

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

IMPERATIVE CARE, INC.,
Petitioner,

v.

INARI MEDICAL, INC.,
Patent Owner.

Case IPR2025-01025
Patent No. 11,974,910

**SUPPLEMENTAL DECLARATION OF TROY L. THORNTON
IN SUPPORT OF PETITIONER'S REPLY
FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 11,974,910**

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1024	Shani, Jacob M.D., et al., Mechanical Manipulation of Thrombus: Coronary Thrombectomy, Intracoronary Clot Displacement, and Transcatheter Aspiration, 72 Am. J. Cardiol. 116G-118G (1993)
1025	Bose, A et al., The Penumbra System: A Mechanical Device for the Treatment of Acute Stroke due to Thromboembolism, 29 Am. J. Neuroradiol. 1409-1413 (Aug. 2008)
1026	Turk, Aquilla S. et al., Initial clinical experience with the ADAPT technique: A direct aspiration first pass technique for stroke thrombectomy, 6 J. NeuroIntervent. Surg. 231-237 (2014)
1027	Turk, Aquilla S. et al., ADAPT FAST study: a direct aspiration first pass technique for acute stroke thrombectomy, 6 J. NeuroIntervent. Surg. 260-264 (2014)
1028	April 24, 2024 Letter from Inari to Imperative Care
1029	Turk, Aquilla S. et al., Aspiration thrombectomy versus stent retriever thrombectomy as first-line approach for large vessel occlusion (COMPASS): a multicentre, randomized, open label, blinded outcome, non-inferiority trial, 393 Lancet 998-1008 (March 2019)
1030	Save, Jeffrey L., Time is Brain – Quantified, American Heart Association Journals, available at http://www.strokeaha.org (2005).
1031	U.S. Patent No. 9,980,813 B1 to Eller (“Eller”)
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1039	AXS Universal Aspiration Set Brochure (2017)
1040	VacLok Negative Pressure Syringe Brochure
1041	O. Nikoubashman et al., Under Pressure: Comparison of Aspiration Techniques for Endovascular Mechanical Thrombectomy, 39 Am. J. Neuroradiol. 905-909 (May 2018) (“Nikoubashman”)
1042	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)
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1049	Ahmed Pasha et al., Successful Management of Acute Massive Pulmonary Embolism Using Angiovac Suction Catheter Technique in a Hemodynamically Unstable Patient, 15 Cardiovasc. Revasc. Med. 240-243 (2014)
1050	Certified File History of U.S. Patent Application 10/371,190 (Schaffer File History)
1051	Maureen Kohi, Catheter Directed Interventions for Acute Deep Vein Thrombosis, 6 Cardiovasc. Diagn. Ther. 599-611 (2016)
1052	Interview Summary from U.S. Patent Application No. 18/329,450 dated January 31, 2024
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1059	Final Written Decision Determining All Challenged Claims Unpatentable (Paper 33) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-00156 (P.T.A.B. Apr. 7, 2026)
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1068	Penumbra, Optimizing Direct Aspiration (May 2013)

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1069	Gibbs, et al., Temporary Stent as a bail-out device during percutaneous transluminal coronary angioplasty: preliminary clinical experience, 71 British Heart J., 372-377 (1994)
1070	Edwards Lifesciences, Fogarty® Occlusion Catheters (product brochure) http://web.archive.org/web/20150228193218/http://www.edwards.com/products/vascular/atraumaticocclusion/pages/occlusioncatheter.aspx
1071	U.S. Patent No. 5,030,201
1072	U.S. Patent No. 8,657,867
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1075	MitraClip Clip Delivery System Instructions for Use (2013)
1076	FDA Summary of Safety and Effectiveness Data (SSED) for the MitraClip Clip Delivery System (2013)
1077	Troy Thornton and Liz McDermott, MitraClip System Design and History of Development, published as Ch. 7 in <i>Percutaneous Mitral Leaflet Repair</i> (1st ed. 2012)
1078	James I. Fann et al., Beating Heart Catheter-Based Edge-to-Edge Mitral Valve Procedure in a Porcine Model Efficacy and Healing Response, 110 <i>Circulation</i> , 988-993 (2004)
1079	U.S. Patent Publication No. 2004/0092962 A1
1080	U.S. Patent Publication No. 2003/0130721 A1
1081	U.S. Patent Publication No. 2010/0145434 A1
1082	U.S. Patent No. 11,638,585

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I, Troy L. Thornton, do hereby declare:

I. INTRODUCTION

A. Engagement

1. I have been retained on behalf of Imperative Care, Inc. (“Imperative” or “Petitioner”) to provide my opinion regarding the patentability of Claims 1-8, 11-15, and 18-20 of U.S. Patent No. 11,974,910 (“the ’910 patent”). For the reasons discussed herein and in my prior Declaration, I have concluded that Claims 1-8, 11-15, and 18-20 of the ’910 patent are unpatentable because the prior art references anticipate the claims or render them obvious.

2. I understand that this Supplemental Declaration supports Imperative’s Reply for the above-captioned *inter partes* review (“IPR”) of the ’910 patent.

3. I reserve the right to supplement, change, clarify, or modify my opinions should additional information and/or documentation become available to me.

4. I am being compensated at my customary hourly rate for my work in this matter and I am being reimbursed at cost for my expenses. My compensation in no way depends upon the substance of my opinions or the outcome of this proceeding. I have no financial interest in any of the parties to this proceeding.

B. Experience and Qualifications

5. My experience and qualifications are summarized in my *curriculum vitae*, which is designated as Exhibit 1004 in this IPR. I have also summarized some of my relevant experience in my previous Declaration submitted in this IPR. See Ex. 1003 at ¶¶ 5-14.

6. I understand that Patent Owner (“PO”) has argued a person of ordinary skill in the art 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; or (2) an interventional radiologist or pulmonologist with at least three years of experience developing and/or using medical devices in thrombectomy procedures, and who would, where necessary, work or consult with others including an engineer to develop such a medical device.

Patent Owner’s Response at 19 (emphasis added). PO does not define “comparable industry experience.”

7. As I explained in my prior Declaration, it is my opinion that a person of ordinary skill in the art would have had “an undergraduate degree in mechanical engineering or a related engineer discipline and 2-4 years of catheter design experience and, where necessary, would have consulted with a physician regarding the methods of treatment.” Ex. 1003 at ¶ 35. I believe that catheter design experience is “comparable industry experience” to “industry experience in

the mechanical thrombectomy industry” at least because aspiration systems for mechanical thrombectomy are primarily made up of a catheter connected to other standard catheter components like valves, filters, syringes, and pumps. Because the catheter is a primary component of any aspiration system, catheter design experience is the relevant experience a person of ordinary skill in the art would need to possess.

8. I also understand that PO has argued that I would not have qualified as a person of ordinary skill in the art with respect to the '910 patent in 2018 under PO's definition because I have not designed a mechanical thrombectomy system or a catheter specifically intended for thrombectomy procedures. *See* Patent Owner's Response at 21-23. I disagree. Even under PO's proposed definition, I qualified as a person of ordinary skill in 2018 because I had more than 30 years of “comparable industry experience.” As discussed in my Declaration and below, I had extensive catheter design experience. I also understand that PO's expert, Dr. Morris, testified that “the common denominator” for what constitutes “comparable industry experience” is “clotting, or clot” and “experience in clot, and mitigating the effects of clots.” Ex. 1065 (Morris Dep. Tr.) at 205:17-206:21. As I detail below, I had extensive experience with blood clots and mitigating the effects of blood clots in 2018.

9. Since 1985, I have spent my career working in the medical device field on devices for cardiovascular procedures, including thermodilution catheters, left ventricular assist devices, a centrifugal blood pump for cardiopulmonary bypass procedures, angioplasty catheters, abdominal aortic aneurysm endoprosthesis (a two-part implant and the two delivery catheters used to deliver the implant), the MitraClip device to treat mitral valve regurgitation that included the implant and the three catheters to deliver the implant, and a blood flow controller to treat acute decompensated heart failure. All these devices were in blood contact, and choosing materials that were biocompatible was a key component of the projects. Knowledge of the potential complications related to blood clots, thrombus, and thromboemboli was a critical part of every project I worked on.

10. As one example, the Instructions for Use (“IFU”) for the MitraClip device, first approved in 2013, includes numerous references to emboli, embolism, thromboembolism, thrombosis, and thrombus. *See* Ex. 1075 (MitraClip IFU) at 3, 6, 20, 40, 42, . I wrote portions of the IFU, and I reviewed and approved every published IFU for the MitraClip system. Thrombosis of the MitraClip device and its potential to cause thromboembolism was one of the many important considerations that I addressed during the device’s development.

11. The FDA's Summary of Safety and Effectiveness Data (SSED) for the MitraClip system similarly identifies the potential for thrombosis and thromboembolism as potential adverse events. *See* Ex. 1076 (MitraClip SSED) at 5, 24, 38-39. Section IX of the SSED details the summary of the pre-clinical studies. *Id.* at 6-12. As the VP of R&D, I was responsible for the testing and results summarized in that section. Tables 2 and 3 reflect that thrombogenicity testing was successfully conducted (per ISO 10993 requirements) on the MitraClip and the catheters. *Id.* a 7. In addition, the protocols and reports for the animal studies described in the SSED specifically required documentation of clot or thrombus on the MitraClip device and related catheters. For chronic animal studies, the pathologist documented any presence of clot or thrombus by microscopic examination of the implant, and also by examination and sectioning of the end organs.

12. I was also the lead author of Chapter 7 of the textbook *Percutaneous Mitral Leaflet Repair* by Ted Feldman, MD and Fredrick St Goar, MD published in 2012. Ex. 1077 (Thornton). In that chapter, I provide an overview of the R&D path for the MitraClip system. For example, I discuss the importance of the polyester fabric covering on the device to encourage tissue ingrowth and encapsulation of the device. *Id.* at 36, 40. In prior iterations of the MitraClip, our team experimented with uncovered metal components and alternative covering

materials, such as ePTFE, and witnessed evidence of thrombus on the implant. These findings led our team to use the polyester covering to, in part, prevent the development of thrombus on the device.

13. I was also an author of the MitraClip chronic animal study results published in the journal *Circulation*. Ex. 1078 (Fann). As I explained above, we inspected the devices used in that study for the presence of thrombus, and the animals were also observed for evidence of thromboembolism. *Id.* at 988, 990-991. Our study found no clinical or pathological evidence of thrombosis, thromboembolism, or infarcts. *Id.*

14. When I worked for Prograft, Inc. (later acquired by WL Gore) from 1995-2000, I led the development of a novel stent-graft to treat abdominal aortic aneurysms. A key component of the design was a smooth ePTFE lining on the stent-graft. This component differed from prior competitive designs where graft was on the outside of the stent. The lining was designed to prevent thrombosis and thromboembolism when the stent-graft was implanted.

15. In patent publication US 2004/0092962 A1, which relates to the two-part steerable guiding catheter system used to deliver the MitraClip device, in which I was the first named inventor, we considered the potential for emboli and the possibility of using the catheter for removal of embolic material:

- Paragraph 190 explains that “the device 14 may have a smooth surface which prevents cellular adhesion thereby *reducing the accumulation of cells having potential for form an emboli*”;
- Paragraph 245 explains that “the delivery catheter of the present invention may be used to deliver other types of devices, particularly endovascular and minimally invasive surgical devices used in angioplasty, atherectomy, stent-delivery, *embolic filtration and removal*,’

Ex. 1079 (’962 Publication) at ¶¶190, 245 (emphases added).

16. I was also an inventor on patent publication US 2003/0130721 A1, which relates to a kink resistant stent graft. Ex. 1080 (’721 Publication). In that patent publication, we discussed the issues with current stent designs, which included the “use of highly thrombogenic material (stainless steels, tantalum, ELGILOY) which are exposed to blood” and may lead to thromboembolism. *Id.* at [0004]-[0005]. We also discussed the issue of turbulent flow through the stent graft caused by reductions in lumen diameter, “which possibly can lead to complications such as thrombosis.” *Id.* at [0019].

17. I was also the first inventor on patent publication US 2010/0145434 A1, which relates to a kink resistant bifurcated endoluminal prosthesis. Ex. 1081 (’434 Publication). In the patent publication, we discussed how a buckle or wrinkle in graft material could form “a potential site for thrombogenic material to

build up.” *Id.* at [0175]. Our design addressed that issue by not including graft material between the apices of the stent so that the graft material did not form a wrinkle. *Id.*

18. Most recently, I have worked on a catheter-based device to aid in the treatment of acute decompensated heart failure patients. I am the first (and only) named inventor on U.S. Patent No. 11,638,585, which relates to a blood flow controller. Ex. 1082 (’585 Patent). In that patent I describe that the “blood flow control devices described herein can have a non-thrombogenic surface on their inside diameter.” *Id.* 7:42-46. This is important to avoid build-up of thrombogenic material and ultimately, thromboembolism. *Id.* I also disclose that portions of the catheter may be “outside of the blood flow path [which] may reduce clotting and hemolysis during use of the blood flow control device.” *Id.* at 8:25-27.

C. Materials Considered

19. In preparing this Supplemental Declaration, I have considered the materials referenced in this Supplemental Declaration. The materials are identified in the attached list of exhibits.

20. I have also relied on my education, training, and experience, and my knowledge of pertinent literature in the field of the ’910 patent.

II. GROUNDS 1A, 2A, 3A, 4A – LAUB, AKLOG, AND GARRISON

A. Garrison’s Rapid Aspiration Method Is Compatible With Prior Art Aspiration Pumps

21. Patent Owner and Mr. Brown argue that Garrison’s method of building up vacuum pressure while the valve is closed is incompatible with an aspiration system that uses an aspiration pump, rather than a syringe. Ex. 2008 (Brown Supp. Decl.) at ¶¶78-89. Patent Owner and Mr. Brown argue that running an aspiration pump while Garrison’s valve is temporarily closed “would starve the pump of fluid, causing the pump to run dry.” *Id.* at ¶79. Patent Owner argues that running dry could cause the pump to “experience significantly increased friction, cavitation, and overheating, potentially leading to mechanical failure.” *Id.* I disagree with Patent Owner and Mr. Brown.

22. In my opinion, a person of ordinary skill in the art would have reasonably expected that available prior-art aspiration pumps used and designed for aspiration procedures, such as those described in Brady, Pons, the Penumbra Pump Max, and the Medela Dominant Flex pump, could be safely used with Garrison’s aspiration method. It is also my opinion that a person of ordinary skill in the art in August 2018 would have possessed the knowledge and skill to select an appropriate aspiration pump to use with the aspiration systems and methods in Garrison, Laub, and Aklog.

1. **Patent Owner Relies Upon Cardiopulmonary Bypass Pumps, Not Aspiration Pumps Designed For Aspiration Procedures**

23. Patent Owner and Mr. Brown identify three allegedly prior art centrifugal pumps that they assert would be incompatible with Garrison's rapid aspiration method: (1) the Medtronic Bio-Pump BP50 or CBBP-50, (2) the Maquet Rotaflow Centrifugal Pump, and (3) the Hugo Sachs Elektronik Pump Drive BVP-BP. Ex. 2008 (Brown Supp. Decl.) at ¶¶80-81 (citing Exs. 2009-2012). None of these pumps are designed or indicated for use in aspiration thrombectomy procedures.

24. Mr. Brown cites instructions for use for the Medtronic Bio-Pump BP-50, CBBP-50. *See* Ex. 2008 (Brown Supp. Decl.) at ¶80 (citing Ex. 2009). As an initial matter, I note that the instructions for use that Mr. Brown relies upon are dated from September 2018, which is after the priority date of the '910 patent, so those instruction for use are not prior art and would not have been available to a person of ordinary skill in the art in August 2018. Ex. 2009 (BP-50 IFU) at 40. Nonetheless, the instructions for use state that: "[t]he Medtronic Bio-Pump centrifugal blood pump is indicated for use **only** with the Medtronic Bio-Console pump speed controller to pump blood through the extracorporeal bypass circuit for extracorporeal circulatory support for periods appropriate to cardiopulmonary bypass procedures (up to 6 hours)." *Id.* at 6 (emphasis added); *see also* Ex. 2011 (Bio-Pump Story) at 20 ("The Medtronic Bio-Pump Plus centrifugal blood pump

is indicated for use only with the Medtronic Bio-Console pump speed controller to pump blood through the extracorporeal bypass circuit for extracorporeal circulatory support for periods appropriate to cardiopulmonary bypass (up to six hours). It is also indicated for use in extracorporeal support systems (for periods up to six hours) not requiring complete cardiopulmonary bypass (eg, valvuloplasty, circulatory support during mitral valve reoperation, surgery of the vena cava or aorta, liver transplants).”). Accordingly, a person of ordinary skill in the art would have understood that the Medtronic Bio-Pump BP-50 is intended only for use in circulating blood during a cardiopulmonary bypass or other extracorporeal support procedures. *Id.* A person of ordinary skill in the art would have likewise recognized that this pump is not indicated for use as an aspiration source for catheter-based thrombectomy aspiration procedures. *Id.*

25. Mr. Brown also cites the Operating Instructions for the Pump Drive BVP-BP manufactured by Hugo Sachs Elektronik. *See* Ex. 2008 (Brown Supp. Decl.) at ¶80 (citing Ex. 2012). The Operating Instructions specify that the pumps “are intended for liquid handling in laboratory and industry” and “must not be used: for medical applications on humans.” Ex. 2012 (BVP-BP Operating Instructions) at 2. Accordingly, a person of ordinary skill in the art would have understood that the BVP-BP pump described in the Operating Instructions is intended only for use in circulating liquids in a laboratory setting, not for any

medical procedures performed on a human patient, including a thrombectomy procedure. *Id.* A person of ordinary skill in the art would have likewise recognized that this pump is not indicated for use as an aspiration source for thrombectomy aspiration procedures. *Id.*

26. Finally, Mr. Brown cites the instructions for use for the Maquet Rotaflow Centrifugal Pump (RF-32). *See* Ex. 2008 (Brown Supp. Decl.) at ¶81 (citing Ex. 2010). The Rotaflow instructions for use state that “[t]he RF-32 centrifugal pump is intended for use in an extracorporeal circulation during a cardiopulmonary bypass within the framework of surgical procedures, or in circulatory support.” Ex. 2010 (RF-32 IFU) at 4. Further, the Rotaflow is specifically contraindicated for use as a suction device. *Id.* A person of ordinary skill in the art would have understood that the vacuum source in an aspiration system functions as a suction device to remove the clot. Accordingly, a person of ordinary skill in the art would have recognized that this pump is not indicated for use as an aspiration source during thrombectomy aspiration procedures. *Id.*

27. Accordingly, all three of the pumps that Patent Owner and Mr. Brown rely upon are intended for use in either cardiopulmonary bypass procedures or laboratory settings. Ex. 2009 (BP-50 IFU) at 40; Ex. 2011 (Bio-Pump Story) at 20; Ex. 2012 (BVP-BP Operating Instructions) at 2; Ex. 2010 (RF-32 IFU) at 4. A person of ordinary skill in the art would not have selected any of

these pumps for use with Garrison, Laub, or Aklog, which all describe aspiration systems.

28. Further, a person of ordinary skill in the art would have understood that aspirated clot material may clog and/or obstruct the flow of blood through an aspiration catheter. For example, the '910 patent states that “the plunger 462 can be cycled when the fluid control device 126 is open to, for example, facilitate the removal of **clot material stuck or clogged within the catheter subsystem 100.**” Ex. 1001 ('910 patent) at 12:8-12 (emphasis added); *see also id.* at 19:51-20:30, 26:15-19, 26:48-28:10. Aklog similarly recognizes that clot material may clog the aspiration catheter and discloses a balloon embolectomy catheter “to remove any material which may have clogged the cannula.” Ex. 1005 (Aklog) at 10:64-67. Thus, a person of ordinary skill in the art would have understood that the aspiration pump may operate without continuous blood flow during an aspiration procedure due to clogging or obstruction of the catheter.

29. Consequently, a person of ordinary skill in the art would have recognized that the risks identified by Mr. Brown with respect to the bypass pumps, including “increased friction, cavitation, and overheating, potentially leading to mechanical failure,” would occur if those pumps were used in aspiration procedures. For this additional reason, a person of ordinary skill in the

art would not have been motivated to use the cardiopulmonary bypass pumps with the aspiration systems in Garrison, Laub, or Aklog.

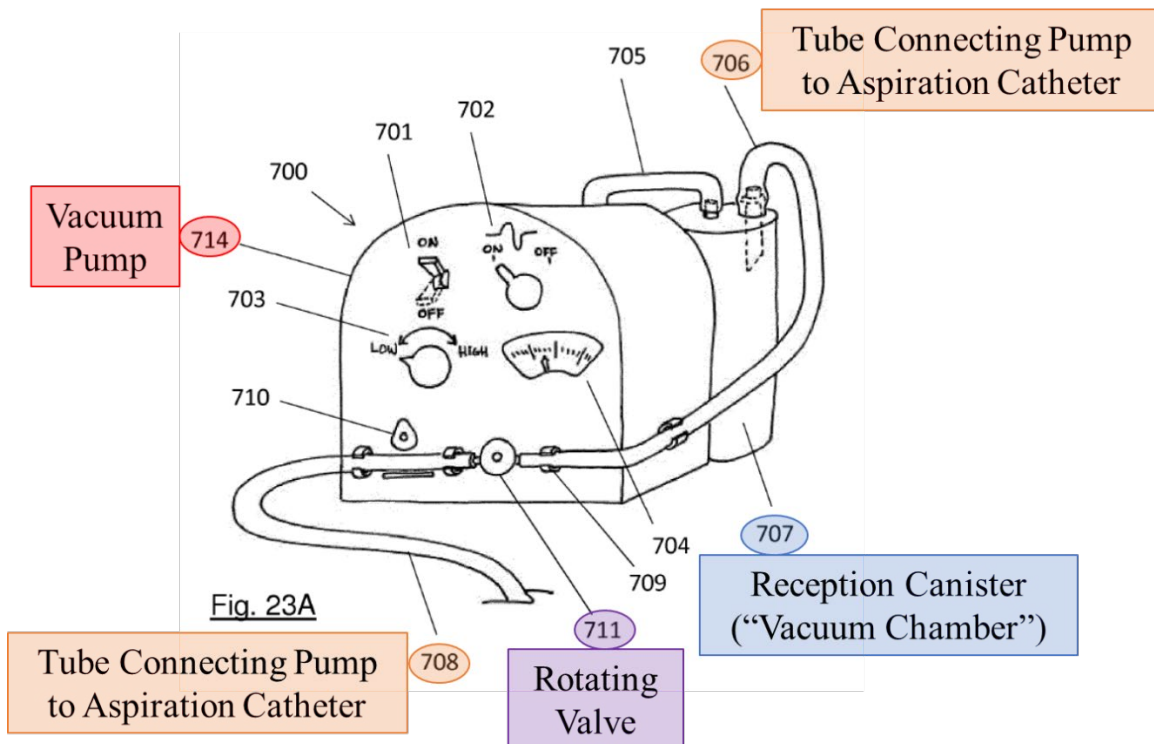
2. A Person Of Ordinary Skill Would Have Known Of Prior Art Aspiration Pumps That Could Be Safely Used With Garrison, Laub, And Aklog

30. A person of ordinary skill in the art in August 2018 would have known of several prior-art aspiration pumps that could be safely used with Garrison's aspiration method and the aspiration systems in Garrison, Laub, and Aklog. As I explain below, the available aspiration pumps did not require continuous blood flow through the pump like the cardiopulmonary bypass pumps.

a. Brady

31. For example, Brady is an international patent publication entitled "A Clot Retrieval System For Removing Occlusive Clot From A Blood Vessel." Ex. 1020 (Brady). Brady discloses blood clot aspiration systems that generate pulsatile vacuum force to dislodge and aspirate stubborn clot material. *Id.* at Abstract, 1:5-17. Brady discloses that its systems are "particularly suited to removing clot from cerebral arteries in patients suffering acute ischemic stroke (AIS), from coronary native or graft vessels in patients suffering from myocardial infarction (MI), and from pulmonary arteries in patients suffering from pulmonary embolism (PE) and from other peripheral arterial and venous vessels in which clot is causing an occlusion." *Id.* at 1:15-17.

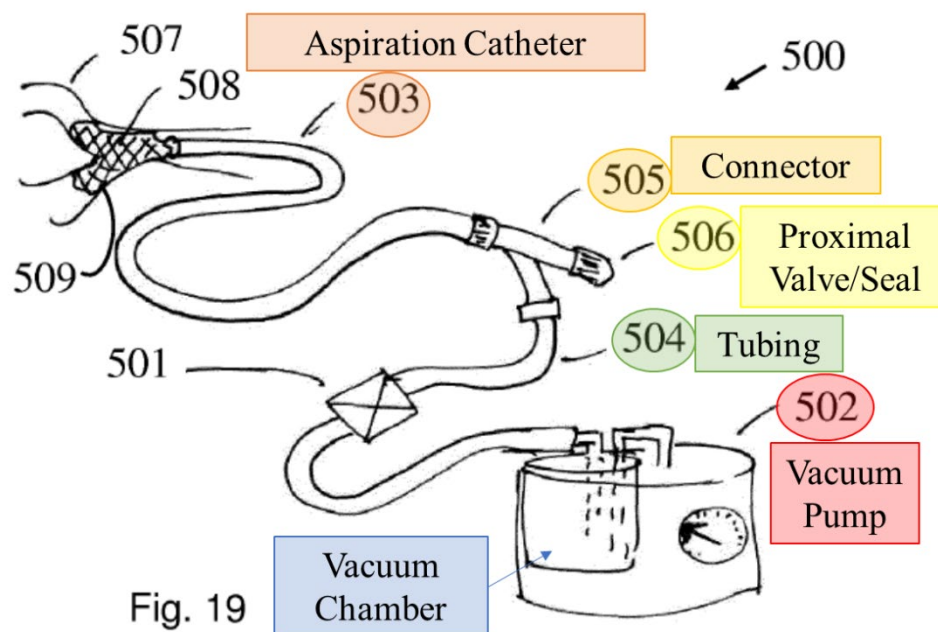
32. Figure 23A of Brady discloses an embodiment having a vacuum pump 714 that “may comprise a diaphragm or vane or piston pump, or a peristaltic pump, or other means of generating a negative pressure differential.” *Id.* at 21:16-19. In this embodiment, the vacuum pump is connected to reception canister 707 via tubing 705:



Id. at 21:16-32, Fig. 23A. As shown in Figure 23A above, the reception canister is connected to an aspiration catheter via tubing 706 and 708. *Id.* Brady explains that when the vacuum pump is turned on, the pump “evacuates the canister 707 via tube 705, and thus a suction or aspiration force is transmitted through tubes 706 and 708.” *Id.* at 21:29-32. By “evacu[at]ing the canister 707,” Brady’s pump

creates vacuum pressure within the canister, which causes the “suction or aspiration force [to be] transmitted through tubes 706 and 708.” *Id.*

33. Figure 19 of Brady also discloses an aspiration system having a vacuum pump 502 with a vacuum chamber. *Id.* at 20:19-29, Fig. 19. As shown in Figure 19 below, the vacuum chamber is connected to the proximal end of an aspiration catheter 503 via tubing 504:

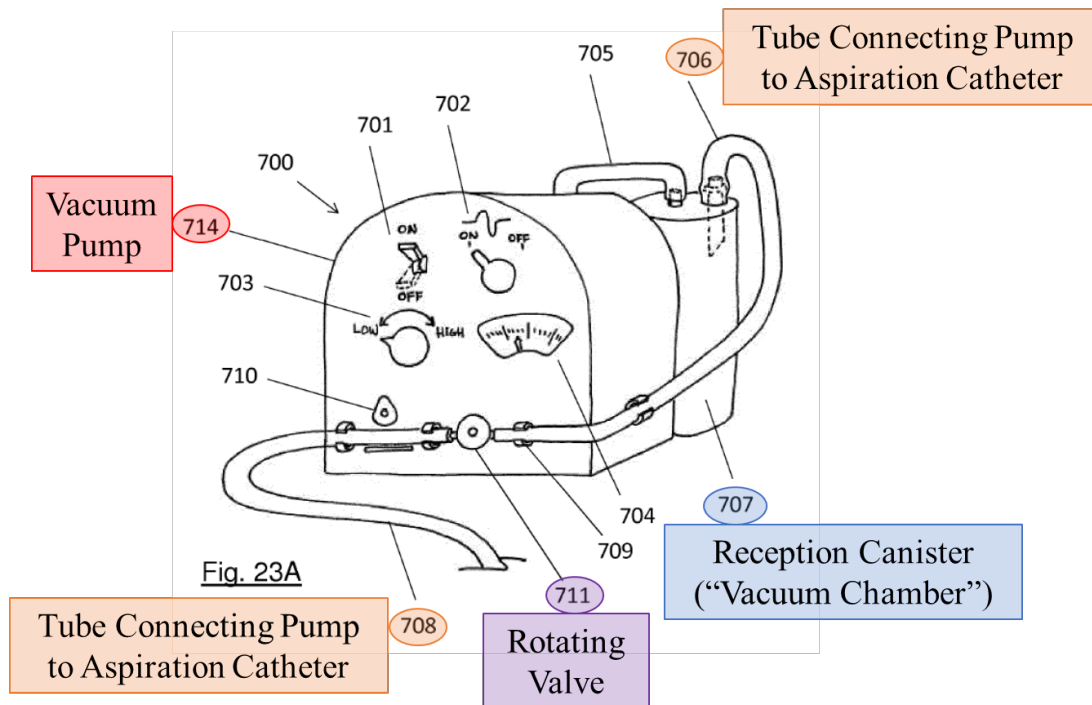


Id.

34. Unlike the cardiopulmonary bypass pumps that Mr. Brown relies upon, Brady’s aspiration pump does not pump blood directly through the pump mechanism, and it therefore does not require continuous blood flow to avoid “friction, cavitation, and overheating.” Instead, Brady’s pump generates vacuum in the canister 707 by evacuating air from the canister. *Id.* at 21:16-32, Fig. 23A.

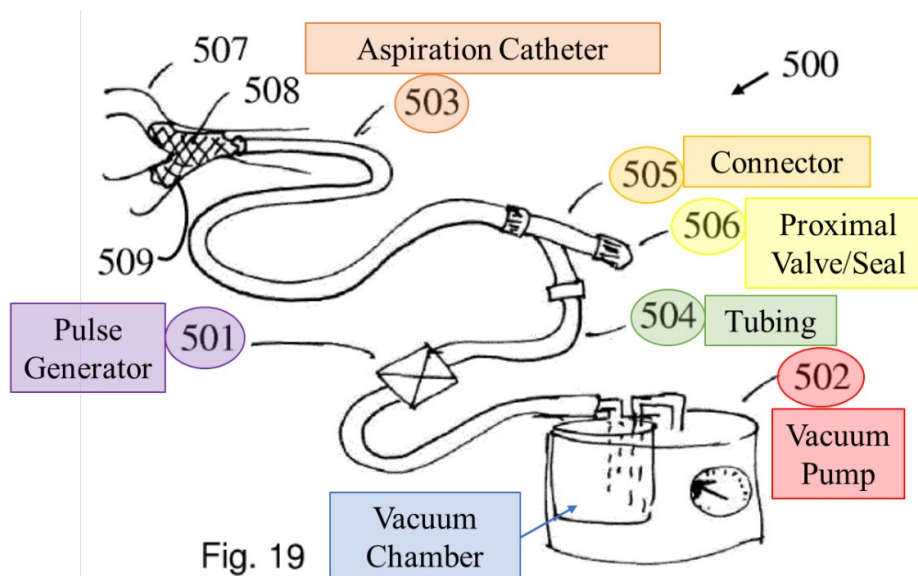
The vacuum in the canister is then applied to the aspiration catheter, which draws blood into the canister, not into the pump mechanism itself. *Id.* Indeed, Brady discloses that its canister includes a “safety valve” to “prevent fluid or material entering tube 705 and damaging the pump.” *Id.*, 21:21-22. In other words, Brady’s pump is designed to always “run dry” without blood flowing through the pump mechanism, regardless of whether the flow controller is open or closed. Because of this design, a person of ordinary skill in the art would have understood that running Brady’s pump while Garrison’s valve is closed would not damage the pump or any of the blood being aspirated by the pump. Rather, the pump would simply continue to build up vacuum in the canister, which would be applied to the aspiration catheter once the Garrison’s valve is opened.

35. In fact, Brady expressly discloses combining the vacuum pump with an on-off valve placed along the fluid path to create a rapid pulse of aspiration pressure that “may be beneficial for the retrieval of stubborn clot material.” *Id.* at 22:5-6. The embodiment in Brady’s Figure 23A includes a rotating valve 711 that may be closed after the vacuum pump is turned on such that “tube 708 is no longer exposed to the vacuum within canister 707”:



Id. at 22:1-24. Brady then explains that the valve may be opened so that “a vacuum pulse may be delivered through tube 708” to aspirate the clot material.

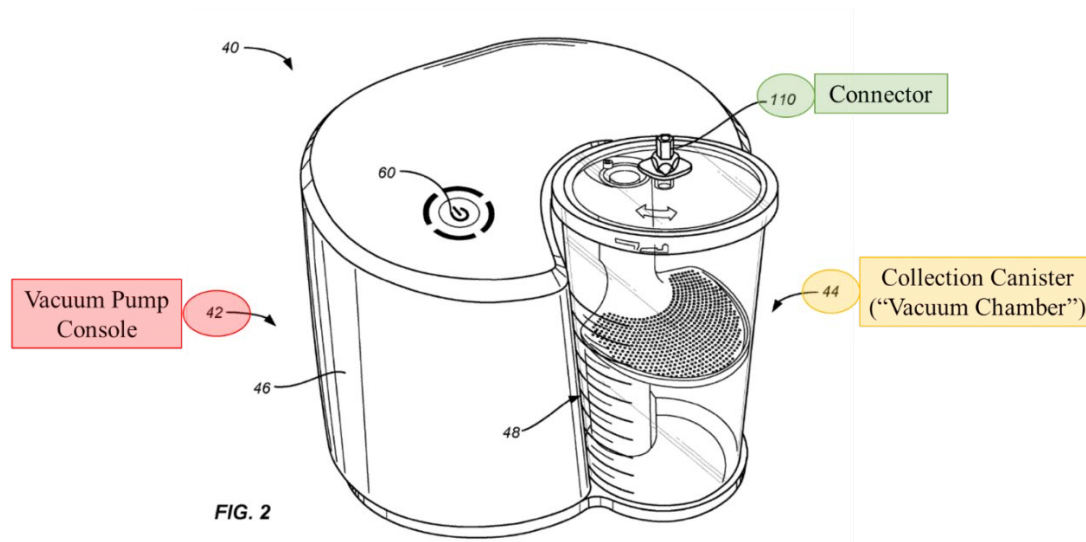
Id., 22:1-24, Fig. 24a-b. The embodiment in Figure 19 uses a similar method that employs a pulse generator 501, which selectively compresses the tubing to create pulsing aspiration:



Id. at 20:19-29, Fig. 19. Brady's express disclosures therefore confirm that its pumps may be safely and effectively operated to build up vacuum while a downstream valve is closed.

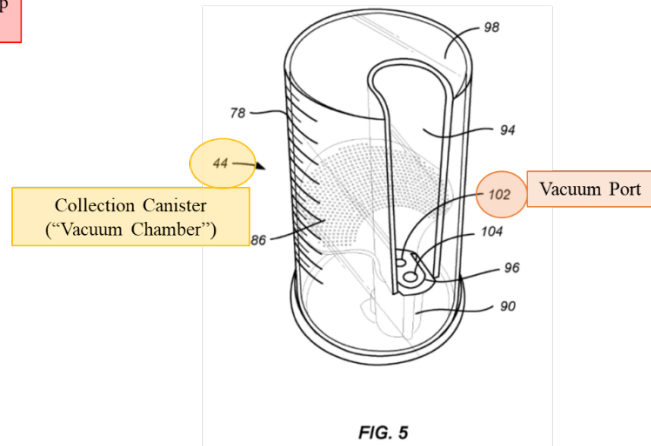
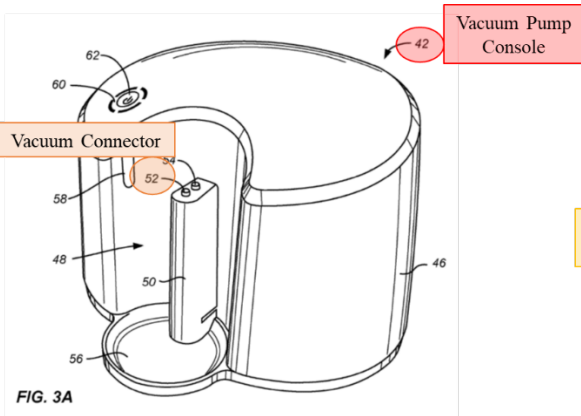
b. Pons

36. Pons, U.S. Patent No. 11,432,835, is entitled Apparatus and Methods for Clot Aspiration and is assigned to Penumbra, Inc. Ex. 1062 (Pons). Pons discloses "improved vacuum systems including a vacuum console and a collection canister for use with mechanical thrombectomy systems." *Id.* at 2:56-58. Pons' system includes a vacuum console 42 that houses a vacuum pump and a collection canister 44 secured to the console:



Id. at 6:27-33, Fig. 2. Pons' collection canister includes a connector 110 at the top "which is attached to a proximal end of a catheter or other tubing" for aspirating blood and thrombus from the patient. *Id.* at 7:63-65. The collection canister also

includes a vacuum port 102 which connects to a vacuum connector 52 on the console:



Id. at 7:1-3, 7:65-8:1, Figs. 3A, 5. Pons explains that when the pump is turned on, the pump “will draw vacuum through the connector 52,” which generates vacuum pressure in the canister to aspirate blood and clot from the patient. *Id.* at 7:1-4. Thus, Pons’ pump operates similarly to Brady’s aspiration pumps by evacuating air from the collection canister to build up vacuum that is then applied to an aspiration catheter. *Id.*

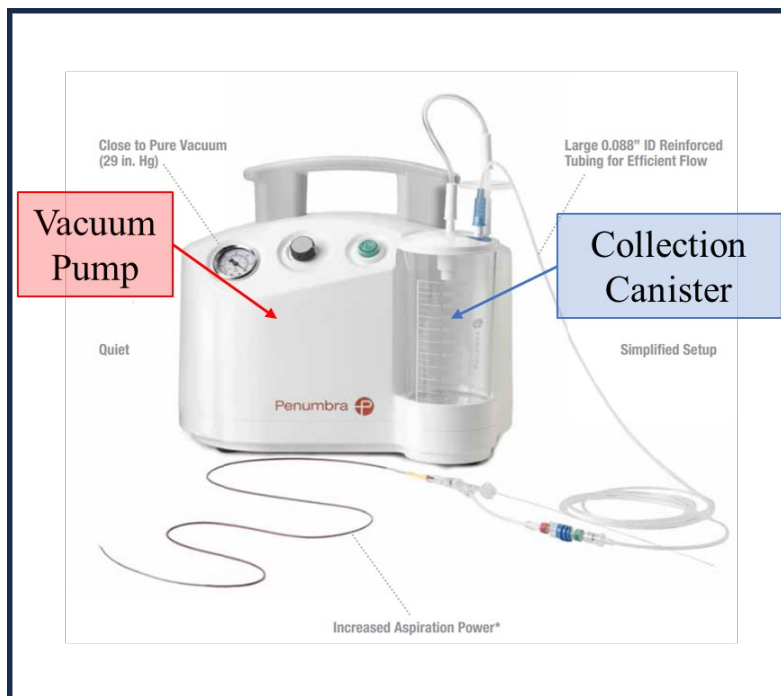
37. Like Brady’s pumps, Pons’ pump was designed to “run dry” without blood flowing through the pump mechanism. For example, Pons explains that the vacuum port in the canister includes a “riser tube[]” so that “vacuum is drawn ... near the top of the canister” to “reduce[] the risk that clot or blood ... will flow into [] the vacuum port ... and interfere with operation of the vacuum console.” *Id.* at 4:39-50; 7:55-59. Pons also discloses that the vacuum port may include a

“filter element in a lumen thereof ... to still further reduce the risk of blood or clot entering the vacuum pump.” *Id.* at 4:51-54. Thus, Pons avoids blood flow into the pump mechanism. A person of ordinary skill in the art would have understood that running Pons’ pump while Garrison’s valve is closed would not damage the pump or any of the blood being aspirated by the pump. Rather, the pump would simply continue to build up vacuum in the canister, which would be applied to the aspiration catheter once Garrison’s valve is opened.

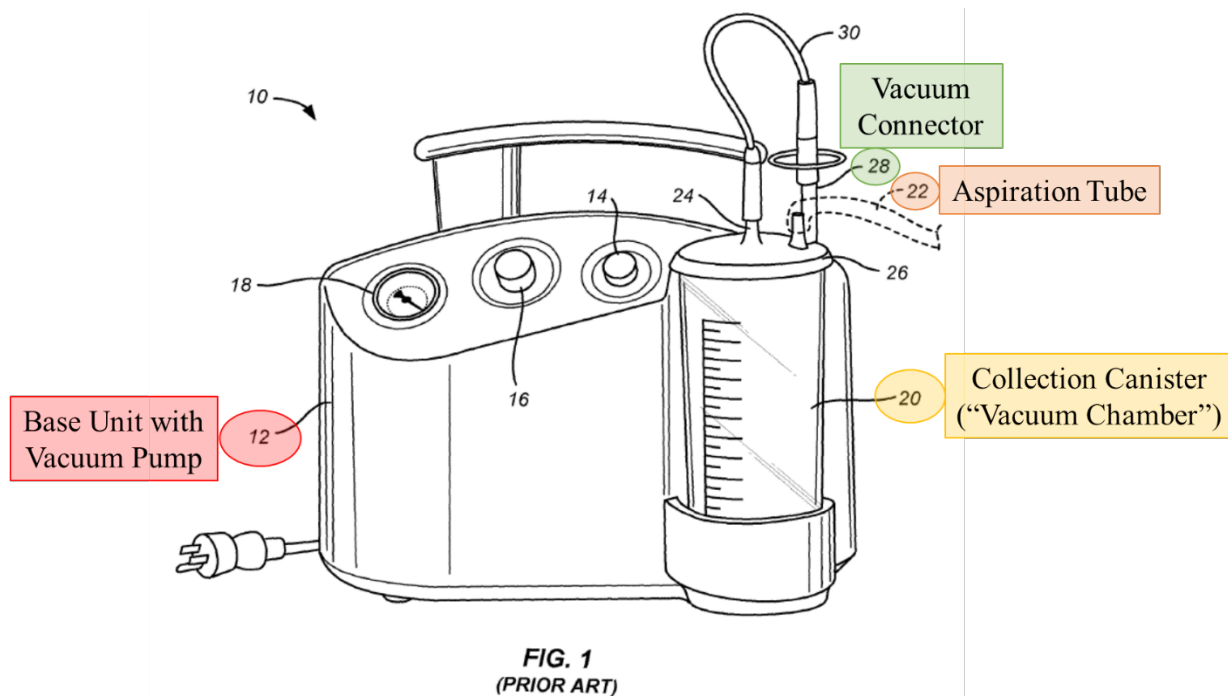
c. Penumbra Pump MAX

38. The Penumbra Pump MAX is another prior-art aspiration pump that was available prior to August 2018 and could have been safely used with Garrison’s valve to build up pressure:

Penumbra Pump



Ex. 1068 (Penumbra). As Pons explains, Penumbra has manufactured and sold thrombectomy systems and components since well before August 2018. *See* Ex. 1062 (Pons) at 2:49-52. Pons describes the prior art Penumbra mechanical thrombectomy system, which “is a fully-integrated system designed specifically for mechanical thrombectomy by aspiration.” *Id.* at 1:53-56. Pons explains that the Penumbra System used an electric aspiration pump known as the Pump MAX aspiration pump, which included a base unit 12 enclosing a vacuum pump, a collection canister 20 connected to the vacuum pump by vacuum connector 28, and an aspiration tube 22 secured to the collection canister:



Id. at 1:64-2:13, Fig. 1. Pons explains that “blood and clot are drawn into the collection canister by a partial vacuum which is provided by [the] vacuum

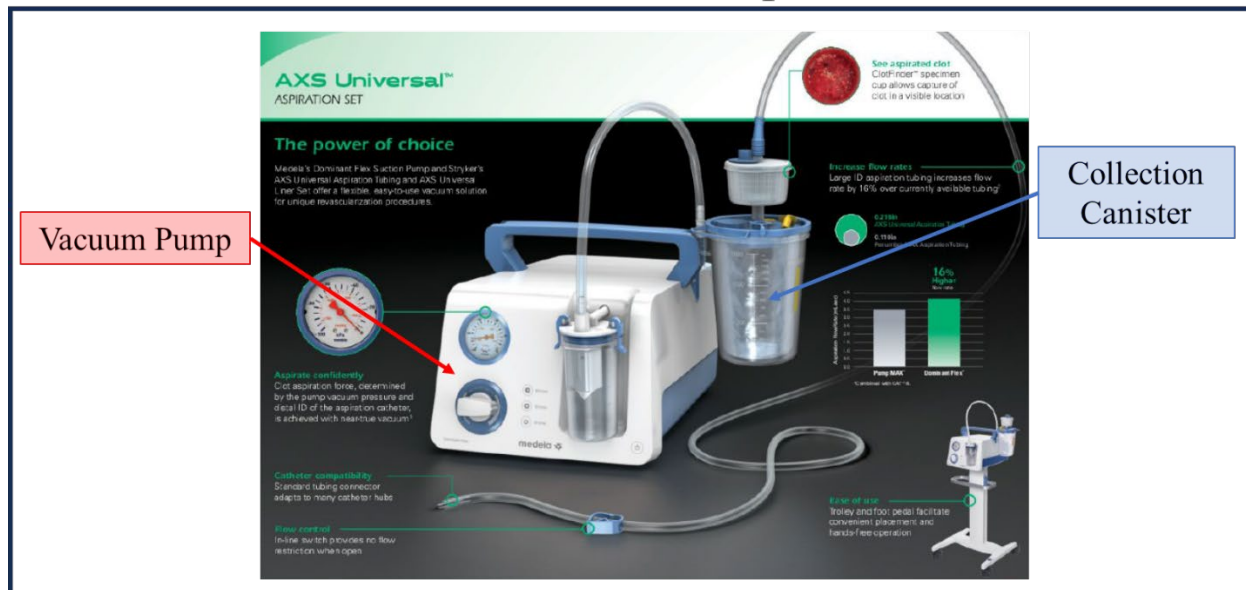
connector 28 on the base unit 12 which is connected to the vacuum pump.” *Id.* at 2:7-10.

39. A person of ordinary skill in the art would have understood that the Penumbra Pump MAX generated vacuum in the collection canister, which was then applied to the aspiration catheter, similar to the aspiration pumps in Brady and Pons. A person of ordinary skill in the art would have further understood that running the Penumbra Pump MAX while Garrison’s valve is closed would not damage the pump or any of the blood being aspirated by the pump. Rather, the pump would simply continue to build up vacuum in the canister, which would be applied to the aspiration catheter once the Garrison’s valve is opened.

d. Medela Dominant Flex Pump

40. The Medela Dominant Flex Pump is another prior-art aspiration pump available before August 2018 and could have been safely used with Garrison’s valve and method of building up pressure. Ex. 1039 (AXS Brochure). The pump generated vacuum in a collection canister via connection tubing:

Medela Pump



Id. A person of ordinary skill in the art would have understood that the Medela pump generated vacuum in the collection canister and did not require continuous blood flow through the pump mechanism like the cardiopulmonary bypass pumps. A person of ordinary skill in the art would have further understood that running the Medela Dominant Flex Pump while Garrison's valve is closed would not damage the pump or any of the blood being aspirated by the pump. Rather, the pump would simply continue to build up vacuum in the canister, which would be applied to the aspiration catheter once the Garrison's valve is opened.

3. A Person Of Ordinary Skill In The Art In Would Have Possessed The Knowledge To Select An Appropriate Aspiration Pump

41. As illustrated above, many prior-art pumps were specifically designed for aspiration thrombectomy procedures and would have been compatible with Garrison's method of building up pressure prior to releasing the

pressure to cause aspiration. *Supra* §II.A.2. A person of ordinary skill in the art in August 2018 would have possessed the skills and knowledge to select an appropriate pump from the available options to use with Garrison’s method and the aspiration systems in Garrison, Laub, and Aklog.

42. The ’910 patent reflects that a person of ordinary skill in the art would have known how to select an appropriate aspiration pump. The ’910 patent discloses closing a valve to build up pressure in the system and states that “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.” Ex. 1001 (’910 patent) at 7:33-41. Yet, every embodiment described in the ’910 patent incorporates a syringe, not a pump. *See id.* at 7:25-16:29. The ’910 patent does not discuss appropriate pumps or disclose any modifications that are required to use the method with an aspiration pump. The ’910 patent therefore presumes that a person of ordinary skill in the art would have known how to select a pump that was compatible with its methods, including the on-off valve.

43. The prior art also reflects that a person of ordinary skill in the art would have possessed the knowledge to select an appropriate pump. For example, Garrison broadly discloses that its aspiration source “may be an aspiration pump, a regular or locking syringe, a hand-held aspirator, hospital suction, or the like.”

Ex. 1006 (Garrison) at [0134]. Aklog also broadly discloses that its pump “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.” Ex. 1005 (Aklog) at 12:9-14. Laub also broadly discloses that its pump may be a “centrifugal pump,” “a rotary pump, peristaltic pump, roller pump, or other form of pump known in the art.” Ex. 1012 (Laub) at [0041]. None of these references are limited to a particular type of aspiration pump, and each of them presumes that a person of ordinary skill in the art would have possessed the knowledge to select an appropriate pump.

44. In addition, a person of ordinary skill in the art would have been particularly motivated to use the types of aspiration pumps disclosed in Brady, Pons, the Penumbra Pump MAX, and the Medela Dominant Flex pump for an aspiration system like those in Garrison, Laub, and Aklog because those pumps were known to be useful in aspiration thrombectomy procedures. For example, Brady discloses that its vacuum pump is “particularly suited to removing clot from cerebral arteries in patients suffering acute ischemic stroke (AIS), from coronary native or graft vessels in patients suffering from myocardial infarction (MI), and from pulmonary arteries in patients suffering from pulmonary embolism (PE) and from other peripheral arterial and venous vessels in which clot is causing an

occlusion.” Ex. 1020 (Brady) at 1:13-17. Pons discloses that its “vacuum systems can find use with any thrombectomy, embolectomy, atherectomy, or other catheter or probe system where blood and clot are withdrawn wholly or partially by application of a vacuum to the proximal end of any reperfusion catheter, aspiration catheter or probe for the purpose of clot extraction.” Ex. 1062 (Pons) at 2:65-3:4. The Penumbra Pump MAX and Medela Dominant Flex pumps were commercially available and used in prior-art aspiration systems. *Id.* at 1:53-56; Ex. 1039 (AXS Brochure).

45. For at least the above reasons, it is my opinion that the cardiopulmonary bypass pumps identified by Patent Owner and Mr. Brown would not have dissuaded a person of ordinary skill in the art from using Garrison’s valve to build up pressure with an aspiration pump, including the aspiration systems in Garrison’s Figure 34, Laub, and Aklog.

B. Garrison’s Aspiration Method Is Compatible With Blood Return

46. Patent Owner and Mr. Brown also argue that Garrison’s method of building up vacuum pressure while the valve is closed is incompatible with reinfusing the patient’s blood after it has been aspirated (i.e., “blood return”). Ex. 2008 (Brown Supp. Decl.) at ¶¶98-114. I disagree.

1. Prior-Art Aspiration Pumps Could Be Used With Blood Return

47. Patent Owner alleges that cardiopulmonary bypass pumps would not be appropriate for blood return for many of the same reasons I addressed in Section II.A above. *See* Ex. 2008 (Brown Supp. Decl.) at ¶¶107-108. I disagree with those arguments for the reasons I explained in that section. *Supra* §II.A.

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

2. Syringes And Receptacles Can Be Used For Blood Return

49. Patent Owner and Mr. Brown also argues that Garrison’s rapid aspiration method is incompatible with blood return because the blood may be aspirated into a receptacle or a syringe, where it remains “static” and “exposed to air” such that it could not be reinfused into the patient. Ex. 2008 (Brown Supp. Decl.) at ¶105. I do not believe this argument is supported by the evidence for several reasons.

50. First, Mr. Brown bases his argument on the following statement from Garrison:

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.

Ex. 1006 (Garrison) at [0135]. However, even this passage of Garrison recognizes that “it is possible to return blood from the external reservoir to the patient.” *Id.* Thus, while this passage does refer to risks of thrombus formation if the blood is exposed to air or static “for a period of time,” a person of ordinary skill in the art would not have interpreted this portion of Garrison to mean that blood aspirated into a syringe or receptacle is *always* unsuitable for reinfusion.

51. Second, Mr. Brown’s argument is directly contradicted by the ’910 patent. The ’910 patent discloses several exemplary systems and methods for reinfusing a patient’s aspirated blood, all of which involve aspirating the blood into a syringe or canister before reinfusing the blood back into the patient. Ex. 1001 (’910 patent) at 30:61-35:7. For example, the ’910 patent discloses that the pressure source in Figure 19 can include a syringe 460 coupled to a canister 1940 with a filter 1942 which separates the aspirated blood from the clot material:

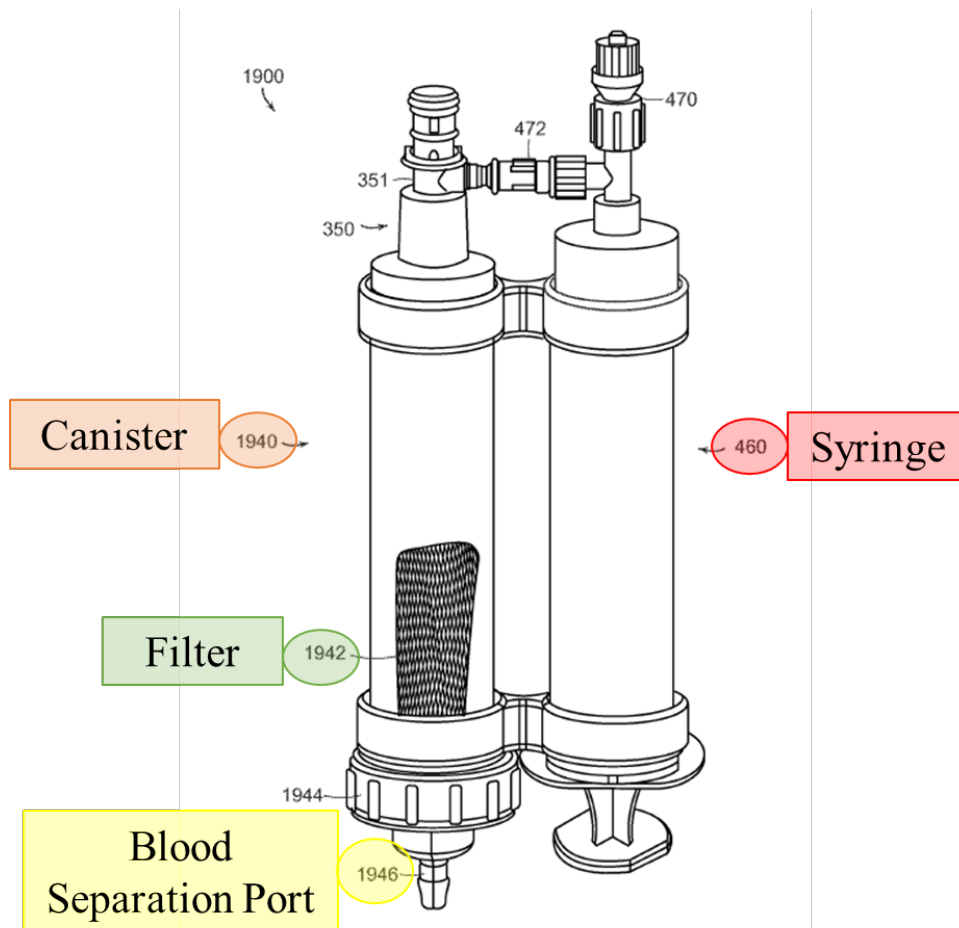
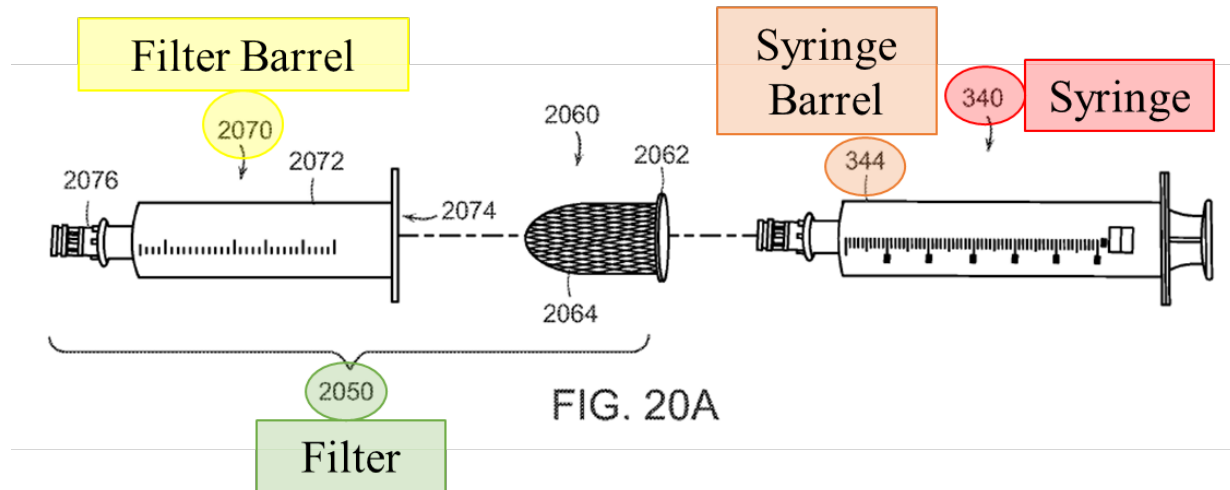


FIG. 19

Id. at 31:9-50, Fig. 19. The '910 patent discloses that “[i]n operation, when blood and clot material are aspirated into the canister 1940 (e.g., via any of the methods described in detail above), the filter 1942 separates the blood from the clot material within the canister 1940” and then “a syringe (not shown) or other device can be fluidly coupled to the blood separation port 1946 and used to draw the blood through the filter 1942 and out of the canister 1940” so that “[t]he filtered blood can then be reintroduced to the patient.” *Id.* at 31:32-43. In another example, illustrated in Figures 20A-E, the '910 patent discloses a filter 2050

placed around the tip of the syringe 340 to inhibit clot material from entering the syringe:



Id. at 31:51-33:5, Fig 20A. The '910 patent discloses that “aspirated blood is collected in the barrel 344 of the syringe 340 while the aspirated clot material is collected in the barrel 2072 of the barrel portion 2070 of the filter device 2050.”

Id. at 32:39-42. The '910 patent further discloses that after the blood is collected in the syringe barrel, “the syringe 340 can be decoupled from the filter device 2050 and directly coupled to the connector 128,” and the blood within the syringe barrel may be reinfused into the patient. *Id.* at 32:44-33:6.

52. Third, Mr. Brown’s argument is also contradicted by the testimony of PO’s other expert, Dr. Morris. Dr. Morris testified that he frequently reinfuses blood into patients that is aspirated into a syringe. Ex. 1065 (Morris Dep. Tr.) at 94:10-98:20. Specifically, Dr. Morris testified that Inari’s FlowTrievers system

uses a syringe as its aspiration source, and he further testified that he always reinfuses the patient's aspirated blood when using the FlowTrieve system. *Id.*

53. Mr. Brown's argument is also inconsistent with my own experience. Prior to 2018, I observed many intravascular medical procedures in which physicians reinfused a patient's blood that had been collected in a syringe. For example, during procedures with the MitraClip device that I developed, the operating physicians would reinfuse the patient's blood. After inserting the Steerable Guide Catheter, the physicians would aspirate blood out of the catheter via a syringe to assure that no air was inside, and they would then reinfuse that blood by injecting it back into the patient via the Guide Catheter.

54. Accordingly, a person of ordinary skill in the art would not have believed that blood aspirated into a syringe or receptacle is unsuitable for reinfusion as Mr. Brown argues.

3. Building Up Pressure With Garrison's Valve Is Compatible With Blood Return

55. Patent Owner and Mr. Brown also argue that Garrison's valve would cause blood to remain "static" in Laub's or Aklog's systems while the valve is closed and vacuum is built-up in the system, which would also make the aspirated blood unsuitable for reinfusion. Ex. 2008 (Brown Supp. Decl.) at ¶105. I disagree.

56. Garrison discloses that the valve is temporarily closed to build up aspiration in the system prior to applying the built-up aspiration once “the tip of the aspiration device ... is near or at the face of the occlusion.” Ex. 1006 (Garrison) at [0134]. A person of ordinary skill in the art would have recognized that this would be a relatively short, temporary step in the procedure. Consequently, to the extent that blood entered the portion of Garrison’s, Laub’s, or Aklog’s systems that are proximal to the valve during this temporary step, a person of ordinary skill in the art would not have expected that any substantial thrombus formation would occur in that blood during this short period.

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

III. CONCLUSION

58. For the above reasons and the reasons I explained in my previous Declaration (Ex. 1003), it is my opinion that challenged claims 1-8, 11-15, and

18-20 of the '910 patent are unpatentable because they are anticipated or obvious in view of the prior art.

59. I declare that the foregoing is true and correct, and further that the foregoing 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.

Executed on June 2, 2026 in San Francisco, CA.

troy thornton

Troy Thornton