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On behalf of **Imperative Care, Inc.**

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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 IPR2025-01021
Patent No. 11,969,333

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

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1002	’333 Patent Prosecution History
1003	Expert Declaration of Troy Thornton
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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. (“Lewis”)
1019	U.S. Patent No. 8,075,510 B2 to Aklog et al.
1020	WIPO Publication No. WO 2018/019829 A1 to Brady et al. (“Brady”)

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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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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)
1046	U.S. Patent No. 7,984,730 B2 to Ziv et al.

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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 <i>Cardiovasc. Revasc. Med.</i> 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 <i>Cardiovasc. Diagn. Ther.</i> 599-611 (2016)
1052	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)
1053	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)
1054	Decision Granting Institution of <i>Inter Partes</i> Review for U.S. Patent No. 11,554,005 (Paper 10) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-00289 (P.T.A.B. June 18, 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. 1052; Ex. 1053.) 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***, the primary reference for Petitioner’s invalidity Grounds 1A-1D and the secondary reference for Petitioner’s invalidity Grounds 3A-3D, was ***not*** of record during prosecution of the ’333 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”) or deep vein thrombosis (“DVT”) and (2) aspiration catheters having larger diameters.

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 *Schaffer*, a secondary reference for Petitioner's invalidity Grounds 1C-1D, 2C-2D, 3C-3D and 4C-4D, was *not* of-record during prosecution of the '333 patent. Schaffer describes features of the hemostasis valve recited in several of the challenged claims. The Board has preliminarily found that Schaffer discloses similar claim limitations in several instituted IPRs. (Ex. 1034; Ex. 1035; Ex. 1054.) Yet, PO ignores Schaffer in its Request. Because the Office did not consider Laub or Schaffer or the arguments raised in the Petition concerning those references, PO's Request fails under *Advanced Bionics*.

Further, even if Laub and Schaffer were substantially the same as some submitted prior art (they are not), PO's Request also fails under the second prong of *Advanced Bionics* because the Examiner materially erred in allowing the challenged claims. The Notice of Allowance demonstrates that the Examiner allowed the challenged claims based on an interview with the inventor. During that interview, the inventor argued that aspiration catheters for removing blood clots in the brain could not be used or combined with aspiration catheters for removing blood clots in other parts of the body such as the lungs (PE) or legs (DVT). The inventor also argued that the diameter of the catheters distinguished 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 DVT. 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, which rejected the original Claims 1-6, 11-14, 16-18, and 20-22 as obvious in view

of US 2018/0064453 A1 (“Garrison II”) (Ex. 1032)¹ in combination with US 2005/0054995 A1 (“Barzell”) (Ex. 1033) and US 8535283 B2 (“Heaton”) (Ex. 1011). (Ex. 1002, 156-173.) The Examiner found that Garrison II disclosed every limitation of the independent claim except: (1) a filter positioned within the clot canister and configured to filter blood from the clot material and (2) a flow path extending from the lumen of the aspiration catheter, through the clot canister, and to the aspiration source. (*Id.*, 157-159.) The Examiner cited Barzell for the filter and Heaton for the flow path. (*Id.*, 159-160.)

After the Non-final Rejection, PO amended the pending claims to recite methods of treating PE or DVT, and PO and Dr. Thomas Tu, one of the named inventors of the ’333 patent, conducted an interview with the Examiner. (*Id.*, 98-99.) According to the Examiner’s Interview Summary, Dr. Tu 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. (*Id.*, 99.) The Interview Summary stated that during the interview, PO “and Examiner agree[d] that incorporating more structural claim language, i.e.

¹ Garrison II is not in the same patent family as Garrison (Ex. 1006), which Petitioner relies upon for the invalidity grounds in the Petition. Garrison II does not disclose the embodiments of Garrison relied on in the Petition, or the disclosure regarding the rapid aspiration steps that are claimed in the ’333 patent. *Infra* §III.B.1.

diameter of the catheter, would make the claim 1 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 challenged claims of the ’333 patent after the interview, expressly relying on PO’s representations. (*Id.*, 46-47.) For example, the Examiner cited to PO’s representations during the interview to conclude 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 [II] device for the current methods.” (*Id.*) The Examiner stated that “Garrison [II] is configured for smaller neurovascular anatomy (see Abstract) and not configured for larger clot/embolisms” and that “it would not be reasonable to combine modified Garrison [II] with the device of Batiste [U.S. Patent Pub. No. 2018/0042623] because Garrison specifically teaches the aspiration catheter being used for neurovascular procedures.” (*Id.*) The Examiner did not cite to any evidentiary support for this conclusion beyond PO’s interview representations.

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 (Paper 5), 38.) Thus, in an effort to satisfy *Advanced Bionics*, PO argues that Laub is "substantially the same as and cumulative" to three prior art references that were before the Patent Office: (1) Aklog's parent, (2) Batiste, and (3) Gelbfish. (*Id.*, 38-45.) All three references disclose systems for aspirating blood clots, including PE and/or DVT. While these prior art references further confirm that the methods claimed in the '333 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" or to "aspirate blood from a patient's vein (e.g., right common femoral vein)." (Petition (Paper 1), 18, 63-65; Ex. 1012, [0005], [0025]; *see also* Ex. 1003, ¶173 (explaining that aspirating from right common femoral vein is method of treating DVT).) Laub

provides specific details about its aspiration system not found in the three 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 1), 43-45 (relying on this disclosure).) The catheter diameters described in Laub are *identical* to those claimed in the ’333 patent. (Ex. 1001, Claims 2-3, 18, 21-22, 37.) As an example, the ’333 patent claims “the aspiration catheter comprises inserting a catheter having a size of 16 French or greater through the vasculature.” (*Id.*, claim 2.)

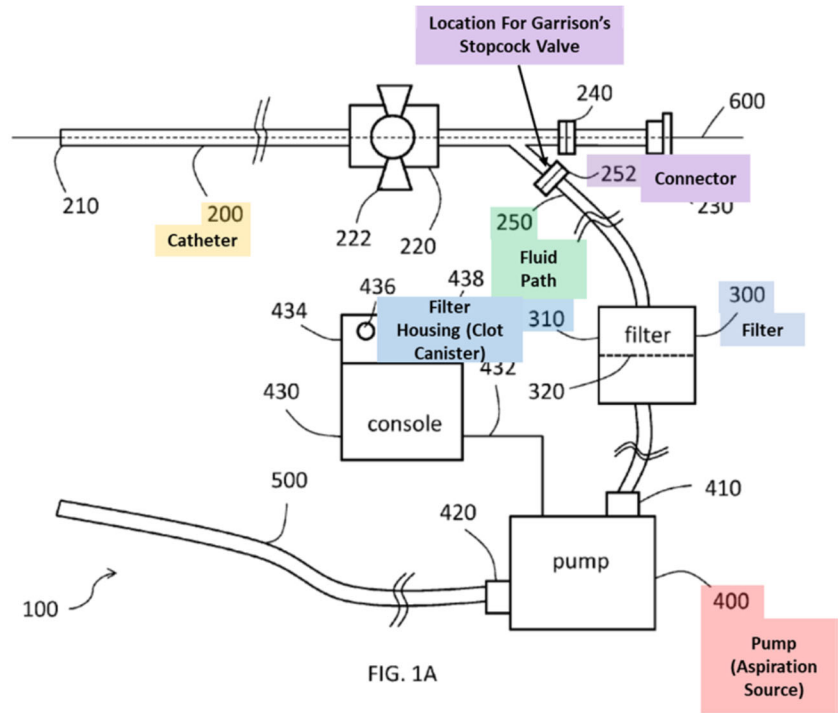
Further, the Examiner specifically cited catheter size as one reason for allowing the challenged claims. In the Applicant-Initiated Interview Summary, the Examiner expressly stated, “Attorney and Examiner agreed that incorporating more structural language, i.e. *diameter of the catheter*, would make the claim 1 allowable over the prior art Garrison.” (Ex. 1002, 99 (emphasis added).) 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., DVT) “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 1), 26 (relying on disclosure); Ex. 1003, ¶83; Ex. 1022, ¶38-41.) Thus, Laub directly rebuts the inventor arguments adopted by the Examiner during prosecution that “a pulmonary embolism or a deep vein thrombosis presents different structures and physiological responses compared to neurovascular clots.” (Ex. 1002, 46-47.) This express disclosure is unique to Laub.

Laub also describes several features that make it particularly suitable for combination with the other prior art references, including Garrison, Goff, and Schaffer. Petitioner relied on these features in its Petition. (Petition (Paper 1), 40, 51, 65-66.) These features are not found in the three references cited by PO in its Request.

First, Laub’s system includes a connector 252, which connects its aspiration catheter 200 to the fluid path 250 and “may allow detachment of fluid path 250 from aspiration catheter 200”:

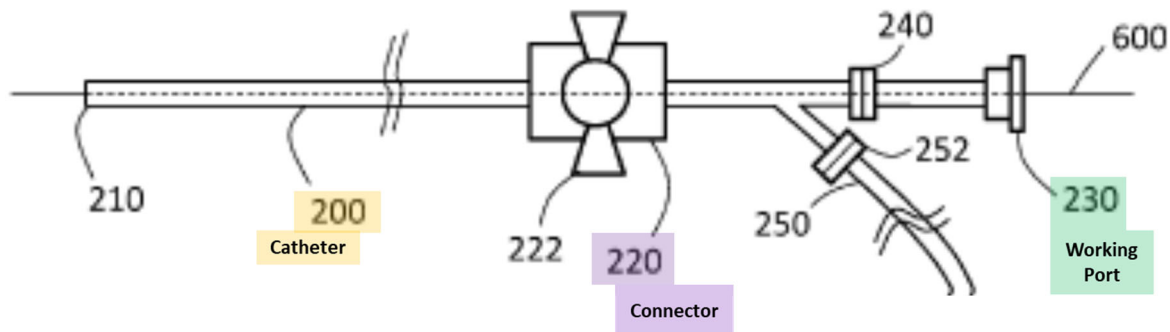


(Ex. 1012, [0039], Fig. 1.) As explained in the Petition, Laub’s connector provides a location for combining Garrison’s valve with Laub’s system. (Petition (Paper 1), 40.) Laub’s connector is located at a similar position to Garrison’s valve. (*Id.*) The combination would permit the user to control the fluid flow between the pump and aspiration catheter, a requirement of the challenged claims. (*Id.*) The three references cited by PO do not disclose a connector like Laub’s connector 252.

Second, several challenged claims require either removing a filter from within a clot canister or removing a portion of the aspirated clot material from clot canister. (Ex. 1001, claims 6-8, 25-27.) Laub specifically discloses these limitations. For example, Laub discloses passing the aspirated blood through a filter, where “the solid materials collected within housing 310 of filter 300 can then be subsequently

disposed of or retrieved for additional analysis.” (Ex. 1012, [0040]; *see* Petition (Paper 1) at 65-66 (relying on disclosure).) The three references cited by PO do not disclose retrieving the aspirated clot material from the filter for additional analysis as disclosed in Laub.

Third, several challenged claims require “selectively providing fluid access to the lumen of the aspiration catheter via a hemostasis valve fluidly coupled to the aspiration catheter.” (Ex. 1001, claims 10-12, 29-31.) Laub’s system includes a working port 230 that “allows insertion of instruments into and/or through the lumen of aspiration catheter 200”:



(Ex. 1012, [0035], Fig. 1A (excerpt); *see also* Petition (Paper 1), 51 (relying on disclosure).) Laub explains that its working port may be “configured to provide a fluid tight seal around stylet 700 or other device inserted through working port 230, for example, so as to prevent leakage of blood out of working port 230 during use,” such as by using a Tuohy-Borst adapter. (*Id.*, [0036].) Laub further discloses that the “working port 230 may include a valve to close working port 230 when not in use.” (*Id.*)

As explained in the Petition, a POSITA would have recognized that Laub's working port is a hemostasis valve. (Petition (Paper 1), 51.) As also explained in the Petition, Laub's disclosure of a hemostasis valve would have motivated a POSITA to combine other hemostasis valves, such as Schaffer, within Laub's working port. (*Id.*, 77-82.) None of the references identified by PO disclose a hemostasis valve for providing a seal around instruments inserted into their aspiration catheters like the valve disclosed in 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), 38.) In the Petition, Petitioner relied on Aklog in Grounds 2A-D and 4A-D. (Petition (Paper 1), 16.) Aklog was *not* of-record during prosecution of the '333 patent, but Aklog's parent was listed on an IDS with a total of 918 references. (Ex. 1002, 362-396.) 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), 38-48.) 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.*, 42.) 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 catheter diameter and system features. (*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, 362-396.) 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 or Gelbfish

PO cursorily argues that Laub is substantially the same as Batiste and Gelbfish, two references cited with the Notice of Allowance. (Request (Paper 5), 44-45.) PO notes that Batiste and Gelbfish both disclose aspiration catheters for treating PE and DVT and, based on that similarity alone argues the references are “substantially the same as” Laub. (*Id.*)

Yet, PO makes no attempt to identify any similarities between the aspiration systems in Batiste/Gelbfish 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. (Request (Paper 5), 44-45.) 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. Schaffer was not Of-Record During Prosecution of the '333 Patent

PO's Request ignores that Schaffer (Ex. 1013), which Petitioner relied upon for *eight* unpatentability grounds (Grounds 1C-D, 2C-D, 3C-D, 4C-D), was not of-record during prosecution.

Schaffer describes different types of hemostasis valves for use with catheters. (Petition (Paper 1), 78-81.) During prosecution of the '333 patent, the Examiner found certain claims allowable over the prior art because they recited a hemostasis valve having, among other things, "a tubular member" and a "filament." (Ex. 1002, 175.) Yet, Schaffer discloses hemostasis valves having these very features. (Petition (Paper 1) at §VIII.) In fact, the Board has preliminarily concluded that Schaffer discloses these limitations in several instituted IPRs. (Ex. 1034; Ex. 1035; Ex. 1054.)

For example, the chart below illustrates the similarities between claims 1 and 4 of the '011 patent (which are the subject of an instituted IPR) and claims 11-12 and 30-31 of the '333 patent:

'333 Patent – Claim 11 ²	'011 Patent – Claim 1
<p>11. The method of claim 10 wherein selectively providing fluid access to the lumen of the aspiration catheter includes decreasing a tension on a filament of the hemostasis valve thereby providing fluid access to the lumen of the aspiration catheter and increasing the tension on the filament to inhibit fluid access to the lumen of the aspiration catheter.</p>	<p>1. A valve, comprising: a tubular member defining a lumen configured to slidably receive a catheter; a constricting mechanism including at least one filament and an actuator coupled to the filament, the filament comprising a first portion extending around at least a portion of the tubular member and a second portion having a first end extending from the first portion in one direction and a second end extending from the first portion in another direction, and the actuator comprises a first member coupled to the first end of the filament and a second member coupled to the second end of the filament, wherein the first member and the second member of the actuator are moveable between (a) a first position wherein the filament circumferentially constricts the lumen to create a seal and (b) a second position wherein the filament is moved to at least partially open the lumen; and a biasing system configured to bias the first member and the second member to the first position.</p>

² Claim 30 of the '333 patent depends from claim 20 but otherwise recites identical limitations as claim 11.

'333 Patent – Claim 12 ³	'011 Patent – Claim 4
<p>12. The method of claim 11 wherein decreasing the tension on the filament includes depressing a button coupled to the hemostasis valve.</p>	<p>4. The valve of claim 1 wherein the first member of the actuator comprises a first button and the second member of the actuator comprises a second button, wherein the first button and the second button are undepressed in the first position, and wherein the first button and the second button are depressed in the second position.</p>

In addition to the '011 Patent IPR, the Board also preliminarily concluded that the combination of Garrison and Schaffer likely renders obvious claims 1 and 4 of U.S. Patent No. 11,554, 005, which is also assigned to PO and claims a similar aspiration system and hemostasis valve as claims 11-12 and 30-31 of the '333 patent. (Ex. 1054.) The chart below illustrates the similarity between claims 11-12 and 30-31 of the '333 patent and claims 1 and 4 of the '005 patent:

'333 Patent – Claim 1	'005 Patent – Claim 1
<p>1. A method of treating a pulmonary embolism within a vasculature of a patient, the method comprising: advancing an aspiration catheter at least partially through the vasculature of the patient such that a distal end portion of the aspiration catheter is positioned proximate to the pulmonary embolism, wherein a</p>	<p>1. A vacuum aspiration system, comprising: a housing; a flow path extending through the housing; an on-off control in the flow path; a first catheter in fluid communication with the flow path and a connector configured to place a</p>

³ Claim 31 of the '333 patent depends from claim 30 but otherwise recites identical limitations as claim 12.

'333 Patent – Claim 1	'005 Patent – Claim 1
<p>lumen of the aspiration catheter is fluidly coupled along a fluid path to a clot canister and an aspiration source proximal to the clot canister;</p> <p>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</p> <p>moving the valve from the first position to a second position thereby applying the vacuum pressure to the lumen of the aspiration catheter such that at least a portion of the pulmonary embolism and blood are aspirated into the clot canister, wherein in the second position the valve permits fluid flow along the fluid path from the lumen of the aspiration catheter to the clot canister, and wherein the clot canister includes a filter configured to filter the blood from the portion of the pulmonary embolism.</p>	<p>source of aspiration in communication with the flow path;</p> <p>a clot cannister fluidly coupled to the flow path; and</p> <p>a hemostasis valve in the housing configured to receive a second catheter and direct the second catheter through the first catheter, wherein the hemostasis valve comprises:</p> <p>a tubular member defining a lumen configured to slidably receive the second catheter;</p> <p>a constricting mechanism including a filament and an actuator coupled to the filament, the filament comprising a first portion extending around at least a portion of the tubular member and a second portion having a first end extending from the first portion in one direction and a second end extending from the first portion in another direction, and the actuator comprises a first member coupled to the first end of the filament and a second member coupled to the second end of the filament, wherein the first member and the second member of the actuator are moveable between (a) a first position wherein the filament circumferentially constricts the lumen to create a seal and (b) a second position wherein the filament is moved to at least partially open the lumen; and</p> <p>a biasing system configured to bias the first member and the second member to the first position.</p>

'333 Patent – Claim 11	'005 Patent – Claim 1
<p>11. The method of claim 10 wherein selectively providing fluid access to the lumen of the aspiration catheter includes decreasing a tension on a filament of the hemostasis valve thereby providing fluid access to the lumen of the aspiration catheter and increasing the tension on the filament to inhibit fluid access to the lumen of the aspiration catheter.</p>	<p>1. A vacuum aspiration system, comprising:</p> <ul style="list-style-type: none"> a housing; a flow path extending through the housing; an on-off control in the flow path; a first catheter in fluid communication with the flow path and a connector configured to place a source of aspiration in communication with the flow path; a clot cannister fluidly coupled to the flow path; and a hemostasis valve in the housing configured to receive a second catheter and direct the second catheter through the first catheter, wherein the hemostasis valve comprises: <ul style="list-style-type: none"> a tubular member defining a lumen configured to slidably receive the second catheter; a constricting mechanism including a filament and an actuator coupled to the filament, the filament comprising a first portion extending around at least a portion of the tubular member and a second portion having a first end extending from the first portion in one direction and a second end extending from the first portion in another direction, and the actuator comprises a first member coupled to the first end of the filament and a second member coupled to the second end of the filament, wherein the first member and the second member of the actuator are moveable between (a) a

'333 Patent – Claim 11	'005 Patent – Claim 1
	<p>first position wherein the filament circumferentially constricts the lumen to create a seal and (b) a second position wherein the filament is moved to at least partially open the lumen; and a biasing system configured to bias the first member and the second member to the first position.</p>

'333 Patent – Claim 12	'005 Patent – Claim 4
<p>12. The method of claim 11 wherein decreasing the tension on the filament includes depressing a button coupled to the hemostasis valve.</p>	<p>4. The vacuum aspiration system of claim 1 wherein the first member of the actuator comprises a first button and the second member of the actuator comprises a second button, wherein the first button and the second button are undepressed in the first position, and wherein the first button and the second button are depressed in the second position.</p>

In the '005 Patent IPR institution decision, the Board preliminarily agreed with Petitioner that a POSITA would have been motivated to combine Schaffer's hemostasis valve with Garrison's aspiration system. (*Id.*, 29.) Petitioner asserts a similar combination of Schaffer's hemostasis valve with the aspiration systems of Laub, Aklog, and Garrison in Grounds 1C-D, 2C-D, 3C-D, 4C-D of the Petition here. (Petition (Paper 1), 77-89.)

Accordingly, the institution decisions in the related IPRs confirm the relevance of Schaffer to several of the challenged claims. Yet, the Examiner did not have an opportunity to consider Schaffer during prosecution. For this additional reason, PO cannot satisfy the first prong of *Advanced Bionics* and this Request should be denied.

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

As shown above, the Examiner did not consider Laub or Schaffer during prosecution. The Examiner also did not consider the prior art combinations or arguments presented in the Petition, particularly those in Grounds 1A-D and 2A-D. For each of those grounds, Petitioner explains that it would have been obvious for a POSITA to incorporate Garrison’s valve and rapid aspiration method into the aspiration systems disclosed by Laub and Aklog. (Petition (Paper 1), 36-42.) PO fails to show that the Examiner considered these arguments during prosecution of the ’333 patent, 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 ’333 patent, the Examiner initially rejected the claims over the aspiration system taught by Garrison II in combination with a filter from Barzell and a flow path from Heaton. (Ex. 1002, 157-159.) PO then conducted

an interview and filed an amendment cancelling all pending claims and adding new Claims 23-60 (which issued as Claims 1-38). (*Id.*, 98-100, 109-115.) During the interview, PO argued that a POSITA would not have found it obvious to treat PE or DVT with the aspiration system in Garrison II because of “the differences between catheters used in cerebral occlusions vs. pulmonary embolisms and deep vein thrombosis.” (*Id.*, 98-100, 116.) The Examiner expressly relied on PO’s interview representations in allowing the claims, stating that “Garrison [II] is configured for smaller neurovascular anatomy (see Abstract) and not configured for larger clot/embolisms” and concluding that “therefore one skilled in the art would not have looked to use the Garrison [III] device for the current methods,” which expressly claimed treating PE or DVT.⁴ (*Id.*, 46-47.)

Thus, the Examiner considered whether Garrison II could be adapted for treating PE and DVTs (albeit on inaccurate information). But the Examiner never considered whether an existing aspiration system for treating PE and DVT, such as Laub or Aklog, could be modified to include each of the components required by the challenged claims. Thus, the Examiner never considered the arguments presented in Petitioner’s Grounds 1A-D and 2A-D.

⁴ As explained below, the Examiner’s conclusion, which was unsupported by evidence or explanation, was material error. (*Infra* §III.B.2.)

Accordingly, “the manner in which petitioner relies on the prior art” in Grounds 1A-D and 2A-D is materially distinct from the arguments previously considered by the Office. See *Advanced Bionics, Advanced Bionics* 2020 WL 740292 at *4 n. 10. 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 ’333 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 and DVT. (Ex. 1003, ¶¶78-88; 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 DVT, and the real-world use of smaller-diameter aspiration catheters for treating PE and DVT. (*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 [Turks and Thornton] Declaration[s] been presented to the Examiner during prosecution of the [’333] patent, there is a reasonable likelihood that the Examiner would have maintained the rejection of the claims of the [’333 patent], and that the [’333] 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 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 '333 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 Any of Petitioner's Prior Art

None of Petitioner's prior art references were mentioned by the Examiner during prosecution, much less asserted in a rejection. See *Becton, Dickinson & Co.*, 2017 WL 6405100, at *6 (factor (c)). Thus, to the extent any of Petitioner's prior art was considered by the Examiner, the Examiner overlooked the teachings of those references, and *Becton, Dickinson* factor (c) strongly weighs against discretionary denial.

As discussed above, Laub and Schaffer were never submitted to the Examiner during prosecution of the '333 patent, so there is no evidence that the Examiner evaluated any of Laub's or Schaffer's disclosures. (*Supra* §§III.A.1-2.)

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 918 references, and never discussed or asserted by the Examiner. (Ex. 1002, 362-396.) Two of Petitioner's other references, Goff and Hartley, were also listed on that same IDS form, and were similarly never discussed or asserted by the Examiner. (*Id.*) Thus, to the extent the Examiner "considered" Aklog, Goff, 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 asserts that “Garrison was extensively considered by the Patent Office” during prosecution but then admits that the “Garrison” reference that was asserted and discussed by the Examiner, Garrison II (Ex. 1032), is a *different* reference than the Garrison reference asserted in the Petition (Ex. 1006). (Request (Paper 5), 8.) Garrison and Garrison II are not from the same patent family, and they do not share the same disclosure. (*Compare* Ex. 1006 *with* Ex. 1032.) Garrison II

does not disclose any of the embodiments from Garrison relied upon in the Petition (i.e., the embodiments described in paragraph [0130]-[0134] and Figures 33-34). Garrison II also does not disclose the rapid aspiration method provided in Garrison, which involves generating vacuum pressure in the aspiration source “while the connection to the flow line is closed prior to the thrombectomy step of the procedure” and then opening the valve to “enable the maximum level of aspiration in a rapid fashion.” (Ex. 1006, [0134].) These are the exact steps recited in the challenged claims of the ’333 patent. (*See* Ex. 1001, claim 1; Petition (Paper 1), 36-42.) Thus, the Examiner never expressly evaluated or asserted the Garrison reference relied upon in the Petition, nor any of the relevant disclosures of Garrison, including Garrison’s disclosure of the aspiration steps recited in the challenged claims. (Ex. 1006, [0134]; Petition (Paper 1), 38.)

Despite the lack of discussion the relevant Garrison reference, PO argues that the Examiner “extensively considered” Garrison because PO listed a continuation application of Garrison on the agenda for an examiner interview. (Request (Paper 5), 9.) But the Examiner did not mention that Garrison continuation in the Interview Summary or the Notice of Allowance. (Ex. 1002, 46-47, 99.) As a result, there is nothing in the prosecution history evidencing that the Examiner evaluated or applied Garrison’s disclosures. Accordingly, like Aklog, Goff, and Hartley, the evidence shows that the Examiner overlooked Garrison’s descriptions, to the extent the

Examiner considered Garrison at all. *See, e.g., Bowtech, Inc.*, 2019 WL 3714325, at *4 (“We have consistently held that a reference that ‘was neither applied against the claims nor discussed by the Examiner’ does not weigh in favor of exercising our discretion under § 325(d).”).

Because the Examiner did not assert, or even discuss, any of the prior art raised in the Petition during prosecution of the ’333 patent, *Becton, Dickinson* factor (c) strongly weighs against discretionary denial. *Id.*

2. The Examiner Materially Erred in Assessing The Prior Art

Petitioner’s unpatentability grounds reflect at least two ways the Examiner of the ’333 patent materially erred in assessing the prior art, confirming that *Becton, Dickinson* factor (e) also weighs heavily against discretionary denial.

First, as explained above, the Examiner solely assessed whether a POSITA would have found it obvious to adapt or modify the aspiration system in Garrison II for treating PE or DVT. (*Supra* §III.A.3; Ex. 1002, 46-47, 156-176.) The Examiner did not consider the combination proposed in Petitioner’s Grounds 1A-D and 2A-D, which would have merely entailed incorporating Garrison’s valve and rapid aspiration method into the PE/DVT aspiration systems of Laub or Aklog. (Petition (Paper 1), 38-41.) The Examiner overlooked this simple combination during prosecution of the ’333 patent, which was material error.

Second, the Petition demonstrates that the Examiner materially erred in allowing the claims over Garrison based on the PE and DVT limitations. (Petition (Paper 1), 20-30.) As explained above, the Examiner relied solely on PO's unsupported and self-serving arguments regarding the alleged differences between cerebral aspiration procedures and PE/DVT. 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 both PE and DVT. (Petition (Paper 1), 26.) Thus, Garrison's catheters are appropriately sized to treat PE and DVT without modification. And to the extent any modification was necessary, 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.*, 24.) In fact, even the '333 patent itself acknowledges that aspiration systems could be used across different parts of the vasculature. (*Id.*, 25.) The Examiner does not appear to have considered 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 or DVT. (*See* Ex. 1002, 46-48.) As a

result, the Examiner materially erred in allowing the challenged claims of the '333 patent over Garrison.

Because of the material error committed during prosecution of the '333 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 Schaffer, 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 '333 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 '333 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 relied entirely upon PO's unsupported attorney argument and self-interested representations by the inventor in allowing the challenged claims. (*See* Ex. 1002, 46-47.) 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 attorney arguments regarding the “different structures and physiological responses” of PE/DVT and neurovascular clots that the Examiner relied upon. (*See* Ex. 1002, 46-47.)⁵ 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 and DVT. *Shenzhen Kean Silicone Prod. Co.*, 2017 WL 6061841, at *7.

Additional evidence presented in the Petition further weighs against discretionary denial. For example, the Petition presents secondary prior art references that evidence real-world aspiration devices with the features recited in the

⁵ The Examiner referenced “photographic evidence during the interview” in the Notice of Allowance, but no such evidence is included in the prosecution history. (Ex. 1002, 46-47.) It is therefore impossible for Petitioner to determine what type of photographs the Examiner’s statement might refer to or how they were represented by PO.

challenged claims, including a 26 Fr. catheter used to treat PE and pump canisters with significantly smaller volumes than clot canisters. (Petition (Paper 1), 44, 59 (citing Exs. 1049, 1038, 1039).)

Accordingly, Petitioner's additional evidence beyond just Laub and Schaffer warrants reconsideration of the patentability of the '333 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/

Joshua J. Stowell (Reg. No. 64,096)

Joseph R. Re (Reg. No. 31,291)

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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 7,599 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 37 C.F.R. § 42.24(a)(1).

Dated: September 16, 2025

By: /Joshua J. Stowell/

Joshua J. Stowell (Reg. No. 64,096)

KNOBBE MARTENS OLSON & BEAR, LLP

CERTIFICATE OF SERVICE

The undersigned hereby certifies that on the date below a copy of **PETITIONER'S OPPOSITION TO PATENT OWNER'S REQUEST FOR DISCRETIONARY DENIAL** and **EXHIBITS 1052-1054** is being served electronically on September 16, 2025 to the email addresses shown below:

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