

Filed September 16, 2025

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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
Patent No. 11,974,910

**PETITIONER'S OPPOSITION TO PATENT OWNER'S REQUEST FOR
DISCRETIONARY DENIAL**

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1001	U.S. Patent No. 11,974,910 (“the ’910 patent”)
1002	’910 Patent Prosecution History
1003	Expert Declaration of Troy Thornton
1004	Resume of Troy Thornton
1005	U.S. Patent No. 8,734,374 B2 to Aklog et al. (“Aklog”)
1006	U.S. Patent Publication No. 2015/0173782 A1 to Garrison et al. (“Garrison”)
1007	WIPO Publication No. WO 2006/124307 A2 to Goff et al. (“Goff”)
1008	U.S. Patent Publication No. 2003/0116731 A1 to Hartley (“Hartley”)
1009	U.S. Patent No. 6,776,770 B2 to Trerotola (“Trerotola”)
1010	U.S. Patent Publication No. 2010/0042118 A1 to Garrison et al.
1011	U.S. Patent No. 8,535,283 B2 to Heaton et al. (“Heaton”)
1012	U.S. Patent Publication No. 2017/0043066 A1 to Laub (“Laub”)
1013	U.S. Patent Publication US 2003/0225379 A1 to Schaffer et al. (“Schaffer”)
1014	U.S. Patent No. 5,938,645 to Gordon (“Gordon”)
1015	U.S. Patent Publication No. 2014/0296868 A1 to Garrison et al.
1016	U.S. Patent No. 7,998,104 B2 to Chang (“Chang”)
1017	U.S. Patent No. 8,157,760 B2 to Criado et al. (“Criado”)
1018	U.S. Patent No. 6,481,439 B1 to Lewis et al.
1019	U.S. Patent No. 8,075,510 B2 to Aklog et al.
1020	WIPO Publication No. WO 2018/019829 A1 to Brady et al. (“Brady”)

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1021	U.S. Patent Application No. 16/117,519 (the “519 application”)
1022	Expert Declaration of Dr. Aquilla S. Turk, III, DO
1023	Resume of Dr. Aquilla Turk, III, D.O.
1024	Shani, Jacob M.D., et al., Mechanical Manipulation of Thrombus: Coronary Thrombectomy, Intracoronary Clot Displacement, and Transcatheter Aspiration, 72 Am. J. Cardiol. 116G-118G (1993)
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1026	Turk, Aquilla S. et al., Initial clinical experience with the ADAPT technique: A direct aspiration first pass technique for stroke thrombectomy, 6 J. NeuroIntervent. Surg. 231-237 (2014)
1027	Turk, Aquilla S. et al., ADAPT FAST study: a direct aspiration first pass technique for acute stroke thrombectomy, 6 J. NeuroIntervent. Surg. 260-264 (2014)
1028	April 24, 2024 Letter from Inari to Imperative Care
1029	Turk, Aquilla S. et al., Aspiration thrombectomy versus stent retriever thrombectomy as first-line approach for large vessel occlusion (COMPASS): a multicentre, randomized, open label, blinded outcome, non-inferiority trial, 393 Lancet 998-1008 (March 2019)
1030	Save, Jeffrey L., Time is Brain – Quantified, American Heart Association Journals, available at http://www.stokeaha.org (2005).
1031	U.S. Patent No. 9,980,813 B1 to Eller (“Eller”)
1032	US 2018/0064453 A1 (“Garrison II”)
1033	US 2005/0054995 A1 (“Barzell”)

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1034	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)
1035	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)
1036	U.S. Patent No. 12,109,384 B2 to Merritt et al.
1037	Patent Owner’s Exhibit 2002 filed in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-00289 (P.T.A.B.)
1038	Indigo Aspiration System-Penumbra Engine Pump and Canister, 510(k) No. K180105 (Mar. 8, 2018) (“Indigo Aspiration System”)
1039	AXS Universal Aspiration Set Brochure (2017)
1040	VacLok Negative Pressure Syringe Brochure
1041	O. Nikoubashman et al., Under Pressure: Comparison of Aspiration Techniques for Endovascular Mechanical Thrombectomy, 39 Am. J. Neuroradiol. 905-909 (May 2018) (“Nikoubashman”)
1042	Inari’s Supplemental Infringement Contentions (without claim charts) from <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , No. 24-cv-3117 (N.D. Cal.) (served February 7, 2025)
1043	Inari’s Notice of Motion and Motion for Leave to File Third Amended Complaint (Dkt. #88) in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 24-cv-03117-EKL (N.D. Cal.) (filed March 5, 2025)
1044	Case Management & Scheduling Order (Dkt. #54) in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 24-cv-03117-EKL (N.D. Cal.) (issued December 19, 2024)
1045	Decision Denying Institution of <i>Inter Partes</i> Review for U.S. Patent No. 11,744,691 (Paper 10) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2024-01257 (P.T.A.B. Feb. 7, 2025)

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1047	Imperative Care's Opposition to Inari's Motion for Leave to File Third Amended Complaint (Dkt. #98) in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 24-cv-03117-EKL (N.D. Cal.) (filed March 26, 2025)
1048	Imperative Care's Notice of Motion and Motion to Stay Pending <i>Inter Partes</i> Review (Dkt. #100) in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 24-cv-03117-EKL (N.D. Cal.) (filed April 2, 2025)
1049	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)
1050	Certified File History of U.S. Patent Application 10/371,190 (Schaffer File History)
1051	Maureen Kohi, Catheter Directed Interventions for Acute Deep Vein Thrombosis, 6 Cardiovasc. Diagn. Ther. 599-611 (2016)
1052	Interview Summary from U.S. Patent Application No. 18/329,450 dated January 31, 2024
1053	Claim Construction Expert Report of Troy Thornton in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 24-cv-03117-EKL (N.D. Cal.)
1054	Decision Denying Patent Owner's Request for Discretionary Denial (Paper 9) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-00289 (P.T.A.B. June 12, 2025)
1055	Decision Referring the Petition to the Board (Paper 9) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-00728 (P.T.A.B. July 31, 2025)

I. INTRODUCTION

Patent Owner (“PO”) has now filed four Requests for Discretionary Denial (“Requests”) of IPRs filed by Petitioner. The Director has already denied two of the Requests, while this Request and another are pending. (Ex. 1054; Ex. 1055.) In the two denied Requests, PO sought discretionary denial under § 314(a). (*Id.*) The Director denied those Requests because “there is no trial date scheduled in the district court” and the “challenged patent issued recently,” among other reasons. (*Id.*) Those facts also apply to this IPR. Thus, PO has abandoned its § 314(a) arguments and instead asks the Director to deny institution based on § 325(d). However, PO’s Request fails both prongs of the *Advanced Bionics* analysis and should be denied.

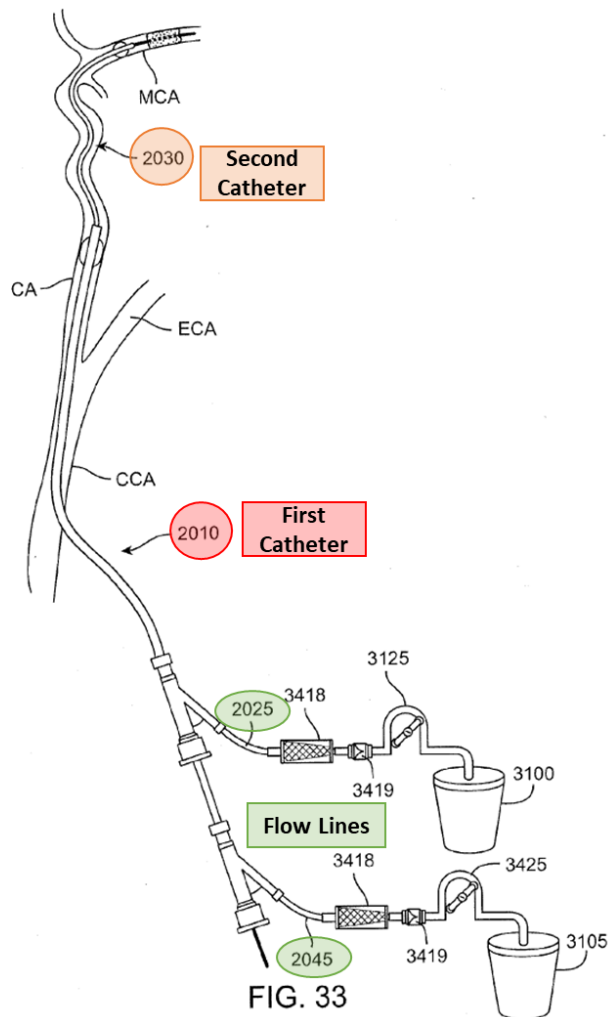
PO’s Request fails the first prong of *Advanced Bionics* because *Laub*, which forms the basis for six of Petitioner’s invalidity grounds, was *not* of-record during prosecution of the ’910 patent. *Laub* discloses the specific limitations the Examiner found were allegedly missing from the prior art, including: (1) an aspiration catheter for treating a pulmonary embolism (“PE”) and (2) a catheter of at least 16 Fr.

PO concedes that *Laub* was not of-record during prosecution. However, PO argues that *Laub* is “substantially the same” as other submitted references. PO is incorrect. As shown below, *Laub* includes unique disclosure not found in the other references that renders the challenged claims invalid.

PO's Request also fails under the first prong of *Advanced Bionics* because *Pasha*, a secondary reference for Petitioner's invalidity Grounds 7-9, was **not** of-record during prosecution of the '910 patent. Pasha describes features of the aspiration catheters recited in several of the challenged claims. Yet, PO ignores Pasha in its Request. Because the Office did not consider Laub or Pasha or the arguments raised in the Petition concerning those references, PO's Request fails under *Advanced Bionics*.

Further, even if Laub and Pasha were substantially the same as of-record prior art (they are not), PO's Request still fails under the second prong of *Advanced Bionics* because the Examiner materially erred in allowing the challenged claims in at least two ways.

First, the Examiner misunderstood the prior-art reference Garrison, which forms the basis of several grounds in the IPR. The Examiner mistakenly believed that two "flow line[s]" (2025 and 2045) were catheters in Garrison's system. Based on this misunderstanding, the Examiner then found that the asserted claims were distinguishable over Garrison because Garrison did not disclose a "second catheter advanceable through the first catheter." Yet, Garrison describes items 2010 and 2030 as the catheters and discloses and illustrates a "second catheter [2030] advanceable through the first catheter [2010]":



(Ex. 1006, [0131], Fig. 33.) The Examiner materially erred in failing to appropriately interpret Garrison's disclosure.

Second, the Examiner allowed the challenged claims based on an inventor interview during prosecution of a different, but related application. During that interview, the inventor argued that aspiration catheters for removing blood clots in the brain could not be combined with aspiration catheters for removing blood clots in other parts of the body such as the lungs (PE) or legs (deep vein thrombosis). The

inventor also argued that the Examiner should allow the challenged claims because they recited a catheter having “a size of 16 French or greater,” which the inventor claimed was not taught in the prior art.

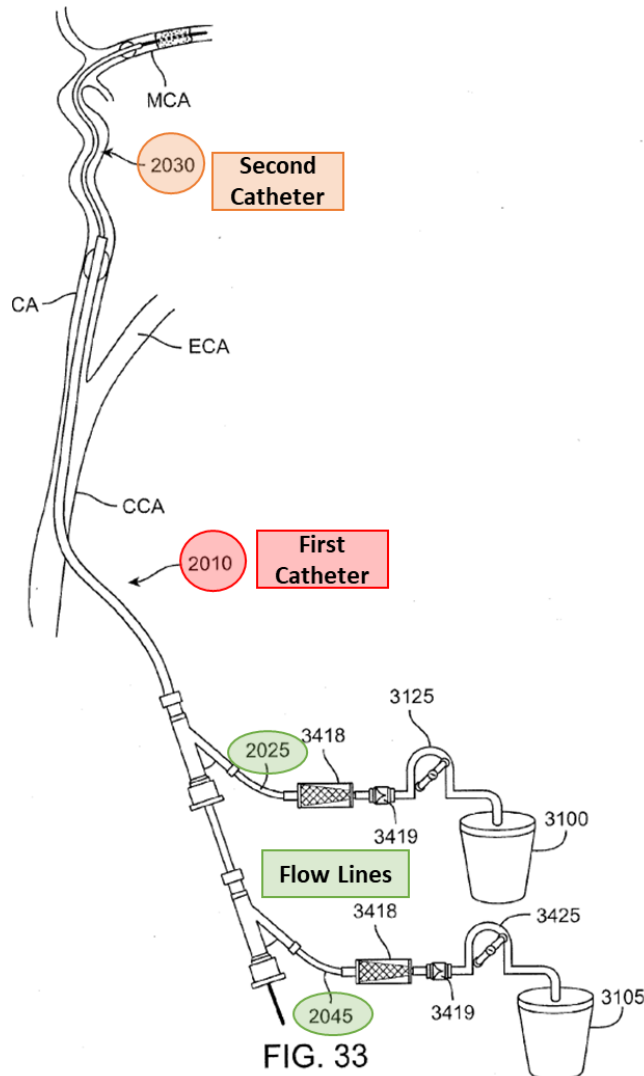
Yet, Laub and the other background references included in the Petition, as well as the supporting expert declarations from Dr. Aquilla Turk and Mr. Troy Thornton submitted with the Petition, show the inventor’s unsupported arguments were incorrect. For example, Laub and the other background references show that POSITAs regularly used or adapted aspiration catheters intended for one part of the body for another, including for use in treating PE and deep vein thrombosis. Likewise, Laub specifically discloses aspiration catheters having “a French size of at least 16 Fr.” The Examiner did not have the benefit of this evidence during prosecution and, therefore, materially erred in allowing the claims. Accordingly, even if PO’s Request satisfies the first prong of *Advanced Bionics*, the Request should still be denied under the second prong.

For these reasons, and the additional reasons provided below, Petitioner respectfully requests that the Director deny PO’s Request for Discretionary Denial and allow this IPR to proceed to an institution determination on the merits.

II. SUMMARY OF PROSECUTION HISTORY

The Examiner issued a single Non-final Office Action during prosecution, rejecting original claim 18 as anticipated by Garrison. (Ex. 1002, 373-382.) The

Examiner also found that Garrison disclosed all the limitations of the other claims except “a second catheter advanceable through the first catheter.” (*Id.*) The Examiner stated that in Garrison, “[t]he second catheter (2045) does not advance through first catheter (2025), as shown in Figure 33.” (*Id.*) The Examiner further stated that “[t]here is no reason to advance the second catheter through the first catheter of Garrison.” (*Id.*) As explained below, the Examiner misunderstood Garrison because items 2025 and 2045 are not catheters, but “flow lines”:



(Ex. 1006, [0131], Fig. 33; *infra* §III.B.2) Garrison’s Figure 33 clearly shows that catheter 2030 is advanced through catheter 2010. (Ex. 1006, [0131], Fig. 33.)

Following the rejection, PO cancelled rejected claim 18 and amended the remaining claims to require a system “for treating clot material comprising a pulmonary embolism in the vasculature of a patient” and to require that the second catheter has a “size of 16 French or greater.” (Ex. 1002, 141-149.) In its remarks, PO argued that the amended claims “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 (‘the ’450 application’), 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.*)

The Interview Summary from the ’450 application was not made of-record during prosecution of the ’910 patent, but Petitioner provided it as an exhibit to the Petition. (*See* Ex. 1052.) According to the Examiner’s Interview Summary from the ’450 application, Dr. Tu, a named inventor on the ’910 patent and ’450 application, argued that there were “differences between catheters used in cerebral occlusions vs. pulmonary embolisms and deep vein thrombosis” that distinguished

the amended claims from Garrison II.¹ (*Id.*) The Interview Summary stated that during the interview, PO “and Examiner agree[d] that incorporating more structural claim language, i.e. diameter of the catheter, would make the claim 1 [of the ’450 application] allowable over the prior art Garrison [II].” (*Id.*) The Summary further stated that PO and “Examiner agree[d] that the newly added method claims would be allowable for reciting the specific use in pulmonary embolism applications.” (*Id.*)

The Examiner allowed the claims of the ’910 Patent following PO’s amendments. (Ex. 1002, 43-51.) In the Notice of Allowance, the Examiner found that Garrison teaches all the limitations of the claims except “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.” (*Id.*, 49.) The Examiner alleged that the “clot treatment device of Garrison is configured for a neurovascular application and not for larger vasculature such as pulmonary embolism” and that “[i]t would be unreasonable to modify the clot treatment device of Garrison to be used for pulmonary embolisms.” (*Id.*) The Examiner did not cite any evidence to support this conclusion and did not reference the interview from the

¹ Garrison (Ex. 1006), was not asserted by the Examiner during prosecution of the ’450 application. The Examiner had instead asserted US 2018/0064453 A1 (“Garrison II”). Garrison and Garrison II are not from the same patent family and do not share the same disclosure.

'450 application, although the interview presumably formed the basis for these undocumented conclusions. (*Id.*)

III. ARGUMENT

A. The Office Did Not Previously Consider Petitioner's Prior Art or Invalidity Grounds

Under the first prong of *Advanced Bionics*, the Director evaluates whether the same or substantially the same prior art or arguments presented in the Petition were previously presented to the Office during prosecution of the challenged patent. *Advanced Bionics, LLC v. MED-EL Elektromedizinische Gertite GmbH*, IPR2019-01469, 2020 WL 740292, at *3 (P.T.A.B. Feb. 13, 2020) (precedential). If those conditions are not met, discretionary denial under § 325(d) is inappropriate, and the Director does not need to address the second prong - whether the Petitioner has demonstrated that the Office erred in a manner material to the patentability of the challenged claims. *Id.*

Whether the same or substantially the same prior art or arguments were previously presented to the Office is a highly factual inquiry that is guided by *Becton, Dickinson* factors (a), (b), and (d):

(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; ... (d) the extent of the overlap between the arguments made during examination and the manner in which petitioner relies on the prior art.

Advanced Bionics, 2020 WL 740292 at *4. Here, the factors demonstrate that the prior art and arguments presented in the Petition were not previously presented to the Office. Thus, PO's Request fails under the first prong of *Advanced Bionics* and should be denied.

1. Laub is not Substantially the Same as the Cited Prior Art

PO concedes that "Laub was not considered by the Patent Office." (Request at 29.) Thus, in an effort to satisfy *Advanced Bionics*, PO argues that Laub is "substantially the same as and cumulative" to two prior art references that were before the Patent Office: (1) Aklog's parent and (2) Batiste. (Request (Paper 5), 29-37.) Both references disclose systems for aspirating blood clots, including PE. While these prior art references further confirm that the aspiration systems claimed in the '910 patent are not novel and nonobvious, they are not substantially the same as Laub. Laub contains specific details about its aspiration system not found in the other references that are relevant to the obviousness combinations raised in the Petition. Accordingly, PO cannot satisfy *Becton, Dickinson* factors (a) and (b). See *Advanced Bionics*, 2020 WL 740292 at *4.

a. Laub Includes Unique Disclosures

As explained in the Petition, Laub discloses aspiration systems "to remove clots from patients suffering from or at risk of pulmonary embolisms." (Petition (Paper 2) at 24; Ex. 1012, [0005].) Laub provides specific details about its aspiration

system not found in the two references cited by PO. For example, Laub discloses a variety of diameters for its aspiration catheters, including aspiration catheters having “a French size of at least 16 Fr.” and “a French size of at least 20 Fr.” (Ex. 1012, [0028]; *see also* Petition (Paper 2), 42 (relying on this disclosure).) The catheter diameters described in Laub encompass those claimed in the '910 patent. (*See* Ex. 1001, Claims 1, 3 (claiming a catheter that “has a size of 16 French or greater” and claiming a catheter having “a size of 24 French”).)

Further, the Examiner specifically cited the claimed 16 Fr. catheter size as one reason for allowing the challenged claims. (Ex. 1002, 49.) None of the prior art references identified by PO include an express disclosure of the catheter sizes disclosed in Laub. Thus, the of-record references are not cumulative of Laub.

Additionally, Laub describes the relationships between different types of clots. Laub explains that clots that form in the legs (e.g., deep vein thrombosis) “can migrate to the vessels of the brain and cause stroke and possibly death” or “can migrate to the lungs and block the lungs main artery, resulting in a potentially fatal pulmonary embolism.” (Ex. 1012, [0004]; *see* Petition (Paper 2), 29 (relying on disclosure); Ex. 1003, ¶84; Ex. 1022, ¶38-41.) This express disclosure is unique to Laub.

Thus, Laub includes unique disclosures relevant to the unpatentability grounds identified in the Petition. Because Laub was not of-record, the Examiner

did not consider Laub or the arguments based on Laub and PO cannot satisfy the first prong of *Advanced Bionics*.

b. Laub is not Substantially the Same as Aklog

PO incorrectly argues that Laub is “substantially the same as and cumulative to Aklog’s parent.” (Request (Paper 5), 29.) In the Petition, Petitioner relied on Aklog in Grounds 2-3, 5-6, and 7-9. (Petition (Paper 2), 21.) Aklog was *not* of-record during prosecution of the ’910 patent, but Aklog’s parent was listed on an IDS with a total of 919 references. (Ex. 1002, 1119-1152.) The Examiner *never* discussed or applied Aklog’s parent during prosecution. (*See infra*. §III.B.1 (explaining that Examiner erred by allowing claims over Aklog combined with other references).)

Further, Laub and Aklog are not related, have different inventors, have different assignees, and do not incorporate each other. Thus, while Aklog describes aspiration systems for removing blood clots from a patient, such as PE, Aklog (and Aklog’s parent) is not “substantially the same as” Laub.

PO argues that Laub is substantially the same as Aklog’s parent because Petitioner relies on Aklog and Laub in combination with Garrison to show that the challenged claims are unpatentable. (Request (Paper 5), 29-36.) For example, PO cherry picks demonstratives of Laub and Aklog from the Petition illustrating that both references disclose conventional components of an aspiration system. (*Id.*, 33-

34.) But PO simply ignores Laub's unique disclosures discussed in the previous section that are relevant to the unpatentability grounds and are *not* found in Aklog, including disclosures regarding the catheter diameters recited in the challenged claims. (*Supra* §III.A.1.a.) Thus, while both references render the challenged claims obvious, PO has failed to show that Laub and Aklog are substantially the same. *See Becton, Dickinson & Co. v. B. Braun Melsungen AG*, IPR2017-01586, 2017 WL 6405100, at *6 (P.T.A.B. Dec. 15, 2017) (precedential as to §III.C.5, first paragraph).

Moreover, PO has failed to show, or even assert, that the Examiner evaluated Aklog's parent, which was buried on an IDS and not mentioned during prosecution. (Ex. 1002, 1119-1152.) Thus, even if Aklog were "substantially the same as Laub," PO has not shown that there is any overlap between the arguments made during examination and Petitioner's arguments regarding Laub and Aklog in the Petition. For this reason, PO has failed to show that factor (d) of the *Becton, Dickinson* factors favors discretionary denial. *Becton, Dickinson & Co.*, 2017 WL 6405100, at *6; *see also, Ecto World, LLC v. Rai Strategic Holdings, Inc.*, IPR2024-01280, 2025 WL 1528304, at *4 (P.T.A.B. May 19, 2025) (precedential as to §A) ("[T]he Board should consider a petitioner's argument based on the volume of the references submitted to the Office during examination ... [which] may demonstrate that discretionary denial under § 325(d) is not warranted.").

c. Laub is not Substantially the Same as Batiste

PO cursorily argues that Laub is substantially the same as Batiste, another reference cited on an IDS form during prosecution of the '910 patent. (Request (Paper 5), 36-37.) PO notes that Batiste discloses aspiration catheters for treating PE and, based on that similarity alone argues Batiste is “substantially the same as” Laub. (*Id.*)

Yet, PO makes no attempt to identify any similarities between the aspiration systems in Batiste and Laub. (*Id.*) PO does not identify any common components between the systems, let alone show that the disclosed systems include “substantially the same” components. Nor does PO discuss any of the unique disclosures found in Laub described in the previous sections. (*See* §III.A.1.a.) Rather, PO effectively argues that any prior art reference merely disclosing an aspiration catheter for treating PE would be cumulative of Laub. (*See* Request (Paper 5), 36-37) PO’s failure to discuss the similarity and material differences between the prior art references renders its argument insufficient under *Becton, Dickinson* factors (a) and (b).

2. Pasha was not Before The Examiner of the '910 Patent

PO’s Request also ignores that Pasha (Ex. 1049), which Petitioner relied upon for Grounds 7-9, was not of-record during prosecution.

Pasha is a prior art article published in 2014 that describes a real-world example of physicians treating PE with “a 26-French Angiovac catheter.” (Ex. 1049, 240-241.) Pasha concludes that the “use of Angiovac suction catheter device[s] provides a novel technique to remove large emboli effectively as an alternative method to other catheter-based devices.” (*Id.*, 242.) Thus, Pasha expressly discloses the treatment of PE using aspiration catheters measuring at least 24F as recited in Claims 3, 12, and 18 of the ’910 patent. (Petition (Paper 2), 83-84.) Pasha therefore directly rebuts the inventor’s argument during prosecution, which was accepted by the Examiner, that using larger catheters measuring 16 French or 24 French for treating PE was novel and nonobvious.

Accordingly, Pasha, which was not considered during prosecution of the ’910 patent, further demonstrates that PO cannot satisfy the first prong of *Advanced Bionics* and that this Request should be denied.

3. The Office did not Previously Consider Petitioner’s Prior Art Combinations or Arguments

As shown above, the Examiner did not consider Laub or Pasha during prosecution. The Examiner also did not consider the prior art combinations or arguments presented in the Petition, providing further basis to deny PO’s request. *See Advanced Bionics* 2020 WL 740292 at *4 n. 10 (noting that *Becton, Dickinson*

factor (d) looks to “the extent of the overlap between the arguments made during examination and the manner in which petitioner relies on the prior art”).

During prosecution of the '910 patent, the Examiner rejected pending claim 18 as anticipated by Garrison but found the other pending claims allowable because Garrison failed to disclose “a second catheter advanceable through the first catheter.” (Ex. 1002, 373-382.)² PO then cancelled pending claim 18 and amended the remaining claims to require a system “for treating clot material comprising a pulmonary embolism in the vasculature of a patient” and to specify that the second catheter in the system has a “size of 16 French or greater.” (*Id.*, 141-149.) In its remarks, PO argued that the amended claims are patentable over Garrison for reasons discussed during an Examiner interview for a *different* application, the '450 application. (*Id.*) PO did not explain what those reasons were. (*Id.*) The interview summary from the '450 application merely states that “Attorney and Examiner agree that the newly added method claims would be allowable for reciting the specific use in pulmonary embolism applications” and that “Dr. Tu [a named inventor on the '910 Patent] discussed the differences between catheters used in cerebral occlusions vs. pulmonary embolisms and deep vein thrombosis.” (Ex. 1052.)

² As explained below, the Examiner’s statement regarding Garrison was clearly erroneous and reflects a misunderstanding of Garrison’s disclosure. (*Infra* §III.B.2.)

The Examiner allowed the claims of the '910 patent following PO's amendment. (Ex. 1002, 43-51.) The Examiner found that Garrison teaches every limitation of the claims except "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." (*Id.*) The Examiner alleged that the "clot treatment device of Garrison is configured for a neurovascular application and not for larger vasculature such as pulmonary embolism" and that "[i]t would be unreasonable to modify the clot treatment device of Garrison to be used for pulmonary embolisms." (*Id.*) The Examiner did not cite any evidence to support this conclusion. (*Id.*) The Examiner also did not discuss any prior art references that disclosed aspiration systems for treating PE, including Laub, Aklog, or Pasha (which were not of-record). (*Id.*)

Accordingly, the Examiner of the '910 patent did not consider any of Petitioner's prior art combinations or arguments, which assert that a POSITA would have found it obvious to adapt Garrison's aspiration system to treat PE using a 16 Fr catheter based on the specific disclosures of Laub and/or Aklog. (Petition (Paper 2), §VI.A.) In fact, the Examiner never mentioned *any* prior art references disclosing aspiration systems for PE in the Notice of Allowance, nor did the Examiner provide any explanation or evidence to support the statement that "[i]t would be unreasonable to modify the clot treatment device of Garrison to be used for

pulmonary embolisms.” (Ex. 1002, 49.) For example, the Examiner did not cite any teaching away of such a modification in Garrison or any other prior art. (*Id.*) Nor did the Examiner identify any technical issues a POSITA might face in making such a modification, which would have merely required a simple substitution of Garrison’s catheters for larger-diameter catheters that were well-known in the art at the time. (*Id.*; *see also* Petition (Paper 2), 23-34, 39-48.) Instead, it appears that the Examiner relied on PO’s unsupported representations regarding aspiration catheters in the ’450 application, but even that is not expressly stated in the Notice of Allowance. (Ex. 1002, 48-49.)

Accordingly, although the Examiner discussed Garrison during prosecution, the Examiner did not consider any of Petitioner’s proposed prior art combinations or arguments involving Garrison. Thus, *Becton, Dickinson* factor (d) weighs against discretionary denial, and the Director should therefore deny PO’s request for this additional reason. *Atlas Copco Tools and Assembly Systems LLC v. Wildcat Licensing WI LLC*, IPR2020-00891, 2020 WL 6470316, at *12 (P.T.A.B. Nov. 3, 2020) (“Patent Owner also does not show where the Office previously considered Gass applied to a reference like Stimpson or Fredrick, even if Gass and references similar to Stimpson and Fredrick were individually considered. . . . We, thus, determine that Petitioner’s arguments were not previously presented to the Office.”); *Bowtech, Inc. v. Mcp IP, LLC*, IPR2019-00382, 2019 WL 3714325, at *4 (P.T.A.B.

Aug. 6, 2019) (“Regardless of whether [t]he Examiner was aware of the *possible* combination of [prior art references], Patent Owner points to no evidence that the Examiner actually considered such a combination.” (internal quotations omitted)); *REG Synthetic Fuels v. Neste Oil, OYJ*, IPR2018-01375, 2019 WL 845658, at *5 (P.T.A.B. Feb. 19, 2019) (“Patent Owner, however, does not show that the Examiner considered the *combination* of Jakkula and Monnier or the *combination* of Jakkula and Oldrich such that there is substantial overlap between the arguments made during examination and the arguments made in the Petition.”).

4. The Office did not Consider Petitioner’s Expert Declarations

In addition to Laub, Petitioner supplies additional material evidence in the form of two expert declarations by Troy Thornton, an engineering expert, and Dr. Aquilla Turk, a practicing interventional neuroradiologist, that were not previously considered by the Examiner during prosecution of the ’910 patent. (*See* Ex. 1003; Ex. 1022.) Petitioner’s new testimonial evidence provides another reason to deny PO’s Request. *See, e.g., Celltrion, Inc. v. Genentech, Inc.*, IPR2017-01140, 2018 WL 576158, at *6 (P.T.A.B. Jan. 25, 2018) (declining to exercise discretion under § 325(d) because “Petitioner’s testimonial evidence presents the prior art in a new light”); *10x Genomics, Inc. v. Univ. of Chicago*, IPR2015-01157, 2015 WL 7304561, at *5 (P.T.A.B. Nov. 16, 2015) (declining to exercise discretion under § 325(d)

where expert “testifies directly on the ... the limitation Patent Owner indicates was the basis for the Examiner’s allowance of the claims”).

Mr. Thornton and Dr. Turk each directly address PO’s unsupported prosecution arguments that aspiration systems used for cerebral blood clots, including Garrison, could not be adapted to treat blood clots in other portions of the vasculature, including PE. (Ex. 1003, ¶¶69-86; Ex. 1022, ¶¶16-41.) In particular, Dr. Turk, a practicing physician with significant experience developing and performing aspiration procedures, explains that “[w]hile there can be some differences between treating neurovascular clots and DVT or PE, the procedures have far more similarities than differences,” and that “the mechanical components required to aspirate a blood clot from the brain (cerebral occlusion) are the same as those required to aspirate a clot from the legs (DVT) or lungs (PE).” (Ex. 1022, ¶¶20, 24.) Dr. Turk also testifies regarding the standard process of “upsiz[ing]” aspiration systems that were originally designed for cerebral vessels to treat PE, and the real-world use of smaller-diameter aspiration catheters for treating PE. (*Id.*, ¶¶30-39.)

Petitioner’s expert declarations are material evidence that was not available to the Examiner during prosecution, and that directly rebuts the reasons for allowance. The Examiner’s reasons for allowance suggest “that had the evidence in the [Turk and Thornton] Declaration[s] been presented to the Examiner during prosecution of

the [’910] patent, there is a reasonable likelihood that the Examiner would have maintained the rejection of the claims of the [’910 patent], and that the [’910] patent would not have issued.” *Prollenium Us Inc. v. Allergan Industrie, SAS*, IPR2019-01617, 2020 WL 1491363, at *24 (P.T.A.B. Mar. 20, 2020).

For this additional reason, PO has failed to satisfy the first prong of *Advanced Bionics* and the Requests should be denied.

B. The Examiner Materially Erred in Allowing the Challenged Claims of the ’910 Patent Over the Prior Art

Even if PO satisfied the first prong of *Advanced Bionics* (it did not), the Director should still deny the Request for discretionary denial because the Examiner materially erred in allowing the challenged claims of the ’910 patent over the prior art. The Examiner’s material error is illustrated by *Becton, Dickinson* factors (c), (e), and (f), each of which strongly weighs against discretionary denial. *See Advanced Bionics*, 2020 WL 740292 at *4.

1. The Examiner did not Expressly Evaluate or Assert Petitioner’s Prior Art Combinations

As explained above, although the Examiner asserted Garrison in a non-final rejection of pending claim 18, the Examiner did not discuss or evaluate any of the other prior art references asserted in the Petition, including Laub, Aklog, and Pasha. (*Supra* §III.A.3; Ex. 1002, 48-50, 375-380.) Thus, to the extent Laub, Aklog, or Pasha were “considered” by the Examiner, the Examiner overlooked the teachings

of those references. *Becton, Dickinson* factor (c) therefore weighs against discretionary denial.

As discussed above, Laub and Pasha were never submitted to the Examiner during prosecution of the '910 patent, so there is no evidence that the Examiner evaluated any of Laub's or Pasha's disclosures. (*Supra* §§III.A.1-2.) In addition, while PO focuses its Request on the listing of Aklog's parent on an IDS during prosecution, PO neglects to mention that Aklog's parent was buried amongst 919 total references on the IDS, and was never discussed or asserted by the Examiner. (Ex. 1002, 1119-1152.) One of Petitioner's other references, Hartley, was also submitted on that same IDS form, and was similarly never discussed or asserted by the Examiner. (*Id.*) Thus, to the extent the Examiner "considered" Aklog and/or Hartley, the record shows that the Examiner did not appropriately apply them. (*Id.*); *see also Ecto World*, 2025 WL 1528304, at *4 ("[T]he Board should consider a petitioner's argument based on the volume of the references submitted to the Office during examination ... [which] may demonstrate that discretionary denial under § 325(d) is not warranted."); *Fasteners for Retail, Inc. v. RTC Indus., Inc.*, IPR2019-00994, 2019 WL 5777769, at *3 (P.T.A.B. Nov. 5, 2019) ("Based on the voluminous number of prior art documents before the examiner, we are skeptical that the examiner was able to devote sufficient time to evaluate all of the asserted art in detail during prosecution. *Becton Dickinson* expressly distinguished the situation 'where

the prior art was simply listed in an IDS during prosecution’ from actual examiner consideration.”); *Xencor, Inc. v. Merus N.V.*, IPR2025-00604, Paper 12, at 2-3 (P.T.A.B. July 17, 2025) (finding that the “Office erred in a manner material to the patentability of the challenged claims by overlooking the teachings of Lazar,” which was cited on an IDS during prosecution).

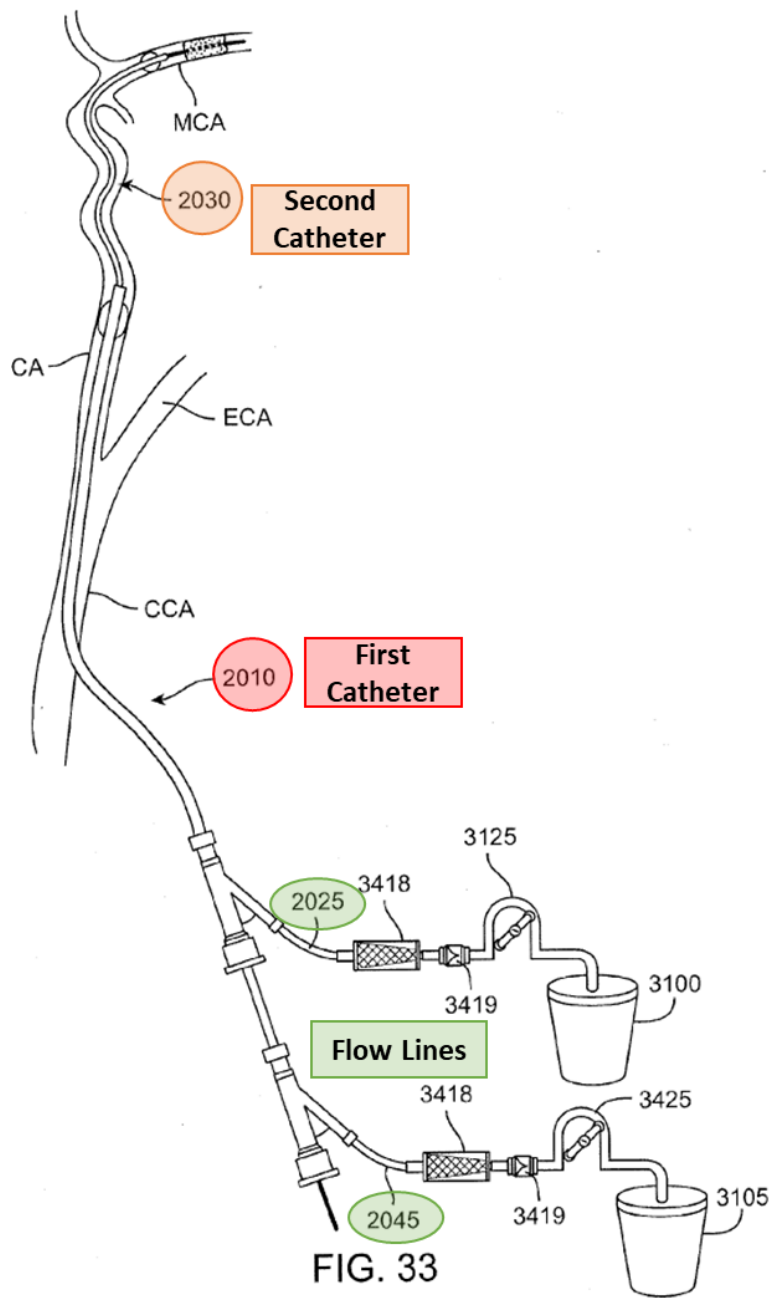
PO also focuses its request on the fact that the Examiner rejected one of the pending claims over Garrison and discussed Garrison in the Notice of Allowance. However, as explained below, the Examiner clearly misunderstood Garrison. (*Infra* §III.B.2.) The Examiner also never evaluated Garrison in combination with the teachings of Petitioner’s other references, like Laub or Aklog, which expressly disclose the limitations the Examiner found to be lacking in Garrison. The Examiner’s treatment of Garrison in isolation therefore highlights the Examiner’s material error in overlooking the teachings Laub and Aklog.

Accordingly, because the Examiner did not assert or evaluate any of Petitioner’s prior art combinations during prosecution of the ’910 patent, *Becton, Dickinson* factor (c) weighs against discretionary denial. *Bowtech, Inc.*, No. IPR2019-00382, 2019 WL 3714325, at *4.

2. The Examiner Materially Erred in Assessing the Prior Art

Petitioner's unpatentability grounds reflect at least two additional ways the Examiner of the '910 patent materially erred in assessing the prior art, confirming that *Becton, Dickinson* factor (e) also weighs heavily against discretionary denial.

First, the Petition demonstrates that the Examiner plainly misunderstood and misapplied Garrison's disclosure with respect to the limitation requiring "a second catheter advanceable through the first catheter." (Ex. 1002, 377.) The Examiner stated that Garrison did not disclose this limitation because the "second catheter (2045) does not advance through first catheter (2025), as shown in Figure 33." (*Id.*) The Examiner was clearly confused regarding Garrison's disclosure. Items 2025 and 2045 in Garrison are "flow lines" that connect the catheters 2010 and 2030 to the aspiration sources. (Ex. 1006, [0130]-[0131] ("Any or all of the arterial access device 2010 and the catheter 2030 may be connected to sources of passive or active aspiration via flow lines 2025 or 2045.") (emphasis added).) The "flow lines" 2025 and 2045 are not the first and second catheters in Garrison's system. (*Id.*) Rather, the first and second catheters are the arterial access device 2010 and the aspiration catheter 2030, and Garrison's catheter 2030 (i.e., second catheter) is clearly advanced through catheter 2010 (i.e., first catheter):



(*Id.*, [0130]-[0131], Fig. 33; Petition (Paper 2), 34-35, 39-40.) Accordingly, the Examiner misunderstood Garrison’s disclosures and materially erred in finding that Garrison lacks “a second catheter advanceable through the first catheter.” (Ex. 1002, 377.)

Second, the Petition demonstrates that the Examiner materially erred in allowing the claims over Garrison based on the PE limitations. (Petition (Paper 2), §VI.A.) As explained above, the Examiner did not cite any evidence or explanation for its findings in the Notice of Allowance and appears to have relied solely on PO's one-sided representations during an interview regarding the alleged differences between cerebral aspiration procedures and PE. But Petitioner's evidence, including Dr. Turk's declaration, shows that PO's representations were incorrect. (*Supra* §III.A.4.)

Indeed, as explained in the Petition and by Dr. Turk, aspiration systems with the same sized catheters as those disclosed by Garrison are commercially used to treat PE. (Petition (Paper 2), 30.) Thus, Garrison's catheters are appropriately sized to treat PE without modification. In addition, the Petition and Dr. Turk explain that it was common practice for practitioners and medical device companies to "upsized" catheters originally designed for one part of the vasculature for another. (*Id.*, 27.) In fact, even the '910 patent itself acknowledges that aspiration systems could be used across different parts of the vasculature. (*Id.*, 28.) The Examiner did not consider any of this evidence and instead relied exclusively on PO's self-serving and inaccurate representations about a POSITA's ability to use or adapt cerebral aspiration systems to treat PE. (*See* Ex. 1002, 49.) As a result, the Examiner materially erred in allowing the challenged claims of the '910 patent over Garrison.

Because of the material error committed during prosecution of the '910 patent demonstrated in the Petition and above, *Becton, Dickinson* factor (e) strongly weighs against discretionary denial. *See, e.g., CSPV Pharm. Grp. Ltd. v. Ipsen Biopharm Ltd.*, IPR2025-00505, Paper 11, at 2-3 (P.T.A.B. July 16, 2025) (declining to exercise discretion under § 325(d) because “Petitioner provides persuasive reasoning, supported by evidence, that ... the Office materially erred during prosecution of the challenged patent”); *Microsoft Corp. v. Partec Cluster Competence Center GMBH*, IPR2025-00318, Paper 9, at 2-3 (P.T.A.B. June 12, 2025) (similar); *Microsoft Corp. v. XI Discovery, Inc.*, IPR2025-00253, Paper 13, at 2 (P.T.A.B. June 25, 2025) (similar); *Tesla, Inc. v. Charge Fusion Techs., LLC*, IPR2025-00152, Paper 11, at 2-3 (P.T.A.B. June 12, 2025) (similar); *Xencor, Inc.*, IPR2025-00604, Paper 12, at 2-3 (similar).

3. Additional Evidence and Facts Presented in the Petition Warrant Denial of PO’s Request

Beyond Laub and Pasha, additional facts and evidence presented in the Petition that were not before the Examiner also warrant the Office’s reconsideration of the patentability of the '910 patent. Therefore, *Becton, Dickinson* factor (f) also strongly weighs against discretionary denial.

As explained above, the Examiner did not have the opportunity to review Petitioner’s testimonial evidence from Dr. Turk or Mr. Thornton, which directly

addresses PO's inaccurate representations that the Examiner relied upon in allowing the '910 patent. (*Supra* §III.A.4.) The Office has repeatedly found that such testimonial evidence directly addressing the Examiner's reasons for allowance weighs against discretionary denial under *Becton, Dickinson* factor (f). *See, e.g., Celltrion, Inc*, 2018 WL 576158, at *6 (declining to exercise discretion under § 325(d) because "Petitioner's testimonial evidence presents the prior art in a new light"); *10x Genomics*, 2015 WL 7304561, at *5 (declining to exercise discretion under § 325(d) where expert "testifies directly on the . . . the limitation Patent Owner indicates was the basis for the Examiner's allowance of the claims"); *Tandus Flooring, Inc. Petitioner v. Interface, Inc. Pat. Owner*, IPR2013-00333, 2013 WL 8595289, at *2 (P.T.A.B. Dec. 9, 2013) (declining to exercise discretion under § 325(d) "in view of the declaration testimony of two experts" that was not before the Examiner).

Petitioner's testimonial evidence is particularly critical here because the Examiner appears to have relied entirely upon PO's unsupported attorney argument and self-interested representations by the inventor in allowing the challenged claims. (*See* Ex. 1002, 49, 147-148.) The Board has found testimonial evidence provided by a Petitioner to be of particular importance in such circumstances. For example, in *Shenzhen Kean Silicone Prod. Co. v. Pkoh Nyc, LLC*, the Board declined to exercise its discretion under § 325(d) because "the arguments presented to the

Examiner were unsupported attorney argument, whereas the Petition presents expert analysis and numerous exhibits related to how a person of ordinary skill in the art would interpret the teachings of” the prior art. IPR2017-01327, 2017 WL 6061841, at *7 (P.T.A.B. Dec. 6, 2017). The same is true here. There is no evidentiary support in the prosecution history for PO’s inventor and attorney arguments that the Examiner appears to have relied upon. (*See* Ex. 1002, 49, 147-148; Ex. 1052.) In contrast, “the Petition presents expert analysis and numerous exhibits related to how a person of ordinary skill in the art would interpret the teachings of” the prior art, particularly as it relates to the treatment of PE. *Shenzhen Kean Silicone Prod. Co.*, IPR2017-01327, 2017 WL 6061841, at *7.

Accordingly, Petitioner’s additional evidence beyond just Laub and Schaffer warrants reconsideration of the patentability of the ’910 patent and weighs against discretionary denial under *Becton, Dickinson* factor (f).

IV. CONCLUSION

For the foregoing reasons, Petitioner respectfully requests that the Director deny PO’s Request for Discretionary Denial and allow this IPR to proceed to an institution determination on the merits.

Dated: September 16, 2025

By: /Joshua J. Stowell/

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IPR2025-01025

Imperative Care, Inc. v. Inari Medical, Inc.

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CERTIFICATE OF COMPLIANCE

Pursuant to 37 C.F.R. § 42.24(d), the undersigned certifies that this **PETITIONER'S OPPOSITION TO PATENT OWNER'S REQUEST FOR DISCRETIONARY DENIAL** contains 5,821 words according to the word-processing program used to prepare this paper. The foregoing word count complies with the 14,000-word type-volume limit specified by the Interim Processes for PTAB Workload Management and 37 C.F.R. § 42.24.

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CERTIFICATE OF SERVICE

I hereby certify that, pursuant to 37 C.F.R. § 42.6(e), a true and correct copy of **PETITIONER'S OPPOSITION TO PATENT OWNER'S REQUEST FOR DISCRETIONARY DENIAL and EXHIBITS 1054-1055** was served electronically on September 16, 2025, to the e-mail addresses shown below:

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