

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

IMPERATIVE CARE, INC.,
Petitioner,

v.

INARI MEDICAL, INC.,
Patent Owner.

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

**PATENT OWNER'S REQUEST FOR
DISCRETIONARY DENIAL**

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EX1001	U.S. Patent No. 11,974,910 (“the ’910 patent”)
EX1002	’910 Patent Prosecution History
EX1003	Expert Declaration of Troy Thornton
EX1004	Resume of Troy Thornton
EX1005	U.S. Patent No. 8,734,374 B2 to Aklog et al. (“Aklog”)
EX1006	U.S. Patent Publication No. 2015/0173782 A1 to Garrison et al. (“Garrison”)
EX1007	WIPO Publication No. WO 2006/124307 A2 to Goff et al. (“Goff”)
EX1008	U.S. Patent Publication No. 2003/0116731 A1 to Hartley (“Hartley”)
EX1009	U.S. Patent No. 6,776,770 B2 to Trerotola (“Trerotola”)
EX1010	U.S. Patent Publication No. 2010/0042118 A1 to Garrison et al.
EX1011	U.S. Patent No. 8,535,283 B2 to Heaton et al. (“Heaton”)
EX1012	U.S. Patent Publication No. 2017/0043066 A1 to Laub (“Laub”)
EX1013	U.S. Patent Publication US 2003/0225379 A1 to Schaffer et al. (“Schaffer”)
EX1014	U.S. Patent No. 5,938,645 to Gordon (“Gordon”)
EX1015	U.S. Patent Publication No. 2014/0296868 A1 to Garrison et al.
EX1016	U.S. Patent No. 7,998,104 B2 to Chang (“Chang”)
EX1017	U.S. Patent No. 8,157,760 B2 to Criado et al. (“Criado”)
EX1018	U.S. Patent No. 6,481,439 B1 to Lewis et al.
EX1019	U.S. Patent No. 8,075,510 B2 to Aklog et al.

EX1020	WIPO Publication No. WO 2018/019829 A1 to Brady et al. (“Brady”)
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EX1022	Expert Declaration of Dr. Aquilla S. Turk, III, DO
EX1023	Resume of Dr. Aquilla Turk, III, D.O.
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EX1025	Bose, A et al., The Penumbra System: A Mechanical Device for the Treatment of Acute Stroke due to Thromboembolism, 29 Am. J. Neuroradiol. 1409-1413 (Aug. 2008)
EX1026	Turk, Aquilla S. et al., Initial clinical experience with the ADAPT technique: A direct aspiration first pass technique for stroke thrombectomy, 6 J. NeuroIntervent. Surg. 231-237 (2014)
EX1027	Turk, Aquilla S. et al., ADAPT FAST study: a direct aspiration first pass technique for acute stroke thrombectomy, 6 J. NeuroIntervent. Surg. 260-264 (2014)
EX1028	April 24, 2024 Letter from Inari to Imperative Care
EX1029	Turk, Aquilla S. et al., Aspiration thrombectomy versus stent retriever thrombectomy as first-line approach for large vessel occlusion (COMPASS): a multicentre, randomized, open label, blinded outcome, non-inferiority trial, 393 Lancet 998-1008 (March 2019)
EX1030	Save, Jeffrey L., Time is Brain – Quantified, American Heart Association Journals, available at http://www.stokeaha.org (2005).
EX1031	U.S. Patent No. 9,980,813 B1 to Eller (“Eller”)
EX1032	US 2018/0064453 A1 (“Garrison II”)
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EX1034	Decision Granting Institution of <i>Inter Partes</i> Review for U.S. Patent No. 11,697,011 (Paper 7) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2024-01157 (P.T.A.B. Jan. 23, 2025)

EX1035	Decision Granting Institution of <i>Inter Partes</i> Review for U.S. Patent No. 11,697,012 (Paper 6) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-00156 (P.T.A.B. Apr. 22, 2025)
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EX1038	Indigo Aspiration System-Penumbra Engine Pump and Canister, 510(k) No. K180105 (Mar. 8, 2018) (“Indigo Aspiration System”)
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EX1049	Ahmed Pasha et al., Successful Management of Acute Massive Pulmonary Embolism Using Angiovac Suction Catheter Technique in a Hemodynamically Unstable Patient, 15 Cardiovasc. Revasc. Med. 240-243 (2014)
EX1050	Certified File History of U.S. Patent Application 10/371,190 (Schaffer File History)
EX1051	Maureen Kohi, Catheter Directed Interventions for Acute Deep Vein Thrombosis, 6 Cardiovasc. Diagn. Ther. 599-611 (2016)
EX1052	Interview Summary from U.S. Patent Application No. 18/329,450 dated January 31, 2024
EX1053	Claim Construction Expert Report of Troy Thornton in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 24-cv-03117-EKL (N.D. Cal.)

Patent Owner's Exhibits	
Exhibit	Description
EX2001	Notice of Allowance from U.S. Patent Application No. 18/329,450
EX2002	U.S. Patent Application Publication No. 2018/0042623 to Batiste ("Batiste")

I. INTRODUCTION

Patent Owner requests that the Office exercise its discretion to deny the petition for IPR of U.S. Patent No. 11,974,910 (the “’910 Patent”) (Paper 1) (hereinafter “Petition”) under 35 U.S.C. § 325(d) because “the same or substantially the same prior art or arguments” were previously presented to and rejected by the Office.

First, the same or substantially the same prior art and arguments set forth in the Petition were considered by the Office. Specifically, the Petition’s primary reference for all grounds, Garrison, was expressly considered by the Office and overcome during prosecution. And, for grounds 1-3 (the only grounds pertaining to the two independent Claims 1 and 11) although the secondary references Aklog and Laub were not specifically considered by the Office, they are substantially and materially similar to Aklog’s parent (EX1019), which was considered. Petitioner does not cite to any portion of Aklog that is not identically found in Aklog’s parent. And, Petitioner relies on Laub only as an alternative that allegedly discloses the same features as Aklog—nothing more.

In fact, grounds 1-3 of the Petition directly contradict at least three independent reasons expressly articulated by the Office for allowing the challenged claims over Garrison and the other references. In particular:

- (1) The Petition requires a finding that Garrison discloses features the Patent Office expressly found Garrison does not disclose,

including “a second catheter advanceable through the first catheter; a second pressure source; and a fluid control device between the second catheter and the second pressure source.” EX1002, p.377; Petition, pp.39-42, 48-54. The Petition relies only on Garrison for that limitation, but this issue was considered and expressly rejected by the examiner during prosecution, resulting in the allowed claims.

- (2) The Petition requires a finding that a POSITA would have been motivated to modify Garrison’s system to treat pulmonary embolism in contrast to the Patent Office’s express finding that such a modification to Garrison would have been “unreasonable.” EX1002, p.49; Petition, pp.22-27, 45, 71-72.
- (3) The Petition requires a finding that a POSITA would have been motivated to modify Garrison’s system to include a 16 French (or larger) inner catheter and an even larger outer catheter, again in contrast to the Examiner’s finding that such a modification to Garrison would have been “unreasonable.” EX1002, p.49; Petition, pp.27-34, 39-48, 71-72.

The Petition fails to provide a sufficient basis to conclude that the Office erred in its previous analysis, such that a do-over a little over a year later is appropriate.

In addition to the prosecution of the challenged claims, the Office has also already considered Garrison, Aklog and Laub or their equivalents when allowing the claims of related U.S. Patent Nos. 11,969,333 & 11,744,691, and when the Office

denied institution of Petitioner’s petition for IPR of related U.S. Patent No. 11,744,691. *See* EX1045. Moreover, in a parallel district court proceeding, Petitioner has raised the same invalidity grounds and issues related to those grounds and a preliminary injunction motion related to those grounds is fully briefed and awaiting a decision. Accordingly, the Office has extensively considered Petitioner’s art and arguments—both pre-grant and post-grant—and the same issues are being and will be considered in district court. The Office should exercise its discretion here to deny considering those arguments and references yet again.

Grounds 4-9 address only dependent claims and thus include nothing that would rectify the deficiencies with respect to grounds 1-3, *i.e.*, grounds 4-9 raise nothing with respect to the independent Claims 1 and 11 that was not already considered by the Patent Office and overcome during prosecution.

Accordingly, Patent Owner requests that the Board deny the Petition under Section 325(d).

II. ARGUMENT

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.8, 2020 WL 740292, at *3 (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, pp.17-18, 2017 WL 6405100, at *6 (P.T.A.B. Dec. 15, 2017) (precedential as to §III.C.5, first paragraph) (“*Becton, Dickinson*”). The Becton, Dickinson factors are: (a) the similarities and material differences between the asserted art and the prior art involved during examination; (b) the 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 of the asserted prior art; and (f) the extent to which additional evidence and facts presented in the Petition

warrant reconsideration of the prior art or arguments. *Becton, Dickinson*, Paper 8, pp.17-18.

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). That is the case here. 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.*, IPR2018-01451, Paper 12 (P.T.A.B. Feb. 19, 2019).

B. The First Part of the Framework is Satisfied: Petitioner's Asserted Art and Arguments are the Same or Substantially the Same and Cumulative to the Prior Art and Arguments Previously Considered and Rejected by the Office.

Petitioner asserts grounds 1-3 for the unpatentability of both independent Claims 1 and 11 of the '910 Patent. Specifically, Petitioner relies on Garrison in

combination with Laub or Aklog for grounds 1 and 2, respectively, and Garrison in combination with both Laub and Aklog for ground 3. Petition, p.21. But, Garrison was the *primary reference* relied on by the Examiner during prosecution of the '910 Patent. In fact, the Examiner extensively evaluated Garrison and expressly allowed independent Claims 1 and 11 over Garrison, first in the sole Office action and second in the Notice of Allowance where the Examiner further distinguished Garrison. *See*, e.g., EX1002, p.49 (“Garrison (US 20150173782 A1) ... fails to teach a clot treatment system for treating clot material comprising a pulmonary embolism in the vasculature of a patient’ and ‘wherein the second catheter has a size of 16 French or greater’”).

Similarly, Aklog’s substantively identical parent was cited during prosecution in an information disclosure statement and appears on the face of the '910 Patent. *Id.* at p.1123; EX1001, p.3. And, while Laub was not cited during prosecution, for the disclosures that the Petition cites, Laub is substantially similar to and cumulative of Aklog’s parent that was analyzed during prosecution. Indeed, Petitioner relies on Laub only as an alternative that allegedly discloses the same features as Aklog—nothing more.

Proposed grounds 1-3 rely on Garrison *alone* as disclosing several limitations the Patent Office expressly found missing in Garrison. And for other limitations, proposed grounds 1-3 further rely on combinations of Garrison with Laub and/or

Aklog that are directly contrary to the Examiner's finding that it would not have been obvious to modify Garrison to include those same features disclosed in Aklog's parent application. More particularly, Petitioner's arguments directly contradict the Examiner's stated reasons for allowing the claims as follows:

- (1) The Petition requires a finding that Garrison discloses "a second catheter" i.e., a second aspiration catheter, "advanceable through the first catheter; a second pressure source; and a fluid control device between the second catheter and the second pressure source" in direct contrast to the Examiner's finding in the non-final Office action that Garrison does not disclose those limitations. EX1002, p.377.
- (2) The Petition requires a finding that it would have been obvious to have modified Garrison's system to treat pulmonary embolism based on Laub and/or Aklog in direct contrast to the Examiner's finding in the Notice of Allowance that such a modification to Garrison would have been "unreasonable." EX1002, p.49.
- (3) The Petition requires a finding that it would have been obvious to have modified Garrison's system to include an inner catheter (the smaller of the two telescoping aspiration catheters) having a size of 16 French or greater based on Laub and/or Aklog again in direct contrast to the Examiner's finding in the Notice of Allowance that such a modification would have been "unreasonable." EX1002, p.49.

1. **The first (a) and second (b) *Becton, Dickinson* factors weigh in favor of denial because Petitioner’s asserted art is the same or substantially the same and cumulative to the prior art previously considered by the Patent Office.**
 - a) **Garrison was extensively considered by the Patent Office.**

Garrison was the primary reference relied on by the Examiner during prosecution of the '910 Patent, and, after extensive consideration and analysis, the Examiner allowed independent Claims 1 and 11 over Garrison. For example, in the sole non-final Office action mailed November 6, 2023, the Examiner relied on Garrison to reject original independent claim 18 as anticipated under 35 U.S.C. § 102(a)(1). EX1002, p.375. In that same Office action, the Examiner found independent claims 1 and 11 (which matured into issued Claims 1 and 11 of the '910 Patent challenged here) to be allowable over Garrison because Garrison fails to disclose “a second catheter advanceable through the first catheter; a second pressure source; and a fluid control device between the second catheter and the second pressure source’.” *Id.* at p.377.

In response to the Office action, Patent Owner canceled independent claim 18 and further distinguished Garrison by amending independent claims 1 and 11 (which matured into independent Claims 1 and 11 of the '910 Patent) to narrow those allowed claims to clot treatment systems “for treating clot material comprising a pulmonary embolism” and wherein the second (e.g., inner) catheter “has a size of 16

French or greater” and “is shaped to be intravascularly advanced through the vasculature of the patient such that the distal portion of the second catheter is positioned proximate to the pulmonary embolism.” *Id.* at pp.142-145. In the response, Patent Owner explained that:

[I]ndependent claims 1 and 11, as amended, are further patentable over Garrison for at least the reasons discussed during the January 25th videoconference interview with the Examiner and his supervisor in related U.S. Patent Application No. 18/329,450, and specifically the Examiner's comments in the Applicant-Initiated Interview Summary mailed January 31, 2024 that “Attorney and Examiner agree that incorporating more structural claim language, i.e. diameter of the catheter, would make the claim 1 allowable over the prior art Garrison.”

Id. at pp.147-148. That is, Patent Owner substantively discussed the disclosure of Garrison in a videoconference interview with the same Examiner in a related application claiming similar subject matter, and further narrowed the allowed claims by amendment based on discussions with the Examiner about Garrison.

Following that amendment, the Examiner agreed and further explained why the claims are patentable over Garrison in the Notice of Allowance:

Claims 1 and 11 are allowable for reciting, inter alia, “a clot treatment system for treating clot material comprising a pulmonary embolism in the vasculature of a patient” and “wherein the second catheter has a size of 16 French or greater”.

Garrison (US 20150173782 A1) ... fails to teach a [“]clot treatment system for treating clot material comprising a pulmonary embolism in the vasculature of a patient” and “wherein the second catheter has a size of 16 French or greater”. The clot treatment device of Garrison is configured for a neurovascular application and not for larger vasculature such as pulmonary embolism. It would be unreasonable to modify the clot treatment device of Garrison to be used for pulmonary embolisms. There is no prior art that teaches all of the limitations. Therefore, claims 1 and 11 are allowable.

Id. at p.49.

Accordingly, Garrison was considered in detail during prosecution. Garrison was the primary reference applied by the Examiner, who expressly explained that Claims 1 and 11 were patentable over Garrison in both the sole Office action and in the Notice of Allowance.

b) Aklog’s disclosure was considered by the Patent Office.

Although Aklog itself was not cited in an information disclosure statement, Aklog’s parent (EX1019) was considered and includes disclosure that is identical to the only portions of Aklog relied upon in the Petition. EX1002, p.1123 (information disclosure statement identifying Aklog’s parent, EX1019). Aklog is a continuation-in-part of Aklog’s parent. EX1005, p.1. The only additional disclosure in Aklog over Aklog’s parent is found in column 18, line 56 to column 20, line 27 of Aklog. This portion of Aklog describes using the system already disclosed in Aklog’s parent to

capture vegetative growths disrupted during another procedure, such as the removal of a pacemaker lead. That disclosure is not related to the claims of the '910 Patent and is not cited or relied upon in the Petition.

Specifically, Petitioner's citations to Aklog are for disclosures that are identical to the disclosures in Aklog's parent as shown in the table below. Therefore, the Office considered Aklog during the prosecution of the '910 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]"); *Benitec Biopharma Ltd. v. Cold Spring Harbor Lab.*, IPR2016-00015, 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.'").

Disclosure of Aklog (EX1005) Relied on By Petitioner

Figure 7 (Petition, pp.7, 26, 44, 50):

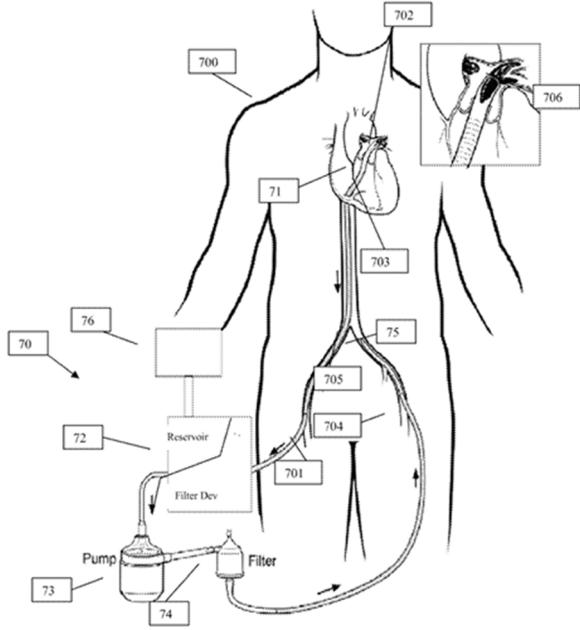


Fig. 7

Identical Disclosure of the Aklog's Parent (EX1019)

Figure 7:

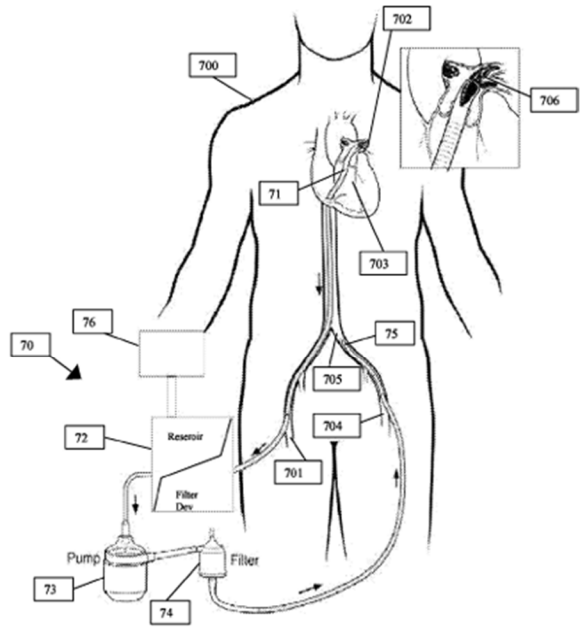


Fig. 7

Figure 6 (Petition, p.26):

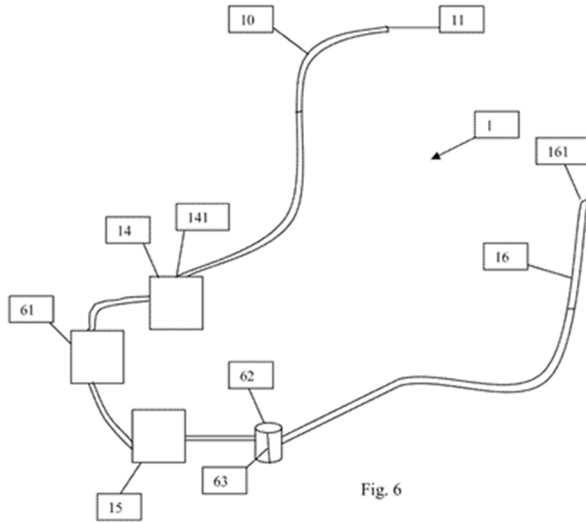


Fig. 6

Figure 6:

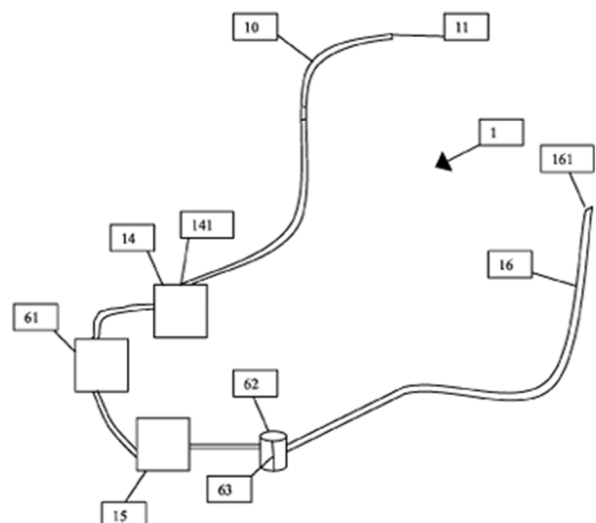
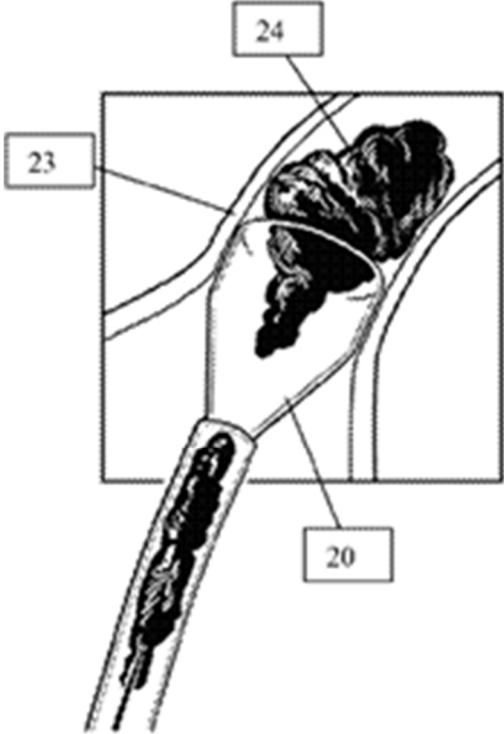
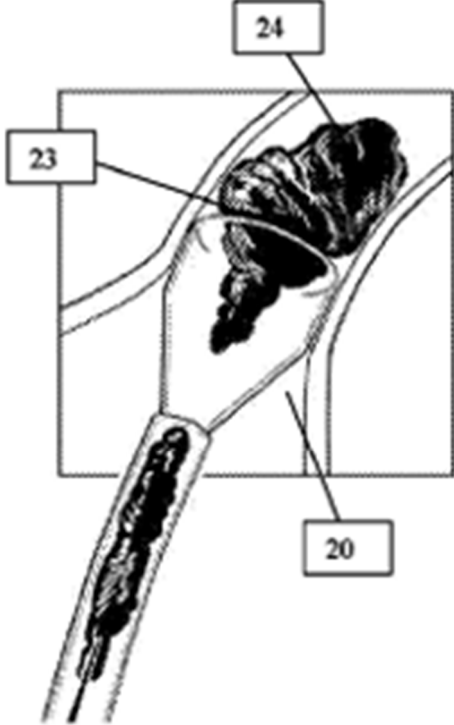
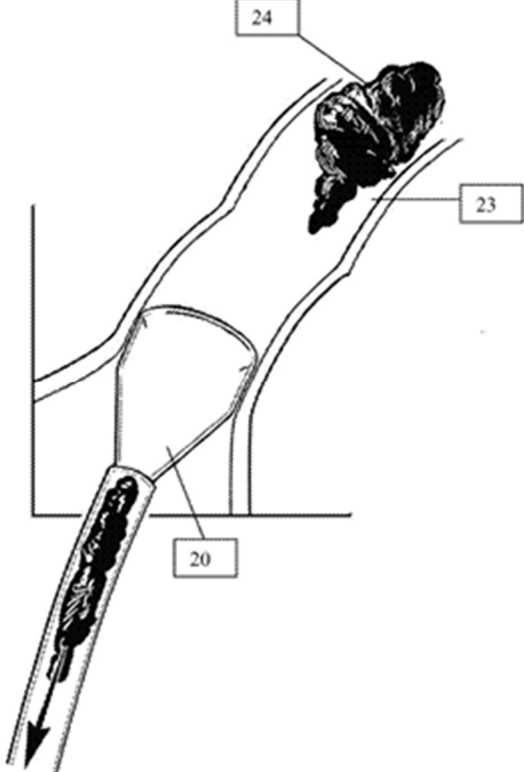
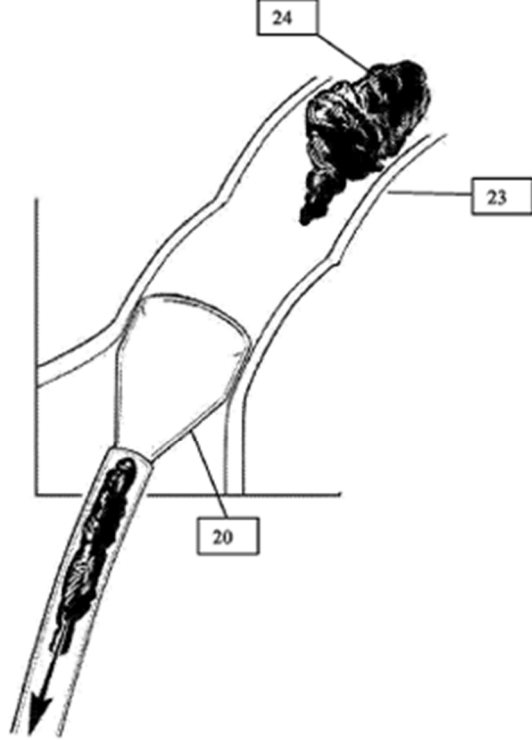
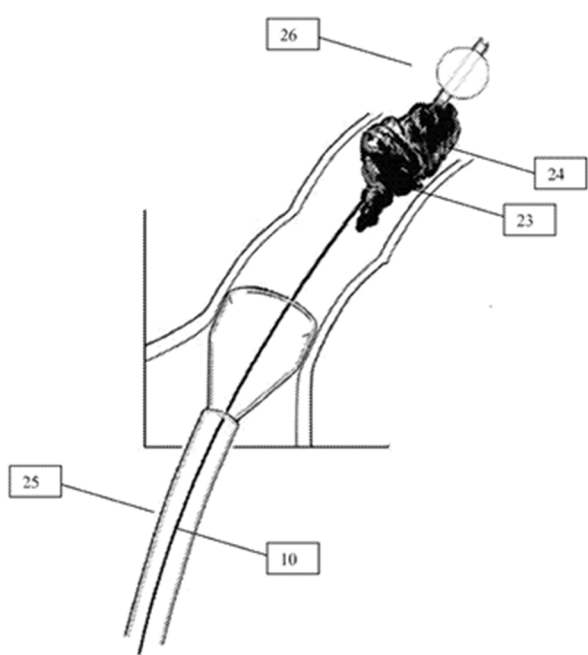
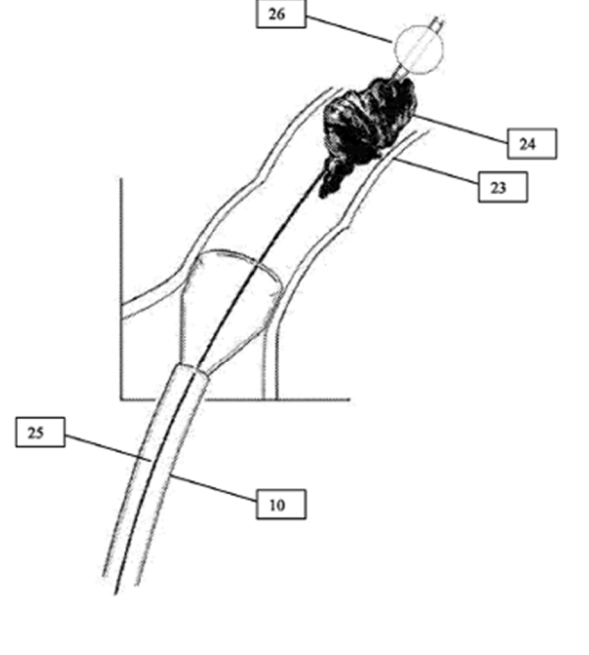
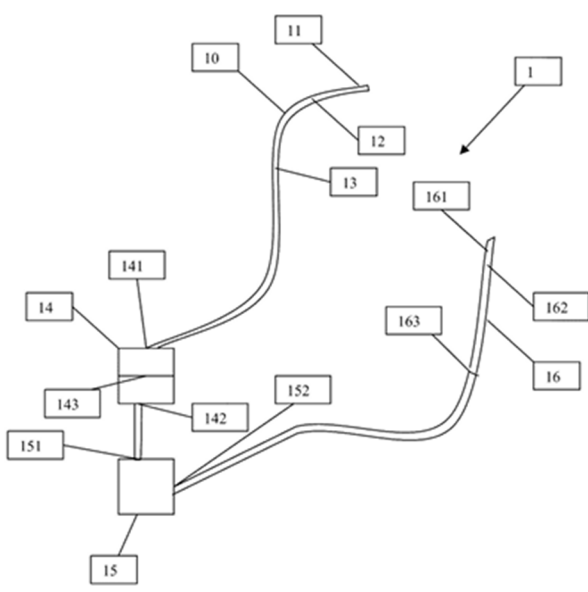
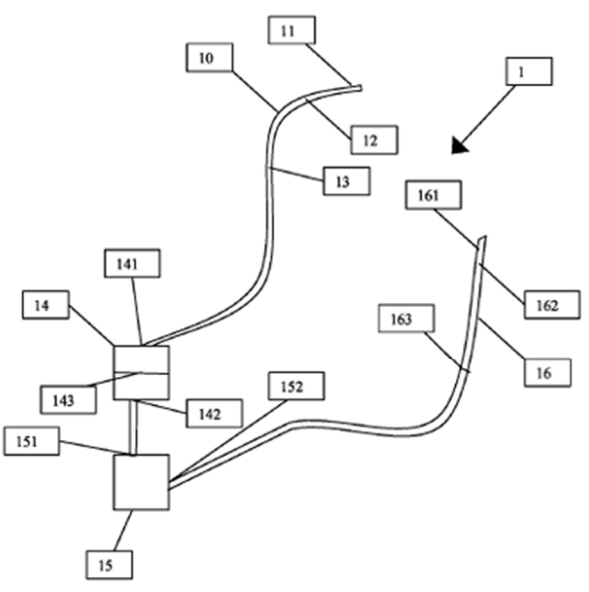


Fig. 6

Disclosure of Aklog (EX1005) Relied on By Petitioner	Identical Disclosure of the Aklog's Parent (EX1019)
<p data-bbox="203 317 597 352"><u>Figure 2C (Petition, p.48):</u></p>  <p data-bbox="440 1266 545 1302">Fig. 2C</p>	<p data-bbox="833 317 992 352"><u>Figure 2C:</u></p>  <p data-bbox="1068 1203 1230 1266">Fig. 2C</p>

Disclosure of Aklog (EX1005) Relied on By Petitioner	Identical Disclosure of the Aklog's Parent (EX1019)
<p data-bbox="203 319 600 352"><u>Figure 2D (Petition, p.48):</u></p>  <p data-bbox="467 1159 548 1186">Fig. 2D</p>	<p data-bbox="828 319 990 352"><u>Figure 2D:</u></p>  <p data-bbox="1084 1228 1198 1270">Fig. 2D</p>

Disclosure of Aklog (EX1005) Relied on By Petitioner	Identical Disclosure of the Aklog's Parent (EX1019)
<p data-bbox="203 319 600 357"><u>Figure 2H (Petition, p.48):</u></p>  <p data-bbox="438 1081 519 1113">Fig. 2H</p>	<p data-bbox="828 319 990 357"><u>Figure 2H:</u></p>  <p data-bbox="1055 1081 1136 1113">Fig. 2H</p>
<p data-bbox="203 1127 584 1165"><u>Figure 1 (Petition, p. 25):</u></p>  <p data-bbox="535 1774 584 1806">Fig. 1</p>	<p data-bbox="828 1127 958 1165"><u>Figure 1:</u></p>  <p data-bbox="1104 1858 1185 1890">Fig. 1</p>

Disclosure of Aklog (EX1005) Relied on By Petitioner	Identical Disclosure of the Aklog's Parent (EX1019)
<p><u>1:17-24 (Petition, p.25):</u></p> <p>The present invention relates to systems and methods for removing undesirable materials from a site of interest within the circulatory system. More particularly, the present invention relates to systems and methods for removing substantially en bloc clots, thrombi, and emboli, among others, from within heart chambers, as well as medium to large vessels, while reinfusing fluid removed from the site of interest back into the patient to minimize fluid loss.</p>	<p><u>1:13-20:</u></p> <p>The present invention relates to systems and methods for removing undesirable materials from a site of interest within the circulatory system. More particularly, the present invention relates to systems and methods for removing substantially en bloc clots, thrombi, and emboli, among others, from within heart chambers, as well as medium to large vessels, while reinfusing fluid removed from the site of interest back into the patient to minimize fluid loss.</p>

2:7-32 (Petition, pp. 6, 25, 29):

In the systemic venous circulation, undesirable material can also cause serious harm. Blood clots can develop in the large veins of the legs and pelvis, a common condition known as deep venous thrombosis (DVT). DVT arises most commonly when there is a propensity for stagnated blood (long-haul air travel, immobility) and clotting (cancer, recent surgery, especially orthopedic surgery). DVT causes harm by (1) obstructing drainage of venous blood from the legs leading to swelling, ulcers, pain and infection and (2) serving as a reservoir for blood clot to travel to other parts of the body including the heart, lungs (pulmonary embolism) and across a opening between the chambers of the heart (patent foramen ovale) to the brain (stroke), abdominal organs or extremities.

In the pulmonary circulation, the undesirable material can cause harm by obstructing pulmonary arteries, a condition known as pulmonary embolism. If the obstruction is upstream, in the main or large branch pulmonary arteries, it can severely compromise total blood flow within the lungs and therefore the entire body, resulting in low blood pressure and shock. If the obstruction is downstream, in large to medium pulmonary artery branches, it can prevent a significant portion of the lung from participating in

2:3-28:

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the exchange of gases to the blood resulting low blood oxygen and build up of blood carbon dioxide. If the obstruction is further downstream, it can cut off the blood flow to a smaller portion of the lung, resulting in death of lung tissue or pulmonary infarction.	the exchange of gases to the blood resulting low blood oxygen and build up of blood carbon dioxide. If the obstruction is further downstream, it can cut off the blood flow to a smaller portion of the lung, resulting in death of lung tissue or pulmonary infarction.

<p><u>5:11-41 (Petition, pp. 7, 25, 26, 48):</u></p> <p>The present invention relates generally to systems and methods for removing undesirable material residing in vessels, such as blood vessels, or within chambers of the heart. More specifically, the subject invention relates to systems and methods for using a cannula to remove substantially en bloc, from a site of obstruction or interest, an undesirable material, such as blood clots, embolisms and thromboembolisms, without significant fragmentation and without excessive fluid loss. In addition, the systems and methods of the present invention may simultaneously reinfuse aspirated (i.e., removed) and filtered fluid, such as blood, back into the patient on a substantially continuous basis to minimize any occurrences of fluid loss and/or shock. The subject invention may be particularly useful, but may not be limited to, the removal of blood clots, tumors, infective vegetations and foreign bodies from medium to large blood vessels and heart chambers.</p> <p>In one embodiment, a system for removing an undesirable material from within a vessel is provided. The system includes a first cannula having a distal end and an opposing proximal end. The distal end of the first cannula, in an embodiment, may include or may be deployable to a diameter relatively larger than that of the proximal end. The first cannula may be designed for</p>	<p><u>5:6-36:</u></p> <p>The present invention relates generally to systems and methods for removing undesirable material residing in vessels, such as blood vessels, or within chambers of the heart. More specifically, the subject invention relates to systems and methods for using a cannula to remove substantially en bloc, from a site of obstruction or interest, an undesirable material, such as blood clots, embolisms and thromboembolisms, without significant fragmentation and without excessive fluid loss. In addition, the systems and methods of the present invention may simultaneously reinfuse aspirated (i.e., removed) and filtered fluid, such as blood, back into the patient on a substantially continuous basis to minimize any occurrences of fluid loss and/or shock. The subject invention may be particularly useful, but may not be limited to, the removal of blood clots, tumors, infective vegetations and foreign bodies from medium to large blood vessels and heart chambers.</p> <p>In one embodiment, a system for removing an undesirable material from within a vessel is provided. The system includes a first cannula having a distal end and an opposing proximal end. The distal end of the first cannula, in an embodiment, may include or may be deployable to a diameter relatively larger than that of the proximal end. The first cannula may be designed for</p>
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maneuvering within the vessel to a site of interest, such that an undesirable material can be captured substantially en bloc through the distal end and removed along the first cannula away from the site. The system may also include a pump, in fluid communication with the proximal end of the first cannula, so as to provide a sufficient suction force for removing the undesirable material from the site of interest.	maneuvering within the vessel to a site of interest, such that an undesirable material can be captured substantially en bloc through the distal end and removed along the first cannula away from the site. The system may also include a pump, in fluid communication with the proximal end of the first cannula, so as to provide a sufficient suction force for removing the undesirable material from the site of interest.

<p><u>7:23-52 (Petition, pp. 6, 25, 32, 33):</u></p> <p>If the catheter is enlarged to accommodate the larger structure and material, such a catheter may aspirate an unacceptable volume of blood, resulting in excessive fluid loss and/or shock in the patient.</p> <p>The present invention overcomes the deficiencies of existing devices and techniques and can act to remove substantially en bloc (i.e., wholly or entirely) undesirable material, such as thrombi and emboli, from the vasculature, including medium to large size blood vessels, and from heart chambers. Vessels 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), systemic venous circulation (e.g., vena cavae, pelvic veins, leg veins, neck and arm veins) or arterial circulation (e.g., aorta or its large and medium branches). The heart chambers may be, for example, in the left heart (e.g., the left ventricular apex and left atrial appendage), right heart (e.g., right atrium and right ventricle), or on its valves. The present invention can also act to remove tumors, infective vegetations and other foreign bodies.</p> <p>Although reference is made to medium and large vessels, it should be appreciated that the systems and</p>	<p><u>7:16-45:</u></p> <p>If the catheter is enlarged to accommodate the larger structure and material, such a catheter may aspirate an unacceptable volume of blood, resulting in excessive fluid loss and/or shock in the patient.</p> <p>The present invention overcomes the deficiencies of existing devices and techniques and can act to remove substantially en bloc (i.e., wholly or entirely) undesirable material, such as thrombi and emboli, from the vasculature, including medium to large size blood vessels, and from heart chambers. Vessels 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), systemic venous circulation (e.g., vena cavae, pelvic veins, leg veins, neck and arm veins) or arterial circulation (e.g., aorta or its large and medium branches). The heart chambers may be, for example, in the left heart (e.g., the left ventricular apex and left atrial appendage), right heart (e.g., right atrium and right ventricle), or on its valves. The present invention can also act to remove tumors, infective vegetations and other foreign.</p> <p>Although reference is made to medium and large vessels, it should be appreciated that the systems and</p>
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Disclosure of Aklog (EX1005) Relied on By Petitioner	Identical Disclosure of the Aklog's Parent (EX1019)
<p>methods, hereinafter disclosed, can be scaled and adapted for use within smaller vessels within the body, if desired.</p> <p>Referring now to FIG. 1, there is illustrated a system 1 for removing an undesirable material, substantially en bloc, from an obstruction site or site of interest within the vasculature, and for reinfusion of fluid removed (i.e., suctioned or aspirated) from the site of interest back into a patient, in order to minimize fluid loss within the patient.</p>	<p>methods, hereinafter disclosed, can be scaled and adapted for use within smaller vessels within the body, if desired.</p> <p>Referring now to FIG. 1, there is illustrated a system 1 for removing an undesirable material, substantially en bloc, from an obstruction site or site of interest within the vasculature, and for reinfusion of fluid removed (i.e., suctioned or aspirated) from the site of interest back into a patient, in order to minimize fluid loss within the patient.</p>

Disclosure of Aklog (EX1005) Relied on By Petitioner	Identical Disclosure of the Aklog's Parent (EX1019)
<p><u>11:12-20 (Petition, pp. 43, 44, 46, 59, 61):</u></p> <p>Cannula 10 of the present invention may be of any sufficient size, so long as it can be accommodated within a pre determined vessel. Such as a medium to large size blood vessel. The size of cannula 10 may also be determined by the size of the undesirable material to be removed, so long as the undesirable material can be removed substantially en bloc without significant fragmentation. In one embodiment, suction cannula 10 may be designed to remove at least 10 cm³ of undesirable material substantially enbloc.</p>	<p><u>11:5-13:</u></p> <p>Cannula 10 of the present invention may be of any sufficient size, so long as it can be accommodated within a pre determined vessel. Such as a medium to large size blood vessel. The size of cannula 10 may also be determined by the size of the undesirable material to be removed, so long as the undesirable material can be removed substantially en bloc without significant fragmentation. In one embodiment, suction cannula 10 may be designed to remove at least 10 cm³ of undesirable material substantially enbloc.</p>

Disclosure of Aklog (EX1005) Relied on By Petitioner	Identical Disclosure of the Aklog's Parent (EX1019)
<p><u>11:62-12:14 (Petition, pp.48, 66):</u></p> <p>Still looking at FIG. 1, system 1 may also be provided with a pump 15 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. In one embodiment, pump 15 may include an intake port 151 in fluid communication with outlet 142 of filter device 14. Intake port 151, as illustrated, may be designed to receive filtered fluid from filter device 14. Pump 15 may also be designed to generate the positive pressure, so as to create a necessary driving force to direct fluid through exit port 152 and downstream of system 1 for reinfusion of fluid removed from the site of interest back into the body. In an embodiment, the Suction force and the drive force may be generated by pump 15 simultaneously and may take place continuously or intermittently for a set duration. Pump 15, as it should be appreciated, may be any commercially available pump, including those for medical applications and those capable of pumping fluids, such as blood. Examples of such a pump includes a kinetic pump, such as a centrifugal pump, and an active displacement pump, such as a rollerhead pump.</p>	<p><u>11:55-12:7:</u></p> <p>Still looking at FIG. 1, system 1 may also be provided with a pump 15 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. In one embodiment, pump 15 may include an intake port 151 in fluid communication with outlet 142 of filter device 14. Intake port 151, as illustrated, may be designed to receive filtered fluid from filter device 14. Pump 15 may also be designed to generate the positive pressure, so as to create a necessary driving force to direct fluid through exit port 152 and downstream of system 1 for reinfusion of fluid removed from the site of interest back into the body. In an embodiment, the Suction force and the drive force may be generated by pump 15 simultaneously and may take place continuously or intermittently for a set duration. Pump 15, as it should be appreciated, may be any commercially available pump, including those for medical applications and those capable of pumping fluids, such as blood. Examples of such a pump includes a kinetic pump, such as a centrifugal pump, and an active displacement pump, such as a rollerhead pump.</p>

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<p><u>13:64-14:2 (Petition, p.48):</u></p> <p>With reference now to FIG. 6, system 1 may also include a reservoir 61. Reservoir 61, in one embodiment, may be situated in fluid communication between filter device 14 and pump 15, and may act to transiently collect fluid filtered from the site of interest, prior to the filtered fluid being directed into reinfusion cannula 16.</p>	<p><u>13:57-62:</u></p> <p>With reference now to FIG. 6, system 1 may also include a reservoir 61. Reservoir 61, in one embodiment, may be situated in fluid communication between filter device 14 and pump 15, and may act to transiently collect fluid filtered from the site of interest, prior to the filtered fluid being directed into reinfusion cannula 16.</p>

15:27-53 (Petition, pp.25, 26):

In general the method of the present invention, in one embodiment, includes, initially accessing a first blood vessel 701 either by surgical dissection or percutaneously with, for instance, a needle and guide wire. The first blood vessel through which suction cannula 71 may be inserted into patient 700 can be, in an embodiment, any blood vessel that can be accessed percutaneously or by surgical dissection such as femoral vein, femoral artery or jugular vein. Next, suction cannula 71 may be inserted into the first blood vessel 701 over the guide wire, and advanced toward a site of interest 702, for instance, in a second vessel or a heart chamber 703 where an undesirable material 706 may be residing. The second blood vessel or heart chamber, in an embodiment, can be the main pulmonary artery, branch pulmonary arteries, inferior vena cavae, superior vena cavae, deep veins of the pelvic, legs, arms or neck, aorta, or any other medium to large blood vessel for which the use of a cannula is suitable for removing undesirable material without causing undesirable damage to the blood vessel. In addition, the advancement of suction cannula 71 may be gauged or documented by fluoroscopic angiography, echocardiography or other suitable imaging modality.

15:19-45:

In general the method of the present invention, in one embodiment, includes, initially accessing a first blood vessel 701 either by surgical dissection or percutaneously with, for instance, a needle and guide wire. The first blood vessel through which suction cannula 71 may be inserted into patient 700 can be, in an embodiment, any blood vessel that can be accessed percutaneously or by surgical dissection such as femoral vein, femoral artery or jugular vein. Next, suction cannula 71 may be inserted into the first blood vessel 701 over the guide wire, and advanced toward a site of interest 702, for instance, in a second vessel or a heart chamber 703 where an undesirable material 706 may be residing. The second blood vessel or heart chamber, in an embodiment, can be the main pulmonary artery, branch pulmonary arteries, inferior vena cavae, superior vena cavae, deep veins of the pelvic, legs, arms or neck, aorta, or any other medium to large blood vessel for which the use of a cannula is suitable for removing undesirable material without causing undesirable damage to the blood vessel. In addition, the advancement of suction cannula 71 may be gauged or documented by fluoroscopic angiography, echocardiography or other suitable imaging modality.

Disclosure of Aklog (EX1005) Relied on By Petitioner	Identical Disclosure of the Aklog's Parent (EX1019)
In the case of pulmonary embolism, the suction cannula 71 may normally be introduced through the femoral, jugular or subclavian vein. Alternatively, the suction cannula 71 may be introduced, if desired, directly into the cardiac chambers using a minimally invasive surgical or endoscopic, thoracoscopic, or pericardioscopic approach.	In the case of pulmonary embolism, the suction cannula 71 may normally be introduced through the femoral, jugular or subclavian vein. Alternatively, the suction cannula 71 may be introduced, if desired, directly into the cardiac chambers using a minimally invasive surgical or endoscopic, thoracoscopic, or pericardioscopic approach.

<p><u>16:27-53 (Petition, p.48):</u></p> <p>... [pump] 73 and any other components of system 70 may also need to be primed with fluid prior to connecting them to the cannulae. In one embodiment, this can be achieved by temporarily connecting these components in fluid communication with other as a closed circuit and infusing fluid through a port, similar to port 51 in FIG. 5, while providing another port through which air can be displaced.</p> <p>Once these components have been fully primed with fluid, the circuit can be detached and connected to the primed suction cannula 71 and reinfusion cannula 75 in the appropriate configuration. Examples of a priming fluid include crystalloid, colloid, autologous or heterologous blood, among others.</p> <p>During operation, pump 73, in one embodiment, may remain activated so that suction and continuous reinfusion of blood can occur continuously for a desired duration or until the removal of the undesirable material has been confirmed, for instance, by visualizing the captured undesirable material in the filter device 72. Alternatively pump 73 can be activated intermittently in short pulses, either automatically or manually by an operator (e.g., surgeon, nurse or any operating room attendant), for a desired duration or until the removal of</p>	<p><u>16:18-45:</u></p> <p>... [pump] 73 and any other components of system 70 may also need to be primed with fluid prior to connecting them to the cannulae. In one embodiment, this can be achieved by temporarily connecting these components in fluid communication with other as a closed circuit and infusing fluid through a port, similar to port 51 in FIG. 5, while providing another port through which air can be displaced.</p> <p>Once these components have been fully primed with fluid, the circuit can be detached and connected to the primed suction cannula 71 and reinfusion cannula 75 in the appropriate configuration. Examples of a priming fluid include crystalloid, colloid, autologous or heterologous blood, among others.</p> <p>During operation, pump 73, in one embodiment, may remain activated so that suction and continuous reinfusion of blood can occur continuously for a desired duration or until the removal of the undesirable material has been confirmed, for instance, by visualizing the captured undesirable material in the filter device 72. Alternatively pump 73 can be activated intermittently in short pulses, either automatically or manually by an operator (e.g., surgeon, nurse or any operating room attendant), for a desired duration or until the removal of</p>
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<p>the undesirable material has been confirmed by visualization of the material within filter device 72.</p> <p>It should be appreciated that since suction cannula 71 may be deployed within any vessel within patient 700, depending on the procedure, in addition to being placed substantially directly against the undesirable material at the site of interest</p>	<p>the undesirable material has been confirmed by visualization of the material within filter device 72.</p> <p>It should be appreciated that since suction cannula 71 may be deployed within any vessel within patient 700, depending on the procedure, in addition to being placed substantially directly against the undesirable material at the site of interest</p>
<p><u>16:66-17:4 (Petition, p.48):</u></p> <p>... [cannula] 71 and to the site of interest, where the undesirable material may be dislodged location for subsequent removal.</p> <p>On the other hand, when suction cannula 71 is positioned within a vessel exhibiting arterial flow and at a distant location from the undesirable material, it may be necessary to place the distal end of suction cannula 71 upstream of the</p>	<p><u>16:56-63:</u></p> <p>... [cannula] 71 and to the site of interest, where the undesirable material may be dislodged location for subsequent removal.</p> <p>On the other hand, when suction cannula 71 is positioned within a vessel exhibiting arterial flow and at a distant location from the undesirable material, it may be necessary to place the distal end of suction cannula 71 upstream of the</p>

c) Laub's disclosure is substantially the same as and cumulative to Aklog's parent and other art of record.

While Laub was not considered by the Patent Office, the disclosure of Laub relied upon in the Petition is substantially the same as and cumulative to Aklog's parent (and thus Aklog) considered during prosecution and other art of record. In fact, Petitioner admits that the disclosure of Laub relied upon in the Petition is similar

to and merely an alternative to Aklog and makes no argument that consideration of that same substantive disclosure in Laub should require a different result here.

Laub discloses a “system for removing thrombi and other unwanted material from the body of a patient, particularly from the patient’s vasculature” and, more particularly, a system “to remove clots from patients suffering from or at risk of pulmonary embolisms.” EX1012, ¶[0005]; *see also* Petition, p.24. The embodiment of Laub relied on by Petitioner is shown in Figure 1A (reproduced below) and includes an aspiration catheter 200 in fluid communication with a filter 300, a pump 400, and a return catheter 500. EX1012, ¶[0024]. The pump 400 operates to suction blood and thrombi through the aspiration catheter 200 and the filter 300 and then drive the filtered blood through the return catheter 500 back into the patient. *Id.*

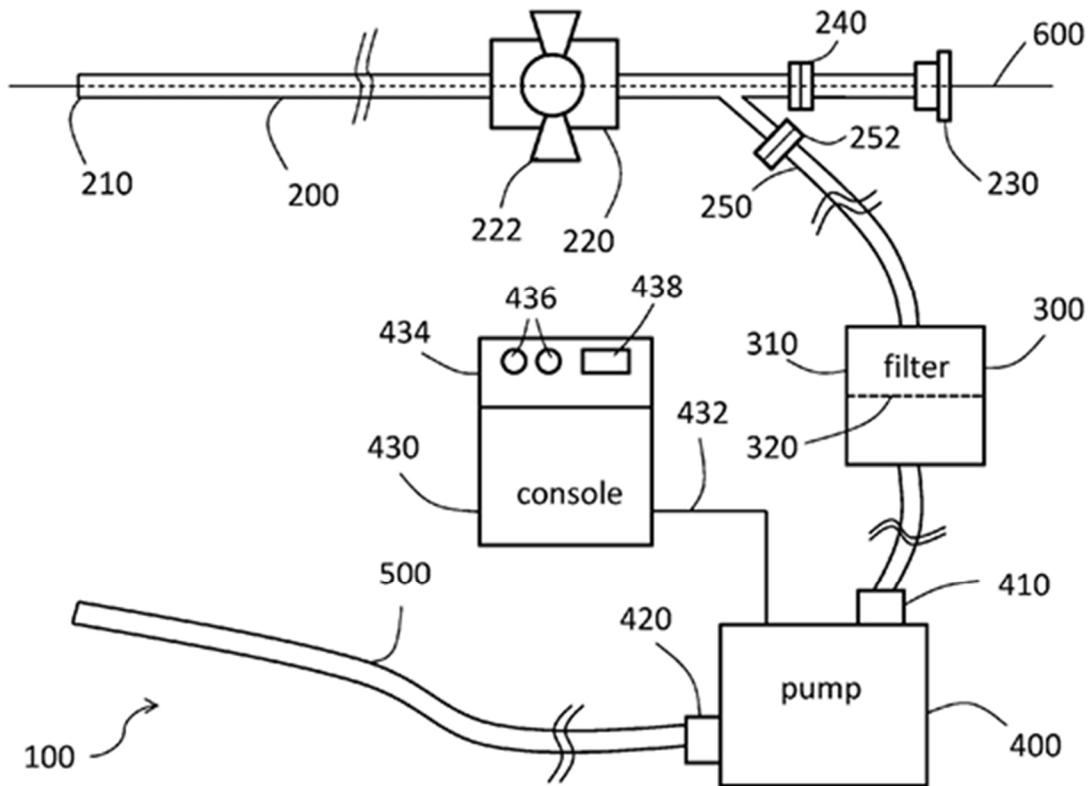


FIG. 1A

Petitioner asserts that “[s]imilarly, Aklog discloses systems and methods for removing clot material from ‘the pulmonary circulation (e.g., pulmonary arteries), systemic venous circulation (e.g., vena cavae, pelvic veins, leg veins, neck and arm veins) or arterial circulation (e.g., aorta or its large and medium branches).’ (Ex. 1005, 7:32-37; *see also id.*, 1:17-24, 5:11-19, 5:28-41, Figs. 1, 6-7.)” Petition, pp.24-25 (emphasis added). Indeed, like Laub, the embodiments of Aklog relied on in the Petition and shown in Figures 1, 6, and 7 of Aklog (Figure 1 reproduced below) include an aspiration catheter (cannula) 10 in fluid communication with a filter device 14, a pump 15, and a reinfusion catheter (cannula) 16. EX1005, 11:24-12:34.

As in Laub, the pump 15 operates to suction blood and thrombi through the aspiration catheter 10 and the filter device 14 and then drive the filtered blood through the reinfusion catheter 16 into the patient. *Id.*

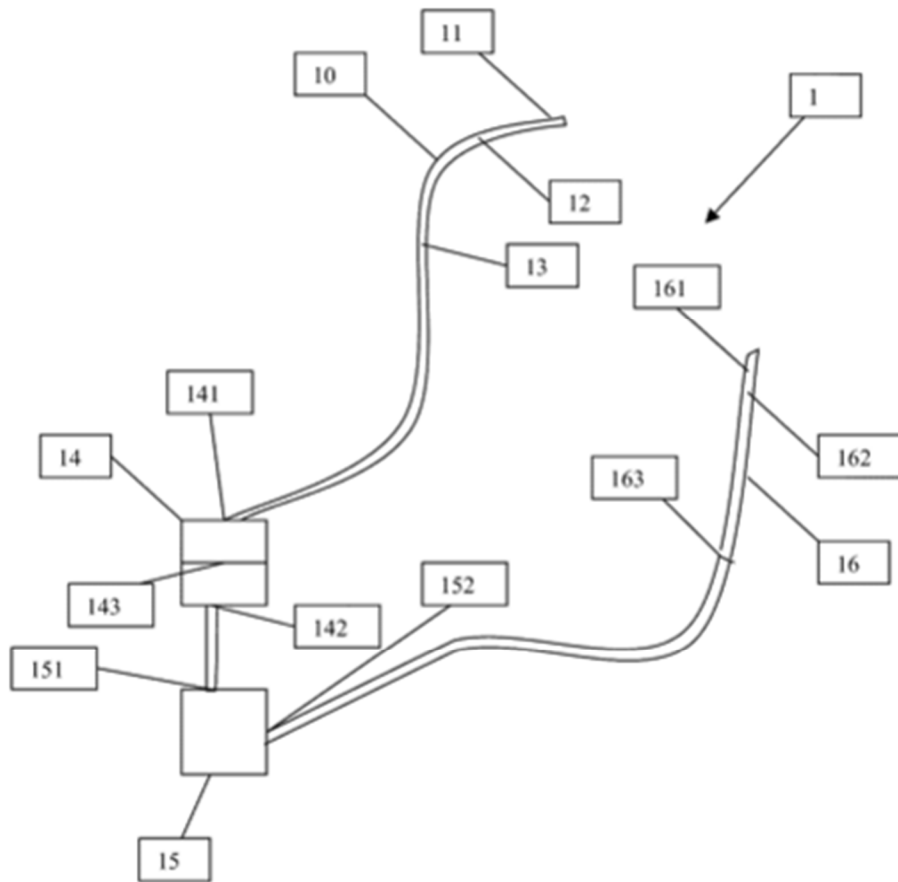
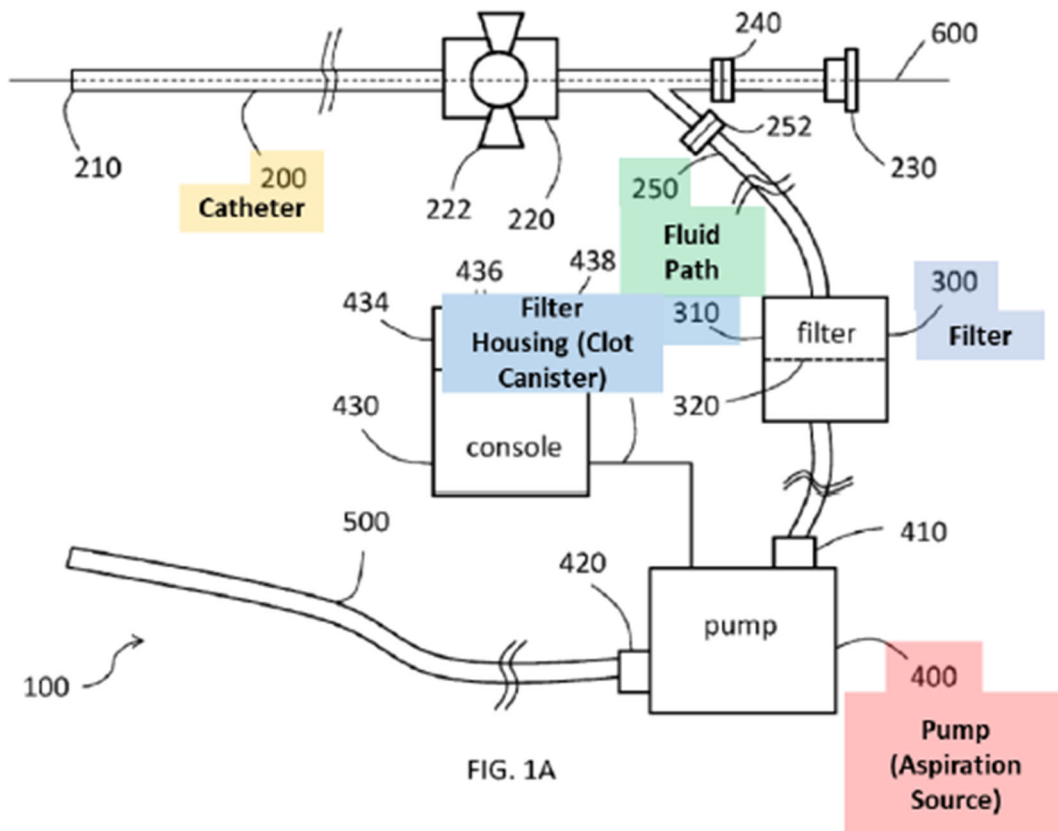


Fig. 1

The Petition includes no argument or fact unique to the proposed combination of Garrison with Laub that is not also found in Aklog, and provides no reason that Laub's disclosure would motivate a person of skill in the art to modify Garrison above what is disclosed in Aklog. To the contrary, Laub is substantially the same as and cumulative to Aklog because both systems operate in the same way to utilize a

pump to (1) aspirate thrombi (including pulmonary embolisms) from a patient, (2) draw the thrombi and blood through a filter, and (3) drive the filtered blood through a reinfusion catheter back into a patient. Indeed, Petitioner's annotations of the components in Aklog and Laub show that they have the same components and operate in the same manner:



Petitioner's Annotations to Figure 1A of Laub. Petition, p.24.

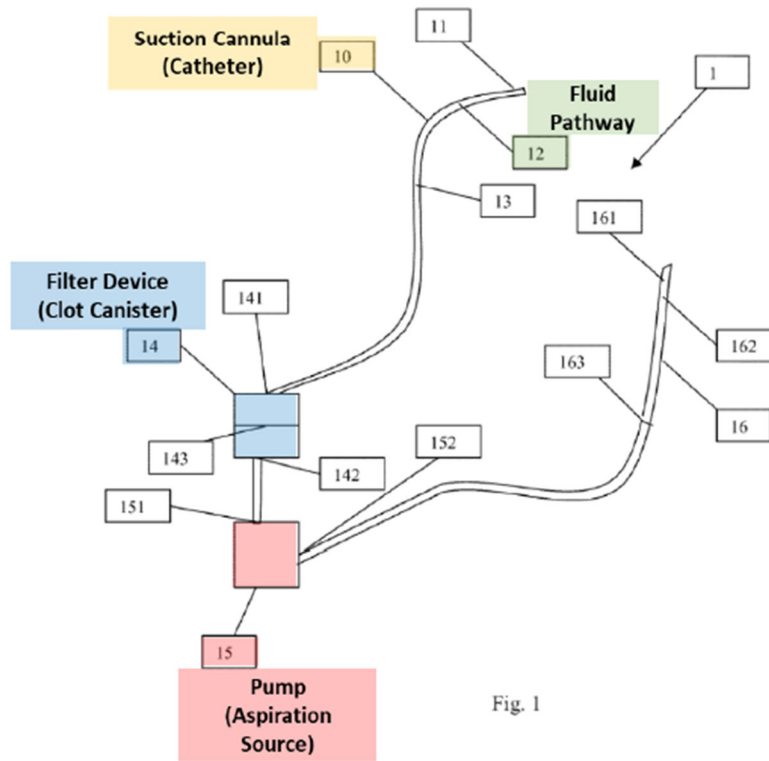


Fig. 1

Petitioner’s Annotations to Figure 1A of Laub. Petition, p.25.

That is, each of Laub and Aklog include a catheter (yellow), a filter (blue), a fluid path (green), and a pump (red). There is no additional disclosure in Laub cited by Petitioner that is not cumulative of and substantially the same as the disclosure of Aklog.

This is further demonstrated by the fact that Petitioner does not rely on Laub for any element not also purportedly disclosed in Aklog. Petitioner relies on Aklog and Laub each to teach two limitations of the Claims: treating pulmonary embolism and a catheter having a size of 16F or larger. Specifically, Petitioner alleges that Aklog and Laub in combination with Garrison (since neither Aklog or Laub disclose

telescoping aspiration catheters) teach: (1) the treatment of pulmonary embolism (e.g., “a clot treatment system for treating clot material *comprising a pulmonary embolism* in a vasculature of a patient” and “wherein the second catheter is shaped to be intravascularly advanced through the vasculature of the patient such that the distal portion of the second catheter is positioned proximate to the *pulmonary embolism*” as recited in independent Claims 1 and 11) and (2) a second (inner) catheter having a “size of 16 French or greater.” Petition, pp.22-24, 42-48, 71-72. But, Petitioner alleges that each of Aklog and Laub *separately* disclose both the treatment of pulmonary embolism and a 16 French catheter, and Petitioner does not identify any characteristic of Laub that distinguishes its disclosure over Aklog’s, which was already considered by the Patent Office. *Id.* at pp.24-25, 42-43. Put differently, Petitioner does not rely on any element or disclosure of Laub different from what Petitioner asserts Aklog discloses as evidenced by the separation of grounds 1 and 2—which separately rely on Laub or Aklog, respectively, for curing the deficiencies of Garrison including the treatment of pulmonary embolism and a second catheter having a size of 16 French or greater.

Similarly, the Petition cites nothing unique to Laub regarding motivation to combine. In fact, Petitioner lumps Aklog and Laub together when discussing motivation to combine, asserting that “[t]he similarities between [Laub’s and Aklog’s] systems would have further motivated a POSITA to use Garrison’s system

to treat clots in other parts of the vasculature, including PEs.” Petition, p.27. As noted in the Petition, those similarities include (1) the access location for the catheter system (“Garrison, Laub, and Aklog, for example, all disclose inserting the catheter system through a small incision in the leg to access the transfemoral vein or artery”), (2) use of a pump (“Garrison, Laub, and Aklog all disclose using a pump, in addition to other suction devices, to generate the necessary suction”), and (3) the same general components (“These references also confirm that aspiration systems for the brain and other parts of the vasculature, including the lungs (PE), use the same general components ... [i]n each reference, the aspiration system includes a pressure source connected by medical tubing to a filter, which is then connected to an aspiration catheter”). Petition, pp.25-26. Petitioner’s motivation to combine analysis based on the similarities of the systems in Laub and Aklog, rather than any allegedly unique disclosures of either reference, therefore confirms that Laub is substantially similar to and cumulative of Aklog.

Laub’s disclosure of treating pulmonary embolism is also substantially similar to and cumulative of Batiste (EX2002), which was also cited in an information disclosure statement during prosecution. EX1002, p.1143. And, the Examiner expressly understood Batiste as disclosing an aspiration catheter for treating pulmonary embolism. For example, in a Notice of Allowance mailed the same day, March 28, 2024, as the Notice of Allowance for the ’333 Patent in a related

application claiming similar subject matter (that issued as U.S. Patent No. 11,969,333), the same Examiner noted that “[p]rior art like Batiste (US 20180042623 A1) teaches an aspiration catheter (see Abstract) used for deep vein thrombosis or pulmonary embolisms (see Paragraph [0004]).” EX2001, p.7. Indeed, similar to Laub and Aklog, Batiste discloses “thrombectomy catheters which are used in the human vascular system to aspirate blood clots” including “pulmonary embolism (PE).” EX2002, ¶¶[0002]-[0004].

Accordingly, Petitioner’s references for each of grounds 1-3 related to independent Claims 1 and 11 were either expressly considered by the Patent Office or are substantially the same as and cumulative of the references cited and expressly considered by the Patent Office such that the first and second *Becton, Dickinson* factors weigh in favor of denial.

2. The fourth (d) *Becton, Dickinson* factor weighs in favor of denial because Petitioner’s arguments were expressly considered by the Patent Office and rejected.

As explained in §II.B.1.a. above, Garrison was the primary reference during examination of the ’910 Patent. As such it was extensively and expressly considered and discussed during examination. In the only Office action, the Examiner found original independent Claims 1 and 11 to be allowable over Garrison because Garrison fails to disclose “a second catheter advanceable through the first catheter; a second pressure source; and a fluid control device between the second catheter and

the second pressure source’.” EX1002, p.377. Petitioner nevertheless asserts here that Garrison discloses those features. Petition, pp.39-42, 48-54. That is, grounds 1-3 require a finding that Garrison discloses features that the Patent Office found Garrison not to disclose.

Patent Owner then amended independent Claims 1 and 11 to *further narrow* those allowable claims to clot treatment systems “for treating clot material comprising a pulmonary embolism” and wherein the second (e.g., inner) catheter “has a size of 16 French or greater” and “is shaped to be intravascularly advanced through the vasculature of the patient such that the distal portion of the second catheter is positioned proximate to the pulmonary embolism.” EX1002, pp.142-145.

Patent Owner explained in the response:

[I]ndependent claims 1 and 11, as amended, are further patentable over Garrison for at least the reasons discussed during the January 25th videoconference interview with the Examiner and his supervisor in related U.S. Patent Application No. 18/329,450, and specifically the Examiner's comments in the Applicant-Initiated Interview Summary mailed January 31, 2024 that “Attorney and Examiner agree that incorporating more structural claim language, i.e. diameter of the catheter, would make the claim 1 allowable over the prior art Garrison.”

Id. at pp.147-148. That is, Patent Owner substantively discussed the disclosure of Garrison in a videoconference interview with the same Examiner in a related

application claiming similar subject matter (that issued as U.S. Patent No. 11,969,333), and further narrowed the allowed claims during prosecution of the '910 Patent based on those discussions with the Examiner about Garrison in the co-pending related application.

So, the Examiner explained in the Notice of Allowance why the claims were patentable over Garrison:

Claims 1 and 11 are allowable for reciting, inter alia, “a clot treatment system for treating clot material comprising a pulmonary embolism in the vasculature of a patient” and “wherein the second catheter has a size of 16 French or greater”.

Garrison (US 20150173782 A1) ... fails to teach a [“]clot treatment system for treating clot material comprising a pulmonary embolism in the vasculature of a patient” and “wherein the second catheter has a size of 16 French or greater”. *The clot treatment device of Garrison is configured for a neurovascular application and not for larger vasculature such as pulmonary embolism. It would be unreasonable to modify the clot treatment device of Garrison to be used for pulmonary embolisms.* There is no prior art that teaches all of the limitations. Therefore, claims 1 and 11 are allowable.

Id. at p.49 (emphasis added).

The Examiner expressly found that it would be unreasonable to modify Garrison to include a 16 French catheter or to treat pulmonary embolisms.

Petitioner's arguments that a POSITA would have modified Garrison to treat pulmonary embolisms and have a larger 16 French catheter size based on Laub or Aklog are therefore completely contrary to the Examiner's reasons for allowance and consideration of Garrison. Petition, pp.22-24, 42-48, 71-72. Put simply, the Patent Office considered Garrison and Aklog's parent having the same disclosure as Aklog and Laub and found that it would be unreasonable to modify Garrison in precisely the manner Petitioner argues here.

What's more, in a Notice of Allowance in the related application claiming similar subject matter (that issued as U.S. Patent No. 11,969,333), the same Examiner found that "Garrison does not teach an aspiration catheter configured to aspirate pulmonary embolism" and explained that (1) "Garrison is configured for smaller neurovascular anatomy (see Abstract) and not configured for larger clot/embolisms" and (2) "a pulmonary embolism ... presents significant different structures and physiological responses as compared to neurovascular clots, and therefore one skilled in the art would not have looked to" modify Garrison to treat those conditions. EX2001, pp.6-7. The Examiner also noted the existence of prior art like Laub and Aklog that disclosed an aspiration catheter used to treat pulmonary embolism, including Batiste (EX2002), but maintained that it would not have been obvious to modify Garrison based on that art:

Prior art like Batiste (US 20180042623 A1) teaches an aspiration catheter (see Abstract) used for deep vein thrombosis or pulmonary embolisms (see Paragraph [0004]) ... However, it would not be reasonable to combine modified Garrison with the device of Batiste because Garrison specifically teaches the aspiration catheter being used for neurovascular procedures. Therefore the device of Garrison would be not be combinable with the device of [Batiste] to teach a method of treating pulmonary embolisms or deep vein thrombosis.”

Id. at p.7. Accordingly, the Examiner was aware of prior art in addition to Laub and Aklog that disclosed the features Petitioner relies on Laub and Aklog for, and still maintained it would not have been obvious to modify Garrison in view of any of that art as Petitioner alleges.

For the foregoing reasons, Petitioner’s specific arguments in the Petition were considered and rejected by the Patent Office as explained in the Patent Office’s findings of patentability such that the fourth *Becton, Dickinson* factor weighs in favor of denial.

C. The Second Part of the Framework is Satisfied: Petitioner has not Demonstrated that the Office Erred in a Manner Material to the Patentability of Challenged Claims.

1. The third (c) *Becton, Dickinson* factor weighs in favor of denial because Petitioner's primary reference Garrison was applied by the Examiner in the sole Office action and extensively evaluated by the Examiner.

As set forth above, Garrison was extensively evaluated by the Patent Office as the Examiner explained the allowability of the Claims over Garrison in both the sole Office action and in the Notice of Allowance. EX1002, pp.49, 147-148, 377. Aklog's relevant disclosure was also before the Patent Office having been cited in an information disclosure statement. *Id.* at p.1123. And, Laub is substantially the same as and cumulative of Aklog's parent (and thus Aklog) and other art of record including Batiste as explained above in §II.B.1.c. Further, as explained in §II.B.2., Petitioner's arguments here contradict the Examiner's stated and well-justified reasons for allowing the claims, including that Garrison does not disclose a second (e.g., inner) catheter and a second fluid control device between the second catheter and a second pressure source, and that it would be unreasonable to modify Garrison to treat pulmonary embolism or include a 16 French or greater second catheter.

Thus, the Patent Office extensively and substantively considered Garrison and Aklog, and Laub by virtue of its substantial sameness with Aklog and other art of record. Therefore, the third *Becton, Dickinson* factor weighs in favor of denial.

2. The fifth (e) *Becton, Dickinson* factor weighs in favor of denial because Petitioner makes no showing of error.

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 of manifest error made during examination.

Instead, Petitioner provides nothing more than conjecture and conclusory statements to assert the Examiner purportedly erred during the prosecution of the ’910 Patent. Petitioner states broadly in the introductory sections of the Petition that the Examiner “mistakenly allowed” the patent over Garrison based on an interview with a named inventor without citing “any evidence to support the conclusion.” Petition, pp.5, 18.

As explained above, Petitioner’s positions strategically ignore the Examiner’s reasons for allowing the challenged claims over Garrison. Specifically, the Examiner explicitly found that Garrison did not disclose telescoping aspiration catheters, *e.g.*, “a second catheter advanceable through the first catheter; a second pressure source; and a fluid control device between the second catheter and the second pressure

source.” EX1002, p.377. Petitioner does not provide any reason why or how this determination was in error. The same is true of the Examiner’s finding that it would be unreasonable to modify Garrison’s system to treat pulmonary embolism or to include a second (inner) catheter having a size 16 French or greater. EX1002, p.49. Put simply, the Petitioner disagrees with the Examiner’s conclusions but does not address how the Patent Office materially erred in its conclusions.

All of Petitioner’s grounds further ignore the substantial and material similarities between Laub and Aklog as well as the similarities with the prior art considered during prosecution, including Aklog’s parent (identical to Aklog in all relevant parts) and Batiste. *See* §B.1.b-c. above.

Therefore, the fifth *Becton, Dickinson* factor weighs in favor of denial—Petitioner has not made a showing of material error for any of its grounds.

3. The sixth (f) *Becton, Dickinson* factor weighs in favor of denial because Petitioner presents no additional evidence or facts warranting reconsideration.

Petitioner does not provide any evidence or facts or articulate any argument warranting a reconsideration of the Office’s allowance of the claims. Petitioner submitted two expert reports (EX1003 and EX1022) in support of its Petition. However, the reports are insufficient to demonstrate that the Examiner erred. *See Regeneron Pharmaceuticals, Inc. v. Kymab Ltd.*, IPR2019-01578, Paper 9, p.7 (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.”).

Thus, the final *Becton, Dickinson* factor weighs in favor of denial.

III. CONCLUSION

For the forgoing reasons, Patent Owner requests that the Office exercise its discretion under Section 325(d) and deny institution.

Respectfully submitted,

Dated: August 18, 2025

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 Request for Discretionary Denial** contains 8,991 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: August 18, 2025

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 August 18, 2025, a copy of **Patent Owner's Request for Discretionary Denial, and Exhibits 2001-2002** was served upon the below-listed counsel by electronic mail:

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Dated: August 18, 2025

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