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Paper: 15
Date: December 11, 2025

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

IMPERATIVE CARE, INC.,
Petitioner,

v.

INARI MEDICAL, INC.,
Patent Owner.

IPR2025-01021
Patent 11,969,333 B2

Before JEFFREY N. FREDMAN, ERIC C. JESCHKE, and TIMOTHY G. MAJORS, *Administrative Patent Judges.*

MAJORS, *Administrative Patent Judge*.

DECISION
Granting Institution of *Inter Partes* Review
35 U.S.C. § 314

Imperative Care v. Inari Medical
IPR2025-01025
Imperative Care Ex. 1060

I. INTRODUCTION

Imperative Care, Inc. ("Petitioner") filed a Petition (Paper 1, "Pet.") requesting *inter partes* review of claims 1–12, 14–31, and 33–38 of U.S. Patent No. 11,969,333 B2 (Ex. 1001, "the '333 patent"). Pet. 1, 15–16. Inari Medical, Inc. ("Patent Owner") filed a Preliminary Response (Paper 8, "Prelim. Resp."). The Director (or his delegate) rejected Patent Owner's request for discretionary denial and referred the Petition to the Board. Paper 11. With our permission, Petitioner filed a Reply to Patent Owner's Preliminary Response (Paper 13, "Prelim. Reply") and Patent Owner filed a Preliminary Sur-reply (Paper 14, "Prelim. Sur-reply").

Under 35 U.S.C. § 314(a), an *inter partes* review may not be instituted unless it is determined that there is a reasonable likelihood that the petitioner will prevail with respect to at least one of the claims challenged in the petition. For reasons explained below, we conclude that Petitioner shows a reasonable likelihood that it will prevail with respect to at least one of the '333 patent's challenged claims. We institute *inter partes* review on all challenged claims and on all asserted grounds. *SAS Inst. Inc. v. Iancu*, 584 U.S. 357, 362–63 (2018); 37 C.F.R. § 42.108(a) ("When instituting *inter partes* review, the Board will authorize the review to proceed on all of the challenged claims and on all grounds of unpatentability asserted for each claim.").

Findings and conclusions at this stage are preliminary and based on the current record. Any final decision will be based on a full trial record.

II. BACKGROUND

A. Real Parties-in-Interest

Petitioner identifies itself as the real party-in-interest. Pet. 90. Patent Owner identifies itself as the real party-in-interest, and represents that it is a wholly-owned subsidiary of Stryker Corporation. Paper 3, 2.

B. Related Matters

The parties identify the following lawsuit involving assertion of the ’333 patent (and additional patents): *Inari Medical, Inc. v. Imperative Care, Inc.*, No. 24-cv-3117 (N.D. Cal.).[1] Pet. 90–91; Paper 3, 2.

The parties inform us that, in the above-noted lawsuit, the district court recently denied Patent Owner’s motion for a preliminary injunction concerning a related patent (U.S. Patent No. 11,974,910 (“the ’910 patent”)). Prelim. Reply 1 (noting the ’910 and ’333 patents share a specification); Ex. 1055 (order denying motion for preliminary injunction)). In its order, the court found that Petitioner raised “substantial questions as to the validity” of the ’910 patent’s claims based on some of the same prior art (i.e., Garrison combined with Laub) asserted in this IPR. Ex. 1055, 17–22 (finding Patent Owner “has not shown that these [validity] challenges lack substantial merit”). Petitioner argues the court’s order confirms the merits of Petitioner’s challenge in this IPR, while Patent Owner argues the order is irrelevant because it is based on different evidence under a different standard. Prelim. Reply 1–2; Prelim. Sur-Reply 1–2. Although we have considered the court’s denial of the motion for preliminary injunction, our

[1] Patent Owner further states that *Inari Medical, Inc. v. Inquis Medical, Inc.*, No. 24-1023-CFC (D. Del.) involves other patents that “are not related by priority to the involved ’333 Patent but may involve related issues.” Paper 3, 2.

decision to institute trial is based on the argument and record before us. In any event, we perceive no inconsistency between the court's determination and our decision here that would warrant a further explanation at this time.

The parties also identify related matters before the Board. Pet. 90–92 (listing matters including, *inter alia*, IPR2024-01157 and IPR2024-01257); Paper 3, 2–3.[2] *Id.* One day after the filing of the present Petition, Petitioner also filed a Petition in IPR2025-01025 ("the 1025 IPR") challenging claims of the '910 patent, and we institute trial in the 1025 IPR concurrent with this Decision.[3]

Patent Owner further identifies several other patents and patent applications as related by priority to the '333 patent. Paper 3, 4.

C. The '333 Patent (Ex. 1001)

The '333 patent is titled "System for Treating Embolism and Associated Devices and Methods." Ex. 1001, code (54). The patent issued April 30, 2024, from an application filed June 5, 2023. *Id.* at codes (22), (45). The earliest application to which the '333 patent claims priority is a provisional application filed August 13, 2018. *Id.* at code (60).

According to the '333 patent, 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." *Id.* at 1:23–26. "[S]ome embodiments of the present technology relate to systems

[2] We previously instituted trial in five related cases (IPR2024-01157; IPR2025-00156; IPR2025-00289; IPR2025-00728; IPR2025-00989). Those cases remain pending. We denied institution in IPR2025-01257.

[3] The '333 and '910 patents issued from sibling continuation applications, sharing the same parent (Application No. 18/167,757). Ex. 1001, code (63).

for releasing stored vacuum pressure to aspirate clot material from a blood vessel." *Id.* at 1:26–28.

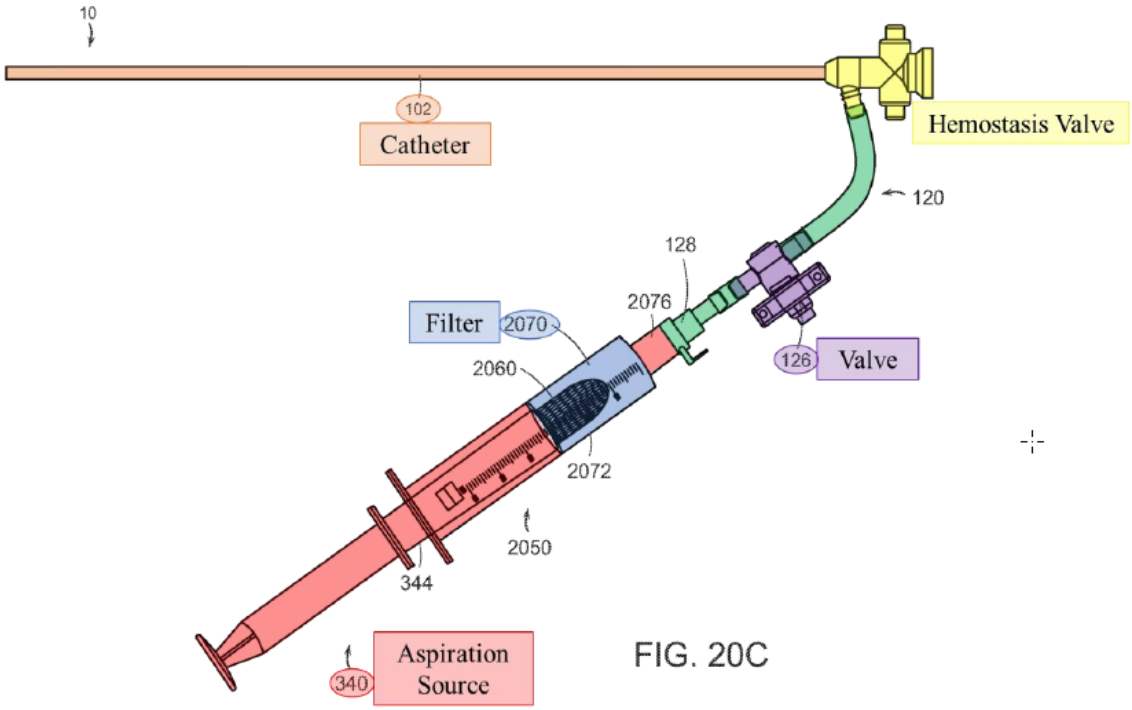
As background, the '333 patent explains that "[t]hromboembolic events are characterized by an occlusion of a blood vessel," which can lead to disorders "such as stroke, pulmonary embolism, heart attack, [and] peripheral thrombosis." *Id.* at 1:32–35. Such "disorders are a major cause of morbidity and mortality." *Id.* at 1:35–37.

Thromboembolic events may develop in arterial or venous circulation. When an artery is occluded by a clot, tissue ischemia may lead to tissue infarction and even death unless "the flow of blood is reestablished rapidly." *Id.* at 1:38–44. "In the venous circulation, occlusive material can also cause serious harm," such as "deep vein thrombosis (DVT)," a condition where clots develop in the large veins of the legs or pelvis, obstructing blood drainage, leading to swelling, ulcers, pain, and infection. *Id.* at 1:45–53. Clots related to DVT can also "travel to other parts of the body including the heart, lungs, [and] brain (stroke)." *Id.* at 1:53–56. In addition, "[i]n the pulmonary circulation, the undesirable [clot] material can cause harm by obstructing pulmonary arteries—a condition known as pulmonary embolism [(PE)]." *Id.* at 1:57–59. Such obstructions can, for example, restrict gas exchange between the blood and lungs "resulting in low blood oxygen and buildup of blood carbon dioxide." *Id.* at 1:59–67.

The '333 patent states that there "are many existing techniques to reestablish blood flow through an occluded vessel." *Id.* at 2:1–2. According to the patent, such techniques include, embolectomies (surgical excision of a clot), balloon angioplasty (percutaneous inflation of a balloon to dilate a stenosis in a vessel), and use of thrombolytic agents to dissolve clots. *Id.* at

2:2–32. However, the patent states, "there exists a need for improved systems and methods for embolic extraction." *Id.* at 2:45–46.

Figure 20C of the '333 patent is reproduced below, with annotations provided by Petitioner.



Pet. 2 (reproducing Fig. 20C of the '333 patent with annotations).

Figure 20C above is a schematic side view of an example clot removal system from the '333 patent. Ex. 1001, 3:60–61, 32:23–43 (describing aspects of Figure 20C), Fig. 20C. The depicted system includes a catheter 102 (colored orange), a hemostasis valve (unnumbered, colored yellow) a fluid control device 126 (labeled "Valve" and colored purple), a tubing subsystem 120 (colored green), filter 2060 in barrel portion 2070 (labeled "Filter" and colored blue), and a pressure source (labeled "Aspiration Source" and colored red), here depicted as a syringe 340. *Id.* at 32:23–43.

The '333 patent explains that the system's fluid control devices can be, for example, a stopcock. *See, e.g.*, Ex. 1001, 6:6–47 (disclosing fluid

control device may be, for example, a stopcock or a clamp that "is externally operable by a user to regulate the flow of fluid therethrough and, specifically, from the lumen . . . of the catheter . . . to the pressure source"). The patent discloses that the pressure source may comprise a "pump" or a "syringe." *Id.* at 7:33–41 ("In general, the pressure source can be any suitable source or combination of sources for generating and/or storing negative pressure."). The '333 patent states that the system may include hemostasis valves like described in U.S. Application No. 16/117,519 (Ex. 1021 in this proceeding), which application the patent states is "incorporated herein by reference in its entirety." *Id.* at 5:56–61.

The '333 patent describes a process for operating a clot removal system. *See, e.g.*, *id.* at 16:30–17:9, Fig. 8 (flow diagram of process). That process may include, *inter alia*, the following steps: positioning a distal portion of a catheter proximate to clot material within a blood vessel; coupling a pressure source (e.g., a syringe or pump) to the catheter via a fluid control device (e.g., stopcock); activating the pressure source to generate a vacuum while the fluid control device is closed; opening the fluid control device to apply the vacuum to the catheter to thereby aspirate at least a portion of the clot material into the catheter; and removing the catheter from the patient (or repeating the steps as necessary). *Id.* at Fig. 8; *see also id.* at Figs. 9A–9C, 10A–B (illustration of a vacuum being generated and applied to aspirate a portion of a clot), 19:51–20:2 (disclosing that the steps at blocks 802–808 of Fig. 8 can be repeated until a desired amount of the clot is removed).

D. Illustrative Claims

Petitioner challenges claims 1–12, 14–31, and 33–38. Claims 1 and 20 are the challenged independent claims. Claim 1 is illustrative and reads:

> 1. A method of treating a pulmonary embolism within a vasculature of a patient, the method comprising:
>
> advancing an aspiration catheter at least partially through the vasculature of the patient such that a distal end portion of the aspiration catheter is positioned proximate to the pulmonary embolism, wherein a lumen of the aspiration catheter is fluidly coupled along a fluid path to a clot canister and an aspiration source proximal to the clot canister;
>
> generating vacuum pressure within the clot canister via the aspiration source while a valve positioned along the fluid path between the aspiration catheter and the clot canister is in a first position that inhibits fluid flow along the fluid path from the lumen of the aspiration catheter to the clot canister; and
>
> moving the valve from the first position to a second position thereby applying the vacuum pressure to the lumen of the aspiration catheter such that at least a portion of the pulmonary embolism and blood are aspirated into the clot canister, wherein in the second position the valve permits fluid flow along the fluid path from the lumen of the aspiration catheter to the clot canister, and wherein the clot canister includes a filter configured to filter the blood from the portion of the pulmonary embolism.

Ex. 1001, 35:51–36:8. Independent claim 20 is similar to claim 1 but recites a "method of treating a deep vein thrombosis." *Id.* at 37:23–47.

To illustrate the subject matter of some of the challenged dependent claims, claim 2 depends from claim 1 and adds "wherein advancing the aspiration catheter comprises inserting a catheter having a size of 16 French or greater through the vasculature." *Id.* at 36:9–11. Claim 5 depends from claim 1 and adds, *inter alia*, a step of "reintroducing the filtered blood into the vasculature of the patient." *Id.* at 36:20–25. Claim 15 depends from claim 1 and adds "the aspiration source is an electric pump." *Id.* at 37:6–7.

E. Prior Art and Asserted Grounds

Petitioner asserts that claims 1–12, 14–31, and 33–38[4] are unpatentable based on the following grounds:

Grounds		Claims Challenged	35 U.S.C. §[5]	Reference(s)/Basis
1	A	1–10, 13–29, 33–38	103	Laub,[6] Garrison[7]
	B	6–8, 17, 25–27, 36	103	Laub, Garrison, Goff[8]
	C	11, 12, 30, 31	103	Laub, Garrison, Schaffer[9]
	D	11, 12, 30, 31	103	Laub, Garrison, Schaffer, Hartley[10]

[4] The Petition includes claim 32 under Grounds 2A, 3A, and 4A (Pet. 16 (table of grounds/challenged claims)), but that appears to be a mistake as the remainder of the Petition does not address claim 32.

[5] The Leahy-Smith America Invents Act ("AIA"), Pub. L. No. 112–29, 125 Stat. 284, 285–88 (2011), revised 35 U.S.C. §§ 102, 103 effective March 16, 2013. Based on the uncontested assertion that August 13, 2018, is the earliest possible priority date for the '333 patent, we apply the AIA versions of §§ 102 and 103 in this Decision. Pet. 13.

[6] Laub, US 2017/0043066 A1, published Feb. 16, 2017 (Ex. 1012 ("Laub")).

[7] Garrison, US 2015/0173782 A1, published June 25, 2015 (Ex. 1006 ("Garrison")).

[8] Goff, WO 2006/124307 A2, published Nov. 23, 2006 (Ex. 1007 ("Goff")).

[9] Schaffer, US 2003/0225379 A1, published Dec. 4, 2003 (Ex. 1013 ("Schaffer")). Petitioner also cites Schaffer's clearer prosecution drawings (Ex. 1050). Pet. 79 n.3 (noting public availability/publication in Dec. 2003).

[10] Hartley, US 2003/0116731 A1, published June 26, 2003 (Ex. 1008 ("Hartley")).

2	A	1–10, 13–29, 33–38	103	Aklog,[11] Garrison
	B	6–8, 17, 25–27, 36	103	Aklog, Garrison, Goff
	C	11, 12, 30, 31	103	Aklog, Garrison, Schaffer
	D	11, 12, 30, 31	103	Aklog, Garrison, Schaffer, Hartley
3	A	1–10, 13–29, 33–38	103	Garrison, Laub
	B	6–8, 17, 25–27, 36	103	Garrison, Laub, Goff
	C	11, 12, 30, 31	103	Garrison, Laub, Schaffer
	D	11, 12, 30, 31	103	Garrison, Laub, Schaffer, Hartley
4	A	1–10, 13–29, 33–38	103	Garrison, Aklog
	B	6–8, 17, 25–27, 36	103	Garrison, Aklog, Goff
	C	11, 12, 30, 31	103	Garrison, Laub, Schaffer
	D	11, 12, 30, 31	103	Garrison, Laub, Schaffer, Hartley

Petitioner also relies on testimony from Troy L. Thornton (Ex. 1003) and Dr. Aquilla S. Turk, III (Ex. 1022) in support of its challenge. Patent Owner provides responsive testimony from Brian Brown. Ex. 2005.

[11] Aklog, US 8,734,374 B2, issued May 27, 2014 (Ex. 1005 ("Aklog")).

III. ANALYSIS

A. Legal Standards

"In an [*inter partes* review], the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable." *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016) (citing 35 U.S.C. § 312(a)(3)).

A claim is unpatentable under 35 U.S.C. § 103 if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious at the time the invention was made[12] to a person having ordinary skill in the relevant art. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and (4) secondary considerations (i.e., objective indicia) of nonobviousness when presented.[13] *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

To show unpatentability based on a combination of teachings, "[a]n obviousness determination [also] requires finding both that a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan

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[12] The AIA revised § 103 such that obviousness is assessed "before the effective filing date of the claimed invention," but *KSR* and other obviousness precedents cited herein remain applicable despite this change in the timing of the obviousness inquiry.

[13] Petitioner states that it is not aware of any objective indicia of nonobviousness (Pet. 90), and Patent Owner does not provide argument about any objective indicia.

would have had a reasonable expectation of success in doing so." *CRFD Rsch., Inc. v. Matal*, 876 F.3d 1330, 1340 (Fed. Cir. 2017) (internal quotation marks omitted).

B. Level of Ordinary Skill in the Art

Petitioner proposes that the person of ordinary skill in the art ("POSA") "would have had 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." Pet. 13 (citing Ex. 1003 ¶ 35).

Patent Owner counters that Petitioner's proposed definition is "insufficient" but does not, in the Preliminary Response, explain why it is "insufficient" or propose a definition of its own. Prelim. Resp. 20 (citing333 Ex. 2005 ¶ 52).[14] Instead, in advancing Patent Owner's counterarguments, "Patent Owner applies Petitioner's definition." *Id.* For this Decision, we apply Petitioner's POSA definition, which appears to be reasonable and consistent with the prior art.

C. Claim Construction

In an IPR, we construe claims using the same claim construction standard used in a civil action before the courts under 35 U.S.C. § 282(b), including construing claim language in accordance with its ordinary and

[14] Mr. Brown opines that a POSA, whether an engineer or a clinician, would have had experience with "thrombectomy" devices and/or procedures. Ex. 2005 ¶ 52. But, like Patent Owner, Mr. Brown applies Petitioner's definition and does not explain why his articulation of the POSA's qualifications should change the result. Patent Owner may, if it chooses, develop argument in its papers about the POSA level at trial.

customary meaning as understood by the POSA, in view of the patent's specification and considering the patent's prosecution history. 37 C.F.R. § 42.100(b). We need only construe terms where the parties dispute a term's meaning and only to the extent needed to resolve the controversy. *Realtime Data, LLC v. Iancu*, 912 F.3d 1368, 1375 (Fed. Cir. 2019).

Petitioner contends that the term "filament" in, for example, dependent claim 11 means at least "one or more threads, lines, cords, ropes, ribbons, flat wires, sheets, or tapes." Pet. 15. Patent Owner notes its disagreement with Petitioner's interpretation of the term "filament" in related proceedings (e.g., IPR2025-00289). Prelim. Resp. 20 n.3. But Patent Owner contends that the claim construction issue in related proceedings "is not germane" to Patent Owner's arguments in the present case and, thus, the Board need not construe that term (or any other term of the '333 patent's challenged claims) at this time.

We need not, at this stage, further construe the '333 patent's claims to address the issues that are presently in dispute.

D. Asserted References

Petitioner asserts, and Patent Owner does not dispute, that each of Laub, Garrison, Aklog, Goff, Schaffer, and Hartley are prior art under 35 U.S.C. § 102(a)(1). Pet. 17. Because the disputed issues at this stage relate to combinations involving Laub, Aklog, and Garrison, the summary below focuses on those references.

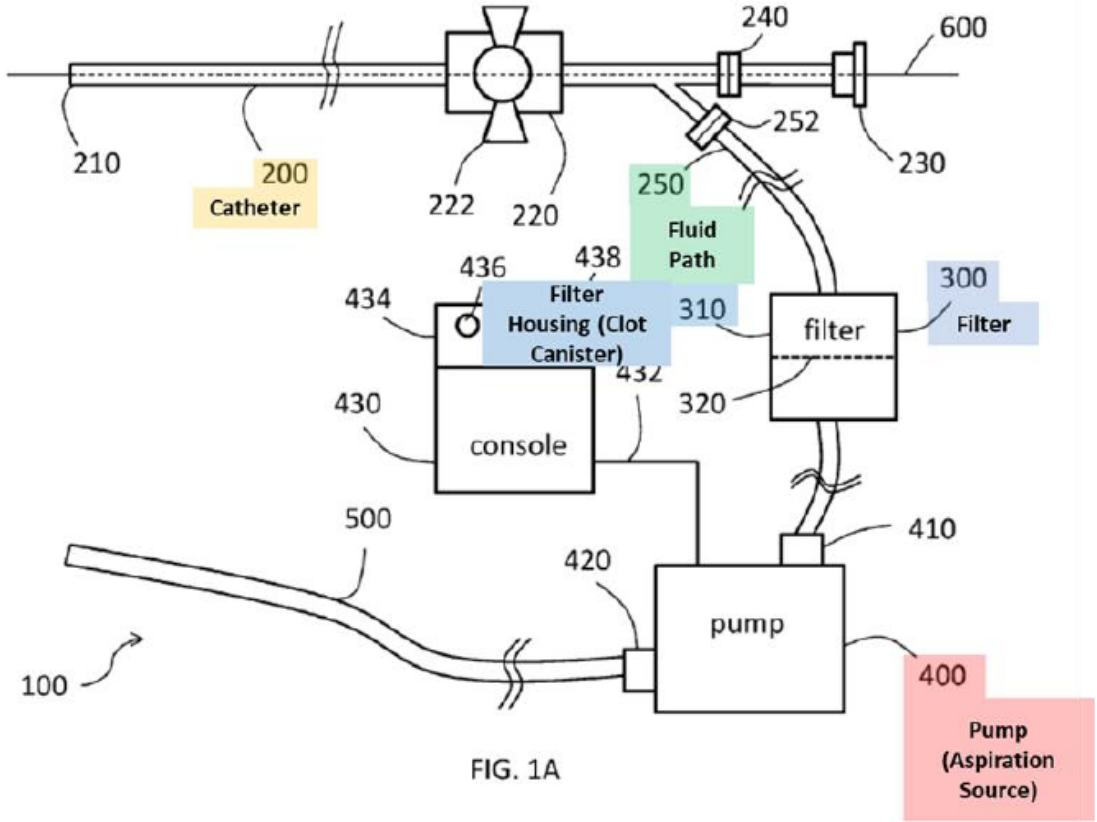
1. Laub (Ex. 1012)

Laub is a published U.S. patent application, which published February 16, 2017. Ex. 1012, code (43). Laub relates to systems for removing material, including thrombi and emboli, from a patient's body. *Id.* ¶ 2 (describing "unwanted material such as emboli, thrombi, tumors, or debris").

In embodiments, Laub's systems comprise a "steerable catheter." *Id.*; *see also id.* ¶ 3 (explaining that "clots are usually comprised of an aggregated mixture of thrombus and fibrin and, if left untreated, may result in deep vein thrombosis, embolisms, or ischemia"), ¶ 4 (explaining that clots in the arteries can lead, for example, to possible migration to the brain and stroke, and clots in the veins can migrate to the lungs resulting in a potentially fatal pulmonary embolism).

Laub states that its systems are suitable for "thrombectomy and/or embolectomy procedures" in the patient's vasculature. *Id.* ¶ 5. Such systems may be used to, for example, "remove clots from patients suffering from or at risk of pulmonary embolisms." *Id.* Further, Laub discloses, "[i]n some embodiments, the system is further configured to return aspirated blood to the patient which, for example, allows for greater suction pressures and/or flow rates according to certain embodiments." *Id.*

An annotated version of Laub's Figure 1A is reproduced below.



Pet. 3 (citing Ex. 1012, Fig. 1A (with Petitioner's annotations)). Figure 1A above is a side view of a system for removing clots from a patient's body. Ex. 1012 ¶ 11. The system 100 includes, among other features, an aspiration catheter 200 (labeled "Catheter" and colored orange) in fluid connection with fluid path 250 (colored green) and a housing 310 and filter 300 (labeled "Filter Housing (Clot Canister)" and colored blue). *Id.* ¶ 24. Downstream from the fluid path and filter is a pump 400 (labeled "Pump (Aspiration Source)" and colored red), which pump is shown with an inlet port 410 and an outlet port 420. *Id.* A return catheter 500 is included in the system shown above and is fluidly connected to the pump's outlet port, which return catheter may be used to send blood expelled from the outlet port back to the patient for reinfusion. *Id.*

Laub teaches that the aspiration catheter, in embodiments, may have a French size of between 5 French and 20 French. *Id.* ¶ 28 (disclosing "[i]n some embodiments, aspiration catheter 200 has a French size of at least 16 Fr" and "[i]n certain preferred embodiments, aspiration catheter has a French size of equal to or greater than 10 Fr to allow for aspiration of large thrombi and/or other solid materials from the patient").

Laub teaches that the pump "is configured to create a suction force to drive system 100 during use" and that such pump may include "a centrifugal pump" or other pumps known in the art. *Id.* ¶ 41 (noting the pump may be "a rotary pump, peristaltic pump, roller pump, or other form of pump known in the art"); *see also id.* ¶¶ 42–44 (disclosing exemplary negative pressures (e.g., 0–400 mmHg) and flow rates (e.g., 100–6000 mL/min) that may be produced by the pump). Laub discloses that the pump may, in embodiments, be configured to "generate a positive pressure at discharge port 420 such that the aspirated blood received through inlet port 410 is expelled through discharge port 420 during use." *Id.* ¶ 45. Moreover, according to Laub:

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

Id. (disclosing blood may be further filtered of undesired material before being returned to the patient).

2. Garrison (Ex. 1006)

Garrison is a published U.S. patent application that published June 25, 2015. Ex. 1006, code (43). Garrison relates generally to medical devices and methods for treating ischemic stroke. *Id.* ¶¶ 2–3 (explaining that

"[a]cute ischemic stroke is the sudden blockage of adequate blood flow to a section of the brain, usually caused by a thrombus or other emboli lodging or forming in one of the blood vessels supplying the brain"), ¶ 4 (explaining, as background, that endovascular treatment of stroke often involves delivery of thrombolytic agents and/or interventional thrombectomy to remove blockages).

Garrison explains that interventions in the cerebral or intracranial vasculature often have special access challenges. *Id.* ¶ 42. For example, according to Garrison, most interventional procedures use a transfemoral access to the carotid or vertebral artery and the "access route is long, often tortuous." *Id.* Moreover, "cerebral vessels are usually more delicate and prone to perforation than coronary or other peripheral vasculature." *Id.* Such challenges, Garrison explains, can make it more difficult to quickly access and restore blood perfusion to the cerebral vasculature. *Id.* ¶¶ 43–44. Garrison describes "methods and devices that optimize clot aspiration through either transfemoral or transcarotid access approaches." *Id.* ¶ 48.

An exemplary clot treatment system is shown below in Garrison's Figure 34 (including Petitioner's annotations).

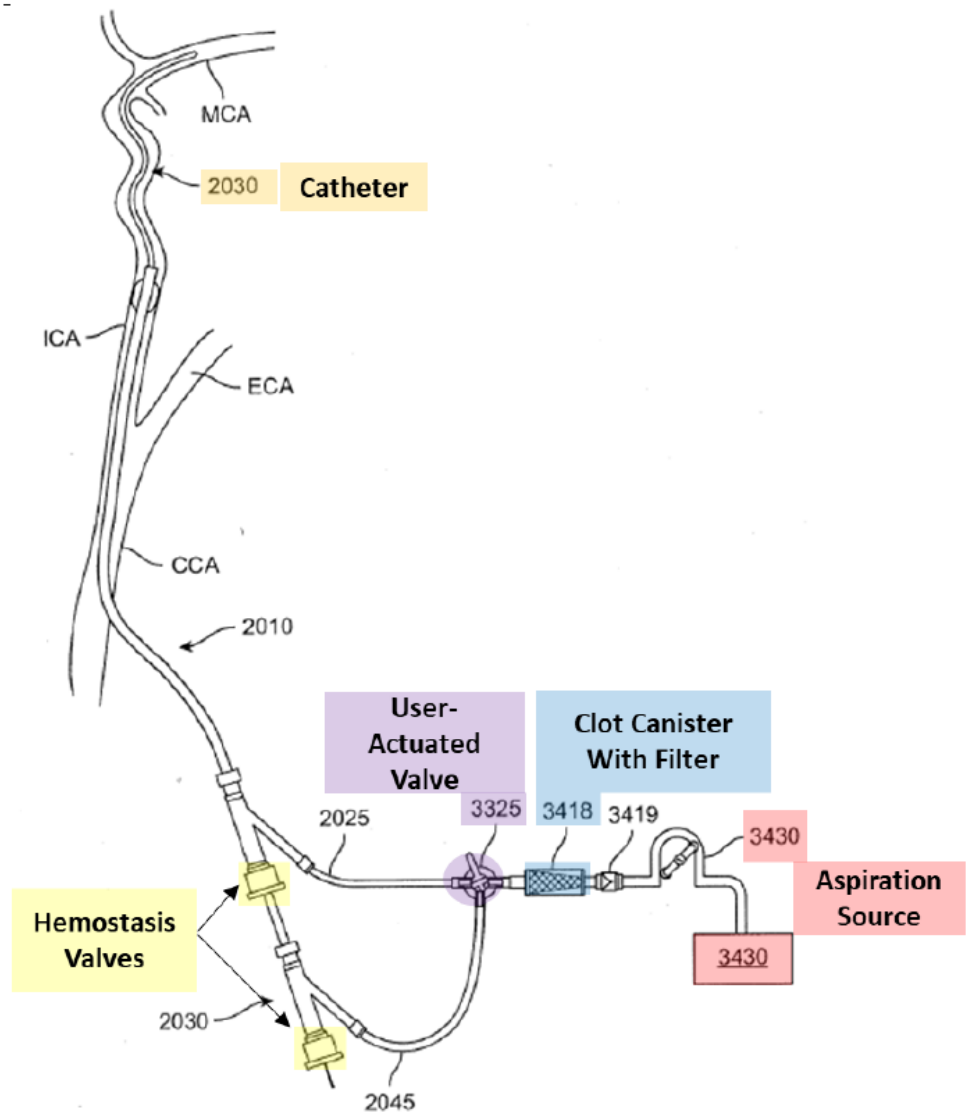


FIG. 34

Pet. 6 (citing Ex. 1006, Fig. 34). Figure 34 is a schematic side view of an embodiment of a clot treatment system depicted in Garrison, and shows a valve 3325 (labeled "User Actuated Valve" and colored purple) disposed in fluid connection with flow lines 2025 and 2045 and between a catheter 2030 (colored orange) on one side, and a filter 3418 (labeled "Clot Canister With Filter" and colored blue) and an aspiration source 3430 (colored red) on the

other side of the valve. Ex. 1006 ¶¶ 130–132. According to Garrison, the "[user-actuated] valve may enable one device [(e.g., catheter 2030)], the other device [(e.g., access device 2010)], both devices, or neither device to be connected to the aspiration source at any given time." *Id.* ¶ 132 (disclosing the valve "may be a 3-way or 4-way stopcock" or "may be a flow controller with a simple actuation" that selects the desired configuration); *see also id.* ¶ 133 (describing flow controller variants). Garrison also teaches its systems may include one or more hemostasis valves (unnumbered, colored yellow in the figure above) "to allow introduction of devices while preventing or minimizing blood loss during the procedure." *Id.* ¶ 53, Fig. 3 (depicting proximal port 2015 with hemostasis valve 2012).

Continuing, Garrison teaches that "[t]he active source of aspiration may be an aspiration pump, a regular or locking syringe, a hand-held aspirator, hospital suction, or the like." *Id.* ¶ 134. For example, Garrison discloses that:

> In one embodiment, a locking syringe (for example a VacLock Syringe) is attached to the flow controller and the plunger is pulled back into a locked position by the user while the connection to the flow line is closed prior to the thrombectomy step of the procedure. During the procedure when the tip of the aspiration device (either the arterial access device or the catheter) is near or at the face of the occlusion, the user may open the connection to the aspiration syringe. This would enable the maximum level of aspiration in a rapid fashion with one user, something that is currently not possible with existing technologies.

Id.

Garrison discloses that a "disadvantage" of current sources of aspiration is that blood received into an external reservoir or syringe is "generally discarded at the end of the procedure, and as such represents

blood loss from the patient." *Id.* ¶ 135. According to Garrison, when blood has been exposed to air or static for a period of time, there is a risk of thrombus formation or damage to the blood cells. *Id.* ("Usually, aspirated blood is not returned to the patient to avoid risk of thromboembolism"). Nonetheless, Garrison then describes an exemplary aspiration pump that is "configured not to harm blood cells and which may be configured to return blood to the central venous system in real time during the procedure, so there is no reservoir in which the blood remains static." *Id.* ¶ 136, Fig. 36.

3. Aklog (Ex. 1005)

Aklog is a U.S. patent that issued May 27, 2014. Ex. 1005, code (45). Aklog relates generally to "systems and methods for removing undesirable material from a site of interest within the circulatory system" and, more specifically, to removing "clots, thrombi, and emboli" from the medium to large vessels of the body, while reinfusing fluid removed from the site of interest back into the patient to minimize fluid loss. *Id.* at 1:17–24.

According to Aklog, "[v]essels from which the undesirable material may be removed, in accordance with an embodiment of the present invention, include, for example, those within the pulmonary circulation (e.g., pulmonary arteries)." *Id.* at 7:32–35. Aklog discloses that undesirable material may also be removed from, for example, the venous circulation in the legs or pelvis. *Id.* at 7:35–37; *see also id.* at 2:7–10 (explaining that DVT arises from clots that develop in the large veins of the legs or pelvis). Aklog discloses that, "[a]lthough reference is made to medium and large vessels, it should be appreciated that the systems and methods . . . can be scaled and adapted for use within the smaller vessels within the body, if desired." *Id.* at 7:43–46.

Aklog's Figure 7 is reproduced below, with Petitioner's annotations.

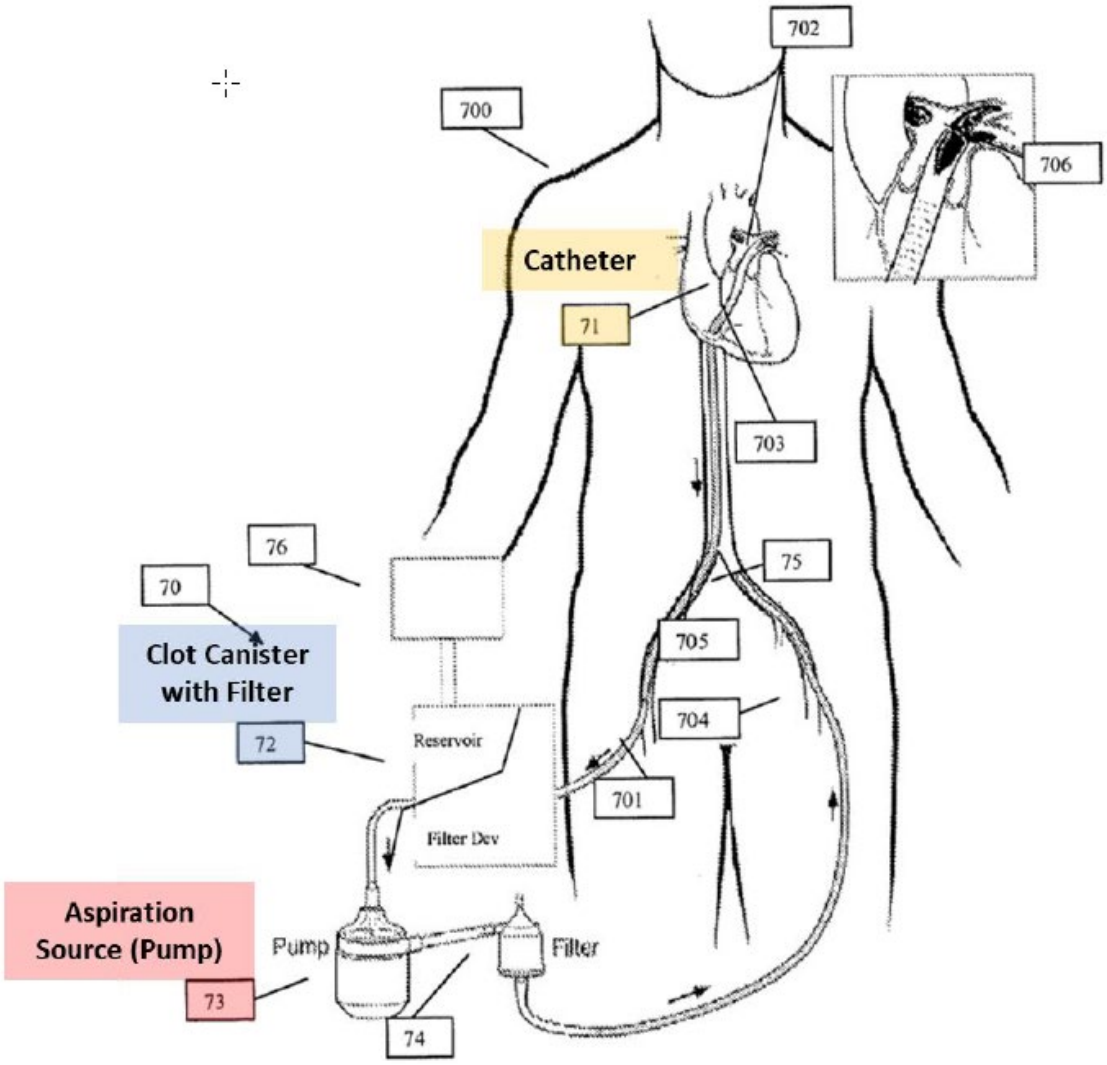


Fig. 7

Pet. 4 (citing Ex. 1005, Fig. 7). Figure 7, reproduced above, is an illustrated view of an embodiment of Aklog's system 70 deployed within a patient 700 for removing undesirable (e.g., clot) material 706 from a site of interest 702. Ex. 1005, 15:18–16:17 ("In the case of pulmonary embolism, the suction cannula 71 may normally be introduced through the femoral, jugular or subclavian veins"). The system includes suction cannula 71 (labeled "Catheter" and colored orange), which is fluidly connected to a filter device

72 (labeled "Clot Canister with Filter" and colored blue) and a pump 73 (labeled "Aspiration Source (Pump)" and colored red). *Id.* The depicted system also includes a second filter device 74 downstream from the pump and a reinfusion cannula 75 for returning aspirated and cleansed blood to the patient. *Id.* at 15:66–16:17.

Aklog discloses that the cannula "may be of any sufficient size, so long as it can be accommodated within a predetermined vessel, such as a medium to large size blood vessel." *Id.* at 11:12–23 (noting the size of the cannula may also be determined based on the size of the material to be removed, and, "[o]f course, cannula . . . can be scaled and adapted for use within smaller vessels in the body and for removing a relatively smaller volume or amount [of] undesirable material, if so desired").

Aklog teaches that the pump may be designed to "generate negative pressure, so as to create a necessary suction force through cannula 10 to pull any undesirable material from the site of interest," and "may also be designed to generate the positive pressure, so as to create a necessary driving force to direct fluid" through an exit port of the pump "for reinfusion of fluid removed." *Id.* at 11:65–12:5. Further, Aklog discloses, the pump "may be any commercially available pump, including those for medical applications and those capable of pumping fluids, such as blood. Examples . . . include[] a kinetic pump, such as a centrifugal pump, and an active displacement pump, such as a rollerhead pump." *Id.* at 12:9–14.

E. Alleged Obviousness over Laub or Aklog in Combination with Garrison (Grounds 1A and 2A); or Garrison in Combination with Laub or Aklog (Grounds 3A and 4A)

1. Overview

The analysis below focuses on Petitioner's contentions and Patent Owner's counterargument for the asserted obviousness of claim 1 over Laub or Aklog in combination with Garrison (Grounds 1A and 2A) and the asserted obviousness of claim 1 over Garrison in combination with either Laub or Aklog (Grounds 3A and 4A). Many of the parties' arguments under Grounds 1A, 2A, 3A, and 4A overlap. *See, e.g.*, Pet. 18–64 (analyzing Grounds 1A–4A in one section); Prelim. Resp. 34–64 (counterargument for Grounds 1A–4A). Petitioner provides argument and evidence supporting its contention that each of the challenged claims would have been obvious, while Patent Owner, at this stage, argues the patentability of the claims as a group. *See, e.g.*, Pet. 18–43 (argument on claim 1), 43–44 (argument on claim 2), 46–48 (argument on claim 5); *see generally* Prelim. Resp. 34–64 (arguing that Petitioner has not shown that independent claims 1 and 20 (and by extension the challenged dependent claims) would have been obvious).

Taking Ground 1A as illustrative of Petitioner's challenge, Petitioner contends that Laub teaches a method for treating pulmonary embolism (PE) as recited in claim 1 but Laub's system and method does not use the recited vacuum generation/application steps. Pet. 18–43. That is, Laub does not disclose claim 1's steps of generating vacuum pressure while a valve is in a first (closed) position and then moving that valve to a second (open) position thereby applying the vacuum pressure to the catheter to aspirate a portion of the clot. *Id.* at 36–42. Petitioner argues, however, that Garrison teaches or suggests those limitations insofar as Garrison discloses systems and methods

that include an in-line fluid valve (e.g., a stopcock) that allow a user to close the valve, generate vacuum pressure with an active aspiration source, then open the valve to apply the vacuum pressure and, thus, provide a rapid aspiration of clot material. *Id.* at 36–38. And, Petitioner argues, a POSA would have had reasons for adding Garrison's valve and using its vacuum generation and rapid aspiration technique in a modified system of Laub to practice the method of claim 1. *Id.* at 38–42 (arguing, *inter alia*, a POSA "would have recognized that Garrison's valve could improve Laub's . . . temporary aspiration power to aspirate PE's more quickly"). Petitioner's combination of Aklog and Garrison (Ground 2A) invokes substantially the same reasoning, with Aklog's system for treating PE or DVT (similar to Laub) modified to use Garrison's fluid-control valve and vacuum generation/application technique. *Id.* at 18–43.

For Grounds 3A and 4A, Petitioner starts with Garrison. According to Petitioner, although Garrison teaches systems and methods for clot removal that include most of claim 1's limitations, Garrison does not expressly disclose using its systems to treat PE. *See, e.g.*, Pet. 21, 26 (noting Garrison focused on removing clots in cerebral blood vessels using catheters with a relatively smaller diameter (e.g., 8 French)). Nonetheless, Petitioner argues, a POSA would have found it obvious to use and optimize (if needed) Garrison's clot treatment system to treat PE based on Laub or Aklog. *Id.* at 21–30. Petitioner cites, for example: the similarities between the aspiration systems of Garrison, Aklog, and Laub; Aklog's and Laub's teachings related to removal of clots from varied portions of a patient's vasculature, including the pulmonary arteries (i.e., PE); and Aklog's teaching that systems designed for targeting clots in medium or larger vessels can be easily scaled and adapted for use within smaller vessels in the body. *Id.* at 21–28. Petitioner

thus argues a POSA would have considered modifications such as resizing Garrison's catheters (e.g., increasing the diameter to 16 French) for targeting clots in larger vessels to have involved no more than simple, routine optimizations.[15] *Id.* at 24–29.

Patent Owner raises several counterarguments. Prelim. Resp. 34–64. Patent Owner argues that Garrison does not teach, for Garrison's Figure 34, the use of a valve to generate and release vacuum pressure as required in the challenged claims. *Id.* at 40–41 (arguing the Petitioner recognizes this deficiency in Figure 34 and, so, turns to another embodiment in Garrison using a flow controller and syringe that allows the user to buildup and release vacuum pressure). Patent Owner also argues that a POSA would not have modified the prior art in the manner proposed by Petitioner. Patent Owner argues, for example, that adding Garrison's valve to Laub's system and using it as proposed would not maximize aspiration and would introduce dangerous flow paths for air to be reinfused into the patient. *Id.* at 43–55. And, Patent Owner argues, a POSA would not have modified Garrison's system to treat PE because increasing the catheter diameter without returning aspirated blood to the patient (which Patent Owner contends Laub and Aklog say is necessary) would be dangerous. *Id.* at 56–64.

The parties' arguments are addressed in more detail in the sections below.

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[15] For claim 2, which recites that the catheter has "a size of 16 French or greater," Petitioner cites, for example, Laub's embodiments where "aspiration catheter 200 has a French size of at least 16 Fr" and Aklog's teaching that a catheter "may be of any sufficient size, so long as it can be accommodated within a predetermined vessel, such as a medium to large size vessel." Pet. 43 (citing Ex. 1012 ¶ 28; Ex. 1005, 11:12–15).

2. Petitioner's Contentions

a) Grounds 1A and 2A

We primarily focus on Petitioner's challenge to claim 1 under Ground 1A (Laub combined with Garrison) as illustrative and note that Ground 2A (Aklog combined with Garrison) is substantially similar.

Petitioner argues that claim 1's preamble reciting a "method of treating a pulmonary embolism within a vasculature of a patient" is disclosed by Laub. Pet. 18–19. Petitioner cites, *inter alia*, Laub's disclosure of an aspiration system that may be used "to remove clots from patients suffering from or at risk of pulmonary embolisms." *Id.* (citing Ex. 1012 ¶¶ 5, 24, Fig. 1A).

Petitioner argues that Laub discloses claim 1's step of "advancing an aspiration catheter . . . such that a distal end portion of the aspiration catheter is positioned proximate to the pulmonary embolism." Pet. 30–32 (citing, e.g., Ex. 1012 ¶¶ 24, 39–40 Fig. 1A, Fig. 7; Ex. 1003 ¶¶ 97–100). Petitioner further contends that Laub discloses that a "lumen of the aspiration catheter is fluidly coupled along a fluid path to a clot canister and an aspiration source" as recited in the advancing step's related wherein clause. *Id.* (citing, e.g., Laub's Fig. 1A and filter housing 310 as being a "clot canister" for trapping solid materials (clots) passed through a filter, and Laub's pump 400 as an aspiration source); *see also id.* at 43 (asserting that Laub's system shown in Fig. 1A includes a "filter" in a clot canister as recited in claim 1's terminal wherein clause).

For claim 1's step reciting "generating vacuum pressure within the clot canister via the aspiration source while a valve . . . is in a first position that inhibits fluid flow," Petitioner turns to Garrison. Pet. 36–41. Petitioner cites, for example, Garrison's teaching related to a user-actuated valve (e.g.,

a stopcock like depicted as structure 3325 in Figure 34) that may be placed along the fluid path between the catheter and a filter/clot canister, enabling the user to control the catheter's fluid connection to the clot canister and aspiration source at any given time. *Id.* at 36–37 (citing Ex. 1006 ¶¶ 131–134, Fig. 34); *see also id.* at 37 (asserting that "[t]he valve can also 'be a flow controller with a simple actuation'" (quoting Ex. 1006 ¶ 132)). Petitioner also cites Garrison's embodiment where an aspiration source (a syringe) is attached to a flow controller and activated while the connection to the flow line is closed prior to the thrombectomy step, which allows for generation of a vacuum pressure when the flow controller is closed and rapid release of that pressure when the flow controller opens the line. *Id.* at 38 (citing Ex. 1006 ¶ 134 (disclosing "the user may open the connection to the aspiration syringe . . . to enable the maximum level of aspiration in a rapid fashion")). According to Petitioner, although this embodiment uses a flow controller as the valve, Garrison suggests a controller may be replaced with a stopcock. *Id.* (citing Ex. 1006 ¶ 132 (identifying flow controllers and stopcocks as alternatives)); Ex. 1003 ¶ 105 (testifying that, although this "particular example includes a flow controller for the valve and a syringe for the pressure source . . . Garrison discloses that the valve could be a stopcock . . . and the aspiration source could also be an aspiration pump" (citing Ex. 1006 ¶¶ 132, 134)).

For claim 1's step of "moving the valve from the first position to a second position thereby applying the vacuum pressure" to the catheter to aspirate a portion of the clot, Petitioner again cites Garrison's teachings. Pet. 41–42 ("Garrison discloses this limitation and Laub or Aklog combined with Garrison render this limitation obvious" (citing Ex. 1003 ¶¶ 48, 112–114)). Petitioner cites Garrison's fluid-control valves and the vacuum

generation and rapid aspiration technique disclosed in Garrison and summarized in the paragraph above. *Id.* (citing, e.g., Ex. 1006 ¶ 134). According to Petitioner, "when Garrison's valve is incorporated into the systems in Laub . . . , moving the valve to the second position would cause at least a portion of the PE and blood to be aspirated into the clot canister." *Id.* (citing Ex. 1003 ¶ 114).

Petitioner contends that a POSA would have been motivated to modify Laub's (or Aklog's) system and method based on the teachings of Garrison with a reasonable expectation of success in arriving at the method of claim 1. Pet. 38–41. Petitioner argues, *inter alia*, that a POSA would have recognized that incorporating Garrison's valve (e.g., a stopcock) and technique of generating pressure while the valve is closed "could improve Laub's . . . temporary aspiration power to aspirate PE's more quickly, making Laub's . . . systems safer and more effective." *Id.* at 38–39 (Ex. 1003 ¶¶ 106, 109). Moreover, Petitioner contends that the proposed modification "would have merely entailed combining known elements (Garrison's valve and Laub's/Aklog's system) according to known methods (positioning the valve between the catheter and filter along the flow path) to yield the predictable result of aspirating clots from the patient's vasculature." *Id.* Petitioner argues that stopcocks are simple mechanical structures that a POSA would have regularly used for connecting and disconnecting fluid lines in medical devices. *Id.* at 39–40 (arguing a POSA "would have understood that a stopcock could be incorporated into Laub's device at the connector to help control the fluid flow" and noting the similar placement in Garrison's aspiration systems (citing Ex. 1003 ¶ 108)).

b) Grounds 3A and 4A

Petitioner's Grounds 3A and 4A start with Garrison's systems and methods and propose that it would have been obvious to modify Garrison's systems/methods for the treatment of PE, which treatment is taught or suggested in Laub and Aklog using a range of catheter sizes or catheters suitably scaled for the portion of the vasculature and clots that are targeted. *See supra* Section III.E.1.

Petitioner offers several reasons supporting the alleged obviousness of using Garrison's systems/methods in this way to practice claim 1's method. Petitioner contends, with the supporting testimony of Dr. Turk, that the procedure for aspirating blood clots is similar whether the clot is located in, for example, the brain, lungs, or legs. Pet. 21–22 (citing Ex. 1022 ¶¶ 21–24 (testifying, *inter alia*, that the components (e.g., catheter, clot container, pressure source (pump or syringe)) are generally the same and, "[w]hile the sizes of some components may vary depending on the clot locations, these basic aspiration components are common across different clot locations")). Further, Petitioner argues, skilled artisans "routinely used aspiration catheters designed for one part of the vasculature to treat different parts of the vasculature," and would have "routinely upsized catheters" if appropriate depending on the clot and portion of vasculature being targeted. *Id.* at 24–25 (citing Ex. 1022 ¶¶ 25–41; Ex. 1003 ¶¶ 80, 83, 85–87); Ex. 1020,[16] 1 (describing catheters for both cerebral clots and PE). Petitioner argues Garrison's somewhat smaller-sized catheters (~ 6–10 French) would have been suitable for use, even without modification, for treating PE and DVT. Pet. 26 (noting Garrison's catheter sizes overlap with known systems using

[16] Brady, WO 2018/019829 A1, published February 1, 2018 (Ex. 1020).

catheter between ~ 5–12 French for treating clots in the peripheral vasculature); Ex. 1022 ¶ 39. And, if any scaling of catheter size was needed for the particular application (e.g., a large clot in a larger blood vessel), Petitioner contends the evidence shows that such a change would have involved no more than simple substitutions and routine optimization. Pet. 27–29 (citing, e.g., Ex. 1005, 7:43–46; Ex. 1003 ¶¶ 80, 83–88, 91, 93–95; Ex. 1022 ¶¶ 30–37).

We have considered Petitioner's argument and evidence in support of its challenge to the claims under Grounds 1A–4A. We have also considered Patent Owner's counterarguments, which we find unavailing at this stage for reasons explained below. *See infra* Section III.E.3. Upon considering the parties' argument and evidence, we find that Petitioner has established that it is reasonably likely to succeed in showing that at least claim 1 would have been obvious under Grounds 1A–4A.

Based on the preliminary record, Petitioner persuades us that a POSA would have had reasons for adding a stopcock (or similar flow-control valve) to Laub's system between the catheter and the cited clot canister and pressure source, as suggested by Garrison. *See, e.g.*, Ex. 1006 ¶¶ 130–134; Ex. 1012, Fig. 1A; Ex. 1006, Fig. 34. Petitioner persuades us that Laub's system, modified as proposed, would allow a user to close the valve while a pressure source (e.g., a pump) creates a negative pressure and vacuum between the valve and the pressure source, which vacuum may then be applied to a distal portion of the catheter upon opening the valve to facilitate a rapid aspiration of a portion of a PE into the clot canister. Pet. 38–42; Ex. 1003 ¶¶ 48, 103–114.

Petitioner also persuades us at this stage that a POSA would have found it obvious to use a system like described in Garrison for the treatment

of PE (as described in Laub and Aklog). *See, e.g.*, Ex. 1003 ¶¶ 89–95. Insofar as any resizing of Garrison's catheters may have been necessary to facilitate the treatment of PE, the preliminary record supports Petitioner's position that skilled artisans would have considered that to be a simple and routine change. *See, e.g.*, Ex. 1005, 11:12–23 (teaching catheters may be "any sufficient size" and can be "scaled and adapted" according to the vessels and clots being targeted for removal); Ex. 1022 ¶¶ 26–32 (testifying it was known that aspiration catheter systems for one part of the vasculature may be used in other parts, and routinely adapted (e.g., resizing of catheters) if needed); Ex. 1003 ¶¶ 83–88 (same).

3. Patent Owner's Counterarguments

Patent Owner argues that none of Laub, Aklog, or Garrison disclose or render obvious claim 1's steps related to the generation and subsequent release of vacuum pressure. Prelim. Resp. 34–36, 39–42. According to Patent Owner, Petitioner is mixing or conflating different embodiments of Garrison in an effort to show that Garrison renders obvious the above steps. *Id.* at 40–42 (asserting, e.g., that in the embodiment shown in Figure 34, the valve (stopcock) is used to connect multiple fluid lines to a single aspiration source (e.g., a peristaltic pump), not to generate a vacuum in the filter canister, and the embodiment in Garrison's paragraph 134 uses a flow controller connected to a syringe (not a stopcock or peristaltic pump) without an intervening filter); Prelim. Sur-reply 2–3.

This argument is unpersuasive on the present record. We see no flaw in Petitioner's alleged mixing of disclosures or features for different embodiments of Garrison—all of which are addressed in a relatively short section of Garrison describing "Exemplary Embodiments of Aspiration and Flow Control." Ex. 1006 ¶¶ 130–142. Indeed, these disclosures in Garrison

suggest that features of those embodiments may be combined. *See, e.g.*, *id.* ¶ 130 (stating, "[d]escribed herein are aspiration and flow control elements configured to be used with an arterial access device, a guide catheter, and/or a catheter of the disclosed system" and "[a]ny or all of the arterial access device 2010 and the catheter 2030 may be connected to sources of passive or active aspiration . . . on the devices"); *see also id.* ¶ 134 (describing an exemplary connection between a locking syringe and "the flow controller," which flow controller and variants is described in more detail in paragraph 133).[17] Moreover, Garrison's disclosures related to the embodiments cited by Petitioner suggest that flow controllers and syringes are example valves and aspiration sources, with stopcocks and aspiration pumps identified as respective alternatives to flow controllers and syringes. *Id.* ¶¶ 132, 134.

Patent Owner also argues that a POSA would not have modified Laub's or Aklog's systems to include Garrison's valve and operate those systems as proposed because doing so would not "enable the maximum level of aspiration." Prelim. Resp. 43–46. According to Patent Owner, Garrison's disclosure about a generating vacuum pressure while a flow controller is closed and then releasing that pressure by opening the flow controller to "enable the maximum level of aspiration in a rapid fashion" is limited to Garrison's use of a syringe as the pressure source. *Id.* at 43–44 (citing Ex. 1006 ¶ 134). But, Patent Owner contends, Garrison's Figure 34 shows a

[17] Garrison also broadly suggests that "[c]ertain features that are described in this specification in the context of separate embodiments can also be implemented in combination in a single embodiment" and "various features that are described in the context of a single embodiment can also be implemented in multiple embodiments separately or in any suitable sub-combination." Ex. 1006 ¶ 175.

peristaltic pump—not a syringe—as the pressure source. *Id.* at 44–45 (arguing Laub and Aklog use positive displacement pumps (not syringes) similar to Garrison's Fig. 34). Patent Owner argues that Petitioner ignores "fundamental difference[s]" between a syringe and a peristaltic pump, which allegedly lacks a fixed volume that is evacuated like a syringe and would not generate a vacuum as claimed. *Id.* at 43–45 (citing, e.g., Ex. 2005 ¶¶ 82–85 (testifying that, with a peristaltic pump, any "maximum level of aspiration" is dictated by the pump's rotational speed). Patent Owner also cites Laub's teaching about reinfusing the patient's blood continuously to "allow[] for greater suction pressure and/or flow rates" to help with dislodging larger clots, which Patent Owner contends shows that a POSA would have simply changed the pump's speed to maximize aspiration, not stop the continuous aspiration and reinfusion for generation of a vacuum pressure like Petitioner proposes. *Id.* at 45–46 (citing Ex. 1012 ¶ 45; Ex. 2005 ¶ 86).

The merits of Patent Owner's argument about whether aspiration pumps, like described in Laub, Aklog, and Garrison would, in the proposed modified systems, generate a vacuum pressure as claimed will be best assessed on a full record at trial. As an initial matter, claim 1 does not recite a "maximum level of aspiration in a rapid fashion." At most, Patent Owner's argument (if accepted) may weaken some of Petitioner's reasoning for modifying the prior art.

In any event, we are at this stage unpersuaded that a pump would not, when a fluid control valve is closed, generate a vacuum pressure and operate in the manner claimed. *See, e.g.*, Ex. 1003 ¶¶ 103–105 (testifying that a stopcock and aspiration pump would generate a vacuum and provide for rapid aspiration). Garrison does not disclose that only syringes have such capability, and Garrison teaches, in the same paragraph where the cited

"maximum level of aspiration in a rapid fashion" appears, that several alternative aspiration sources may be used in its systems ("active source[s] of aspiration may be an aspiration pump, a regular or locking syringe, a hand-held aspirator, hospital suction, or the like"). Ex. 1006 ¶ 134. Garrison's disclosure is, thus, not limited to use of syringes or even peristaltic pumps (as allegedly depicted in Figure 34). We also note (as pointed out by Petitioner) that the '333 patent indicates that ***both*** pumps and syringes generate and store negative/vacuum pressure in an aspiration system.[18] Ex. 1001, 7:28–41, dependent claim 15 (aspiration source comprises "an electric pump"); Prelim. Reply 5. That a POSA would have understood that both syringes and pumps, like disclosed in Garrison, can generate a vacuum pressure to permit rapid aspiration of clots also finds further evidentiary support in Dr. Turk's testimony that surgeons have used pumps and syringes for that purpose since the early 2010s. Ex. 1022 ¶ 23. Moreover, although Laub teaches that running a pump continuously at high flow rates can assist with dislodging clots, Petitioner persuades us on the present record that a POSA would see benefit in modifying Laub's system to also allow for an initial or intermittent rapid burst of vacuum pressure to help remove a clot. Ex. 1003 ¶¶ 106, 109.

Patent Owner further argues that Laub and Aklog disclose continuous aspiration and recognize the need to return aspirated blood to the patient, yet Petitioner's proposed modifications are "incompatible" with continuous

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[18] The '333 patent indicates that a negative relative pressure is a vacuum. *See, e.g.*, Ex. 1001, 6:57–60 ("The pressure source . . . is configured to generate (e.g., form, create, charge, build-up, etc.) a ***vacuum*** (***e.g., negative relative pressure***) and store the vacuum for subsequent application to the catheter subsystem[.]") (emphasis added).

aspiration and reinfusion. Prelim. Resp. 46–49 (noting the absence of any "valve" like claimed in Laub's or Aklog's systems). According to Patent Owner, failing to return blood to the patient when high volumes of blood are aspirated continuously and at high flow rates can result in dangerous levels of blood loss. *Id.* (citing Ex. 1012 ¶ 45). In Petitioner's modification, Patent Owner alleges, adding Garrison's valve and closing it while a vacuum is generated "would prevent the continuous/simultaneous reinfusion" that Laub and Aklog teach is more effective and critical for patient safety. *Id.* at 48–49 (arguing, "when the valve is closed, the pump in either modified system could operate to reinfuse but not aspirate—rendering those operations discontinuous"); Ex. 2005 ¶¶ 88–90.

Relatedly, Patent Owner argues that embodiments of Garrison cited by Petitioner are unsuitable for blood return. Prelim. Resp. 49–52. Patent Owner cites Garrison's disclosure about "[o]ne disadvantage of current sources of aspiration" where blood received into an external reservoir or syringe remains static or is exposed to air for a time, thereby increasing the risk of thrombus formation. *Id.* (citing Ex. 1006 ¶ 135 (disclosing that "pumps such as centrifugal or peristaltic pumps are known to cause damage to blood cells" and "[u]sually, aspirated blood is not returned to the patient to avoid risk of thromboembolism")). Thus, Patent Owner argues, a POSA would not have modified Laub or Aklog with Garrison's embodiments because a POSA would have understood them to be incompatible with blood return. *Id.* (citing Ex. 2005 ¶¶ 92–94).

Patent Owner's arguments do not undermine Petitioner's challenge at this stage. We include the following preliminary observations: (1) Garrison teaches that blood may be returned to the patient and describes an exemplary

pump that may be useful for doing so (*see, e.g.*, Ex. 1006 ¶ 136, Fig. 36)[19]; (2) although Garrison notes "disadvantages" with some aspiration sources, such "disadvantages" should be considered in context of the other cited art—Laub and Aklog, for example, teach that aspirated blood (including blood aspirated with conventional pumps, like centrifugal or peristaltic pumps) can safely be returned to the patient (Ex. 1012 ¶ 41; Ex. 1005, 12:9–14); (3) Laub and Aklog do not require continuous aspiration—their systems can run continuously or intermittently (*see, e.g.*, Ex. 1005, 12:6–9); (4) although Laub indicates that, "[i]n certain embodiments, reinfusing the patient's blood continuously" at high flow rates can help dislodge clots (Ex. 1012 ¶ 45), as noted above, we are persuaded at present that a POSA would have seen a benefit in a system that also allows the user to apply a rapid burst of vacuum pressure; and (5) the valve closure and vacuum generation would seem to be a temporary step to enable a rapid burst of suction—without blood being withdrawn from the patient during this brief window—so we are skeptical that potential blood loss or thrombus formation would have been a concern sufficient to discourage the proposed modification. Prelim. Reply 6 (noting that Garrison discloses closing the valve prior to the thrombectomy step (Ex. 1006 ¶ 134), and asserting that once Garrison's valve in the modified system is opened, the system could run continuously). The parties may consider further developing the trial record to address the above issues.

[19] Patent Owner argues that the pump of Garrison shown in Figure 36 is configured to provide for continuous, real-time aspiration and reinfusion of blood to the patient and, thus, is incompatible with a modification that would pause such continuous operation to allow a vacuum pressure to be generated and to provide for a short burst of aspiration. Prelim. Resp. 59–62. We will revisit this argument, if preserved by Patent Owner at trial, on a full record.

Patent Owner also argues that Petitioner's modifications to Laub and Aklog would introduce dangerous flow paths. Prelim. Resp. 52–55. More specifically, Patent Owner argues that a POSA would not have been motivated to add a 3-way or 4-way stopcock (as the alleged "valve" cited by Petitioner) in the systems like depicted in Laub's Figure 1A or Aklog's Figure 7, where only two portions of tubing would have been joined together at the valve. *Id.* (citing Ex. 2005 ¶¶ 95–97). If, Patent Owner explains, a 3-way stopcock would have been added to two portions of tubing—rather than three portions of tubing like shown in Garrison's Figure 34—one port of the stopcock would remain open and exposed to the surrounding environment. *Id.* And, when this stopcock was placed into fluid connection with a pressure source and actuated, air would be sucked into the unconnected port and "be reinfused into the patient in real-time leading to a dangerous and potentially deadly air embolism." *Id.* Patent Owner contends that a POSA would not, therefore, have made or used such a system. *Id.*

We acknowledge Patent Owner's argument insofar as it seizes on Petitioner's assertion that "Garrison's valve 3325" could be used in a modified system of Laub or Aklog. Prelim. Resp. 52 (citing Pet. 38–41); Ex. 1006, Fig. 34 (depicting valve 3325 as an apparent 3-way stopcock, connecting three tubing sections). Nonetheless, the obviousness analysis presumes that the POSA is one of "ordinary creativity, not an automaton." *KSR*, 550 U.S. at 421. As one of ***skill***, the POSA would not simply have used a stopcock with an open port that would allow air to be sucked into the system (or blood to spill out of it). But that does not mean that a skilled artisan would have foregone the use of Garrison's stopcocks altogether. We reject the premise of Patent Owner's argument to the contrary. *In re Sovish*, 769 F.2d 738, 743 (Fed. Cir. 1985) (rejecting an argument that "presumes

stupidity rather than [ordinary] skill"). As Petitioner contends, stopcocks are well-known and simple mechanical structures, Garrison describes 3-way or 4-way stopcocks as exemplary, and, even if a 3-way stopcock was used to connect only two tubing sections, a POSA would have readily understood how to prevent air ingress, such as by capping the unused port. Prelim. Reply 6–7 (citing Ex. 1006 ¶ 132; Ex. 1003 ¶¶ 107–108, 139).

Patent Owner argues that Petitioner's modifications would "needlessly complicate" Laub and Aklog and, thus, would not have been made. Prelim. Resp. 55–56. According to Patent Owner, each of Laub's and Aklog's systems allow the user (e.g., a surgeon) to control the speed and other attributes of the pumps directly, and adding a separate user-actuated valve that the user would have to manually control would only unnecessarily complicate those systems. *Id.* (citing Ex. 1005, 11:62–12:14; Ex. 1012 ¶ 41; Ex. 2005 ¶ 101).

We disagree. That a user might have adjusted, for example, a pump's speed via controls on the pump itself does not mean that the user could, absent Petitioner's proposed modification, have generated and applied a rapid burst of vacuum pressure like described in Garrison—at least that has not been supported by persuasive evidence on this record. Moreover, as Petitioner points out, stopcocks are simple devices and, if added to the tubing sections of Laub's and Aklog's systems, would have been closer to the operative site for ease of use by the physician. Prelim. Reply 7 (citing Ex. 1003 ¶¶ 106, 109; Ex. 1022 ¶ 23).

Lastly, with reference to Grounds 3A and 4A, Patent Owner argues that a POSA would not have modified Garrison's systems to treat PE.

Prelim. Resp. 56–62.[20] But, here again, the thrust of Patent Owner's argument is that Garrison's systems are incompatible with returning aspirated blood to the patient, which blood return Patent Owner contends Laub and Aklog suggest is necessary when treating PE (or DVT) and in those instances when blood is withdrawn at high volumes and flow rates. *Id.* (citing Ex. 1012 ¶ 45 ("Without returning the blood back to the patient, such high flow rates [(e.g., 2–4 L/min)] could quickly result in exsanguination of the patient.")). We direct Patent Owner to our "preliminary observations" above and emphasize that, based on the asserted prior art, a POSA would have known and reasonably expected that aspirated blood (including blood aspirated with electric pumps) could be returned safely to the patient, if needed, to minimize fluid loss. Patent Owner's counterargument is unavailing on this preliminary record.

4. Conclusion

For the reasons above and based on the record at this stage, we find Petitioner has met its institution burden, and established that it is reasonably likely to prevail in showing that at least claim 1 is unpatentable under Grounds 1A, 2A, 3A, and 4A.

F. Other Grounds (Grounds 2B–D, 3B–D, 4B–D)

Petitioner's other grounds challenge various dependent claims and rely on additional features taught or suggested in Goff, Schaffer, and

[20] Patent Owner cites the Examiner's conclusion during prosecution that "it would not be reasonable" to modify Garrison to treat PE or DVT. Prelim. Resp. 63–64 (citing Ex. 1002, 46–47). As explained above, the evidence in this proceeding is to the contrary and supports a preliminary determination that using aspiration catheter systems designed for one part of the vasculature in another part, and resizing a catheter if needed, would have been a routine and obvious undertaking for the POSA.

Hartley. *See, e.g.*, Pet. 65–71 (asserting that dependent claim 6, reciting "removing the filter from within the clot canister," would have been obvious over Goff's teaching of disposable and removable filter elements when added to the systems of Laub, Aklog, and Garrison). Patent Owner provides no counterargument to these additional grounds beyond its counterargument for Grounds 1A, 2A, 3A, and 4A. Prelim. Resp. 64–65. That counterargument is unavailing at this stage as we explained above.

IV. CONCLUSION

Based on this preliminary record, we determine that Petitioner has shown a reasonable likelihood that it will prevail with respect to at least one of the claims challenged in the Petition. We institute trial on all challenged claims under the grounds raised in the Petition. *PGS Geophysical AS v. Iancu*, 891 F.3d 1354, 1360 (Fed. Cir. 2018) (explaining that institution of *inter partes* review "require[s] a simple yes-or-no institution choice . . . embracing all challenges included in the petition"); 37 C.F.R. § 42.108(a).

Any argument not raised in a Patent Owner Response to the Petition, or as permitted in another manner during trial, shall be deemed forfeited and/or waived even if asserted in the Preliminary Response. *In re Google Tech. Holdings LLC*, 980 F.3d 858, 862–64 (Fed. Cir. 2020) (holding an argument forfeited when not timely raised before the Board); *In re NuVasive, Inc.*, 842 F.3d 1376, 1380–81 (Fed. Cir. 2016) (holding Patent Owner waived an argument addressed in the Preliminary Response by not raising the same argument in the Patent Owner Response).

V. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that, pursuant to 35 U.S.C. § 314(a), *inter partes* review of all challenged claims of the ’333 patent is instituted on the grounds of unpatentability set forth in the Petition; and

FURTHER ORDERED that, pursuant to 35 U.S.C. § 314(a) and 37 C.F.R. § 42.4, notice is given of institution of trial commencing on the entry date of this Decision.

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