

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. IPR2025-01562
Patent No. 12,109,384

**PATENT OWNER'S REQUEST FOR
DISCRETIONARY DENIAL UNDER 35 U.S.C. § 325(d)**

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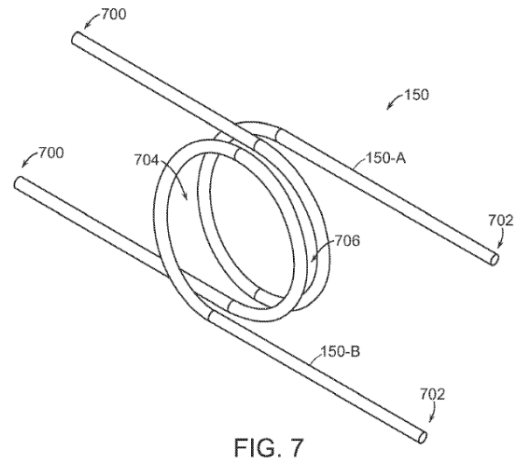
I. INTRODUCTION

Patent Owner requests that the Office exercise its discretion to deny the petition for IPR of U.S. Patent No. 12,109,384 (“the ’384 Patent”) (Paper 2) (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 for grounds 1-3 directed to the independent claims (*i.e.*, Claims 1, 15, and 23), each of the three references relied upon in the Petition, Schaffer (EX1005), Hartley (EX1006), and Eller (EX1007), were previously considered by the Office during prosecution of the ’384 Patent. The arguments relied upon by Petitioner for these three references are substantially the same as those already considered by the Office in issuing the ’384 Patent. The remaining grounds 4 to 6 relate to dependent claims and thus include nothing that would remedy the deficiencies with respect to grounds 1 to 3 or add anything material that was not already considered by the Office during prosecution of the independent claims.

While the Board has not exercised its discretion to deny a petition for IPR of a different but related patent, U.S. Patent No. 11,844,921 (IPR2025-00728, Paper 9, July 31, 2025), the Board should take a different approach here. First, the ’384 Patent’s claims at issue here include limitations not found in the claims challenged in the prior petition. And second, in contrast to the prior challenged Patent, all three of Petitioner’s references for grounds 1-3 were previously considered by the Office.

As such, the Office’s prior determination regarding discretionary denial is not relevant to the discretionary denial issues here.

For example, the ’384 Patent’s independent claims require two filaments, namely, “a first filament [configured/extending] in a first loop” and “a second filament [configured/extending] in a second loop.” EX1001, claims 1, 15, and 23. In Figure 7, right, the ’384 Patent discloses just that, reciting that “FIG. 7 is a perspective view of two filaments of a valve, each of the filaments forming a loop.” EX1001, 5:40-41.



Petitioner relies upon a single string in Hartley as purportedly disclosing both the first and second filaments configured/extending in first and second loops. Petitioner asserts that Harlley’s single string 14 discloses a “first filament” and a “second filament” as recited in independent Claims 1, 15, and 23 because, according to Petitioner, a “POSITA would have understood that Hartley’s string 14 would be formed from at least two threads twisted together” and that “[e]ach thread forming the string is a ‘filament.’” Petition, p.28. But, the Office concluded the opposite, explaining in the Notice of Allowance that Hartley “fails to disclose ... a second filament.” EX1002, p.20. Petitioner’s same arguments regarding Eller fail for the same reasons. Petition, p.42 (alleging that “the twisted ‘strands and/or fibers’

comprising Eller's wire member are each a flexible filament." Petitioner has provided no reason why the Office's prior finding constitutes material error or why the Board should second guess the Office's prior finding.

Accordingly, Patent Owner requests that the Board deny the Petition in the interest of efficacy and fairness under Section 325(d).

II. ARGUMENT

A. Legal Standard.

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

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

Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH, IPR2019-01469, Paper 6, p.8 (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 (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. 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.

1. The first (a) and second (b) *Becton, Dickinson* factors weigh in favor of denial because Petitioner’s asserted art is the same as the prior art previously considered by the Patent Office during examination.

Petitioner asserts grounds 1 to 3 for independent Claims 1, 15, and 23 of the ’384 Patent based upon various combinations of Schaffer and Hartley and/or Eller. Specifically, Petitioner relies on Schaffer in combination with Hartley for ground 1, Schaffer in combination with Eller for ground 2, and Schaffer in combination with Hartley and Eller for ground 3. Petition, p.19. But each of Schaffer, Hartley, and Eller was expressly considered by the Office.

First, Schaffer was identified by the Applicant in an information disclosure statement (“IDS”). EX1002, p.274. Schaffer also appears on the face of the ’384 Patent. EX1001, p.5. The citation of Schaffer 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 IDS that identified Schaffer. EX1002, p.61.

Hartley and Eller were also considered during prosecution. Both Hartley and Eller were identified in an IDS and appear on the face of the ’384 Patent. EX1002, pp.266-67; EX1001, pp.4-5. The Examiner also signed the IDS that identified Hartley and Eller. EX1002, pp.53-54. The Examiner substantively discussed Hartley and Eller in the Notice of Allowance identifying them as the “closest prior art of record” (such that these references appear on the face of the ’384 Patent with an “*” next to the patent document number, EX1002, pp.4-5) before finding that both references fail to “disclose the device” claimed in the Claims challenged here. EX1002, pp.20-21. The Examiner explained that Hartley “fails to disclose that the actuator is as a pair of actuators; a second filament” and that Eller “fails to disclose that the actuator is a pair....” *Id.* Therefore, the Office considered each of Hartley and Eller during prosecution. The Board regularly denies institution where the examiners substantively addressed the cited art during prosecution. *See, e.g.,*

Medtronic Corevalve, IPR2021-00241, Paper 9; *ZTE (USA) Inc. v. Fractus, S.A.*, IPR2018-01451, Paper 12 (P.T.A.B. Feb. 19, 2019).

Accordingly, each of Petitioner's references for grounds 1-3 directed to the independent Claims 1, 15, and 23 was expressly considered by the Office. Petitioner provides no reference for grounds 1-3 not 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 there is substantial overlap between Petitioner's arguments related to Schaffer, Hartley, and Eller and the positions considered by the Office when finding patentability.

Grounds 1-3 asserted by Petitioner rely on Schaffer in combination with Hartley or Eller alone or together. Petition, p.19.

Independent claims 1 and 15 recite "a first filament configured in a first loop" and "a second filament configured in a second loop." Similarly, independent claim 23 recites "a first filament extending in a first loop" and "a second filament extending in a second loop." In Figure 7 the '384 Patent discloses just that and recites that "FIG. 7 is a perspective view of two filaments of a valve, each of the filaments forming a loop." EX1001, 5:40-41.

Yet, despite Hartley disclosing only a single string 14, Petitioner asserts that string 14 discloses a "first filament" and a "second filament" as recited in independent Claims 1, 15, and 23 because a "POSITA would have understood that

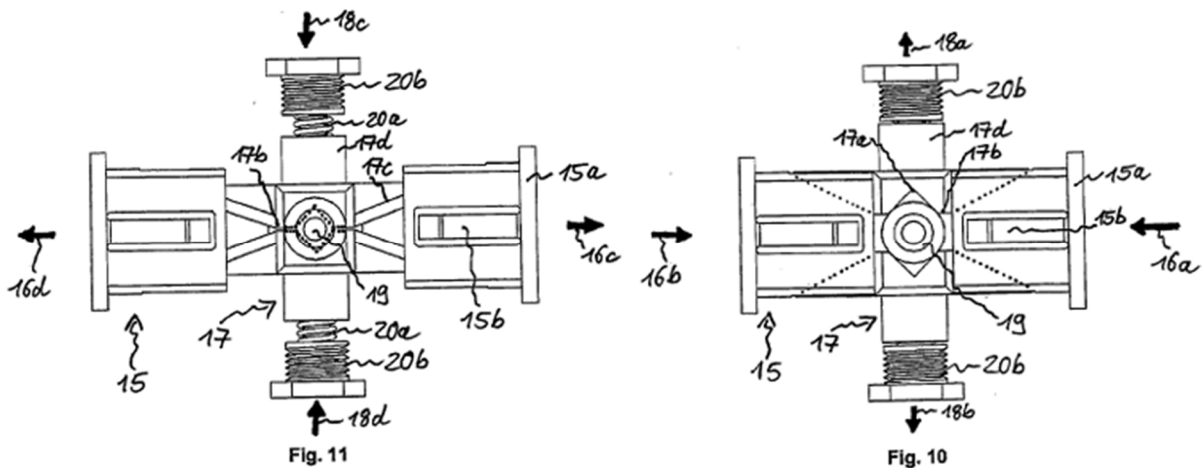
Hartley's string 14 would be formed from at least two threads twisted together" and that "[e]ach thread forming the string is a 'filament.'" Petition, p.28. But that argument is directly contrary to the Office's finding in the Notice of Allowance that Hartley "fails to disclose ... a second filament." EX1002, p.20.

The Petition makes the same argument regarding Eller, which as explained above, was also expressly considered by the Office in the Notice of Allowance. Petition, p.42 (alleging that "the twisted 'strands and/or fibers' comprising Eller's wire member are each a flexible filament."). As such, Eller fails to disclose the first and second filaments and first and second loops for the same reasons as Hartley. And, while Eller discloses multiple wires, as explained below the Examiner recognized Eller's disclosure, yet allowed the claims over Eller (and Schaffer and Hartley). *See, e.g.*, EX1007, FIGS. 8-10.

While the Examiner did not specifically discuss Schaffer in the Notice of Allowance, the Petition does not assert that Schaffer discloses the first and second filaments configured in first and second loops. Petition, p.26 ("Schaffer's filament configuration is slightly different from the filament configuration recited in claim 1."). Moreover, the Examiner identified Wong (EX1010), which discloses a substantially similar valve to Schaffer such that the Office not only considered Schaffer, but also expressly considered the combination of a reference similar to Schaffer with Hartley and Eller. EX1002, pp.20-21. Specifically, the Examiner

second position such that gases and fluids can pass therethrough as shown in Figure 34. *Id.* at ¶[0077].

Like Schaffer, Wong discloses a valve 13 having an elastic valve member 19, a pair of rigid actuating first sliders 15, and a pair of second sliders 17 each including a V-shaped groove 17a that is disposed about the elastic valve member 19:



EX2019, ¶[0042], [0052]. Two resilient members 20a (e.g., coil springs) bias the actuating first sliders 15 such that the second sliders 17 compress and seal the elastic valve element 19 in a sealed first position shown in Figure 11. *Id.* at ¶[0061]. Actuating the second sliders 15 moves the second sliders 17 against the biasing force of the resilient members 20a to permit the elastic valve element 19 to move to an unsealed second position such that gases and fluids can pass therethrough as shown in Figure 10. *Id.* at ¶[0060]. Accordingly, Wong's valve is substantially the same as Schaffer's valve for the purposes relied upon in the Petition:

<u>Disclosure of Schaffer</u>	<u>Substantially the Same Disclosure of Wong</u>
Stasis valve 10	Haemostatic valve 13
Seal module 100	Elastic valve element 19
Actuators 50	First sliders 15
Actuating members 55	Second sliders 17
Resilient members 267	Resilient members 20a
Biased, sealed first position of the stasis valve 10 shown in Figure 32	Biased, sealed first position of the haemostatic valve 13 shown in Figure 11
Unsealed second position of the stasis valve 10 shown in Figure 34	Unsealed second position of the haemostatic valve 13 shown in Figure 10

Like the Petitioner alleges here regarding Schaffer, the Examiner found that Wong disclosed “a pair of actuators 17/17d (see Figs. 10-11) movable from a first position (Fig. 11) to a second position (Fig. 10); in the first position, the actuators are positioned to tension, thereby constrict the lumen of the tubular member, Fig. 11; the second position, the actuators are positioned to loosen, thereby permitting the tubular member to expand, see Fig. 10.” EX1002, pp.20-21. And, the Examiner found that Wong did not disclose the claimed arrangements of the “first filament” and the “second filament” recited in independent Claims 1, 15, and 23. *Id.* at p.21.

So, the Examiner found Wong to disclose substantially the same features of Claims 1, 15, and 23 that Petitioner relies on Schaffer for.

Nevertheless, the Office did not issue any rejection on the basis of a combination of Wong with Hartley's single string or Eller's wire member(s) to arrive at the claims and instead allowed the claims over those references and Schaffer. That is, the Examiner did not conclude, as Petitioner asserts, that it would have been obvious to modify a valve like Schaffer (i.e., Wong's valve having a pair of actuators for compressing a tubular member but no filaments) to somehow include two of Hartley's strings or two of Eller's wire members, each forming loops in addition to the other claim limitations. Such a potential combination was insufficient to support a Section 103 rejection.

Accordingly, Petitioner's arguments with respect to grounds 1-3 relying upon Schaffer in combination with Hartley and/or Eller are substantially similar to the art and positions already considered and rejected by the Office such that the fourth *Becton, Dickinson* factor weighs in favor of denial, and supports a finding that the first part of the Advanced Bionics framework is satisfied.

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 the Office substantively evaluated Hartley, Eller, and at least one reference substantially the same as Schaffer.

As set forth above, Hartley and Eller were both explicitly discussed in the Notice of Allowance and appear on the face of the '384 Patent with a "*" next to the patent document. EX1002, pp. 20-21 (discussing Hartley and Eller); EX1001, p.4 (identifying Eller), p.5 (identifying Hartley). Specifically, in the Notice of Allowance, the Examiner identified Hartley and Eller as the "closest prior art of record." EX1002, p.20. Likewise, the Examiner expressly considered at least one reference that is substantially the same and cumulative of Schaffer. Wong discloses a tubular member and a pair of actuators movable to a first and second position wherein the lumen of the tubular member is constricted at one position and loosened in the other. *See* EX1002, pp.20-21. Thus, the Office substantively considered Hartley and Eller, along with Wong which is substantially the same as Schaffer. Therefore, the third *Becton, Dickinson* factor weighs in favor of denial.

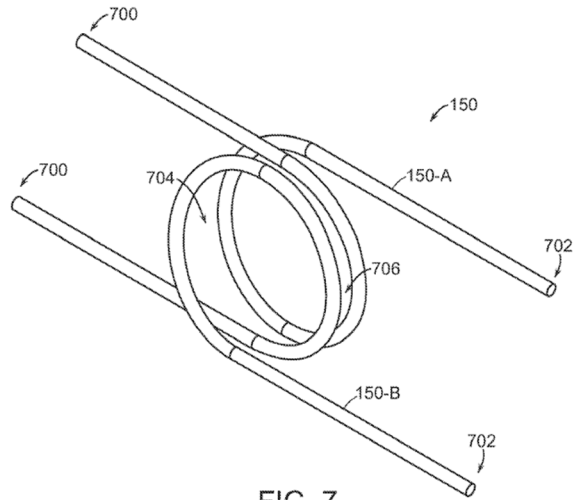
2. The fifth (e) *Becton, Dickinson* factor weighs in favor of denial because Petitioner makes no showing of error.

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

Bionics, IPR2019-01469, Paper 6, pp.10-11. “[I]f the alleged error is a disagreement with a specific finding of record by the Office, then ordinarily the petitioner’s required showing of material error must overcome persuasively that specific finding of record.” *Id.* Petitioner makes no such showing that the Examiner erred in evaluating or overlooked any disclosure in Schaffer, Hartley, or Eller—which were each cited by the Applicant in an IDS and before the Office—during examination.

As explained above, despite Hartley disclosing a string 14, Petitioner asserts that string 14 discloses a “first filament” and a “second filament” as recited in independent Claims 1, 15, and 23 because a “POSITA would have understood that Hartley’s string 14 would be formed from at least two threads twisted together” and that “[e]ach thread forming the string is a ‘filament.’” Petition, p.28. The Petition makes the same argument with respect to Eller. Petition, p.42. But that argument is directly contrary to the Office’s finding in the Notice of Allowance that Hartley “fails to disclose ... a second filament.” EX1002, p.20.

Moreover, independent claims 1 and 15 recite “a first filament configured in a first loop” and “a second filament configured in a second loop.” Similarly, independent claim 23 recites “a first filament extending in a first loop” and “a second filament extending in a second loop.” In Figure 7, right, the '384 Patent discloses just that, reciting that “FIG. 7 is a perspective view of two filaments of a valve, each of the filaments forming a loop.” EX1001, 5:40-41.



Petitioner’s reliance on the '384 Patent’s claim 6 is misplaced. Petition, p.28. Claim 6 recites “the valve assembly of claim 1 wherein the first filament and the second filament each comprise a plurality of strands woven together.” That claim does not mean that a single string made up of twisted or woven fibers constitutes both the first and second filament and first and second loops. To the contrary, claim 6 distinguishes the first and second filaments because “each comprise a plurality of strands woven together.” And, Petitioner’s assertion that it would be obvious to include “a first filament [configured/extending] in a first loop” and “a second filament [configured/extending] in a second loop” as recited in the independent Claims just because its expert says so is insufficient to demonstrate material error.

And as explained above, Petitioner’s arguments regarding Eller fail to demonstrate a material error for the same reasons.

Similarly, that the ’384 Patent discloses that “the filament can comprise a single strand such as, for example, a monofilament, and in some embodiments, the filament can comprise a plurality of strands that can be, for example, twisted, woven, grouped, and/or fused to form the filament” (EX1001, 9:17-21) does not mean that a single string even if manufactured from multiple twisted strands discloses “a first filament [configured/extending] in a first loop” and “a second filament [configured/extending] in a second loop” as recited in the independent Claims.

Finally, Petitioner ignores the similarities between Schaffer and the prior art discussed by the Examiner in the Notice of Allowance, including Wong which is substantially the same and cumulative of Schaffer’s disclosure as addressed above. And, Petitioner ignores that the Examiner expressly recognized the disclosure of Hartley’s string and Eller’s multiple wires in view of Wong. Petitioner fails to make any showing as to how the Examiner’s express analysis of Wong in view of Hartley and Eller was erroneous or that the examiner overlooked any disclosure of Schaffer, Hartley or Eller.

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’s mere submission of an expert report in support of its petition does not provide such evidence. *See Regeneron Pharms., Inc. v. Kymab Ltd.*, IPR2019-01578, Paper 9, p.15 (P.T.A.B. Apr. 1, 2020) (“Petitioner asserts that Dr. DeFranco’s Declaration is new evidence that was not previously before the Office and warrants ‘serious consideration.’...But the fact that an expert declaration was not before the Examiner during prosecution does not itself demonstrate that the Examiner erred.”).

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

III. CONCLUSION

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

Respectfully submitted,

Dated: November 26, 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** is limited to 20-pages.

Dated: November 26, 2025

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

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), I certify that on November 26, 2025, a copy of **Patent Owner's Request for Discretionary Denial** was served upon the below-listed counsel by electronic mail:

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Dated: November 26, 2025

By: / Kate Rose /
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Senior Paralegal