

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

IMPERATIVE CARE, INC.,
Petitioner,

v.

INARI MEDICAL, INC.,
Patent Owner.

Case No. IPR2025-01264
U.S. Patent No. 12,016,580

PATENT OWNER'S RESPONSE

TABLE OF CONTENTS

EXHIBIT LIST	iv
I. INTRODUCTION	1
II. BACKGROUND	6
A. Overview of the ’580 Patent.....	6
B. Prosecution History	12
C. Person of Ordinary Skill in the Art	13
D. The Testimony of Petitioner’s Purported Experts Should be Afforded Little or No Weight.....	17
E. Claim Construction	18
III. INDEPENDENT CLAIM 1 AND DEPENDENT CLAIMS 5, 9, 11- 14, 18, 21-22, 24-28, 30, AND 33-34 ARE NOT ANTICIPATED BY GARRISON (GROUND 1).....	19
A. Garrison does not disclose “engaging the interventional device with a second portion of the clot material remaining within the blood vessel”	19
B. Garrison does not disclose “pre-charging a vacuum in a pressure source; fluidly connecting the pressure source to the elongated shaft to apply the pre-charged vacuum to the elongated shaft to aspirate a first portion of the clot material into the elongated shaft”	26
IV. INDEPENDENT CLAIM 1 AND DEPENDENT CLAIMS 5-6, 9, 11- 18, 21-30, AND 33-34 ARE NOT RENDERED OBVIOUS BY GARRISON ALONE (GROUND 2) OR IN COMBINATION WITH SCHAFFER (GROUND 3) OR HARTLEY (GROUND 4).....	31
V. DEPENDENT CLAIMS 15-29 ARE NOT RENDERED OBVIOUS BY GARRISON IN COMBINATION WITH ANY OF SCHAFFER, HARTLEY, AND/OR GOFF (GROUNDS 5-8)	36

VI.	DEPENDENT CLAIMS 18, 21-22, AND 24-28 ARE NOT ANTICIPATED BY GARRISON (GROUND 1), AND DEPENDENT CLAIMS 18-29 ARE NOT RENDERED OBVIOUS BY GARRISON ALONE OR IN COMBINATION WITH ANY OF SCHAFFER, HARTLEY, AND/OR GOFF (GROUNDS 2-4, 6-8).....	37
VII.	DEPENDENT CLAIM 10 IS NOT RENDERED OBVIOUS BY GARRISON IN COMBINATION WITH ANY OF LAUB, AKLOG, SCHAFFER, AND/OR HARTLEY (GROUNDS 9-14)	40
VIII.	CONCLUSION.....	48

TABLE OF AUTHORITIES

CASES

<i>Aug. Tech. Corp. v. Camtek, Ltd.</i> , 655 F.3d 1278 (Fed. Cir. 2011)	31
<i>Axonics, Inc. v. Medtronic, Inc.</i> , 73 F.4th 950 (Fed. Cir. 2023)	31
<i>Chamberlain Grp., Inc. v. Techtronic Indus. Co.</i> , 935 F.3d 1341 (Fed. Cir. 2019)	26
<i>In re Gleave</i> , 560 F.3d 1331 (Fed. Cir. 2009)	19
<i>Innogenetics, N.V. v. Abbott Labs.</i> , 512 F.3d 1363 (Fed. Cir. 2008)	31
<i>Kyocera Senco Indus. Tools Inc. v. Int'l Trade Comm'n</i> , 22 F.4th 1369 (Fed. Cir. 2022)	17

STATUTES

35 U.S.C. § 102	13, 30
-----------------------	--------

EXHIBIT LIST

	Petitioner's Exhibits
Exhibit	Description
EX1001	U.S. Patent No. 12,016,580 ("the '580 Patent")
EX1002	'580 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	U.S. Patent Publication No. 2015/0352325 A1 to Quick ("Quick")
EX1010	U.S. Patent Publication No. 2010/0042118 A1 to Garrison et al.
EX1011	U.S. Patent No. 8,734,374 B2 to Aklog et al. ("Aklog")
EX1012	U.S. Patent Publication No. 2017/0043066 A1 to Laub ("Laub")
EX1013	U.S. Patent No. 6,776,770 B2 to Trerotola ("Trerotola")
EX1014	U.S. Patent No. 5,938,645 to Gordon ("Gordon")
EX1015	U.S. Patent Publication No. 2014/0296868 A1 to Garrison et al.
EX1016	Certified File History of U.S. Patent Application 10/371,190 (Schaffer File History)
EX1017	U.S. Provisional Patent Application No. 62/554,931 (the "'931 application")

	Petitioner's Exhibits
Exhibit	Description
EX1018	U.S. Patent No. 6,481,439 B1 to Lewis et al.
EX1019	U.S. Patent No. 5,256,150 to Quiachon et al.
EX1020	WIPO Publication No. WO 2018/019829 A1 to Brady et al. ("Brady")
EX1021	U.S. Patent No. 12,109,384 B2 to Merritt et al.
EX1022	Expert Declaration of Dr. Aquilla S. Turk, III, DO
EX1023	Resume of Dr. Aquilla Turk, III, D.O.
EX1024	Shani, Jacob M.D., et al., Mechanical Manipulation of Thrombus: Coronary Thrombectomy, Intracoronary Clot Displacement, and Transcatheter Aspiration, 72 Am. J. Cardiol. 116G-118G (1993)
EX1025	Bose, A et al., The Penumbra System: A Mechanical Device for the Treatment of Acute Stroke due to Thromboembolism, 29 Am. J. Neuroradiol. 1409-1413 (Aug. 2008)
EX1026	Turk, Aquilla S. et al., Initial clinical experience with the ADAPT technique: A direct aspiration first pass technique for stroke thrombectomy, 6 J. NeuroIntervent. Surg. 231-237 (2014)
EX1027	Turk, Aquilla S. et al., ADAPT FAST study: a direct aspiration first pass technique for acute stroke thrombectomy, 6 J. NeuroIntervent. Surg. 260-264 (2014)
EX1028	April 24, 2024 Letter from Inari to Imperative Care
EX1029	Turk, Aquilla S. et al., Aspiration thrombectomy versus stent retriever thrombectomy as first-line approach for large vessel occlusion (COMPASS): a multicentre, randomized, open label, blinded outcome, non-inferiority trial, 393 Lancet 998-1008 (March 2019)
EX1030	Save, Jeffrey L., Time is Brain – Quantified, American Heart Association Journals, available at http://www.stokeaha.org (2005).

	Petitioner's Exhibits
Exhibit	Description
EX1031	Decision Granting Institution of IPR, IPR2024-01157, U.S. Patent No. 11,697,011 B2
EX1032	Decision Granting Institution of IPR, IPR2025-00156, U.S. Patent No. 11,697,012 B2
EX1033	Decision Granting Institution of IPR, IPR2025-00289, U.S. Patent No. 11,554,005 B2
EX1034	Merriam-Webster's Collegiate Dictionary – Previously Submitted by Patent Owner as Ex. 2002 in IPR2024-00289 – Definition of “Loosen”
EX1035	U.S. Patent No. 7,998,104 B2 to Chang
EX1036	U.S. Patent No. 8,157,760 B2 to Craido et al.
EX1037	Plaintiff Inari's Supplemental Preliminary Disclosure of Asserted Claims and Infringement Contentions Pursuant to Patent Local Rules 3-1 and 3-2 in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 5:24-cv-03117-EKL (N.D. Cal.)
EX1038	Case Management and Scheduling Order (Dkt. #54) in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 5:24-cv-03117-EKL (N.D. Cal.)
EX1039	Imperative Care, Inc.'s Notice of Motion and Motion to Stay Pending <i>Inter Partes</i> Review in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 5:24-cv-03117-EKL (N.D. Cal.)
EX1040	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.)
EX1041	Order Denying Motion for Preliminary Injunction (Dkt. #136) in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 24-cv-03117-EKL (N.D. Cal.) (issued September 29, 2025)

	Petitioner's Exhibits
Exhibit	Description
EX1042	Decision Denying Patent Owner's Request for Discretionary Denial (Paper 9) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-00289 (P.T.A.B. June 12, 2025)
EX1043	Decision Referring the Petition to the Board (Paper 9) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-00728 (P.T.A.B. July 31, 2025)
EX1044	Decision Referring the Petitions to the Board (Paper 11) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-01021 (P.T.A.B. Oct. 10, 2025)
EX1045	Decision Referring the Petitions to the Board (Paper 11) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-01025 (P.T.A.B. Oct. 10, 2025)
EX1046	Order Granting In Part Motion To Stay (Dkt. #137) in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 24-cv-03117-EKL (N.D. Cal.) (issued September 29, 2025)
EX1047	Redacted Excerpts of Deposition Transcript of PO's Expert Brian Brown dated August 27, 2024, submitted as Exhibit 1019 to R. Tyler Kendrick's Declaration in Support of Inari's Statement Regarding Truvic's Administrative Motion Pursuant to Civil L.R. 79-5(C)(1) & (F) (Dkt. #85-1) in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 24-cv-03117-EKL (N.D. Cal.) (filed February 26, 2025)
EX1048	Deposition Transcript of PO's Expert Paul Zalesky, Ph.D. dated June 23, 2025
EX1049	Joint Stipulation to Continue the Stay of Litigation Pending IPR Decisions and Vacate Upcoming Case Management Conference (Dkt. #139) in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 24-cv-03117-EKL (N.D. Cal.) (filed January 21, 2026)
EX1050	Order Granting Joint Stipulation to Continue the Stay of Litigation Pending IPR Decisions and Vacate Upcoming Case Management

	Petitioner's Exhibits
Exhibit	Description
	Conference (Dkt. #140) in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 24-cv-03117-EKL (N.D. Cal.) (issued January 21, 2026)

	Patent Owner's Exhibits
Exhibit	Description
EX2001	Prosecution History Excerpt from U.S. Patent Application No. 17/865,307
EX2002	U.S. Patent No. 11,849,963 B2 to Quick ("Quick")
EX2003	Declaration of Brian Brown
EX2004	Hearing Transcript, dated February 6, 2026
EX2005	Supplemental Declaration of Brian Brown
EX2006	Deposition Transcript of Petitioner's Expert, Troy L. Thornton (February 18, 2026)
EX2007	Deposition Transcript of Petitioner's Expert, Troy L. Thornton (February 19, 2026)
EX2008	Deposition Transcript of Aquilla S. Turk (February 25, 2026)
EX2009	U.S. Patent No. 11,974,910 to Merritt, et al. ("910 Patent")

I. INTRODUCTION

Petitioner has failed to demonstrate by a preponderance of evidence that any of challenged Claims 1, 5-6, 9-30, and 33-34 (“the Claims”) of the ’580 Patent are unpatentable. Rather, as explained herein, the Claims are directed to innovations pioneered by patentee that are not disclosed or obvious in view of the prior art.

Occlusions (blockages) in blood vessels are a leading cause of disease and death worldwide. EX1001, 1:31-65; EX2005, ¶30. For example, venous thromboembolism (“VTE”) is the formation of blood clots in veins. *Id.* Pulmonary embolism (“PE”) and deep vein thrombosis (“DVT”) are common and particularly dangerous types of VTE. *Id.* The ’580 Patent discloses systems and methods for removing clot material from a blood vessel of a human patient to treat VTE, including PE and DVT. EX1001, 1:31-65. For example, in some embodiments these systems and methods include aspiration of clot material followed by mechanical engagement with an interventional device to remove remaining clot material. EX1001, 3:46-49, 4:45-49, 21:41-52; EX2005, ¶37. Among other benefits described in the ’580 Patent, these systems and methods avoid the risk and trauma associated with more invasive surgical techniques and avoid the delay and risks of hemorrhage associated with chemical agents designed to dissolve clot material. *See* EX. 1001, 1:66-2:53; EX2005, ¶¶34-37.

Claim 1 recites a method for the intravascular treatment of clot material within

a blood vessel including steps of (i) “positioning a distal portion of an elongated shaft proximate to the clot material within the vessel,” (ii) aspirating some of the clot material by “pre-charging a vacuum in a pressure source” and then “fluidly connecting the pressure source to the elongated shaft to apply the pre-charged vacuum to the elongated shaft to aspirate a first portion of the clot material into the elongated shaft,” then (iii) engaging leftover clot material by “advancing an interventional device distally through the attachment member and the elongated shaft” and then “engaging the interventional device with a second portion of the clot material remaining within the blood vessel.” EX1001, cl.1.; EX2005, ¶37.

Particularly relevant, Claim 1 recites a “method for the intravascular treatment of clot material within a blood vessel” by aspirating “a first portion of the clot material” with the pre-charged vacuum, and then, “engaging the interventional device with a second portion of *the clot material* remaining within the blood vessel.” EX1001, cl.1 (emphasis added); EX2005, ¶49. Accordingly, “clot material within a blood vessel” recited in the preamble provides antecedent basis for “the clot material” in the phrases “aspirate a first portion of the clot material” and “a second portion of the clot material remaining within the blood vessel” recited in Claim 1, confirming that the claimed method steps must be performed in a particular order and that the first and second portions of the clot material are parts of the same clot material within the blood vessel.

The method of Claim 1 rapidly generates large suction forces (and corresponding fluid flow velocities) by pre-charging and then applying a stored vacuum to effectively aspirate and remove part of the clot material from the patient. EX1001, 21:7-15; EX2005, ¶38. In some circumstances, despite aspiration, a more strongly-attached or chronic portion of the clot may remain in the blood vessel. EX2005, ¶39. The method of Claim 1 treats this remaining second portion with the interventional device. EX1001, Cl.1; EX2005, ¶39.

In each of grounds 1-4, Petitioner relies on Garrison alone for allegedly disclosing what Petitioner labels limitation [1F] of Claim 1: “engaging the interventional device with a second portion of the clot material remaining within the blood vessel” after pre-charging a vacuum and then applying that vacuum to perform aspiration. Petition, pp.35-37. But Garrison does not disclose that limitation or render it obvious. Instead as detailed below, Garrison discloses treating *two separate occlusions* spaced apart from each other at *separate* treatment sites: “if a secondary more distal treatment site needs to be reached *after removal of a first occlusion*, a second, smaller diameter catheter may be inserted through the first catheter, and positioned at the distal treatment site.” EX1006, ¶[0166]; Petition, p.35 (emphasis in Petition); EX2005, ¶52.

Each of Petitioner's citations to Garrison misses the mark. The portions of Garrison Petitioner cites may disclose various devices that can be inserted in a

catheter (e.g., Garrison, ¶¶[0054], [0143]), devices for rotating within a catheter to prevent clogging within the catheter during aspiration (e.g., Garrison, ¶¶[0125]-[0126]), or devices that may be substituted in place of a catheter within a different “arterial access device” (e.g., Garrison, ¶¶[0165], [0166]). But none of Petitioner's citations to Garrison disclose or suggest the sequence or methodology recited in Claim 1, including aspirating a first portion of clot material before advancing and engaging an interventional device with a second portion of the clot material that remains in the blood vessel after aspiration. *See* EX2005, ¶¶53-57, 62, 63.

Petitioner also fails to demonstrate that Garrison discloses or renders obvious limitations [1B] and [1C], reciting steps of “pre-charging a vacuum in a pressure source” and “fluidly connecting the pressure source to the elongated shaft to apply the pre-charged vacuum to the elongated shaft to aspirate a first portion of the clot material into the elongated shaft.” EX1001, cl.1. Instead, as discussed below, Petitioner mixes separate, distinct, and incompatible embodiments in Garrison, but none disclose, and the combination does not render obvious, all the limitations of Claim 1 in the claimed arrangement.

Likewise, the Petition fails to demonstrate that the dependent claims are anticipated and/or obvious over the Petitioner's references. For example, Claim 18 recites the method of Claim 1 “wherein the method further comprises collecting at least some of the first portion of the clot material within a filter chamber *fluidly*

coupled between the pressure source and the elongated shaft.” EX1001, cl.18 (emphasis added). As explained herein, Garrison does not disclose that limitation in combination with the other limitations, and a POSA would not have modified Garrison, alone, or in view of any other reference, to include “a filter chamber” between “the pressure source and the elongated shaft” while also performing the steps of “pre-charging a vacuum in a pressure source” and then applying the stored vacuum. EX1001, cls.1, 18. In contrast, Garrison discloses a syringe attached to a flow controller and catheter without an intervening filter chamber, to apply a “maximum level of aspiration.” A POSA would have understood that including a filter chamber between a “pressure source and the elongated shaft” would have the lessened aspiration rather than enable Garrison’s intended “maximum level of aspiration.” Claims 19-29 depend on Claim 18 and are therefore patentable for this additional reason. And for Claim 10, Garrison, whether considered alone or in combination with the other cited references, does not disclose or suggest a method for intravascular treatment of clot material within a pulmonary blood vessel. EX2005, ¶77.

Accordingly, grounds 1-4 do not demonstrate that Claim 1 was anticipated or obvious. Grounds 5-14 pertain only to the dependent claims, so Grounds 5-14 fail for at least the same reasons as grounds 1-4, and for the additional limitations of the dependent claims (e.g., claims 10 and 18 discussed in additional detail below).

Petitioner has therefore failed to demonstrate that any of the Claims are unpatentable under any of grounds 1-14.

II. BACKGROUND

A. Overview of the '580 Patent

The '580 Patent is directed to improved clot treatment systems and methods for removing clot material from a blood vessel of a human patient. EX1001, 1:21-23. For example, in some embodiments, the systems and methods include aspiration of clot material followed by mechanical engagement with an interventional device to remove the clot material remaining after aspiration. EX1001, 3:46-49, 4:45-49, 21:41-52; EX2005, ¶37. The disclosed systems and methods are particularly well-suited for treating venous thromboembolism ("VTE"), a disease caused by blood clot formation in the veins of the body that is, unfortunately, a leading cause of both death and disease worldwide. EX1001, 1:31-65; EX2005, ¶30. Pulmonary embolism ("PE") and deep vein thrombosis ("DVT") are common and particularly dangerous types of VTE. *Id.* DVT is a type of blood clot that typically forms in the deep veins of a limb, such as the leg, and can develop into PE if portions of the clot break off and migrate to the pulmonary system. EX1001, 1:44-46; EX2005, ¶33. PE is a life-threatening condition that occurs when a clot breaks free and becomes lodged in the arteries of the lungs, blocking the oxygenation of blood necessary to sustain the entire body. EX1001, 1:55-65; EX2005, ¶33.

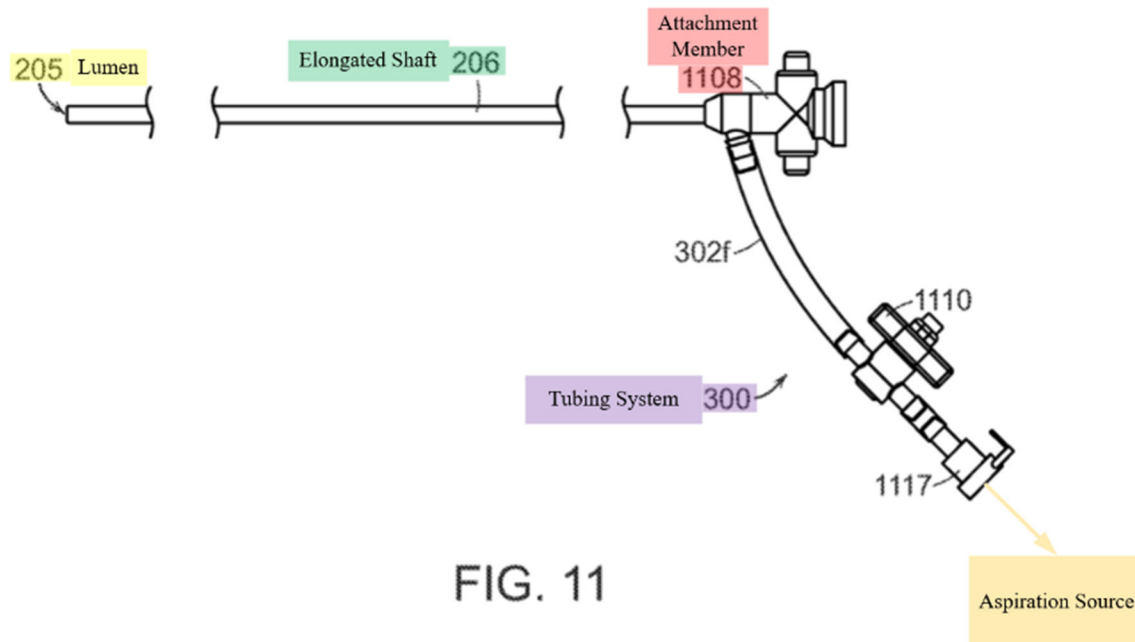
PE has traditionally been treated with drugs (thrombolytic agents) or invasive surgeries. EX1001, 2:24-29; EX2005, ¶34. However, those approaches have significant drawbacks. For example, thrombolytic agents do not always work, take hours or even days to be successful, can cause hemorrhage of the blood vessel, and cannot be used at all in many patients. EX1001, 2:26-29; EX2005, ¶¶35-36.

The sole independent claim—Claim 1—is directed to a method for the intravascular treatment of clot material with a blood vessel. EX1001, cl.1. The method includes steps of (i) “positioning a distal portion of an elongated shaft proximate to the clot material within the vessel,” (ii) aspirating some of the clot material by “pre-charging a vacuum in a pressure source” and then “fluidly connecting the pressure source to the elongated shaft to apply the pre-charged vacuum to the elongated shaft to aspirate a first portion of the clot material into the elongated shaft”, followed by (iii) engaging leftover clot material by “unsealing an attachment member coupled to a proximal portion of the elongated shaft” and “advancing an interventional device distally through the attachment member and the elongated shaft,” and then “engaging the interventional device with a second portion of the clot material remaining within the blood vessel.” *Id.*; EX2005, ¶37.

By pre-charging a vacuum, the method of Claim 1 can generate large suction forces (and corresponding fluid flow velocities) to effectively aspirate and remove all or a portion of the clot material from the patient. EX1001, 21:7-19; EX2005, ¶38.

If any of that same clot material remains within the blood vessel after aspirating (e.g., a strongly lodged or chronic portion of the clot material or particularly large clots), Claim 1 provides steps for deploying the interventional device, including “unsealing an attachment member coupled to a proximal portion of the elongated shaft,” “advancing an interventional device distally through the attachment member and the elongated shaft,” and then “engaging the interventional device with a second portion of the clot material remaining within the blood vessel.” EX1001, cl.1; EX2005, ¶39. The attachment member can be a user-actuatable hemostasis valve. EX1001, 17:46-18:67; EX2005, ¶40. In this manner, the interventional device treats a portion of the same clot that remains in the vessel after aspiration. EX2005, ¶39.

Figure 11 of the '580 Patent illustrates one example of a clot treatment system that can be used to carry out the method of Claim 1. EX2005, ¶40. The system includes a catheter 206 (e.g., an elongated shaft) having a distal portion configured to be positioned near clot material within a blood vessel and a proximal portion coupled to an attachment member 1108:



EX1001, 17:7-9; EX2005, ¶40. The attachment member 1108 can be a hemostasis valve structured to be selectively opened and closed to provide access to a lumen 205 of the catheter 206. EX1001, 17:46-18:67, FIGS. 13A-13B; EX2005, ¶40. The system can further include a tubing system 300 having a tube 302f fluidly connected to the lumen 205 of the catheter, a connector 1117 that can be connected to an aspiration source (not shown in Figure 11 but annotated above), and a stopcock 1110 for controlling flow (e.g., blocking or allowing flow) from the catheter 206 to the aspiration source. EX1001, 17:12-27; EX2005, ¶40.

The '580 Patent explains that a “syringe or other pressure source can be fluidly coupled directly to the connector 1117 and used to aspirate the guide catheter 206.” EX1001, 20:58-61. Accordingly, “opening of the stopcock 1110 fluidly connects the

syringe to the lumen 205 of the guide catheter 206 and closing of the stopcock 1110 fluidly disconnects the syringe from the lumen 205 of the guide catheter 206.” *Id.* at 20:61-65. The “syringe or other pressure source can be pre-charged with a vacuum—such as by drawing a plunger of the syringe with the stopcock 1110 closed” and the “stopcock 1110 can then be opened to instantaneously or nearly instantaneously (e.g., immediately) apply the stored vacuum pressure to the tubing system 300 and to the lumen 205 of the guide catheter 206, thereby generating suction throughout the guide catheter 206.” *Id.* at 20:65-21:5.

If a portion of the clot material remains in the blood vessel after a step of aspirating the catheter 206, the '580 Patent discloses further steps for introducing a mechanical interventional device: unsealing the attachment member 1108 to provide access to the lumen 205 of the catheter 206 by, for example, depressing one or more buttons of the attachment member (e.g., a hemostasis valve). *Id.* at 18:41-48; EX2005, ¶42. Then, advancing an interventional device through the catheter 206 to engage the remaining clot material as shown in, for example, Figures 2A-2G of the '580 Patent:

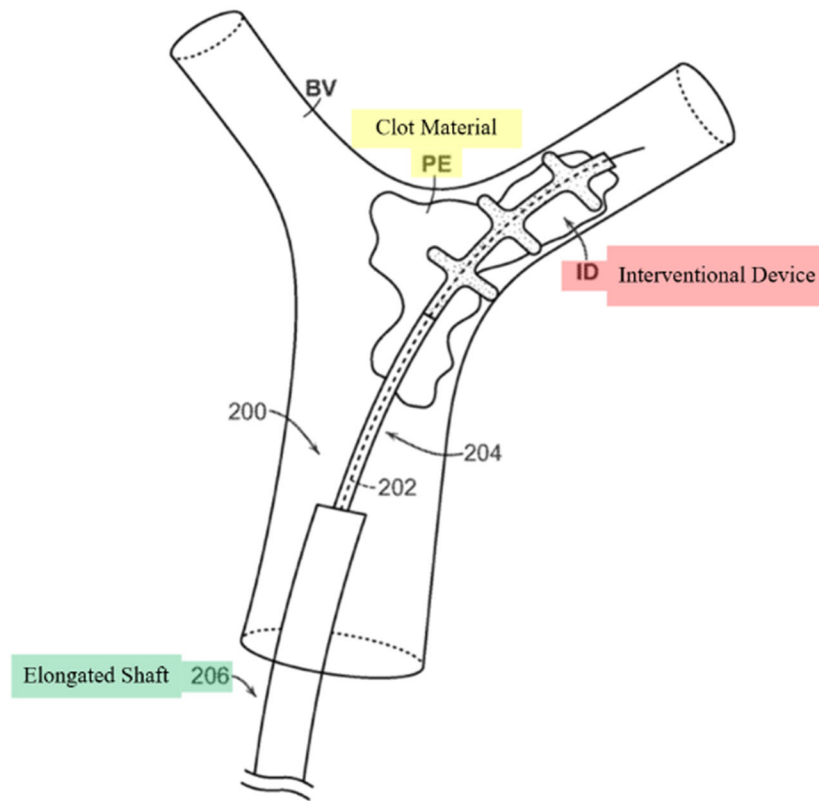


FIG. 2C

EX1001, 21:41-52; EX2005, ¶42. The interventional device can be retracted through the remaining portion of the clot material to physically engage and disrupt the clot material and/or pull all or a portion of it into the catheter 206:

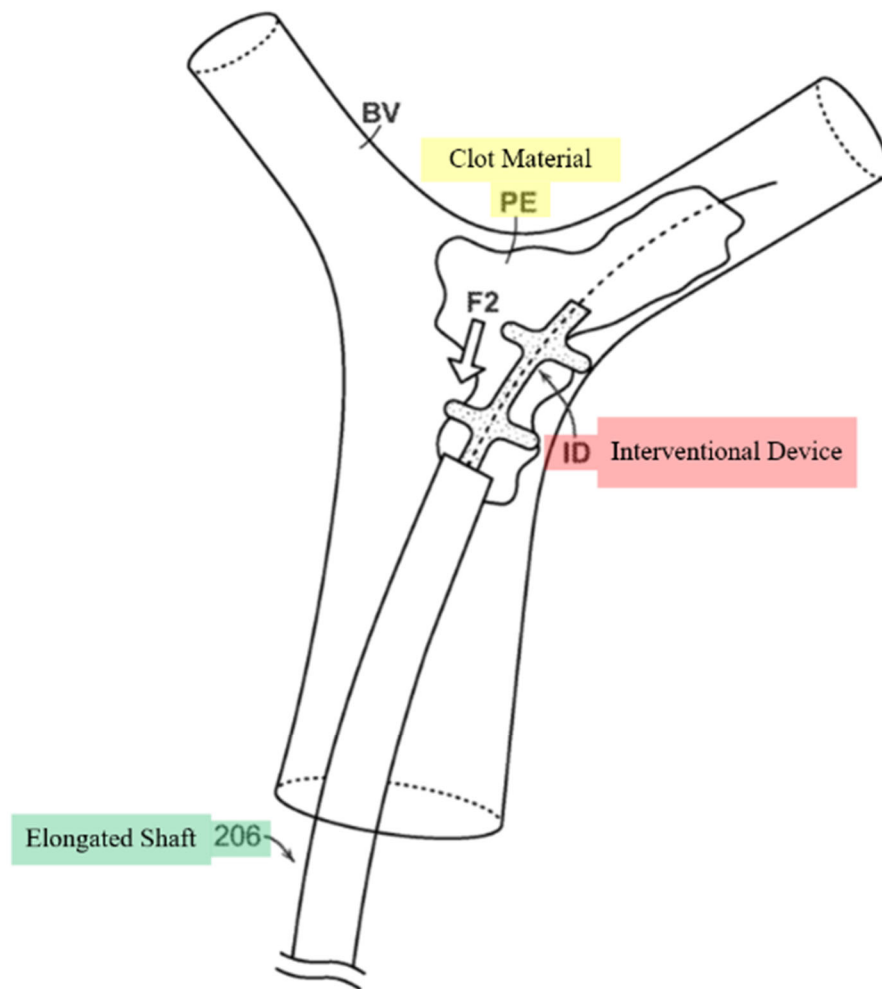


FIG. 2F

EX2005, ¶42. Accordingly, the methods claimed in the '580 Patent first utilize aspiration via pre-charged vacuum and then subsequent mechanical engagement with an interventional device to effectively remove and treat clot material such as PE and DVT. *Id.*

B. Prosecution History

In the sole Office action during prosecution of the '580 Patent, the Examiner

allowed independent claim 21 (which matured into Claim 1 of the '580 Patent), but rejected the other independent claim 32 as anticipated under 35 U.S.C. § 102(a)(1) over U.S. Patent Application No. 2015/0352325 (EX1009; "Quick"). EX1002, pp.1045-1047. The Examiner found independent claim 21 to be allowable over Quick because Quick did not disclose or suggest "the step of pre-charging the syringe then release valve 310 to apply vacuum to the clot material." *Id.* at p.1050.

In response to the Office action, Patent Owner canceled independent claim 32 and added new dependent claims 41-63 from allowable independent claim 21. *Id.* at pp.701-708. In the Notice of Allowance, the Examiner referred back to their statements of allowance in the Office action as grounds for allowing the claims. *Id.* at p.679.

C. Person of Ordinary Skill in the Art

A POSA as of January 26, 2018 (the earliest priority date of the '580 Patent) 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. *See* EX2005, ¶45.

Petitioner's proposed definition of a POSA omits the field of the invention of the '580 Patent and should be rejected. Specifically, petitioner proposes that a POSA would have "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, p.11.

First, there is no meaningful dispute regarding the field of the invention of the '580 Patent, namely, "devices and methods for the intravascular treatment of emboli and/or thrombi within a blood vessel of a human patient." EX1001, 1:21-23. Petitioner's purported expert, Mr. Thornton, agrees. Mr. Thornton testified that there is no difference between the field of the invention of the '580 Patent and that of related U.S. Patent No. 11,974,910 ("910 Patent"), and that the field of the invention for the '910 Patent (and correspondingly, the field for the '580 Patent) is "devices for aspirating unwanted material from a patient." EX2006, 21:25-22:12; 26:22-24; EX2009. He also confirmed that the recitation of "the present technology relates generally to systems, methods, and devices for the intravascular treatment of emboli and/or thrombi within a blood vessel of a human patient[,]" which is recited nearly verbatim in the '580 Patent (EX1001, 1:21-23), is a reasonable description of the technical field of the related '910 Patent, and is the same in substance to his assertion

that the field is “devices for aspirating unwanted material from a patient” set forth in his declaration. EX1003, ¶26; *see* EX2006, 22:23-23:20, 26:3-9 (“in my three declarations, we used the same sentence that the field is devices for aspirating unwanted material from a patient.”).

So, although Petitioner's proposed definition of a POSA includes a similar level of education, Petitioner's proposed POSA omits any experience in the field of the invention of the '580 Patent. Instead, Petitioner asserts that only “catheter design experience” is necessary, proposing that a POSA has “2-4 years of catheter design experience.” Petition, p.11. Petitioner's omission of experience in the field of the invention of the '580 Patent demonstrates an improper understanding of the '580 Patent, which is reflected in Petitioner's misunderstanding of at least limitation [1F], as discussed in detail below.

Moreover, Petitioner's purported expert, Mr. Thornton, has no experience in the field of the invention, which he characterizes as “devices for aspirating unwanted material from a patient (EX1003, ¶26) or which the '580 Patent describes as “devices and methods for the intravascular treatment of emboli and/or thrombi within a blood vessel of a human patient.” EX1001, 1:21-23. Mr. Thornton testified that:

[Q.] Have you ever designed a catheter to aspirate emboli, blood clot, or a thrombus from a patient?

[A.] No. The catheters that I developed, though, I would argue are more complex and have probably more design requirements than the single

lumen aspiration catheters that are disclosed in these patents.

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

[A.] No.

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

[A.] I'll answer no again.

EX2006, 49:24-50:10.

And, while Petitioner proposes in its definition that a POSA, "where necessary, would have consulted with a physician," Mr. Thornton testified that he did not do so in preparing his opinions in this matter, referring to preparation of his declaration for the related '910 patent as follows:

[Q.] And did you consult with any physician in preparing your declaration with respect to the '910 patent?

[A.] No.

[Q.] Did you rely on any statement from any physician in preparing your declaration with respect to the '910 patent?

[MR. BARNES:] Object to the form.

[THE WITNESS:] I don't believe so.

EX2006, 43:9-17.

Because Mr. Thornton's opinions are not based on the perspective of the correct POSA, and because Mr. Thornton has no experience in the field of the '580 Patent, he is not qualified as an expert in this proceeding and his testimony should

be afforded no weight.¹

D. The Testimony of Petitioner's Purported Experts Should be Afforded Little or No Weight.

Petitioner's purported expert testimony should be afforded little weight, and should not be credited over the testimony of Patent Owner's expert, Brian Brown. First as explained above, Petitioner's purported engineering expert, Mr. Thornton, fails to qualify as a POSA, let alone as an expert, because he has no experience in the field of the invention of the '580 Patent. EX2006, 49:24-50:10. As such, his testimony should be afforded no weight and should not be credited over the testimony of Patent Owner's expert.

Similarly, Petitioner's other purported expert Dr. Aquilla Turk's testimony should be afforded little weight and should not be credited over Patent Owner's expert. At deposition, Dr. Turk admitted that he did not review the '580 patent at all, let alone the Claims at issue here. EX2008, 33:12-22 (Q. "Do you know whether you reviewed U.S. Patent Number 12,016,580?" A. "Again, I seriously doubt it."). He

¹ Mr. Thornton's testimony should also be excluded from the record because he does not have the minimum experience required for a POSA in the field of the '580 Patent. *Kyocera Senco Indus. Tools Inc. v. Int'l Trade Comm'n*, 22 F.4th 1369, 1377 (Fed. Cir. 2022).

also stated that his declaration did not render an opinion regarding the patentability of the Claims. *Id.* at 34:7-35:7. He further testified that in preparing his declaration, he did not read the primary references Garrison, Aklog, or Laub. *Id.* at 69:7-11. Dr. Turk's testimony is not relevant to the '580 Patent's claims, the asserted references, or Petitioner's grounds here.

Moreover, Dr. Turk is also biased. At deposition Dr. Turk testified that he is the Chief Medical Officer (CMO) of Petitioner, receiving a compensation of \$250K per year and that he has "a lot" of equity in Petitioner. *Id.* at 13:18-15:9. Patent Owner has sued Petitioner for patent infringement of the '580 Patent. Paper 4, p.2. As such, Dr. Turk has a strong financial incentive in the success of Petitioner in general, and in particular, in the outcome of this IPR.

In direct contrast to Petitioner's purported experts, Patent Owner's expert, Brian Brown, is highly qualified to render testimony in this IPR, and that testimony should be credited over Petitioner's purported expert testimony. Specifically, Brian Brown is qualified as an expert in the field of the '580 Patent and has experience in designing devices in the actual field of the '580 Patent. EX2005, ¶¶7-16, 45.

E. Claim Construction

Petitioner proposes a claim construction for a single term, "filament," recited in dependent Claims 15-17. Petition, pp.11-13. This claim construction issue is not germane to Patent Owner's arguments here that focus on other aspects of the claims,

and it is therefore not necessary to analyze that claim term for this proceeding. Patent Owner has proposed an express definition in other pending IPR proceedings.

III. INDEPENDENT CLAIM 1 AND DEPENDENT CLAIMS 5, 9, 11-14, 18, 21-22, 24-28, 30, AND 33-34 ARE NOT ANTICIPATED BY GARRISON (GROUND 1)

Petitioner fails to demonstrate by a preponderance of evidence that any of Claims 1, 5, 9, 11-14, 18, 21-22, 24-28, 30, and 33-34 of the '580 Patent are anticipated by Garrison. Anticipation requires that “each and every element of the claimed invention” must be disclosed either explicitly or inherently and that the “elements must be arranged or combined in the same way as in the claim” in a single reference. *In re Gleave*, 560 F.3d 1331, 1334 (Fed. Cir. 2009).

A. Garrison does not disclose “engaging the interventional device with a second portion of the clot material remaining within the blood vessel”

The method of Claim 1 treats one instance of “clot material within a blood vessel.” EX1001, Cl.1. In one step of the method, which Petitioners label [1C]², “a first portion of the clot material” is aspirated, *then* in a subsequent step (limitation [1F]), the “interventional device” engages the remaining portion of the clot material, *i.e.*, the “second portion of the clot material.” *See, e.g.*, EX1001, FIGS. 2A-2G

² Use of Petitioner's nomenclature for claim limitations is for convenience only, and does not indicate concession of, nor agreement with, any of Petitioner's positions.

(illustrating removal of one clot in multiple “passes”). There can be no dispute that the claim language requires those steps in that order. Yet, Garrison fails to disclose at least limitation [1F]: “engaging the interventional device with a second portion of *the* clot material remaining within the blood vessel.” EX1001, cl.1 (emphasis added); EX2005, ¶49.

Accordingly, and consequently, Petitioner fails to demonstrate by a preponderance of evidence that Garrison discloses all the steps recited in Claim 1 and as arranged in Claim 1, including the step of engaging an interventional device with a second portion of a clot remaining in a blood vessel *after* aspirating a first portion of that same clot. EX2005, ¶51. Petitioner cites various portions of Garrison, but none of the cited portions disclose or suggest this step or sequence. Petition, pp.35-37. Instead, to the extent Garrison discloses any subsequent treatments after aspiration, such subsequent treatments are only for a *separate clot* at “a secondary more distal treatment site.” EX1006, ¶[0166] (“if a secondary more distal treatment site needs to be reached after removal of a first occlusion, a second, smaller diameter catheter may be inserted through the first catheter, and positioned at the distal treatment site.”); EX2005, ¶52.

Petitioner's position is that Garrison's catheter 2030 is the claimed “elongated shaft” in Claim 1. Petition, pp.18-19. Petitioner does not allege that anything else in Garrison meets limitation [1A]. *Id.* Petitioner then alleges that Garrison discloses

aspirating clot material into Garrison's catheter 2030. Petition, pp.21-22. Then, Petitioner asserts that various additional devices inserted through that catheter 2030 are the "interventional device" recited in Claim 1. Petition, pp.32-34. But, Garrison does not disclose that any of those additional devices engage "a second portion of *the* clot material remaining within the blood vessel" *after* the first portion of the clot material is aspirated as claimed. EX1001, Cl.1; EX2005, ¶51.

Specifically, Petitioner first alleges that Garrison discloses limitation [1F] based on its disclosure that "if a secondary more distal treatment site needs to be reached *after removal of a first occlusion*, a second, smaller diameter catheter may be inserted through the first catheter, and positioned at the distal treatment site." EX1006, ¶[0166]; Petition, p.35 (emphasis in Petition). But that describes treating a *separate* and *different clot* (a second occlusion) at a separate treatment site after removing a first clot, which Petitioner itself emphasizes ("*after removal of a first occlusion*"). EX2005, ¶52; Petition, p.35 (emphasis in Petition). Garrison's paragraph [0166] does not disclose using the second catheter to treat a remaining portion of the *same clot* after a first portion is aspirated. *Id.* Instead, Garrison discloses removing a first occlusion (clot) then treating a different, separate, and more distal clot. Accordingly, Garrison does not disclose treating a second (remaining) portion of the same clot material as required by Claim 1. *Id.*

Petitioner's ultimate conclusion that "Garrison describes engaging an

interventional device with a second portion of clot material” highlights Garrison’s deficiency and misrepresents Claim 1. By omitting “the” before “clot material,” Petitioner fails to acknowledge that Claim 1 requires engaging a second portion of *the* clot material, meaning the same clot material, a first portion of which was partially removed during aspiration. Petition, p.35. Accordingly, each of Petitioner’s citations to Garrison misses the mark. Petitioner’s citations to paragraphs [0054] and [0143] of Garrison at best demonstrate that Garrison discloses various devices that can be inserted through a catheter, but they do not disclose the methodology of Claim 1. EX2005, ¶53. Indeed, Petitioner vaguely asserts that “Garrison discloses many interventional devices including, for example, an expandable member deliverable through a microcatheter that can remove portions of a clot,” but that does nothing to address the sequence of aspirating of a first portion followed by engagement with a second portion of the same clot. Petition, p.35; EX2005, ¶53.

Turning specifically to Petitioner’s citation of Garrison’s paragraph [0143], Garrison’s thrombectomy device 15 shown in Figure 39 is “configured to remove an occlusion *as a single piece by not breaking the occlusion into multiple pieces*” to “minimize or eliminate the creation of emboli distal to the location of the clot.” EX1006, ¶[0143] (emphasis added). Removing the occlusion “as a single piece” is not what is recited in Claim 1 in which aspirating removes a first portion of the clot material, and then the interventional device engages a second portion of the clot

material remaining in the blood vessel. EX2005, ¶53.

Even if Garrison discloses accessory devices and a catheter 2030 that can be aspirated, that does not disclose the methodology recited in Claim 1 including aspirating a first portion of clot material before engaging an interventional device with a second portion of the clot material that remains in the blood vessel after aspiration. EX2005, ¶54. Petitioner argues that “Garrison solves the very problem the ’580 patent purportedly addresses - deploying separate devices to remove a clot” merely because Garrison incorporates “accessory devices, such as thrombectomy device 4100, into the system,” but this is also insufficient because the sequence in Claim 1 requires more. Petition, p.35. Claim 1 requires a specific sequence of steps—aspirating a first portion of a clot by applying a pre-charged vacuum and then removing a remaining portion of the clot by engaging it with an interventional device—which is not disclosed or rendered obvious by Garrison. Petitioner cites Garrison’s paragraph [0046] as a purported example, but this bare disclosure of “multiple attempts and/or adjunct mechanical thrombectomy devices” does not disclose or render obvious the sequence of steps in Claim 1. EX1006, ¶[0046]; EX2005, ¶54. Claim 1 requires first “advancing an interventional device distally through the attachment member and the elongated shaft” and then “engaging the interventional device with a second portion of the clot material remaining within the blood vessel.” EX1001, cl.1. Garrison’s paragraph [0046] discloses the use of an

adjunct mechanical device, but does not disclose whether the adjunct device is used prior, during, or after the initial aspiration or that the adjunct device is advanced through the attachment member and the elongated shaft. EX1006, ¶[0046]; EX2005, ¶54. The adjunct device of Garrison could travel beside (next to) the aspiration catheter or in another catheter. *Id.*

Petitioner also cites Garrison's paragraph [0166] to conclude "that the user can deploy these devices after aspirating a first clot portion" (Petition, p.35), but as explained above, Garrison's paragraph [0166] describes a process that is materially different from Claim 1's treatment of the *same* clot with aspiration and an interventional device: Garrison fully removes a first occlusion (clot) then treats a different, separate clot at a different location with a different catheter. EX1001, Cl.1; EX2005, ¶¶51, 52; EX1006, ¶[0166].

Finally, Petitioner cites Garrison's paragraphs [0125]-[0126], which also fail to disclose limitation [1F]. Petition, p.36. Rather, Garrison describes a catheter with a "structure for morcelating the thrombotic occlusion as it is being aspirated into the catheter," the structure having an "expandable distal segment" which is "positioned *inside the lumen*," and which is "expanded proximal to the distal tip of the catheter" (i.e., expanded *within* the catheter during aspiration). EX1006, ¶[0125] (emphasis added); EX2005, ¶55. Such a "thrombus disruption device 5105" stays within the catheter and may be "rotated throughout the aspiration step to ensure that the clot is

never clogging the distal tip of the catheter.” EX1006, ¶[0126], FIG. 53 (below); EX2005, ¶55. Accordingly, the device(s) Garrison describes in paragraphs [0125]-[0126] stays within the catheter during aspiration and Garrison has no description of or indication that the devices engage “clot material remaining within the blood vessel” after aspiration as required by Claim 1. Petition, p.36; EX2005, ¶¶55-56.

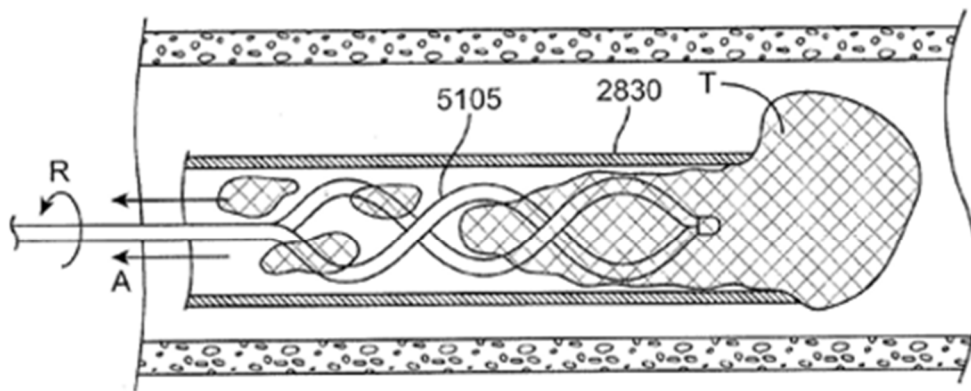


FIG. 53

Further, the Garrison device described in paragraphs [0125]-[0126] and shown in FIG. 53 cannot meet the requirements in Claim 1 of “engaging the interventional device with a second portion of the clot material remaining within the blood vessel” *after* the steps of “aspirate a first portion of the clot material into the elongated shaft,” “unsealing an attachment member” and “advancing [the] interventional device distally through the attachment member and the elongated shaft” because Garrison’s device is positioned within the catheter *before* aspiration and used *during* the aspiration treatment: “a separate thrombus disruption device

with an expandable distal segment is inserted into the catheter.... [a]spiration is *then* initiated at the proximal end of the catheter.” EX1006, ¶[0125] (emphasis added); EX2005, ¶55.

Because Garrison does not disclose “engaging the interventional device with a second portion of the clot material remaining within the blood vessel,” Petitioner has failed to demonstrate that the Claims are unpatentable over Garrison.

B. Garrison does not disclose “pre-charging a vacuum in a pressure source; fluidly connecting the pressure source to the elongated shaft to apply the pre-charged vacuum to the elongated shaft to aspirate a first portion of the clot material into the elongated shaft”

“[W]hen a reference discloses elements in different locations in the disclosure, the relevant question is whether the reference is sufficiently clear in disclosing the combinability of those elements such that a skilled artisan would ‘at once envisage’ the claimed combination.” *Chamberlain Grp., Inc. v. Techtronic Indus. Co.*, 935 F.3d 1341, 1350 (Fed. Cir. 2019) (the reference’s disclosure as to the combinability of the embodiments was “less than clear”). Here, Petitioner fails to demonstrate by a preponderance of evidence that limitations [1B] and [1C] are both disclosed in Garrison and arranged in the same way as in Claim 1. As explained below, a POSA would not have envisaged an embodiment in Garrison in which there is both “pre-charging a vacuum in a pressure source” ([1B]) and “fluidly connecting the pressure source to the elongated shaft to apply the pre-charged vacuum to the elongated shaft

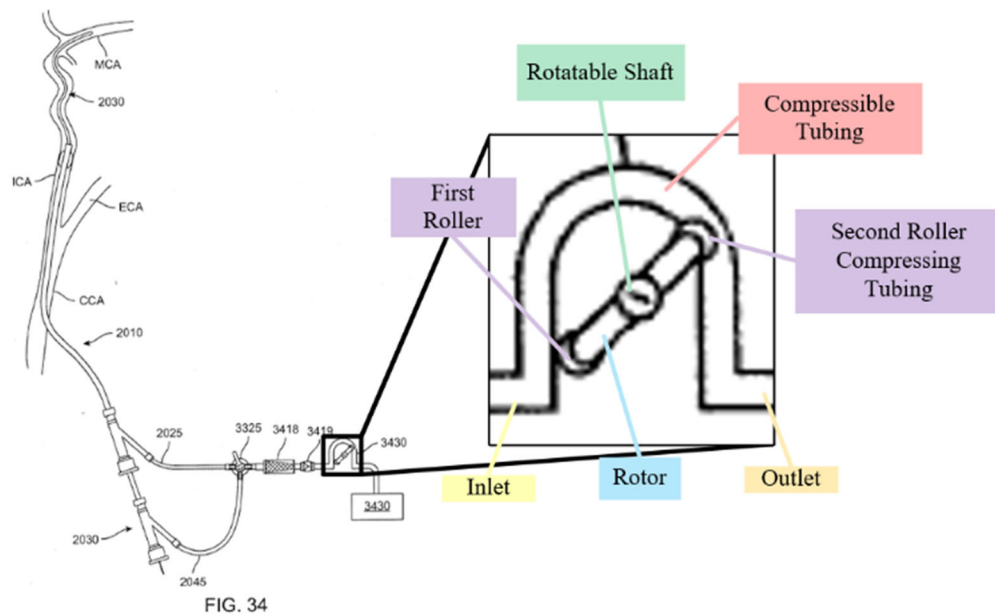
to aspirate....” ([1C]). EX1001, Cl.1. Rather, Petitioner's reading of Garrison cobbles together incompatible embodiments, without any clear link among them.

Specifically, Claim 1 recites “pre-charging a vacuum in a pressure source” ([1B]) **and** “fluidly connecting the pressure source to the elongated shaft to apply the pre-charged vacuum to the elongated shaft to aspirate” ([1C]). EX1001, cl.1. For connecting the pressure source, the Petition relies on a switching valve 3325 in Garrison's Figure 34, and for pre-charging the vacuum, the Petition relies on a separate and distinct embodiment mentioned in connection with Garrison's Figure 35. Petition, pp.20, 21. But Petitioner fails to connect those two (or more) disparate embodiments in a way that demonstrates that Garrison discloses both limitations [1B] and [1C] and all other limitations as arranged in claim 1.

Specifically, the valve 3325 is not used to pre-charge a vacuum as Petitioner alleges, but instead is used to control the connection of two different pathways (i.e., the arterial access device 2010 or the catheter 2030) to the same aspiration source 3340 (a peristaltic pump). EX1006, ¶[0132], FIG. 34; EX2005, ¶59. To attempt to resolve that deficiency in Garrison, Petitioner turns to a different embodiment described in paragraph [0134] to allegedly show the claimed pre-charge of vacuum. Petition, p.20. But that disclosure is for generating vacuum pressure with a *syringe*, rather than with a peristaltic *pump* as shown in Figure 34, and Garrison does not show any drawings of embodiments that include such a syringe. EX1006, ¶[0134];

EX2005, ¶59. Similarly, Garrison's disclosure of the rapid action associated with the syringe embodiment in paragraph [0134] does not teach using another type of aspiration source (e.g., a peristaltic pump, centrifugal, rotary, positive displacement, or other continuous pump) to create a vacuum. *Id.*; see EX1006, ¶[0134].

And for that embodiment, Garrison's stated objective is to "enable the maximum level of aspiration" with the syringe. EX1006, ¶[0134]. A POSA would have understood that a syringe includes a barrel in which a vacuum is generated when a plunger is withdrawn. EX1006, ¶[0134]; EX2005, ¶60. That barrel has a fixed volume with one opening for both input and output, and which both sets and limits the "maximum level of aspiration." *Id.* In contrast, the peristaltic pump in Garrison's Figure 34 (and centrifugal and other positive displacement pumps) does not have a fixed volume that provides a "maximum level of aspiration" but instead includes a rotor with rollers that compress and seal tubing to push material along, alternating the compression and relaxation of the tubing to draw material into the pump through an inlet and propel that material away from the pump through an outlet:



EX2005, ¶61.

Accordingly, a POSA would have understood that there is no fixed volume of the peristaltic pump or other continuous pumps (e.g., centrifugal and other positive displacement pumps that continuously shuttle fluid through a conduit) that can be evacuated like the fixed barrel volume of a syringe to store vacuum pressure. EX2005, ¶61. Accordingly, Garrison's syringe is not interchangeable with the pump in the embodiment Petitioner relies upon related to Figure 34 (and it is not disclosed as such). *Id.* Therefore, it is clear that the syringe concepts Petitioner relies upon are not associated with the valve 3325 and the other aspects of Figure 34. *Id.* Accordingly, Petitioner fails to demonstrate that Garrison discloses pre-charging a vacuum in a pressure source and fluidly connecting the vacuum to an elongated shaft, as required by Claim 1.

Critical to the failure of the Petition, Petitioner's mixing and matching of disparate embodiments cannot satisfy the requirements for anticipation under 35 U.S.C. § 102. Petitioner does not argue obviousness for either element [1B] or [1C].

For at least the foregoing reasons, Petitioner has failed to demonstrate by a preponderance of evidence that Garrison anticipates Claim 1. In particular, Petitioner fails to demonstrate that Garrison discloses an embodiment that anticipates limitations [1B] and [1C], "pre-charging a vacuum in a pressure source; fluidly connecting the pressure source to the elongated shaft to apply the pre-charged vacuum to the elongated shaft to aspirate a first portion of the clot material into the elongated shaft." EX1001, Cl.1; EX2006, ¶61. Likewise, no portions of Garrison, including those that Petitioner cites, disclose limitation [1F], which requires "engaging the interventional device with a second portion of the clot material remaining within the blood vessel." EX2005, ¶57. Instead, Garrison relates to treating two separate clots, or using unrelated devices in sequences that are materially different from the sequence in Claim 1.

Therefore, Claim 1 is not anticipated by Garrison. Dependent Claims 5, 9, 11-14, 18, 21-22, 24-28, 30, and 33-34 depend from independent Claim 1. Therefore, those claims are also not anticipated by Garrison because they incorporate all the features of independent Claim 1, and because of their additional features. For example, claims 18, 21-22, and 24-28 are addressed in further detail below.

IV. INDEPENDENT CLAIM 1 AND DEPENDENT CLAIMS 5-6, 9, 11-18, 21-30, AND 33-34 ARE NOT RENDERED OBVIOUS BY GARRISON ALONE (GROUND 2) OR IN COMBINATION WITH SCHAFFER (GROUND 3) OR HARTLEY (GROUND 4)

A claim is not obvious if a limitation of the claim is missing in the cited art. *See Aug. Tech. Corp. v. Camtek, Ltd.*, 655 F.3d 1278, 1290 (Fed. Cir. 2011) (finding that asserted claims are not rendered obvious in view of the cited prior art because they do not supply the missing element for purposes of obviousness analysis). Moreover, to demonstrate obviousness, Petitioner must provide a reason why a POSA would have been motivated to modify/combine the prior art to achieve the claimed invention. *Innogenetics, N.V. v. Abbott Labs.*, 512 F.3d 1363, 1374 (Fed. Cir. 2008); *see also Axonics, Inc. v. Medtronic, Inc.*, 73 F.4th 950, 957 (Fed. Cir. 2023) (“When an obviousness challenge asserts a combination of identified prior art, the motivation-to-combine portion of the inquiry is ‘whether a ‘skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention.’”).

Here, Garrison alone or in combination with Schaffer or Hartley does not render obvious at least limitation [1F] of independent Claim 1 of the '580 Patent (“*engaging the interventional device with a second portion of the clot material remaining within the blood vessel*”). EX2005, ¶¶63-69. Petitioner relies only on Garrison, and on no portion of Schaffer or Hartley, for allegedly rendering obvious

limitation [1F]. Petition, pp.35-37.

First, as explained above, Garrison alone fails to disclose limitation [1F]. Rather, for example, Garrison's disclosure relates to removing two separate clots at separate locations, Garrison's various additional devices do not address removal of a second portion of the same clot, and Garrison's morcellating technique using a "thrombus disruption device" only functions within a catheter itself and is in place before and used throughout aspiration. *See* §III, *supra*.

Attempting to resolve only some of these deficiencies in Garrison, Petitioner offers only one alleged motivation to modify Garrison, and that motivation is based on Petitioner's incorrect understanding of Garrison. Petition, p.36. For context, recall that Petitioner's position for Claim 1 is based on Petitioner's correlation of Garrison's catheter 2030 with Claim 1's "elongated shaft," and as Petitioner acknowledges, Garrison's "catheter 2030 is placed through the arterial access device 2010 or the guide catheter 2105." EX1006, ¶[0164], Petition, pp.18-19.

Turning to limitation [1F], Petitioner incorrectly asserts that Garrison's paragraph [0165] supports Petitioner's assertion that "a POSITA would have been motivated to engage the interventional device inserted through **catheter 2030** with the second clot portion," but Garrison's paragraph [0165] *does not disclose inserting any interventional device through the catheter 2030* (Petitioner's alleged "elongated shaft"), and Garrison's paragraph [0165] does not disclose removing a

second portion of clot material remaining after aspirating a first portion of that same clot material. Petition, pp.36-37 (emphasis added); EX2005, ¶66. Instead, Garrison's paragraph [0165] relates to deploying a device through the "arterial access device, or the guide catheter," *not* the aspiration catheter 2030. EX1006, ¶[0165]; EX2005, ¶¶66, 67. Indeed, Garrison's immediately preceding paragraph distinguishes catheter 2030 from arterial access device 2010: "catheter 2030 is placed through the arterial access device 2010." EX1006, ¶[0164]; EX2005, ¶66.

Petitioner's misunderstanding of Garrison is fatal to Petitioner's alleged motivation to modify Garrison. Specifically, Petitioner relies entirely on Garrison's vague disclosure in paragraph [0165] that if "it is not possible to remove the occlusion via aspiration alone," a "thrombectomy device 15 may be deployed through the *arterial access device* to remove the clot." Petition, p.36; EX1006, ¶[0165] (emphasis added). The phrase "it is not possible to remove the occlusion via aspiration alone" (EX1006, ¶[0165]), indicates that no first portion has been removed. EX2005, ¶66. Moreover, the arterial access device through which the thrombectomy device 15 is deployed is *not* the catheter 2030 that Petitioner alleges is the "elongated shaft" of Claim 1. *Id.* at ¶¶66, 67; *see* EX1006, FIG. 32 (below, showing the arrangement specified in paragraph [0165] in which a thrombectomy device is inserted through the arterial access device, and in which catheter 2030 is not shown). *Id.* at ¶66. Petitioner and its expert fail to acknowledge that difference.

In other words, Claim 1 requires what Garrison does not suggest: an “interventional device” to be advanced through “the elongated shaft” to which a pre-charged vacuum was previously applied. EX1001, cl.1.; EX2005, ¶68.

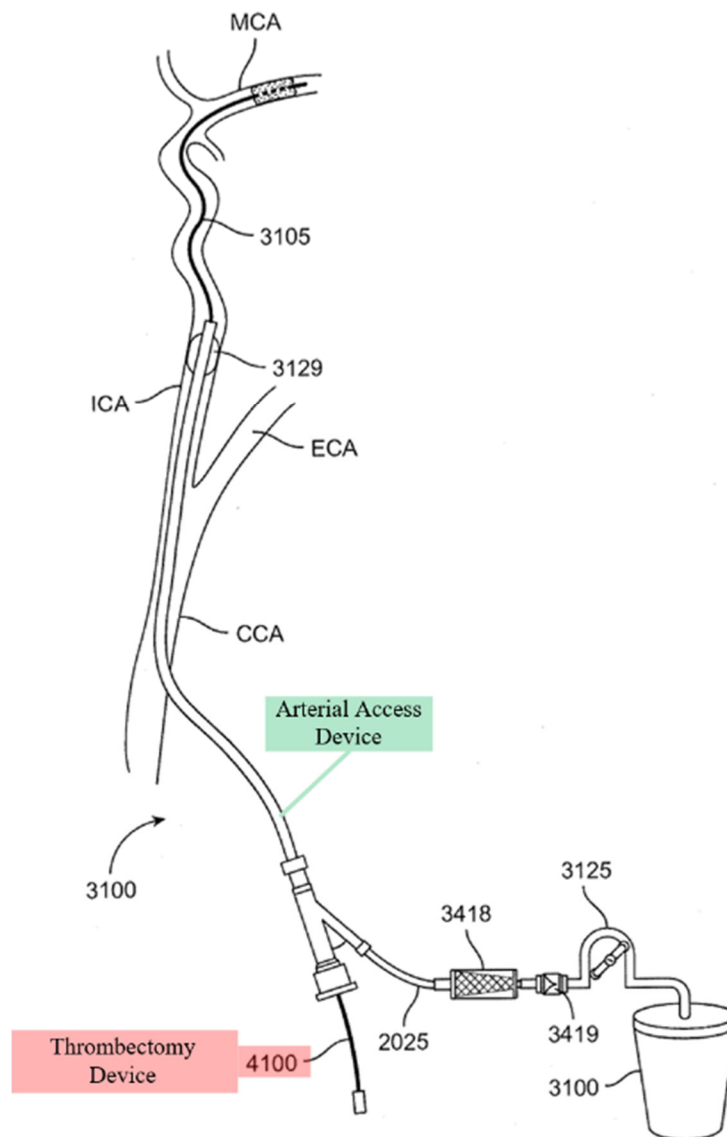


FIG. 32

Consequently, Petitioner does not explain why a POSA would have inserted a thrombectomy device through a different device (e.g., through the catheter 2030,

which is not even shown in Figure 32) than the device Garrison actually discloses for receiving the thrombectomy device (i.e., the arterial access device labeled 3129 in Figure 32, and labeled 2010 in Figures 33 and 34) or why a POSA would have inserted a thrombectomy device through that different device after aspirating a first portion of clot material in the manner required by Claim 1, instead Petitioner simply, and improperly, concludes that one would, without support.

To reiterate, the sole paragraph of Garrison ([0165]) that Petitioner cites for motivation in its obviousness argument discloses inserting a thrombectomy device through a different part of Garrison's system—the arterial access device 2010—and not the catheter 2030 that Petitioner alleges is the “elongated shaft” of Claim 1. EX2005, ¶67. Therefore, Petitioner has failed to demonstrate that a POSA would have been motivated “to engage the interventional device inserted through catheter 2030 with the second clot portion” as Petitioner alleges. *Id.*; Petition, pp.36-37. Grounds 2-4 fail at least for those reasons.

Accordingly, as explained above and in §III, no portion of Garrison cited by Petitioner discloses or suggests the methodology of Claim 1 including “engaging [an] interventional device with a second portion of the clot material remaining within the blood vessel” *after* aspirating a first portion of the clot material. EX2005, ¶68. And, a POSA would not have been motivated to modify Garrison to advance an interventional device through the catheter 2030 based on paragraph [0165] of

Garrison—the only portion of Garrison cited by Petitioner to support its obviousness assertions—because that paragraph discloses that if aspiration alone is insufficient to remove a clot a thrombectomy device can be inserted through the arterial access device 2010, not the catheter 2030. *Id.* Petitioner does not cite Hartley or Schaffer to attempt to resolve these deficiencies.

Petitioner does not rely on Schaffer or Hartley for those limitations. So, for at least the foregoing reasons, Garrison alone or in combination with Hartley and Schaffer fail to disclose or render obvious the method of Claim 1 including “engaging the interventional device with a second portion of the clot material remaining within the blood vessel.” Moreover, as noted above, Petitioner does not allege that limitations [1B] or [1C] are obvious. Dependent Claims 5, 6, 9, 11-18, 21-30, and 33-34 depend from independent Claim 1. Therefore, those claims are also not rendered obvious by Garrison alone or in combination with Hartley and Schaffer because they incorporate all the features of independent Claim 1, and for the additional features of those claims.

V. DEPENDENT CLAIMS 15-29 ARE NOT RENDERED OBVIOUS BY GARRISON IN COMBINATION WITH ANY OF SCHAFFER, HARTLEY, AND/OR GOFF (GROUNDS 5-8)

As set forth in §§III-IV above, independent Claim 1 is not anticipated by Garrison, not rendered obvious by Garrison alone, and not rendered obvious by Garrison in combination with Schaffer or Hartley. Dependent Claims 15-29 depend

from independent Claim 1. Petitioner does not allege that Schaffer and Hartley (ground 5; claims 15-17), Goff (ground 6; claims 18-22 and 24-28), Schaffer and Goff (ground 7; claims 18-29), or Hartley and Goff (ground 8; claims 18-22 and 24-28) disclose any of the limitations of independent Claim 1 discussed above, including limitation [1F]. Therefore, those dependent Claims are also not rendered obvious by Garrison in combination with Schaffer, Hartley, and/or Goff as explained above with respect to Claim 1 because they incorporate all the features of their independent Claim 1, and for the additional features of those claims.

VI. DEPENDENT CLAIMS 18, 21-22, AND 24-28 ARE NOT ANTICIPATED BY GARRISON (GROUND 1), AND DEPENDENT CLAIMS 18-29 ARE NOT RENDERED OBVIOUS BY GARRISON ALONE OR IN COMBINATION WITH ANY OF SCHAFFER, HARTLEY, AND/OR GOFF (GROUNDS 2-4, 6-8)

As set forth in §§III-V above, dependent claims 18, 21-22, and 24-28 are not anticipated by Garrison, and dependent claims 18-29 are not rendered obvious by Garrison alone or in combination with any of Schaffer, Hartley, and/or Goff, at least because these claims depend from independent claim 1.

Claim 18 depends from claim 1 and further recites: “[t]he method of claim 1 wherein the method further comprises collecting at least some of the first portion of the clot material within a filter chamber fluidly coupled between the pressure source and the elongated shaft.” EX1001, Cl.18. In other words, claim 18 requires, *inter alia*, a filter chamber located between “the pressure source and the elongated shaft.”

But, a POSA would have understood that Garrison does not teach or suggest an embodiment in which the filter 3418 (i.e., the alleged “filter chamber”) is used in connection with a pre-charged vacuum in the claimed location. EX2005 ¶72. As explained above in §III.B, Petitioner relies on Garrison alone for limitations [1B] and [1C] related to the pre-charged vacuum. And as explained above in §III.B, for connecting the pressure source ([1C]), the Petition relies on a switching valve 3325 in Garrison's Figure 34, but for pre-charging the vacuum in the pressure source ([1B]), the Petition relies on a separate and disparate embodiment, and Petitioner fails to connect those multiple disparate embodiments. Petition, pp.20, 21. Petitioner does not argue that the combination of separate embodiments in Garrison would have been obvious. Similarly, Petitioner relies solely on Garrison's filter 3418 to allege anticipation of claim 18, but the filter 3418 is exclusively part of the Figure 34 embodiment, not Garrison's paragraph [0134] (the syringe embodiment). *Id.* Petitioner does not connect these embodiments. Petition, pp.59, 60.

In fact, Garrison teaches away from using the filter 3418 in the syringe embodiment—which is required for Petitioner's allegations of a pre-charged vacuum in limitation [1B], and which is the only embodiment Petitioner relies upon for the pre-charged vacuum limitation. EX2005, ¶73. For the syringe embodiment, Garrison discloses that the syringe is “attached” to a flow controller, not via a filter and a check valve like the peristaltic pump embodiment in Figure 34. EX1006,

¶[0134]; EX2005, ¶73. Garrison discloses that arrangement for “the maximum level of aspiration.” *Id.*; EX1006, ¶[0134]. But a POSA would have understood that the intermediate filter 3418 and associated tubing of Figure 34 would increase the total volume relative to the direct connection, and thus prevent the maximum vacuum and level of aspiration, because removing the same volume of fluid (Garrison's syringe volume) from a larger volume (the filter 3418, tubing, etc.) rather than a smaller volume (the direct connection to the flow controller as Garrison teaches), results in less vacuum pressure. EX2005, ¶73. Specifically:

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

Id. Accordingly, the initial volume controls the final vacuum pressure such that Petitioner's purported arrangement with a syringe instead of the peristaltic pump in Figure 34 would generate less vacuum pressure and a correspondingly smaller “level of aspiration” than Garrison's disclosure of attaching the syringe to the flow controller. *Id.*

In other words, a POSA would not have understood Garrison's Figure 34 to include or relate to Garrison's syringe embodiment, so Figure 34 cannot be a basis for anticipation or obviousness of Claim 18, which requires both pre-charging a vacuum (Claim 1) and collecting clot material in a filter chamber (claim 18). *Id.*

For at least the foregoing reasons, Claim 18 is not anticipated by Garrison, nor rendered obvious by Garrison alone or in combination with any of Schaffer, Hartley, and/or Goff. Claims 21, 22, and 24-28 depend from claim 18. Petitioner does not allege that Schaffer and/or Hartley (grounds 3, 4, 7, 8) disclose any of the limitations of claim 18 discussed above. Therefore, those dependent Claims are also not rendered obvious by Garrison in combination with Schaffer, Hartley, and/or Goff as explained above with respect to Claim 18 because they incorporate all the features of Claim 18, and for the additional features of those claims.

VII. DEPENDENT CLAIM 10 IS NOT RENDERED OBVIOUS BY GARRISON IN COMBINATION WITH ANY OF LAUB, AKLOG, SCHAFFER, AND/OR HARTLEY (GROUNDS 9-14)

As set forth in §§III-IV above, independent Claim 1 is not anticipated by Garrison, not rendered obvious by Garrison alone, and not rendered obvious by Garrison in combination with Schaffer or Hartley. Dependent Claim 10 depends from independent Claim 1. Petitioner does not allege that Laub (ground 9), Aklog (ground 10), Laub and Schaffer (ground 11), Laub and Hartley (ground 12), Aklog and Schaffer (ground 13), or Aklog and Hartley (ground 14) disclose any of the limitations of independent Claim 1 discussed above, including limitation [1F]. Therefore, dependent Claim 10 is also not rendered obvious by Garrison in combination with Laub, Aklog, Schaffer, and/or Hartley as explained above with respect to Claim 1 at least because dependent Claim 10 incorporates all the features of independent Claim 1.

In addition, Claim 10 recites “[t]he method of claim 1 wherein the blood vessel is a pulmonary blood vessel.” EX1001, cl.10. In other words, Claim 10 relates to treating pulmonary embolism (PE). EX2005, ¶76. Petitioner alleges that “Garrison discloses this claim,” but Petitioner fails to cite any evidence of such disclosure. Petition, p.81. Instead, Petitioner acknowledges that Garrison’s system is for “treatment of cerebral occlusions.” EX1006, ¶[0002]; Petition, p.81. Accordingly, Garrison does not disclose a method for intravascular treatment of clot material within a pulmonary blood vessel. EX2005, ¶77.

Cerebral occlusions and the vessels in which they reside within the brain are materially smaller than occlusions in pulmonary vessels, so a POSA would not have considered using Garrison’s system in a method to treat an occlusion in a pulmonary vessel. EX2005, ¶78. Despite Garrison’s incompatibility with treatment of PE, Petitioner turns to each of Laub and Aklog to argue that it would have been “obvious to use and optimize Garrison’s clot treatment system for PE.” Petition, p.81. But a POSA would not have found it obvious to use or modify Garrison, based on Laub or Aklog, for use in a method for treating PE. EX2005, ¶¶78-81. Petitioner does not cite Schaffer or Hartley for any aspect of Claim 10.

Petitioner asserts that each of Laub and Aklog discloses a system for removing clots from patients suffering from PE. Petition, pp.81,82. Petitioner attempts to draw similarities among Garrison, Laub, and Aklog by asserting they all disclose “similar”

procedures and “the same general components,” including inserting a catheter into the leg, and generating suction. Petition, pp.83-84. Petitioner misleadingly suggests that each of Garrison, Laub, and Aklog “using a syringe or pump,” but Laub and Aklog do not disclose a syringe. Petition, pp.83-84 (citing portions of Laub and Aklog that only suggest a pump). On those mere similarities, Petitioner baselessly speculates that “using Garrison’s system to treat PEs would have been nothing more than the predictable use of prior art elements according to their established function.” Petition, p.84. But, as explained above, a POSA would not have modified Garrison’s system to arrive at independent claim 1, so simply using Garrison’s system to treat PE would not disclose Claim 10.

Petitioner further suggests that Garrison’s system could simply be enlarged to treat PE based on, for example, “similarities” with “clots in other parts of the body.” Petition, pp.85-86, 88-89. Again, that modification still does not meet all the claim limitations and thus does not render Claim 10 obvious for the reasons set forth above.

Moreover, it would not have been obvious to increase the size of Garrison’s components for use in a method of treating PE. EX2005, ¶79. Specifically, a POSA would not have modified Garrison as Petitioner asserts (i.e., in a method of treating PE) because Petitioner’s references recognized that reintroducing blood to the patient is critical to patient health and safety when treating large clots like PE in large vessels with high blood flow volumes, and Garrison expressly discloses that the

embodiments relied on by Petitioner are not suitable for blood reintroduction. EX2005, ¶80.

For example, omitting substantially continuous blood return “could quickly result in exsanguination of the patient” (EX1012, ¶[0045]) and/or lead to “occurrences of fluid loss and/or shock” (EX1011, 5:19-23). EX2005, ¶80. And the embodiment of Garrison relied on by Petitioner in Figure 34 and paragraph [0134] (the syringe embodiment) is not suitable for returning blood. EX1006, ¶[0135] (“One disadvantage of current sources of aspiration is that the aspirated blood is received into an external reservoir or syringe. This blood is generally discarded at the end of the procedure, and as such represents blood loss from the patient.”); EX2005, ¶80. In particular, in Garrison, blood is pumped to a receptacle 3420 in Figure 34 or received in a syringe in the disparate embodiment in paragraph [0134] and, in both cases, remains “static” and/or is “exposed to air” such that it is not suitable for blood return. EX1006, ¶[0135]. EX2005, ¶80.

Accordingly, a POSA would have understood that in each embodiment of Garrison relied on by Petitioner the aspirated blood is not suitable for blood return and should be “discarded at the end of the procedure.” EX1006, ¶[0135]; EX2005, ¶80. For at least that reason, a POSA would not have found it obvious to modify Garrison in the first instance let alone use that modified Garrison to treat PE, because Laub and Aklog each emphasize the critical nature of blood return for patient health

when treating large clots in large vessels like pulmonary vessels suffering from PE—and the embodiments of Garrison relied on by Petitioner are not suitable for reintroducing blood to a patient. EX2005, ¶¶80-81. As such, a POSA would not have optimized Garrison's system to treat PE in a manner not disclosed by Garrison and in a manner discouraged by all three of Garrison, Laub, and Aklog. *Id.*

To try to address issues with blood return, Petitioner turns to yet another incompatible embodiment in Garrison, citing an “aspiration pump device 3250” in Garrison's Figure 36, which “may be configured to return blood to the central venous system *in real time* during the procedure, so there is no reservoir in which the blood remains static.” EX1006, ¶[0136] (emphasis added); Petition, pp.89-90. But this device is incompatible with the other embodiments Petitioner tries to mix and match together, and Petitioner fails to connect these disparate embodiments.

Specifically, Garrison's Figure 36 illustrates the aspiration pump device 3250 connected to either or both of the flow lines of the arterial access device or smaller inner catheter and having a chamber 3220 connected to a vacuum source 3230, which is configured to generate (1) negative pressure in the chamber 3220 to cause the expandable portion 3210 of the flow line 2025 to expand to draw blood into the expandable portion 3210 through the upstream one-way check valve 3235 and (2) subsequent normalized pressure in the chamber 3220 to permit the expandable

portion 3210 to contract to expel blood from the expandable portion 3210 through the downstream one-way check valve 3235:

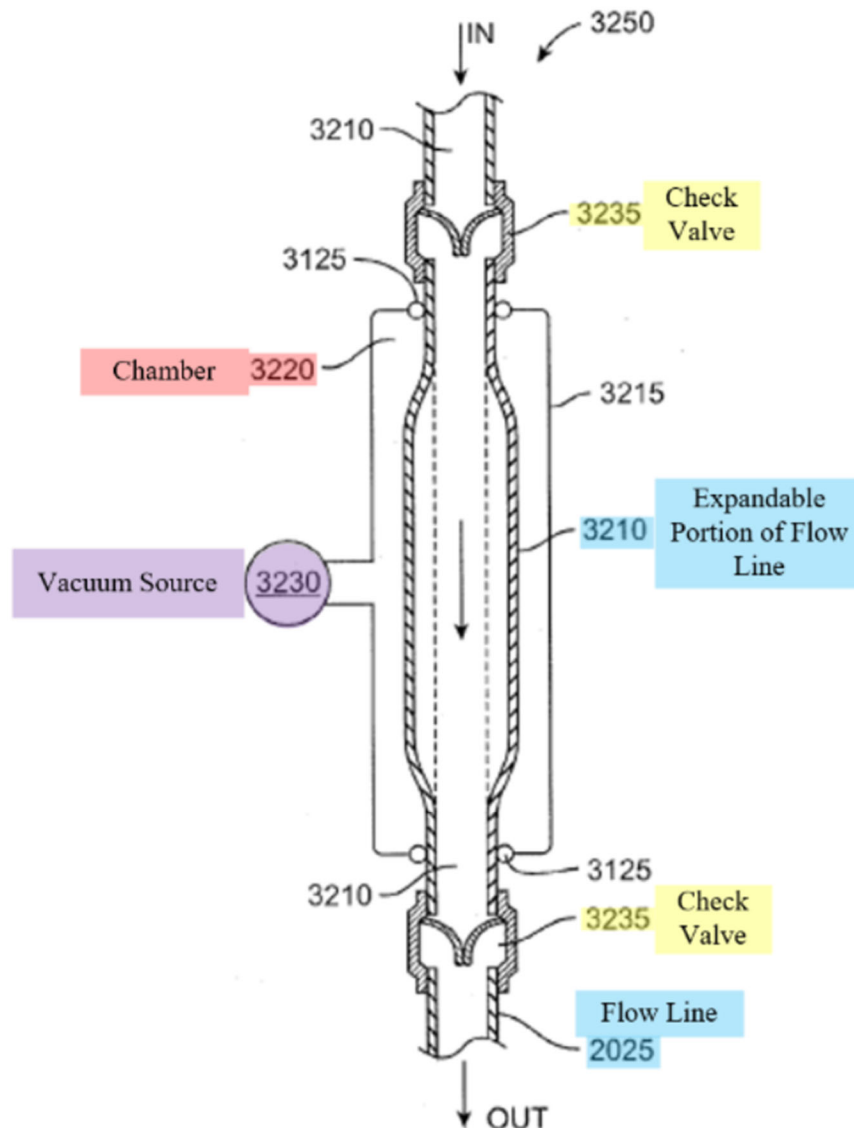


FIG. 36

EX2005, ¶82; EX1006, ¶¶[0136]-[0137]. That is, in this different/alternative embodiment of Garrison, the pump device operates to “return blood to the central

venous system in real time” by operating the vacuum source to oscillate the expandable portion between the expanded and retracted states to, together with the one-way check valves, thereby drive fluid through the flow line. *Id.*

A POSA would have understood that the pump device in Figure 36 of Garrison is to be used in a system *without* what Petitioner characterizes as a “fluid control device” (i.e., the valve 3325, *see* Petition, p.34), in direct contrast with the embodiment Petitioner relies on in Figure 34 to provide the alleged pre-charging function of limitation [1B], because blood in the Figure 36 device is continuously aspirated and reinfused in *real time* to prevent the blood from remaining static so it can be returned to the patient. EX2005, ¶83. Blood return would not be continuous/real time and blood would remain static if a “fluid control device” were included in Garrison’s system and closed to create a vacuum, as Petitioner requires in its arguments against limitations [1B] and [1C] of Claim 1 relating to pre-charging a vacuum. *Id.*

Likewise, Laub and Aklog also disclose continuous aspiration/blood return. *Id.* at ¶84. EX1012, ¶[0045] (“reinfusing the patient’s blood continuously during aspiration allows for greater suction pressure and/or flow rates (e.g., 2-4 L/min) which can assist in dislodging and removing larger clots and/or tumors than would otherwise be possible”); EX1011, 5:19-23 (Aklog’s system “simultaneously reinfuse[s] aspirated (i.e., removed) and filtered fluid, such as blood, back into the

patient on a substantially continuous basis to minimize any occurrences of fluid loss and/or shock”).

Thus, each of Garrison, Laub, and Aklog need continuous aspiration and re-infusion when blood is returned to the patient without, and separate from, “pre-charging a vacuum in a pressure source” and “fluidly connecting the pressure source to the elongated shaft to apply the pre-charged vacuum to the elongated shaft to aspirate a first portion of the clot material into the elongated shaft” as required in Claim 1. EX1001, Cl.1; EX2005, ¶85. It follows that a POSA would have understood such continuous systems to be incompatible with the pre-charged vacuum aspect of independent Claim 1, which is required by dependent Claim 10. Garrison, Laub, and Aklog teach away from Claim 10. *Id.*

Petitioner simply asserts that “Garrison already accounts for one challenge POSITAs encountered when using larger aspiration catheters – a larger catheter ‘may aspirate an unacceptable volume of blood, resulting in excessive fluid loss and/or shock in the patient’” based on the embodiment in Figure 36 of Garrison. Petition, pp.89-90. But, as explained above, the embodiment of Figure 36 is fundamentally different than the embodiments in Figure 34 and paragraph [0134] of Garrison relied on by Petitioner, in which blood is unsuitable to be returned. Moreover, a POSA would have understood the embodiment in Figure 36 not to include the valve Petitioner relies upon to meet limitations [1B] and [1C]. EX2005, ¶86.

Accordingly, Petitioner has not demonstrated by a preponderance of evidence that Claim 10 is invalid. Instead, for at least the foregoing reasons, Claim 10 is patentable over Garrison, Laub, Aklog, Schaffer, and Hartley, whether considered alone or in combination.³

VIII. CONCLUSION

Petitioner failed to establish by a preponderance of evidence that the Claims of the '580 Patent are unpatentable. Accordingly, for each of the above reasons, Patent Owner respectfully requests that the Board find all the Claims patentable.

Respectfully submitted,

Dated: March 12, 2026

By: / Joseph P. Hamilton /
Joseph P. Hamilton
Reg. No. 51,770
Lead Counsel for Patent Owner

³ Petitioner's heading on page 81 of the Petition also lists Goff, but Petitioner does not discuss Goff in connection with Claim 10, and Petitioner's listing of asserted grounds on page 14 does not include Goff in any of grounds 9-14.

CERTIFICATE OF COMPLIANCE

Pursuant to 37 C.F.R. § 42.24(d), I, Joseph P. Hamilton, certify that **PATENT OWNER'S RESPONSE** contains 10,113 words, excluding those portions identified in 37 C.F.R. § 42.24(a), as measured by the word-processing system used to prepare this paper.

Dated: March 12, 2026

By: / Joseph P. Hamilton /
Joseph P. Hamilton
Reg. No. 51,770

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), I certify that on March 12, 2026, a copy of **PATENT OWNER'S RESPONSE and Exhibits 2005-2009** were served upon the below-listed counsel by electronic mail:

Joshua J. Stowell
2jys@knobbe.com
Joseph R. Re
2jrr@knobbe.com
Brian C. Barnes
2bcb@knobbe.com
BoxImperative580@knobbe.com

Dated: March 12, 2026

By: / Kate Rose /
Kate Rose