

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. IPR2026-00169
U.S. Patent No. 12,156,669

DECLARATION OF BRIAN BROWN

TABLE OF CONTENTS

I.	INTRODUCTION	1
II.	BACKGROUND AND QUALIFICATIONS	4
III.	BASES OF MY OPINION	8
A.	Materials Considered	8
B.	Relevant Legal Principles	8
IV.	SUMMARY OF OPINIONS	11
V.	THE '669 PATENT	11
A.	Overview	11
B.	Prosecution History	23
C.	Person of Ordinary Skill in the Art (POSITA)	24
D.	Claim Construction	25
VI.	DEPENDENT CLAIMS 4 AND 18: GARRISON DOES NOT ANTICIPATE OR RENDER CLAIMS 4 OR 18 OBVIOUS, EITHER ALONE OR IN COMBINATION WITH GOFF	26
VII.	DEPENDENT CLAIMS 8 AND 22: GARRISON, ALONE OR IN COMBINATION WITH GOFF, DOES NOT RENDER CLAIMS 8 OR 22 OBVIOUS	32
A.	Garrison Alone (or in View of Trerotola) Does Not Render Obvious Claims 8 or 22	33
B.	Garrison in Combination with Goff Does Not Render Obvious Claims 8 or 22	41
VIII.	DEPENDENT CLAIMS 10 AND 24: GARRISON DOES NOT ANTICIPATE OR RENDER CLAIMS 10 OR 24 OBVIOUS, EITHER ALONE OR IN COMBINATION WITH GOFF	42
A.	Garrison Alone Does Not Anticipate or Render Obvious Claims 10 or 24	44

B. Garrison in Combination with Goff Does Not Render Obvious
Claims 10 or 24 48

IX. SECONDARY CONSIDERATIONS 50

X. CONCLUSION.....50

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

I. INTRODUCTION

1. My name is Brian Brown. I have been retained by counsel for Patent Owner as an independent expert consultant in this *inter partes* review (IPR) proceeding, IPR2026-00169, concerning U.S. Patent No. 12,156,669 (“the ’669 Patent”; EX1001), pending before the U.S. Patent and Trademark Office’s Patent Trial and Appeal Board (“Board”).
2. I understand that Imperative Care, Inc. (“Petitioner”) has filed a petition for *inter partes* review asserting that Claims 1-5, 8, 10-12, 14-19, 22, 24-28, and 30 of the ’669 Patent are unpatentable. More specifically, I understand that Petitioner has asserted the following grounds of unpatentability:

Ground 1: Claims 1-5, 10-11, 14-19, 24-25, and 30 of the ’669 Patent are unpatentable under 35 U.S.C. § 102 as anticipated by U.S. Patent Application Publication No. 2015/0173782 to Garrison et al. (EX1006; “Garrison”);

Ground 2: Claims 1-5, 8, 10-11, 14-19, 22, 24-25, and 30 of the ’669 Patent are unpatentable under 35 U.S.C. § 103 as obvious over Garrison;

Ground 3: Claims 1-5, 8, 10-11, 14-19, 22, 24-25, and 30 of the ’669 Patent are unpatentable under 35 U.S.C. § 103 as obvious

over Garrison in combination with International Patent Application Publication No. WO2006/124307 to Goff et al. (EX1005; “Goff”);

Ground 4: Claims 14 and 30 of the ’669 Patent are unpatentable under 35 U.S.C. § 103 as obvious over Garrison in combination with International Patent Application Publication No. WO2018/019829 to Brady et al. (EX1010; “Brady”);

Ground 5: Claims 14 and 30 of the ’669 Patent are unpatentable under 35 U.S.C. § 103 as obvious over Garrison in combination with Goff and Brady;

Ground 6: Claims 14 and 30 of the ’669 Patent are unpatentable under 35 U.S.C. § 103 as obvious over Garrison in combination with U.S. Patent No. 11,432,835 to Pons et al. (EX1011; “Pons”);

Ground 7: Claims 14 and 30 of the ’669 Patent are unpatentable under 35 U.S.C. § 103 as obvious over Garrison in combination with Goff and Pons;

Ground 8: Claims 12 and 26-28 of the ’669 Patent are unpatentable under 35 U.S.C. § 103 as obvious over Garrison in combination with U.S. Patent Application Publication No. 2003/0225379 to Schaffer et al. (EX1007; “Schaffer”);

Ground 9: Claims 12 and 26-28 of the '669 Patent are unpatentable under 35 U.S.C. § 103 as obvious over Garrison in combination with Goff and Schaffer;

Ground 10: Claims 12 and 26-28 of the '669 Patent are unpatentable under 35 U.S.C. § 103 as obvious over Garrison in combination with Schaffer and U.S. Patent Application Publication No. 2003/0116731 to Hartley (EX1008; "Hartley"); and

Ground 11: Claims 12 and 26-28 of the '669 Patent are unpatentable under 35 U.S.C. § 103 as obvious over Garrison in combination with Goff, Schaffer, and Hartley.

Petition, pg. 20. I have been asked by counsel for Patent Owner to opine on the patentability of certain claims of the '669 Patent, specifically with respect to Claims 4, 8, 10, 18, 22, and 24. I have not formed opinions regarding the patentability of the other challenged claims, for which I provide no opinion. I understand that Patent Owner may provide additional expert testimony and argument regarding other claims of the '669 Patent for which I have not provided an opinion.

3. Along with my years of education, research, and experience, my opinions are based on my review of the 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 the 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, materials 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 more than 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 with directing 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 six 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 the College of Fellows of the 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 60 issued U.S. medical device patents covering a wide variety of technologies, including two aspiration thrombectomy patents and several others directed to 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, and the like) 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, and extrinsic evidence must not be used to contradict intrinsic evidence.
22. I have been informed that Petitioner bears the burden of proving unpatentability by a preponderance of the evidence. I have been told that this means that Petitioner must prove that it is more likely than not that the claims of the '669 Patent are anticipated by Garrison, obvious over Garrison alone, or obvious over Garrison in combination with one or more of Goff, Brady, Pons, 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 '669 Patent, January 26, 2018. Petitioner also applies January 26, 2018, as the priority date for the '669 Patent. Petition, pg. 16.

24. I understand that for a patent claim to be anticipated, each claim limitation must be present in a single piece of prior art. It is my understanding from counsel that a prior art reference anticipates a claimed invention if the prior art reference discloses each of the claimed limitations of the invention either expressly or inherently.
25. I understand that a claimed invention is obvious 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.
26. I understand there are four fact-based inquiries involved in determining patent obviousness. These include: (1) the scope and content of the prior art; (2) the differences between the claimed invention and the prior art; (3) the level of ordinary skill in the art; and (4) objective indicia of non-obviousness. I have been informed that examples of objective indicia include unexpected results, commercial success of the invention, whether the invention satisfied a long-felt need in the industry, failure of others to find a solution to the problem at hand, commercial acquiescence via licensing, professional approval, and copying and praise by infringers.

27. I understand that even if all limitations of a claimed invention are disclosed by the prior art combination, the patent challenger must demonstrate a reason to combine the known elements in the fashion of the patent claim at issue and that a person of ordinary skill in the art would have reasonable expectation of success in pursuing that combination.
28. I understand that a prior art reference teaches away from a proposed modification when a person of ordinary skill in the art would be discouraged from following the path set out in the reference or would be led in a direction divergent from the path followed by and claimed in the patent.

IV. SUMMARY OF OPINIONS

29. For the reasons I discuss below, I believe that Claims 4, 8, 10, 18, 22, and 24 of the '669 Patent are not anticipated by Garrison, rendered obvious by Garrison alone, or rendered obvious by any combination of the prior art asserted in the Petition against those claims. For example, Claims 4, 8, 10, 18, 22, and 24 are not anticipated by Garrison, rendered obvious by Garrison, or rendered obvious by Garrison in combination with Goff.

V. THE '669 PATENT

A. Overview

30. Thrombi and emboli are blood clots that cause blockages (also called occlusions) of blood vessels or arteries. Blocking blood flow results in oxygen deprivation of tissues and can result 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 (VTE) and the related health conditions, e.g., deep vein thrombosis (DVT) and pulmonary embolism (PE), are a huge problem, affecting approximately 900,000 people in the United States every year. *See, e.g.,* (<https://www.cdc.gov/blood-clots/data-research/facts-stats/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 id.*

31. A blood clot is essentially a living polymer, comprising a matrix of intertwined and cross-linked strands within which are situated red and white blood cells, platelets and numerous other proteins and components. The mechanical properties of a clot are influenced by the relative percentages of other materials and red blood cells, and clots that are highly fibrous (and highly organized) and have lower red blood cell content tend to be firmer and more cohesive than clots with higher red-blood-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.

32. Clots that are less organized and that have high red-cell content have been found to be less cohesive, more friable—meaning more easily crumbled or broken up—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.
33. DVT is a type of blood clot (thrombus) that typically forms in the deep veins of a limb, such as the leg. EX1001, 1:53-55. 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 PE may result if such embolus lodges in an artery or branch thereof of the lungs. *Id.* at 1:64-2:7. Because of their location and how they are formed, DVT and PE clots tend to be larger, older, more highly organized, and more fibrous than arterial clots, such as clots in the cerebral vasculature that cause strokes.
34. Treatment of PE and DVT has long been a challenge, with the existing methods of treatment failing to significantly improve patient mortality rates over

the last five decades. For example, PE and DVT have traditionally been treated with drugs, e.g., anticoagulants (also called blood thinners), streptokinase (also called SK manufactured by pharmaceutical makers including GSK and BBT Biotech GmbH), urokinase (also called Abbokinase or Kinlytic, manufactured by companies including Abbott Laboratories), or other drugs in a class of agents called “thrombolytics” (or just “lytics”) that break down and dissolve the clot over hours or days, but do not physically remove the clot material from the body. EX1001, 2:32-37. Doctors can treat patients with lytics by introducing the drugs through an IV line or, preferably in 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) is the most common and recommended treatment for PE and DVT in guidelines issued by medical organizations such as the American College of Chest Physicians, European Society of Cardiology, American Heart Association, and Society of Interventional Radiology.

35. Lytics have many disadvantages. First, they can take many hours to work. EX1001, 2:34-35. 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 2:36-37. 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 an increased risk of bleeding (e.g., active bleeding, recent brain bleed/hemorrhage, recent brain or spine surgery, severe hypertension, severe kidney disease, and the like).

36. Anticoagulant drugs also have many disadvantages. Their side effects include bleeding risk and loss of bone density. Anticoagulants also are not effective against existing clots, and instead primarily prevent clots from forming or continuing to form (to some degree).
37. The '669 Patent discloses “devices and methods for the intravascular treatment of emboli and/or thrombi within a blood vessel of a human patient.” EX1001, 1:30-32. In particular, the '669 Patent discloses methods and systems for removing clot material—such as PE or DVT—from the vasculature of a patient. EX1001, 1:32-36, 1:52–2:61, 4:4-6, 5:1-6.
38. Independent Claims 1 and 15 of the '669 Patent, the limitations of which are incorporated into Claims 4, 8, and 10, and into Claims 18, 22, and 24, respectively, are directed to aspiration systems (e.g., systems for intravascularly aspirating clot material from the vasculature of a human patient). Claim 1 recites:

1. An aspiration system, comprising:

a vacuum source;

connection tubing fluidically coupled to the vacuum source;

a catheter fluidically coupled to the vacuum source;

a filter chamber fluidically coupled to the connection tubing at a

location apart from the vacuum source, wherein the filter

chamber comprises a housing and a filter within the hous-

ing, and wherein the housing includes—

a port configured to be fluidically coupled to the catheter;

and

a fluid connector configured to be fluidically coupled to

the connection tubing; and

wherein the filter is in the housing along a first fluid path,

wherein the first fluid path fluidically couples the

port and the fluid connector, and wherein the cathe-

ter is fluidically coupled to the vacuum source via

the filter chamber along the first fluid path;

a flow controller fluidically coupling the filter chamber to the

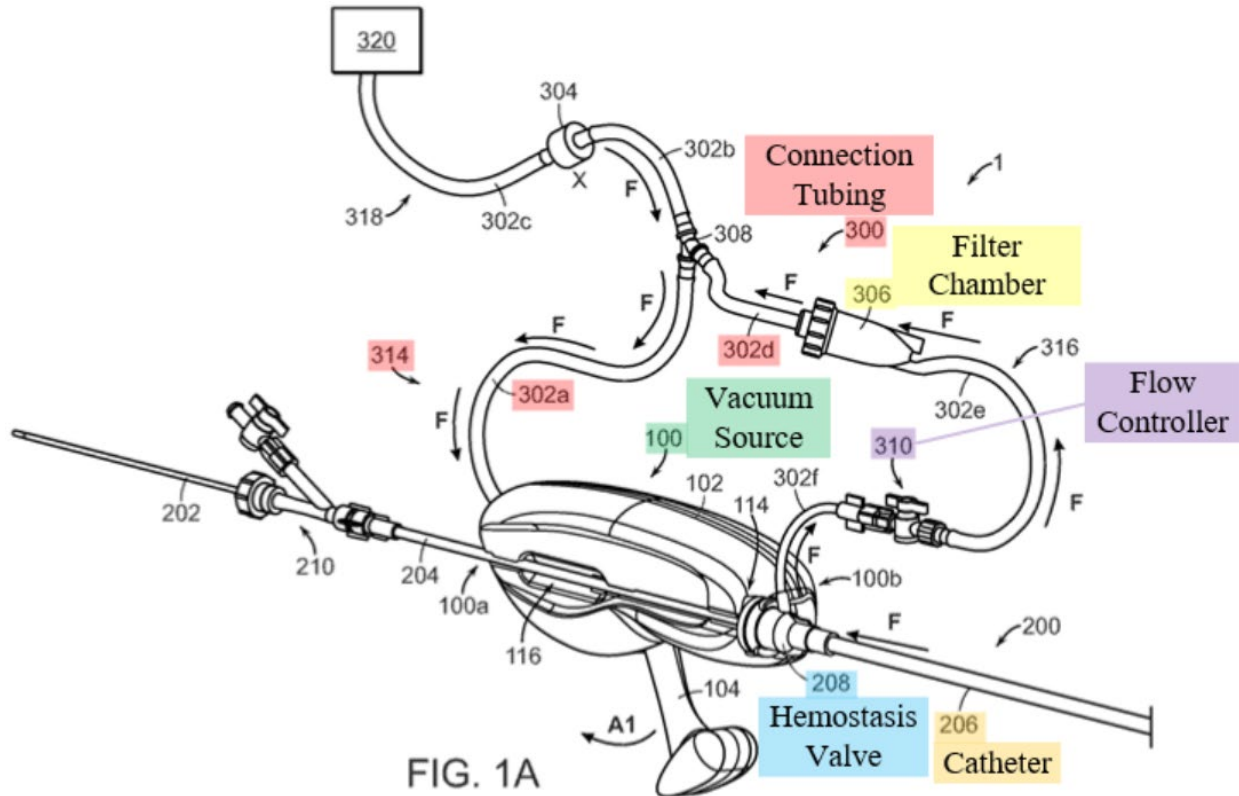
catheter, wherein the flow controller is along the first fluid

path between the filter chamber and the catheter; and

a hemostasis valve fluidically coupled to the catheter along a second fluid path at least partially different than the first fluid path, wherein the hemostasis valve is configured to maintain hemostasis by inhibiting proximal fluid flow along the second fluid path when an interventional device is inserted through the hemostasis valve and the catheter.

EX1001, cl. 1. Independent Claim 15 includes many similar features to independent Claim 1. It omits “connection tubing” and instead recites that the catheter is fluidically coupled to the vacuum source through a first fluid path and that the filter chamber is along that path. EX1001, cl. 15. Claim 15 also requires a housing with a first port configured to be fluidically coupled to the catheter and a second port configured to be fluidically coupled to the vacuum source. *Id.*

39. Figures 1A and 1B of the '669 Patent illustrate an example aspiration system consistent with Claims 1 and 15. As annotated below, the system 1 includes a device 100 having a vacuum source, a catheter 206, a filter chamber 306, a flow controller 310, a hemostasis valve 208, and connection tubing 300 having in part a first portion 314 comprising tubing sections 302a and 302d that fluidically couple the filter chamber 306 and the vacuum source 100:



EX1001, 4:42-64, 6:1-7:28. The '669 Patent discloses that the vacuum source can be a syringe (*id.* at 6:4-5), but it also incorporates by reference U.S. Patent No. 9,526,864 (EX1044) which discloses a broader range of vacuum sources, including that the vacuum source “can be any suitable pressure-generating device, such as an electrical pump or other mechanical pump” like “an electrical pump controlled by an on/off switch” (EX1044, 5:19-24). The catheter 206 is fluidically coupled to the vacuum source 100 via the filter chamber 306 “to enable material (e.g., blood and clot material) aspirated from the catheter system 200 to flow into the tubing system 300” with the filter chamber 306 capturing the clot material while permitting blood to pass therethrough.

- EX1001, 4:52-56, 9:34-37. The flow controller 310 “can be a stopcock or a clamp that is externally operated to regulate the flow of liquid through” the tubing system 300 between the filter chamber 306 and the catheter 206. *Id.* 7:19-23. The filter chamber 306 is fluidically coupled to the connection tubing 300 at a location apart from the vacuum source 100 by, for example, the separation of tubing sections 302a and 302d of the first portion 314 of the connection tubing 300.
40. Figures 3A-3C of the '669 Patent provide more focused illustrations of the filter chamber 306. *Id.* at 8:62-64. The filter chamber 306 includes a housing 322, a filter 321 positioned within the housing 322 (e.g., a chamber 323 thereof), a port 324 configured to be fluidically coupled (e.g., distally, downstream) to the catheter 206, and a fluid connector 332 configured to be fluidically coupled (e.g., proximally, upstream) to the connection tubing 300:

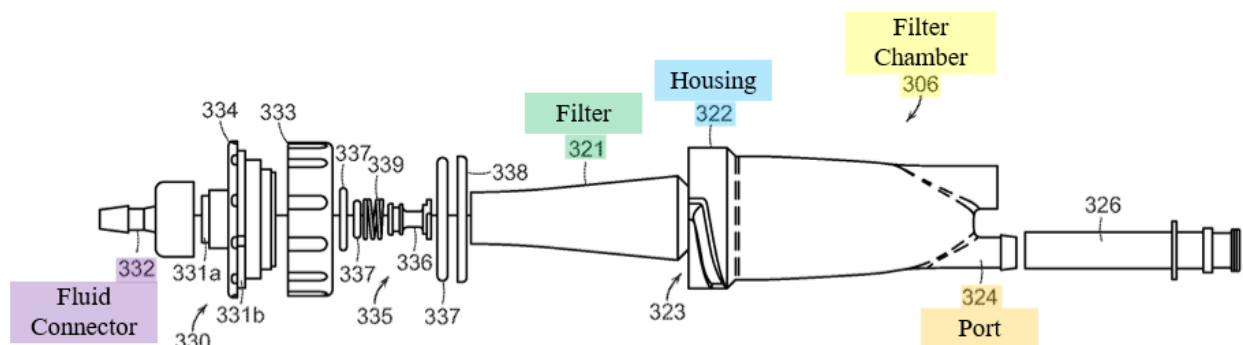


FIG. 3A

Id. at 8:54-9:3, 9:11-13. The filter 321 is in the housing along a first fluid path that fluidically couples the port 324 and the fluid connector 332:

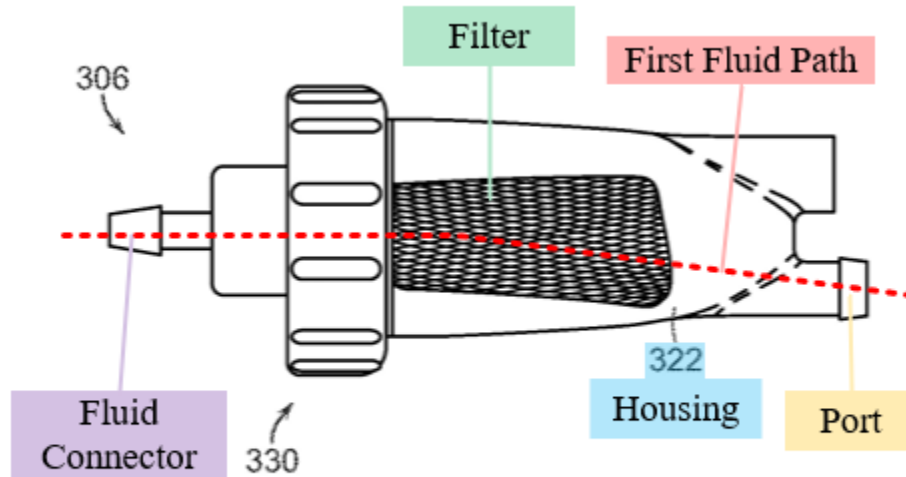
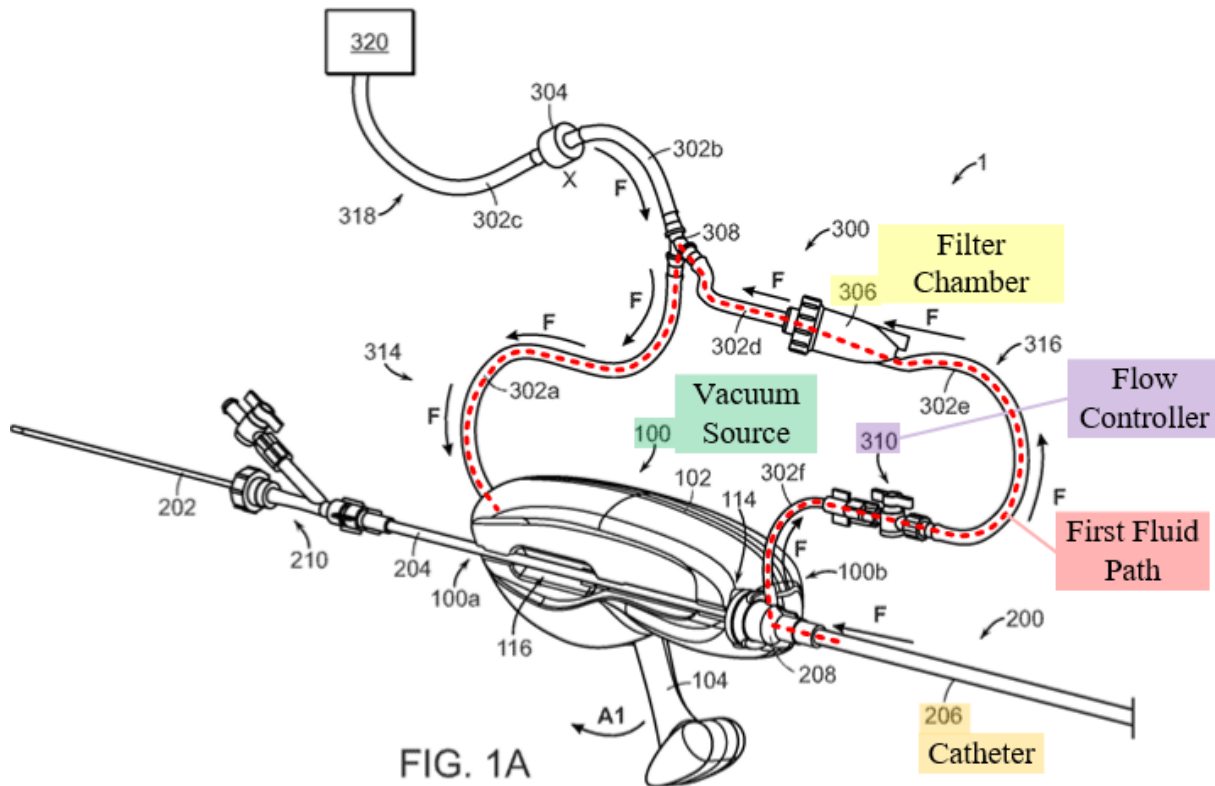


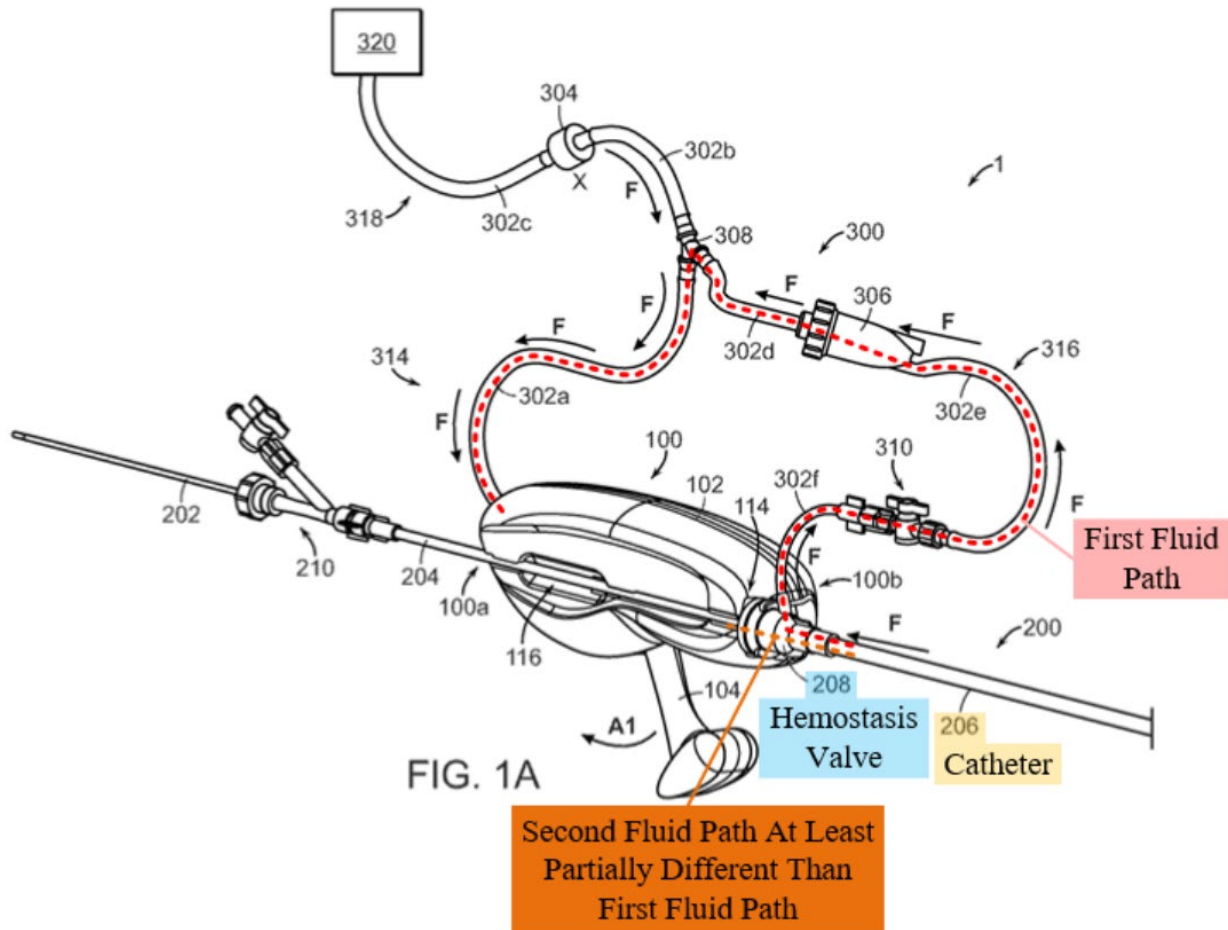
FIG. 3B

Id. at 9:31-37.

41. As shown in Figures 1A and 1B, the catheter 206 is fluidically coupled in series to the vacuum source along the first fluid path, and the flow controller 310 is along that first fluid path running between the catheter 206 and then the filter chamber 306:



More specifically, the first fluid path extends from catheter 206 through the flow controller 310 and the filter chamber 306 to the vacuum source 100. Tubing section 302f provides a side-port connection. EX1001, 10:9-13, 17:53-56. In contrast, the hemostasis valve 208 is coupled to the proximal end of the catheter 206 such that the hemostasis valve 208 is fluidically coupled to the catheter 206 along a second fluid path at least partially different than the first fluid path:



Id. at 6:17-22, 10:4-6, 17:48-52.

42. The hemostasis valve 208 is configured to maintain hemostasis by inhibiting proximal fluid flow along that second fluid path when an interventional device (e.g., the interventional device ID shown in Figures 2A-2F) is inserted through the hemostasis valve 208 and the catheter 206. *Id.* at FIGS. 13A-13B, 17:38-18:59. In particular, the '669 Patent incorporates by reference and attaches as an appendix U.S. Provisional Patent Application No. 62/554,931 (EX1019), which further supplements the description of a garrote-type hemostasis valve illustrated in Figures 13A-13B of the '669 Patent. EX1001, 17:41-47.

B. Prosecution History

43. I have reviewed the prosecution history of the '669 Patent, including the only Office Action mailed October 25, 2023 (EX1002, pgs. 316-321), the Examiner Interview Summary and the Applicant's interview agenda regarding the November 9, 2023 telephone interview (*id.* at pgs. 312-315), the Amendments and Response to the Office Action filed November 27, 2023 (*id.* at pgs. 298-307), and the Notice of Allowance mailed December 29, 2023 (*id.* at pgs. 270-277). In the sole Office Action, the Examiner allowed then-pending claims 1-9 and 11-22 (including independent claims 1 and 12 that became independent Claims 1 and 15 of the '669 Patent challenged here), but rejected dependent claim 10 as indefinite under 35 U.S.C. § 112(b). *Id.* at pgs. 318-320. The Examiner found claims 1-9 and 11-22 allowable because "no art of record alone or in combination teach[es] an aspiration system that includes the combination of recited limitations." *Id.* at pg. 320.
44. In response to the Office Action, Patent Owner made clarifying amendments to claims 1, 4, 10-12, 15, and 20-22, and added new claims 23-30 after discussing the claims with the Examiner in the November 9, 2023, telephone interview. *Id.* at pgs. 298-307. In the Notice of Allowance, the Examiner allowed claims 1-30 and generally repeated their statements for allowance from the October 25 Office Action. *Id.* at pgs. 275-276.

C. Person of Ordinary Skill in the Art (POSITA)

45. 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. 16. 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 '669 Patent according to both standards.

46. In this field, a POSITA requires some experience in the thrombectomy space, which is the field of invention of the '669 Patent. EX1001, 1:30-32 (“The present technology relates generally to devices and methods for the intravascular treatment of emboli and/or thrombi within a blood vessel of a human patient.”). Petitioner’s proposed definition does not require any thrombectomy experience. That distinction is meaningful with respect to the Claims of the '669 Patent at least because an understanding of what type of clot (e.g., neurovascular, pulmonary embolism, etc.) a device is designed to treat impacts the design considerations.

D. Claim Construction

47. Petitioner proposes a construction for the term “filament” recited in dependent Claims 12 and 26-28. Petition, pgs. 16-19. Because my analysis here focuses only on the patentability of dependent Claims 4, 8, 10, 18, 22, and 24, I have not provided a construction of “filament.”
48. Additionally, Petitioner notes various different constructions (other than “filament”) proposed by the parties in the co-pending litigation. *Id.* at pg. 19. I have provided constructions for those terms in connection with co-pending litigation and, accordingly, agree with Patent Owner’s proposed constructions

for those terms. Nevertheless, the differences in the constructions do not affect my analysis here so I have not provided any additional support for those constructions in this Declaration.

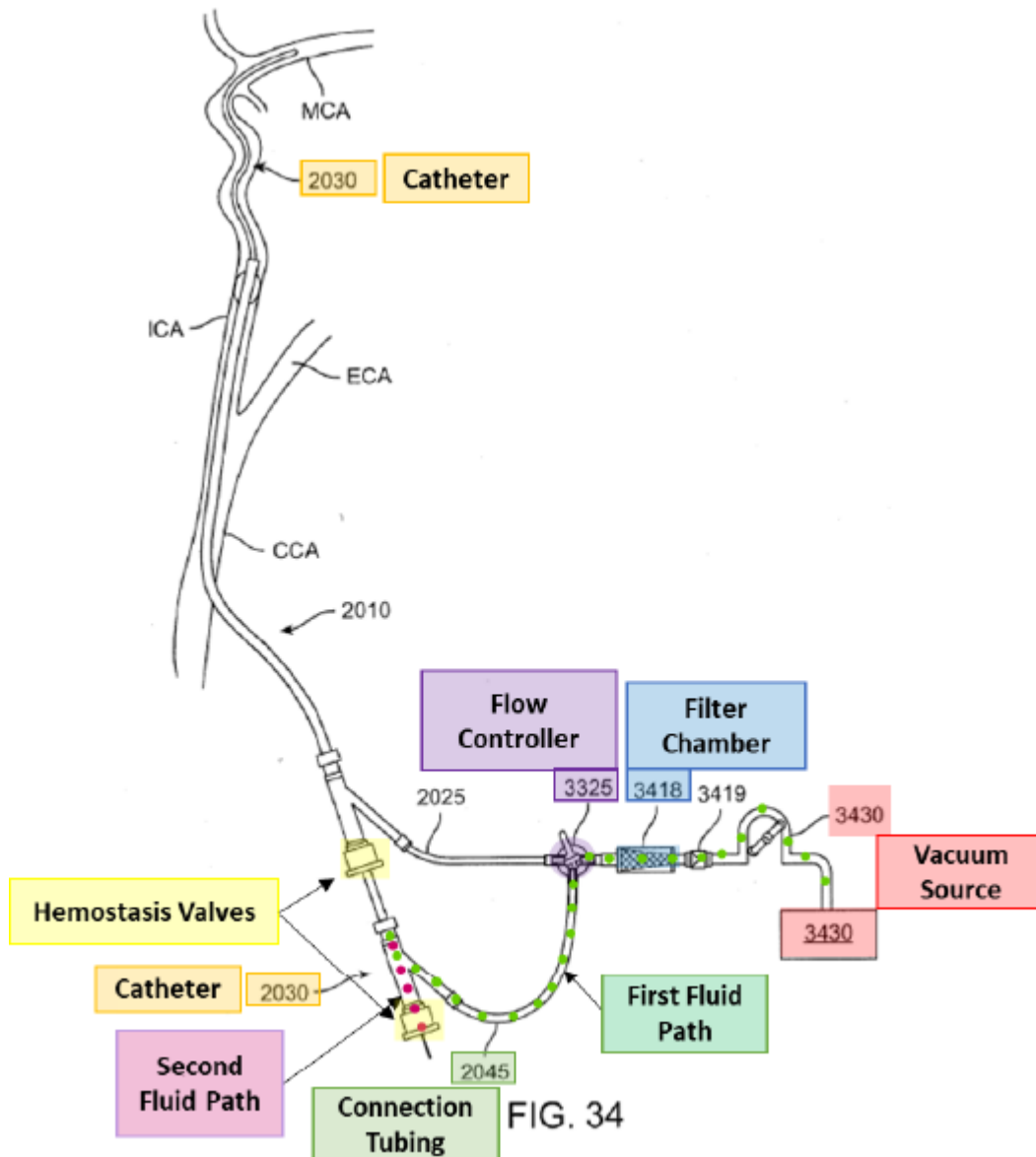
VI. DEPENDENT CLAIMS 4 AND 18: GARRISON DOES NOT ANTICIPATE OR RENDER CLAIMS 4 OR 18 OBVIOUS, EITHER ALONE OR IN COMBINATION WITH GOFF

49. Petitioner and its expert, Mr. Thornton, contend that Garrison anticipates or renders dependent Claims 4 and 18 obvious. Petition, pgs. 44, 62. Petitioner further contends that Garrison in combination with Goff renders those claims obvious. *Id.* at pg. 69. I disagree for the reasons I discuss in further detail in this section.
50. As I explained above, I understand that for a patent claim to be anticipated, each claim limitation must be present in a single piece of prior art. It is my understanding from counsel that a prior art reference can anticipate a claimed invention if the prior art reference discloses each of the claimed limitations of the invention either expressly or inherently in the same configuration or arrangement as claimed.
51. As I also explained above, I understand that a patent claim is obvious 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. Even if all limitations of a claimed invention are disclosed by the prior art combination, Petitioner must demonstrate a 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 a 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.

52. Here, independent Claim 1 requires “a catheter fluidically coupled to [a] vacuum source,” a “filter chamber” having a “housing” with a filter “in the housing along a first fluid path,” and “wherein the catheter is fluidically coupled to the vacuum source via the filter chamber along the first fluid path.” EX1001, cl. 1. Independent Claim 15 similarly requires “a catheter fluidically coupled to [a] vacuum source via a first fluid path” and “a filter chamber along the first fluid path.” *Id.* at cl. 15. Dependent Claims 4 and 18 narrow independent Claims 1 and 15, respectively, by further requiring that the “**catheter is fluidically connected *in serial* to the filter chamber along the first fluid path.**” *Id.* at cls. 4, 18.

53. As shown in Petitioner's annotations to Figure 34 of Garrison (reproduced below), Petitioner alleges that "Garrison's aspiration catheter 2030 is fluidically connected in serial to the filter 3418 (i.e., filter chamber) along the first fluid path":



Petition, pg. 45; EX1003, ¶ 117; EX1006, FIG. 34.

54. However, the catheter 2030 in Garrison is fluidically connected to the filter 3418 *together with* the arterial access device 2010 via the valve 3325. In particular, the “valve 3325 controls which device is connected to the aspiration source 3430” and “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]. Accordingly, Garrison’s catheter 2030 and arterial access device 2010 are connected to the filter 3418 via a Y-connection:

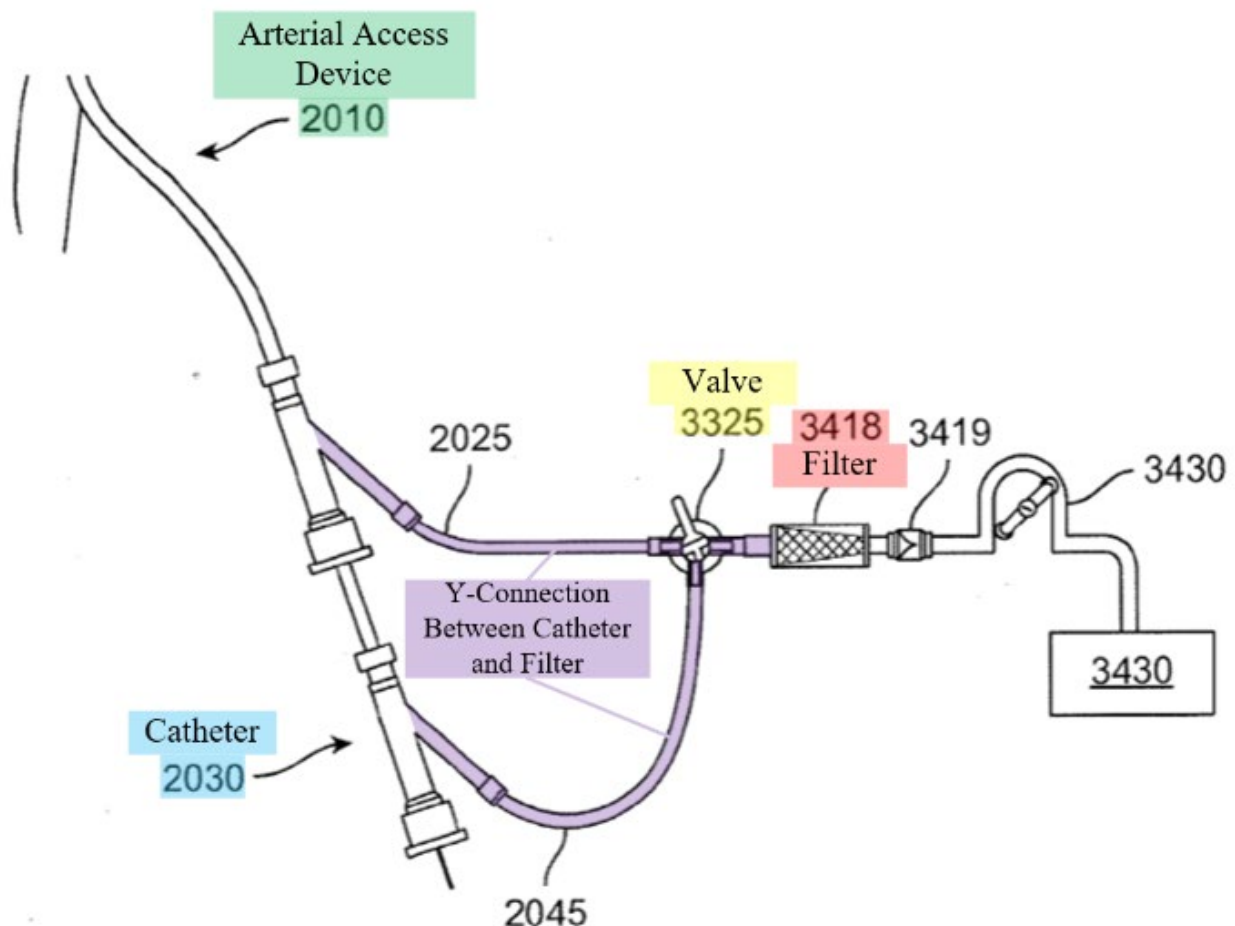
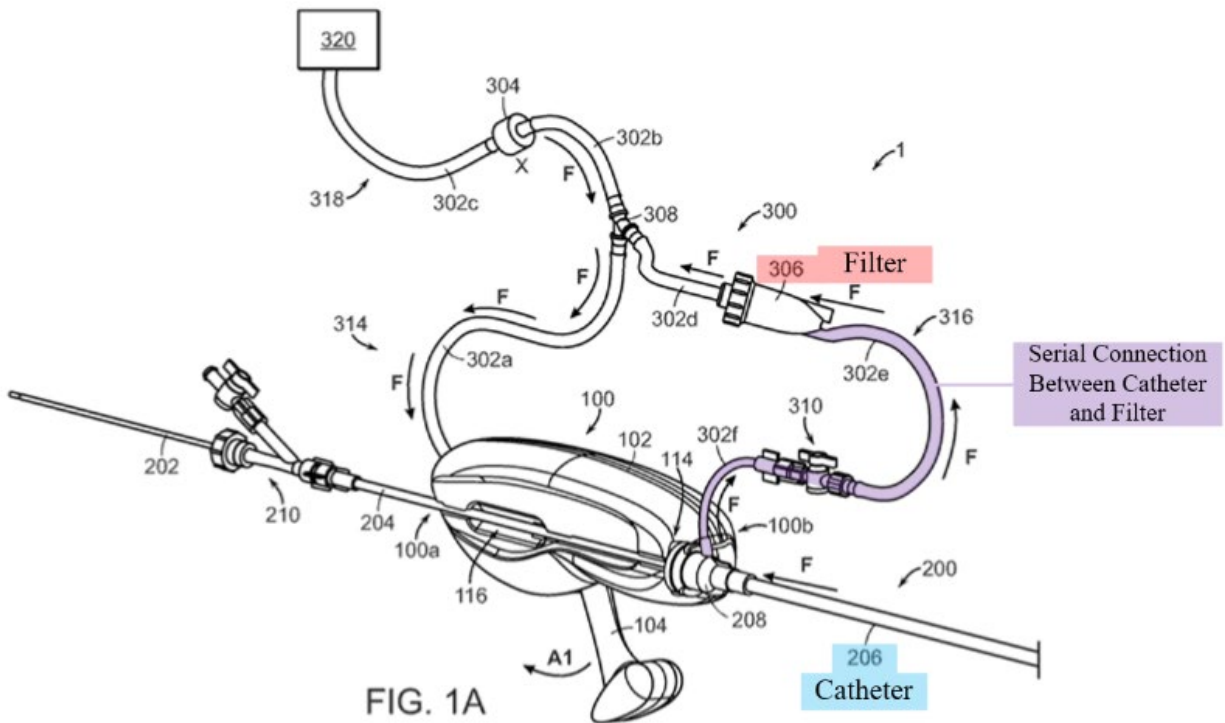


FIG. 34

EX1006, FIG. 34 (enlarged).

55. Therefore, the catheter 2030 is fluidically coupled to the filter 3418 in tandem or parallel with the arterial access device 2010 rather than “fluidically connected *in serial* to” the filter 3418 as required by Claims 4 and 18. In direct contrast, the ’669 Patent illustrates a single, serial fluidic connection between the catheter 206 and the filter chamber 306 as I have annotated below and as shown generally by the arrows F:



EX1001, FIG. 1A. Garrison does show a serial connection similar to the ’669 Patent in Figure 33, which does not include the valve 3325 but instead separate filters 3418 and “separate” aspiration sources 3125/3425 connected to the arterial access device 2010 and the catheter 2030. Thus, that embodiment

(which Petitioner does not rely on here) has a serial connection but does not include the claimed “flow controller.” And Garrison’s Figure 33 embodiment does not need the flow controller from Figure 34 because the arterial access device 2010 and the catheter 2030 are connected to the separate aspiration sources 3425 and 3125, respectively. In other words, there is no need for a 3-way stopcock, such as in Figure 34. Specifically, in Figure 34, the valve 3325 “enables one device, the other device, both devices, or neither device to be connected to the aspiration source at any given time.” EX1006, ¶ [0132]. A POSITA would understand that such control—i.e., switching the connection between the catheters to a single aspiration source—is not needed when the catheters are connected to separate aspiration sources as shown in Figure 33 because each aspiration source can be operated independently (e.g., turned off and turned on) such that there is no reason to include the valve 3325 from Figure 34.

56. Because the embodiments of Garrison on which Petitioner relies do not disclose a catheter fluidically connected in series with a filter chamber, as Claims 4 and 18 require, Garrison neither anticipates nor renders those claims obvious. For the same reason, Garrison in combination with Goff does not render Claims 4 or 18 obvious, because Petitioner does not argue that Goff supplies this missing limitation.

VII. DEPENDENT CLAIMS 8 AND 22: GARRISON, ALONE OR IN COMBINATION WITH GOFF, DOES NOT RENDER CLAIMS 8 OR 22 OBVIOUS

57. Petitioner and its expert, Mr. Thornton, contend that Garrison alone renders dependent Claims 8 and 22 obvious. Petition, pgs. 49-50, 62. Petitioner also relies on Garrison in combination with Goff with respect to these claims. *Id.* at pg. 72. I disagree for the reasons I discuss in further detail in this section.
58. As I explained above, I understand that a patent claim is obvious 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. Even if all limitations of a claimed invention were disclosed by a prior art combination (e.g., Garrison, Trerotola, and Goff), Petitioner must still demonstrate an adequate 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 a 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.

59. Here, independent Claims 1 and 15 each require a “filter chamber” that “comprises a housing and a filter within the housing.” EX1001, cls. 1, 15. Dependent Claims 8 and 22 narrow independent Claims 1 and 15, respectively, by further requiring that the “filter is *removable* from within the housing.” *Id.* at cls. 8, 22.

A. Garrison Alone (or in View of Trerotola) Does Not Render Obvious Claims 8 or 22

60. I agree with Petitioner that Garrison does not “disclose that the filter is removable from the filter housing.” Petition, pg. 49. Indeed, Garrison only references the filter 3418 in a single paragraph and provides no description other than that element 3418 is a “filter.” EX1006, ¶ [0131]. However, I disagree that a POSITA would have found it obvious to include a removable filter in Garrison’s system. *Id.*; EX1003, ¶ 123. Neither Garrison nor Trerotola discloses the claimed removable filter. They do not individually or together teach or otherwise render obvious a removable filter either.

61. First, Petitioner points to Trerotola¹ as support for its assertion that a person of ordinary skill in the art would have used a removable filter in Garrison. Petition, pgs. 49-50. But Trerotola, like Garrison, does not disclose a

¹ I note that Trerotola is not actually cited as a prior art reference in a combination for any of Petitioner’s grounds.

removable filter. Instead, Trerotola discloses a device 20 for “filtering and salvaging ... removed blood” that includes a housing 22 having first and second housing portions 30, 40 that “are detachable so that the valve can be cleaned if needed during the procedure”:

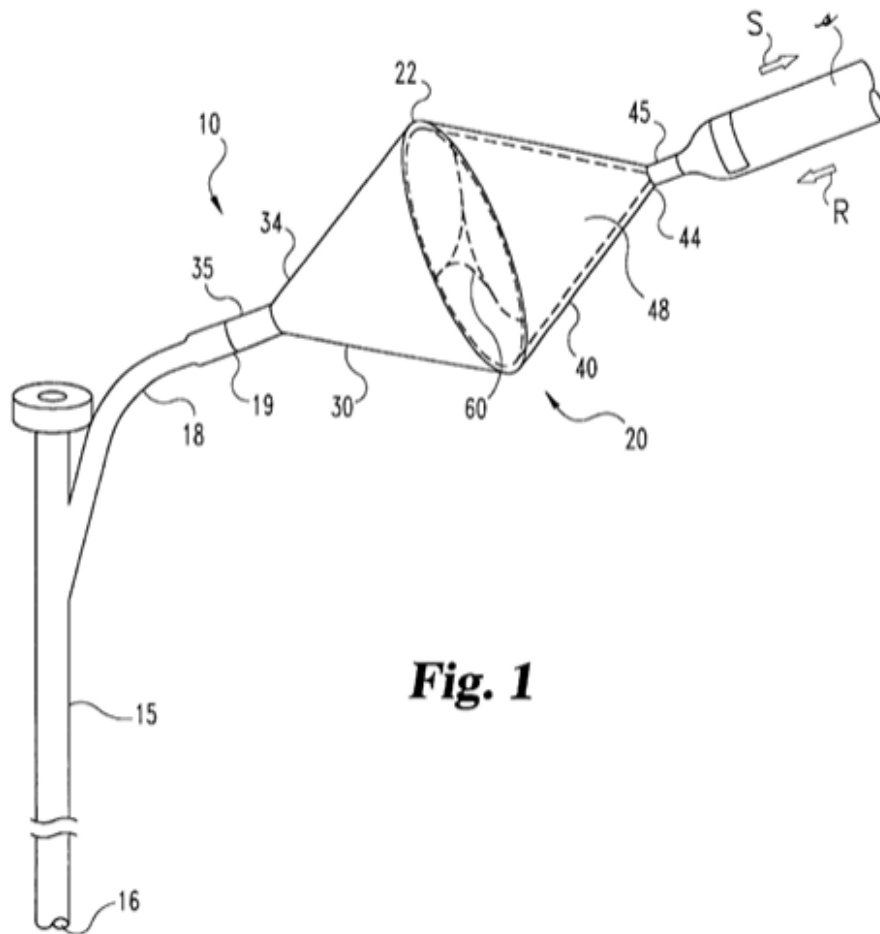
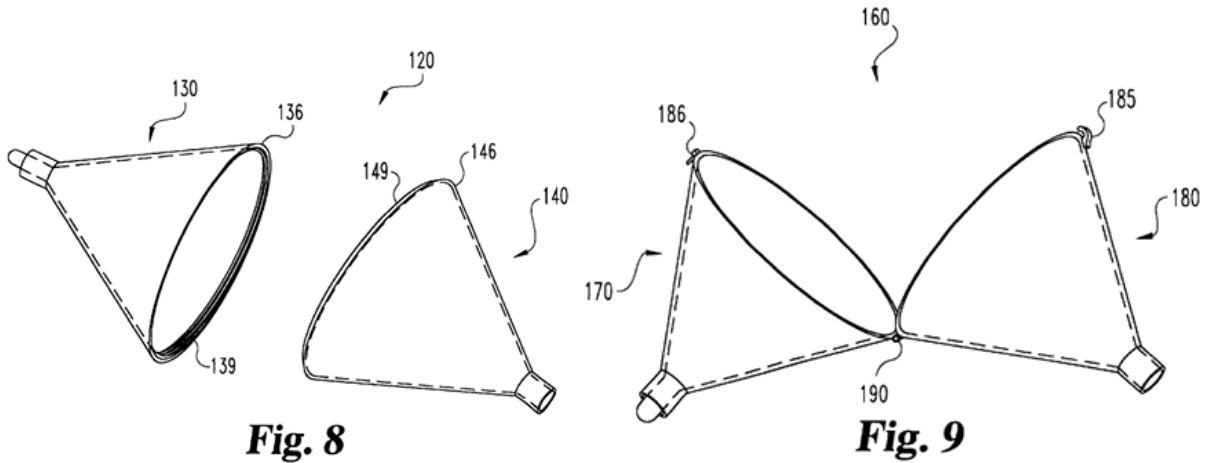


Fig. 1



EX1012, 4:30-31, 5:65-6:1, FIGS. 1, 8, & 9. The valve 60 in Trerotola “is fitted into the opposite end 36 of first housing portion 30” and “includes a plurality of valvate leaflets 61, 62, 63 that resemble the valves of a human heart”:

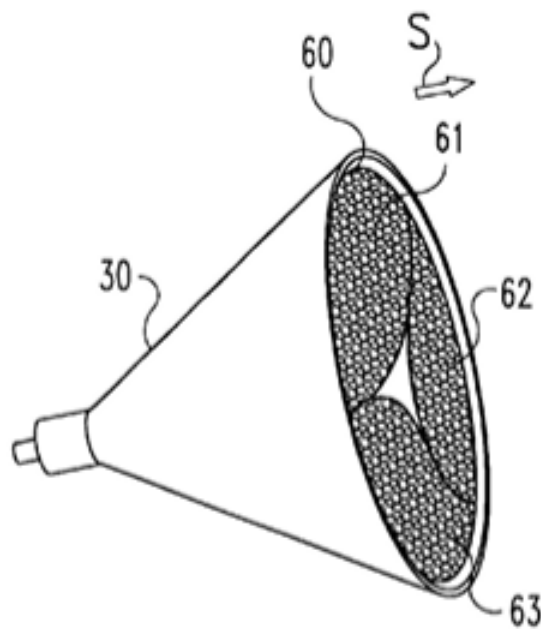


Fig. 4

Id. at 4:66-5:1, 5:29-34. The “[l]eaflets 61, 62, 63 are disposed circumferentially adjacent to one another from an interior surface of either the first housing portion 30 or the second housing portion 40” and “are deformable from the closed position to the open position in which their tips or ends 61’, 62’, 63’ are deflected toward the direction of the suction force S.” *Id.* at 5: 38-44.

62. Accordingly, a POSITA would have understood that the valve 60 is fixed within the housing 22 of Trerotola such that the leaflets 61, 62, 63 are able to deflect at their tips under the suction force S. Nowhere does Trerotola disclose that the valve 60 or any other component inside the housing 22 is “removable” as recited in dependent Claims 8 and 22. Instead, a POSITA would have understood that when Trerotola discloses that housing portions 30, 40 “are detachable so that the valve can be cleaned if needed during the procedure”—that means that the housing 22 is opened to allow cleaning of the valve 60 which is fixed therein without removing the valve 60. EX1012, 5:65-6:1. Trerotola confirms that when it states that “[i]f the valve becomes full or clogged, the housing portions can be disengaged to access and clean the valve.” *Id.* at 6:55-58. That is, Trerotola discloses that the valve is accessed but not removed by opening the housing portions 30, 40.

63. Because neither Garrison nor Trerotola disclose the limitations of Claims 8 and 22, specifically that the filter “is removable from within the housing,” it is my opinion that Garrison does not render obvious those claims.
64. Second, and more generally, a POSITA would not have modified Garrison to make filter 3418 removable for two reasons: (1) Garrison is directed to neurovascular clots that are comparatively small and unlikely to require filter cleaning or replacement during use; and (2) removing or replacing the filter would add time to a stroke procedure, where time is critical. A POSITA would understand that concerns for increased procedure speed in Garrison would predominate over any small risk of clot material clogging the system. As Petitioner has admitted over the course of the IPR proceedings related to the ’669 Patent, “Garrison focuses on the ‘treatment of cerebral occlusions.’” *See, e.g.,* EX2015, pg. 24. Indeed, Garrison’s disclosure is directed “to medical methods and devices for the treatment of acute ischemic stroke” and, more particularly, to “methods and systems for transcarotid access of the cerebral arterial vasculature and treatment of cerebral occlusions.” EX1006, ¶ [0002]. For example, in Figure 34 of Garrison relied on by Petitioner, like other disclosures in Garrison, the catheter 2030 is positioned in the middle cerebral artery (MCA):

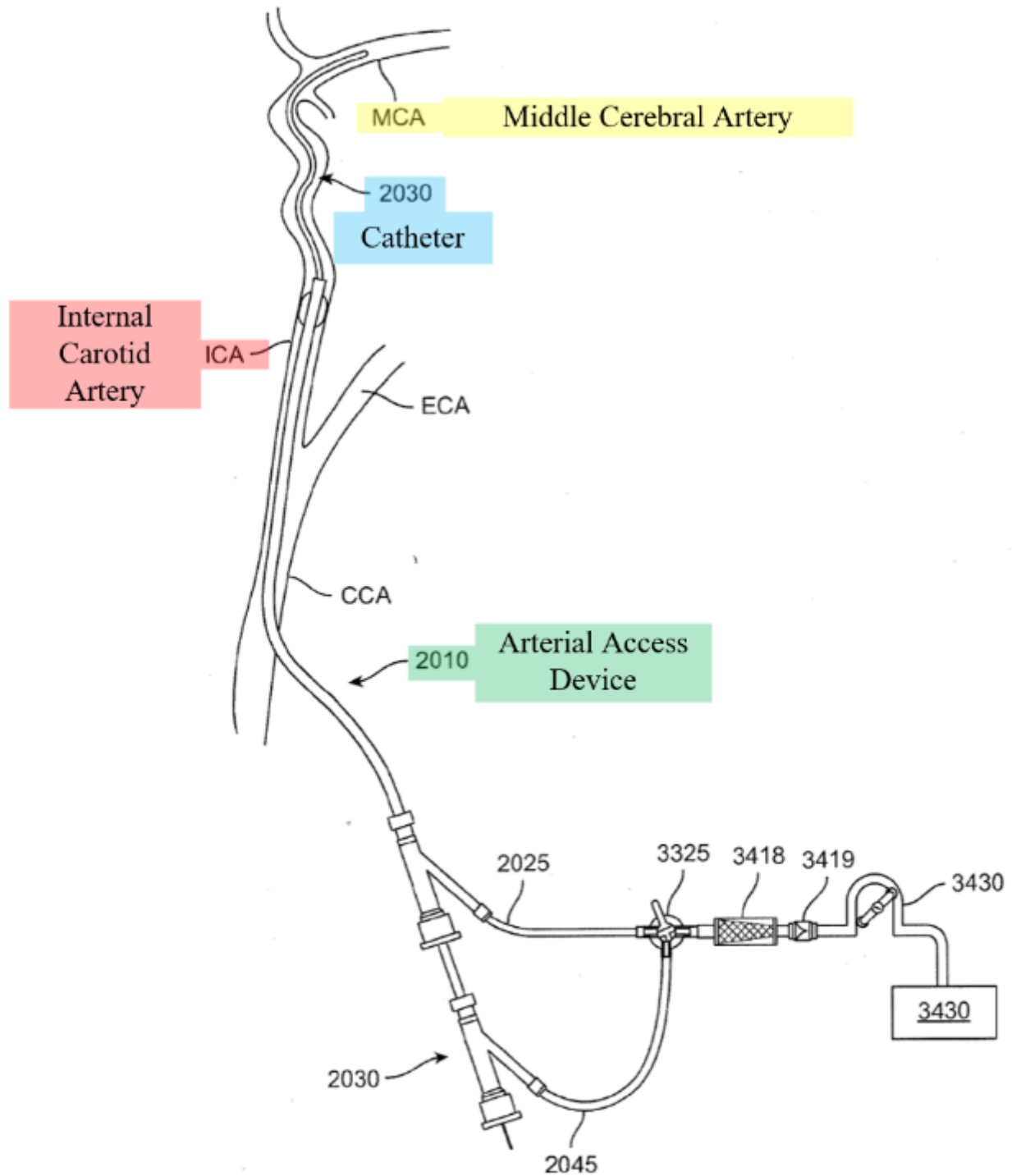


FIG. 34

As also shown in Figure 34 above, the arterial access device 2010 is positioned in the internal carotid artery (ICA).

65. The average volume of clots causing ischemic stroke in the ICA and MCA—the vessels Garrison’s system is intended to treat—is 52 cubic millimeters (mm^3). EX2013, pgs. 6-7. To contextualize that small size, 52 mm^3 is the approximate volume of a match head or a single unpopped popcorn kernel. Given the small clot volumes that Garrison intends to treat, a POSITA would not have expected routine clearing, emptying, or declogging of the filter to be necessary. Put another way, the clot burden is so small that it is unlikely to clog or interfere with the filter in any meaningful way. Accordingly, a POSITA would not have modified Garrison’s filter to be removable in a manner not taught by Garrison or Trerotola “so that the physician could retrieve samples, empty the housing, and clean or replace the filter” as alleged by Petitioner. Petition, pg. 49.
66. In contrast, the ’669 Patent is particularly directed to systems for treating PE and DVT. EX1001, 1:32-2:61. DVT and PE clots are substantially larger than those found in the cerebral vessels. In PE, the clot material can have a complex geometry that extends into branch vessels. For example, one study reports an average PE clot volume of 3403.3 mm^3 . EX2014, pg. 1. That average clot size is approximately 65 times greater than the reported average (52 mm^3) of the cerebral clots Garrison intends to treat. Thus, PE/DVT clots are

much more likely to impact the function of a filter in a manner that requires removal of the filter for clearing or cleaning.

67. Further, a POSITA would not have been motivated to modify Garrison to make the filter removable because replacing or removing Garrison's filter would slow Garrison's neurovasculature treatment where time is critical. Garrison discloses that an advantage of its disclosed system for treating acute stroke is decreased procedure time, namely that "[i]n the setting of acute ischemic stroke where 'time is brain,'" any "extra [procedural] difficulties have a significant clinical impact." EX1006, ¶ [0043]. Adding the ability to remove Garrison's filter 3418 would provide no benefit where the aspirated clots are of such small size and, if implemented during a procedure as Petitioner suggests, would simply slow Garrison's procedure while the physician opened, removed, and replaced the filter—which could have a significant clinical impact where time is "brain." Petition, pg. 49.
68. Accordingly, for the foregoing reasons, a POSITA would not have modified Garrison to make the filter 3418 removable because it would provide no benefit given the small size of the neurovascular clots Garrison intends to treat, and would slow down Garrison's procedure. Therefore, it is my opinion that Garrison does not render obvious Claims 8 and 22 of the '669 Patent, which require that "the filter is removable from within the housing."

B. Garrison in Combination with Goff Does Not Render Obvious Claims 8 or 22

69. Although Goff discloses that “[i]n an exemplary embodiment, the filter housing has an upper shell and a lower shell which may be taken apart to permit introduction, removal, and replacement of the filter element in the interior of the housing,” a POSITA would not have modified Garrison based on Goff to make the filter removable for the reasons I describe in § VII.A. EX1005, ¶ [0015]. In particular, the modification would offer little or no benefit for the comparatively small neurovascular clots Garrison addresses and could delay a time-sensitive stroke procedure.
70. Additionally, Goff is directed to devices for “separating materials in fluid aspirates removed from a hollow body structure” such as “blood vessels, cysts, pseudocysts, abscesses, blood vessel grafts, lung passages, bile ducts, ureters, urethras, fallopian tubes, ear canals, joint capsules, the gastrointestinal tract, and the like.” EX1005, ¶¶ [0007]-[0008]. Unlike the treatment of small neurovascular clots in the MCA and ICA, the structures Goff intends to treat are more likely to have large material constituents (e.g., pus, cyst material, bile, and the like) removed from the body for which replacement or removal of a filter for cleaning or clearing has utility. Treating those structures and material constituents are generally not as time critical as treating acute ischemic stroke where “time is brain.”

VIII. DEPENDENT CLAIMS 10 AND 24: GARRISON DOES NOT ANTICIPATE OR RENDER CLAIMS 10 OR 24 OBVIOUS, EITHER ALONE OR IN COMBINATION WITH GOFF

71. Petitioner and its expert, Mr. Thornton, contend that Garrison anticipates or renders dependent Claims 10 and 24 obvious. Petition, pgs. 50-52, 62. Petitioner also contends that Garrison in combination with Goff renders those claims obvious. *Id.* at pgs. 72-74. I disagree for the reasons I discuss below.
72. As I explained above, I understand that for a patent claim to be anticipated, each claim limitation must be present in a single piece of prior art. It is my understanding from counsel that a prior art reference can anticipate a claimed invention only if the prior art reference discloses each of the claimed limitations of the invention either expressly or inherently and in the same configuration or arrangement as claimed.
73. As I also explained above, I understand that a patent claim is obvious 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. Even if all limitations of a claimed invention are disclosed by the prior art combination, Petitioner must demonstrate a 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

a 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.

74. Here, independent Claims 1 and 15 each require a “filter chamber” that “comprises a housing and a filter within the housing.” EX1001, cls. 1, 15. Independent Claim 1 further requires that the housing includes a “fluid connector configured to be fluidically coupled to the connection tubing.” *Id.* at cl. 1. And, similarly, independent Claim 15 requires that the housing includes a “second port configured to be fluidically coupled to the vacuum source.” *Id.* at cl. 15. Dependent Claims 10 and 24 narrow the filter/housing recited in independent Claims 1 and 15, respectively, by further requiring that the “filter ***encloses a region*** within the housing” and that the “fluid connector [or second port] is proximal to the enclosed region along the first fluid path.” *Id.* at cls. 10, 24.
75. Accordingly, Claims 10 and 24 require that the enclosed region be positioned on the fluid-connector or second-port side of the filter chamber, such that the fluid connector or second port is proximal to that enclosed region. As I have annotated below, Figure 3A of the ’669 Patent illustrates that arrangement:

the filter encloses a region within the housing and opens at a proximal end toward the fluid connector or second port:

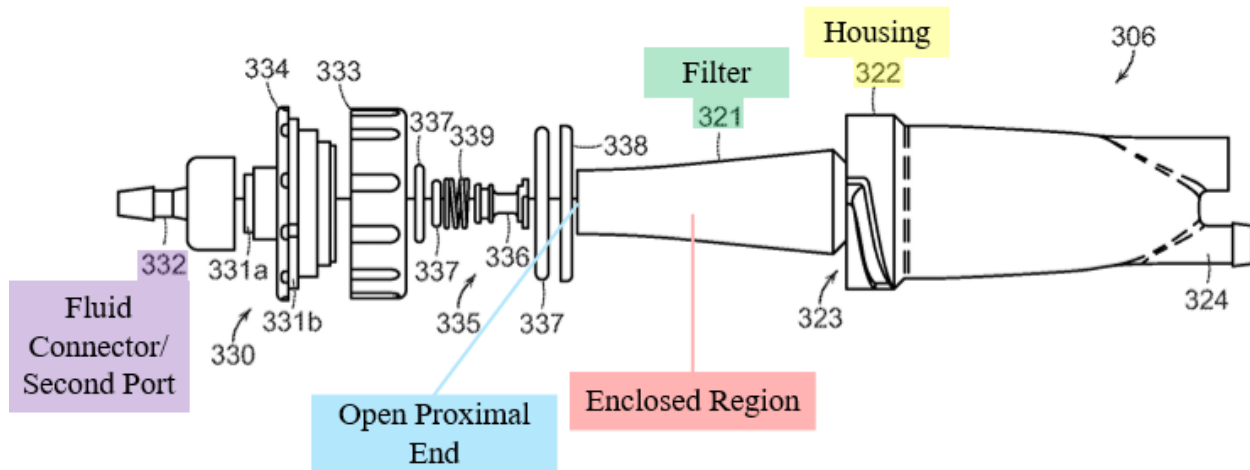
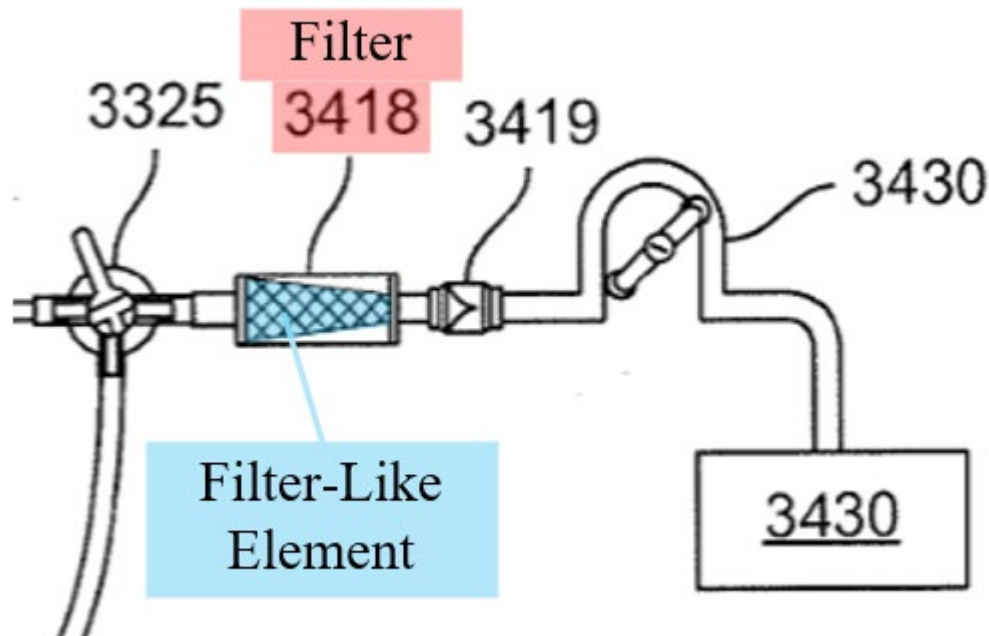


FIG. 3A

A. Garrison Alone Does Not Anticipate or Render Obvious Claims 10 or 24

76. Petitioner and its expert state only that “Garrison’s filter encloses a region within the filter housing,” based on Figure 34 in Garrison. Petition, pgs. 50-51; *see also* EX1003, ¶ 126. They do not identify any alleged enclosed region. Their position therefore appears to rest on the assumption that any filter necessarily encloses a region. I disagree. Garrison’s filter does not necessarily enclose a region, much less the particular enclosed region required by Claims 10 and 24, where the fluid connector or second port is proximal to that region.
77. As I explained above, Garrison only references the filter 3418 in a single paragraph and provides no written disclosure other than that element 3418 is a “filter.” EX1006, ¶ [0131]. That is Garrison’s only disclosure of the filter

3418. The same filter 3418 is illustrated in each of Figures 32-34 of Garrison, and those figures depict a filter-like element (labeled in my annotations below) having a truncated conical shape that spans entirely between the inflow and outflow ends of the filter 3418:

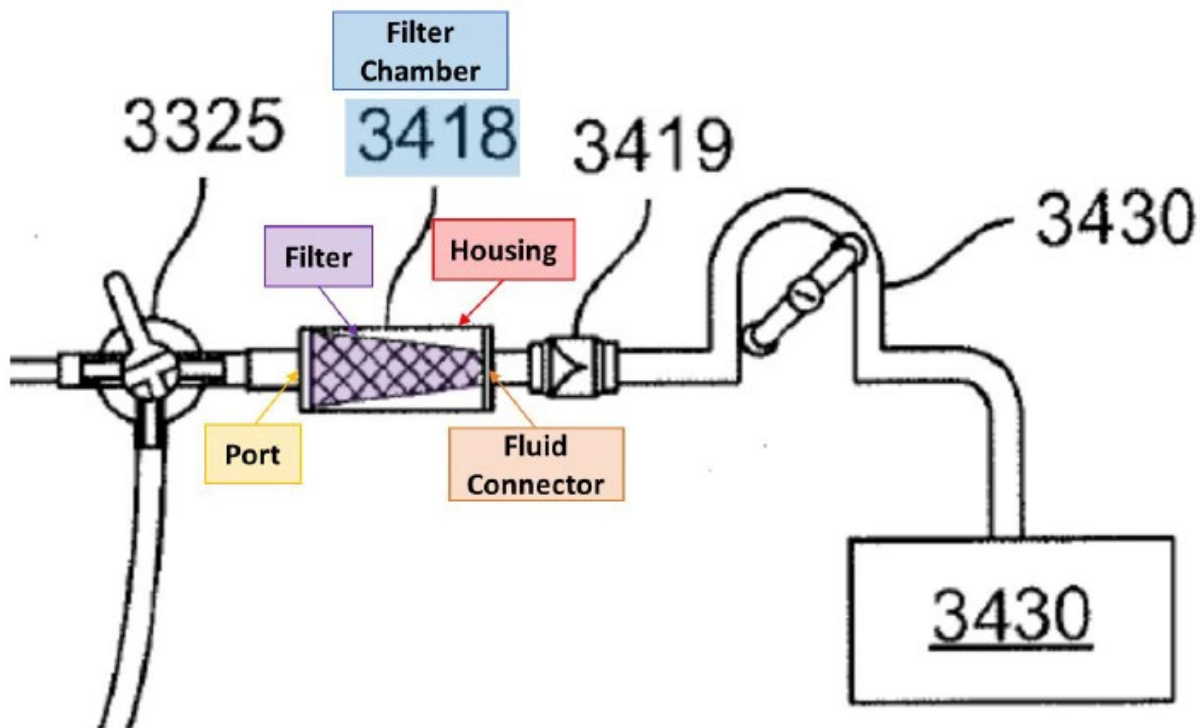


EX1006, FIG. 34 (enlarged).

78. But, Garrison does not describe the structure of the filter-like element. It is therefore unclear whether the element encloses any region. Filters can take many forms, not all of which enclose a region. For example, the filter element could have a solid porous structure or body that fills the entire filter volume, such as gauze, foam, sintered metal, and/or the like. The filter-like element could also be a planar mesh screen, which by its two-dimensional nature does not enclose a region. Accordingly, because Garrison provides no disclosure

of the filter-like element other than that it is a filter, and because the filter-like element could have many different structures, a POSITA would understand that the filter-like element within Garrison's filter does not necessarily "en-
close[] a region."

79. Moreover, as shown in Petitioner's annotations to Figure 34 of Garrison below, the filter-like element is illustrated abutting the alleged fluid connector and the port:



Petition, pg. 51; *see also* EX1003, ¶ 126. In that arrangement, a POSITA could understand the filter to be solid, as I discuss above, or to be open at the distal port and closed at the proximal fluid connector, like a bag or pocket filter. That would permit clot to flow into that interior filter arrangement and

would prevent the clot from flowing entirely through the filter out of the fluid connector. But in that arrangement, the alleged fluid connector is not “proximal to the enclosed region” because the enclosed region is opposite to that of the '669 Patent, in which the filter encloses a region within the housing and opens at a proximal end toward the fluid connector/second port such that the fluid connector/second port is proximal to that enclosed region:

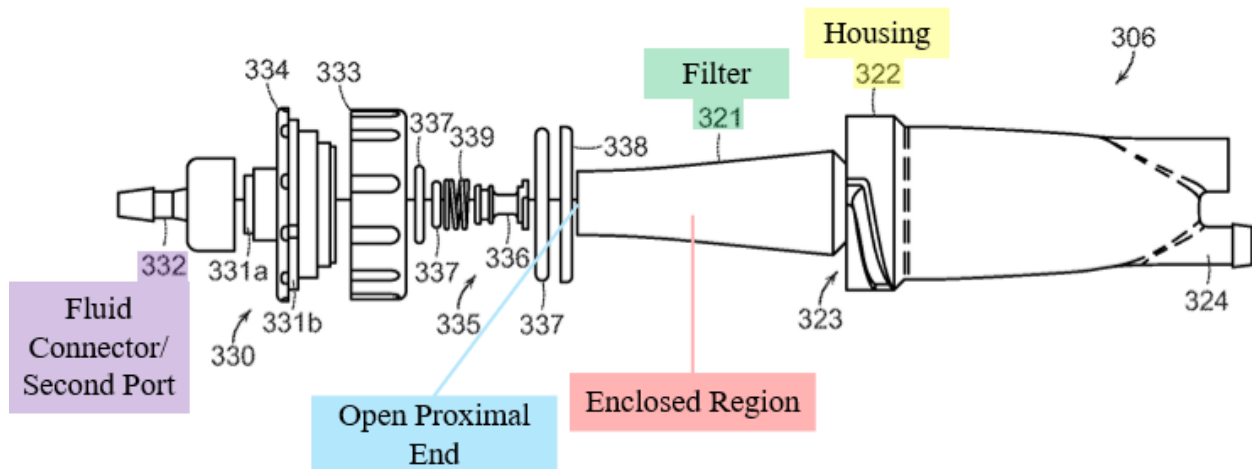
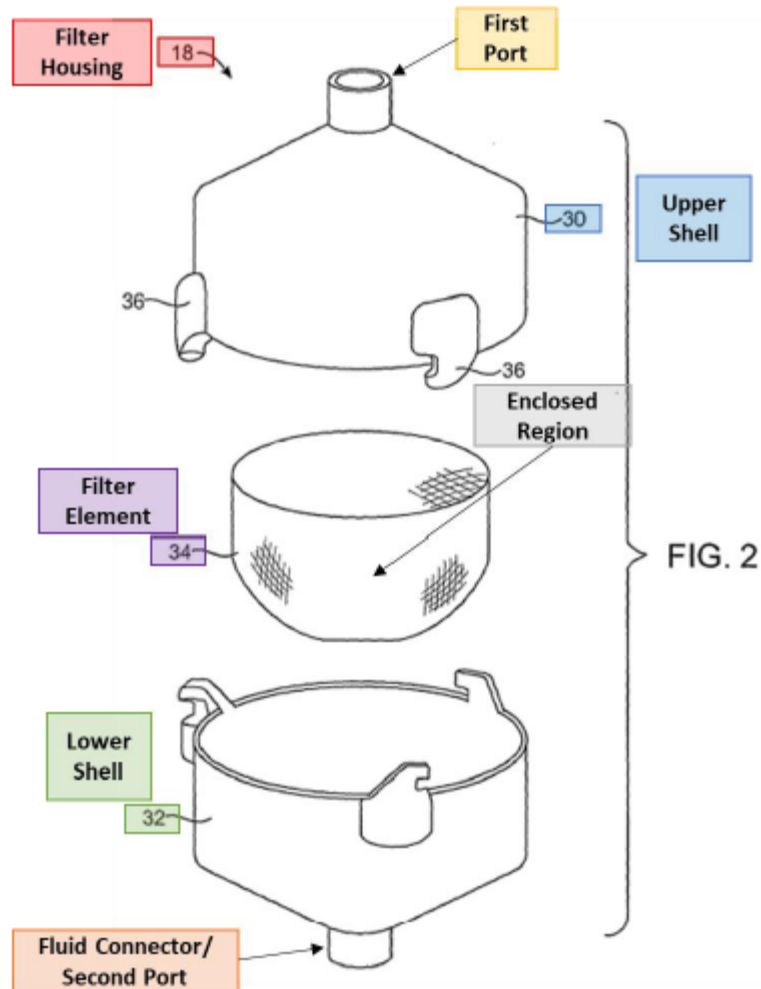


FIG. 3A

80. Because the portions of Garrison relied on by Petitioner do not disclose the limitations of Claims 10 and 24, including not disclosing that the “filter *encloses a region* within the housing” and that the “fluid connector [or second port] is proximal to the enclosed region along the first fluid path,” it is my opinion that Garrison does not anticipate Claims 10 or 24 or alone render those claims obvious (grounds 1 and 2).

B. Garrison in Combination with Goff Does Not Render Obvious Claims 10 or 24

81. Petitioner and its expert contend that in Figure 2 of Goff, “Goff’s filter element encloses a region within the filter housing (i.e., the region enclosed by the cylindrical filter element), and the fluid connector is proximal to that enclosed region along the fluid path.” Petition, pgs. 73-74; EX1003, ¶ 177. Like grounds 1-2 based on Garrison, Petitioner and its expert do not identify any region enclosed by Goff’s filter. It therefore appears that Petitioner and its expert presume that Goff’s filter encloses a region simply because it is a filter.
82. I disagree that Goff’s filter necessarily encloses a region at all, let alone the “enclosed region” specified by Claims 10 and 24 in which the “fluid connector [or second port] is proximal to the enclosed region,” for the same reasons I explain above with respect to Garrison. Namely, like Garrison, Goff’s filter element 34 abuts the alleged fluid connector/second port because the “filter element 34 is constructed so that it nests within the lower shell 32 of the filter assembly” (EX1005, ¶ [0026]), as shown in Petitioner’s annotations to Figure 2 of Goff:



Petition, pg. 73. Accordingly, if Goff's filter element 34 was not a solid porous structure (a solid porous structure would not enclose a region), a POSITA would understand the filter element 34 to have an open distal end facing the alleged port or first port rather than the alleged fluid connector or second port to the vacuum source. But in that arrangement, the alleged fluid connector is not "proximal to the enclosed region" because the enclosed region is opposite that of the '669 Patent, in which the filter encloses a region within the housing and opens at a proximal end toward the fluid connector/second port such that

the fluid connector/second port is proximal to that enclosed region. Accordingly, it is also my opinion that the combination of Garrison and Goff does not render obvious Claims 10 or 24.

IX. SECONDARY CONSIDERATIONS

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

X. CONCLUSION

84. For all the foregoing reasons, it is my opinion that Petitioner has not shown by a preponderance of the evidence that any of the challenged Claims 4, 8, 10, 18, 22, and 24 are unpatentable on the grounds addressed in this declaration.

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: 25 Aug 2026

By:

A handwritten signature in blue ink, appearing to be 'Brian Brown', written over a horizontal line.

Brian Brown

ATTACHMENT 1

Brian J. Brown

C (763) 458-8551

bb.browntech@gmail.com

Professional Experience

**Brown-Tech, LLC.
President**

Hanover, MN

Sept 2017-Present

- 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)
President**

Maple Plain, MN

Mar 2018-July 2020

- 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.
VP of R&D and Operations**

Minnetonka, MN

Nov 2016 – June 2017

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
Chief Technology Officer**

Irvine CA and Edina, MN

2016

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
R&D, Vice President, Cardiovascular (2004-2014)

Feb 1990 – Jan 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. 12,156,669 (“the ’669 patent”)
EX1002	’669 Patent Prosecution History
EX1003	Expert Declaration of Troy Thornton
EX1004	Resume of Troy Thornton
EX1005	WIPO Publication No. WO 2006/124307 A2 to Goff et al. (“Goff”)
EX1006	U.S. Patent Publication No. 2015/0173782 A1 to Garrison et al. (“Garrison”)
EX1007	U.S. Patent Publication US 2003/0225379 A1 to Schaffer et al. (“Schaffer”)
EX1008	U.S. Patent Publication No. 2003/0116731 A1 to Hartley (“Hartley”)
EX1009	Certified File History of U.S. Patent Application 10/371,190 (Schaffer File History)
EX1010	WIPO Publication No. WO 2018/019829 A1 to Brady et al. (“Brady”)
EX1011	U.S. Patent No. 11,432,835 B2 to Pons et al. (“Pons”)
EX1012	U.S. Patent No. 6,776,770 B2 to Treretola
EX1013	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)
EX1014	Merriam-Webster’s Collegiate Dictionary (11th ed. 2014), definitions of “port” and “tighten”
EX1015	Merriam-Webster’s Collegiate Dictionary (11th ed. 2014), submitted by Patent Owner as Exhibit 2009 in IPR2024-00157
EX1016	Deposition Transcript of PO’s Expert Paul Zalesky, Ph.D. dated June 23, 2025
EX1017	Deposition Transcript of PO’s Expert Paul Zalesky, Ph.D. dated August 27, 2025
EX1018	Deposition Transcript of PO’s Expert Paul Zalesky, Ph.D. dated November 7, 2025

EXHIBIT/PAPER No.	DESCRIPTION
EX1019	U.S. Provisional Patent Application No. 62/554,931
EX1020	Order Regarding Case Schedule and Motion to Stay in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 5:24-cv-03117-EKL (N.D. Cal.)
EX1021	U.S. Patent No. 11,697,011 (“the ’011 patent”)
EX1022	U.S. Provisional Application No. 62/474,383
EX1023	U.S. Provisional Application No. 62/516,582
EX1024	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)
EX1025	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)
EX1026	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)
EX1027	Decision Granting Institution of <i>Inter Partes</i> Review for U.S. Patent No. 11,844,921 (Paper 13) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-00728 (P.T.A.B. Oct. 10, 2025)
EX1028	Decision Granting Institution of <i>Inter Partes</i> Review for U.S. Patent No. 11,865,291 (Paper 10) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-00989 (P.T.A.B. Oct. 23, 2025)
EX1029	U.S. Patent Publication No. 2015/0352325 to Quick (“Quick”)
EX1030	Patent Owner’s Response for U.S. Patent No. 11,697,011 (Paper 13) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2024-01157 (Apr. 18, 2025)
EX1031	U.S. Patent Publication No. 2010/0042118 A1 to Garrison et al.
EX1032	U.S. Patent No. 5,938,645 to Gordon (“Gordon”)
EX1033	U.S. Patent Publication No. 2014/0296868 A1 to Garrison et al.
EX1034	U.S. Patent Publication No. 2017/0043066 A1 to Laub (“Laub”)

EXHIBIT/PAPER No.	DESCRIPTION
EX1035	U.S. Patent No. 8,734,374 B2 to Aklog et al. (“Aklog”)
EX1036	Penumbra, Optimizing Direct Aspiration (May 2013)
EX1037	AXS Universal Aspiration Set Brochure (2017)
EX1038	U.S. Patent No. 12,109,384
EX1039	Supplemental Declaration of Paul Zalesky Ph.D. submitted by Patent Owner as Exhibit 2008 in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2024-01157, U.S. Patent No. 11,697,011
EX1040	International Standards Organization, Small-bore Connectors for Liquids and Gasses in Healthcare Applications Part 7: Connectors for Intravascular or Hypodermic Applications, 80369-7 (Edition 1, 2016) (“ISO 80369-7”)
EX1041	O. Nikoubashman et al., Under Pressure: Comparison of Aspiration Techniques for Endovascular Mechanical Thrombectomy, <i>Am J. Neuroradiol.</i> (May 2018) (“Nikoubashman”)
EX1042	Record of Oral Hearing held on October 29, 2025 in <i>Inter Partes</i> Review for U.S. Patent No. 11,697,011 (Paper 34) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2024-01157 (P.T.A.B. Nov. 17, 2025)
EX1043	Dorland’s Illustrated Medical Dictionary, 32nd ed. (2012) - Definition of “Port”
EX1044	U.S. Patent No. 9,526,864 B2 to Quick
EX1045	Decision Granting Institution of <i>Inter Partes</i> Review for U.S. Patent No. 11,969,333 (Paper 15) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-01021 (P.T.A.B. Dec. 11, 2025)
EX1046	Decision Granting Institution of <i>Inter Partes</i> Review for U.S. Patent No. 11,974,910 (Paper 15) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-01025 (P.T.A.B. Dec. 11, 2025)
EX2002	Deposition Transcript of Petitioner’s Expert, Troy L. Thornton (August 11, 2026)
EX2003	U.S. Patent No. 11,849,963 to Quick (“the ’963 Patent”)
EX2004	Non-Final Office Action in the ’963 Patent (mailed September 15, 2022)

EXHIBIT/PAPER No.	DESCRIPTION
EX2005	Deposition Transcript of Petitioner's Expert, Troy L. Thornton (February 18, 2026) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-01264
EX2006	Supplemental Declaration of Paul Zalesky (EX2026) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-00289
EX2007	U.S. Patent No. 11,697,012 ("the '012 Patent")
EX2008	U.S. Patent No. 11,554,005 ("the '005 Patent")
EX2009	Supplemental Declaration of Paul Zalesky (EX2009) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-00989
EX2010	Supplemental Declaration of Paul Zalesky (EX2033) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-00728
EX2011	Deposition Transcript of Troy Thornton (June 25, 2025) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-00156
EX2012	Petition for <i>Inter Partes</i> Review for U.S. Patent No. 12,016,580 (Paper 1) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-01264 (P.T.A.B. July 8, 2025)
EX2013	Santos, Emilie M M et al. "Automated Entire Thrombus Density Measurements for Robust and Comprehensive Thrombus Characterization in Patients with Acute Ischemic Stroke." PloS one vol. 11,1 e0145641. 14 Jan. 2016, doi:10.1371/journal.pone.0145641
EX2014	Aghayev, Ayaz et al. "The rate of resolution of clot burden measured by pulmonary CT angiography in patients with acute pulmonary embolism." AJR. American journal of roentgenology vol. 200,4 (2013): 791-7. doi:10.2214/AJR.12.8624
Paper 2	Petition: As Filed