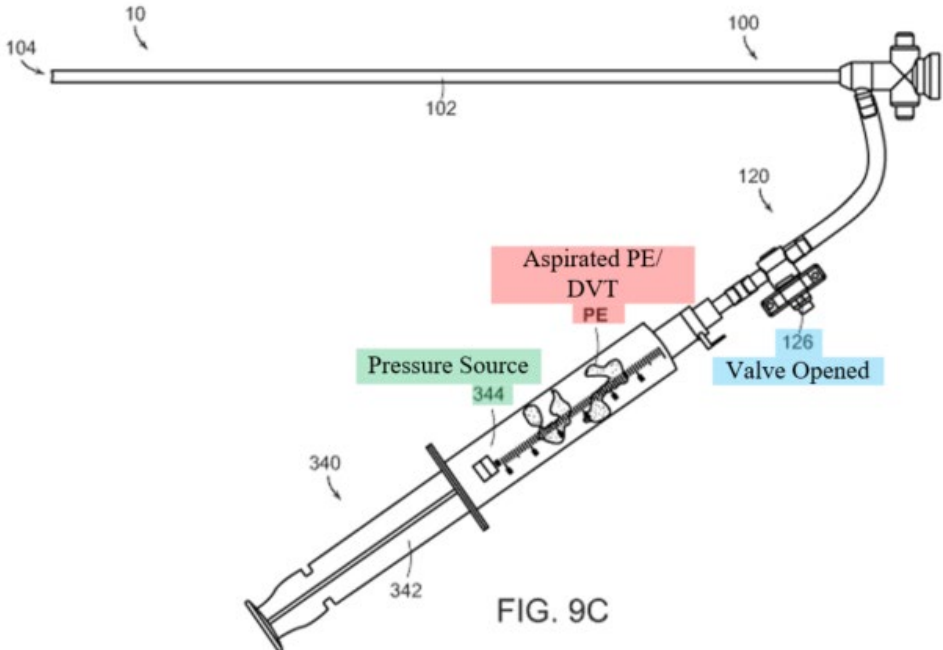
FIG. 10A

Id. at 16:57-17:9. Then, as shown in Figure 9B, the pressure source is used to generate and build up (e.g., pre-charge) vacuum pressure while the valve is closed:



Id. at 18:11-41. While Figure 9B illustrates a syringe without a filter, a POSITA would understand that the filtering embodiments of Figures 19-20E or other filtering embodiments described in the '333 Patent could be substituted for the pressure source 340.

44. The built-up vacuum pressure is then applied to the catheter to aspirate the PE/DVT by opening the valve as shown in Figures 9C and 10B:



Id. at 18:43-19:9.

B. Prosecution History

45. I have reviewed the prosecution history of the '333 Patent, including the only Office Action mailed October 30, 2023 (EX1002, pgs. 154-176), the Amendments and Response to the Office Action filed January 30, 2024 (*Id.* at pgs. 109-119), the Examiner Interview Summary Record mailed January 31, 2024 (*id.* at pgs. 99-104), and the Notice of Allowance mailed March 1, 2024 (*Id.* at pgs. 43-49). In the sole Office action, the Examiner rejected then-pending claims 1–6, 11–14, 16–18, and 20–22 under 35 U.S.C. § 103 over a combination of Garrison II (EX1032), Barzell (EX1033), and Heaton (EX1011). EX1002, pgs.154-176. Garrison II is a different reference than Garrison applied by Petitioner here, but shares common inventors (Michi E. Garrison and Tony M. Chou) and assignee (Route 92 Medical Inc.). EX1006, pg. 1; EX1032, pg. 1. And, both Garrison and Garrison II are directed to catheter systems for treating neurovascular clots (e.g., acute ischemic stroke), each stating that “[t]he present disclosure relates generally to medical methods and devices for the treatment of acute ischemic stroke.” EX1006, ¶[0002]; EX1032, ¶[0003].
46. In response to that Office action, Patent Owner canceled the then-pending claims 1-22 and added new claims 23-60 that matured into Claims 1-38 of the '333 Patent. EX1002, pgs. 109-119. Before filing the response, I see that

Patent Owner conducted a videoconference interview with the Examiner, his supervisor, and an inventor of the '333 Patent, Dr. Thomas Tu, on January 25, 2024. During that interview, Patent Owner discussed the proposed new independent claims and also specifically called attention to the disclosure of Garrison relied on by Petitioner here. For example, in the Examiner Interview Summary Record mailed January 31, 2024, the Examiner attached an agenda for discussion submitted by Patent Owner as an Office action appendix. EX1002, pgs. 101-104. That agenda included discussion points for the proposed new claims, the Section 103 rejection over the combination of Garrison II, Barzell, and Heaton, and further noted for discussion at listed items (3)(a) and (3)(b) of the agenda:

(3) Discussion of additional prior art of record.

(a) U.S. Patent Application Publication No. 2017/0274180 (“Garrison”). See, e.g., Figure 34 and paragraphs [0132]-[0134] and [0162]-[0172].

(b) U.S. Patent Application Publication No. 2013/0035628 (“Garrison”). See, e.g., Figure 16 and paragraph [0085].

47. U.S. Patent Application Publication No. 2017/0274180 (EX2001) identified by Patent Owner to the Examiner is a direct continuation of Garrison and, as such, contains identical disclosure to Garrison relied on by Petitioner here.

EX2001, pg. 1. U.S. Patent Application Publication No. 2013/0035628 (EX2002) identified by Patent Owner to the Examiner also contains some disclosure identical to that of Garrison extensively relied on by Petitioner, including Figures 15-17 identical to Figures 32-34 of Garrison and related description, including paragraph [0085] identical to paragraph [0134] of Garrison. *See, e.g.,* Petition, pgs. 6, 7, 21-23, 35, 37-39, 42, 63-64.

48. Patent Owner's response to the Office action further summarizes discussions of Garrison with the Examiner:

Additionally, during the January 25th videoconference interview, the parties discussed proposed new independent claims 23 and 42 in view of U.S. Patent Application Publication No. 2017/0274180 ("Garrison II") and U.S. Patent Application Publication No. 2013/0035628 ("Garrison III"). For example, FIG. 15 and Paragraph [0085] of Garrison III were specifically discussed with respect to claims 23 and 42. At that time, the Examiner and his supervisor provisionally agreed that new independent claims 23 and 42 also patentably distinguish over Garrison II and Garrison III.

EX1002, pg. 117. Accordingly, Patent Owner specifically brought the relevant disclosure of Garrison to the Examiner's attention despite Garrison not being cited in the sole Office action. Following that amendment, the Examiner

agreed and further explained why the claims are patentable over the various

Garrison references in the Notice of Allowance:

Claim 23 and 42 are allowable for reciting, *inter alia*, “a method of treating a *pulmonary embolism* within a vasculature ...” and “applying the vacuum pressure to the lumen of the aspiration catheter such that at least a portion of the pulmonary embolism and blood are aspirated into the clot canister.[”]

Garrison, Barzell, and Heaton teaches an aspiration catheter, as described in Non-Final Rejection filed on 10/30/2023. However, modified Garrison does not teach an aspiration catheter configured to aspirate pulmonary embolism or deep vein thrombosis. The aspiration catheter of modified Garrison is configured for smaller neurovascular anatomy (see Abstract) and not configured for larger clot/embolisms. As explained by inventor during the interview on 1/25/2024, and further supported by photographic evidence during the interview, a pulmonary embolism or a deep vein thrombosis presents significant different structures and physiological responses as compared to neurovascular clots, and therefore one skilled in the art would not have looked to use the Garrison device for the current methods.

Prior art like Batiste (US 20180042623 A1) teaches an aspiration catheter (see Abstract) used for deep vein thrombosis or pulmonary embolisms (see Paragraph [0004]). However, it would not be reasonable to combine modified Garrison with the device of Batiste because Garrison specifically teaches the aspiration

catheter being used for neurovascular procedures. Therefore the device of Garrison would be not be combinable with the device of Garrison to teach a method of treating pulmonary embolisms or deep vein thrombosis. There is no prior art that reads on the combination of limitations of claim 23 or 42. **Claims 24-41** are allowable for depending on claim 23. **Claims 43-60** are allowable for depending on claim 42.

49. EX1002, pgs. 46-47. In summary, in allowing the Claims challenged here, the Examiner considered the disclosure of Garrison and found that a POSITA would not have modified Garrison to treat pulmonary embolism or deep vein thrombosis, and also found that there is no prior art that reads on the Claims including in view of Batiste which the Examiner described as teaching an aspiration catheter used to treat deep vein thrombosis and pulmonary embolism.
50. Accordingly, Garrison was considered in detail during prosecution. Garrison's disclosure was specifically brought to the Examiner's attention by Patent Owner, and the Examiner considered Garrison and expressly explained that the Claims were patentable over Garrison in the Notice of Allowance.
51. As I explain below, I agree with the Examiner that a POSITA would not have modified Garrison to treat PE or DVT, or modified other references like Batiste for treating PE/DVT based on Garrison.

C. Person of Ordinary Skill in the Art

52. 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 and, where necessary, would have consulted with a physician regarding the methods of treatment.” Petition, pg. 13. Rather, a POSITA would have been (1) a person with a Bachelor of Science degree in engineering or an equivalent field, with two to four years of academic or industry experience in the mechanical thrombectomy industry or comparable industry experience who would, where necessary or desired, work or consult with others including a physician to develop thrombectomy devices (including for smaller arteries); or (2) an interventional radiologist or pulmonologist with at least three years of experience developing and/or using medical devices in thrombectomy procedures (including for smaller arteries), and who would, where necessary, work or consult with others including an engineer to develop such a medical device. A person with less education but more relevant practical experience, or more relevant education but less practical experience, may also meet this standard. I was also at least a person of ordinary skill in

the art as of the priority date of the '333 Patent according to both standards, and my opinions herein are the same under either standard.

D. Claim Construction

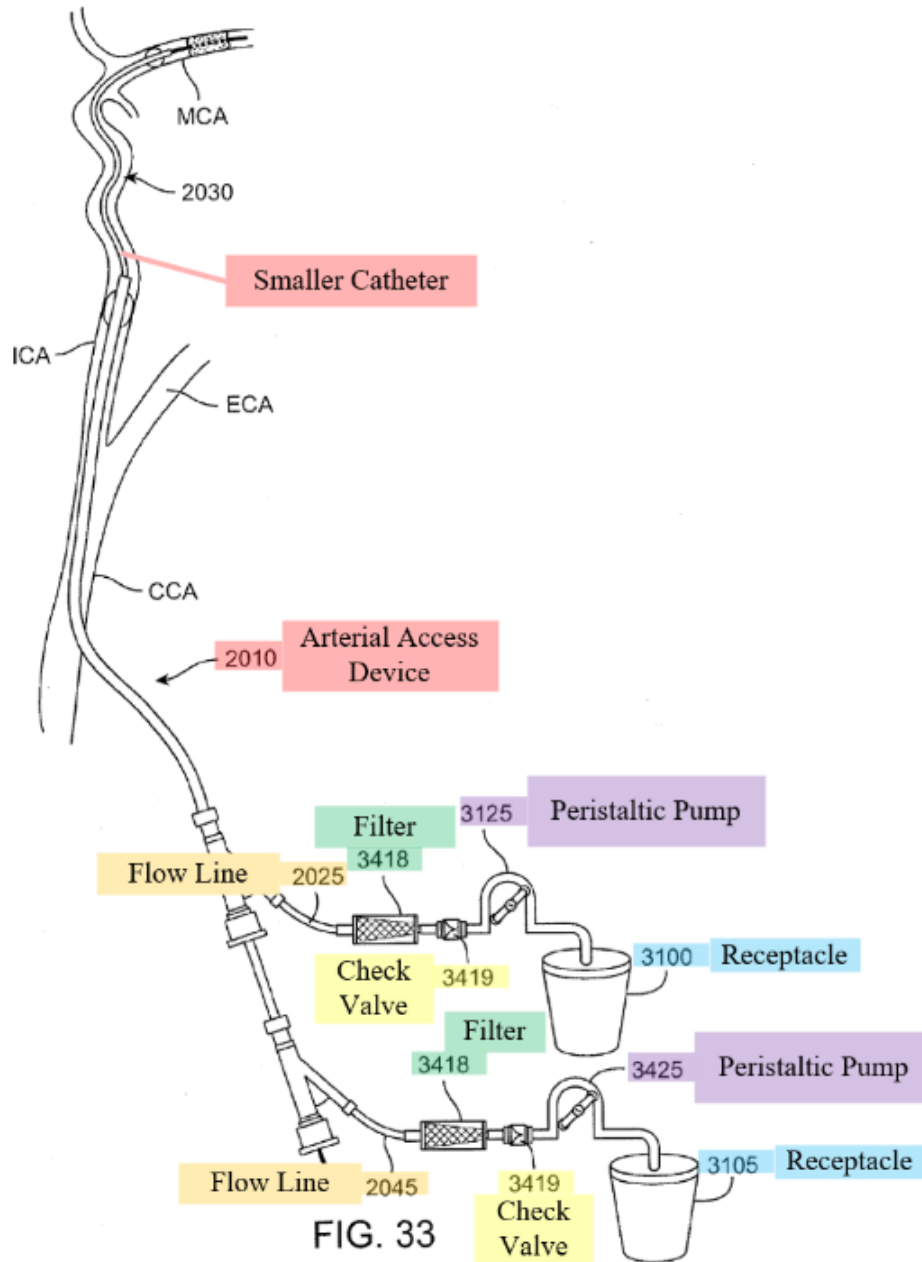
53. Petitioner proposes a construction only for the term “filament” recited in dependent Claims 11-12 and 30-31. Petition, pgs. 13-15. Because my analysis here focuses on the patentability of independent Claims 1 and 20, and not on Claim 7 specifically, I have not provided a construction of “filament” at this time in this matter, but I have in other matters..

VI. REFERENCES

A. Garrison

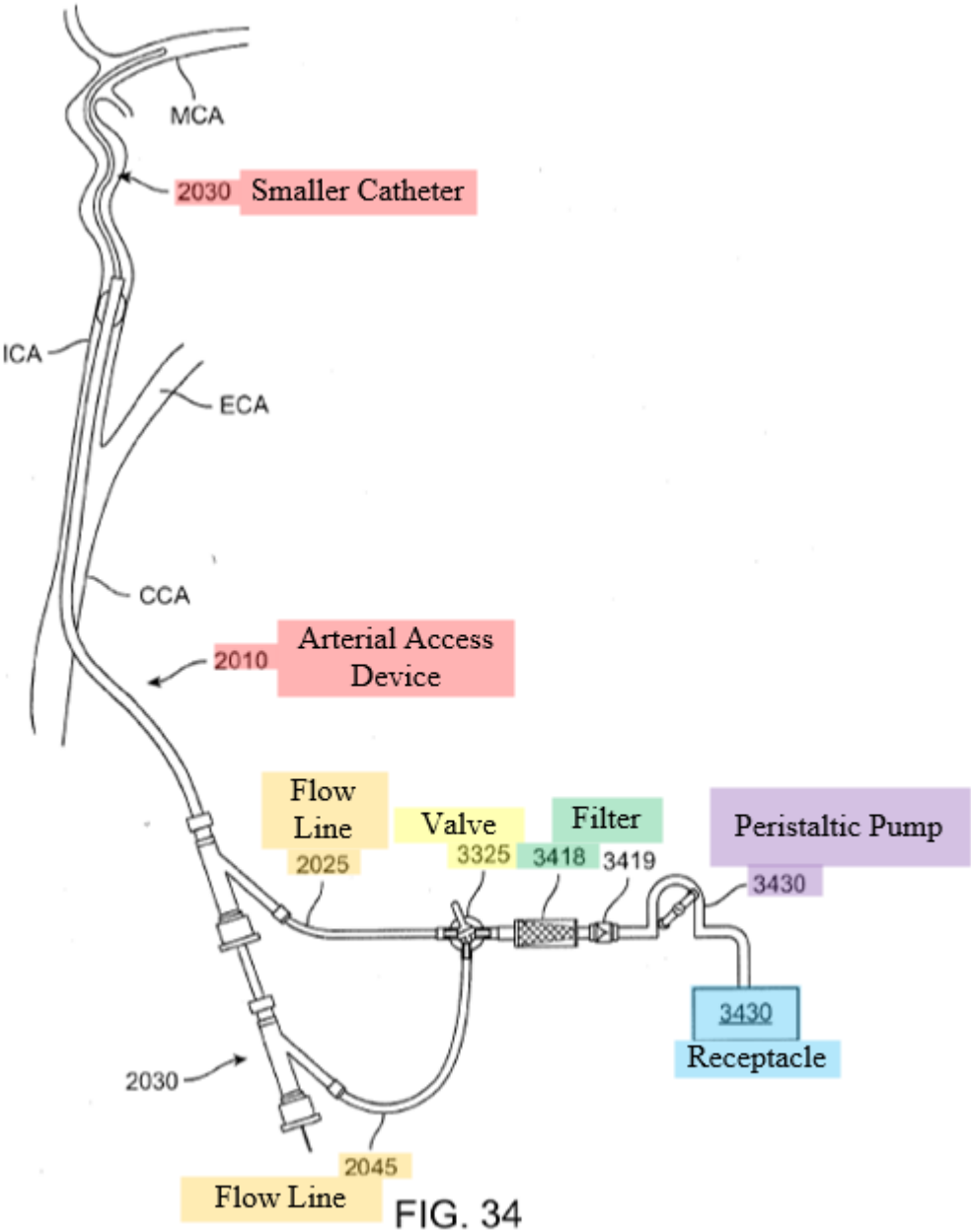
54. Garrison is directed to systems for treating acute ischemic stroke caused by small cerebral clots in the cerebral arterial vasculature rather than, for example, treating large clots (e.g., PE and DVT) in the venous vasculature that is much larger in diameter than the cerebral vessels, as described in the '333 Patent. EX1006, ¶[0002]. For example, Figure 33 (reproduced below) of Garrison shows an arterial access device 2010 that provides access to the common carotid artery (CCA), and a smaller catheter 2030 inserted through the arterial access device 2010 such that a distal tip of the catheter 2030 is positioned in the middle cerebral artery (MCA). EX1006, ¶[0131]. The arterial access device 2010 is connected to a flow line 2025, which is connected in series to a filter 3418, a check valve 3419, a source of aspiration 3125 (a peristaltic

pump), and a receptacle 3100, respectively. *Id.* The catheter 2030 is similarly connected to a flow line 2045, a filter 3418, a check valve 3419, a source of aspiration 3425 (a peristaltic pump), and a receptacle 3105. *Id.*



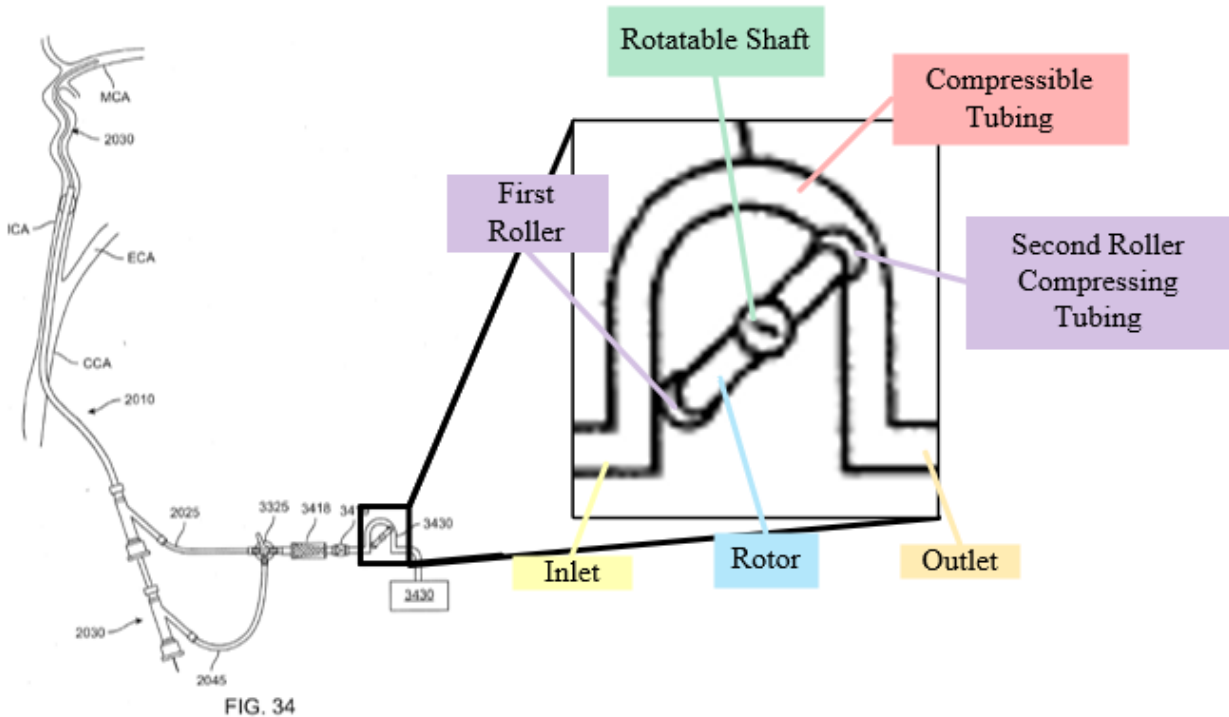
As can be seen above, Figure 33 does not include any valve in either flow path between the peristaltic pumps and connected catheter would allow for building up and then releasing vacuum pressure.

55. Figure 34 of Garrison (reproduced below) shows a similar system in which “both the arterial access device 2010 and catheter 2030 are connected to the same aspiration source 3430 via flow lines 2025 and 2045, respectively.” *Id.* at ¶[0132]. A “valve 3325 controls which device is connected to the aspiration source 3430 ... [t]he valve may enable one device, the other device, both devices, or neither device to be connected to the aspiration source at any given time.” *Id.* Downstream of the aspiration source 3430 is a receptacle for receiving and holding aspirated blood.



56. A POSITA would recognize that the aspiration sources 3125/3425 in Figures 33 and 34 are peristaltic pumps based on their 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 34 below:



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 one or both of the flow lines 2025/2045 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 3430. 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.

57. Garrison discloses “one embodiment” of a syringe-based system in which “a locking syringe (for example a VacLok Syringe) is attached to the flow controller and the plunger is pulled back into a locked position by the user while the connection to the flow line is closed prior to the thrombectomy step of the procedure.” *Id.* at ¶[0134]. Accordingly, when the syringe is used in that one embodiment, the syringe is attached directly to the flow controller (e.g., valve) to “enable the maximum level of aspiration” by reducing any dead volume between the syringe and the valve. *Id.* Then, “[d]uring the procedure when the tip of the aspiration device ... is near or at the face of the occlusion, the user may open the connection to the aspiration syringe ... [t]his would enable the maximum level of aspiration in a rapid fashion with one user.” *Id.* In this

embodiment, the locking syringe is actuated with the connection to the flow line closed such that vacuum is generated in the syringe.

58. With reference to the embodiments shown in Figures 33 and 34 of Garrison and the different locking syringe embodiment disclosed (but not illustrated) in paragraph [0134], Garrison goes on to explain that those embodiments are disadvantageous:

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

Id. at ¶[0135]. That is, when blood is pumped to a downstream receptacle as shown in Figures 33 and 34, or directly collected in a syringe, the blood is not suitable for reinfusion to the patient because the blood remains static and/or is exposed to air such that it can clot or blood cells can otherwise be damaged.

59. To address that disadvantage, Garrison discloses a different system in Figure 36 “which is configured not to harm blood cells and which may be configured

to return blood to the central venous system in real time during the procedure, so there is no reservoir in which the blood remains static.” *Id.* at ¶[0136]. Figure 36 illustrates a pump device 3250 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:

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. *Id.* at ¶¶[0136]-[0137]. 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. *Id.* 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. The pump in Figure 36 of Garrison is another type of positive displacement pump like a peristaltic pump, but that operates without rollers that compress tubing.

B. Laub

61. Laub discloses a “system for removing thrombi and other unwanted material from the body of a patient, particularly from the patient’s vasculature” and,

more particularly, a system “to remove clots from patients suffering from or at risk of pulmonary embolisms.” EX1012, ¶[0005]. The embodiment of Laub relied on by Petitioner is shown in Figure 1A (reproduced below) and includes a single aspiration catheter 200 in fluid communication with a filter 300, a pump 400, and a return catheter 500:

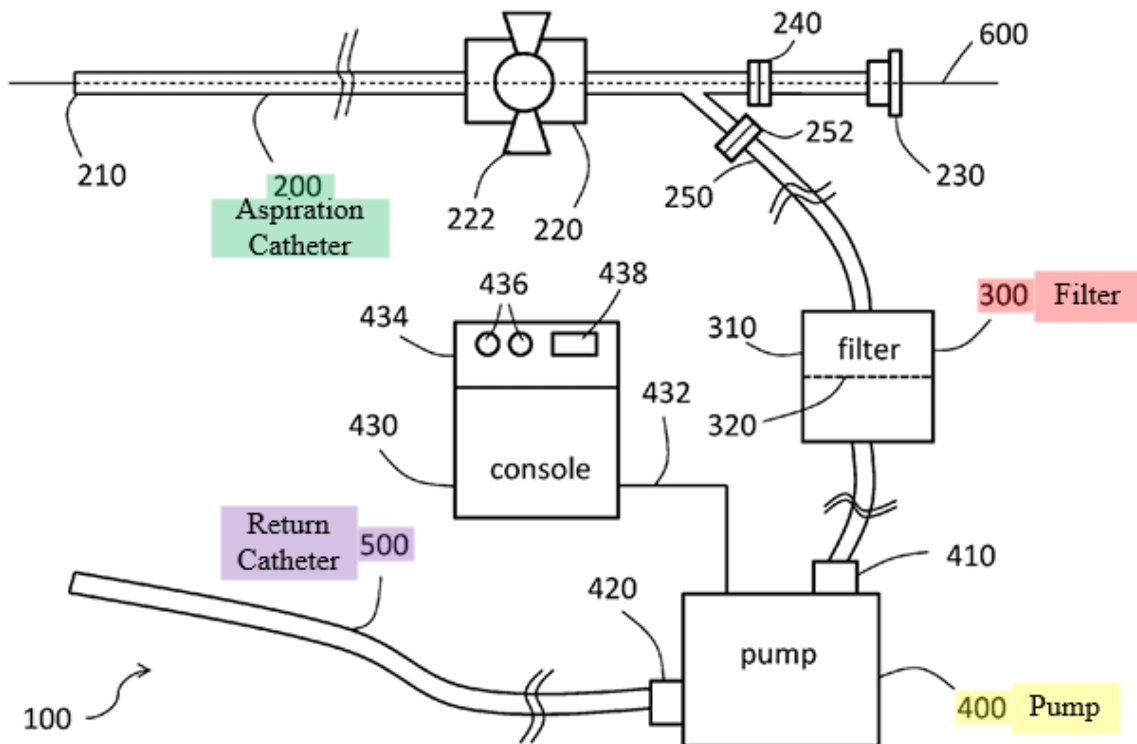


FIG. 1A

Id. at ¶[0024]. Because there is no valve in the flow path, the pump 400 operates to continuously suction blood and thrombi through the aspiration catheter 200 and the filter 300 and then drive the filtered blood through the return catheter 500 back into the patient. *Id.* In other words, it does not generate a stored vacuum pressure. Accordingly, Laub discloses that “[i]n preferred

embodiments, pump 400 is a centrifugal pump” while “[i]n other embodiments, pump 400 may be a rotary pump, peristaltic pump, roller pump, or other form of pump known in the art.” *Id.* at ¶[0041].

62. Laub discloses that the aspiration catheter 200 can have a wide range of sizes, but emphasizes that “[i]n certain preferred embodiments, aspiration catheter has a French size of equal to or greater than 10 Fr to allow for aspiration of large thrombi and/or other solid materials from the patient.” *Id.* at ¶[0028]. A POSITA would understand that PE and DVT are large clots. Laub also discloses a wide range of flow rates including flow rates up to 6 liters per minute. *Id.* at ¶¶[0043]-[0044].
63. Because of those large flow rates enabled by a large catheter, Laub correctly recognizes the need for blood reinfusion: “Without returning the blood back to the patient, such high flow rates could quickly result in exsanguination of the patient.” *Id.* at ¶[0045]. That is, the patient will bleed out and die if the blood is not returned. “By returning the aspirated blood back to the patient, embodiments of the present system 100 allows for aspiration while minimizing the blood loss of the patient.” *Id.* Laub also discloses that “reinfusing the patient’s blood continuously during aspiration allows for greater suction pressure and/or flow rates (e.g., 2-4 L/min) which can assist in dislodging and removing larger clots and/or tumors than would otherwise be possible.” *Id.*

Accordingly, a POSITA would understand that Laub's system is intended to be operated to continuously aspirate and return blood at a high flow rate so that large clots, such as PE and DVT, can be removed. Laub discloses that its system would endanger the patient if blood were not returned.

C. Aklog

64. A POSITA would understand Aklog's system to be largely the same as Laub's. Indeed, like Laub, the embodiments of Aklog relied on in the Petition and shown in Figures 1, 6, and 7 of Aklog (Figure 1 reproduced below) include an aspiration catheter (cannula) 10 in fluid communication with a filter device 14, a pump 15, and a reinfusion catheter (cannula) 16:

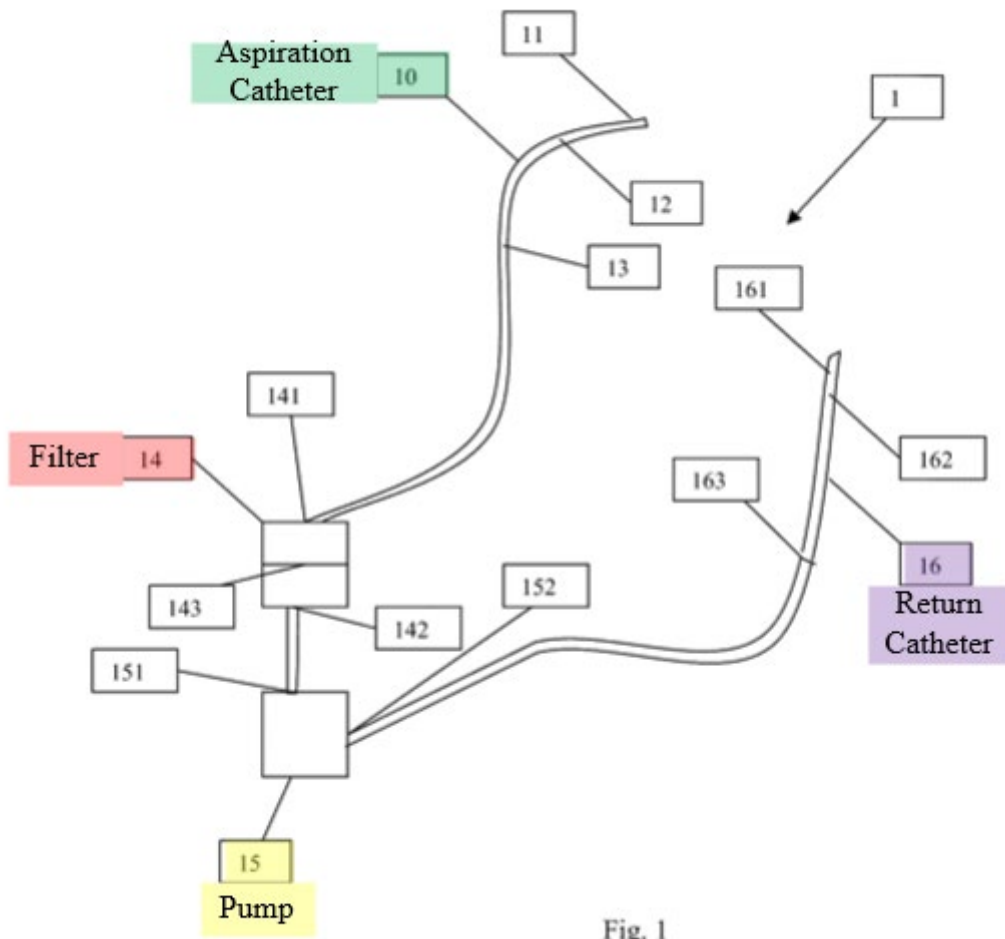


Fig. 1

EX1005, 11:24-12:34. Just like in the Laub reference, because there is no valve in the flow path, the pump 15 operates to continuously suction blood and thrombi through the aspiration catheter 10 and the filter device 14 and then drive the filtered blood through the reinfusion catheter 16 into the patient. *Id.* Aklog also does not disclose any other mechanism for building up a stored vacuum pressure either, employing a continuous pump.

65. The aspiration catheter 10 “may be of any sufficient size, so long as it can be accommodated within a predetermined vessel, such as a medium to large size

blood vessel.” *Id.* at 11:12-15. For example, “the suction cannula 10 may be designed to remove at least 10 cm³ of undesirable material substantially en bloc.” *Id.* at 11:18-20. A POSITA would understand that a clot of 10 cm³ is much larger than neurovascular clots and more akin to the size of a PE or DVT. And, “[b]ecause the normal rate of blood flow through the heart and large blood vessels can be significant, suction cannula 11 and reinfusion cannula 16, when used around the heart and other large vessels, may displace a relatively large volume of fluid into and out of the patient's circulatory system.” *Id.* at 19:57-62.

66. Given the large clots that Aklog is designed to treat, Aklog correctly recognizes that “[i]f 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.” *Id.* at 7:23-26. That is, the patient will be harmed due to excessive blood removal if the blood is not returned. To address this, Aklog’s system “simultaneously reinfuse[s] 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.” *Id.* at 5:19-23. Aklog further teaches that the “suction and reinfusion of blood can occur, in an embodiment, continuously for a desired duration to minimize fluid loss in the patient.” EX1005, 5:20-23. Accordingly,

like Laub, a POSITA would understand that Aklog's system is intended to be operated to continuously aspirate and return blood so that large clots, which PE and DVT are, can be removed. Aklog discloses that its system would endanger the patient if blood were not returned.

VII. GROUNDS 1A AND 2A: THE COMBINATION OF LAUB OR AKLOG AND GARRISON DOES NOT RENDER OBVIOUS ANY OF CLAIMS 1-10, 13-29, OR 32-38

67. Petitioner and its expert, Mr. Thornton, allege that Laub in combination with Garrison (ground 1A) renders obvious Claims 1-10, 13-29, and 33-38 of the '333 Patent and that Aklog in combination with Garrison (ground 2A) renders obvious Claims 1-10, 13-29, and 32-38 of the '333 Patent. I disagree for the reasons I discuss in further detail in this section.
68. As I explained above, I understand that for a patent claim to be rendered obvious, 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, the claimed invention is obvious. Even if all limitations of a claimed invention are disclosed by the prior art combination, Petitioner 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. 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.

69. First, as I explain in §VII.A. below, Petitioner relies on the valve 3325 in Garrison for allegedly disclosing a “valve”, e.g., a fluid control device, and Garrison alone for the claimed buildup of vacuum pressure in a clot canister having a filter and subsequent release of vacuum pressure using that valve, as recited in independent Claims 1 and 20, and then imports that valve into the system of Laub and Aklog. Petition, pgs. 36-42. But Garrison does not disclose that the valve 3325 is used to carry out the claimed methodology. Instead, in the embodiment of Figure 34 the valve 3325 merely selects whether one catheter, the other catheter, both catheters, or neither catheter is connected to the peristaltic pump pressure source. EX1006, ¶[0132]. And a POSITA would understand that the peristaltic pump pressure source in Figure 34 is not intended to run (e.g., be turned on to generate vacuum) without connection to at least one of those catheters as I explain below. Because of that deficiency, Petitioner relies on aspects of the different and incompatible syringe embodiment described in paragraph [0134] of Garrison to allegedly show the claimed

buildup and release of pressure. Petition, pg. 38. But, that disclosure in paragraph [0134] is for generating vacuum pressure within a syringe rather than with a peristaltic pump as shown in Figure 34 of Garrison. In the syringe embodiment, the syringe is “attached” to the flow controller rather than a filter 3418 and a check valve 3419 like the peristaltic pumps in Figure 34 specifically to “enable the maximum level of aspiration.” EX1006, ¶[0134]. That is, the syringe embodiment in [0134] does not include any “clot canister” having a filter in which vacuum pressure is built up as recited in the Claims of the ’333 Patent. Accordingly, Garrison does not disclose generating vacuum pressure in a clot canister having a filter while a valve is closed using a peristaltic pump in the embodiment shown in Figure 34 of Garrison and relied on by Petitioner.

70. Second, I see that Board preliminarily found “no flaw in Petitioner’s alleged mixing of disclosures or features for different embodiments” finding that Garrison’s disclosure suggests that the various embodiments “may be combined.” Institution Decision, pgs. 31-32. However, while Garrison’s flow controllers and stopcocks may be alternative valves, and while Garrison’s syringes and pumps may be alternative aspiration sources, the flaw in Petitioner’s mixing of disclosures is that a POSITA would not have found it obvious to mix and match the various features of Garrison to arrive at a system in which vacuum

pressure is built up in a clot canister having a filter (e.g., Garrison's filter 3418) as recited in the Claims of the '333 Patent. Namely, a POSITA would not have found it obvious to operate the peristaltic pump of Figure 34 of Garrison (or Laub's or Aklog's centrifugal/positive displacement pumps) with any valve closing off fluid flow to its inlet because such operation would starve the pump of fluid leading to pump damage and blood damage. And, attaching a syringe to the filter 3418 rather than directly to a valve ("flow controller") would decrease the level of aspiration rather than enable the maximum level of aspiration. That Garrison does not disclose any single embodiment including the features of the Claims highlights exactly why it would not have been obvious to a POSITA to have modified Garrison, Laub, and Aklog as Petitioner suggests.

71. First, as I explain in §§VII.B-C. below, a POSITA would understand that continuous blood pumps like the centrifugal, peristaltic, rotary, and like pumps disclosed in Figure 34 of Garrison and in both Aklog and Laub are not intended to be operated with any valve—or other restriction (e.g., kink) in the inflow path—shutting off or restricting fluid flow to their inlet. Stopping fluid flow to the inlet of such a pump would lead to pump starvation—a state in which the pump begins to heat up, seize, and shake because there is no fluid flowing through the inlet, leading to significant damage to the pump. In fact,

I have reviewed manuals for conventional blood pumps that warned and cautioned against operating those pumps in the absence of flow or with kinking in the tubing that might restrict flow for exactly that reason. EX2009, pgs. 7-8 (“[d]o not operate the centrifugal blood pump for more than 30 s in the absence of flow ... [t]he temperature within the pump could rise,” “[d]o not operate the centrifugal blood pump unprimed; damage to the internal components will occur”); EX2010, pgs. 4-5. And, in addition to the potential for pump damage, operating such a pump without inlet flow as proposed by Petitioner would significantly harm any blood therein and potentially generate bubbles (e.g., cavitations) that could be reintroduced to the patient when blood is returned. Again, manuals for conventional blood pumps warned and cautioned against such an operating state based on those concerns. EX2009, pgs. 7-8 (“in the absence of flow ... [t]he temperature within the pump could rise and increased cellular damage may result,” “[d]o not operate the blood pump with its inlet clamped ... [t]his will generate negative pressure in the blood pump and could cause air bubbles to form in the blood.”); EX2010, pg. 5 (“when clamping the tube: ... turn the flow regulator to zero to prevent hemolysis,” “[r]emove any air bubbles detected”).

72. It is for those reasons of pump and blood damage that Garrison does not disclose operating—and a POSITA would not have found it obvious to mix and

match Garrison's various embodiments to operate—Garrison's system in Figure 34 to build up vacuum pressure in the filter 3418 using the peristaltic pump 3425. EX1006, ¶[0132]. Likewise, a POSITA would not have included Garrison's valve in Laub's or Aklog's systems and operated their pumps with that valve closed to build up pressure because pump and blood damage would occur. Laub and Aklog emphasize the critical nature, even necessity of blood return when treating large clots in large vessels, like PE and DVT, using large catheters. EX1012, ¶[0045]; EX1005, 5:19-23. Petitioner's proposed combination would therefore not make "Laub's and Aklog's systems safer and more effective" but rather less safe and less effective by damaging blood. Petition, pg. 39.

73. And, Garrison's disclosure of the syringe embodiment in paragraph [0134] does not teach using another type of aspiration source (e.g., a peristaltic pump, centrifugal, rotary, positive displacement, or like continuous pump) to build up vacuum pressure in a clot canister. Instead, Garrison's syringe "is attached to the flow controller" without an intervening filter 3418 to "enable the maximum level of aspiration in a rapid fashion." EX1006, ¶[0134]; Petition, pg. 38. That arrangement maximizes the level of aspiration because there is a minimal volume between the syringe and valve. In contrast, in Petitioner's proposed combination, the filter 3418 and associated tubing is between the

syringe and Garrison's valve 3325 such that the total volume between Garrison's syringe and Garrison's valve is greater than directly connecting the syringe to Garrison's valve. A POSITA would understand that increased volume decreases the maximum vacuum pressure because removing the same volume of fluid (Garrison's syringe volume) from a larger volume (the filter 3418, tubing, etc.) rather than a smaller volume (the direct connection to the flow controller as Garrison teaches), results in less vacuum pressure and less aspiration.

74. Accordingly, a POSITA would not have mixed and matched Garrison's embodiments as Petitioner alleges. Specifically, a POSITA would not have operated Garrison's system in Figure 34 with the valve 3325 closed while the peristaltic pump runs to generate vacuum in the filter 3418 because that would damage the pump and blood therein. And, a POSITA would not have used Garrison's syringe to build up vacuum in the filter 3418 because that arrangement would lessen aspiration rather than "enable the maximum level of aspiration."
75. Second, as I explain in VII.D. below, a POSITA would not have been motivated to include Garrison's valve in Laub or Aklog and use that valve in a method to build up pressure in a clot canister to treat PE/DVT because that modification would not "enable the maximum level of aspiration,"

Petitioner's purported motivation to combine. Petition, pgs. 38-41. The level of aspiration in a pump-based system like Laub or Aklog is controlled by the operational speed of the pump rather than by evacuating a fixed volume as in Garrison's syringe. And, Laub teaches that "reinfusing the patient's blood **continuously during aspiration allows for greater suction pressure and/or flow rates** (e.g., 2-4 L/min) which can assist in dislodging and removing larger clots and/or tumors than would otherwise be possible." EX1012, ¶[0045] (emphasis added). That is, Laub discloses that to achieve the "maximum level of aspiration" the system is operated continuously—which is the opposite of Petitioner's proposed combination adding a valve that is closed to build up vacuum before subsequently being opened. Notably, a constant flow rate of 2-4 L/min would cause massive blood loss in a relatively short time of aspiration, necessitating blood return.

76. Third, as I explain §VII.E. below, a POSITA would further not have been motivated to include Garrison's valve in Laub or Aklog and use that valve as a fluid control valve in a method to build up pressure in a clot canister to treat PE/DVT because that modification would be incompatible with Laub's and Aklog's systems that continuously aspirate and reinfuse blood so that large clots, which PE and DVT are, can be removed without endangering the patient with excessive blood loss. EX1012, ¶[0045]; EX1005, 5:19-23. Incorporating

Garrison's valve and then operating those systems to close the valve to build up vacuum pressure and open the valve to apply that vacuum pressure as recited in the Claims of the '333 Patent would prevent the continuous/simultaneous aspiration and reinfusion disclosed by Laub or Aklog when the valve is closed.

77. Fourth, as I explain in §VII.F. below, a POSITA would further not have been motivated to include Garrison's valve in Laub or Aklog and use that valve in a method to build up pressure in a clot canister to treat PE/DVT because Garrison's valve (a 3-way or 4-way stopcock) would provide dangerous flow paths for sucking air into the system through the unconnected port of valve that could be reinfused into the patient to cause an air embolism.
78. Lastly, as I explain §VII.G. below, a POSITA would further not have been motivated to include Garrison's valve in Laub or Aklog and use that valve in a method to build up pressure in a clot canister to treat PE/DVT because the valve would needlessly complicate the systems of Laub and Aklog in which the surgeon controls the procedure simply by controlling the pump.
79. Accordingly, for those reasons and the reasons set forth below, it is my opinion that independent Claims 1 and 20 are not rendered obvious by the combinations of Laub or Aklog and Garrison. Dependent Claims 2-10 and 13-19 depend from independent Claim 1, and dependent Claims 21-29 and 32-38

depend from independent Claim 20. Therefore, these claims are also not rendered obvious by any combination of Laub or Aklog and Garrison because they incorporate all the features of their respective independent Claims 1 or 20.

A. None of Garrison, Laub, or Aklog Disclose the Methods of Claims 1 or 20 Including the Buildup and Release of Vacuum Pressure in a Clot Canister Having a Filter

80. As I explain in §V.A. above, independent Claims 1 and 20 of the '333 Patent recite methods including “generating vacuum pressure within the clot canister via the aspiration source while a valve positioned along the fluid path between the aspiration catheter and the clot canister is in a first position that inhibits fluid flow along the fluid path from the lumen of the aspiration catheter to the clot canister” and “moving the valve from the first position to a second position thereby applying the vacuum pressure to the lumen of the aspiration catheter ... wherein the clot canister includes a filter configured to filter the blood from the portion” of the “pulmonary embolism” (Claim 1) or “deep vein thrombosis” (Claim 20). That is, the Claims require building up vacuum pressure in the clot canister (which includes a filter) and subsequently applying that vacuum to the aspiration catheter.
81. Petitioner does not allege that Laub or Aklog disclose such a methodology, and instead relies on Garrison for allegedly disclosing those features. Petition,

pgs. 36-42. Specifically, Petitioner alleges that a POSITA would have been motivated to incorporate the valve 3325 shown in Figure 34 of Garrison in Laub (ground 1A) or Aklog (2A) to perform the claimed methodology to “enable the maximum level of aspiration in a rapid fashion with one user” and to “improve Laub’s or Aklog’s temporary aspiration power to aspirate PE’s more quickly, making Laub’s and Aklog’s systems safer and more effective.” Petition, pgs. 38-39; EX1006, ¶[0134].

82. But, Garrison does not disclose a method of operating the system of Figure 34 to build up and subsequently release vacuum pressure in a clot canister having a filter as recited in the Claims of the ’333. Instead, in Figure 34, “both the arterial access device 2010 and the catheter 2030 are connected to the same aspiration source 3430” and the “valve 3325 controls which device is connected to the aspiration source 3430 [t]he 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]. That is, because the arterial access device 2010 and the catheter 2030 are connected to the same pressure source 3430, the valve 3325 (“a 3-way or 4-way stopcock”) is simply used to control the connection of those catheters to the pressure source 3430. *Id.* A POSITA would understand that Garrison does not disclose using the valve 3325 to build up negative pressure in the system of Figure 34 (e.g., in the filter

3418) by closing the valve to stop flow to the pump 3430 because, as I explain below, ceasing fluid flow to the inlet of such a pump would starve the pump of fluid potentially damaging the pump and harming blood therein.

83. Because of that deficiency, Petitioner relies on a different embodiment of Garrison described in paragraph [0134] to allegedly show the claimed buildup and release of pressure:

In one embodiment, a locking syringe (for example a VacLok Syringe) is attached to the flow controller and the plunger is pulled back into a locked position by the user while the connection to the flow line is closed prior to the thrombectomy step of the procedure. During the procedure when the tip of the aspiration device (either the arterial access device or the catheter) is near or at the face of the occlusion, the user may open the connection to the aspiration syringe. This would enable the maximum level of aspiration in a rapid fashion with one user.

EX1006, ¶[0134]; Petition, pgs. 36-38. But that disclosure is for generating vacuum pressure with a syringe rather than with a peristaltic pump as shown in Figure 34 of Garrison, and that syringe is “attached” to the flow controller rather than a filter 3418 and a check valve 3419 like the peristaltic pump in Figure 34. And, as I explain below, a POSITA would have understood that arrangement of the syringe described in paragraph [0134] to maximize the level of aspiration. In particular, a syringe is capable of evacuating a fixed

amount of fluid such that that including Garrison's filter 3418, check valve 3419, and associated tubing between the syringe and Garrison's valve 3325 would decrease the level of vacuum and aspiration achievable using the syringe by increasing the volume available to the syringe with no increase in the amount of fluid that is able to be evacuated from that volume. Accordingly, Garrison does not disclose generating vacuum pressure in a clot canister having a filter while a valve is closed.

84. Petitioner conflates the different embodiments in Figure 34 and paragraph [0134] of Garrison, stating that “[b]ecause the valve (e.g., stopcock 3325) is distal to the filter, the vacuum pressure builds up in the filter canister via the pressure source.” Petition, pg. 38. But Garrison does not disclose building up pressure in the filter 3418 in Figure 34 using the peristaltic pump shown there. And, as I explain below, a POSITA would not have done so because of the potential of pump and blood damage caused by pump starvation while the a valve is closed and the pump operates without fluid flow. In the arrangement with the syringe in paragraph [0134] of Garrison in which pressure is built up therein, the syringe is “attached” to the flow controller without an intervening volume including the filter 3418 and the check valve 3419 like shown in Figure 34. A POSITA would not have used the system of Figure 34 of Garrison to build up pressure in the filter 3418 using a syringe because that would not

enable the maximum level of aspiration—it would decrease the level of aspiration compared to a syringe alone connected to the valve 3325 as expressly disclosed by Garrison in paragraph [0134].

85. Put differently, Garrison discloses that the valve 3325 in Figure 34 is operated simply to switch the different connections of the catheters to the aspiration source rather than to build up vacuum pressure in any clot canister, such as the filter 3418 alleged by Petitioner. So that embodiment does not disclose the claimed methods including “generating vacuum pressure within the clot canister ... while a valve positioned along the fluid path between the aspiration catheter and the clot canister is in a first position” and “moving the valve from the first position to a second position thereby applying the vacuum pressure to the lumen of the aspiration catheter.” A POSITA would have understood that arrangement is intended to prevent Garrison’s pump from running without fluid flow to the inlet (i.e., pump starvation). And, the embodiment in paragraph [0134] is a completely different and incompatible arrangement with a syringe rather than a peristaltic pump that does not include any clot canister in the flow path because the syringe is attached directly to a flow controller, and so vacuum cannot be generated in any clot canister as recited in Claims 1 and 20. There, the vacuum and aspiration levels are maximized *without* the

filter 3418 (i.e., Petitioner’s alleged “clot canister”) as expressly taught by Garrison.

B. A POSITA Would Not Have been Motivated to Include Garrison’s Valve in Laub or Aklog Because that Modification Would Likely Damage the Systems of Laub and Aklog

86. A POSITA would not have been motivated to add Garrison’s valve or a like valve to “generat[e] pressure while the valve is closed into Laub’s or Aklog’s aspiration systems” because a POSITA would understand such a modification to be incompatible with the centrifugal/positive displacement pumps of Laub and Aklog by for example, potentially damaging those pumps and systems. Petition, pgs. 38-41.
87. Laub and Aklog both utilize a centrifugal or positive displacement pump that operates to mechanically (e.g., via a vane, rollers, or the like) pull fluid through an inlet and discharge that fluid through an outlet. For example, Laub discloses that “[i]n preferred embodiments, pump 400 is a centrifugal pump” while “[i]n other embodiments, pump 400 may be a rotary pump, peristaltic pump, roller pump, or other form of pump known in the art.” EX1012, ¶[0041]. Likewise, the pump 15 of Aklog “may be any commercially available pump, including those for medical applications and those capable of pumping fluids, such as blood. Examples of such a pump includes a kinetic pump, such as a centrifugal pump, and an active displacement pump, such as

a rollerhead pump.” EX1005, 12:9-14. Positive displacement pumps, like the peristaltic and roller pumps, operate by trapping a fixed volume of fluid received through an inlet and then forcing that fluid out of the outlet. Centrifugal pumps operate using a vane or impeller that is driven to rotate to impart velocity to the fluid received through the inlet and to force the fluid out of the outlet.

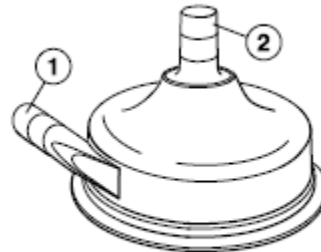
88. In Petitioner’s proposed combinations, the pumps of Laub or Aklog would run to “generat[e] pressure while [Garrison’s inserted] valve is closed” in “Laub’s or Aklog’s aspiration systems.” Petition, pg. 38. But, a POSITA would have understood that neither Laub nor Aklog disclose such a valve, and would not have modified either to include such a valve to be closed while the pump operates, because such centrifugal/positive displacement pumps are not intended to operate without fluid flow to their inlet. A POSITA would understand that running/operating a centrifugal, peristaltic, rotary, or like pump as disclosed by Laub and Aklog with the fluid inlet (i.e., suction inlet) closed as in Petitioner’s proposed combination would starve the pump of fluid, causing the pump to run dry, leading to damaging the pump. In particular, without fluid flowing through the pump, the pump would experience significantly increased friction, cavitation, and overheating, potentially leading to mechanical failure. More specifically, with Garrison’s valve closed in Petitioner’s

purported combinations, Laub's pump or Aklog's pump would be unable to move fluid therethrough, thereby risking creating a vacuum that causes remaining fluid to boil and vaporize, destroying seals and bearings of the pump, while also cavitating and generating cavitation bubbles that could violently collapse within the pump and damage the pump. Likewise, without fluid to remove heat, the internal casing temperature of Laub's pump or Aklog's pump would rise rapidly, leading to eventual component failure. And, without fluid lubricating the pump components, the internal adjoining surfaces of Laub's or Aklog's pumps could seize.

89. A POSITA would have readily understood for all the foregoing reasons that the continuous pumps disclosed by Laub and Aklog would not be operated with a valve to the pump inlet closed shutting off fluid flow as Petitioner alleges. As one example, Aklog discloses that its pump "may be any commercially available pump, including those for medical applications and those capable of pumping fluids, such as blood." EX1005, 12:9-12. I understand that one such commercially available blood pump at the time of the invention of the '333 Patent was the Bio-Pump™ BP-50. Instructions for use for the BP-

50 pump¹ describe the pump as a “centrifugal blood pump” having an inlet and outlet:

Figure 1. • Figura 1. • Figure 1.



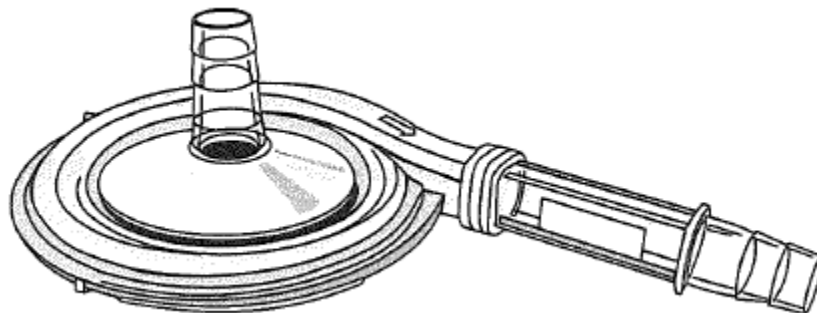
EN 1 Outlet
 2 Inlet

EX2009, pgs. 5-6. And, as a POSITA would expect based on the operation of such pumps, I note that the instructions for use for the BP-50 pump specifically warned and instructed users: (1) “[d]o not operate the centrifugal blood pump for more than 30 s in the absence of flow ... [t]he temperature within the pump could rise,” (2) “[a]ttach tubing in a manner that prevents kinks or restrictions that may alter flow,” and (3) “[d]o not operate the centrifugal blood pump unprimed; damage to the internal components will occur.” *Id.* at pgs. 7-8. I also note that similar instructions for using the BP-50 pump (or

¹ While these instructions are dated September 12, 2018—after the priority date of the ’333 Patent—I believe they reflect what POSA would have understood of how the BP-50 pump (which was commercially available as early as 1985 well before the priority date of the ’333 Patent) should and should not be operated.

similar pumps, such as the larger BP-80 version) warn against operating the pump dry (without liquid therein) as would occur in Petitioner’s proposed combinations. EX2012, pgs. 3, 5, 11. That is, the instructions for use for the BP-50 pump confirm what a POSITA would have understood—operating Laub’s or Aklog’s continuous centrifugal/positive displacement pumps without fluid flow therethrough (i.e., in the absence of flow, with kinks or restrictions, and/or unprimed) as in Petitioner’s proposed combinations could damage the pump.

90. Similarly, I understand that another commercially available blood pump at the time of the invention was the ROTAFLOW Centrifugal Pump from Maquet, the instructions for use for which disclose that the “ROTAFLOW Centrifugal Pump (RF-32) has a spinning rotor with flow channels which imparts rotary motion to the incoming blood, directing it through a spiral housing to the out-flow port”:



EX2010, pgs. 1 & 4. Again, unsurprisingly, the instructions for use for the ROTAFLOW Centrifugal Pump warned and instructed users: (1) “attach tubing in such a manner as to prevent kinks or any restrictions that may alter flow” and (2) “[r]educer the pump speed to the minimum speed before clamping the tube, then turn the flow regulator to zero.” *Id.* at pgs. 4-5. That is, just like a POSITA would have understood, the ROTAFLOW pump is not intended to be operated without flow to its inlet. Those instructions for use likewise confirm that a POSITA would have understood that operating Laub’s or Aklog’s continuous centrifugal/positive displacement pumps without fluid flow therethrough (i.e., with kinks or restrictions, or with clamped tubing) as in Petitioner’s proposed combinations is not advised.

91. Accordingly, a POSITA would not have modified Laub or Aklog to include a valve as in Petitioner’s proposed combination because operating those systems with the valve closed would likely damage the pumps of Laub and Aklog. That is, rather than “making Laub’s and Aklog’s systems safer and more effective” and improving their aspiration systems as alleged by Petitioner, Petitioner’s combination would likely make those systems less safe and less effective. Petition, pgs. 38-41. Even if aspiration power were momentarily increased by including a valve, a POSITA still would not have included

such a valve because any subsequent aspiration might be hindered by degradation of the pump from starvation of fluid to the pump.

C. A POSITA Would Not Have been Motivated to Include Garrison's Valve in Laub or Aklog Because that Modification Would Endanger the Patient by Compromising Blood Return

92. As I explain in §§VI.B-C. both Laub and Aklog emphasize the critical nature of blood return to patient health and safety when treating large clots, such as PE and DVT. For example, Laub discloses that “[b]y returning the aspirated blood back to the patient, embodiments of the present system 100 allows for aspiration while minimizing the blood loss of the patient ... [w]ithout returning the blood back to the patient, such high flow rates could quickly result in exsanguination of the patient.” EX1012, ¶[0045]. Likewise, Aklog’s system “simultaneously reinfuse[s] 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.” EX1005, 5:19-23.
93. Incongruent with that goal of blood return, a POSITA would understand that utilizing the pumps of Laub or Aklog to generate vacuum pressure with a valve closed as in Petitioner’s proposed combinations of Laub/Aklog and Garrison would be dangerous to the patient by harming blood meant for return. As I explain in the section §VII.B. directly above, closing a valve between Laub’s aspiration catheter and pump 400 and/or closing a valve between

Aklog's aspiration catheter and pump 15 while operating those pumps would likely damage those pumps due to pump starvation—i.e., no fluid flow through the fluid inlet of the pump. Even if those pumps could somehow be operated without damage in such a state, a POSITA would understand that such an operating state would damage the blood in Laub's and Aklog's systems such that it was unsuitable and unsafe for blood return.

94. Specifically, the same conditions such as increased friction, overheating, etc., that act to damage the pump in a starvation (i.e., no-inflow) state as in Petitioner's purported combinations would also act to damage blood already in the system (e.g., blood in the system downstream of the valve). For example, a POSITA would understand that heating blood or repeatedly contacting that blood could lead to blood damage. I note that in alignment with that understanding, the instructions for use for the BP-50 pump specifically warned that "in the absence of flow ... [t]he temperature within the pump could rise and *increased cellular damage* may result." EX2009, pg.7 (emphasis added). Likewise, the instructions for use for the ROTAFLOW Centrifugal Pump instructed the user to reduce flow to zero to prevent hemolysis of blood (i.e., the destruction of red blood cells) when a tube to the pump is clamped: "when clamping the tube: ... turn the flow regulator to zero *to prevent hemolysis.*" EX2010, pg.5 (emphasis added). Those instructions confirm that a POSITA

would have understood that operating Laub or Aklog with Garrison's valve as proposed by Petitioner would damage blood in those systems.

95. A POSITA would also not have included a valve in Laub's system or Aklog's system and operated their pumps with that valve closed because such operation could cause bubbles to form that could be reinfused into the patient in those continuous aspiration/reinfusion systems. Such bubbles pose a serious concern of embolism. Specifically, a POSITA would have understood that when a centrifugal/positive displacement pump inlet like those of Laub and Aklog is closed and the pump continues to run (i.e., the pump is "starved" of fluid), the suction pressure will drop below the vapor pressure of the fluid (e.g., blood) in the system causing the liquid to flash to vapor bubbles. Those bubbles may violently collapse in a manner that damages the pump, or if they do not collapse, the bubbles could be reinfused to the patient through Laub's return catheter 500 or Aklog's reinfusion cannula 16. Such bubbles are a serious danger to the patient because they could form an embolism where the bubbles lodge in a blood vessel blocking fluid flow. Again, in line with that understanding, I note that conventional pumps such as the BP-50 pump recognized that danger and warned: "[d]o not operate the blood pump with its inlet clamped. This will generate negative pressure in the blood pump and

could cause air bubbles to form in the blood.” EX2009, pgs.8 & 10; see also EX2010, pg. 5 (“[r]emove any air bubbles detected”).

96. Because Laub and Aklog both disclose the criticality of blood return to patient health and safety when treating large clots like PE/DVT, a POSITA would not have included the valve 3325 of Garrison in either Laub and Aklog, let alone operate those systems as proposed by Petitioner, because doing so would endanger the patient. That is, rather than “making Laub’s and Aklog’s systems “safer and more effective”—Ppetitioner’s proposed combination would make both Laub and Aklog more dangerous to the patient by damaging blood in those systems and potentially introducing bubbles that could lead to downstream embolism. Petition, pg. 39. Even if aspiration power were momentarily increased by including a valve, a POSITA still would not have included such a valve and operated Laub’s or Aklog’s systems in the manner recited in the Claims because it would damage blood returned to the patient and introduce dangerous bubbles.

97. Moreover, Garrison itself discloses that the very embodiments relied on by Petitioner in Figure 34 and paragraph [0134] (the syringe embodiment) are not suitable for returning blood:

One disadvantage of current sources of aspiration is that the aspirated blood is received into an external reservoir or syringe. This blood is generally discarded at the end of the procedure, and

as such represents blood loss from the patient. In addition, pumps such as centrifugal or peristaltic pumps are known to cause damage to blood cells. Although it is possible to return blood from the external reservoir to the patient, the blood has been exposed to air or has been static for a period of time, and there is risk of thrombus formation or damage to the blood cells. Usually, aspirated blood is not returned to the patient to avoid risk of thromboembolism.

EX1006, ¶[0135]. In Figure 34 of Garrison relied on by Petitioner for disclosing a “fluid control device,” blood is pumped to the receptacle 3430 (an “external reservoir”) where it remains “static” and is “exposed to air” such that it is not suitable for blood return. In the locking syringe embodiment disclosed in paragraph [0134] of Garrison, blood is aspirated into the syringe where it remains “static” such that it is not suitable for blood return.

98. Accordingly, a POSITA would have understood those systems to be poorly-suited for returning blood and would not have modified Laub or Aklog—where blood return is critical in the context of larger PE/DVT clots—based on those systems to preserve the important ability to return blood. More specifically, for example, adding the valve 3325 shown in Figure 34 into Laub as Petitioner proposes would cause blood to remain static in Laub’s system when the valve is closed as I show below:

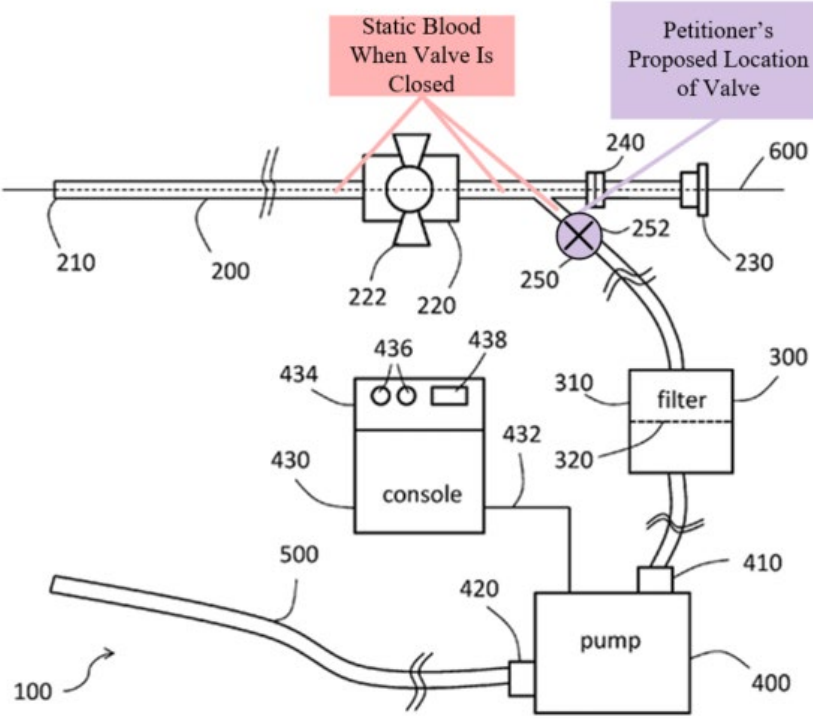


FIG. 1A

Petition, pgs. 38-40. Likewise, adding the valve 3325 shown in Figure 34 into Aklog as Petition proposes would cause blood to remain static in Aklog's system when the valve is closed as I show below:

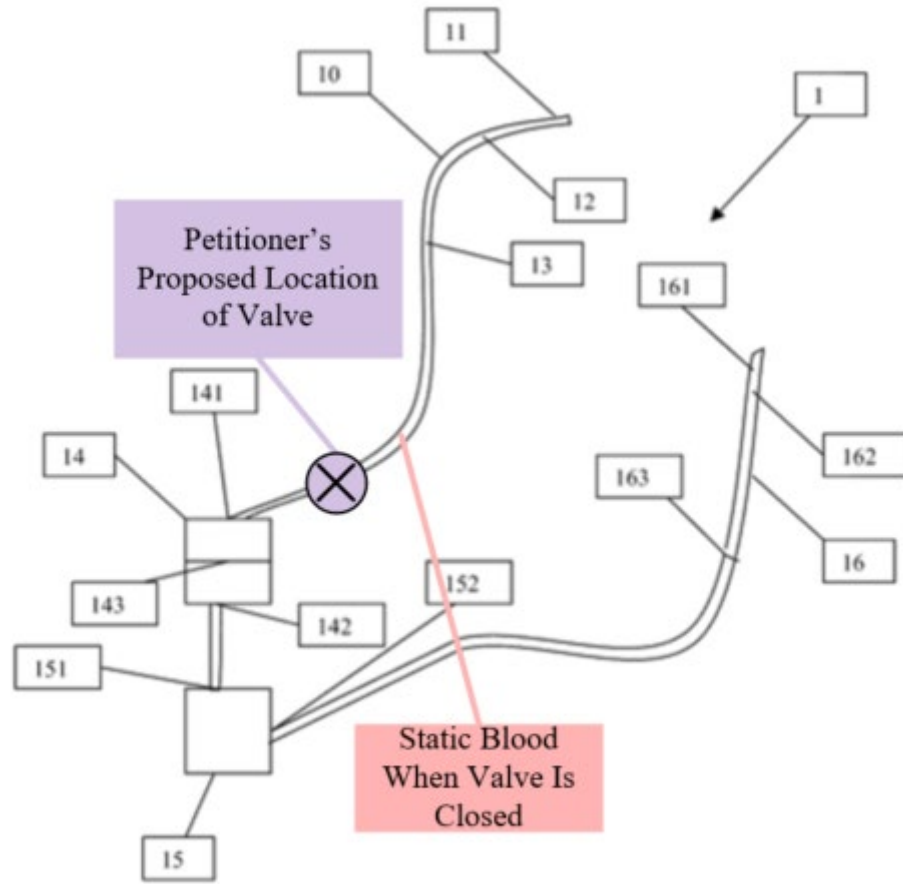


Fig. 1

Petition, pg. 41.

99. As I explain above, a POSITA would understand based on Garrison that when “the blood ... has been static for a period of time, and there is risk of thrombus formation or damage to the blood cells” such that the blood is “[u]sually ... not returned to the patient to avoid risk of thromboembolism.” EX1006, ¶¶[0135]. Because Laub and Aklog both disclose the criticality of blood return to patient health and safety, a POSITA would not have included the valve

3325 of Garrison in those systems to “avoid the risk of thromboembolism” from static blood that may make the blood unsuitable for return to the patient.

100. I see that in the Institution Decision, the Board preliminarily found that Patent Owner’s arguments in its Preliminary Response regarding blood return did “not undermine Petitioner’s challenge at this stage” based on a number of preliminary observations (1)-(5). Institution Decision, pgs. 35-36. I disagree with those preliminary observations; a POSITA would not have found it obvious—and in fact would have found it disadvantageous and dangerous—to include a valve in the aspiration systems of Laub or Aklog and close that valve to build up vacuum pressure as proposed by Petitioner.
101. More specifically, the Board’s preliminary observation (1) that Garrison teaches an embodiment in Figure 36 that is compatible with blood return actually reinforces that a POSITA would not have added a valve in either Laub or Aklog as proposed by Petitioner. Institution Decision, pgs. 35-36. In fact, Garrison expressly contrasts the embodiments relied on by Petitioner (Figures 34 and paragraph [0134]) that are unsuitable for blood return with the embodiment in Figure 36 “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.” EX1006, ¶[0136] (my emphasis added). So just, like Laub and Aklog,

Garrison's embodiment in Figure 36 that is suitable for blood return operates to continuously return blood without any intervening valve that is closed to generate vacuum. A POSITA would not have operated the valve in Figure 36 of Garrison—a positive displacement pump—with the inlet clamped to starve the pump of fluid flow for the same reasons I explain above (i.e., pump damage, blood damage).

102. Regarding the Board's preliminary observation (2) that Laub and Aklog "teach that aspirated blood (including blood aspirated with conventional pumps, like centrifugal or peristaltic pumps) can safely be returned to the patient," even so neither those references nor Garrison disclose that blood can safely be returned in a system like Petitioner's proposed combinations including a valve between the aspiration catheter and the centrifugal/positive displacement pump. Institution Decision, pg. 36. Indeed, as I detail above, a POSITA would have understood that such a modification would damage the blood and potentially introduce dangerous bubbles for reinfusion to the patient.
103. Similarly regarding the Board's preliminary observation (3), even if Laub and Aklog can run "intermittently," a POSITA would understand that intermittent operation does not mean using a valve to shut off fluid flow and build vacuum pressure while a pump operates. Instead, intermittent operation simply means

turning the pump on or off with the pump inlet and pump outlet unobstructed to prevent pump starvation and the negative consequences I describe above.

Institution Decision, pg. 36.

104. Likewise, regarding the Board’s preliminary observation (4), a POSITA would not have added a valve to Laub or Aklog and operated those systems to build up pressure as alleged by Petitioner to provide any “rapid burst of vacuum” based on the potential for pump and blood damage, as well as the generation of cavitation bubbles that may be reintroduced to the patient. Institution Decision, pg. 36. Finally, regarding the Board’s preliminary observation (5) that “the valve closure and vacuum generation would seem to be a temporary step to enable a rapid burst of suction—*without blood being withdrawn from the patient* during this brief window,” a POSITA would understand that it is precisely because blood or other fluid is not being withdrawn while the pump operates in Petitioner’s proposed combination that pump damage and blood damage would occur. Institution Decision, pg. 36 (my emphasis added).

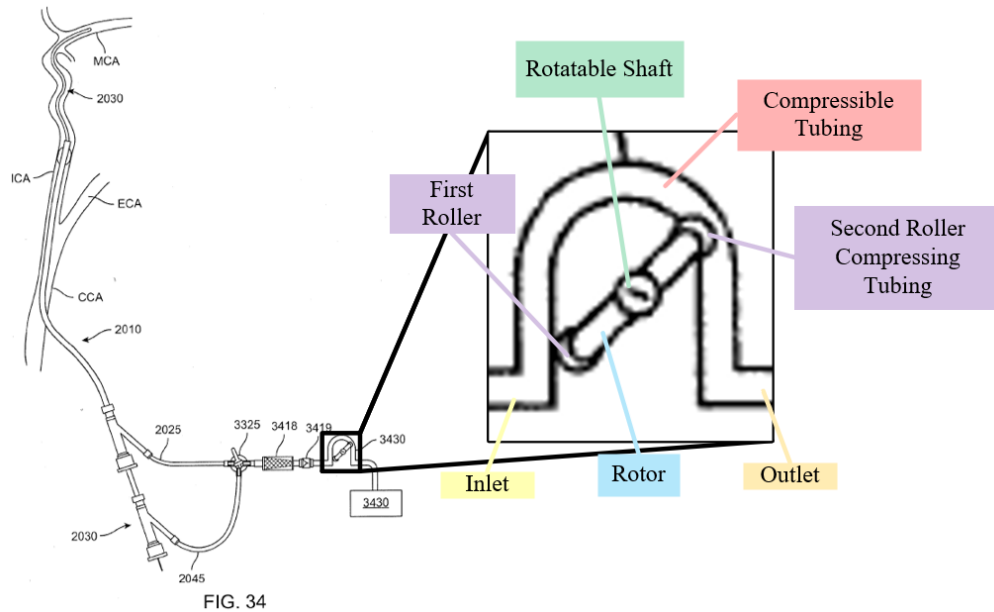
D. A POSITA Would Not Have Been Motivated to Include Garrison’s Valve in Laub or Aklog Because that Modification Would not “Enable the Maximum Level of Aspiration”

105. Petitioner assertions that a “POSITA would have been motivated to incorporate Garrison’s valve 3325 and method of generating pressure while the valve

is closed into Laub's or Aklog's aspiration systems" to "enable the maximum level of aspiration in a rapid fashion with one user" and to "improve Laub's or Aklog's temporary aspiration power to aspirate PE's more quickly, making Laub's and Aklog's systems safer and more effective" ignores the fundamental difference between a syringe and a peristaltic pump. Petition, pgs. 38-41; EX1006, ¶[0134].

106. As I explain above, the only disclosure in Garrison of building up pressure with a valve closed relates to the syringe embodiment in paragraph [0134]. There, Garrison discloses that withdrawing the syringe plunger with the valve closed "would enable the maximum level of aspiration." EX1006, [0134]. A syringe includes a barrel in which vacuum pressure is generated when a plunger is withdrawn. EX1006, ¶[0134]. That barrel has a fixed volume to generate the vacuum pressure for aspiration, and that volume sets and thus limits the "maximum level of aspiration." Therefore, when the syringe plunger is withdrawn with the flow controller closed as disclosed in paragraph [0134] of Garrison, the maximum level of vacuum in the syringe is achieved because the full barrel is evacuated.
107. In contrast, a peristaltic pump like that shown in Figure 34 of Garrison does not have a fixed volume that limits the "maximum level of aspiration" but instead includes a rotor rotated by a shaft such that rollers compress and seal

tubing, alternating the compression and relaxation of the tubing to draw content into the pump through an inlet and propel that content away from the pump through an outlet:



Accordingly, there is no fixed volume of the peristaltic pump that can be evacuated like a syringe to store vacuum pressure if a valve were closed to generate a “maximum level of aspiration.” Any “maximum level of aspiration” is dictated by the speed of the pump—i.e., how quickly the rotor rotates to drive material through the pump—and there is not a fixed volume in the peristaltic pump like a syringe that would be evacuated to generate vacuum if a valve were included and closed.

108. Like Figure 34 of Garrison, both Laub and Aklog use a pump that pulls fluid through an inlet and discharges it through an outlet, rather than a syringe, to

generate vacuum. For example, Laub discloses that “[i]n preferred embodiments, pump 400 is a centrifugal pump” while “[i]n other embodiments, pump 400 may be a rotary pump, peristaltic pump, roller pump, or other form of pump known in the art.” EX1012, ¶[0041]. Likewise, the pump 15 of Aklog “may be any commercially available pump, including those for medical applications and those capable of pumping fluids, such as blood. Examples of such a pump includes a kinetic pump, such as a centrifugal pump, and an active displacement pump, such as a rollerhead pump.” EX1005, 12:9-14.

109. Laub confirms that when using pumps, the pump is controlled to generate different negative pressures and flow rates. EX1012, ¶¶[0042]-[0044]. In fact, Laub discloses that in the context of treating large clots (e.g., PE or DVT), “reinfusing the patient’s blood **continuously during aspiration allows for greater suction pressure and/or flow rates** (e.g., 2-4 L/min) which can assist in dislodging and removing larger clots and/or tumors than would otherwise be possible.” *Id.* at ¶[0045] (emphasis added). That is, Laub discloses that to achieve the “maximum level of aspiration” the system is operated continuously—which is the *opposite* of Petitioner’s proposed combinations adding a valve that is closed to build up vacuum before subsequently being opened.
110. For the above reasons, a POSITA would not have added Garrison’s valve 3325 into Laub or Aklog to achieve maximum aspiration using their pumps

and would have, instead, simply increased the operational speed of the pumps or operated the system continuously and not with valves closing and opening if increased or maximal aspiration were desired.

E. A POSITA Would Further Not Have Been Motivated to Include Garrison's Valve in Laub or Aklog and Use that Valve in a Method to Build Up Pressure in a Clot Canister to Treat PE/DVT Because that Modification Would Be Incompatible with Laub's and Aklog's Continuous Reinfusion

111. Neither Laub or Aklog have a "valve" as recited in the Claims to connect and disconnect aspiration. This is because their systems operate to continuously aspirate blood and clot material from a patient through an aspiration catheter and then reinfuse that blood into the patient on a continuous basis. That is, aspiration and reinfusion happen simultaneously. Both Laub and Aklog disclose the importance of that continuous aspiration and reinfusion to patient health and safety and clot aspiration efficiency. For example, Laub discloses:

By returning the aspirated blood back to the patient, embodiments of the present system 100 allows for aspiration while minimizing the blood loss of the patient. In certain embodiments, reinfusing the patient's blood continuously during aspiration allows for greater suction pressure and/or flow rates (e.g., 2-4 L/min) which can assist in dislodging and removing larger clots and/or tumors than would otherwise be possible. Without returning the blood back to the patient, such high flow rates could quickly result in exsanguination of the patient.

EX1012, ¶[0045]. Based on that disclosure, a POSITA would understand that Laub's system operates to continuously aspirate and return blood at a high flow rate so that large clots, such as PE and DVT, can be removed without endangering the patient.

112. Similarly, Aklog recognizes that “[i]f the catheter is enlarged to accommodate the larger structure and material, such a catheter may aspirate an unacceptable volume of blood, resulting in excessive fluid loss and/or shock in the patient.” EX1005, 7:23-26. That is, the patient will be harmed due to excessive blood removal if the blood is not returned. To address this, Aklog's system “**simultaneously** reinfuse[s] 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.” *Id.* at 5:19-23 (emphasis added). Aklog further discloses that the “suction and reinfusion of blood can occur, in an embodiment, continuously for a desired duration to minimize fluid loss in the patient.” EX1005, 5:20-23. Accordingly, a POSITA would understand that, like Laub, Aklog's system operates to continuously/simultaneously aspirate and return blood so that large clots, such as PE and DVT, can be removed without endangering the patient.
113. Accordingly, a POSITA would not have modified Laub or Aklog to include the valve 3325 in Figure 34 of Garrison, and then operated those systems to

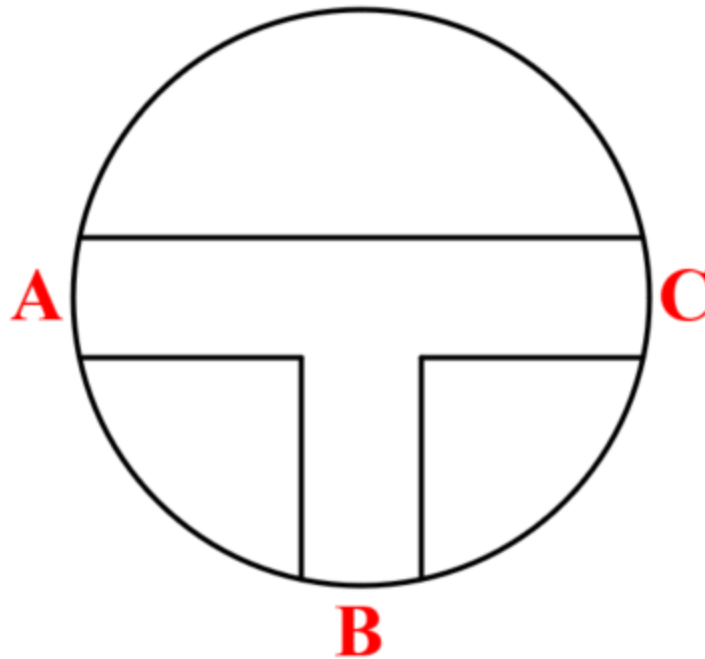
close the valve to build up vacuum pressure and open the valve to apply that vacuum pressure as recited in the Claims of the '333 Patent because the valve would prevent the continuous/simultaneous aspiration and reinfusion disclosed by Laub or Aklog when the valve is closed to build up vacuum pressure. Specifically, when the valve is closed, the pump could operate to reinfuse but not aspirate. And, when the valve is closed, aspirated blood may remain in the system distal to the valve where it could not be reinfused until the valve is opened.

F. A POSITA Would Further Not Have Been Motivated to Add Garrison's Valve in Laub or Aklog and Use that Valve in a Method to Build Up Pressure in a Clot Canister to Treat PE/DVT Because that Modification Would Introduce Dangerous Flow Paths for Air to Be Reinfused Into the Patient

114. Petitioner assertion that a "POSITA would have been motivated to incorporate **Garrison's valve 3325**" of Figure 34 into "Laub's device at the connector [252] to help control the fluid flow" and "into Aklog's flow path between the catheter and filter/clot canister" is also incorrect because a POSITA would not have included that valve—a "3-way or 4-way stopcock" or a "flow controller." Petition, pgs. 38-41 (emphasis added); EX1006, ¶[0132]. Garrison's valve 3325 is a 3-way or 4-way stopcock to "enable one device, the other device, both devices, or neither device to be connected to the aspiration source at any given time." *Id.* Like the 3-way or 4-way stopcock, Garrison's flow

controller has a “simple actuation which selects the configuration as described above.” *Id.*

115. A POSITA would understand based on that disclosure that Garrison’s valve is attached to three separate tubing sections (i.e., the flow line 2025 to the arterial access device 2010, the flow line 2045 to the catheter 2030, and tubing to the filter 3418) and thus includes at least three different ports to connect to those tubing sections. But, in Petitioner’s combinations each valve is attached only to two tubes—that is the two tubing sections on either side of the connector 252 in Laub and two tubing sections of the aspiration catheter 10 in Aklog. Petition, pgs. 40-41. Thus, the valves in both combinations control the flow through a single flow line such that the valve 3325 would have at least one port not connected to anything and open to the surrounding environment.
116. More specifically, below I provide a schematic illustration of the different ports of the valve 3325 in Figure 34 and associated flow paths through the valve:



Port A connects to the flow line 2025 to the arterial access device 2010, port B connects to the flow line 2045 to the catheter 2030, and port C connects to the tubing to the filter 3418 and the aspiration source 3430. When the valve “enable[s] one device ... to be connected to the aspiration source” it connects only port A to port C to fluidly connect the aspiration source 3430 to the arterial access device 2010. EX1006, ¶[0132]. When the valve “enable[s] ... the other device ... to be connected to the aspiration source” it connects only port B to port C to fluidly connect the aspiration source 3430 to the catheter 2030. *Id.* When the valve “enable[s] ... both devices ... to be connected to the aspiration source” it connects both ports A and B to port C to fluidly connect the aspiration source 3430 to the arterial access device 2010 and the catheter

2030. *Id.* When the valve “enable[s] ... neither device ... to be connected to the aspiration source” it connects neither port A nor port B to port C. *Id.*

117. In Petitioner’s proposed arrangement one of port A or port B would not be connected to anything (because there are only two tubes connected to the valve) and thus open to the surrounding environment. A POSITA would not include such a valve with a non-connected port in either Laub’s system or Aklog’s system first because it would complicate those systems and second because it would potentially endanger the patient. Specifically, if the valve were actuated to connect the non-connected port to the aspiration source in Laub, the system would continuously suck air through the port and the pump 400 and drive that air through the return catheter 500 into the patient. Likewise, if the valve were actuated to connect the non-connected port to the aspiration source in Aklog, the system would continuously suck air through the port and the pump 15 and drive that air through the reinfusion catheter 16 into the patient. This would occur in two states of the valve: when both ports A and B are connected to the aspiration source via port C, and when the unconnected one of ports A and B is individually connected to the aspiration source via port C.
118. But, a POSITA would understand the danger of potentially reinfusing air into the patient in Petitioner’s proposed addition of Garrison’s valve 3325 in Laub

and Aklog. Namely, if the valve were actuated to connect Laub's pump 400 or Aklog's pump 15 to the unconnected port, air would be reinfused into the patient in real-time causing a dangerous and potentially deadly air embolism. For these reasons, a POSITA would not have included Garrison's valve 3325 of Figure 34 in either Laub or Aklog as Petitioner asserts.

G. A POSITA Would Not Have Been Motivated to Include Garrison's Valve in Laub or Aklog and Use that Valve in a Method to Build Up Pressure in a Clot Canister to Treat PE/DVT Because that Modification Would Needlessly Complicate Laub's and Aklog's Systems

119. A POSITA would understand that in both of Laub's and Aklog's systems, the surgeon controls the system only by interacting with the pump to control aspiration. For example, in Laub, a "console 430 may be operated by the user (e.g., surgeon) to adjust the speed, pressure, or other attributes of pump 400 during use." EX1012, ¶[0046]. Similarly in Aklog, the surgeon need only control the pump 15 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" and "generate the positive pressure, so as to create a necessary driving force to direct fluid through exit port 152 and downstream of system 1 for reinfusion of fluid removed from the site of interest back into the body." EX1005, 11:62-12:14.

120. In Petitioner’s purported combinations of Laub or Aklog with Garrison, Garrison’s valve 3325 is “user-actuated” such that the valve must be manually operated by the surgeon (or other healthcare technician) to close and open the valve to build up and then apply vacuum pressure. Petition, pg. 37 (“User-actuated valve”), pg. 41 (“User-Actuated Valve”). Accordingly, in Petitioner’s combination, the user must not only control the pump as disclosed in Laub and Aklog but also manually control the closing and opening of the valve. A POSITA would not have included the valve 3325 because it would complicate the aspiration methods of Laub and Aklog by requiring that additional surgeon interaction when those references disclose that controlling the pump is all that is needed to effectuate aspiration and reinfusion. And, if the surgeon were to purposely (or inadvertently) close Petitioner’s added valve while the pumps of Laub and Aklog ran, that inhibited flow condition would lead to system and blood damage as I describe above.

VIII. GROUNDS 3A AND 4A: THE COMBINATION OF LAUB OR AKLOG AND GARRISON DOES NOT RENDER OBVIOUS ANY OF CLAIMS 1-10, 13-29, OR 32-38

121. Petitioner and its expert, Mr. Thornton, allege that Garrison in combination with Laub (ground 3A) renders obvious Claims 1-10, 13-29, and 32-38 of the ’333 Patent and that Garrison in combination with Aklog (ground 4A) renders

obvious Claims 1-10, 13-29, and 32-38 of the '333 Patent. I disagree for the reasons I discuss in further detail in this section.

122. As I explained above, I understand that for a patent claim to be rendered obvious, 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, the claimed invention is obvious. Even if all limitations of a claimed invention are disclosed by the prior art combination, Petitioner 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. 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.
123. First, Garrison does not disclose the claimed buildup of vacuum pressure in a clot canister having a filter and subsequent release of vacuum pressure recited in Claims 1 and 20, as I explain above in §VII.A. And a POSITA would not have combined the various embodiments of Garrison to arrive at a method

including building up vacuum pressure in Garrison’s filter 3418 (i.e., the alleged “clot canister”). Petition, pgs. 36-37. In particular, using the peristaltic pump shown in Figure 34 with Garrison’s valve closed would likely damage the pump and blood in the system as I explain above in §§VII.B-C. And, a POSITA would not have used a syringe instead of the pump with the filter 3418 because that would not generate a “maximum level of aspiration” as Garrison discloses for the syringe embodiment and as Petitioner relies on. Petition, pgs. 36-42; EX1006, ¶[0134].

124. Second, a POSITA would not have used Garrison to treat large clots like PE or DVT—even if the catheter were “upsized”—because Petitioner’s references recognize the criticality of blood reintroduction to patient health and safety when treating such large clots, and Garrison expressly discloses that the embodiments relied on by Petitioner are not suitable for blood reintroduction. EX1006, ¶[0135].
125. Accordingly, for those reasons and the reasons set forth below, it is my opinion that independent Claims 1 and 20 are not rendered obvious by the combinations of Garrison and Laub or Aklog. Dependent Claims 2-10 and 13-19 depend from independent Claim 1, and dependent Claims 21-29 and 32-38 depend from independent Claim 20. Therefore, these claims are also not rendered obvious by the combinations of Garrison and Laub or Aklog because

they incorporate all the features of their respective independent Claims 1 or 20.

A. None of Garrison, Laub, or Aklog disclose the Methods of Claims 1 or 20 Including the Buildup and Release of Vacuum Pressure in a Clot Canister Having a Filter

126. Independent Claims 1 and 20 of the '333 Patent recite methods including “generating vacuum pressure within the clot canister via the aspiration source while a valve positioned along the fluid path between the aspiration catheter and the clot canister is in a first position that inhibits fluid flow along the fluid path from the lumen of the aspiration catheter to the clot canister” and “moving the valve from the first position to a second position thereby applying the vacuum pressure to the lumen of the aspiration catheter ... wherein the clot canister includes a filter configured to filter the blood from the portion” of the “pulmonary embolism” (Claim 1) or “deep vein thrombosis” (Claim 20).
127. As I explain in detail in §VII.A. above, Petitioner does not allege that Laub or Aklog disclose such a methodology, and instead relies on Garrison for allegedly disclosing those features. Petition, pgs. 36-42. But, Garrison does not expressly disclose a method of operating the system of Figure 34 to build up and subsequently release vacuum pressure in a clot canister having a filter as recited in the Claims of the '333. Because of that deficiency, Petitioner relies on the different syringe embodiment described in paragraph [0134] of

Garrison to allegedly show the claimed buildup and release of pressure. *Id.* But, again, that disclosure in paragraph [0134] is for generating vacuum pressure with a syringe rather than with a peristaltic pump as shown in Figure 34 of Garrison, and that syringe is “attached” to the flow controller rather than a filter 3418 and a check valve 3419 like the peristaltic pumps in Figure 34. Accordingly, Garrison does not disclose generating vacuum pressure in a clot canister while a valve is closed using a peristaltic pump in the embodiment shown in Figure 34 of Garrison and relied on by Petitioner. And a POSITA would not have done so due to the potential for damage to the pump and blood in the system when operating in a fluid-starved state.

B. A POSITA Would Not Have Modified Garrison to Build Up Vacuum Pressure in the Filter 3418.

128. As I explain above, Garrison does not disclose any embodiment that builds up and subsequently releases vacuum pressure in a clot canister having a filter as recited in the Claims of the '333 Patent. I see that in the Institution Decision, the Board implicitly saw “no flaw in Petitioner’s alleged mixing of disclosures or features for different embodiments of Garrison.” Institution Decision, pgs. 31-32. I disagree—there is a flaw in that mixing of disclosures—a POSITA would not have operated Garrison’s peristaltic or centrifugal pumps with a valve closed, and a POSITA would not have used a syringe in a system

including Garrison's filter 3418 because that would not "enable the maximum level of aspiration." Petition, pg. 38.

129. As I explain above, Garrison discloses various embodiments that utilize different aspiration sources. In Figure 34 primarily relied on by Petitioner and including a peristaltic pump, "both the arterial access device 2010 and the catheter 2030 are connected to the same aspiration source 3430" (peristaltic pump) and the "valve 3325 controls which device is connected to the aspiration source 3430 [t]he 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]; Petition, pg. 37. That is, because the arterial access device 2010 and the catheter 2030 are connected to the same aspiration source 3430 (a peristaltic pump), the valve 3325 ("a 3-way or 4-way stopcock" or "flow controller") is used to control the connection of those catheters to the peristaltic pump 3430. For all the reasons I explain above, a POSITA would have understood that the aspiration source 3430 (i.e., peristaltic pump) should not be run while the connections to both the arterial access device 2010 and the catheter 2030 are closed—pump damage would result and, if blood return were to be implemented (like Laub and Aklog disclose as critical for treating PE/DVT), blood would be damaged. Indeed, for at least that reason, Garrison

does not disclose any such methodology at all related to Figure 34; the valve is simply used to switch flow paths between catheters.

130. Because of that deficiency, Petitioner apparently points to the different embodiment of Garrison described in paragraph [0134] including the locking syringe for allegedly disclosing the purported build up and release of vacuum pressure. EX1006, ¶[0134]; Petition, pg. 38. But, there is no disclosure of a “filter” in that embodiment as recited in the Claims of the ’333 Patent. Accordingly, Petitioner incorporates that embodiment into Figure 34 by stating that “‘the user may open the connection to the aspiration syringe’ to ‘enable the maximum level of aspiration in a rapid fashion’ ... [b]ecause the valve (e.g., stopcock 3325) is distal to the filter, the vacuum pressure builds up in the filter canister via the pressure source.” Petition, pg. 38. That is, Petitioner alleges that substituting the syringe embodiment of paragraph [0134] into Figure 34 instead of the peristaltic pump would enable the maximum level of aspiration. That substitution would not enable the maximum level of aspiration.
131. In the locking syringe embodiment of paragraph [0134], Garrison discloses that the syringe is “attached” directly to a flow controller rather than indirectly via a filter and a check valve like the peristaltic pump in Figure 34. EX1006, ¶[0134]. That arrangement maximizes the level of aspiration because there is

a minimal volume between the syringe and valve (e.g., just the minimal space between the syringe tip and valve). That is, it eliminates dead space in the system that cannot be directly evacuated. Indeed, Garrison's disclosure of the syringe embodiment in paragraph [0134] does not describe any other type of aspiration source (e.g., a pump) to generate a vacuum pressure in such a "maximum" way, and it does not describe creating a vacuum in a clot canister or filter. In contrast, in Petitioner's proposed combination, the filter 3418, check valve 3419, and associated tubing is between the syringe and Garrison's valve 3325 such that the total volume between Garrison's syringe and Garrison's valve is greater than directly connecting the syringe to Garrison's valve. Put differently, the filter 3418, check valve 3419, and tubing increase the available volume for evacuation if Garrison's syringe were attached in place of the peristaltic pump in Figure 34. That increased volume decreases the maximum achievable vacuum pressure because removing the same volume of fluid (Garrison's syringe volume) from a larger volume (including the filter 3418, check valve 3419, and associated tubing) rather than a smaller volume (the direct connection to the flow controller as Garrison teaches), results in less vacuum pressure. Specifically:

$$Pressure_{Final} = Pressure_{Initial} \left(\frac{Volume_{Initial} - \Delta Volume_{Removed}}{Volume_{Initial}} \right)$$

Accordingly, the initial volume controls the final vacuum pressure such that Petitioner's purported arrangement with a syringe instead of the peristaltic pump in Figure 34 would generate less vacuum pressure and a correspondingly smaller "level of aspiration" than Garrison's express disclosure of attaching the syringe to the flow controller where there is no intervening fluid volume.

132. Taken altogether, a POSITA would not have operated the system shown in Figure 34 of Garrison to build up vacuum pressure in the filter 3418 using a peristaltic or like pump because that would damage the pump and blood in the system. And, a POSITA would not have simply replaced the peristaltic pump of Garrison's Figure 34 with a syringe because in that combination the volume of the filter 3418, check valve 3419, and associated tubing would decrease—not "maximize"—the level of vacuum that could be generated.

C. A POSITA Would Not Have Modified Garrison's System to Treat PE or DVT Because Petitioner's References Teach that Such a System Would Endanger the Patient

133. Claim 1 requires a "method of treating a pulmonary embolism within a vasculature of a patient" including "advancing an aspiration catheter at least partially through the vasculature of the patient such that a distal end portion of the aspiration catheter is positioned proximate to the pulmonary embolism" and "moving the valve from the first position to a second position thereby

applying the vacuum pressure to the lumen of the aspiration catheter such that at least a portion of the pulmonary embolism and blood are aspirated into the clot canister.” Claim 20 recites those same steps for treating deep vein thrombosis.

134. As Petitioner admits, “Garrison focuses on the “treatment of cerebral occlusions.” Petition, pg. 21. Indeed, Garrison discloses “methods and systems for transcarotid access of the cerebral arterial vasculature and treatment of cerebral occlusions.” EX1006, ¶[0002]. Petitioner then asserts that a “POSITA would have found it obvious to use, or optimize, Garrison’s clot treatment system to treat PE based on Laub or Aklog” and that a “POSITA would have found it obvious to use or optimize Garrison’s aspiration system to treat DVT based on Laub or Aklog.” Petition, pgs. 21-30 & 64.
135. But, a POSITA would not have modified Garrison to treat PE or DVT because Petitioner’s references recognize the criticality of blood reintroduction to patient health and safety when treating large clots like PE or DVT in large vessels with high blood flow volumes, and Garrison expressly discloses that the embodiments relied on by Petitioner are not suitable for blood reintroduction. What’s more, Petitioner’s proposed combination in which a pump runs against a closed valve would further harm the blood beyond what is disclosed by Garrison as set forth in §IV.B.2. above.

136. As I explain in §VI.B. above, Laub discloses a system for removing clots, including PE, from a patient including a pump 400 that operates to continuously suction blood and thrombi through an aspiration catheter 200 and a filter 300 and then drive the filtered blood through a return catheter 500 back into the patient:

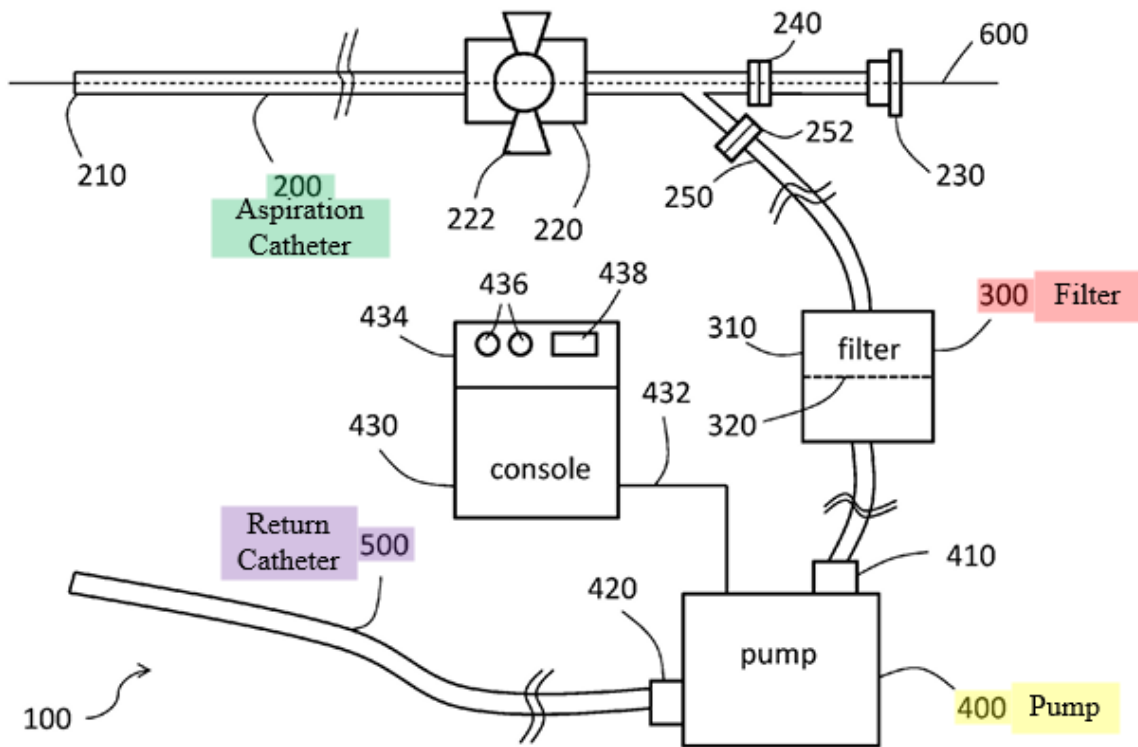


FIG. 1A

EX1012, ¶¶[0005], [0024]. To effectively treat large clots in large vessels (e.g., PE and DVT), Laub discloses a relatively large aspiration catheter (in “preferred embodiments, aspiration catheter has a French size of equal to or greater than 10 Fr to allow for aspiration of large thrombi and/or other solid

materials from the patient”) and high aspiration flow rates (up to “6000 mL/min”). *Id.* at ¶¶[0028], [0044].

137. Because of those large flow rates, Laub correctly recognizes the need for blood reinfusion because of the large volume of blood removed from the patient: “Without returning the blood back to the patient, such high flow rates could quickly result in exsanguination of the patient.” *Id.* at ¶[0045]. That is, the patient will bleed out and die or go into shock if the blood is not returned. “By returning the aspirated blood back to the patient, embodiments of the present system 100 allows for aspiration while minimizing the blood loss of the patient.” *Id.* Accordingly, a POSITA would understand from Laub that when treating large clots like PE and DVT, blood return is critical and that without it, such a system would endanger the patient.
138. As I explain in §VI.C. above, Aklog discloses a system for removing large clots, that like Laub includes a pump 15 that continuously operates to suction blood and thrombi through an aspiration catheter 10 and a filter device 14 and then drive the filtered blood through a reinfusion catheter 16 into the patient:

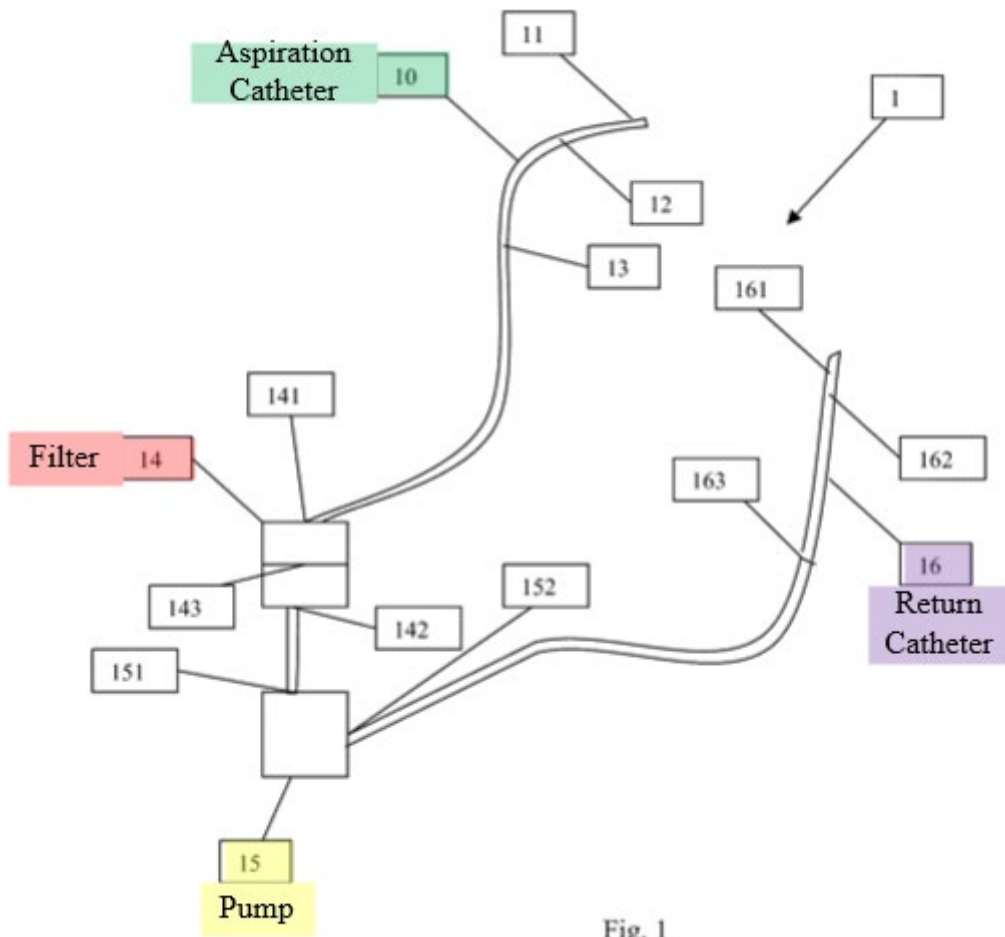


Fig. 1

EX1005, 11:24-12:34. To effectively treat large clots in large vessels (e.g., PE and DVT), Aklog discloses a relatively large aspiration catheter (“the suction cannula 10 may be designed to remove at least 10 cm³ of undesirable material substantially en bloc”) and high aspiration volumes/flow rates (“suction cannula 11 ... when used around the heart and other large vessels, may displace a relatively large volume of fluid into and out of the patient's circulatory system”). *Id.* at 11:18-20, 19:57-62.

139. Because of those large aspiration volumes, Aklog correctly recognizes the need for blood reinfusion: “[i]f 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.” *Id.* at 7:23-26. That is, the patient will be harmed due to excessive blood removal if the blood is not returned. To address this, Aklog’s system “simultaneously reinfuse[s] 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.” *Id.* at 5:19-23. Accordingly, a POSITA would also understand from Aklog that when treating large clots like PE and DVT, blood return is critical and that without it, such a system would endanger the patient.
140. Accordingly, both Laub and Aklog recognize the need to reintroduce blood when treating PE and DVT. But, Garrison itself discloses that the very embodiments relied on by Petitioner in Figure 34 and paragraph [0134] (the locking syringe embodiment) are not suitable for returning blood:

One disadvantage of current sources of aspiration is that the aspirated blood is received into an external reservoir or syringe. This blood is generally discarded at the end of the procedure, and as such represents blood loss from the patient. In addition, pumps such as centrifugal or peristaltic pumps are known to cause

damage to blood cells. Although it is possible to return blood from the external reservoir to the patient, the blood has been exposed to air or has been static for a period of time, and there is risk of thrombus formation or damage to the blood cells. Usually, aspirated blood is not returned to the patient to avoid risk of thromboembolism.

EX1006, ¶[0135]. In Figure 34 relied on by Petitioner for disclosing a “fluid control device,” blood is likewise pumped to the receptacle 3430 (an “external reservoir”) where it remains “static” and is “exposed to air” such that it is not suitable for blood return. In the syringe embodiment disclosed in paragraph [0134], blood is aspirated into the syringe where it remains “static” such that it is not suitable for blood return.

141. Accordingly, a POSITA would understand based on Garrison’s express disclosure that in each embodiment of Garrison relied on by Petitioner the aspirated blood is not suitable for blood return and should be “discarded at the end of the procedure.” EX1006, ¶[0135]. For this reason, a POSITA would not have found it obvious to use or optimize Garrison to treat PE or DVT because Laub and Aklog each emphasize the critical nature of blood return for patient health when treating large clots in large vessels like PE and DVT—and Garrison discloses that the embodiments relied on by Petitioner are not suitable for blood return. As such, a POSITA would not optimize Garrison’s system

in a manner not disclosed by Garrison and in a manner discouraged by Garrison and both Laub and Aklog.

142. After recognizing the deficiencies of embodiments relied on by Petitioner for returning blood, Garrison discloses a different embodiment in Figure 36 “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.” EX1006, ¶[0136]. Figure 36 illustrates a pump device 3250 connected to either or both of the flow lines of the arterial access device or smaller inner catheter and having a chamber 3220 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:

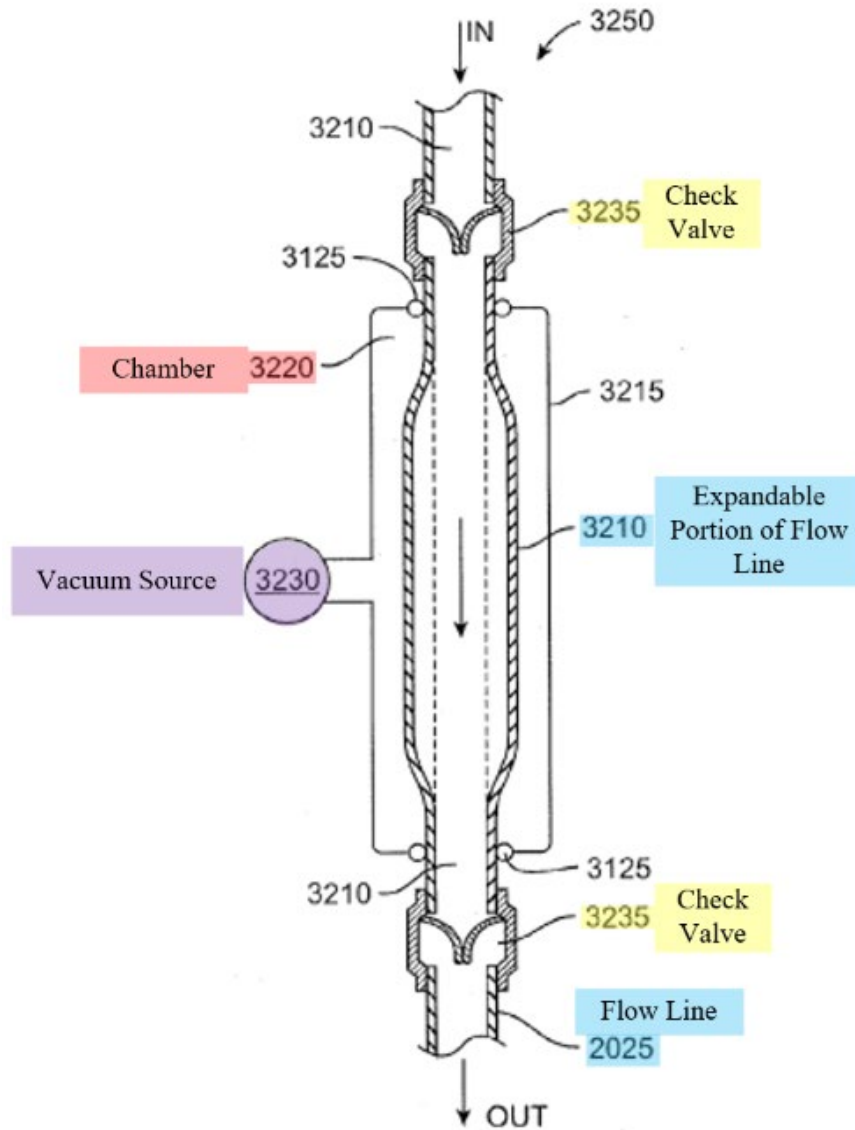


FIG. 36

Id. at ¶¶[0136]-[0137]. In that different embodiment, 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. *Id.* (emphasis added).

143. A POSITA would understand that the pump device in Figure 36 of Garrison is intended to be used in a system without any “valve” unlike the embodiment shown in Figure 34, because blood is continuously aspirated and reinfused in real time to prevent the blood from remaining static so it can be returned to the patient. Indeed, the system of Figure 36 of Garrison is more like the systems of Laub and Aklog, which also disclose the continuous nature of aspiration/blood return. For example, Laub discloses that “reinfusing the patient’s blood **continuously** during aspiration allows for greater suction pressure and/or flow rates (e.g., 2-4 L/min) which can assist in dislodging and removing larger clots and/or tumors than would otherwise be possible.” EX1012, ¶[0045] (emphasis added). And, Aklog’s system “**simultaneously** reinfuse[s] 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.” EX1005, 5:19-23 (emphasis added). Thus, each of Garrison, Laub, and Aklog disclose continuous aspiration and reinfusion when blood is returned to the patient.
144. A POSITA would understand such systems to be incompatible with the challenged Claims including the treatment of PE and DVT and the buildup and

subsequent release of pressure by moving a valve between different positions (i.e., “generating vacuum pressure within the clot canister via the aspiration source while a valve positioned along the fluid path between the aspiration catheter and the clot canister is in a first position that inhibits fluid flow along the fluid path from the lumen of the aspiration catheter to the clot canister” and moving the valve from the first position to a second position thereby applying the vacuum pressure to the lumen of the aspiration catheter ... wherein in the second position the valve permits fluid flow along the fluid path from the lumen of the aspiration catheter to the clot canister”).

145. Petitioner simply asserts that “Garrison already accounts for one challenge POSITAs encountered when moving from smaller to larger aspiration catheters – a larger catheter ‘may aspirate an unacceptable volume of blood, resulting in excessive fluid loss and/or shock in the patient’” based on the embodiment in Figure 36 of Garrison. Petition, pgs. 29-30. But, as I explain above, a POSITA would understand that embodiment not to include any “valve” as recited in Claims 1 and 20 to enable continuous (“real time”) aspiration and reinfusion, just like the systems of Laub and Aklog. And, a POSA would not operate that pump against a closed valve for the same reasons a POSA would not have operated the peristaltic, centrifugal, or like pumps of Garrison, Laub, and Aklog, i.e., pump starvation and blood damage. That is, Figure 36 of

Garrison would not suggest to a POSA that Petitioner's modified system would account for the blood return issues I describe above.

146. And, I note also that the Examiner of the '333 patent expressly considered Garrison during prosecution, and understood that a POSITA would not have modified Garrison to treat PE or DVT even in view other references that did teach aspiration of those types of clots:

Claim 23 and 42 are allowable for reciting, *inter alia*, “a method of treating a *pulmonary embolism* within a vasculature ...” and “applying the vacuum pressure to the lumen of the aspiration catheter such that at least a portion of the pulmonary embolism and blood are aspirated into the clot canister.[”]

Garrison, Barzell, and Heaton teaches an aspiration catheter, as described in Non-Final Rejection filed on 10/30/2023. However, modified Garrison does not teach an aspiration catheter configured to aspirate pulmonary embolism or deep vein thrombosis. The aspiration catheter of modified Garrison is configured for smaller neurovascular anatomy (see Abstract) and not configured for larger clot/embolisms. As explained by inventor during the interview on 1/25/2024, and further supported by photographic evidence during the interview, a pulmonary embolism or a deep vein thrombosis presents significant different structures and physiological responses as compared to neurovascular clots, and therefore one skilled in the art would not have looked to use the Garrison device for the current methods.

Prior art like Batiste (US 20180042623 A1) teaches an aspiration catheter (see Abstract) used for deep vein thrombosis or pulmonary embolisms (see Paragraph [0004]). However, it would not be reasonable to combine modified Garrison with the device of Batiste because Garrison specifically teaches the aspiration catheter being used for neurovascular procedures. Therefore the device of Garrison would be not be combinable with the device of Garrison to teach a method of treating pulmonary embolisms or deep vein thrombosis. There is no prior art that reads on the combination of limitations of claim 23 or 42. **Claims 24-41** are allowable for depending on claim 23. **Claims 43-60** are allowable for de pending on claim 42.

EX1002, pgs. 46-47. In summary, in allowing the Claims challenged here, the Examiner considered the disclosure of Garrison and found that a POSITA would not have modified Garrison to treat pulmonary embolism or deep vein thrombosis, and also found that there is no prior art that reads on the Claims including in view of Batiste which, similar to Laub and Aklog, the Examiner described as teaching an aspiration catheter used to treat DVTand PE.

IX. GROUNDS 1B-1D, 2B-2D, 3B-3D, AND 4B-4D: THE COMBINATIONS OF LAUB AND GARRISON, AKLOG AND GARRISON, GARRISON AND LAUB, AND GARRISON AND AKLOG FURTHER IN VIEW OF GOFF, SCHAFFER, AND/OR HARTLEY DO NOT RENDER OBVIOUS ANY OF CLAIMS 6-8, 11-12, 17, 25-27, 30-31, AND 36

147. As I explain §VII. above, independent Claims 1 and 20 are not rendered obvious by Laub in combination with Garrison, Aklog in combination with

Garrison, or Garrison in combination with Laub, or Garrison in combination with Aklog. Dependent Claims 6-8, 11-12, and 17 depend from independent Claim 1, and dependent Claims 25-27, 30-31, and 36 depend from independent Claim 20. Petitioner does not allege that Goff (grounds 1B, 2B, 3B, and 4B; Claims 6-8, 17, 25-27, and 36), Schaffer (grounds 1C, 2C, 3C, and 4C; Claims 11-12 and 30-31), or Schaffer and Hartley (grounds 1D, 2D, 3D, and 4D; Claims 11-12 and 30-31) disclose any of the features of independent Claims 1 or 20. Therefore, those dependent Claims are also not rendered obvious by Petitioner's combinations because they incorporate all the features of their respective independent Claims 1 or 20.

X. SECONDARY CONSIDERATIONS

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

XI. CONCLUSION


149. 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 1–20.

Declaration of Brian Brown

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: 12 MAR 2026

By: 
Brian Brown

ATTACHMENT 1

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

IPR2025-01025
First Attachment to Declaration of Brian Brown

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

ATTACHMENT 2

MATERIALS CONSIDERED

EXHIBIT/PAPER No.	DESCRIPTION
EX1001	U.S. Patent No. 11,974,910 (“the ’910 patent”)
EX1002	’910 Patent Prosecution History
EX1003	Expert Declaration of Troy Thornton
EX1004	Resume of Troy Thornton
EX1005	U.S. Patent No. 8,734,374 B2 to Aklog et al. (“Aklog”)
EX1006	U.S. Patent Publication No. 2015/0173782 A1 to Garrison et al. (“Garrison”)
EX1007	WIPO Publication No. WO 2006/124307 A2 to Goff et al. (“Goff”)
EX1008	U.S. Patent Publication No. 2003/0116731 A1 to Hartley (“Hartley”)
EX1009	U.S. Patent No. 6,776,770 B2 to Trerotola (“Trerotola”)
EX1010	U.S. Patent Publication No. 2010/0042118 A1 to Garrison et al.
EX1011	U.S. Patent No. 8,535,283 B2 to Heaton et al. (“Heaton”)
EX1012	U.S. Patent Publication No. 2017/0043066 A1 to Laub (“Laub”)
EX1013	U.S. Patent Publication US 2003/0225379 A1 to Schaffer et al. (“Schaffer”)
EX1014	U.S. Patent No. 5,938,645 to Gordon (“Gordon”)
EX1015	U.S. Patent Publication No. 2014/0296868 A1 to Garrison et al.
EX1016	U.S. Patent No. 7,998,104 B2 to Chang (“Chang”)
EX1017	U.S. Patent No. 8,157,760 B2 to Criado et al. (“Criado”)
EX1018	U.S. Patent No. 6,481,439 B1 to Lewis et al.
EX1019	U.S. Patent No. 8,075,510 B2 to Aklog et al.

EXHIBIT/PAPER No.	DESCRIPTION
EX1020	WIPO Publication No. WO 2018/019829 A1 to Brady et al. (“Brady”)
EX1021	U.S. Patent Application No. 16/117,519 (the “519 application”)
EX1022	Expert Declaration of Dr. Aquilla S. Turk, III, DO
EX1023	Resume of Dr. Aquilla Turk, III, D.O.
EX1024	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)
EX1025	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)
EX1026	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)
EX1027	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)
EX1028	April 24, 2024 Letter from Inari to Imperative Care
EX1029	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)
EX1030	Save, Jeffrey L., Time is Brain – Quantified, American Heart Association Journals, available at http://www.stokeaha.org (2005).
EX1031	U.S. Patent No. 9,980,813 B1 to Eller (“Eller”)
EX1032	US 2018/0064453 A1 (“Garrison II”)
EX1033	US 2005/0054995 A1 (“Barzell”)

EXHIBIT/PAPER No.	DESCRIPTION
EX1034	Decision Granting Institution of <i>Inter Partes</i> Review for U.S. Patent No. 11,697,011 (Paper 7) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2024-01157 (P.T.A.B. Jan. 23, 2025)
EX1035	Decision Granting Institution of <i>Inter Partes</i> Review for U.S. Patent No. 11,697,012 (Paper 6) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-00156 (P.T.A.B. Apr. 22, 2025)
EX1036	U.S. Patent No. 12,109,384 B2 to Merritt et al.
EX1037	Patent Owner's Exhibit 2002 filed in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-00289 (P.T.A.B.)
EX1038	Indigo Aspiration System-Penumbra Engine Pump and Canister, 510(k) No. K180105 (Mar. 8, 2018) ("Indigo Aspiration System")
EX1039	AXS Universal Aspiration Set Brochure (2017)
EX1040	VacLok Negative Pressure Syringe Brochure
EX1041	O. Nikoubashman et al., Under Pressure: Comparison of Aspiration Techniques for Endovascular Mechanical Thrombectomy, 39 Am. J. Neuroradiol. 905-909 (May 2018) ("Nikoubashman")
EX1042	Inari's Supplemental Infringement Contentions (without claim charts) from <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , No. 24- cv-3117 (N.D. Cal.) (served February 7, 2025)
EX1043	Inari's Notice of Motion and Motion for Leave to File Third Amended Complaint (Dkt. #88) in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 24-cv-03117-EKL (N.D. Cal.) (filed March 5, 2025)
EX1044	Case Management & Scheduling Order (Dkt. #54) in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 24-cv-03117-EKL (N.D. Cal.) (issued December 19, 2024)
EX1045	Decision Denying Institution of <i>Inter Partes</i> Review for U.S. Patent No. 11,744,691 (Paper 10) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2024-01257 (P.T.A.B. Feb. 7, 2025)
EX1046	U.S. Patent No. 7,984,730 B2 to Ziv et al.

EXHIBIT/PAPER No.	DESCRIPTION
EX1047	Imperative Care's Opposition to Inari's Motion for Leave to File Third Amended Complaint (Dkt. #98) in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 24-cv-03117-EKL (N.D. Cal.) (filed March 26, 2025)
EX1048	Imperative Care's Notice of Motion and Motion to Stay Pending <i>Inter Partes</i> Review (Dkt. #100) in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 24-cv-03117-EKL (N.D. Cal.) (filed April 2, 2025)
EX1049	Ahmed Pasha et al., Successful Management of Acute Massive Pulmonary Embolism Using Angiovac Suction Catheter Technique in a Hemodynamically Unstable Patient, 15 <i>Cardiovasc. Revasc. Med.</i> 240-243 (2014)
EX1050	Certified File History of U.S. Patent Application 10/371,190 (Schaffer File History)
EX1051	Maureen Kohi, Catheter Directed Interventions for Acute Deep Vein Thrombosis, 6 <i>Cardiovasc. Diagn. Ther.</i> 599-611 (2016)
EX1053	Decision Referring the Petition to the Board (Paper 9) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-00728 (P.T.A.B. July 31, 2025)
EX1054	Decision Granting Institution of <i>Inter Partes</i> Review for U.S. Patent No. 11,554,005 (Paper 10) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-00289 (P.T.A.B. June 18, 2025)
EX1055	Order Denying Motion for Preliminary Injunction (Dkt. #136) in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 24-cv-03117-EKL (N.D. Cal.) (issued September 29, 2025)
EX1056	Joint Stipulation to Continue to Stay of Litigation Pending IPR Decisions and Vacate Upcoming Case Management Conference (Dkt. #139) in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 24-cv-03117-EKL (N.D. Cal.) (dated January 21, 2026)
EX1057	Order Granting Joint Stipulation to Continue the Stay of Litigation Pending IPR Decisions and Vacate Upcoming Case Management Conference (Dkt. #140) in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 24-cv-03117-EKL (N.D. Cal.) (issued January 21, 2026)

EXHIBIT/PAPER No.	DESCRIPTION
EX2001	U.S. Patent Application Publication No. 2017/0274180 to Garrison et al.
EX2002	U.S. Patent Application Publication No. 2013/0035628 to Garrison et al.
EX2003	U.S. Patent Application Publication No. 2018/0042623 to Batiste (“Batiste”)
EX2004	U.S. Patent No. 6,059,745 to Gelbfish (“Gelbfish”)
EX2006	Order Granting in Part Motion to Stay, <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , No. 5:24-cv-03117-EKL (N.D. Cal. Sept. 29, 2025), ECF No. 137
EX2007	Hearing Transcript, dated February 6, 2026
EX2009	Instructions for Use for Medtronic Bio-Bump™ BP-50, CBBP-50
EX2010	Instructions for Use for Maquet Getinge Group ROTAFLOW Centrifugal Pump
EX2011	40 Year Bio Pump Timeline
EX2012	OPERATING INSTRUCTIONS for the Pump Drive BVP-BP for centrifugal blood pump heads BP-50/BP-80 and SP-45
EX2013	Deposition Transcript of Troy L. Thornton (February 18, 2026)
EX2014	Deposition Transcript of Troy L. Thornton (February 19, 2026)
EX2015	Deposition Transcript of Aquilla S. Turk (February 25, 2026)
EX2016	Declaration of Dr. Christopher S. Morris
EX2017	Redacted version of Declaration of Brian Brown, <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , No. 5:24-cv-03117-EKL (N.D. Cal. July 24, 2024), ECF No. 24-2
Paper 1	Petition for <i>Inter Partes Review</i>
Paper 15	Decision Granting Institution of <i>Inter Partes Review</i>