

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. IPR2025-01021
U.S. Patent No. 11,969,333

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

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EX1007	WIPO Publication No. WO 2006/124307 A2 to Goff et al. (“Goff”)
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EX1010	U.S. Patent Publication No. 2010/0042118 A1 to Garrison et al.
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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.
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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)
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EX1050	Certified File History of U.S. Patent Application 10/371,190 (Schaffer File History)
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	Patent Owner's Exhibits
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EX2001	U.S. Patent Application Publication No. 2017/0274180 to Garrison et al.
EX2002	U.S. Patent Application Publication No. 2013/0035628 to Garrison et al.
EX2003	U.S. Patent Application Publication No. 2018/0042623 to Batiste ("Batiste")
EX2004	U.S. Patent No. 6,059,745 to Gelbfish ("Gelbfish")

I. INTRODUCTION

Patent Owner requests that the Office exercise its discretion to deny the petition for IPR of U.S. Patent No. 11,969,333 (the “333 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 considered and overcome during prosecution.

First, the same or substantially the same prior art and arguments set forth in the Petition were considered by the Patent Office. Specifically, the Petition relies on Garrison as a key reference for all grounds, but Garrison was expressly considered by the Office and overcome during prosecution. In particular, while Garrison was not used as a basis for rejection by the Examiner in the sole Office action despite being previously cited in an information disclosure statement, Patent Owner voluntarily brought the disclosure of Garrison to the Examiner’s attention and discussed Garrison with the Examiner during an interview.

The Examiner subsequently found the Claims allowable over Garrison and the other art of record because “Garrison does not teach an aspiration catheter configured to aspirate pulmonary embolism or deep vein thrombosis’ and because “Garrison is configured for smaller neurovascular anatomy (see Abstract) and not configured for larger clot/embolisms.” EX1002, p.46. The Examiner further explained that “a pulmonary embolism or a deep vein thrombosis presents

significant different structures and physiological responses as compared to neurovascular clots, and therefore one skilled in the art would not have looked to use the Garrison device for the current methods.” *Id.* at pp.46-47. As such, the Petition requires a finding that directly contradicts the Examiner’s articulated reasons for allowance including that it would not have been obvious to modify Garrison to treat pulmonary embolism or deep vein thrombosis for grounds 1 and 2.

And, although Aklog and Laub were not specifically considered by the Office, they are substantially and materially similar to Aklog’s parent (EX1019), which was cited in an Information Disclosure Statement. 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. Further, the Examiner was aware of numerous other prior art references that disclose aspiration catheters for treating pulmonary embolism and deep vein thrombosis—just like Petitioner alleges here regarding Laub and Aklog—including Batiste (EX2003) and Gelbfish (EX2004) that were expressly considered by the Examiner. For example, in the Notice of Allowance the Examiner found “[p]rior art like Batiste (US 20180042623 A1) teaches an aspiration catheter (see Abstract) used for deep vein thrombosis or pulmonary embolisms.” EX1002, p.47. Yet, the Examiner did not find it would have been obvious to have modified Garrison in view of that prior art like Petitioner alleges for grounds 3 and 4 or to have modified

that prior art in view of Garrison like Petitioner alleges for grounds 1 and 2. The Petition fails to provide a sufficient basis to conclude that the Office manifestly erred in its previous analysis requiring a do-over a little over a year later.

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. 11,974,910 & 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 1B-1D, 2B-2D, 3B-3D, and 4B-4D address only dependent claims and thus include nothing that would rectify the deficiencies with respect to grounds 1A, 2A, 3A, and 4A, *i.e.*, grounds 1B-1D, 2B-2D, 3B-3D, and 4B-4D raise nothing with respect to the independent Claims 1 and 20 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 1A, 2A, 3A, and 4A for both independent Claims 1 and 20 of the '333 Patent based upon various combinations of Garrison, Aklog and Laub. Specifically, Petitioner relies on Laub or Aklog in combination with Garrison for grounds 1A and 2A, respectively, and Garrison in combination with Laub or Aklog for grounds 3A and 4A, respectively. Petition, p.16. But the disclosure of Garrison—relied on by Petitioner for all grounds—was extensively considered by the Patent Office and overcome during prosecution when the Office allowed the claims. Specifically, Patent Owner brought the disclosure of Garrison to the attention of the Office in response to the sole non-final Office action despite Garrison not being applied in that Office action. EX1002, pp.101-104, 116. In response, the Examiner explained in the Notice of Allowance that a POSITA would not have modified Garrison to treat pulmonary embolism or deep vein thrombosis, which directly contradicts the arguments raised in the Petition here. *Id.* at pp.46-47. Thus, Petitioner's arguments for grounds 3 and 4 were expressly considered and rejected by the Patent Office.

Similarly, Aklog's substantively identical parent (EX1019) was cited during prosecution in an information disclosure statement and appears on the face of the

'333 Patent. *Id.* at pp.186, 366; EX1001, p.3. Petitioner incorrectly asserts that “Aklog’s parent (Patent No. 8,075,510) ... does not include Figure 7” of Aklog—which it plainly does. Petition, p.5. 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 and other art of record including Batiste and Gelbfish that were analyzed during prosecution. Indeed, Petitioner relies on Laub only as an alternative that allegedly discloses the same features as Aklog—nothing more.

So, for grounds 1 and 2, the Examiner considered the disclosure of Aklog (and Laub based on its substantially similar and cumulative disclosure), and references including Batiste and Gelbfish that, like Laub and Aklog, are directed to aspiration catheters for treating pulmonary embolism or deep vein thrombosis, and did not find that it would have been obvious to have modified any of those references to arrive at the features of the Claims. *Id.* at p.47. Thus, all of Petitioner’s art and arguments were considered and rejected by the Patent Office.

Whether considering Laub or Aklog in combination with Garrison for grounds 1A and 2A, or Garrison in combination with Laub or Aklog for grounds 3A and 4A makes no difference, the Office has considered the disclosure or substantially the same disclosure of all three references and found the claims patentable over those references.

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.

Petitioner relies on Garrison for all grounds 1-4. But, Garrison was before the Patent Office and expressly considered by the Patent Office. Garrison was cited in an information disclosure statement and appears on the face of the ’333 Patent. EX1001, p.6; EX1002, pp.204, 384.

In the sole non-final Office action mailed October 30, 2023, the Examiner rejected then-pending claims 1–6, 11–14, 16–18, and 20–22 under 35 U.S.C. § 103 over a combination of Garrison II (EX1032), Barzell (EX1033), and Heaton (EX1011). EX1002, pp.154-176. Garrison II is a different reference than Garrison applied by Petitioner here, but shares common inventors (Michi E. Garrison and Tony M. Chou) and assignee (Route 92 Medical Inc.). EX1006, p.1; EX1032, p.1. And, both Garrison and Garrison II are directed to catheter systems for treating neurovascular clots (e.g., acute ischemic stroke), each stating that “[t]he present disclosure relates generally to medical methods and devices for the treatment of acute ischemic stroke.” EX1006, ¶[0002]; EX1032, ¶[0003].

In response to that Office action, Patent Owner canceled the then-pending claims 1-22 and added new claims 23-60 that matured into Claims 1-38 of the ’333

Patent. Before filing the response, Patent Owner conducted a videoconference interview with the Examiner, his supervisor, and an inventor of the '333 Patent, Dr. Thomas Tu, on January 25, 2024. During that interview, Patent Owner discussed the proposed new independent claims and also specifically called attention to the disclosure of Garrison relied on by Petitioner here. For example, in the Examiner Interview Summary Record mailed January 31, 2024, the Examiner attached an agenda for discussion submitted by Patent Owner as an Office action appendix. EX1002, pp.101-104. That agenda included discussion points for the proposed new claims, the Section 103 rejection over the combination of Garrison II, Barzell, and Heaton, and further noted for discussion at listed items (3)(a) and (3)(b) of the agenda:

- (3) Discussion of additional prior art of record.
 - (a) U.S. Patent Application Publication No. 2017/0274180 (“Garrison”). *See, e.g.*, Figure 34 and paragraphs [0132]-[0134] and [0162]-[0172].
 - (b) U.S. Patent Application Publication No. 2013/0035628 (“Garrison”). *See, e.g.*, Figure 16 and paragraph [0085].

EX1002, p.104. U.S. Patent Application Publication No. 2017/0274180 (EX2001) identified by Patent Owner to the Examiner is a direct continuation of Garrison and, as such, contains identical disclosure to Garrison relied on by Petitioner here.

EX2001, p.1. U.S. Patent Application Publication No. 2013/0035628 (EX2002) identified by Patent Owner to the Examiner also contains some disclosure identical to that of Garrison extensively relied on by Petitioner, including Figures 15-17 identical to Figures 32-34 of Garrison and related description, including paragraph [0085] identical to paragraph [0134] of Garrison. *See, e.g.*, Petition, pp.6, 7, 21-23, 35, 37-39, 42, 63-64.

Patent Owner's response to the Office action further summarizes discussions of Garrison with the Examiner:

Additionally, during the January 25th videoconference interview, the parties discussed proposed new independent claims 23 and 42 in view of U.S. Patent Application Publication No. 2017/0274180 ("Garrison II") and U.S. Patent Application Publication No. 2013/0035628 ("Garrison III"). For example, FIG. 15 and Paragraph [0085] of Garrison III were specifically discussed with respect to claims 23 and 42. At that time, the Examiner and his supervisor provisionally agreed that new independent claims 23 and 42 also patentably distinguish over Garrison II and Garrison III.

EX1002, p.117.

Accordingly, Patent Owner specifically brought the relevant disclosure of Garrison to the Examiner's attention despite Garrison not being cited in the sole Office action. Following that amendment, the Examiner agreed and further

explained why the claims are patentable over the various Garrison references in the Notice of Allowance:

Claim 23 and 42 are allowable for reciting, *inter alia*, “a method of treating a *pulmonary embolism* within a vasculature ...” and “applying the vacuum pressure to the lumen of the aspiration catheter such that at least a portion of the pulmonary embolism and blood are aspirated into the clot canister.[”]

Garrison, Barzell, and Heaton teaches an aspiration catheter, as described in Non-Final Rejection filed on 10/30/2023. However, modified Garrison does not teach an aspiration catheter configured to aspirate pulmonary embolism or deep vein thrombosis. The aspiration catheter of modified Garrison is configured for smaller neurovascular anatomy (see Abstract) and not configured for larger clot/embolisms. As explained by inventor during the interview on 1/25/2024, and further supported by photographic evidence during the interview, a pulmonary embolism or a deep vein thrombosis presents significant different structures and physiological responses as compared to neurovascular clots, and therefore one skilled in the art would not have looked to use the Garrison device for the current methods.

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 Garrison to teach a method of treating pulmonary embolisms or deep vein thrombosis. There is no prior art that reads on the combination of limitations of claim 23 or 42. **Claims 24-41** are allowable for depending on claim 23. **Claims 43-60** are allowable for de pending on claim 42.

EX1002, pp.46-47. In summary, in allowing the Claims challenged here, the Examiner considered the disclosure of Garrison and found that a POSITA would not have modified Garrison to treat pulmonary embolism or deep vein thrombosis, and also found that there is no prior art that reads on the Claims including in view of Batiste which the Examiner described as teaching an aspiration catheter used to treat deep vein thrombosis and pulmonary embolism.

Accordingly, Garrison was considered in detail during prosecution. Garrison's disclosure was specifically brought to the Examiner's attention by Patent Owner, and the Examiner considered Garrison and expressly explained that the Claims were patentable over Garrison 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, pp.186, 366; EX1001, p.3 (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 '333 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 at the end of this section. Therefore, the Office considered Aklog during the prosecution of the '333 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.*, IPR201600014, 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.'").

What's more, while Petitioner concedes that Aklog's parent "was listed on an IDS," Petitioner asserts that "Aklog's parent (Patent No. 8,075,510) ... does not include Figure 7" of Aklog. Petition, p.5. That is plainly incorrect. As shown in the table below, Aklog's parent does indeed include the identical Figure 7 as Aklog. At most, the lead lines in Aklog are slightly shifted a consistent amount such that they

do not terminate on the referenced components as shown in Figure 7 of Aklog's parent. But that difference is not substantive and provides no additional disclosure over Aklog's parent.

Disclosure of Aklog (EX1005) Relied on By Petitioner

Figure 7 (Petition, pp.4, 22, 47, 64):

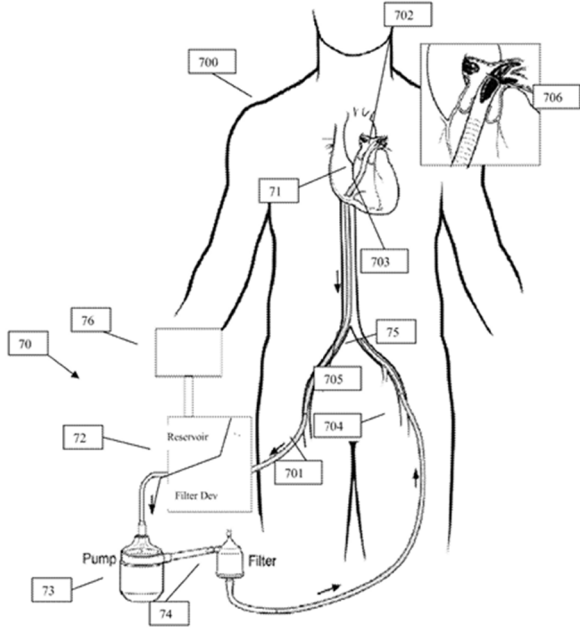


Fig. 7

Identical Disclosure of the Aklog's Parent (EX1019)

Figure 7:

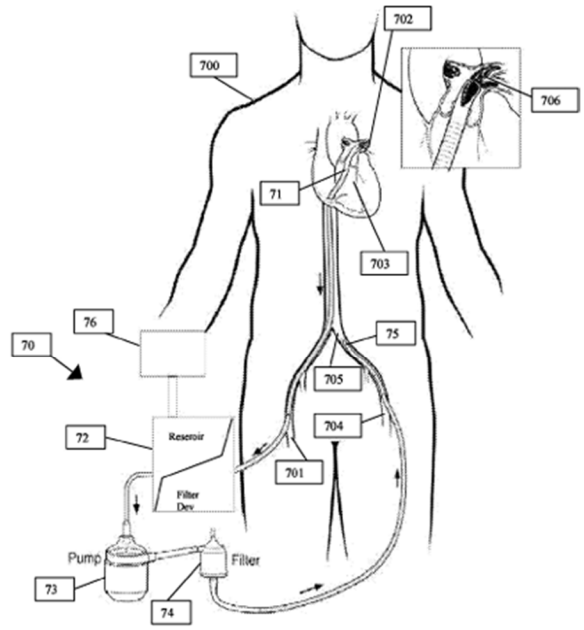


Fig. 7

Figure 6 (Petition, pp.19, 22, 64):

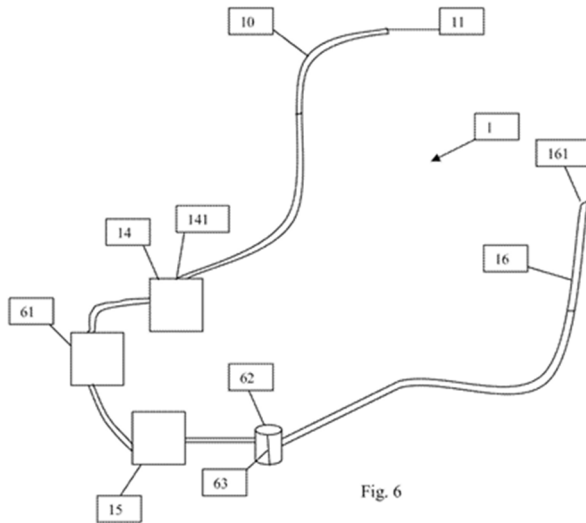


Fig. 6

Figure 6:

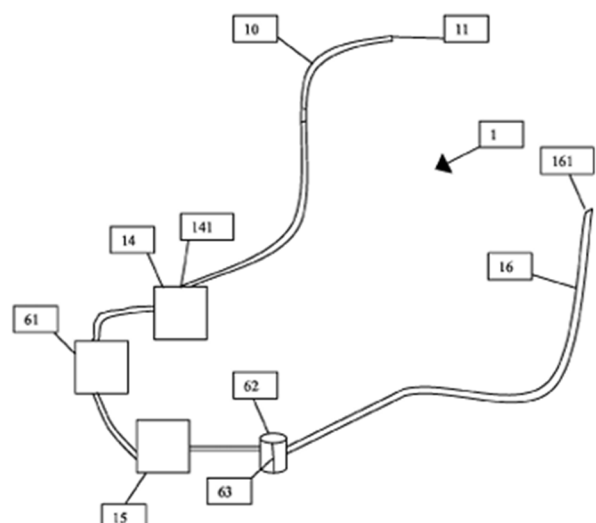
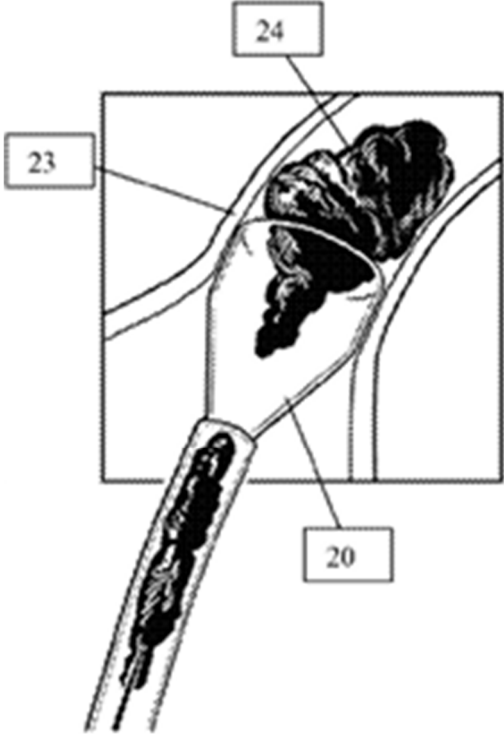
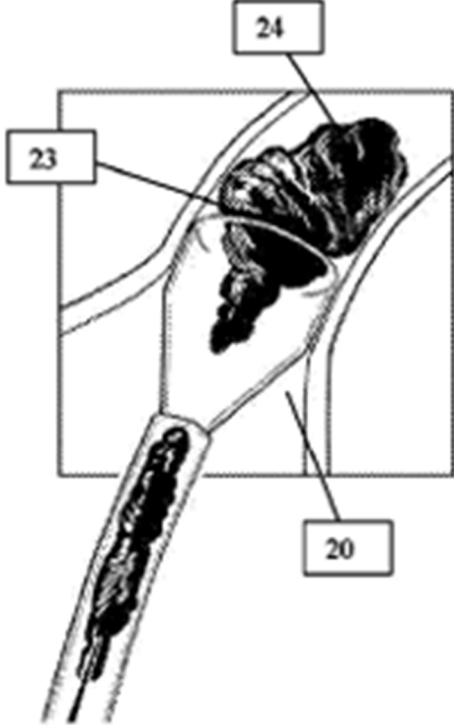
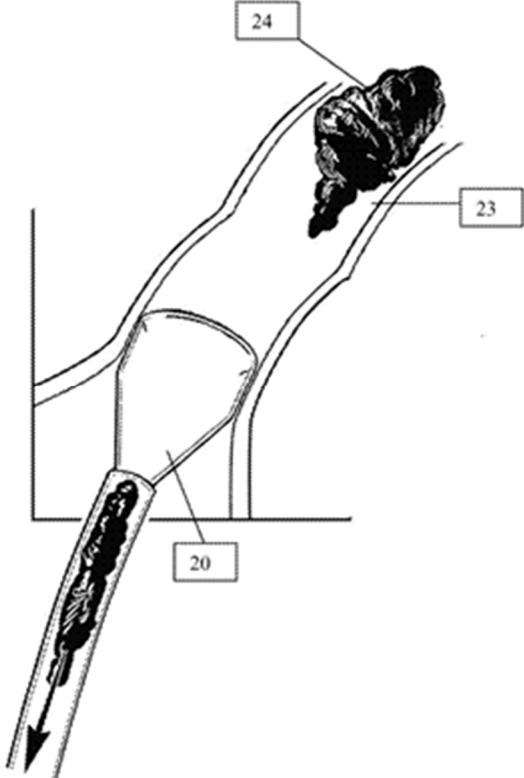
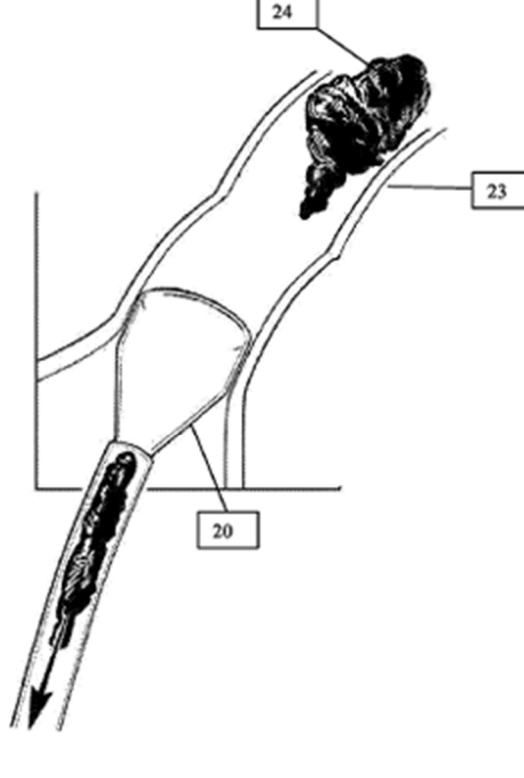
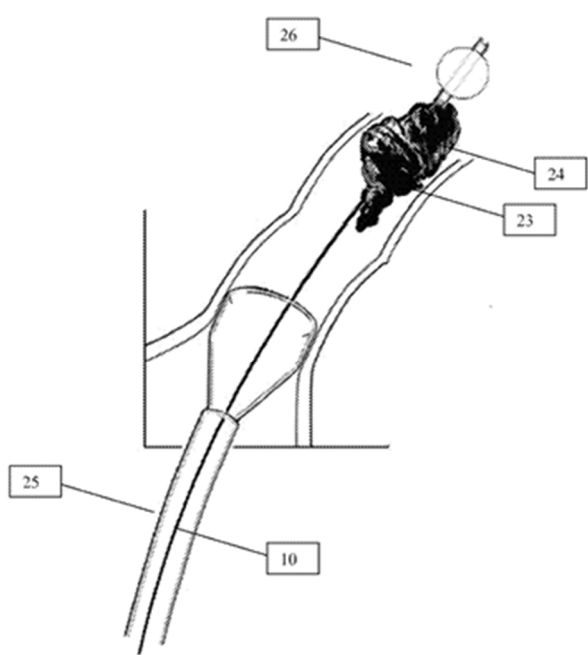
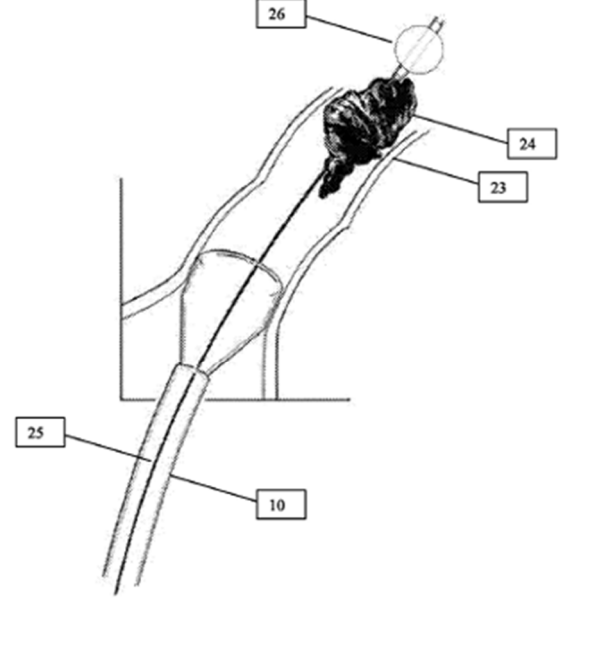
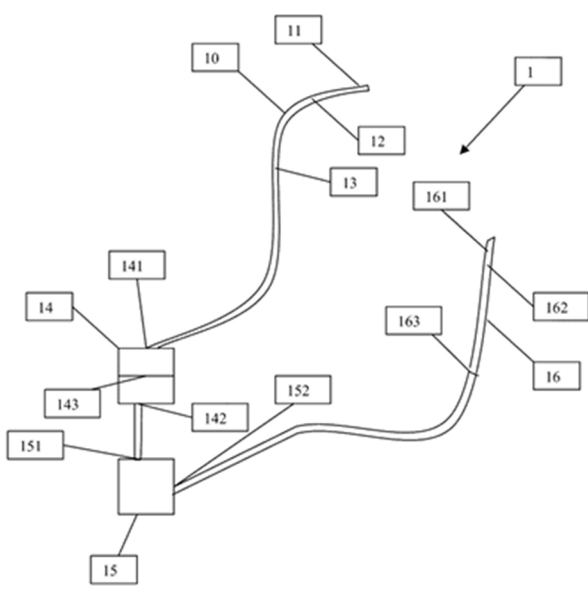
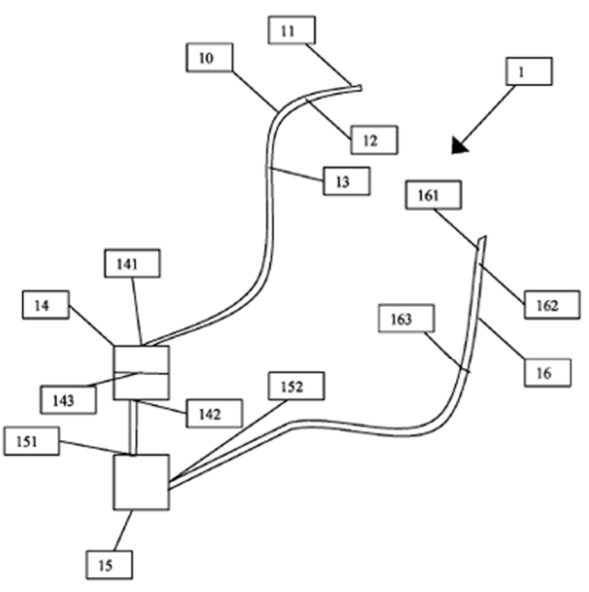


Fig. 6

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.34):</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="203 317 600 352"><u>Figure 2D (Petition, p.34):</u></p>  <p data-bbox="467 1157 548 1184">Fig. 2D</p>	<p data-bbox="831 317 993 352"><u>Figure 2D:</u></p>  <p data-bbox="1096 1224 1177 1251">Fig. 2D</p>

Disclosure of Aklog (EX1005) Relied on By Petitioner	Identical Disclosure of the Aklog's Parent (EX1019)
<p data-bbox="203 315 600 357"><u>Figure 2H (Petition, p.34):</u></p>  <p data-bbox="438 1081 519 1113">Fig. 2H</p>	<p data-bbox="828 315 990 357"><u>Figure 2H:</u></p>  <p data-bbox="1055 1081 1136 1113">Fig. 2H</p>
<p data-bbox="203 1127 795 1169"><u>Figure 1 (Petition, pp.19, 20, 33, 41, 64):</u></p>  <p data-bbox="535 1774 584 1806">Fig. 1</p>	<p data-bbox="828 1127 958 1169"><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, pp.4, 19, 64):</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.4, 19, 26):

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:

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

Disclosure of Aklog (EX1005) Relied on By Petitioner	Identical Disclosure of the Aklog's Parent (EX1019)
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.19, 22, 34, 64):</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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Disclosure of Aklog (EX1005) Relied on By Petitioner	Identical Disclosure of the Aklog's Parent (EX1019)
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>7:23-64 (Petition, pp.4, 19, 28, 29, 33, 64):</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</p>	<p><u>7:16-57:</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</p>
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Disclosure of Aklog (EX1005) Relied on By Petitioner	Identical Disclosure of the Aklog's Parent (EX1019)
<p>appreciated that the systems and 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. System 1, in an embodiment, may be provided with a first or Suction cannula 10 for capturing and removing en bloc the undesirable material from the site of interest, such as that within a blood vessel or a heart chamber. Cannula 10, in an embodiment, may be an elongated tube and may include a distal end 11 through which the undesirable material can be captured and removed. Cannula 10 may also include a lumen or pathway 12 extending along a body portion of cannula 10. Pathway 12, in one embodiment, provides a passage along which the captured material and aspirated circulatory fluid. Such as blood, that may be captured therewith may be transported and directed away from the site of interest.</p>	<p>appreciated that the systems and 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. System 1, in an embodiment, may be provided with a first or Suction cannula 10 for capturing and removing en bloc the undesirable material from the site of interest, such as that within a blood vessel or a heart chamber. Cannula 10, in an embodiment, may be an elongated tube and may include a distal end 11 through which the undesirable material can be captured and removed. Cannula 10 may also include a lumen or pathway 12 extending along a body portion of cannula 10. Pathway 12, in one embodiment, provides a passage along which the captured material and aspirated circulatory fluid. Such as blood, that may be captured therewith may be transported and directed away from the site of interest.</p>

Disclosure of Aklog (EX1005) Relied on By Petitioner	Identical Disclosure of the Aklog's Parent (EX1019)
<p><u>10:55-60 (Petition, p.53):</u></p> <p>In certain embodiments, lumen 41 may also be used to accommodate other devices, such as other catheters or surgical instruments, for use in connection with a variety of purposes. For example, a device may be inserted and advanced along lumen 41 through the distal end 11 of suction cannula 10 to dislodge the undesirable material.</p>	<p><u>10:48-53:</u></p> <p>In certain embodiments, lumen 41 may also be used to accommodate other devices, such as other catheters or surgical instruments, for use in connection with a variety of purposes. For example, a device may be inserted and advanced along lumen 41 through the distal end 11 of suction cannula 10 to dislodge the undesirable material.</p>
<p><u>11:4-7 (Petition, p.52):</u></p> <p>To introduce other devices, such as catheter 25 with balloon 26, into lumen 41 or pathway 12, cannula 10 may be provided with a port 51, as shown in FIG. 5, located at the proximal end 13 of cannula 10.</p>	<p><u>10:64-67:</u></p> <p>To introduce other devices, such as catheter 25 with balloon 26, into lumen 41 or pathway 12, cannula 10 may be provided with a port 51, as shown in FIG. 5, located at the proximal end 13 of cannula 10.</p>
<p><u>11:12-20 (Petition, pp.43, 44):</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>

<p><u>11:24-12:14 (Petition, pp. 33, 34, 47, 55, 58, 61, 63, 66, 67):</u></p> <p>Looking again at FIG. 1, System 1 can also include filter device 14 in fluid communication with the proximal end 13 of cannula 10. Filter device 14, in one embodiment, may include an inlet 141 through which fluid removed from the site of interest along with the captured undesirable material can be directed from cannula 10. Filter device 14 may also include an outlet 142 through which filtered fluid from within device 14 may be directed downstream of system 1. To prevent the undesirable material captured from the site of interest from moving downstream of system 1, filter device 14 may further include a permeable sheet 143 positioned within the fluid flow between the inlet 141 and the outlet 142.</p> <p>Permeable sheet 143, in an embodiment, may include a plurality of pores sufficiently sized, so as to permit fluid from the site of interest to flow therethrough, while preventing any undesirable material captured from the site of interest from moving downstream of system 1. Examples of permeable sheet 143 includes coarse netting, fine netting, a screen, a porous filter, a combination thereof, or any other suitable filter material capable of permitting fluid to flow through while impeding movement of the captured undesirable material. It should be noted</p>	<p><u>11:17-12:7:</u></p> <p>Looking again at FIG. 1, System 1 can also include filter device 14 in fluid communication with the proximal end 13 of cannula 10. Filter device 14, in one embodiment, may include an inlet 141 through which fluid removed from the site of interest along with the captured undesirable material can be directed from cannula 10. Filter device 14 may also include an outlet 142 through which filtered fluid from within device 14 may be directed downstream of system 1. To prevent the undesirable material captured from the site of interest from moving downstream of system 1, filter device 14 may further include a permeable sheet 143 positioned within the fluid flow between the inlet 141 and the outlet 142.</p> <p>Permeable sheet 143, in an embodiment, may include a plurality of pores sufficiently sized, so as to permit fluid from the site of interest to flow therethrough, while preventing any undesirable material captured from the site of interest from moving downstream of system 1. Examples of permeable sheet 143 includes coarse netting, fine netting, a screen, a porous filter, a combination thereof, or any other suitable filter material capable of permitting fluid to flow through while impeding movement of the captured undesirable material. It should be noted</p>
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Disclosure of Aklog (EX1005) Relied on By Petitioner	Identical Disclosure of the Aklog's Parent (EX1019)
<p>that, rather than just one, a plurality of permeable sheets 143 may be used. Alternatively, one permeable sheet 143 may be folded to provide multiple surfaces, similar to an accordion, for use in connection with filter device 14. By using a plurality of permeable sheets 143 or by folding sheet 143, the number of filtration surfaces through which the fluid must flow increases to enhance filtration and further minimize any occurrence of any undesirable material from moving downstream of system 1.</p> <p>Although a permeable sheet 143 is described, it should be appreciated that filter device 14 may be provided with any design capable of entrapping the undesirable material, while allowing fluid to move therethrough. To that end, filter device 14 may include a mechanical trap to remove the undesirable material from the fluid flow. Such a mechanical trap may be any trap known in the art and may be used with or without permeable sheet 143.</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</p>	<p>that, rather than just one, a plurality of permeable sheets 143 may be used. Alternatively, one permeable sheet 143 may be folded to provide multiple surfaces, similar to an accordion, for use in connection with filter device 14. By using a plurality of permeable sheets 143 or by folding sheet 143, the number of filtration surfaces through which the fluid must flow increases to enhance filtration and further minimize any occurrence of any undesirable material from moving downstream of system 1.</p> <p>Although a permeable sheet 143 is described, it should be appreciated that filter device 14 may be provided with any design capable of entrapping the undesirable material, while allowing fluid to move therethrough. To that end, filter device 14 may include a mechanical trap to remove the undesirable material from the fluid flow. Such a mechanical trap may be any trap known in the art and may be used with or without permeable sheet 143.</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</p>

Disclosure of Aklog (EX1005) Relied on By Petitioner	Identical Disclosure of the Aklog's Parent (EX1019)
<p>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>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>

Disclosure of Aklog (EX1005) Relied on By Petitioner	Identical Disclosure of the Aklog's Parent (EX1019)
<p><u>12:29-31 (Petition, p.47):</u></p> <p>Reinfusion cannula 16, in an embodiment, may be designed to permit filtered fluid, directed from filter device 14 by way of pump 15, to be reinfused back into a patient at a desired site.</p>	<p><u>12:21-34:</u></p> <p>Reinfusion cannula 16, in an embodiment, may be designed to permit filtered fluid, directed from filter device 14 by way of pump 15, to be reinfused back into a patient at a desired site.</p>
<p><u>13:64-14:2 (Petition, p.34):</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>

<p><u>15:27-53 (Petition, pp.19, 22, 64):</u></p> <p>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.</p>	<p><u>15:19-45:</u></p> <p>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.</p>
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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.

Disclosure of Aklog (EX1005) Relied on By Petitioner	Identical Disclosure of the Aklog's Parent (EX1019)
<p><u>16:4-8 (Petition, p.33):</u></p> <p>The undesirable material 706 and circulatory fluid removed from the site of interest 702 may thereafter be directed along suction cannula 71 into filter device 72 where the undesirable material 706 can be entrapped and removed from the fluid flow.</p>	<p><u>15:63-67:</u></p> <p>The undesirable material 706 and circulatory fluid removed from the site of interest 702 may thereafter be directed along suction cannula 71 into filter device 72 where the undesirable material 706 can be entrapped and removed from the fluid flow.</p>

<p><u>16:27-53 (Petition, p.34):</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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Disclosure of Aklog (EX1005) Relied on By Petitioner	Identical Disclosure of the Aklog's Parent (EX1019)
<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>

Disclosure of Aklog (EX1005) Relied on By Petitioner	Identical Disclosure of the Aklog's Parent (EX1019)
<p><u>16:66-17:4 (Petition, p.34):</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>

Disclosure of Aklog (EX1005) Relied on By Petitioner	Identical Disclosure of the Aklog's Parent (EX1019)
<p><u>18:7-20 (Petition, p.74):</u></p> <p>The method of the present invention may, in an embodiment, be employed to remove a plurality of undesirable materials, for instance, within the same vessel or its branches, from multiple vessels within the same vascular bed (e.g. left and right pulmonary arteries), from different vascular beds (e.g. pulmonary artery and iliofemoral veins), or a combination thereof. In such an embodiment, after the first undesirable material has been removed, the suction force may be deactivated. The next undesirable material to be removed may then be located, for example, using an appropriate imaging modality. Suction cannula 71 may thereafter be advanced to the location of this second undesirable material, and the suction force reactivated as above until this second undesirable material may be removed.</p>	<p><u>17:65-18:11:</u></p> <p>The method of the present invention may, in an embodiment, be employed to remove a plurality of undesirable materials, for instance, within the same vessel or its branches, from multiple vessels within the same vascular bed (e.g. left and right pulmonary arteries), from different vascular beds (e.g. pulmonary artery and iliofemoral veins), or a combination thereof. In such an embodiment, after the first undesirable material has been removed, the suction force may be deactivated. The next undesirable material to be removed may then be located, for example, using an appropriate imaging modality. Suction cannula 71 may thereafter be advanced to the location of this second undesirable material, and the suction force reactivated as above until this second undesirable material may be removed.</p>

Disclosure of Aklog (EX1005) Relied on By Petitioner	Identical Disclosure of the Aklog's Parent (EX1019)
<p><u>18:38-48 (Petition, p.54):</u></p> <p>In a situation where the undesirable material may be adherent to a vessel wall, or for some other reason cannot be dislodged by simply applying Suction to the site of interest, the balloon catheter can be inserted through the side port of Suction cannula 71, advanced past a distal end of cannula 71, and past the adherent undesirable material. The balloon catheter may then be inflated distal to the undesirable material. Once inflated, the suction force may be activated and the inflated catheter withdrawn along the Suction cannula 71. As it is withdrawn, the balloon catheter can act to drag the undesirable material into suction cannula 71.</p>	<p><u>18:29-39:</u></p> <p>In a situation where the undesirable material may be adherent to a vessel wall, or for some other reason cannot be dislodged by simply applying Suction to the site of interest, the balloon catheter can be inserted through the side port of Suction cannula 71, advanced past a distal end of cannula 71, and past the adherent undesirable material. The balloon catheter may then be inflated distal to the undesirable material. Once inflated, the suction force may be activated and the inflated catheter withdrawn along the Suction cannula 71. As it is withdrawn, the balloon catheter can act to drag the undesirable material into suction cannula 71.</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 Aklog 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.18. 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.*

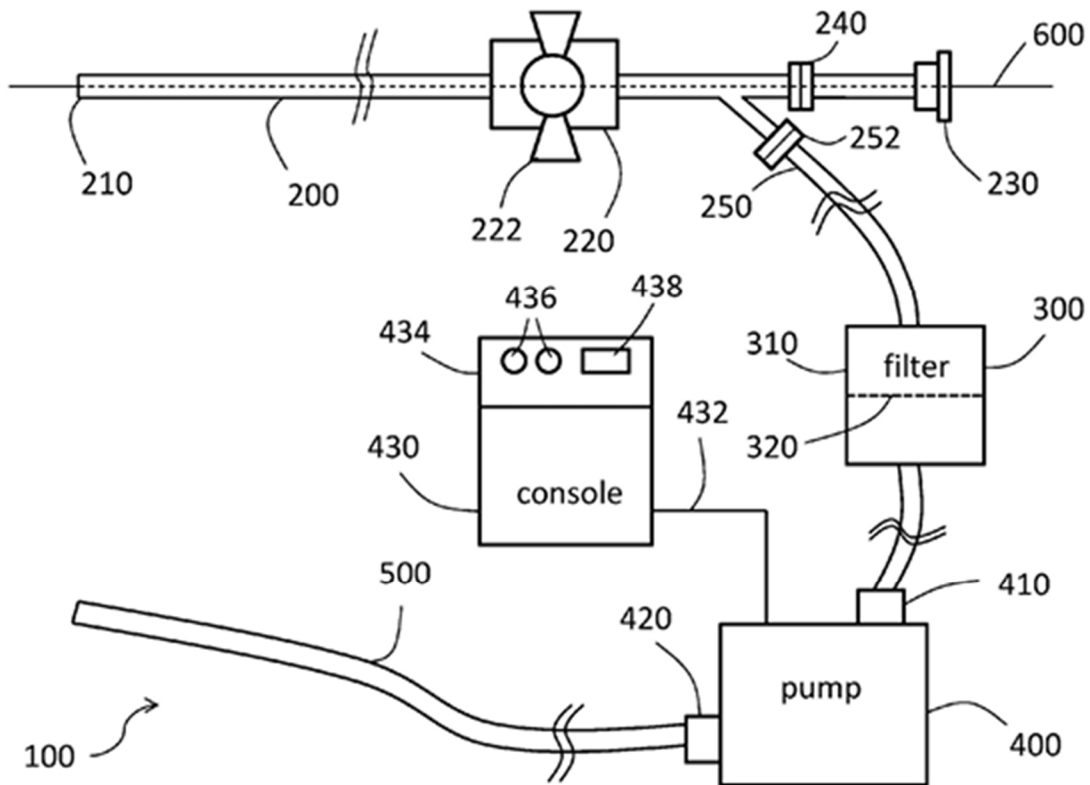


FIG. 1A

After describing Laub, Petitioner asserts that Aklog “*also* discloses an aspiration system for removing PEs and DVTs from blood vessels” and “*also* discloses ways to optimize aspiration systems to treat PE and DVT, including returning the aspirated blood to the patient to reduce blood loss.” Petition, p.4 (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.*

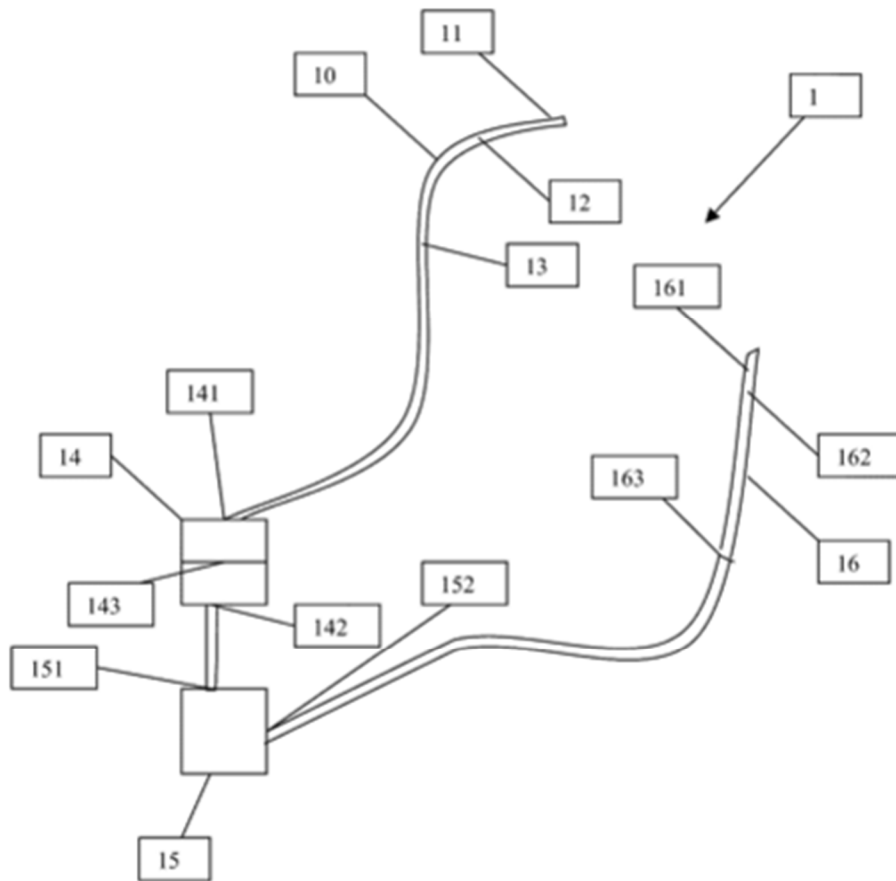
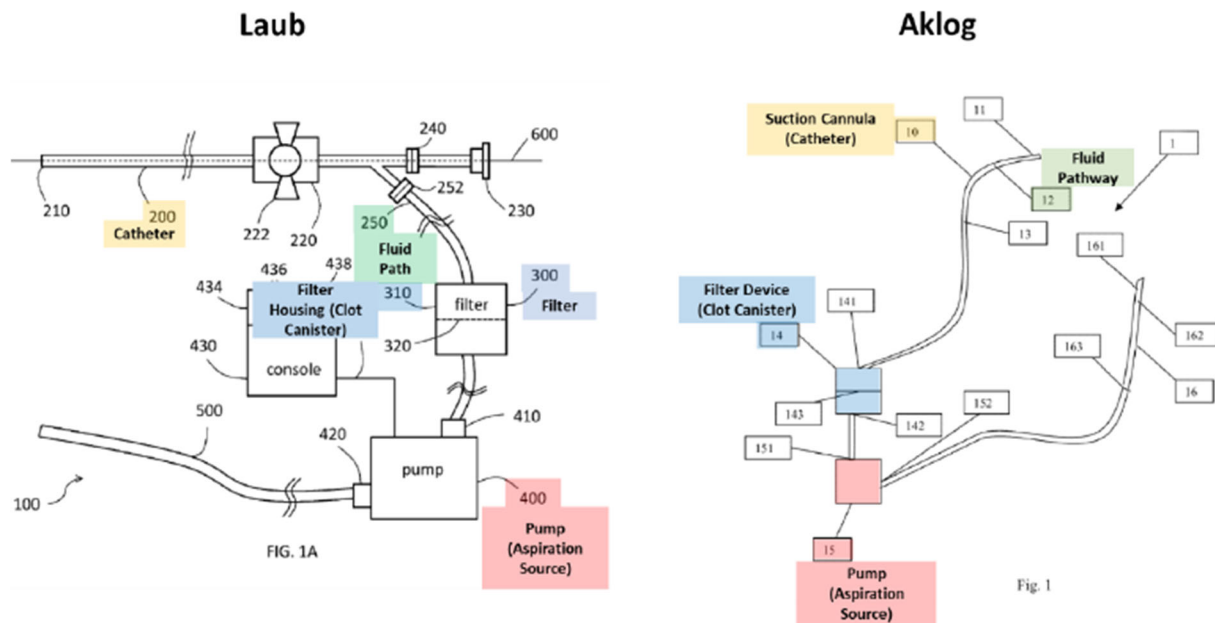


Fig. 1

The Petition includes no argument or fact unique to the proposed combinations of Garrison and Laub that is not also found in Aklog in Petitioner's proposed combinations of Garrison and 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 and deep vein thrombi) 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 reproduced side-by-side in the Petition demonstrate that they have the same components and operate in the same manner:



Petition, p.24. 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 the limitations of independent Claims 1 and 20 other than recited operations of the valve (e.g., “generating vacuum pressure within the clot

canister via the aspiration source while a valve positioned along the fluid path between the aspiration catheter and the clot canister is in a first position that inhibits fluid flow along the fluid path from the lumen of the aspiration catheter to the clot canister” and “moving the valve from the first position to a second position thereby applying the vacuum pressure to the lumen of the aspiration catheter ... ” as recited in independent Claims 1 and 20). Petition, pp.18-43, 63-64. But, Petitioner alleges that each of Aklog and Laub *separately* disclose the features of Claims 1 and 20 including a “method of treating pulmonary embolism” or “deep vein thrombosis,” and “advancing an aspiration 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. *See, e.g., id.* at pp.18-19, 30-34. 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 (Laub or Aklog in combination with Garrison) and grounds 3 and 4 (Garrison in combination with Laub or Aklog)—in which Laub or Aklog are used separately to teach the same features in the combinations with Garrison.

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 POSITAs to use Garrison’s system

to treat clots in other parts of the vasculature, including PEs and DVTs.” Petition, p.22. 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 devices, to generate 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 legs (DVT) and 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”). *Id.* at pp.21-22. 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 and deep vein thrombosis is also substantially similar to and cumulative of Batiste (EX2003) which the Examiner expressly considered, explaining in the Notice of Allowance 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]).” EX1002, p.47. 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).” EX2003, ¶¶[0002]-[0004].

Laub’s disclosure of treating pulmonary embolism and deep vein thrombosis is also substantially similar to and cumulative of Gelbfish (EX2004) which the Examiner expressly considered, listing Gelbfish in a Notice of References Cited that accompanied the Notice of Allowance such that Gelbfish appears with an (*) next to its patent number on the face of the ’333 Patent. EX1002, p.49; EX1001, p.2. Indeed, similar to Laub and Aklog, Gelbfish discloses systems for treating clot “[i]n the venous system, [where the] clot can obstruct the drainage pathways, leading to poor blood drainage back to the heart and a buildup in back pressure” and where “venous clot may also break off and travel to the heart and lungs ... [t]his condition is known as pulmonary embolism and is often fatal.” EX2004, 1:13-21. Those systems can include a catheter that “utilizes suction to aspirate severed clot pieces” having an “inlet port element 10 [that] may be connected to the suction channel of the instrument.” *Id.* at 7:27-30.

Petitioner’s references for each of grounds 1-4 related to independent Claims 1 and 20 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, the disclosure of Garrison was brought to the Examiner's attention during prosecution and discussed in an Examiner interview before the Examiner allowed the claims. As such it was extensively and expressly considered during examination. In the Notice of Allowance, the Examiner found the Claims allowable over Garrison and the other art of record because "modified Garrison does not teach an aspiration catheter configured to aspirate pulmonary embolism or deep vein thrombosis ... [t]he aspiration catheter of modified Garrison is configured for smaller neurovascular anatomy (see Abstract) and not configured for larger clot/embolisms." EX1002, p.46. The Examiner also explained that "a pulmonary embolism or a deep vein thrombosis presents significant different structures and physiological responses as compared to neurovascular clots, and therefore one skilled in the art would not have looked to use the Garrison device for the current methods." *Id.* at pp.46-47.

Petitioner nevertheless alleges for grounds 3 and 4 (Garrison in combination with Laub or Aklog, respectively) that "[w]hile Garrison focuses on the 'treatment of cerebral occlusions,' a POSITA would have found it obvious to use, or optimize, Garrison's clot treatment system to treat PE based on Laub or Aklog" or a "POSITA would have found it obvious to use or optimize Garrison's aspiration system to treat

DVT based on Laub or Aklog and the knowledge of a POSITA.” Petition, pp.21, 64. But those exact arguments were considered and rejected by the Office as set forth in the Office’s findings of allowability that a POSITA would not have modified Garrison to treat pulmonary embolism or deep vein thrombosis.

Additionally, the Patent Office explained in the Notice of Allowance that the prior art also disclosed aspiration catheters for treating pulmonary embolism and deep vein thrombosis (just like Petitioner alleges regarding Laub and Aklog), but that it still would not have been obvious to modify Garrison to treat such conditions:

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.

EX1002, p.47. Indeed, similar to Laub and Aklog, Batiste discloses “thrombectomy catheters which are used in the human vascular system to aspirate blood clots” including “[d]eep vein thrombosis (DVT)” and “pulmonary embolism (PE).” EX2003, ¶¶[0002]-[0004]. Accordingly, the Patent Office found that “it would not

be reasonable to combine” Garrison with Batiste in precisely the same manner Petitioner alleges here regarding the combinations of Garrison and Laub or Aklog.

Regarding grounds 1 and 2, the Patent Office expressly considered the disclosure of Aklog and art like Aklog, including Batiste and Gelbfish, in the Notice of Allowance, and did not find that it would have been obvious to have modified Aklog, Batiste, Gelbfish or any other prior art based on Garrison to have arrived at the features of independent Claims 1 and 20.

For the foregoing reasons, Petitioner’s 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 art, including Garrison used for all grounds, was extensively evaluated by the Examiner.

As set forth above, the disclosure of Garrison was extensively evaluated by the Patent Office because Patent Owner voluntarily brought the disclosure of Garrison to the Examiner’s attention (even though not applied in the sole Office action) and discussed that disclosure with the Examiner. And, the Examiner explained the allowability of the Claims over Garrison in the Notice of Allowance.

EX1002, pp.46-47. Aklog's relevant disclosure was also before the Patent Office having been cited in an information disclosure statement. *Id.* at pp.186, 366. And, Laub is substantially the same as and cumulative of Aklog's parent (and thus Aklog) and other art of record including Batiste and Gelbfish as explained above in §II.B.1.c.

Further, as explained in §II.B.2. above, Petitioner's arguments here contradict the Examiner's reasons for allowing the claims. First, regarding grounds 3 and 4, the Petition requires a finding that a POSITA would have been motivated to have modified Garrison to aspirate pulmonary embolism or deep vein thrombosis in contrast to the Examiner's finding of allowability that a POSITA would not have based on Garrison's disclosure of treating the "smaller neurovascular anatomy (see Abstract) and [that is] ... not configured for larger clot/embolisms." EX1002, p.46. And, regarding grounds 1 and 2, the Examiner considered the disclosure of Aklog (and Laub based on its substantially similar disclosure), and references like Laub and Aklog including Batiste and Gelbfish directed to aspiration catheters for treating pulmonary embolism or deep vein thrombosis, and did not find that it would have been obvious to have modified any of those references based on Garrison to arrive at the features of the Claims. *Id.* at p.47.

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.

Indeed, the Petitioner here does not articulate any argument that the Examiner committed error. The Petitioner does not assert error or mistake in the Petition. Rather, Petitioner merely states that the Examiner relied on Patent Owner’s representations during prosecution and that the “Examiner cited no evidentiary support” for certain conclusions regarding Garrison. *See* Petition, p.12. But even there, Petitioner does not conclude that these actions by the Examiner were in error.

And, as explained above, the Examiner specifically found that Garrison is “not configured for larger clot/embolisms” and also explained that “a pulmonary

embolism or a deep vein thrombosis presents significant different structures and physiological responses as compared to neurovascular clots, and therefore one skilled in the art would not have looked to use the Garrison device for the current methods.” EX1002, pp.46-47. So, contrary to Petitioner’s conclusory statement, the Examiner did refer to evidentiary support for their findings of allowability—namely, that pulmonary embolism and deep vein thrombosis are significantly different indications requiring different components than Garrison’s treatment of neurovascular clots. Petitioner does not provide any reason why or how the Examiner’s determination was in error. 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 in all relevant parts), Batiste, and Gelbfish. *See* §B.1.b-c. above. And, to the extent that Petitioner suggests that any error stems from the Examiner not considering Aklog’s Figure 7 because Aklog’s parent “does not include Figure 7,” that is plainly false because Aklog’s parent indeed does include Figure 7 as shown in §II.B.1.b. Petition, p.5.

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.

The sixth *Becton, Dickinson* factor concerns whether Petitioner has presented additional evidence or facts warranting reconsideration. *Advanced Bionics*, IPR2019-01469, Paper 6, pp.10-11. 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 11,351 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 2001-2004** was served upon the below-listed counsel by electronic mail:

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Dated: August 18, 2025

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