

Filed October 17, 2025

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 No. IPR2025-01264
Patent No. 12,016,580

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

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1006	U.S. Patent Publication No. 2015/0173782 A1 to Garrison et al. (“Garrison”)
1007	U.S. Patent Publication US 2003/0225379 A1 to Schaffer et al. (“Schaffer”)
1008	U.S. Patent Publication No. 2003/0116731 A1 to Hartley (“Hartley”)
1009	U.S. Patent Publication No. 2015/0352325 A1 to Quick (“Quick”)
1010	U.S. Patent Publication No. 2010/0042118 A1 to Garrison et al.
1011	U.S. Patent No. 8,734,374 B2 to Aklog et al. (“Aklog”)
1012	U.S. Patent Publication No. 2017/0043066 A1 to Laub (“Laub”)
1013	U.S. Patent No. 6,776,770 B2 to Trerotola (“Trerotola”)
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1022	Expert Declaration of Dr. Aquilla S. Turk, III, DO
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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)
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1031	Decision Granting Institution of IPR, IPR2024-01157, U.S. Patent No. 11,697,011 B2
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1047	Redacted Excerpts of Deposition Transcript of PO's Expert Brian Brown dated August 27, 2024, submitted as Exhibit 1019 to R. Tyler Kendrick's Declaration in Support of Inari's Statement Regarding Truvic's Administrative Motion Pursuant to Civil L.R. 79-5(C)(1) & (F) (Dkt. #85-1) in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 24-cv-03117-EKL (N.D. Cal.) (filed February 26, 2025)
1048	Deposition Transcript of PO's Expert Paul Zalesky, Ph.D. dated June 23, 2025

I. INTRODUCTION

This is Patent Owner’s (“PO’s”) fifth Request for Discretionary Denial in these related IPRs. The Director has denied the previous four Requests. (Exs. 1042-1045.) In its first two Requests, PO sought discretionary denial under § 314(a). (Exs. 1042-1043.) 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 apply here with even more force because the Court recently stayed the litigation in view of Petitioner’s IPRs. (Ex. 1046.) In its next two Requests, PO abandoned its § 314(a) arguments and requested discretionary denial under § 325(d) as it has done in this IPR. (Exs. 1044-1045.) The Director denied PO’s Requests because they “present[ed] the same discretionary [denial] considerations” as those in PO’s first two Requests. (*Id.*) The same is true here. (*Id.*)

Like PO’s recently denied Requests in IPR2025-01021 (the ’333 patent IPR) and IPR2025-01025 (the ’910 patent IPR), PO’s current § 325(d) arguments fail under both prongs of *Advanced Bionics*. During prosecution of the ’580 patent, the Examiner did not substantively discuss **any** of the prior art references raised in the Petition. Further, several of the prior art references raised in the Petition were never disclosed to the Examiner.

For example, **Schaffer**, which discloses a hemostasis valve having the “attachment member” recited in all the challenged claims, was not before the

Examiner of the '580 patent. PO concedes that Schaffer was not of record during prosecution. However, PO argues that Schaffer is “substantially the same” as other submitted references. PO is incorrect. As shown below, Schaffer includes unique disclosure that renders the challenged claims invalid.

Similarly, **Laub** and **Aklog**, secondary references for Petitioner’s invalidity Grounds 9-14, were not of record during prosecution of the '580 patent. Laub and Aklog each disclose systems for aspirating blood clots, including clots in a patient’s pulmonary blood vessels (i.e., pulmonary embolisms) as recited in challenged Claim 10. PO does not address either reference in its Request.

Further, even if PO met the first prong of *Advanced Bionics* (it does not), PO’s Request still fails under the second prong of *Advanced Bionics* because the Examiner materially erred in allowing the challenged claims over the prior art, particularly Garrison. The Examiner allowed the challenged claims based on the method step requiring “pre-charging a vacuum in a pressure source” and applying “the pre-charged vacuum to the elongated shaft to aspirate a first portion of the clot material.” (Ex. 1002, 1050-1051.) However, as shown in the Petition, Garrison expressly discloses this step, along with every other step recited in the sole independent claim of the '580 patent. (Petition (Paper 1), 16-37.) The Examiner never applied, or even mentioned, Garrison during prosecution, likely because it was buried on an IDS form along with hundreds of other references. As shown below, the Examiner materially

erred in not applying Garrison’s disclosure when allowing the challenged claims, making discretionary denial inappropriate under *Advanced Bionics*’s 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 of the ’580 patent issued a single Non-final Office Action during prosecution, which allowed claims 21-31 and rejected claims 32-40. (Ex. 1002, 1044-1051.) For claims 21-31, the Examiner found that Quick (US 2015/0352325) (Ex. 1009) was the best prior art and that it disclosed every limitation except “pre-charging a vacuum in a pressure source and fluidly connecting the pressure source to the elongated shaft to apply the pre-charged vacuum to the elongated shaft to aspirate a first portion of the clot material into the elongated shaft.” (*Id.*, 1050-1051.) After the Rejection, PO cancelled claims 32-40 and added claims 41-63. (*Id.*, 701-705.) The Examiner then allowed the claims without further application of the prior art. (*Id.*, 679.)

Neither PO nor the Examiner substantively discussed any of the prior art references raised in the Petition during prosecution of the ’580 patent.

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 Gerate 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.

Id. 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. Schaffer Was Not Of Record During Prosecution

PO concedes that Schaffer (Ex. 1007), which Petitioner relied upon for *five* unpatentability grounds (Grounds 3, 5, 7, 11, 13), was “not cited to the Office” during prosecution of the ’580 patent. (Request (Paper 5), 2.) Schaffer describes different types of hemostasis valves for use with catheters. (Petition (Paper 1), 26-29.) Schaffer’s hemostasis valve includes the “attachment member” recited in all the challenged claims, as well as many additional limitations recited in the dependent claims (e.g., a “tubular member,” a “button,” and a “filament coupled to the button and the tubular member”). (*Id.*, 26-29, 37-40, 41-42, 46-58, 71, 78.) In fact, the Board has preliminarily concluded that Schaffer discloses these additional limitations in several instituted IPRs and that a POSITA would have been motivated to combine Schaffer’s hemostasis valve with Garrison’s aspiration system. (Ex. 1033, 29; Ex. 1031; Ex. 1032.) Accordingly, the institution decisions in the related IPRs confirm the relevance of Schaffer to the challenged claims. Yet, the Examiner did not have an opportunity to consider Schaffer during prosecution of the ’580 patent.

PO argues that Schaffer is cumulative of Garrison and Hartley, which were listed on IDS forms amongst hundreds of other references. (Request (Paper 5), 8-11.) However, PO ignores Schaffer’s unique disclosures that are relevant to the challenged claims. For example, Claims 6, 15-17, 23, and 29 each recite that

unsealing the attachment member involves actuating at least one button. (Ex. 1001, Claims 6, 15-17, 23, 29.) Schaffer's hemostasis valve in Figures 30-34 includes two actuator buttons on opposite sides of its housing that are depressed to unseal the valve. (Petition (Paper 1), 41-42.) While Garrison and Hartley disclose hemostasis valves, neither expressly discloses a valve with depressible buttons like Schaffer.

Moreover, the Examiner never mentioned or applied Garrison or Hartley. (Ex. 1002, 1091-1121.) Thus, even if Schaffer was substantially the same as Garrison or Hartley, PO has failed to show that factor (d) of the *Becton, Dickinson* factors favors discretionary denial. *Becton, Dickinson & Co. v. B. Braun Melsungen AG*, IPR 2017-01586, 2017 WL 6405100, at *6 (P.T.A.B. Dec. 15, 2017); *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.”).

Accordingly, Schaffer contains specific details about its hemostasis valve not found in Garrison or Hartley that are relevant to the obviousness combinations raised in the Petition. Therefore, PO cannot satisfy *Becton, Dickinson* factors (a) and (b). *See Advanced Bionics*, 2020 WL 740292 at *4.

2. Laub and Aklog Were Not Of Record During Prosecution

PO's Request also ignores that Laub (Ex. 1012) and Aklog (Ex. 1011), which Petitioner relies upon for Grounds 9-14, were not of record during prosecution of the '580 patent. Laub and Aklog disclose aspiration systems for aspirating blood clots from a patient's pulmonary vessels (i.e., pulmonary embolism), as recited in challenged Claim 10 of the '580 patent. (Petition (Paper 1), 81-90.) Accordingly, Laub and Aklog are further evidence 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 Schaffer, Laub, or Aklog 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").

Although some of Petitioner's asserted references were listed on IDS forms during prosecution, amongst hundreds of other references, neither PO nor the Examiner ever substantively discussed any of the references, including Garrison and Hartley, let alone the specific grounds raised in the Petition. Accordingly, PO

identifies no evidence showing that the Examiner considered Petitioner's prior art combinations or arguments, including (1) Petitioner's argument that Garrison discloses the "pre-charging" limitation that formed the basis for the Examiner's allowance and (2) Petitioner's argument regarding the combination of Garrison's aspiration system with the hemostasis valves disclosed in Schaffer and Hartley. (*See* Petition (Paper 1), 16-37.) Thus, *Becton, Dickinson* factor (d) weighs against discretionary denial, and the Director should therefore deny PO's request for this additional reason. *See, e.g., H-E-b, Lp v. Digital Retail Apps, Inc.*, IPR2020-00347, 2020 WL 3669643, at *4-5 (P.T.A.B. July 6, 2020) (finding that the office had not previously considered petitioner's prior art or arguments where reference was identified on an IDS but never asserted or discussed by the examiner); *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.”).

B. The Examiner Materially Erred In Allowing The Challenged Claims

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 ’580 patent over the prior art, particularly Garrison. 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, if the Examiner considered some of Petitioner’s prior art (e.g., Garrison or Hartley), the Examiner overlooked the teachings of those references, and *Becton, Dickinson* factor (c) strongly weighs

against discretionary denial. *See, e.g., 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 does not contest that the Examiner never mentioned or applied Garrison, or any of Petitioner’s other references, during prosecution of the ’580 patent. (*See* Request (Paper 5), 11-12.) Instead, PO argues that “the Examiner was aware of Garrison when allowing the claims of the ’580 Patent” because Garrison was asserted in a rejection during prosecution of a different, related application (the ’307 application) that was pending when the ’580 patent was allowed. (*Id.*) But the rejected claims of the ’307 application did **not** recite the limitation leading to allowance for the ’580 patent—pre-charging a vacuum in a pressure source. (Ex. 2001, 7-8.) Thus, allowance of the ’307 application does not resolve whether Garrison discloses the limitation. (*See id.*) Moreover, even if the ’307 application

showed that “the Examiner was aware of Garrison,” that would merely “emphasize the apparent error by the Examiner ... in overlooking [Garrison] in the examination of [the ’580 patent].” *Sonos, Inc. v. Google LLC*, IPR2023-00119, 2023 WL 5065201, at *9 (P.T.A.B. May 19, 2023). Accordingly, the prosecution of the ’307 application does not show that the Examiner evaluated Garrison during prosecution of the ’580 patent, and it does not support denying institution under § 325(d).

2. The Examiner Materially Erred In Assessing The Prior Art

Petitioner’s unpatentability grounds reflect that the Examiner of the ’580 patent materially erred in assessing the prior art, confirming that *Becton, Dickinson* factor (e) also weighs heavily against discretionary denial.

As explained above, the Examiner allowed the challenged claims of the ’580 patent based on a finding that the prior art did not disclose “pre-charging a vacuum in a pressure source and fluidly connecting the pressure source to the elongated shaft to apply the pre-charged vacuum to the elongated shaft to aspirate a first portion of the clot material into the elongated shaft.” (Ex. 1002, 1050-1051.) Yet, the Petition demonstrates that Garrison discloses this exact step, in addition to the other limitations of the sole independent claim. (Petition (Paper 1), 16-37.)

Specifically, Garrison discloses an embodiment where “a locking syringe (for example a VacLok Syringe) is attached to the flow controller and the plunger is pulled back into a locked position by the user *while the connection to the flow line*

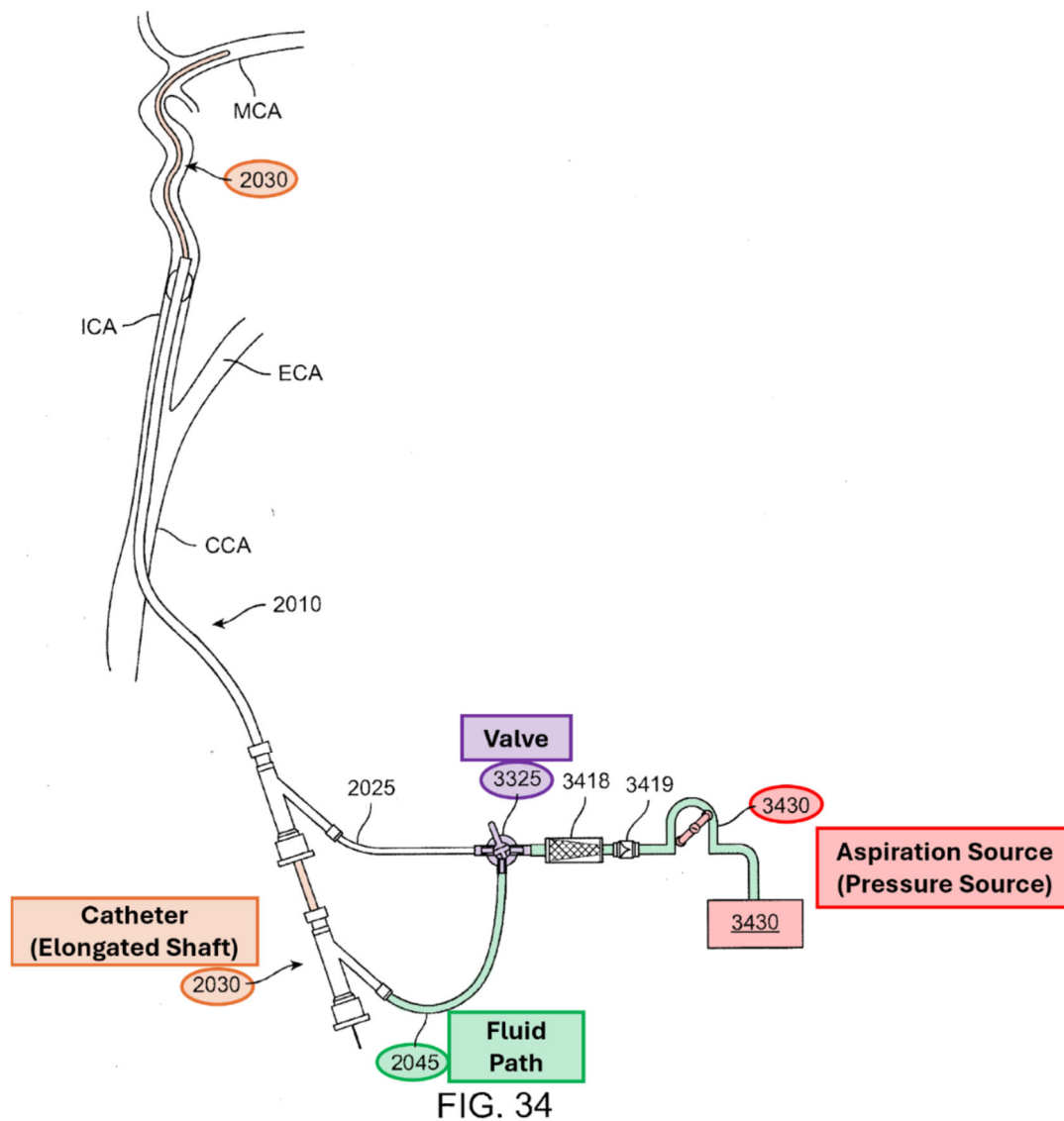
is closed prior to the thrombectomy step of the procedure.” (Ex. 1006, [0134] (emphasis added).) Garrison then explains that “when the tip of the aspiration device (either the arterial access device or the catheter) is near or at the face of the occlusion, the user may open the connection to the aspiration syringe [which] would enable the maximum level of aspiration in a rapid fashion with one user.” (*Id.*) Thus, Garrison expressly discloses the very step that the Examiner found was missing from the prior art, and the Examiner materially erred by overlooking that disclosure.

PO’s expert in the related district court litigation, Dr. Brian Brown, confirmed that Garrison discloses the step of pre-charging a vacuum in a pressure source that the Examiner found missing from the prior art. During his deposition, Dr. Brown agreed that Garrison discloses a “first pressure source [that] is configured to generate vacuum pressure while the fluid control device is in the closed position.” (Ex. 1047, 97:19-98:12.) Dr. Brown further agreed that Garrison discloses “upon movement of the fluid control device from the closed position to the open position, the vacuum pressure is applied to the first catheter to generate suction at a distal portion of the first catheter.” (*Id.*, 99:7-13.) In addition, in a related IPR filed by Petitioner, PO’s expert Dr. Paul Zalesky testified that between 1995 and 2005, he had witnessed aspiration procedures “where the plunger and the syringe would be pulled back with a stopcock in the closed position and then released ... presumably to apply an abrupt pressure change.” (Ex. 1048, 62:16-64:3.) The testimony from PO’s experts further

confirms that the “pre-charging” limitation was not novel, and that the Examiner materially erred in allowing the challenged claims based on that limitation.

Despite these admissions from its own experts, PO cursorily suggests that Garrison does not disclose pre-charging a vacuum, at least for the embodiment depicted in Garrison’s Figure 34. (Request (Paper 5), 14.) PO references its yet-to-be filed preliminary response and asserts that it plans to argue that “[G]rounds 1-4 require the mixing and matching of various embodiments of Garrison including combining the embodiments of Figures 2 and 34, with portions of a different embodiment in ¶[0134] that is not compatible with and thus would not include the claimed features.” (*Id.*, 14-15.) PO does not explain the basis for any of these arguments, and they are incorrect.

Petitioner does not “mix[] and match[]” any incompatible embodiments from Garrison. Paragraph 134 of Garrison describes an exemplary method of pre-charging a vacuum in the pressure source that is fully compatible with the aspiration system in Garrison’s Figure 34. For example, Figure 34 includes an aspiration source 3430 and a valve 3325 that can be positioned to close off the aspiration source from the aspiration catheters:



(Ex. 1006, [0132], Fig. 34 (annotations added by Petitioner).) Garrison explains that the valve in Figure 34 may alternatively be a “flow controller,” and it explains that the aspiration source in Figure 34 “may be an aspiration pump, a regular or locking syringe, a hand-held aspirator, hospital suction, or the like.” (*Id.*, [0132], [0134].) In other words, the aspiration system depicted in Figure 34 includes the exact same components used for the exemplary method described in paragraph 134 (i.e., a

locking syringe and a flow controller/valve). (*Id.*; Ex. 1003, ¶¶81-84.) There is nothing incompatible about these disclosures, and PO's unexplained argument to the contrary fails to justify discretionary denial under § 325(d).

Due to the Examiner's material error during prosecution of the '580 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

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

'580 patent. Therefore, *Becton, Dickinson* factor (f) also strongly weighs against discretionary denial

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 '580 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 the Examiner's mistaken conclusion that the prior art did not disclose the "pre-charging" step recited in the challenged claims. For example, Mr. Thornton explains how Garrison discloses that step along with every other limitation of the sole independent claim of the '580 patent. (Ex. 1003, ¶¶49, 74-117.) And Dr. Turk, a practicing physician with significant experience developing and performing aspiration procedures, explains:

One of the techniques my fellow surgeons and I have done since the early 2010s is to place a tube clamp on the tubing running from the aspiration catheter to the syringe or pump. We then pull back the syringe or turn on the pump to create negative pressure in the tubing before removing the tube clamp. This technique increases the suction immediately applied to the clot. The suction caused by the syringe or pump draws the clot into the catheter.

(Ex. 1022, ¶23.) Dr. Turk's declaration is consistent with the testimony of PO's expert, Dr. Zalesky, who testified to having witnessed similar procedures between 1995 and 2005. (Ex 1048, 62:16-64:3.)

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 ['580] patent, there is a reasonable likelihood that the Examiner would have maintained the rejection of the claims of the ['580 patent], and that the ['580] 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).

Accordingly, Petitioner's additional evidence beyond just Schaffer, Laub, and Aklog warrants reconsideration of the patentability of the '580 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: October 17, 2025

By: /Joshua J. Stowell/

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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 1042-1048** was served electronically on October 17, 2025, to the e-mail addresses shown below:

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