

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. IPR2024-01257
U.S. Patent No. 11,744,691

PATENT OWNER'S PRELIMINARY RESPONSE

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EXHIBIT LIST

	Petitioner's Exhibits
Exhibit	Description
1001	U.S. Patent No. 11,744,691 ("the '691 Patent")
1002	'691 Patent Prosecution History
1003	Expert Declaration of Troy Thornton
1004	Resume of Troy Thornton
1005	U.S. Patent No. 8,734,374 B2 to Aklog et al. ("Aklog")
1006	U.S. Patent Publication No. 2015/0173782 A1 to Garrison et al. ("Garrison")
1007	WIPO Publication No. WO 2006/124307 A2 to Goff et al. ("Goff")
1008	U.S. Patent Publication No. 2003/0116731 A1 to Hartley ("Hartley")
1009	U.S. Patent No. 6,776,770 B2 to Treretola ("Treretola")
1010	U.S. Patent Publication No. 2010/0042118 A1 to Garrison et al.
1011	U.S. Patent No. 8,535,283 B2 to Heaton et al. ("Heaton")
1012	U.S. Patent Publication No. 2005/0004534 A1 to Lockwood et al. ("Lockwood")
1013	U.S. Patent Publication No. 2015/0352325 A1 to Quick et al. ("Quick")
1014	U.S. Patent No. 5,938,645 to Gordon ("Gordon")
1015	U.S. Patent Publication No. 2014/0296868 A1 to Garrison et al.
1016	U.S. Patent No. 7,998,104 B2 to Chang ("Chang")
1017	U.S. Patent No. 8,157,760 B2 to Criado et al. ("Criado")

	Petitioner's Exhibits
Exhibit	Description
1018	U.S. Patent No. 6,481,439 B1 to Lewis et al. ("Lewis")
1019	U.S. Patent No. 8,075,510 B2 to Aklog et al.
1020	WIPO Publication No. WO 2018/019829 A1 to Brady et al. ("Brady")
1021	U.S. Patent Application No. 16/117,519 (the "519 application")
1022	Expert Declaration of Dr. Aquilla S. Turk, III, DO
1023	Resume of Dr. Aquilla Turk, III, D.O.
1024	Shani, Jacob M.D., et al., Mechanical Manipulation of Thrombus: Coronary Thrombectomy, Intracoronary Clot Displacement, and Transcatheter Aspiration, 72 Am. J. Cardiol. 116G-118G (1993)
1025	Bose, A et al., The Penumbra System: A Mechanical Device for the Treatment of Acute Stroke due to Thromboembolism, 29 Am. J. Neuroradiol. 1409-1413 (Aug. 2008)
1026	Turk, Aquilla S. et al., Initial clinical experience with the ADAPT technique: A direct aspiration first pass technique for stroke thrombectomy, 6 J. NeuroIntervent. Surg. 231-237 (2014)
1027	Turk, Aquilla S. et al., ADAPT FAST study: a direct aspiration first pass technique for acute stroke thrombectomy, 6 J. NeuroIntervent. Surg. 260-264 (2014)
1028	April 24, 2024 Letter from Inari to Imperative Care
1029	Turk, Aquilla S. et al., Aspiration thrombectomy versus stent retriever thrombectomy as first-line approach for large vessel occlusion (COMPASS): a multicentre, randomized, open label,

	Petitioner's Exhibits
Exhibit	Description
	blinded outcome, non-inferiority trial, 393 Lancet 998-1008 (March 2019)
1030	Save, Jeffrey L., Time is Brain – Quantified, American Heart Association Journals, available at http://www.stokeaha.org (2005).

	Patent Owner's Exhibits
Exhibit	Description
2001	Declaration of Brian Brown
2002	Prosecution History of U.S. Patent No. 11,642,209
2003	U.S. Patent Publication No. 2013/0281788 to Garrison (“Garrison ‘788 publication”)
2004	U.S. Patent Application No. 2016/0220741
2005	Excerpt of Prosecution History of U.S. Patent No. 11,554,005 (October 5, 2022, Non-Final Office Action)
2006	Amended Complaint in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 4:24-cv-03117-YGR (N.D. Cal.), Dkt. 20
2007	Time to Trial Data from Last 5 Years in Northern District of California

I. INTRODUCTION

The Board should deny institution. First, the Petition relies on the exact same prior art disclosures and arguments already fully considered by the Patent Office, meriting discretionary denial under Section 325(d). Second, on the merits, the Patent Office got it right: Petitioner's primary reference for all grounds, Garrison, does not disclose a "valve [] configured to be closed while negative pressure is generated in the first and second chambers," as recited in all of the independent claims of the '691 Patent. Because the remaining challenged dependent claims depend either directly or indirectly from those independent claims, Petitioner's attacks for those also fail.¹

Every independent claim of the '691 Patent recites, *inter alia*, an "aspiration system" comprising "an aspiration pump in communication with a first chamber," "a second chamber," and a "valve [] configured to be closed while negative pressure is generated in the first and second chambers." EX1001, Claims 1, 14, 23, 28. Grounds 1 and 2 rely on Garrison (EX1006) alone. Petition (Paper 2), p.23. Similarly, Grounds 3-8 cite Garrison as the primary reference and simply refer to the Petition's application of Garrison to Claim 1 for the limitations requiring a negative

¹ There are additional independent reasons that the claims are patentable over the Petitioner's cited art, but Patent Owner focuses here on deficiencies that are common to all of Petitioner's grounds.

pressure to be generated in both a first and second chamber. Petition, pp.26-30, 35-36, 80, 83, 86. The Petition does not rely on or cite any other reference or make any further arguments for those key limitations.

But the Patent Office *already* determined during prosecution of a parent application of the '691 Patent that a Garrison disclosure (specifically the “Garrison '788 publication” (EX2003)) with substantially and materially the same disclosure as the Garrison reference relied on by Petitioner here does not render those limitations unpatentable. During prosecution of the “Parent '315 Application,” the Patent Office did not maintain a rejection of a pending claim over the Garrison '788 publication after applicant amended the claim to include a “valve [] configured to be closed while negative pressure is generated in the *first and second* chambers”² because the Garrison publication did not disclose or render obvious this limitation. EX2002, pp. 64-70, 102. Accordingly, the Patent Office has previously considered the *same disclosure* as the Garrison reference Petitioner relies on here and determined that it does not disclose an “aspiration system” comprising “an aspiration pump in communication with a first chamber,” “a second chamber,” together with a “valve [] configured to be closed while negative pressure is generated in the first and

² All emphasis added unless otherwise noted.

second chambers,” limitations that are also recited in every independent claim of the challenged '691 Patent. EX2002, pp. 64-70, 102.

Not only that, but, during prosecution of the '691 Patent, the Patent Office considered the exact Garrison reference cited in the Petition along with Petitioner's other cited art (or materially identical art). Indeed, Petitioner does not dispute that all of Garrison, Hartley, and Goff were before the Patent Office during prosecution of the '691 Patent itself. Petition, p.88; EX1002, p.323 (citing Garrison), p.364 (citing Goff), & p.360 (citing Hartley). As to Petitioner's final cited reference, Aklog (EX1005), the Office considered Aklog's parent (EX1019), which includes the identical figures and description upon which Petitioner now relies. EX2001, ¶¶99-102. The Patent Office has therefore already considered all of the Petitioner's cited prior art or the same disclosures as are found in them—and has found that limitations recited in the independent Claims 1, 14, 23, and 28 of the '691 Patent are patentable over everything relied on in the Petition. Patent Owner accordingly requests that the Board exercise its discretion to deny the Petition under Section 325(d).

Additionally, apart from Section 325(d), the Board can and should deny the Petition because Petitioner cannot demonstrate a reasonable likelihood that it will prevail with respect to the patentability of any of Claims 1-31 of the '691 Patent. Like the Patent Office has already determined, Garrison fails to disclose or render obvious an aspiration system comprising “an aspiration pump in communication

with a first chamber,” “a second chamber,” and a “valve [] configured to be closed while negative pressure is generated in [both of] the first and second chambers,” as recited in all independent claims of the '691 Patent. To the contrary, the purported first chamber in Garrison, a receptacle (3100), is located downstream from (*e.g.*, proximal to) Garrison's aspiration pump such that Garrison's aspiration pump cannot generate negative pressure in that receptacle, as required by the claims.

As shown in the portion of Figure 32 annotated below, the alleged first chamber, receptacle 3100, is located proximal to item 3125, a peristaltic pump:

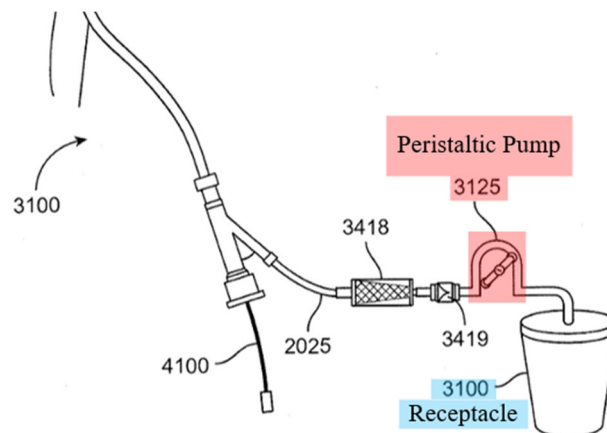


FIG. 32

EX1006, Fig. 32 (annotated).

That same configuration is also shown in Figure 34—a peristaltic pump followed by a receptacle. In either case, the pump delivers fluid (*e.g.*, blood) to the receptacle via positive pressure such that the pump does not and cannot generate negative pressure in the receptacle.

Petitioner makes no argument that a POSITA would have modified Garrison to arrive at “an aspiration pump in communication with a first chamber” and a “valve [] configured to be closed while negative pressure is generated in the first and second chambers,” as claimed, or that any other reference discloses or renders obvious those limitations. Instead, Petitioner’s entire obviousness argument for those limitations (Ground 2) rises and falls on whether Garrison itself discloses those limitations—which it does not. Petition, p.24 n.2 (Ground 2 relying on the principle that “anticipation is the epitome of obviousness”). Moreover, a POSITA also would not have modified Garrison’s disclosed system to generate negative pressure in the receptacle because the pump is intended to deliver blood to the receptacle to be easily discarded or returned to the patient without disconnecting the aspiration source. This is not possible if the receptacle is upstream from (proximal to) the aspiration source, as required to generate negative pressure in the receptacle. EX2001, ¶88.

Accordingly, Petitioner fails to demonstrate that Garrison discloses that “negative pressure is generated in the first and second chambers,” and does not assert, let alone provide any evidence, that a POSITA would find those limitations obvious over Garrison or any other combination of references. Every challenged independent claim recites this, and Petitioner therefore fails to demonstrate a reasonable likelihood that it would prevail with respect to the patentability of any one of Claims 1-31 of the ’691 Patent.

Finally, the Petition should be denied under Section 314 to ensure efficiency and fairness in view of the ongoing parallel litigation in District Court that includes the same parties, claims, and issues, including claim construction.

For those and the following reasons, Patent Owner requests that the Petition be denied.

II. BACKGROUND

A. Overview of the '691 Patent

The '691 Patent is directed to improved aspiration systems with rapid accelerated response for removing clot material from a blood vessel of a human patient. EX1001, 4:17-19. The systems 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. *Id.* at 1:45-67; EX2001, ¶¶30, 32. Pulmonary embolism ("PE") and deep vein thrombosis ("DVT") are common and particularly dangerous types of VTE. EX1001, 1:45-67; EX2001, ¶33. 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, 1:45-67; EX2001, ¶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, 1:45-67; EX2001, ¶33.

VTE has traditionally been treated with drugs (thrombolytic agents) or invasive surgeries. EX1001, 2:1-33; EX2001, ¶34. However, these approaches have their 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 in many patients thrombolytic agents cannot be used at all. EX1001, 2:28-32; EX2001, ¶¶35-36. Invasive surgical procedures involve exposing a patient to surgery and may be traumatic to the patient. EX1001, 2:10-12. Even today, most commercially available treatment systems do not use the type of rapid aspiration described in the '691 Patent, instead employing a multitude of alternative solutions that have varying disadvantages. EX2001, ¶37.

The '691 Patent discloses aspiration systems that pre-charge or store negative (vacuum) pressure in chambers before applying the vacuum to an aspiration catheter positioned near clot material (*e.g.*, PE or DVT) in a blood vessel to rapidly generate large suction forces (and corresponding fluid flow velocities) needed to effectively aspirate and remove the clot material from the patient. EX1001, 4:34-50; EX2001, ¶37. The generated suction forces and corresponding fluid flow velocities are greater than conventional systems, more effectively removing clot material, even clot material that is strongly lodged or attached within the blood vessel, such as chronic clots. EX 1001, 4:42-47, 10:14-27; EX2001, ¶37.

The '691 Patent's claims recite an aspiration system with accelerated response, including:

- an aspiration pump in communication with a first chamber;
- an aspiration catheter in fluid communication with the first chamber via an aspiration tube;
- a second chamber between the aspiration pump and the aspiration catheter; and
- a user-actuable valve between the second chamber and the aspiration catheter to connect or disconnect negative pressure, allowing pressure to build up in the first and second chambers before connecting negative pressure to the aspiration catheter to aspirate clot material.

EX1001, Claim 1; EX2001, ¶38. When the user-actuable valve is opened to the pre-charged negative pressure generated in the first and second chambers, the vacuum is applied all at once to the aspiration catheter to generate rapid aspiration and high flow rates that are needed to effectively remove and treat clot material. EX2001, ¶38.

Figure 1 of the '691 Patent schematically shows an aspiration system including a pressure source in fluid communication with an aspiration catheter via a user-actuable valve:

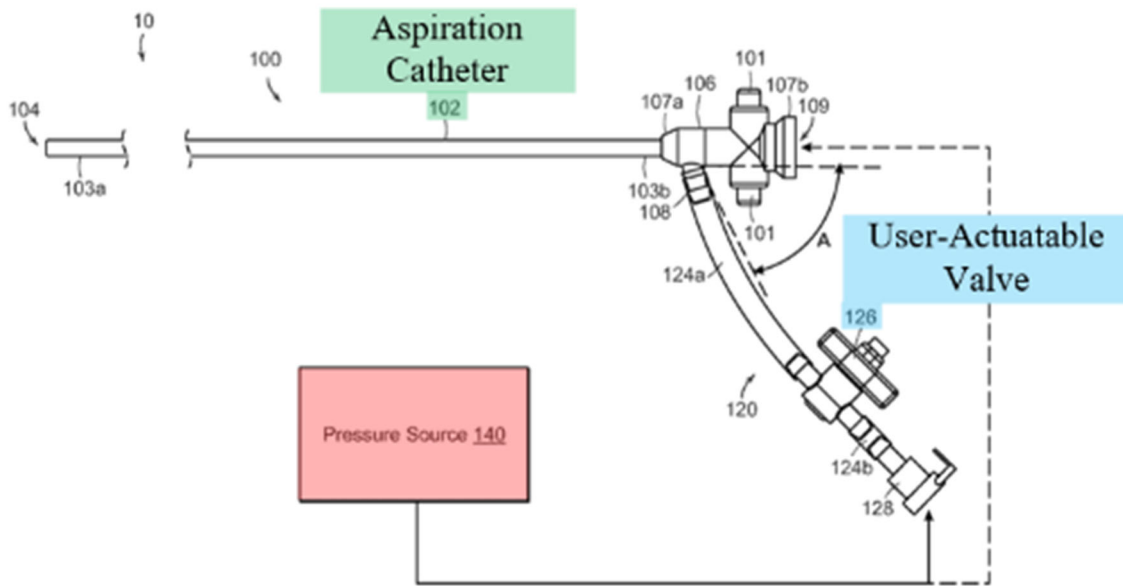
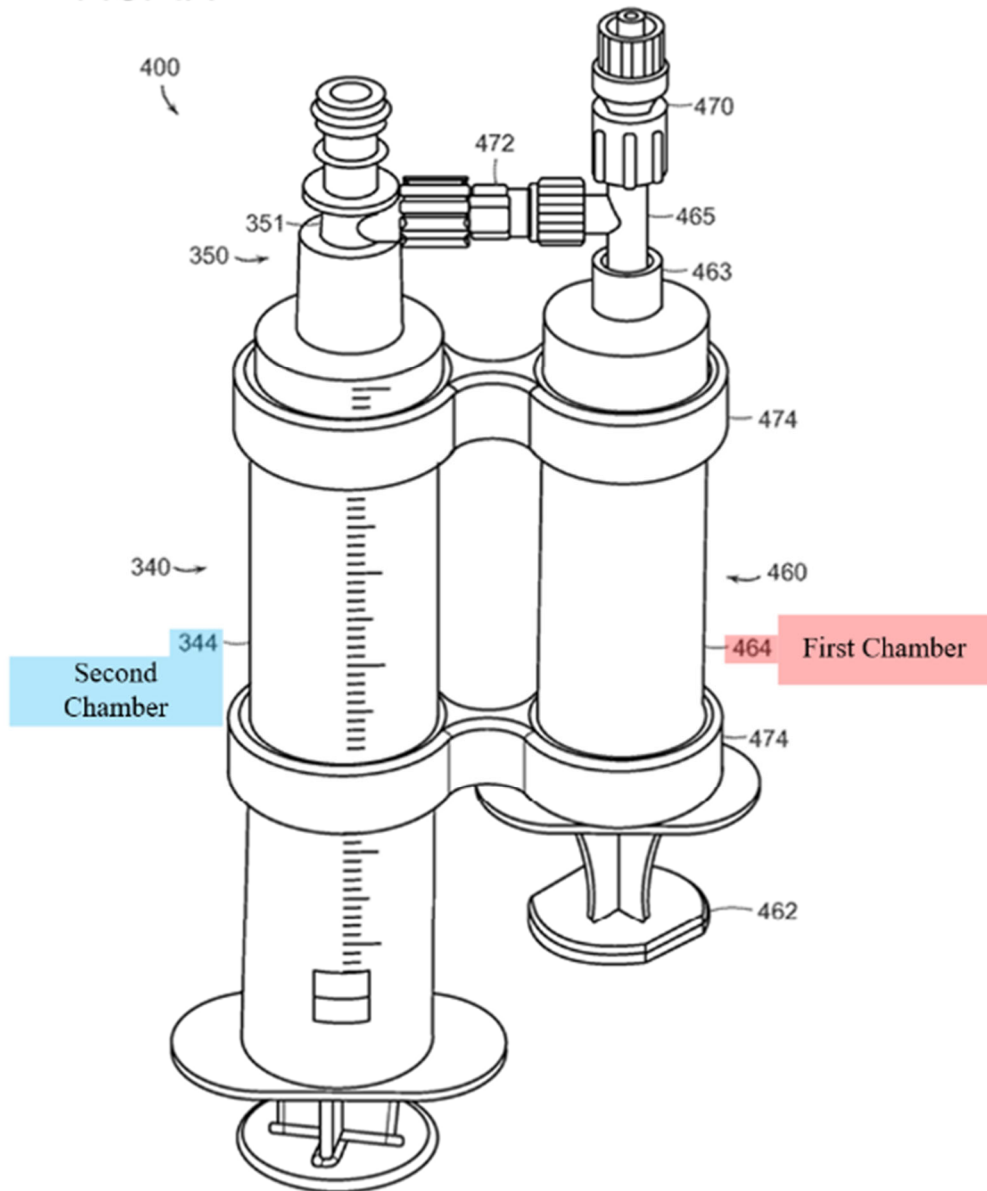


FIG. 1

EX1001, Fig. 1 (annotated); EX2001, ¶39. The '691 Patent describes that the pressure source “can be a pump (e.g., an electric pump coupled to a vacuum chamber) while, in other embodiments, the pressure source can include one or more syringes that can be actuated or otherwise activated by a user...to generate and store a vacuum therein.” EX1001, 7:33-38; EX2001, ¶40.

Figure 4 of the '691 Patent illustrates an example pressure source that includes a first chamber and a second chamber in fluid communication with one another:

FIG. 4A



EX1001, Fig. 4A (annotated); EX2001, ¶41. While the first chamber 464 is illustrated as a syringe in Figure 4, the '691 Patent discloses that "the secondary syringe 460 can comprise a pump or vacuum source other than a syringe." EX1001, 12:46-48; EX2001, ¶42.

The pump operates to generate negative pressure in the first and second chambers when the valve is closed such that the pressure is built up or charged in the chambers. EX2001, ¶43; EX1001, 6:60-64. This happens when the “user-actuable valve” is closed so that the first and second chambers are fluidly disconnected to the aspiration catheter. EX2001, ¶43; EX1001, 6:66-7:1. When the valve is opened, the first and second chambers are fluidly connected to the aspiration catheter. EX2001, ¶43; EX1001, 7:1-7:10. Fluid (*e.g.*, clot and blood) is rapidly aspirated into the second chamber by the built-up negative pressure in the second chamber, typically in less than a second. EX2001, ¶43; EX1001, 7:1-22, 10:1-13, 18:52-57. As the pressure increases in the second chamber after opening the valve, a pressure differential builds between the first and second chambers and causes fluid to flow from the second chamber to the first chamber to aid in rapid aspiration. EX2001, ¶43.

B. Claims

Every independent claim of the '691 Patent recites, *inter alia*, an “aspiration system” comprising at least “an aspiration pump in communication with a first chamber,” “a second chamber” and a “valve [] configured to be closed while negative pressure is generated in the first and second chambers.”

Specifically, independent Claim 1 recites in full:

An aspiration system with accelerated response, comprising:

an aspiration pump in communication with a first chamber;

a coupled assembly including:

an aspiration catheter configured for placement into fluid communication with the first chamber by way of an aspiration tube;

a second chamber in between the aspiration pump and the aspiration catheter; and

a hemostasis valve; and

a user-actuatable valve between the second chamber and the aspiration catheter, wherein *the valve is configured to be closed while negative pressure is generated in the first and second chambers*, and wherein the valve is configured to be opened after the negative pressure is generated in the first and second chambers;

wherein upon user actuation to open the valve with the negative pressure having been generated in the first and second chambers, fluid flow at least partially from the second chamber into the first chamber causes rapid aspiration into the second chamber.

Independent Claims 14, 23, and 28 each recite those same limitations as Claim

1, in addition to other limitations, as follows:

[14./23./28.] *An aspiration system* with accelerated response, comprising:

an aspiration pump in communication with a first chamber;

an aspiration catheter configured for placement into fluid communication with the first chamber by way of an aspiration tube;
a second chamber in between the aspiration pump and the aspiration catheter

a user-actuatable valve between the second chamber and the aspiration catheter, wherein *the valve is configured to be closed while negative pressure is generated in the first and second chambers*, and wherein the valve is configured to be opened after the negative pressure is generated in the first and second chambers;

wherein upon user actuation to open the valve with the negative pressure having been generated in the first and second chambers, fluid flow at least partially from the second chamber into the first chamber causes

C. Prosecution History

Patent Owner filed the application that became the '691 Patent on March 7, 2023. In the only Office action, the Examiner rejected the pending independent claims (then numbered 1 and 15) (i) for nonstatutory double patenting over parent U.S. Patent No. 11,642,209 ("the '209 Patent") and (ii) under 35 U.S.C. § 103 over a combination of Heaton (EX1011) and Lockwood (EX1012). EX1002, pp.258-65.

The Examiner found dependent Claims 6-10, 12, 17, and 18 allowable, and specifically observed that the prior art did not teach a coupled assembly including the second chamber, the aspiration catheter, and a hemostasis valve or where the second chamber is removably coupled between the aspiration pump and the catheter. *Id.* at pp.268-69. In response, Patent Owner canceled independent claims 1 and 15, and rewrote dependent Claims 6, 10, 17, and 18 in independent form. *Id.* at pp.245-53. Those claims were subsequently allowed and issued as independent Claims 1, 14, 23, and 28, respectively, of the '691 Patent. *Id.* at 51-52.

During prosecution of the '691 Patent, Patent Owner identified to the Office every reference asserted by Petitioner in Grounds 1-8 or a related reference with materially the same disclosure. Specifically, Garrison, Goff, and Hartley are cited in Information Disclosure Statements ("IDSs") (EX1002, pp. 323, 364, 360, respectively) and appear on the face of the '691 Patent. Likewise, another IDS submitted during the prosecution of the '691 Patent (EX1002, p.305) includes Aklog's parent (EX1019)—which, as described in detail below in Section III, contains the same disclosure of Aklog relied on in the Petition.

The Examiner also substantively considered and discussed Garrison's disclosure during prosecution of U.S. Patent Application No. 17/865,315 ("the Parent '315 Application"), which is a parent of the '691 Patent. EX1001, p.2 ("Related U.S. Application Data"). On the same day Applicant filed the '691 Patent (March 7, 2023),

Applicant amended the claims in the Parent '315 Application in response to a final Office Action. As shown in the following table the then pending claim 1 of the '315 Application is substantially similar to the '691 Patent's original Claim 1:

Pending Claim 1 of the Parent '315 Application at Time of 2/10/2023 Final Office Action	Originally-Filed Claim 1 of the '691 Patent
An aspiration system with accelerated response, comprising:	An aspiration system with accelerated response, comprising:
an aspiration pump in communication with a first chamber;	an aspiration pump in communication with a first chamber;
an aspiration catheter configured for placement into fluid communication with the first chamber by way of an aspiration tube;	an aspiration catheter configured for placement into fluid communication with the first chamber by way of an aspiration tube;
a second chamber in between the aspiration pump and the catheter; and	a second chamber in between the aspiration pump and the catheter; and
a valve between the second chamber and the aspiration catheter, wherein the valve is configured to be closed while negative pressure is generated in the first and second chambers, and wherein the valve is configured to be opened after the negative pressure is generated in the first and second chambers;	a <u>user-actuatable</u> valve between the second chamber and the aspiration catheter, wherein the valve is configured to be closed while negative pressure is generated in the first and second chambers, and wherein the valve is configured to be opened after the negative pressure is generated in the first and second chambers;
wherein upon <u>opening of the valve with the negative pressure in the first and second chambers</u> , fluid flow at least partially from the second chamber into the first chamber causes rapid aspiration into the second chamber.	wherein upon <u>user actuation to open the valve with the negative pressure having been generated in the first and second chambers</u> , fluid flow at least partially from the second chamber into the first chamber causes rapid aspiration into the second chamber.

EX1002, p.567; EX2002, p.2691. The two claims differ only in the portions underlined above.

The same Primary and Assistant Examiners examined the Parent '315 Application and the application that became the '691 Patent and recognized the similarity of the claims in both applications. *See* EX1002, pp.258-60 (double patenting rejection); *compare* EX1001, p.1 with EX2002, p.10 (identifying same examiners). As explained below in Section III, the Office expressly considered the Garrison '788 publication, which has the same disclosure and figures as the portions of Garrison relied on by Petitioner here, during prosecution of the Parent '315 Application, for instance.

The Examiner noted in an interview that an amendment “to more specifically describe how fluid flows [in the system] overcome[s] the prior art” including the Garrison '788 publication. EX2002, p.112. Then in response to an amendment adding the limitation “the valve is configured to be closed while negative pressure is generated in the first and second chambers, and wherein the valve is configured to be opened after the negative pressure is generated in the first and second chambers,” the Examiner found the rejections including the Garrison '788 patent moot and asserted other references. EX2002, p.71.

D. Claim Construction

Petitioner proposes a claim construction for a single term, “filament,” recited

in Claims 3 and 23. This claim construction issue is not germane to Patent Owner's arguments here, and it is therefore not necessary at this time to analyze that claim term. Patent Owner reserves the right to construe "filament" according to its plain and ordinary meaning during the trial phase, if needed.³

E. Person of Ordinary Skill in the Art

Petitioner asserts that a POSITA has "an undergraduate degree in mechanical engineering or a related engineering discipline and 2-4 years of catheter design experience." Petition, p.20. This is insufficient to qualify as a POSITA. Nevertheless, Patent Owner applies Petitioner's definition herein as, even under this definition, Petitioner has failed to meet its burden.

F. Garrison and the Garrison '788 Publication

Garrison is the primary reference relied on by Petitioner in each of Grounds 1-8. The Office extensively analyzed the Garrison '788 publication which contains the same disclosure as Garrison. The following summarizes the disclosure found in both the Garrison reference (EX1006) relied upon by Petitioner (and disclosed in an

³ Petitioner has proposed the same construction for the term "filament" here as it did in IPR2024-01157 (Paper 1). The construction of the term there mattered to the arguments presented in opposition to the Petition there, so Patent Owner provided its views on the proper construction of this term in IPR2024-01157 (Paper 5).

IDS to the Examiner) and the Garrison '788 publication (EX2003; which the same Examiner considered during prosecution of the Parent '315 Application and is substantively identical in relevant part to the Garrison reference relied upon by Petitioner).

Garrison is generally directed to methods and devices for treating acute ischemic stroke caused by small clots in the cerebral arterial (rather than venous) vasculature. EX1006, ¶2; EX2003, ¶2; EX2001, ¶50. Garrison discloses various systems of devices for accessing the cerebral arterial vasculature (e.g. the middle cerebral artery ("MCA") or intermediate cerebral artery ("ICA")) through the common carotid artery ("CCA"). EX1006, ¶50; EX2003, ¶45; EX2001, ¶50. The systems can include an aspiration device or structure. EX1006, ¶130; EX2003, ¶84; EX2001, ¶50.

For example, Figure 32 of Garrison, which also is in Garrison '788 (Figure 15), discloses an arterial access device (also called an access sheath) connected to a delivery location, such as a receptacle, via a flow line. EX1006, ¶131; EX2003, ¶85; EX2001, ¶51. A source of aspiration, a filter, and a check valve are positioned sequentially along the flow line:

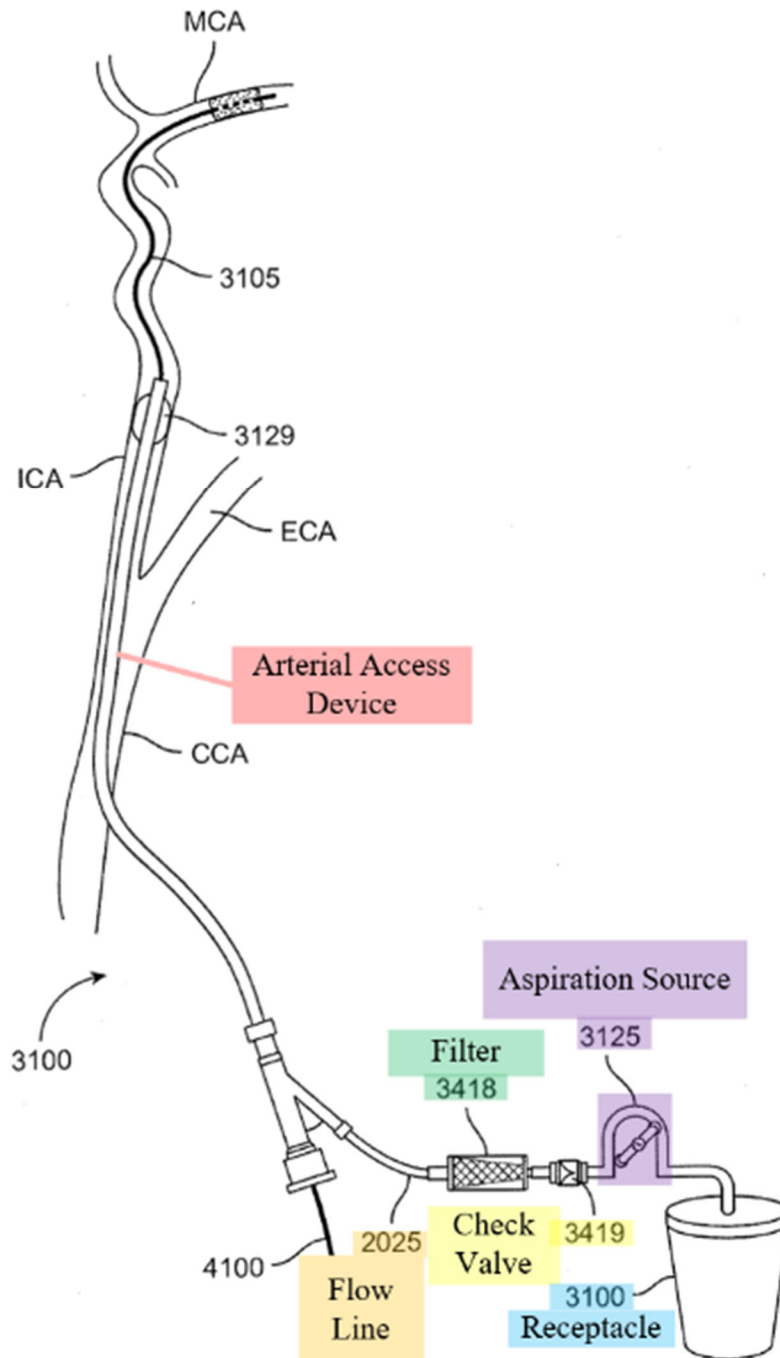


FIG. 32

EX1006, Fig. 32 (annotated), ¶131; EX2003, ¶85; EX2001, ¶51.

A POSITA would recognize the aspiration source 3125 as a peristaltic pump

based on its depiction including compressible tubing and a rotatable shaft connected to a rotor that carries multiple rollers for compressing the tubing:

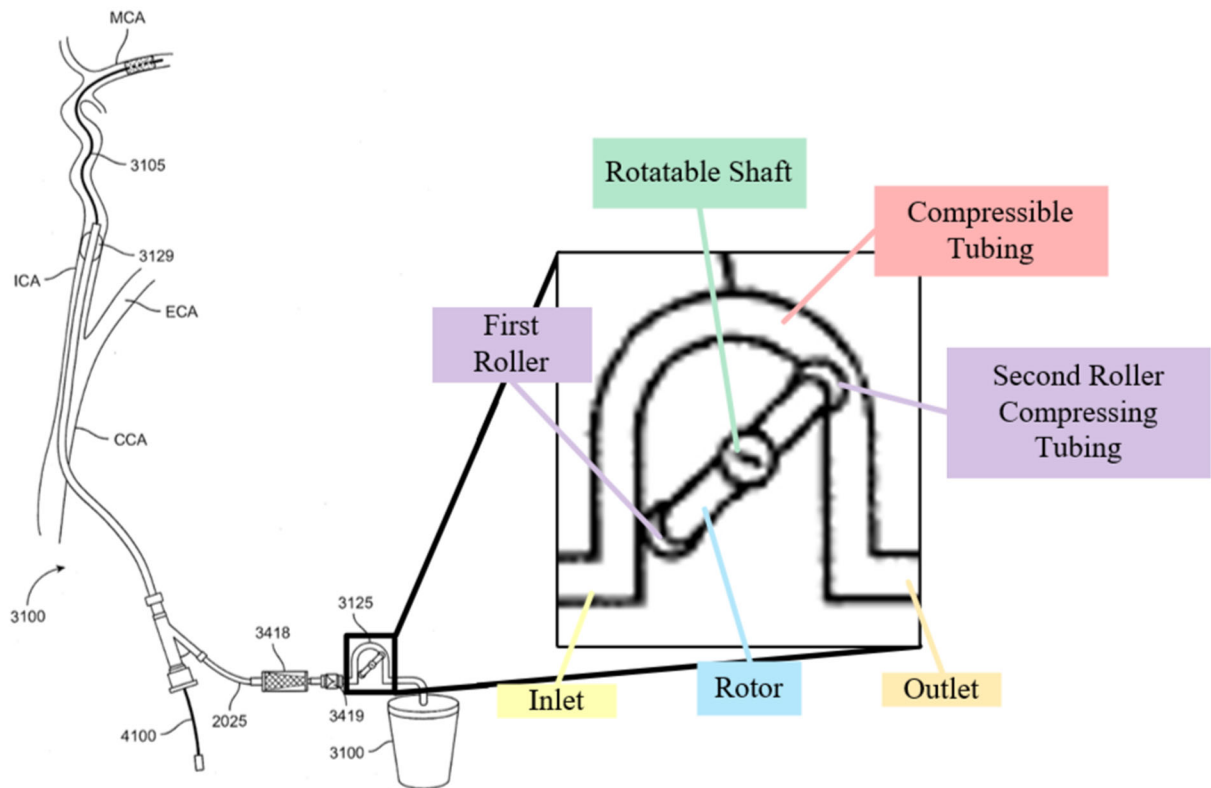


FIG. 32

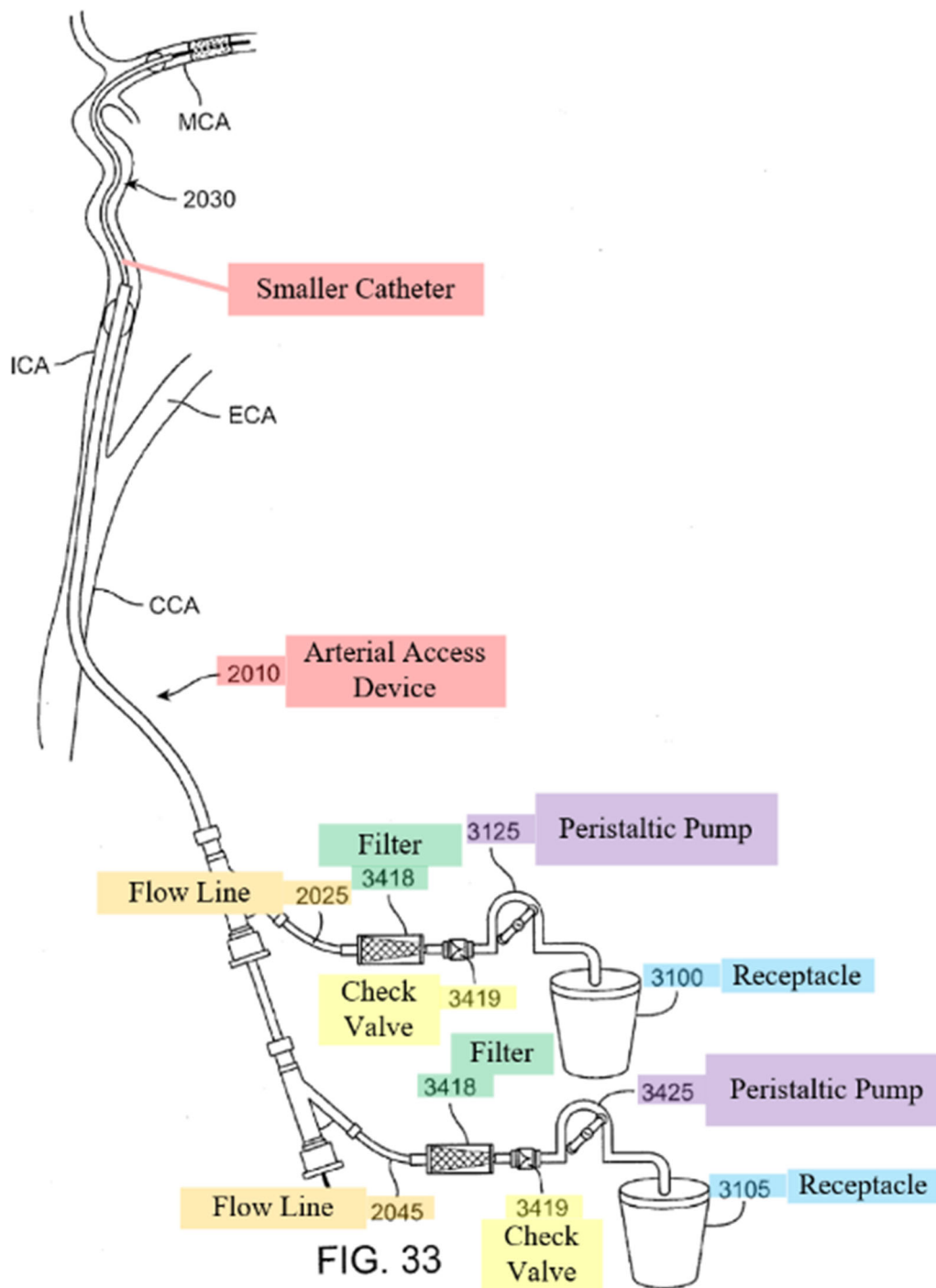
EX1006, Fig. 32 (annotated); EX2001, ¶52. The peristaltic pump operates by rotating the shaft to rotate the rotor, such that the rollers compress the tubing to: (1) generate negative pressure to draw fluid through the flow line 2025 through the inlet of the pump, (2) transport the fluid through the pump, and (3) expel the fluid through the outlet of the pump for delivery to the receptacle 3100. EX2001, ¶52. Accordingly, negative pressure is only generated on the inlet side of the pump (e.g.,

toward the catheter), and positive pressure is only generated on the outlet side of the pump (e.g., toward the receptacle). *Id.*

The specifics of this configuration are important. In contrast to the '691 Patent, Garrison's pump **cannot** generate negative pressure downstream of the outlet with this arrangement, such as in the receptacle. *Id.* Instead, the pump would generate positive pressure in the receptacle if it were sealed, or the receptacle would remain at atmospheric pressure if the receptacle were vented. *Id.* Those are the only two options. *Id.*

A POSITA would further understand the peristaltic pump to advantageously contain blood entirely within the tubing as it moves through the peristaltic pump such that the blood does not directly contact any of the pump parts which could lead to contamination of the blood and require cleaning or disposal of the pump parts contacting the blood as opposed to simply discarding just the tubing. *Id.* at ¶53.

Figure 33 of Garrison which also is in Garrison '788 (Figure 16), illustrates a similar system to Figure 32 but further including a second and smaller catheter inserted through the arterial access device and containing similar flow connections to a second separate peristaltic pump and downstream receptacle via a separate flow line:



EX1006, Fig. 33 (annotated), ¶131; EX2003, ¶85; EX2001, ¶54.

Figure 34 of Garrison, which also is in Garrison '788 (Figure 17), illustrates the connection of the flow lines from the arterial access device and smaller catheter

to the peristaltic pump and downstream receptacle via a valve:

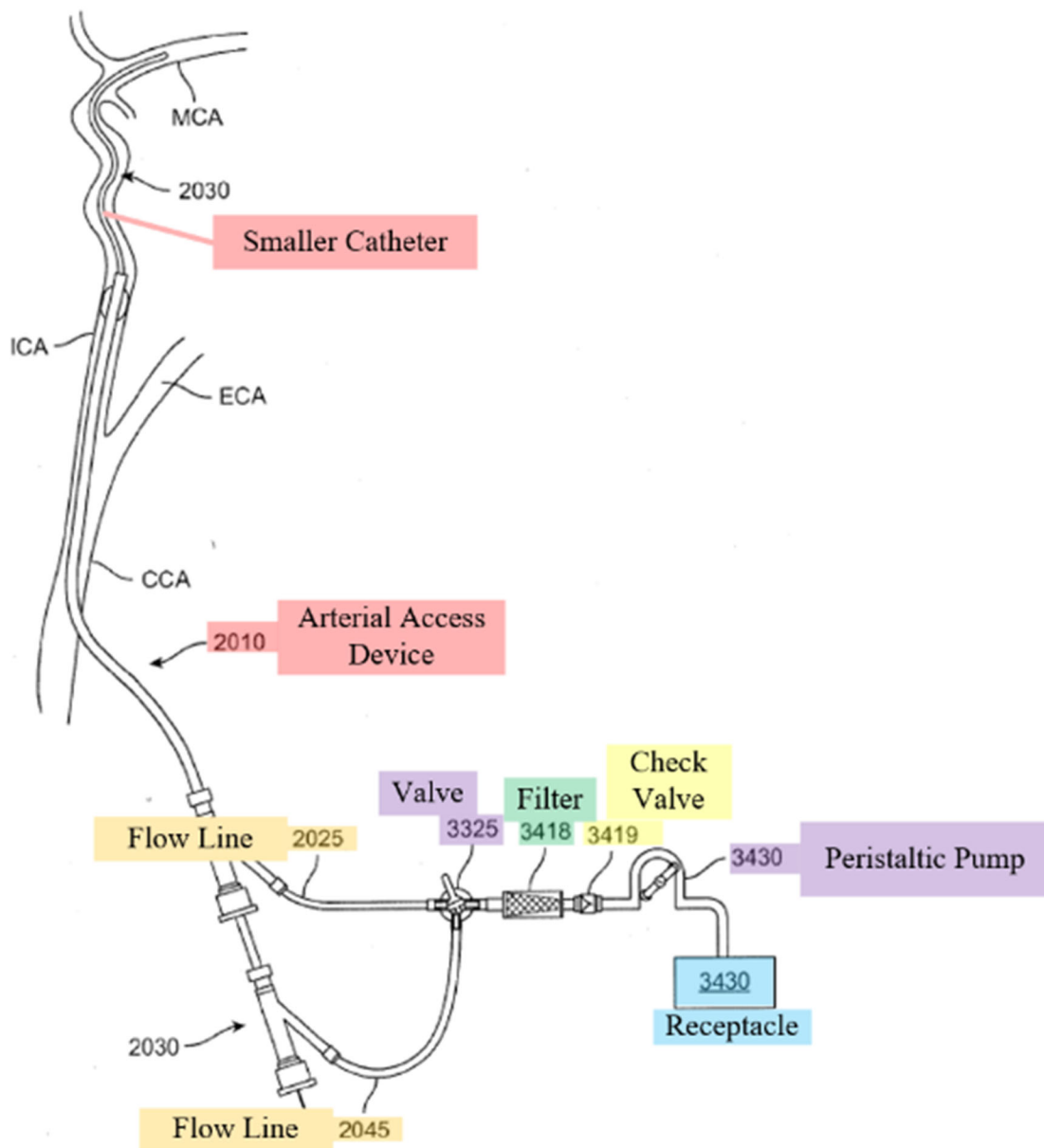


FIG. 34

EX1006, Fig. 34 (annotated), ¶132; EX2003, ¶86; EX2001, ¶55. The valve controls which device—the arterial access device or smaller catheter—is connected to the aspiration source. EX1006, ¶132; EX2003, ¶86; EX2001, ¶55. Specifically, the

valve may enable one device, the other device, both devices, or neither device to be connected to the aspiration source at any given time. EX1006, ¶132; EX2003, ¶86; EX2001, ¶55.

Garrison discloses that “receptacle 3100 and source of aspiration 3125 may be separate or may be combined into a single device such as a syringe.” EX1006, ¶131; EX2003, ¶85. Garrison further distinguishes an aspiration pump from a syringe as an aspiration source. EX2001, ¶56. For example, Garrison discloses the syringe as a distinct alternative to the pump: the “active source of aspiration may be an aspiration pump, a regular or locking syringe, a hand-held aspirator, hospital suction, **or** the like.” EX1006, ¶134; EX2003, ¶88; *see also*, EX1006, ¶71 (“aspiration source such as a pump or a syringe”).

Figure 36 of Garrison which also is in Garrison ’788 (Figure 19), discloses a “pump device” 3250 that can be configured to return blood to the central venous system in real time. EX1006, ¶¶136-137; EX2003, ¶¶90-91. This pump device is connected to either of the flow line of (a) the arterial access device or (b) smaller inner catheter, or both, and further includes a housing (3215) that encloses a chamber (3220) that is not fluidically connected to the catheter:

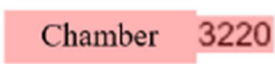


FIG. 36

EX1006, Fig. 36 (annotated), ¶136; EX2003, ¶90; EX2001, ¶57. The chamber 3220 is connected to a vacuum source 3230 configured to generate (1) negative pressure in the chamber to cause the expandable portion of the flow line to expand to draw

blood into the expandable portion through the upstream one of the check valves and (2) subsequent normalized pressure in the chamber to permit the expandable portion to contract to expel blood from the expandable portion through the downstream one of the check valves. EX1006, ¶¶136-137; EX2003, ¶¶90-91; EX2001, ¶58. Thus, like a peristaltic pump, the pump device operates to pull blood through an inlet and subsequently expel blood through an outlet using positive pressure. EX2001, ¶58. The pump device is “configured to return blood to the central venous system in real time during the procedure, so there is no reservoir in which the blood remains static” by operating the vacuum source so as to oscillate the expandable portion between the expanded and retracted states to thereby drive fluid through the flow line via the one-way check valves. EX1006, ¶¶136-137; EX2003, ¶¶90-91; EX2001, ¶58.

III. THE PETITION SHOULD BE DENIED UNDER SECTION 325(d)

The Board should exercise its discretion to deny the Petition because “the same or substantially the same prior art or arguments” were previously presented to the Patent Office. 35 U.S.C. § 325(d). Here, Applicant cited Garrison and every other reference or its substantial equivalent to the Office during prosecution of the '691 Patent claims. Further, the Office also substantively evaluated Garrison '788, which is materially identical to Garrison, during the prosecution of the Parent '315 Application where the Office found limitations identical to those challenged here to be patentable over Garrison's disclosure. The Petition offers nothing that the Office has

not already considered and rejected.

A. Legal Standard

The Board applies a “two-part framework” for evaluating whether to exercise discretion under Section 325(d) as set forth in *Advanced Bionics*:

1. whether the same or substantially the same art previously was presented to the Office or whether the same or substantially the same arguments previously were presented to the Office; and
2. if either condition of the first part of the framework is satisfied, whether the petitioner has demonstrated that the Office erred in a manner material to the patentability of challenged claims.

Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH, IPR2019-01469, Paper 6 (P.T.A.B. Feb. 13, 2020) (hereinafter “*Advanced Bionics*”). As part of evaluating this framework, the Board analyzes the six factors identified in *Becton, Dickinson & Co. v. B. Braun Melsungen AG*, IPR2017-01586, Paper 8, 17-18 (P.T.A.B. Dec. 15, 2017) (precedential as to § III.C.5, first paragraph) (“*Becton, Dickinson*”).⁴

⁴ The *Becton, Dickinson* factors are: (a) the similarities and material differences between the asserted art and the prior art involved during examination; (b) the

The Board considers *Beckton, Dickinson* factors (a), (b) and (d) under the first part of the *Advanced Bionics* framework and *Beckton, Dickinson* factors (c), (e) and (f) to address the second part of the framework and determine whether the Office materially erred. *Advanced Bionics*, Paper 6, p.4. As set forth below, every factor favors denial.

In *Becton, Dickinson*, the Board denied institution under Section 325(d) because the base reference asserted by the Petitioner had already been considered by the Office in the same manner during the prosecution of the parent to the challenged patent. IPR2017-01586, Paper 8, p.28 (P.T.A.B. Dec. 15, 2017). The Board confirmed that citation of a reference in a signed IDS is sufficient for the reference to

cumulative nature of the asserted art and the prior art evaluated during examination; (c) the extent to which the asserted art was evaluated during examination, including whether the prior art was the basis for rejection; (d) the extent of the overlap between the arguments made during examination and the manner in which a Petitioner relies on the prior art or a Patent Owner distinguishes the prior art; (e) whether a Petitioner has pointed out sufficiently how the Examiner erred in its evaluation the asserted prior art; and (f) the extent to which additional evidence and facts presented in the Petitioner warrant reconsideration of the prior art or arguments. *Becton, Dickinson*, Paper 8, pp.17-18.

be considered previously presented for purposes of Section 325(d), even absent substantive discussion of that reference by the Examiner or reliance upon it for an office action. Decision Denying Institution of *Inter Partes* Review, *Nu Mark LLC v. Fontem Holdings I, B.V.*, IPR2016-01309, Paper 11, pp.6-8 (P.T.A.B. Dec. 15, 2016); *Benitec Biopharma Ltd. v. Cold Spring Harbor Lab'y*, IPR2016-00014, Paper 7, p.10 (P.T.A.B. Mar. 23, 2016) (“An Examiner's initials on an IDS form ‘provides...a clear record in the application to indicate which documents have been considered by the examiner in the application.’”). The Board regularly denies institution where the examiners substantively addressed the cited art during prosecution. *See, e.g., Medtronic Corevalve LLC v. Speyside Med., LLC*, IPR2021-00241, Paper 9 (P.T.A.B. July 23, 2021); *ZTE (USA) Inc. v. Fractus, S.A.*, Case IPR2018-01451, Paper 12 (P.T.A.B. Feb. 19, 2019).

B. Petitioner's Asserted Art is Substantively Identical and Cumulative to the Prior Art Previously Considered by the Office

The Office previously considered every one of Petitioner's cited art, or a substantively identical and cumulative reference, during the prosecution of the '691 Patent and during the prosecution of related applications.

First, Petitioner's art, or substantively identical references, is cited in IDS's before the Office during the prosecution of the '691 patent. Garrison, Petitioner's primary reference, Hartley, and Goff were explicitly cited in that IDS. EX1002,

p.323 (citing Garrison), p.364 (citing Goff), & p.360 (citing Hartley). The same IDS's identify Aklog's substantively identical parent. EX1002, p.340 (citing Aklog's parent). As such, these references were before the Office during prosecution of the '691 Patent.

Second, Petitioner relies upon Garrison alone to argue that Claim 1 is not patentable, and Garrison serves as the base reference for all of Petitioner's Grounds directed to the remaining independent claims. Petition, p.23. But the Office has already considered the disclosure of Garrison and found that the same limitations recited in Claim 1 here are patentable over the Garrison '788 publication, which includes the same relevant disclosure as Garrison. EX2001, ¶¶95-98.

1. All of Petitioner's cited art was before the Office during prosecution.

Petitioner relies on Garrison alone or as the primary reference in combinations with Hartley, Goff, and/or Aklog in Grounds 1-8. Petition, p.23. Garrison, Hartley, and Goff were cited in an IDS and, as such, were before the Office during prosecution of the '691 Patent. EX1002, p.323 (citing Garrison), p.364 (citing Goff), & p.360 (citing Hartley).

And, although Aklog itself is not cited in the IDS, the IDS cited Aklog's parent with disclosure that is identical to what is relied on in the Petition. EX1002, p.305 (identifying Aklog, EX1019); EX2001, ¶¶99-102. Petitioner does not cite any

disclosure from Aklog not before the '691 Examiner. *See* EX2001, ¶¶99-102 (Petitioner's only cites to Aklog are for disclosures also contained in Aklog's parent).⁵

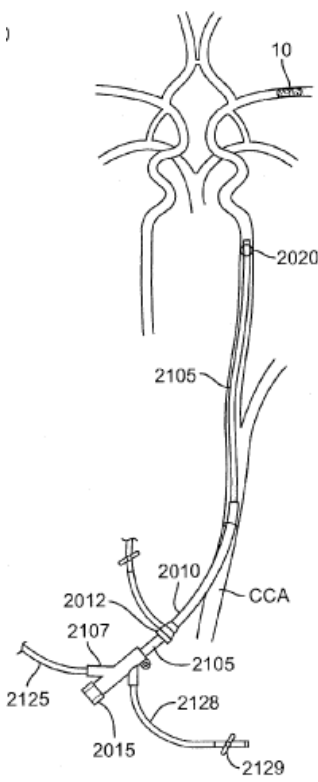
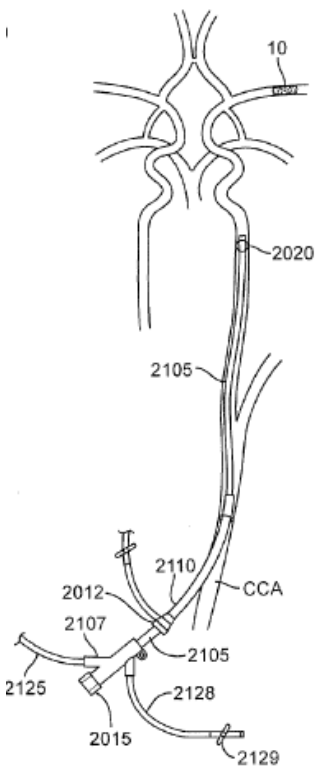
Therefore, the Office considered all of Petitioner's cited art during the prosecution of the '691 Patent. *Advanced Bionics*, Paper 6, pp.7-8 ("Previously presented art includes ... art provided to the Office by an applicant, such as on an [IDS]"); *NuMark LLC*, Paper 11, pp.6-8; *Benitec Biopharma Ltd.*, Paper 7, p.10 ("An Examiner's initials on an IDS form 'provides...a clear record in the application to indicate which documents have been considered by the examiner in the application.'").

2. Garrison's disclosure cited in Petition is identical and cumulative to the disclosure of the Garrison '788 Publication previously considered by the Office.

The Office expressly considered the same disclosure found in Garrison during prosecution of the Parent '315 Application—a fact that Petitioner omits in its arguments here. During prosecution of the Parent '315 Application, the Office rejected the then-pending claims over the Garrison '788 publication. EX2001, ¶¶92-95. As

⁵ Petitioner admits that the only additional disclosure in Aklog is directed to the use of the embodiment shown in Figure 7 of Aklog to capture vegetive material dislodged by another procedure, such as a procedure to remove a pacemaker lead. *Petition*, pp.87-88. *See also* EX1005, 18:56-20:27; EX2001, ¶100. Petitioner does not cite to that description in the petition.

shown below, the Garrison '788 publication discloses the same embodiments of Garrison that Petitioner relies on in the Petition.⁶

Disclosure of Garrison (EX1006) Relied on By Petitioner for Claims 1, 14, 23, and 28	Corresponding Disclosure of the Garrison '788 publication (EX2003)
 FIG. 3 <i>See, e.g., Petition, p.33.</i>	 FIG. 2 EX2003, Fig.2.

⁶ An accompanying description to the figures shown is provided in a complete comparison of the portions of the Garrison '788 publication to Petitioner's cites in Mr. Brown's accompanying declaration. EX2001, ¶98.

Disclosure of Garrison (EX1006) Relied on By Petitioner for Claims 1, 14, 23, and 28

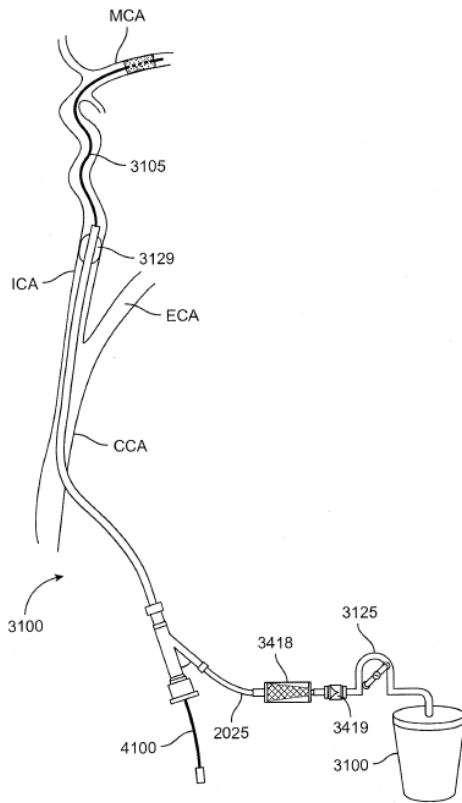


FIG. 32

See, e.g., Petition, p.28.

Corresponding Disclosure of the Garrison '788 publication (EX2003)

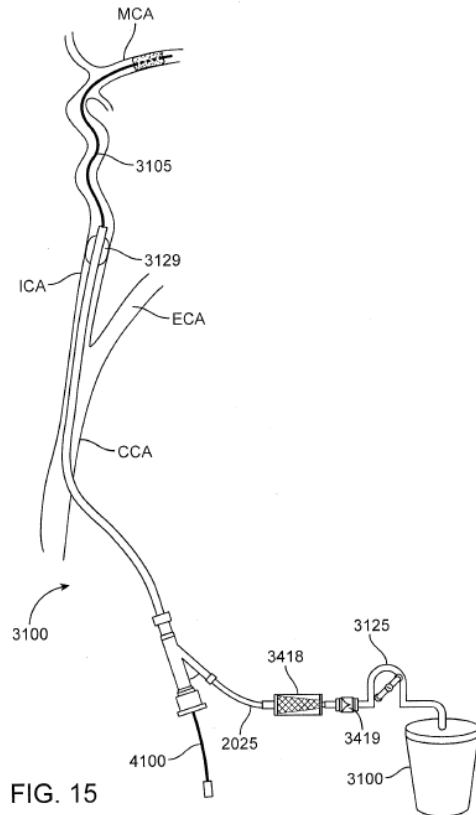


FIG. 15

EX2003, Fig.15.

**Disclosure of Garrison (EX1006) Relied
on By Petitioner for Claims 1, 14, 23,
and 28**

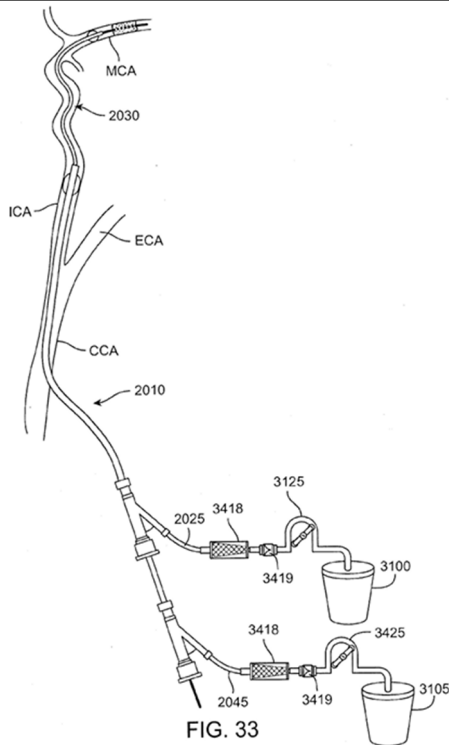


FIG. 33

See, e.g., Petition, p.28.

**Corresponding Disclosure of the
Garrison '788 publication (EX2003)**

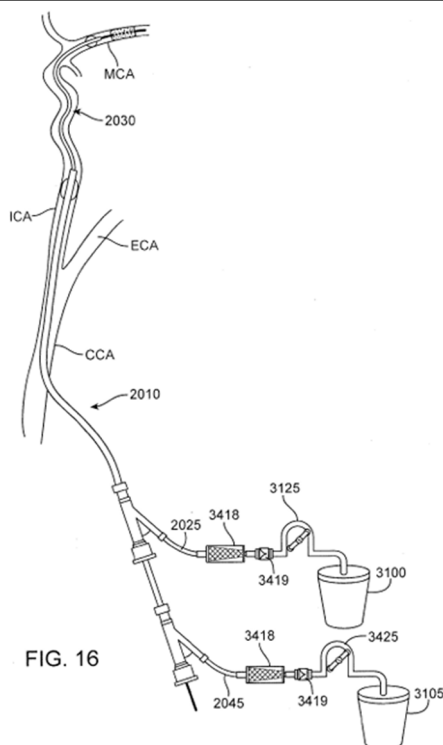


FIG. 16

EX2003, Fig.16.

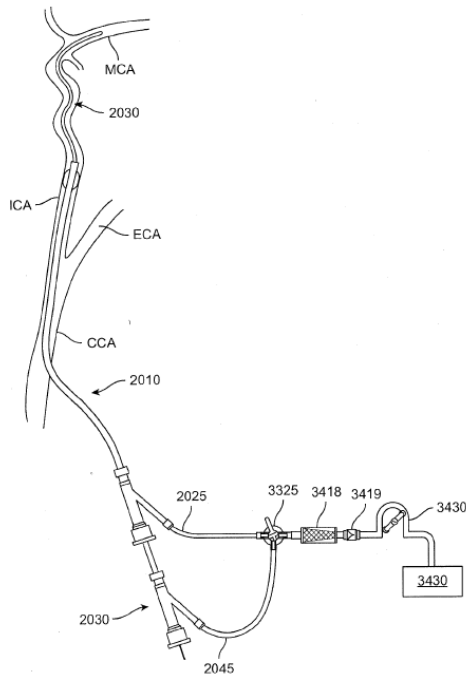


FIG. 34

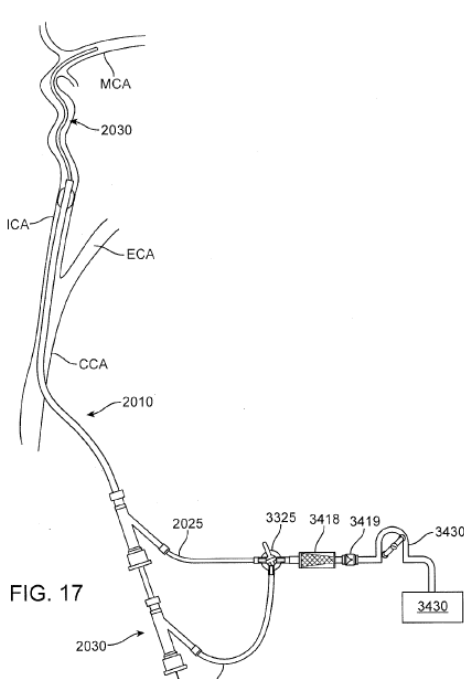
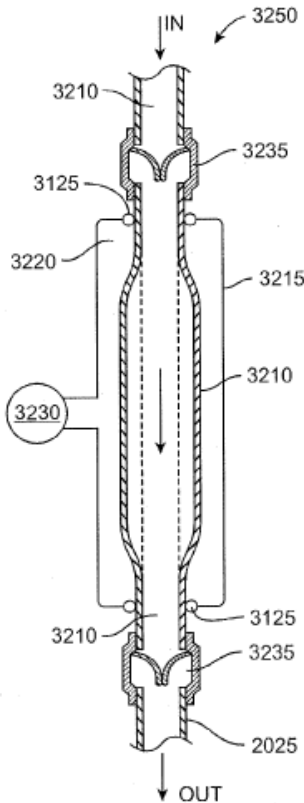
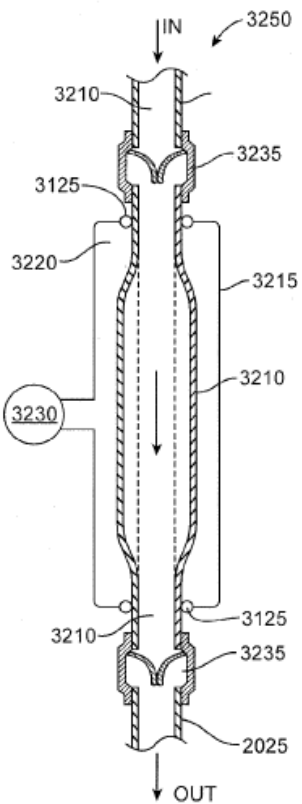


FIG. 17

Disclosure of Garrison (EX1006) Relied on By Petitioner for Claims 1, 14, 23, and 28	Corresponding Disclosure of the Garrison '788 publication (EX2003)
<i>See, e.g.,</i> Petition, p.27.	EX2003, Fig.17.
 FIG. 36 <i>See, e.g.,</i> Petition, p.29.	 FIG. 19 EX2003, Fig.36.

While the Garrison '788 publication does not include paragraph [0129] of Garrison (*see* EX2001, ¶97), Petitioner itself admits that paragraph [0129] is cumulative to other portions of Garrison that are found in the Garrison '788 publication. *See* Petition, p.36 (referencing paragraph [0129] and reciting that “[t]hus, Garrison includes multiple disclosures of closing a valve to generate negative pressure and opening the valve after the negative pressure is generated.”). Moreover, paragraph

[0129] in Garrison merely recites a description of testing the flow rates of systems with different catheter sizes to determine aspiration rates using the locking syringe methodology described in paragraph [0134] of Garrison, which is found in the Garrison '788 publication. EX2001, ¶97. Paragraph [0129] and does not recite any prior art components, structure, or functions different than the identical disclosure of paragraph [0134] in Garrison '788 (e.g., paragraph [0088]). *Id.*

Accordingly, the Office had all of Petitioner's cited art or materially identical art before it during prosecution. For these reasons, the first *Becton, Dickinson* factor weighs heavily in favor of denial and supports a finding that the first part of the *Advanced Bionics* framework is satisfied. *See Medtronic Corevalve*, Paper 9, pp.9-10. Indeed, institution can and should be denied on this reason alone. *See R.J. Reynolds Vapor Co. v. Fontem Holdings I B.V.*, IPR2017-01118 and IPR2017-01119, Papers 8, 10, pp.4-5 (P.T.A.B. Oct. 4, 2017).

C. Garrison Is Wholly Cumulative of the Garrison '788 Publication Considered by the Office

There is complete substantive overlap between the disclosures of Garrison and the Garrison '788 publication. EX2001, ¶¶95-98; *compare* EX1006 with EX2003. Petitioner's other cited art is also identical or substantively identical to the art previously considered by the Office. *See* Section III.B.1, *supra*. Accordingly, the second *Becton, Dickinson* factor also weighs in favor of denial and further supports a finding

that the first prong of the *Advanced Bionics* framework is satisfied because the art cited in the Petition is at most wholly cumulative of what the Office previously considered.

D. Garrison's Disclosure Was Substantively Considered During Examination

The third *Becton, Dickinson* factor also weighs in favor of denial because the Office substantively evaluated Garrison's disclosure during the prosecution of the related Parent '315 Application including as a basis for rejection as set forth below.

As shown above, the Office effectively found the same limitation recited in every independent claim of the '691 Patent patentable over Garrison's disclosure during prosecution of the Parent '315 Application. The Application's original claim 1 recited "an aspiration system" comprising an "aspiration pump in communication with a first chamber" "a second chamber," as follows:

1. An aspiration system with accelerated response, comprising:
an aspiration pump in communication with a first chamber;
an aspiration catheter configured for placement into fluid communication with the first chamber by way of an aspiration tube;
a second chamber in between the aspiration pump and the catheter; and
a valve between the second chamber and the aspiration catheter;
wherein upon opening of the valve with negative pressure in the first and second chambers,
fluid flow between the second chamber and the first chamber causes rapid aspiration into the second chamber.

EX2002, p.2691.

On September 23, 2022, the Office rejected claim 1 over, *inter alia*, the Garrison '788 publication relying on Figure 15 and its accompanying text (which is identical to Figure 32 of Garrison) as follows:

Garrison teaches an arterial access device (2010) connected to a receptacle (3100) and a source of aspiration (3125), wherein the receptacle is connected to a flow line (2025) and a valve (check valve (3419)) between the second chamber and the aspiration catheter (check valve (3419) is located between aspiration source (3125) and aspiration catheter (3105), see Figure 15), wherein upon opening of the valve with negative pressure (valve (3419) is a one way check valve that passively opens with negative pressure from the pump (3125), see Paragraph [0085]).

EX2002, p.126.

In response, the Patent Owner and Examiner conducted an interview, and the Examiner agreed that “amending claims 1 and 10 to more specifically describe how fluid flows” in the system “would overcome the prior art [including Garrison '788 patent].” EX2002, p.112. To that end, Patent Owner amended Claim 1 to recite that “the valve is configured to be closed while negative pressure is generated in the first and second chambers, and wherein the valve is configured to be opened after the negative pressure is generated in the first and second chambers” as follows:

1. (Currently Amended) An aspiration system with accelerated response, comprising:
an aspiration pump in communication with a first chamber;
an aspiration catheter configured for placement into fluid communication with the first chamber by way of an aspiration tube;
a second chamber in between the aspiration pump and the catheter; and
a valve between the second chamber and the aspiration catheter, wherein the valve is configured to be closed while negative pressure is generated in the first and second chambers, and wherein the valve is configured to be opened after the negative pressure is generated in the first and second chambers;
wherein upon opening of the valve with the negative pressure in the first and second chambers, fluid flow ~~between~~ at least partially from the second chamber and into the first chamber causes rapid aspiration into the second chamber.

EX2002, p.102.

The Examiner then found the rejections on the basis of the Garrison '788 publication moot and issued a final Office action with rejections based on other references. EX2002, pp.64-70. The Examiner noted that claim 2, which depended from claim 1, as amended above, would be allowable if rewritten in independent form as to overcome the rejections on the basis of the other non-Garrison references. *Id.* In other words, the Office explicitly considered the disclosure of Garrison relied on by Petitioner here during prosecution of the Parent '315 Application and allowed claims reciting, *inter alia*, "the valve is configured to be closed while negative pressure is generated in the first and second chambers, and wherein the valve is configured to be opened after the negative pressure is generated in the first and second chambers."

The same Examiners examined both the Parent '315 Application and the '691

Patent and recognized the similarity of the claims in both applications—issuing a nonstatutory double patenting rejection during the '691 Patent's prosecution over claims in the Parent '315 Application. EX1002, pp.258-60. Indeed, just like the amended claim 1 (and allowable claim 2) of the Parent '315 Application found patentable over the Garrison '788 publication, every independent claim of the '691 patent recites “the valve is configured to be closed while negative pressure is generated in the first and second chambers, and wherein the valve is configured to be opened after the negative pressure is generated in the first and second chambers.” In sum, the Office determined that a claim reciting this limitation is patentable over the Garrison '788 publication. EX2002, pp.112, 64-70 (Garrison-based rejections moot). Yet, the Petition relies solely on substantively identical disclosures in Garrison.

The Office also considered another Garrison reference, U.S. Patent Application No. 2016/0220741 (“Garrison '741”) (EX2004), in continuation applications of the '691 Patent, specifically U.S. Patent Application No. 17/865,280 (“'280 application”). EX2005, pp.3-8 (non-final office action from '280 application rejecting claims as anticipated by Garrison '741). Garrison '741 even incorporates the Garrison reference relied on by the Petitioner. *See* EX2004, [0002] (“This application is also related to the following U.S. patent applications, which are incorporated by reference in their entirety: (1) U.S. patent application Ser. No. 14/576,953, filed Dec.

19, 2014.”). The Office plainly knew of Garrison’s disclosure and has substantively evaluated it numerous times.

Therefore, the third *Becton, Dickinson* factor weighs in favor of denial because the Office substantively considered Garrison’s disclosure.

E. Petitioner’s Arguments Regarding Garrison Are Nearly Identical to the Issues Previously Considered by the Office

Where, as here, the Petitioner relies on the same art considered during prosecution, the Board need not evaluate the fourth *Becton, Dickinson* factor. *Medtronic CoreValve*, IPR2021-00241, Paper 9, p.10. However, if the Board were to evaluate this factor, it should find that it weighs in favor of denial. Here, Petitioner’s arguments regarding Garrison are nearly identical to the issues raised during the prosecution of the Parent ’315 Application when the Office substantively evaluated the Garrison ’788 publication with respect to the exact claim limitations also recited in every independent claim of the ’691 Patent.

As explained in Section III.D, *supra*, the Office, determined that a claim reciting, *inter alia*, “the valve is configured to be closed while negative pressure is generated in the first and second chambers, and wherein the valve is configured to be opened after the negative pressure is generated in the first and second chambers,” (recited in every challenged independent claim) is patentable over the Garrison ’788 publication, which includes substantively identical disclosure of Garrison here.

EX2002, pp.112, 64-70.

Therefore, the fourth *Becton, Dickinson* factor weighs in favor of denial and supports a finding that the first part of the *Advanced Bionics* framework is satisfied.

F. Petitioner Ignores the Prior Consideration of Garrison

The fifth *Becton, Dickinson* factor concerns whether Petitioner has demonstrated the Examiner erred in evaluating the asserted prior art. *Advanced Bionics*, IPR2019-01469, Paper 6, pp.10-11. “[I]f the alleged error is a disagreement with a specific finding of record by the Office, then ordinarily the petitioner's required showing of material error must overcome persuasively that specific finding of record.” *Id.* Petitioner makes no such showing. Indeed, the Petition makes no attempt to do so, and misleadingly argues that the “Examiner primarily relied on prior art for treating wounds on the skin surface” rather than “prior art relied upon in [the Petition] which is all related to aspiration catheters.” Petition, pp.88-89. But the same Examiner substantively evaluated Garrison’s disclosure (a so-called “aspiration catheter” reference) in a related application, and all of the references cited in the Petition (or their equivalent), including Garrison, were before the Office during prosecution of the ’691 Patent. *See* Sections III.B. and III.D., above.

Petitioner has not made a showing of material error. Thus, the fifth *Becton, Dickinson* factor weighs in favor of denial.

G. Petitioner Presents No Additional Evidence or Facts Warranting Reconsideration of Garrison

Petitioner does not provide any evidence or facts or articulate any argument warranting a reconsideration of Garrison's disclosure. Petitioner's expert report in support of its Petition does not provide such evidence. *See Regeneron Pharms., Inc. v. Kymab Ltd.*, IPR2019-01578, Paper 9, p.15 (P.T.A.B. Apr. 1, 2010) ("Petitioner asserts that Dr. DeFranco's Declaration is new evidence that was not previously before the Office and warrants 'serious consideration.' ... But the fact that an expert declaration was not before the Examiner during prosecution does not itself demonstrate that the Examiner erred.").

Nor does Petitioner's reliance on combinations that add Hartley, Goff, and/or Aklog in combination with Garrison provide sufficient reason to reconsider Garrison's disclosure because Garrison is the only reference cited for the limitations "the valve is configured to be closed while negative pressure is generated in the first and second chambers, and wherein the valve is configured to be opened after the negative pressure is generated in the first and second chambers," as recited in every independent claim. The Office has already evaluated Garrison's disclosure with respect to these claim limitations. *See* Section III.D, *supra*. All of the other cited art in the Petition was also before the Office. Section III.B, *supra*. Thus, the final *Becton, Dickinson* factor weighs in favor of denial.

All of the *Becton, Dickinson* factors weigh in favor of denial. Instituting the proceeding would thus present an undue “burden and expense to Patent Owner in having to defend the...patent based on substantially the same prior art or arguments already considered by the Office.” *Nu Mark LLC*, IPR2016-01309, Paper 11, p.11. Patent Owner accordingly requests that the Board exercise its discretion to deny the Petition under Section 325(d).

IV. CLAIMS 1-2, 5-6, 10-11, AND 13 ARE NOT ANTICIPATED BY GARRISON (GROUND 1)

Even if the Board does not exercise its discretion to deny institution of the Petition under Section 325(d), it should deny institution because Petitioner has failed to show that it has a reasonable likelihood of success on any challenged claim because none of the cited art discloses or renders obvious where “negative pressure is generated in the first and second chambers” as the '691 Patent requires.

Beginning with Ground 1, anticipation requires that “each and every element of the claimed invention” must be disclosed either explicitly or inherently and 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) (internal quotation marks and citation omitted).

Here, Garrison fails to disclose the aspiration system of Claim 1 including “an aspiration pump in communication with a first chamber” wherein “the valve is

configured to be closed while negative pressure is generated in the first and second chambers, and wherein the valve is configured to be opened after the negative pressure is generated in the first and second chambers” [limitation [1D] identified by Petitioner] or wherein “upon user actuation to open the valve with the negative pressure having been generated in the first and second chambers, fluid flow at least partially from the second chamber into the first chamber causes rapid aspiration into the second chamber” [limitation [1E] identified by Petitioner], as recited in Claim 1. The same limitations are included in the other independent claims (Claims 14, 23, and 28), as discussed below. The dependent claims incorporate each of these limitations, as well.

Petitioner fails to identify any embodiment of Garrison that discloses (or renders obvious) an aspiration system including an aspiration pump in which negative pressure is generated in a first chamber and a second chamber when a valve is closed, or that the valve is opened with negative pressure having been generated in the first and second chambers to cause rapid aspiration. Rather, Garrison discloses an aspiration pump that is positioned upstream of a receptacle such that the pump delivers fluid (*e.g.*, blood) to the receptacle via positive pressure and thus cannot generate negative pressure in the receptacle. This allows the blood to be easily discarded from the system via the receptacle or reintroduced into the patient from the receptacle without disconnecting the aspiration source.

A. Garrison Does Not Disclose “Wherein the Valve Is Configured to be Closed While Negative Pressure Is Generated in the First and Second Chambers, and Wherein the Valve Is Configured to be Opened After the Negative Pressure Is Generated in the First and Second Chambers”

- 1. Garrison discloses an aspiration pump that generates positive pressure in a “first chamber” rather than negative pressure, or a “first chamber” that remains at atmospheric pressure if it is vented.**

Petitioner points to embodiments illustrated in and described with reference to Figures 32-36 of Garrison to support its assertion that Garrison anticipates Claim 1, but those embodiments do not disclose that “negative pressure is generated in the first and second chambers” in combination with the other claim limitations. Petition, pp.24-29. Instead, whenever Garrison discloses a pump in the embodiments identified by Petitioner—whether a peristaltic pump as shown in Figures 32-34, a centrifugal pump, or the pump device 3250 shown in Figure 36—the pump is positioned to draw fluid through an inlet and expel the fluid out of an outlet via positive pressure to a downstream delivery location such as a receptacle or blood return line. Such a pump would not and could not generate negative pressure in the downstream delivery location (the receptacle the Petition alleges is the first chamber) for multiple reasons—and therefore would not generate negative pressure in any “first chamber” identified by Petitioner.

First, Petitioner's argument for Figures 32-33 of Garrison that the source of aspiration 3125/3425 and the receptacle 3100/3105 disclose an “aspiration source”

and a “first chamber,” respectively, as claimed fails because when the source of aspiration 3125/3425 is a pump, the pump is a peristaltic pump (commonly referred to as a roller pump (EX2001, ¶65)) positioned upstream of the receptacle 3100/3105 that delivers fluid to the receptacle 3100 via positive pressure:

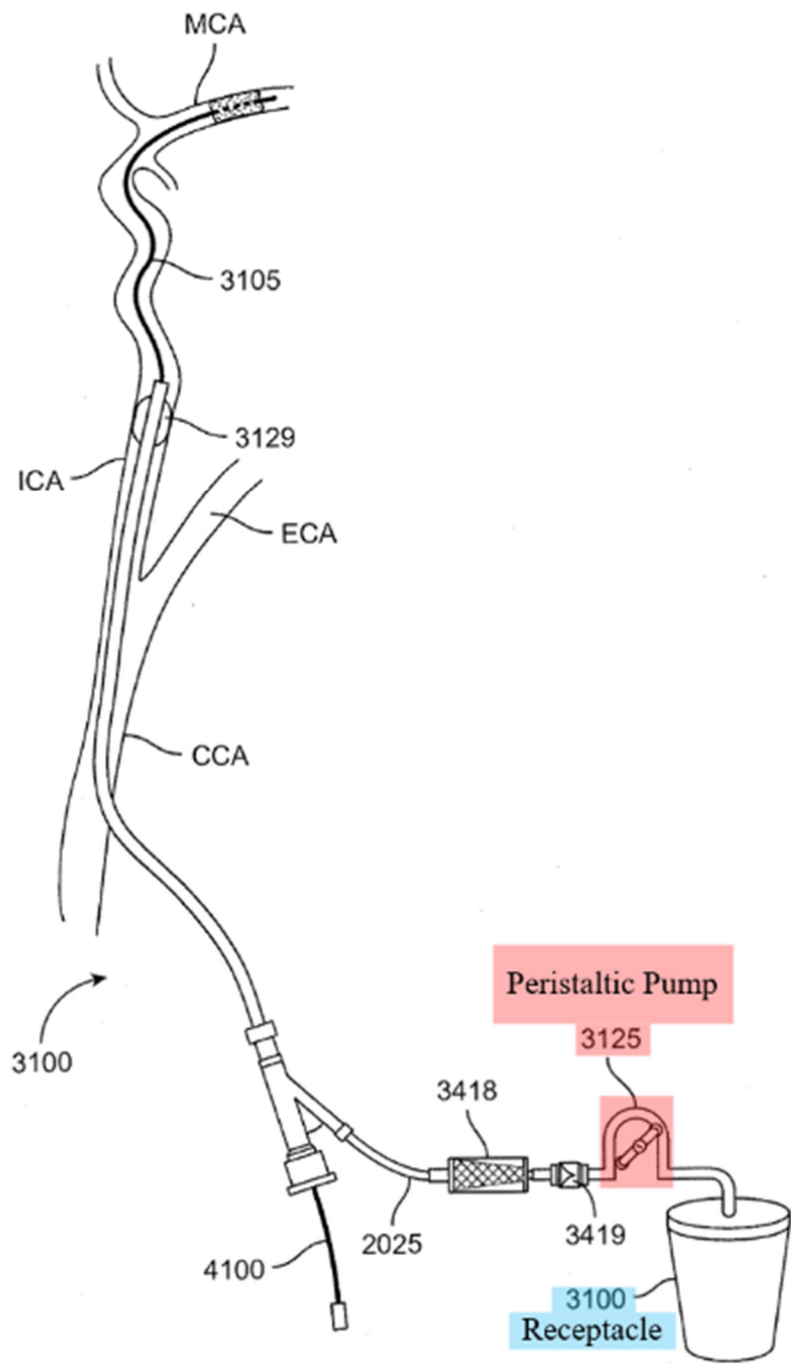
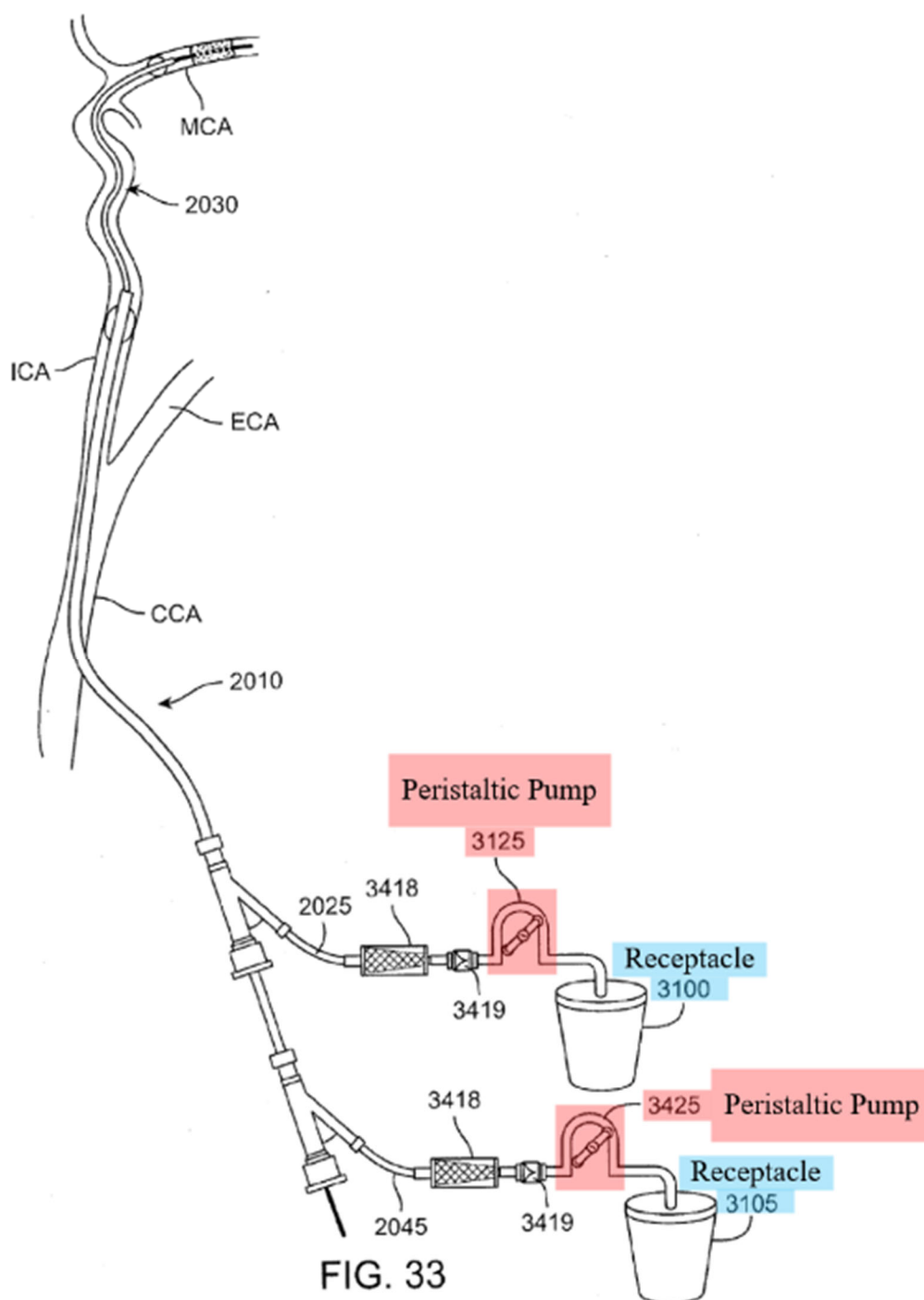
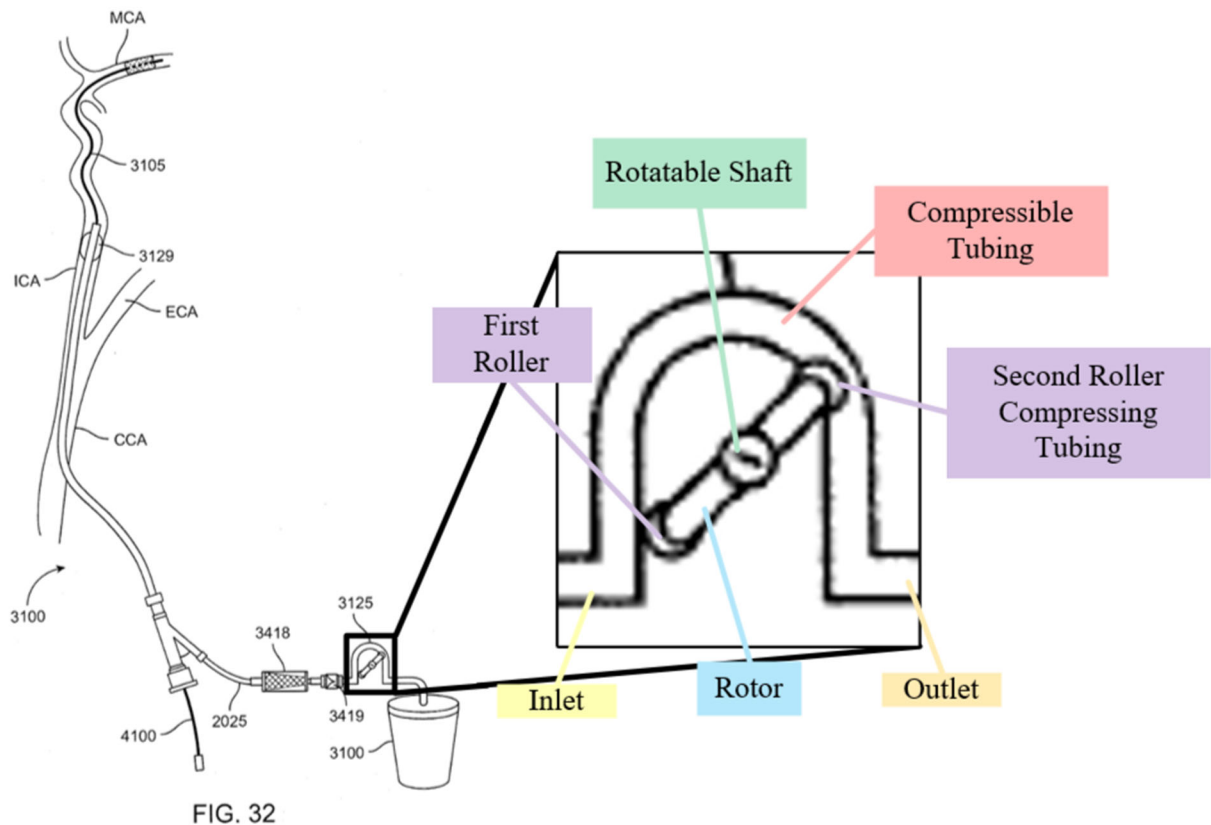


FIG. 32



EX1006, Figs. 32-33 (annotated); EX2001, ¶65; Petition, p.28.

A POSITA would recognize the aspiration source 3125/3425 as a peristaltic pump based on its depiction including compressible tubing and a rotatable shaft connected to a rotor that carries multiple rollers for compressing the tubing:



EX1006, Fig. 32 (annotated); EX2001, ¶¶66-67. The peristaltic pump operates by rotating a shaft to rotate the rotor such that the rollers compress the tubing to: (1) generate negative pressure to draw fluid through the flow line 2025 through the inlet of the pump (labeled above), (2) transport the fluid through the pump, and (3) expel the fluid through the outlet of the pump (labeled above) for delivery to the receptacle 3100/3105. EX2001, ¶67.

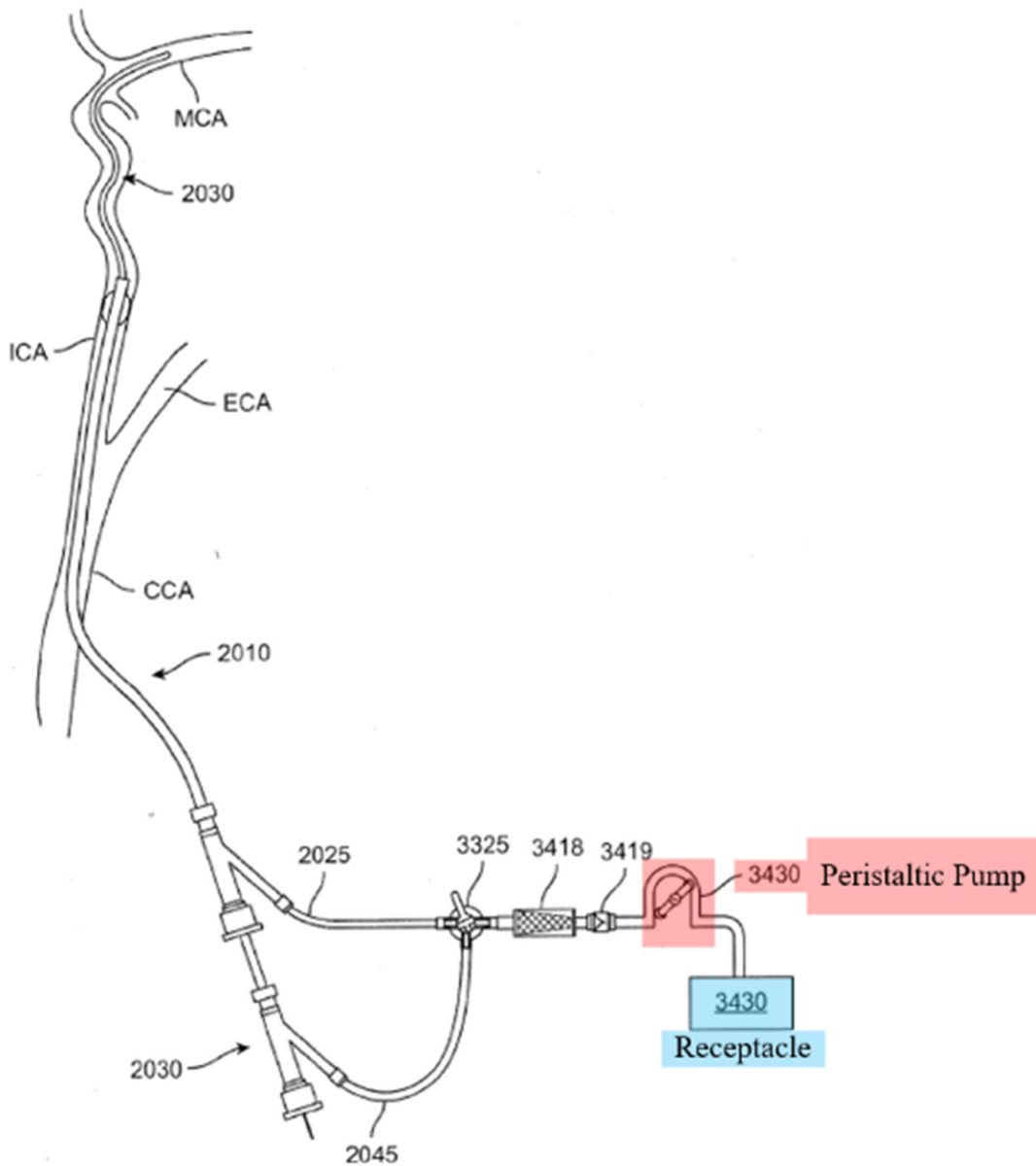
Therefore, even if the valve 3325 of Figure 34 of Garrison were somehow incorporated into the embodiments of Figures 32-33, the peristaltic pump 3125/3425 would prevent negative pressure from being built up in the receptacle 3100/3105 when the valve was closed and would instead (1) build up positive pressure in the receptacle via its fluid connection to the positive pressure outlet of the pump if the receptacle was sealed or (2) maintain atmospheric pressure in the receptacle if the receptacle was vented. *Id.* at ¶68. That is, with the peristaltic pump (or any pump) positioned upstream of the receptacle, the only configuration taught or logical in view of Garrison, positive pressure rather than negative pressure is generated in the receptacle or the receptacle remains, at most, at atmospheric pressure if vented to atmosphere. *Id.* Accordingly, the embodiment shown in Figures 32-33 does not generate negative pressure in the receptacle 3100/3105, which Petitioner asserts is the claimed “first chamber.”

Petitioner's citation to Garrison's disclosure that the “receptacle 3100 and source of aspiration 3125 may be separate or may be combined into a single device such as a syringe” is inapposite. Petition, p.28; EX1006, ¶131. Garrison provides only a single example of a combined device comprising a syringe—which is not an “aspiration pump” as recited in Claim 1. EX2001, ¶69. And nowhere does Garrison disclose a combination of the receptacle 3100/3105 and the aspiration pump

3125/3145 in which the aspiration pump is positioned to generate negative rather than positive pressure or atmospheric pressure in the receptacle. *Id.*

Garrison's disclosure that the "receptacle 3100 and source of aspiration 3125 may be separate or may be combined into a single device such as a syringe," (EX1006, ¶131), means just that, namely, the receptacle and the source of aspiration can be combined in a single device. EX2001, ¶70. It does not mean that when the source of aspiration is an aspiration pump, the receptacle and aspiration pump are combined and reconfigured such that negative pressure is generated in the receptacle in contrast to the disclosed embodiments of an aspiration pump in Garrison. *Id.*

Petitioner's second argument with reference to Figure 34 of Garrison that the aspiration source 3430 discloses an "aspiration source" and a "first chamber" also fails—and for the same reason. Petition, p.27. Just like in Figures 32 and 33, Figure 34 shows that when the source of aspiration is a pump, it is positioned upstream of the receptacle to deliver fluid to the receptacle via positive pressure and thus cannot generate negative pressure in that receptacle:



EX1006, Fig. 34 (annotated); EX2001, ¶71.

Third, Garrison explains that “pumps such as centrifugal or peristaltic pumps are known to cause damage to blood cells” before disclosing an aspiration pump device 3250 in Figure 36 that “is configured not to harm blood cells.” EX1006,

¶¶135-136. A POSITA would understand based on this disclosure that the pump shown in Figures 32-34 could be the illustrated peristaltic pump, a centrifugal pump, or the pump shown in Figure 36, as each of these pumps operates similarly to draw fluid into an inlet and expel the fluid out of an outlet. EX2001, ¶72. In each embodiment, the pump would not and could not create a negative pressure in the receptacle the Petition alleges is the first chamber.

For example, centrifugal pumps operate to draw fluid into an outlet and push the fluid out of an outlet by the rotation of an impeller. *Id.* at ¶73. Accordingly, a POSITA would have understood at the time of the invention that using a centrifugal pump instead of the peristaltic pump shown in Figures 32-34 would have the same result of generating positive pressure rather than negative pressure in the downstream receptacle (or maintaining atmospheric pressure if the receptacle were vented) because the centrifugal pump pushes fluid from the outlet to the receptacle via the connection therebetween. *Id.*

The pump device 3250 illustrated in Figure 36 of Garrison would have the same effect of generating positive pressure in the downstream receptacle in Garrison's system if it were substituted for the peristaltic pump shown in Figures 32-34. *Id.* at ¶74. Namely, the pump device 3250 operates to cause "blood to be pulled into the expandable portion 3210 from the sheath side of the flow line, shown by the 'in' arrow, as controlled by the check valves 3235...[and t]he check valves

3235 cause[] the blood within the previously-expanded region of the flow line 2025 to be expelled towards location 3120, as shown by the 'out' arrow in FIG. 36.” EX1006, ¶137. Thus, like a peristaltic pump and a centrifugal pump, the pump device 3250 operates to pull blood through an inlet and subsequently expel the blood out of an outlet in a manner that would pressurize a downstream receptacle rather than generate negative pressure therein. EX2001, ¶74.

Moreover, Petitioner's argument that the chamber 3220 of the pump device 3250 is a “first chamber” is incorrect because the chamber 3220 is not “configured for placement into fluid communication with the [the aspiration catheter] by way of an aspiration tube,” as required in Claim 1. Petition, p.29; EX2001, ¶75. Rather, with the chamber 3220 out of fluid communication with the flow line 2025 (which is in fluid communication with the arterial access device or the smaller inner catheter): (1) negative pressure in the chamber 3220 acts external to the expandable portion 3210 to cause the expandable portion 3210 of the flow line 2025 to expand to draw blood into the expandable portion 3210 and (2) equalized pressure in the chamber 3210 acts external to the expandable portion 3210 to permit the expandable portion 3210 to contract to expel blood from the expandable portion 3210:

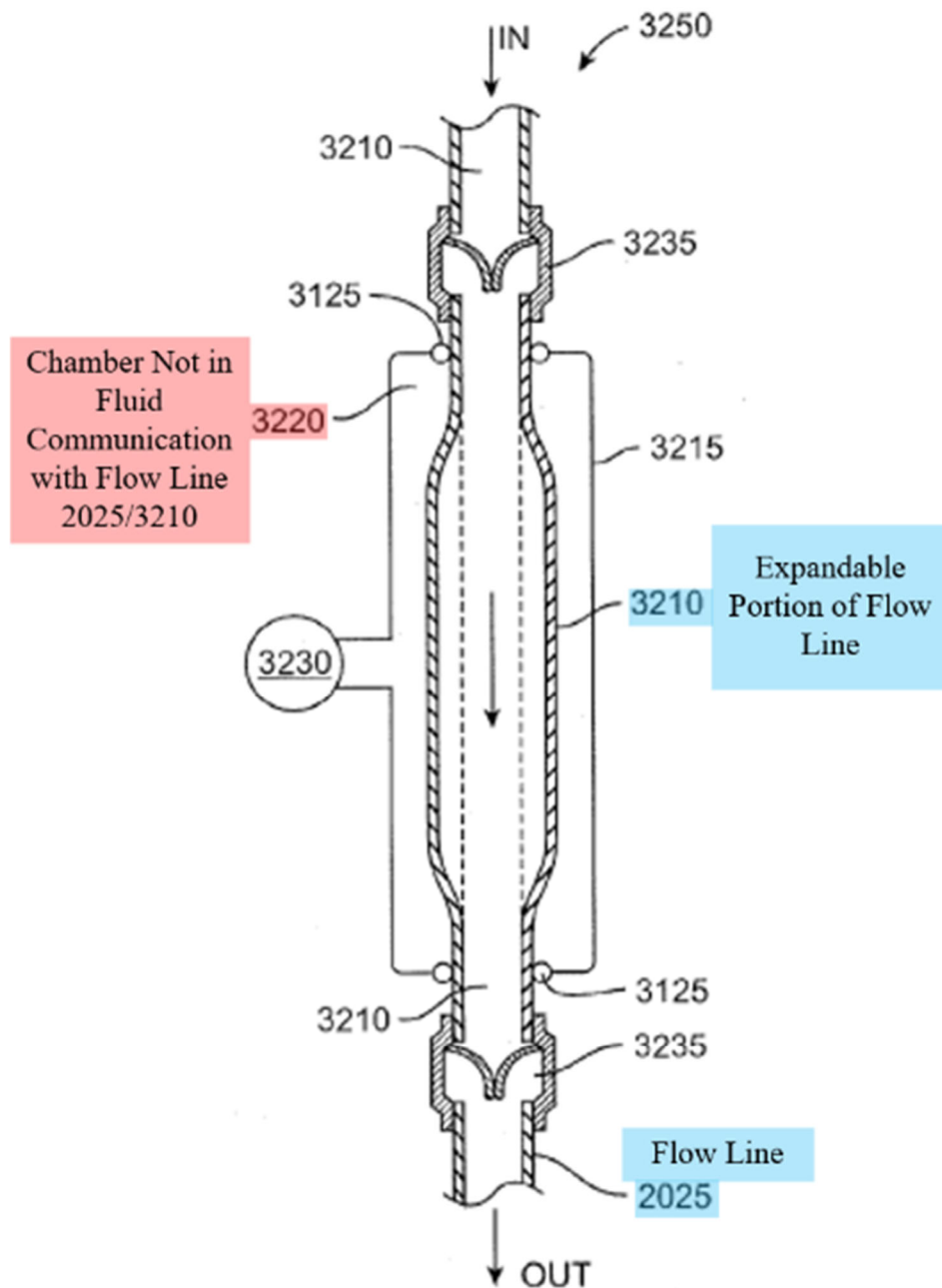


FIG. 36

EX1006, Fig. 36 (annotated), ¶[0137]; EX2001, ¶75.

Therefore, whenever Garrison discloses an aspiration pump—whether a peristaltic pump as shown in Figures 32-34, a centrifugal pump, or the pump device

3250 shown in Figure 36—the pump is positioned to draw fluid through an inlet and expel the fluid out of an outlet via positive pressure to a downstream delivery location, such as a receptacle. EX2001, ¶76. Such a pump would not and could not generate vacuum pressure in a downstream receptacle to which it delivers blood. *Id.*

Accordingly, Garrison fails to disclose (or render obvious, as discussed below) the aspiration system of Claim 1 including “an aspiration pump in communication with a first chamber” and “the valve is configured to be closed while negative pressure is generated in the first and second chambers....” Petitioner has failed to demonstrate a reasonable likelihood that Garrison anticipates or renders obvious Claim 1 for that reason alone.

2. Garrison’s locking syringe embodiments do not disclose the generation of negative pressure in first and second chambers in a system with an aspiration pump.

Because Petitioner cannot identify any embodiment of Garrison that discloses an aspiration system including an aspiration pump in which negative pressure is generated in first and second chambers when a valve is closed, Petitioner relies on Garrison’s disclosure of using a locking syringe instead of a pump as the source of aspiration. Petition, pp.45-47. Petitioner’s position is incorrect for two reasons: first Garrison specifies that a syringe is not an aspiration pump; and second a syringe would not generate a negative pressure in the “first chambers” identified by

Petitioner for the same reasons an aspiration pump cannot generate a negative pressure in such first chambers. EX2001, ¶¶77-80.

First, Garrison itself distinguishes a syringe from a pump in the various embodiments: the “active source of aspiration may be an aspiration pump, a regular or locking syringe, a hand-held aspirator, hospital suction, **or** the like.” EX1006, ¶134; *see also, id.* at ¶71 (“aspiration source such as a pump or a syringe”). Moreover, Petitioner admits that a syringe is not an aspiration pump by noting that Garrison’s locking syringe embodiment “specifically includes a ... syringe” then arguing that “the aspiration source could be an aspiration pump.” Petition, pp.35-36; *see also* EX1003, ¶85 (the “particular example includes ... a syringe for the pressure source” but “the aspiration source could also be an aspiration pump” and the “aspiration pump could also generate the described rapid aspiration”).

Second, that Garrison discloses an aspiration pump alternative to a syringe does not demonstrate Garrison discloses that negative pressure would be generated in any of Garrison’s receptacles 3100/3105, 3430, 3220 (the alleged first chamber) when an aspiration pump is used. Petitioner does not attempt to explain how an aspiration pump instead of a syringe could generate negative pressure in any of those alleged “first chambers.” That is, after alleging each of the receptacles 3100/3105 of Figures 32-33, the aspiration source 3430 of Figure 34, and the chamber 3220 of Figure 36 as the “first chamber” with regard to Petitioner’s limitation [1A] (Petition,

pp.26-30), Petitioner does not assert or explain how negative pressure is generated in any of those components with relation to Petitioner's limitation [1D], instead relying only on Garrison's syringe embodiments.

In fact, Garrison specifically identifies that a drawback of using a syringe is that the syringe needs to be “disconnect[ed]” and “remove[d] and empt[ied]” in contrast to when the system includes a “continuous source of aspiration” (*e.g.*, a pump) and a downstream “collection receptacle such as [a] blood-collection bag.” EX1006, ¶134; EX2001, ¶79. That is, having the downstream receptacle advantageously permits blood to be continuously aspirated and delivered to the receptacle without the need to disconnect the aspiration source. EX2001, ¶79.

And, although Garrison discloses that the aspiration source and receptacle could be combined, Garrison only discloses embodiments in which the pumps are upstream of the receptacles 3100/3104/3220/3430—never are the receptacles upstream of the aspiration source or otherwise configured to have negative pressure. EX2001, ¶80. As a result, Garrison does not disclose the combination of a receptacle and an aspiration pump in which the aspiration pump is positioned to generate negative pressure in the receptacle. *Id.*

Petitioner's conclusion that Garrison discloses closing a valve to generate negative pressure and opening the valve after the negative pressure is generated “in multiple locations in the specification” pertains only to syringe embodiments, and

does not address whether an aspiration pump embodiment would subject the first and second chamber to negative pressure, as required by the claims. Petition, pp.46-47. Garrison does not disclose an aspiration pump generating negative pressure in both first and second chambers.

B. Garrison Does Not Disclose “Wherein Upon User Actuation to Open the Valve with the Negative Pressure Having Been Generated in the First and Second Chambers, Fluid Flow at Least Partially from the Second Chamber into the First Chamber Causes Rapid Aspiration into the Second Chamber”

Because Garrison does not disclose a system including an aspiration pump that generates negative pressure a first with a valve closed as explained above, Garrison cannot disclose “wherein upon user actuation to open the valve with the negative pressure having been generated in the first and second chambers, fluid flow at least partially from the second chamber into the first chamber causes rapid aspiration into the second chamber” either.

Nevertheless, Petitioner incorrectly asserts that “[o]nce the user generates the negative pressure and positions the tip of the aspiration catheter near the occlusion, ‘the user may open the connection to the aspiration syringe’ **or other negative pressure source,**” citing paragraph [0134] of Garrison. Petition, p.37. Garrison does not disclose opening the connection to any “other negative pressure source” with negative pressure having been generated in first and second chambers. EX2001, ¶82.

Instead, Garrison expressly discloses that “the user may open the connection to the aspiration syringe.” EX1006, ¶134.

Petitioner's annotations to Figure 34 of Garrison to purportedly show the claimed rapid aspiration and fluid flow when the valve is opened also ignore the peristaltic pump that would prevent negative pressure from being generated in the alleged “first chamber” shown in the Figure:

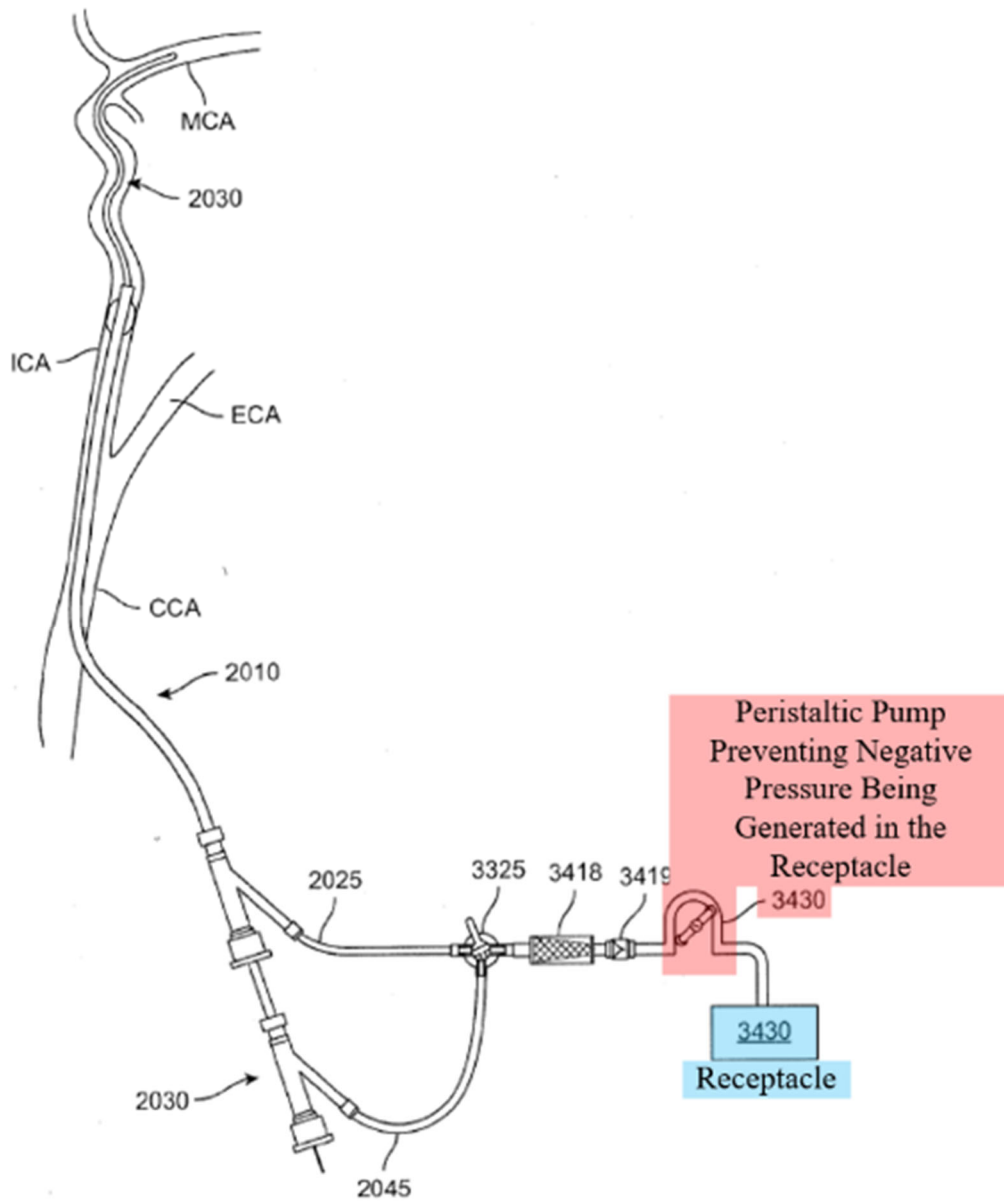


FIG. 34

EX1006, Fig. 34 (annotated); EX2001, ¶83.

Petitioner has failed to demonstrate a reasonable likelihood that Garrison anticipates Claim 1 for that reason alone.

**V. CLAIMS 1-31 ARE NOT OBVIOUS OVER GARRISON ALONE
(GROUND 2)**

Obviousness over a single prior art reference requires that it is “obvious to modify that reference to arrive at the patented invention.” *Arendi S.A.R.L. v. Apple Inc.*, 832 F.3d 1355, 1366 (Fed. Cir. 2016) (finding “conclusory statement is insufficient” to support obviousness and reversing PTAB finding of unpatentability). Whether “combining multiple embodiments from a single reference, or selecting from large lists of elements in a single reference, there must be a motivation to make the combination and a reasonable expectation that such a combination would be successful, otherwise a skilled artisan would not arrive at the claimed combination.” *In re Stepan Co.*, 868 F.3d 1342, 1346 n.1 (Fed. Cir. 2017) (reversing and vacating PTAB finding of obviousness). As the Federal Circuit explained *In re Kahn*, the rationale underlying the motivation-suggestion-teaching test serves as a safeguard against the improper use of hindsight in an obviousness analysis. 441 F.3d 977, 986 (Fed. Cir. 2006).

Petitioner fails to demonstrate a reasonable likelihood that Claim 1, or claims that depend therefrom, are obvious over Garrison alone. Petitioner's only assertion that Claim 1 is obvious over Garrison (Ground 2) is that Garrison anticipates Claim 1 (Ground 1)—it does not. In other words, Petitioner provides no separate obvious analysis at all for Ground 2. But as explained above, Garrison does not disclose

Claim 1 and Petitioner has failed to provide any motivation to first pick and choose varying aspects of different Garrison embodiments and then further modify those aspects to arrive at the claimed invention.

In fact, Petitioner does not analyze how Garrison would or could be modified as claimed or provide any motivation for a POSITA to modify Garrison as claimed. Instead, Petitioner's only assertion that Claim 1 is rendered obvious by Garrison is that Garrison anticipates Claim 1. Petition, p.24 (citing *Data, LLC v. Iancu*, 912 F.3d 1368, 1373 (Fed. Cir. 2019) ("It is well settled that a 'disclosure that anticipates under §102 also renders the claim invalid under §103, for anticipation is the epitome of obviousness.'")). For the reasons set forth above in Section IV, Garrison does not anticipate Claim 1. Relying only on the analysis for Ground I, Petitioner has also failed to demonstrate a reasonable likelihood that Garrison renders obvious independent Claim 1, or any claims that depend from Claim 1.⁷

Petitioner's expert's naked assertion that Claim 1 is obvious simply because Garrison includes boiler plate language that various embodiments could be modified

⁷ Further, a POSITA would not have modified any of the embodiments of Garrison to arrive at the claimed features. EX2001, ¶¶87-89.

is insufficient motivation to modify Garrison as claimed.⁸ EX1003, ¶91 (citing EX1006, ¶[0175]). Petitioner's expert does not explain how or why a POSITA could or would have modified the embodiments of Garrison to include a system with an aspiration pump in which negative pressure is generated in a "first chamber" contrary to the embodiments of Garrison. EX2001, ¶91. A POSITA would not have been so motivated. *Id.*

As set forth above, that the aspiration source could be an aspiration pump rather than a syringe does not demonstrate that negative pressure would be or could be generated in a first chamber with an aspiration pump. EX2001, ¶90. Garrison discloses several systems with a pump, but in each one the pump is positioned to draw fluid through an inlet and expel the fluid out of an outlet to a downstream

⁸ Because the Petition does not include this argument, it should not be considered. 37 C.F.R. §42.6(a)(3) ("Arguments must not be incorporated by reference from one document into another document."); *3M Co. v. Evergreen Adhesives, Inc.*, 860 F. App'x 724, 728 (Fed. Cir. 2021) (affirming the Board did not abuse its discretion in concluding that Petitioner's incorporation by reference of its expert's declaration including arguments related to obviousness were improper when the obviousness arguments in the Petition were "skeletal at best").

receptacle (the alleged first chamber) via positive pressure such that the pump would not and could not generate vacuum pressure in the receptacle. *Id.*

VI. GROUNDS 3-8 FAIL FOR THE SAME REASONS AS GROUNDS 1 AND 2

For the same reasons set forth with respect to Grounds 1 and 2, Petitioner has failed to demonstrate a reasonable likelihood that independent claims 14, 23, and 28, and the claims that depend from those claims, are unpatentable under Grounds 3-8. Like Claim 1, independent Claims 14, 23, and 28 each recite: “an aspiration pump in communication with a first chamber” wherein “the valve is configured to be closed while negative pressure is generated in the first and second chambers....” And Grounds 3-8 solely refer back to Petitioner’s arguments for Claim 1 relying on Garrison as allegedly disclosing those limitations. Petition, pp.80, 83, 86.

Accordingly, Petitioner has failed to demonstrate a reasonable likelihood that any of Claims 1-31 are unpatentable over Garrison, either alone or further in view of Hartley, Goff, and/or Aklog under any ground.

VII. THE PETITION SHOULD BE DENIED UNDER 35 U.S.C. § 314(a)

The Board also can and should exercise its discretion under Section 314(a) to deny this Petition based on the parallel Northern District of California litigation (*In-ari Medical, Inc. v. Imperative Care, Inc.*, 4:24-cv-03117-YGR (N.D. Cal.)).

The Board considers numerous factors when analyzing whether to discretionarily deny a petition under Section 314(a), including factors relating to efficiency

and fairness. *See Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11, p.6 (P.T.A.B. Mar. 20, 2020) (precedential) (considering (a) “whether the court granted a stay or evidence exists that one may be granted if a proceeding is instituted;” (b) “proximity of the court’s trial date to the Board’s projected statutory deadline for a final written decision;” (c) “investment in the parallel proceeding by the court and the parties;” (d) “overlap between issues raised in the petition and in the parallel proceeding;” (e) “whether the petitioner and the defendant in the parallel proceeding are the same party;” and (f) “other circumstances that impact the Board’s exercise of discretion, including the merits.”). These factors, on balance, weigh in favor of denial here.

The first *Fintiv* factor is neutral. The Court in the parallel district court litigation has not granted a stay, and there is no evidence that it will grant one. Patent Owner asserts the same ’691 Patent in the parallel district court litigation as well as other related patents. EX2006, ¶¶5, 55; *see U.S. Venture, Inc. v. Sunoco Partners Mktg. & Terminals L.P.*, No. IPR2020-00728, 2020 WL 5848121, at *3 (P.T.A.B. Oct. 1, 2020) (“[A]bsent a stay of the related litigation and no indication based on evidence in the record that it will be stayed, this factor is neutral.”).

The second *Fintiv* factor is neutral. Trial has not yet been set in the parallel litigation. However, trial may be set and a judgement on the merits received before the projected statutory deadline for a final written decision. In the Northern District of California, over 20% of cases that reach trial do so in less than 18 months. *See*

EX2007. Even if trial were not to take place prior to the statutory deadline, the parties will have made substantial investment in the parallel litigation prior to the Board's statutory deadline—as explained below. Therefore, this factor is neutral.

The third and fourth *Fintiv* factors weigh in favor of denial. Substantial work has already been done in the parallel litigation, including with respect to legal and factual issues of patentability and claim construction, and even more work will be done by the time the Board makes a decision on institution. For example, Patent Owner has filed, and the parties have fully briefed and conducted discovery (with multiple depositions, including of expert witnesses), a preliminary injunction motion that addresses claim construction and patentability for a patent related to the '691 Patent. *See Inari*, Dkt. 24; Dkts. 36, 40. The issues addressed in the preliminary injunction briefing overlap substantially with the issues before the Board here. For instance, the sole claim construction proposed by Petitioner in its Petition is identical to the claim construction issues raised before the district court. *See* Dkt. 36-14, ¶¶48-53 (T. Thorton Declaration in Support of Opposition). The parties have conducted extensive discovery already associated with the preliminary injunction, including depositions, expert reports, and substantially similar patentability positions. Work into invalidity contentions and discovery related to those contentions will likely be substantially underway by the time Board issues its decision on institution and certainly completed by the statutory deadline for a final written decision. The parties

are even using the same experts here as were used in the parallel litigation, where the experts submitted declarations and were deposed. *See* Dkt. 24-02; Dkt. 36-14.

A hearing on Inari's preliminary injunction motion is likely to occur in December 2024. Thus, by the time of the Board's decision on institution, it is likely that the district court will have already ruled on or will be in the process of ruling on overlapping issues, including claim construction. For these reasons, the third and fourth *Fintiv* factors weigh in favor of denial.

The fifth *Fintiv* factor favors denial too. The exact same parties are before the district court as here. *See, e.g.*, Dkt. 20 (identifying the Plaintiff as "Inari Medical, Inc." and the Defendant as "Imperative Care, Inc."). And some of the same claims before the Board in the Petition are at issue in the district court. For instance, Patent Owner's amended complaint identifies at least Claims 14, 19, 20, and 22 of the '691 Patent as infringed. EX2006, ¶¶130-31. In its answer, Imperative Care asserted that Claims 14, 19, 20, and 22 of the '691 Patent "are invalid under 35 U.S.C. § 102 and/or § 103 in view of, but not limited to" Garrison, which is the same primary reference for every Ground asserted in this IPR. Dkt. 25, ¶¶41-42.

Moreover, Petitioner has not entered or offered a *Sotera* or even a *Sand* stipulation to mitigate the risk of the overlapping patentability issues being evaluated in multiple forums. *See Sotera Wireless, Inc. v. Masimo Corp.*, Case IPR2020-01019, Paper 12 (P.T.A.B. Dec. 1, 2020) (finding that in view of a stipulation that the

petitioner would not pursue in the district court proceeding the specific asserted grounds or any other ground that was raised or could have been reasonably raised in the IPR petition, the fourth *Fintiv* factor weighed strongly against a discretionary denial); *Sand Revolution II, LLC v. Cont'l Intermodal Grp. – Trucking LLC*, IPR2019-01393, Paper 24, pp.11-12 (P.T.A.B. June 16, 2020) (“[I]f the IPR is instituted, Petitioner will not pursue the same grounds in the district court litigation.”); *see also Zhuhai Cosmx Battery Co. v. Ningde Amperex Tech. Ltd.*, IPR2023-00587, Paper 12, p.27 (P.T.A.B. Sept. 22, 2023) (“Petitioner has not submitted a *Sotera*-type stipulation that would make discretionary denial inappropriate.”).

The Board should also deny the Petition because the Petitioner has failed to show that key limitations are disclosed or rendered obvious by Garrison alone or in combination with the other cited art. *See* Sections IV-V, *supra*. As such, the Petition lacks merit. Moreover, the Office already knew of and/or evaluated every reference (or a substantially similar reference) cited by Petitioner. *See* Section III, *supra*.

Given the balance of these factors, Patent Owner requests that the Board should exercise its discretion under Section 314(a) to deny institution because proceeding would not be consistent with the objective of the AIA to “provide an effective and efficient alternative to district court litigation.” *NHK Spring Co. v. Intri-Plex Techs., Inc.*, IPR2018-00752, Paper 8, p.20 (P.T.A.B. Sept. 12, 2018)

(quoting *Gen. Plastic Indus. Co. v. Canon Kabushiki Kaisha*, IPR2016-01357, Paper 19, pp.16-17 (P.T.A.B. Sept. 6, 2017) (precedential)).

VIII. THERE IS NO GOOD CAUSE FOR A PRE-INSTITUTION REPLY

In view of the deficiencies in the Petition discussed above, Petitioner might seek to file a pre-institution reply. There would be no good cause for a pre-institution reply, however. All of Patent Owner's arguments above address the merits of the Petition, and Petitioner could have—and should have—addressed these issues in the Petition itself. *See, e.g., Ontel Prods. Corp. v. Guy A. Shaked Invs. Ltd.*, IPR2020-01703, Paper 10, p.2 (P.T.A.B. Feb. 4, 2021) (denying reply for “subjects that Petitioner should have developed in its Petition”).

IX. CONCLUSION

For all the above reasons, Patent Owner respectfully requests that the Board deny institution.

Respectfully submitted,

Dated: November 27, 2024

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

CERTIFICATE OF COMPLIANCE

Pursuant to 37 C.F.R. § 42.24(d), I, Joseph Hamilton, certify that **PATENT OWNER'S PRELIMINARY RESPONSE** contains 12,194 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: November 27, 2024

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

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), I certify that on November 27, 2024, a copy of **PATENT OWNER'S PRELIMINARY RESPONSE** was served upon the below-listed counsel by electronic mail:

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