

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
U.S. Patent No. 12,016,580

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

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STATUTES

35 U.S.C. § 325(d)	1, 2, 4, 18
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	Petitioner's Exhibits
Exhibit	Description
1001	U.S. Patent No. 12,016,580 (“the ’580 patent”)
1002	’580 Patent Prosecution History
1003	Expert Declaration of Troy Thornton
1004	Resume of Troy Thornton
1005	WIPO Publication No. WO 2006/124307 A2 to Goff et al. (“Goff”)
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”)
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	Certified File History of U.S. Patent Application 10/371,190 (Schaffer File History)
1017	U.S. Provisional Patent Application No. 62/554,931 (the “’931 application”)
1018	U.S. Patent No. 6,481,439 B1 to Lewis et al.
1019	U.S. Patent No. 5,256,150 to Quiachon et al.

1020	WIPO Publication No. WO 2018/019829 A1 to Brady et al. (“Brady”)
1021	U.S. Patent No. 12,109,384 B2 to Merritt et al.
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)
1025	Bose, A et al., The Penumbra System: A Mechanical Device for the Treatment of Acute Stroke due to Thromboembolism, 29 Am. J. Neuroradiol. 1409-1413 (Aug. 2008)
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	Decision Granting Institution of IPR, IPR2024-01157, U.S. Patent No. 11,697,011 B2
1032	Decision Granting Institution of IPR, IPR2025-00156, U.S. Patent No. 11,697,012 B2
1033	Decision Granting Institution of IPR, IPR2025-00289, U.S. Patent No. 11,554,005 B2

1034	Merriam-Webster’s Collegiate Dictionary – Previously Submitted by Patent Owner as Ex. 2002 in IPR2024-00289 – Definition of “Loosen”
1035	U.S. Patent No. 7,998,104 B2 to Chang
1036	U.S. Patent No. 8,157,760 B2 to Craido et al.
1037	Plaintiff Inari’s Supplemental Preliminary Disclosure of Asserted Claims and Infringement Contentions Pursuant to Patent Local Rules 3-1 and 3-2 in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 5:24-cv-03117-EKL (N.D. Cal.)
1038	Case Management and Scheduling Order (Dkt. #54) in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 5:24-cv-03117-EKL (N.D. Cal.)
1039	Imperative Care, Inc.’s Notice of Motion and Motion to Stay Pending <i>Inter Partes</i> Review in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 5:24-cv-03117-EKL (N.D. Cal.)
1040	Order Regarding Case Schedule and Motion to Stay in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 5:24-cv-03117-EKL (N.D. Cal.)

	Patent Owner's Exhibits
Exhibit	Description
2001	Prosecution History Excerpt from U.S. Patent Application No. 17/865,307
2002	U.S. Patent No. 11,849,963 B2 to Quick ("Quick")

I. INTRODUCTION

Patent Owner requests that the Office exercise its discretion to deny the petition for IPR of U.S. Patent No. 12,016,580 (“the ’580 Patent”) (Paper 1) (hereinafter “Petition”) under 35 U.S.C. § 325(d) because “the same or substantially the same prior art or arguments” were previously considered by the Office. Specifically, the Petition’s primary reference for all grounds, Garrison, was identified in an Information Disclosure Statement submitted during prosecution and therefore considered by the Office. Indeed, of the four grounds 1-4 directed to the only independent claim, Claim 1, Garrison is the primary reference. Garrison is the only reference cited for grounds 1 and 2, and for grounds 3 and 4 Garrison is the primary reference in combination with Schaffer or Hartley, respectively.

Contrary to Petitioner’s implication that Garrison was buried in an IDS “with hundreds of other references” (Petition, p.4), while Garrison was not the subject of an Office action during prosecution of the ’580 Patent, at the same time the Examiner was examining the claims of the ’580 Patent Garrison was considered by that same Examiner in an Office action in a related application, U.S. Patent Application No. 17/865,307, which is a direct continuation of the ’580 Patent. Ex. 2001, pp.7-8. There, the Examiner specifically referenced many of the same paragraphs and figures of Garrison relied upon in the Petition here. *Id.* As such when the Office

allowed the claims of the '580 Patent, the Examiner was aware of and considered Garrison.

Hartley was also identified in an Information Disclosure Statement submitted during prosecution and therefore considered by the Office. And, while Schaffer was not cited to the Office, Schaffer is substantially cumulative of Hartley with respect to the sole limitation of Claim 1 for which Schaffer is applied—"unsealing an attachment member." Schaffer is also cumulative to the portion of Garrison relied upon in the Petition as purportedly disclosing that same limitation. More specifically, Petitioner relies on Schaffer for disclosing a hemostasis valve (an "attachment member" as Petitioner alleges) that can be unsealed, but also alleges that Garrison and Hartley individually disclose such a hemostasis valve without any argument as to why Schaffer's disclosure offers anything different. Therefore, for all grounds directed to the sole independent claim of the '580 Patent, the Petition relies on art that has already been considered by the Office or that is cumulative of other references considered by the Office. The Petition further fails to provide a sufficient basis to conclude that the Office erred in its previous analysis.

Grounds 5-14 address only dependent claims and thus include nothing that would rectify the deficiencies with respect to grounds 1-4, *i.e.*, grounds 5-14 raise nothing with respect to the independent Claim 1 that was not already considered by the Office.

Accordingly, because the Office has considered Petitioner's art and arguments, the Office should exercise its discretion here to deny considering the same art and arguments yet again.

II. ARGUMENT

A. Legal Standard.

The Board applies a "two-part framework" for evaluating whether to exercise discretion under Section 325(d) as set forth in *Advanced Bionics*:

1. whether the same or substantially the same art previously was presented to the Office or whether the same or substantially the same arguments previously were presented to the Office; and
2. if either condition of the first part of the framework is satisfied, whether the petitioner has demonstrated that the Office erred in a manner material to the patentability of the challenged claims.

Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH, IPR2019-01469, Paper 6, p.8, 2020 WL 740292, at *3 (P.T.A.B. Feb. 13, 2020) (hereinafter "*Advanced Bionics*"). As part of evaluating this framework, the Board analyzes the six factors identified in *Becton, Dickinson & Co. v. B. Braun Melsungen AG*, IPR2017-01586, Paper 8, pp.17-18, 2017 WL 6405100, at *6 (P.T.A.B. Dec. 15, 2017) (precedential as to §III.C.5, first paragraph) ("*Becton, Dickinson*"). The *Becton, Dickinson* factors are: (a) the similarities and material differences between the asserted art and the prior art involved during examination; (b) the cumulative nature

of the asserted art and the prior art evaluated during examination; (c) the extent to which the asserted art was evaluated during examination, including whether the prior art was the basis for rejection; (d) the extent of the overlap between the arguments made during examination and the manner in which a Petitioner relies on the prior art or a Patent Owner distinguishes the prior art; (e) whether a Petitioner has pointed out sufficiently how the Examiner erred in its evaluation of the asserted prior art; and (f) the extent to which additional evidence and facts presented in the petition warrant reconsideration of the prior art or arguments. *Becton, Dickinson*, Paper 8, pp.17-18.

The Board considers *Beckton, Dickinson* factors (a), (b) and (d) under the first part of the *Advanced Bionics* framework and *Beckton, Dickinson* factors (c), (e) and (f) to address the second part of the framework and determine whether the Office materially erred. *Advanced Bionics*, Paper 6, p.4. As set forth below, every factor favors denial.

In *Becton, Dickinson*, the Board denied institution under Section 325(d) because the base reference asserted by the Petitioner had already been considered by the Office in the same manner during the prosecution of the parent to the challenged patent. IPR2017-01586, Paper 8, p.28 (P.T.A.B. Dec. 15, 2017). That is the case here. The Board regularly denies institution where the examiners substantively addressed the cited art during prosecution. *See, e.g., Medtronic Corevalve LLC v.*

Speyside Med., LLC, IPR2021-00241, Paper 9 (P.T.A.B. July 23, 2021); *ZTE (USA) Inc. v. Fractus, S.A.*, IPR2018-01451, Paper 12 (P.T.A.B. Feb. 19, 2019).

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

Petitioner asserts grounds 1, 2, 3, and 4 for the sole independent Claim 1 of the '580 Patent based upon various combinations of Garrison, Schaffer, and Hartley. Specifically, Petitioner relies on Garrison alone for grounds 1 and 2, and Garrison in combination with Schaffer or Hartley for grounds 3 and 4, respectively. Petition, p.14. But the disclosure of Garrison and Hartley was considered by the Office. And, Schaffer is duplicative of both Garrison and Hartley.

Specifically, Garrison was (and related Garrison applications were) disclosed to the Office in an Information Disclosure Statement and appears on the face of the '580 Patent. Ex. 1001, p.6; Ex. 1002, p.1120. The Examiner signed the Information Disclosure Statement prior to issuing a notice of allowance. Ex. 1002, p.1122. Thus, the Office has considered Garrison, the primary reference relied on by the Petitioner for all grounds.

Similarly, the Office has already considered Hartley which was also identified in an Information Disclosure Statement and appears on the face of the '580 Patent. Ex. 1002, p.1102; Ex. 1001, p.5. So, of the four grounds directed to the sole

independent Claim 1, the Office has already considered all of the references cited for three of those four grounds, namely, grounds 1, 2, and 4.

Regarding ground 3, the Petitioner relies on a combination of Garrison and Schaffer. While Schaffer was not explicitly considered by the Office, it is cumulative of both Hartley and Garrison for the purpose that it is cited in the Petition. Petitioner relies on Schaffer for a single limitation in Claim 1 directed to “unsealing an attachment member.” *See* Petition, pp.26-27. But Petitioner relies on Garrison for disclosing that same limitation in grounds 1 and 2, and Hartley for disclosing that same limitation in ground 4, and makes no argument that is unique to the combination of Garrison and Schaffer that is different from Petitioner’s arguments regarding Garrison alone or the combination of Garrison with Hartley. *See* Petition, pp.23-31 (making the same arguments that each of Garrison, Hartley, and Schaffer individually disclose a hemostasis valve that can be unsealed to allow an instrument to be inserted therethrough). Petitioner does not explain why the disclosure of Schaffer is different from Garrison alone or Hartley in combination with Garrison to satisfy the limitation for ground 3 or how Schaffer provides any non-cumulative disclosure over Garrison and Hartley. Indeed, while Garrison, Schaffer, and Hartley disclose hemostasis valves that may operate differently and have different constructions, they each disclose a hemostasis valve that can be unsealed which is what Petitioner relies on those references as disclosing.

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

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

- a) **Garrison was considered by the Office.**

Petitioner relies on Garrison as the primary reference for grounds 1-4, the only grounds directed to the sole independent claim of the '580 Patent. But, Garrison was before the Office. Garrison was cited in an Information Disclosure Statement and appears on the face of the '580 Patent. Ex. 1001, p.6; Ex. 1002, p.1120. The citation of Garrison on a signed Information Disclosure Statement is sufficient to be considered previously for the purposes of 325(d) even absent substantive discussion of that reference by the Examiner or reliance upon it for an office action. *See* Decision Denying Institution of Inter Partes Review, *Nu Mark LLC v. Fontem Holdings I, B.V.*, IPR2016-01309, Paper 11, pp.6-8 (P.T.A.B. Dec. 15, 2016); *Benitec Biopharma Ltd. v. Cold Spring Harbor Lab'y*, IPR2016-00014, Paper 7, p.10 (P.T.A.B. Mar. 23, 2016) ("An Examiner's initials on an IDS form 'provides...a clear record in the application to indicate which documents have been considered by

the examiner in the application.”). Here, the Examiner signed the Information Disclosure Statement that identified Garrison. Ex. 1002, p.1122.

Accordingly, Garrison was considered during prosecution.

b) Hartley was considered by the Office.

For the same reasons as Garrison discussed above, the Office has already considered Hartley. Hartley was also identified in an Information Disclosure Statement and appears on the face of the '580 Patent. Ex. 1002, p.1102; Ex. 1001, p.5.

c) Schaffer's Disclosure Is Cumulative of Hartley and Garrison

While Schaffer was not considered by the Office during the prosecution of the '580 Patent, the disclosure of Schaffer relied upon in the Petition is substantially the same as and cumulative of both Garrison and Hartley, both of which were considered during prosecution.

Petitioner relies on Garrison for every limitation of independent Claim 1 in grounds 1 and 2, and in grounds 3 and 4 relies on Schaffer and Hartley, respectively, as allegedly also disclosing limitation [1D], directed to “unsealing an attachment member coupled to a proximal portion of the elongated shaft.” That “attachment member” can be a hemostasis valve. Ex. 1001, 10:62-65 (“[T]he attachment member 408 can further include a valve 445 ... [t]he valve 445 can be, for example, a

hemostasis valve ...”). As such, Petitioner is simply relying on Schaffer (or Hartley, or Garrison alone) for the disclosure of a hemostasis valve.

First, Petitioner relies on Garrison itself for the disclosure of a hemostasis valve that unseals. *See* Petition, pp.23-26. Schaffer’s disclosure of a hemostasis valve that operates to unseal is thus cumulative of that disclosure because Petitioner’s reliance on Garrison and Schaffer is the same—disclosure of a hemostasis valve that unseals—irrespective of how they are constructed or operate. Petitioner asserts as much stating that “Garrison describes ... ‘an adjustable-opening valve’ and that “Schaffer discloses an adjustable-opening valve.” *Id.* at p.27. While Petitioner goes into detail about the specific construction and operation of Schaffer’s valve, how Schaffer’s valve operates is not germane to Claim 1 of the ’580 Patent or Petitioner’s reliance on Schaffer as disclosing “unsealing an attachment member.” *Id.* at pp.26-27.

Second, because Hartley discloses another hemostasis valve that unseals and that Petitioner asserts could be combined with Garrison, Schaffer’s disclosure relied on in the Petition is cumulative of Hartley. Petition, pp.26, 29. There is no material difference in the use of Hartley and Schaffer asserted by the Petitioner. Petitioner’s reliance on Hartley and Schaffer is only for different options of a hemostasis valve (which Petitioner asserts Garrison already discloses) and that Petitioner contends a person of ordinary skill in the art could have used. Again, the details of the specific

operation and construction of Schaffer's valve which are different than the operation and construction of Hartley's valve are immaterial, and Petitioner does not assert that those differences are germane to the purported disclosure of "unsealing an attachment member." As such, Hartley and Schaffer serve substantially the same purpose, they are types of hemostasis valves that purportedly improve upon the hemostasis valve disclosed in Garrison. Indeed, Petitioner's grounds for each are nearly identical save for the images used and citations. *Compare* Petition, pp.26-29 with pp.29-31.

Put differently, Petitioner does not rely on any element or disclosure of Schaffer different from what Petitioner asserts Hartley discloses as evidenced by the combined argument regarding grounds 3 and 4 (Garrison in combination with Hartley or Schaffer) in which Schaffer or Hartley are both used to teach the same features in the combination with Garrison. And, although Petitioner contends a POSA would be motivated to combine Schaffer's valve with Garrison in ground 3, Petitioner does not explain why one would do so in any way that is relevant to the challenged claims that is different from the proposed combination of Garrison and Hartley in ground 4 or Garrison alone in grounds 1 and 2. Therefore, Schaffer is cumulative of the disclosure in Garrison and Hartley. And, both Garrison and Hartley were before the Office during prosecution, as explained above.

Accordingly, Petitioner's references for each of grounds 1-4 related to independent Claim 1 were either considered by the Office or are substantially the same as and cumulative of the references considered by the Office such that the first and second *Becton, Dickinson* factors weigh in favor of denial.

2. The fourth (d) *Becton, Dickinson* factor weighs in favor of denial because the Office substantively considered Garrison in related prosecution.

As explained in §II.B.1.a. above, Garrison was identified in an Information Disclosure Statement submitted by the Patent Owner and considered by the Examiner as demonstrated by the Examiner's signature on the Information Disclosure Statement. As such it was considered during examination.

Petitioner's implication that Garrison was overlooked because it was submitted in an Information Disclosure Statement "with hundreds of other references" (Petition, p.4) is incorrect. While Garrison was not the subject of an Office action during prosecution of the '580 Patent, at the same time the Examiner was examining the claims of the application that matured into the '580 Patent, Garrison was expressly considered by that same Examiner in an Office action in a related application, including specific reference by the Examiner to many of the same paragraphs and figures of Garrison relied upon in the Petition here. As such the Examiner was aware of Garrison when allowing the claims of the '580 Patent.

Specifically, U.S. Patent Application No. 17/865,307 (“the ’307 application”) issued as U.S. Patent No 11,849,963 and claims priority as a direct continuation to the application that issued as the ’580 Patent. Ex. 2002, p.1 (claiming priority to U.S. Patent Application No. 17/498,642, which issued as the ’580 Patent). During prosecution of the ’307 application the same Examiner as the ’580 Patent relied upon Garrison, including many of the primary embodiments and features of Garrison cited by Petitioner here. *See* Ex. 2001, pp.7-8, 11 (Primary Examiner Tuan V. Nguyen referencing Garrison Figures 2, 34, and ¶¶[0131]-[0132]).

That Office action was mailed on September 15, 2022. *See id.* at p.1. At the same time, the same Examiner was examining the ’580 Patent, which subsequently issued on June 25, 2024. Ex. 1001, cover page (“*Primary Examiner* — Tuan V Nguyen”). As such, the Examiner of the ’580 Patent was aware of and had substantively considered the disclosure of Garrison relied upon by Petitioner here. Yet, the Examiner did not reject the Claims of the ’580 Patent over Garrison.

For the foregoing reasons, in view of the overlap between the consideration of Garrison during examination and the manner in which Petitioner relies on Garrison, the fourth *Becton, Dickinson* factor weighs in favor of denial.

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

1. The third (c) *Becton, Dickinson* factor weighs in favor of denial because Petitioner's art, including Garrison used for all grounds, was evaluated by the Examiner.

As set forth in §II.B.2 above, the disclosure of Garrison was considered by the Office because it was cited in an Information Disclosure Statement and the Examiner was aware of the disclosure of Garrison relied upon in the Petition because Garrison was expressly considered in a related application. Yet the Examiner allowed the claims over Garrison. Further, Hartley was also identified to the Office via an Information Disclosure Statement and, as such, considered by the Examiner when allowing the claims at issue. And, Schaffer's relevant disclosure was also before the Office because it is substantially similar and cumulative of the disclosures of Garrison and Hartley as explained above in §II.B.1.b. Ex. 1002, p.1120.

That the Office did not expressly identify Garrison (or Hartley or Schaffer) as the basis for rejection during prosecution of the '580 Patent does not negate that the references were considered and the claims were allowed over those references.

Therefore, the third *Becton, Dickinson* factor weighs in favor of denial.

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

The fifth *Becton, Dickinson* factor concerns whether Petitioner has demonstrated the Examiner erred in evaluating the asserted prior art. *Advanced*

Bionics, IPR2019-01469, Paper 6, pp.10-11. Petitioner makes no such showing of error made during examination.

Petitioner's alleged error that the Office overlooked Garrison's disclosure because Garrison was submitted in an Information Disclosure Statement "with hundreds of other references" (Petition, p.4) is incorrect. As explained above, the same Examiner was aware of and expressly considered Garrison in related prosecution. Ex. 2001, pp.7-8, 11. Petitioner's disagreement with the Office allowing the Claims of the '580 Patent over Garrison is insufficient to demonstrate error.

Moreover, Petitioner asserts that the Examiner mistakenly overlooked Garrison's purported disclosure of "pre-charging a vacuum in a syringe (pressure source) connected to the aspiration catheter (elongated shaft) by pulling back the plunger on the syringe 'while the connection to the flow line is closed.'" Petition, pp.4-5. So, Petitioner asserts that a POSA would have included the "pre-charged" syringe in the embodiment of Figure 34. But, as explained above, the Examiner expressly considered Garrison during prosecution of a related application and was aware of that disclosure. And, as will be explained in Patent Owner's preliminary response, grounds 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. Petitioner's assertion that the Examiner overlooked that disclosure does not demonstrate clear error, and instead simply demonstrates Petitioner's disagreement with the Office allowing the claims over Garrison.

The Petition does not allege any error regarding the Office's consideration of Hartley, and thus also the cumulative disclosure of Schaffer, with respect to grounds 3 and 4.

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

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

The sixth *Becton, Dickinson* factor concerns whether Petitioner has presented additional evidence or facts warranting reconsideration. *Advanced Bionics*, IPR2019-01469, Paper 6, pp.10-11. Petitioner does not provide any evidence or facts or articulate any argument warranting a reconsideration of the Office's allowance of the claims. Petitioner submitted two declarations in support of its Petition (Ex. 1003 and Ex. 1022). The first "expert" declaration (Ex. 1003) is insufficient to demonstrate that the Examiner erred. *See Regeneron Pharmaceuticals, Inc. v. Kymab Ltd.*, IPR2019-01578, Paper 9, p.7 (P.T.A.B. Apr. 1, 2010) ("Petitioner asserts that Dr. DeFranco's Declaration is new evidence that was not previously before the Office and warrants 'serious consideration.' But the fact that an expert

declaration was not before the Examiner during prosecution does not itself demonstrate that the Examiner erred.”).

Moreover, Petitioner’s second “expert” declaration is from an individual who is Petitioner’s own Chief Medical Officer. Ex. 1022, ¶1 (“I am also the Chief Medical Officer of Imperative Care, Inc. (hereinafter referred to as ‘Imperative Care’ or ‘Petitioner’)”). And, Patent Owner has accused Petitioner of infringing the ’580 Patent in related litigation. Paper 4, p.2. So at minimum, Petitioner’s Chief Medical Officer has some level of self-interest in the outcome of this matter. As such, that self-interested declaration is also insufficient to warrant reconsideration of the Office’s allowance of the claims of the ’580 Patent over Petitioner’s references here.

The merits also favor denial. As will be explained in Patent Owner’s preliminary response, Garrison (and the combinations with Hartley and Schaffer) in grounds 1-4 require the mixing and matching of portions of various embodiments of Garrison in a manner that is not disclosed by Garrison or obvious over Garrison. Specifically, a POSA would not have combined the portions of the embodiments of Figures 2 and 34, with portions of a different embodiment in ¶[0134] that is both not compatible with the other embodiments and that would not include the claimed features.

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

III. CONCLUSION

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

Respectfully submitted,

Dated: September 17, 2025

By: / Joseph P. Hamilton /
Joseph Hamilton
Reg. No. 51,770
Lead Counsel for Patent Owner

CERTIFICATE OF COMPLIANCE

Pursuant to 37 C.F.R. § 42.24(d), I, Joseph Hamilton, certify that **Patent Owner's Request for Discretionary Denial** contains 3,659 words, excluding those portions identified in 37 C.F.R. § 42.24(a), as measured by the word-processing system used to prepare this paper.

Dated: September 17, 2025

By: / Joseph P. Hamilton /
Joseph Hamilton
Reg. No. 51,770

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), I certify that on September 17, 2025, a copy of **Patent Owner's Request for Discretionary Denial, and Exhibits 2001-2002** was served upon the below-listed counsel by electronic mail:

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Dated: September 17, 2025

By: / Kate Rose /
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