

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. IPR2025-00728
U.S. Patent No. 11,844,921

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

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Petitioner’s Exhibits	
Exhibit	Description
1001	U.S. Patent No. 11,844,921 (“the ’921 Patent”)
1002	’921 Patent Prosecution History Excerpt
1003	Expert Declaration of Troy Thornton
1004	Resume of Troy Thornton
1005	U.S. Patent Publication US 2003/0225379 A1 to Schaffer et al. (“Schaffer”)
1006	U.S. Patent Publication US 2003/0116731 A1 to Hartley (“Hartley”)
1007	U.S. Patent No. 9,980,813 B1 to Eller (“Eller”)
1008	Certified File History of U.S. Patent Application 10/371,190 (Schaffer File History)
1009	U.S. Patent No. 5,429,616 to Schaffer (“Schaffer ’616”)
1010	U.S. Patent No. 3,438,607 to Williams et al.
1011	U.S. Patent Publication US 2015/0173782 A1 to Garrison et al. (“Garrison”)
1012	U.S. Patent No. 11,697,011 (“the ’011 patent”)
1013	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).
1014	Google Dictionary Definition of “String”
1015	Cambridge Dictionary Definition of “String”
1016	U.S. Patent No. 12,109,384 B2 to Merritt et al.

1017	Decision Granting Institution of <i>Inter Partes</i> Review of 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)
1018	PCT Patent Publication WO 2018/019829 A1 to Brady et al.
1019	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)
1020	U.S. Patent No. 6,776,770 B2 to Treretola
1021	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)

Patent Owner's Exhibits	
Exhibit	Description
2001	Complaint for Patent Infringement in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 5:24-cv-03117-EKL (N.D. Cal.), Dkt. 1
2002	First Amended Complaint for Patent Infringement in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 4:24-cv-03117-YGR (N.D. Cal.), Dkt. 20
2003	Second Amended Complaint for Patent Infringement in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 5:24-cv-03117-EKL (N.D. Cal.), Dkt. 68
2004	Third Amended Complaint for Patent Infringement in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 5:24-cv-03117-EKL (N.D. Cal.), Dkt. 112
2005	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.), Dkt. 100
2006	Motion For Preliminary Injunction in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 5:24-cv-03117-EKL (N.D. Cal.), Dkt. 24
2007	Opposition to Motion for a Preliminary Injunction in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 5:24-cv-03117-EKL (N.D. Cal.), Dkt. 36
2008	Corrected Opposition to Motion for a Preliminary Injunction in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 5:24-cv-03117-EKL (N.D. Cal.), Dkt. 40
2009	Stipulated Protective Order in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 5:24-cv-03117-EKL (N.D. Cal.), Dkt. 76
2010	Joint Letter Brief Concerning Plaintiff's Motion to Compel Production of Materials Relating to Defendant's Blood Return System in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 5:24-cv-03117-EKL (N.D. Cal.), Dkt. 94

2011	Order Re Inari Medical’s Motion to Compel Production of Materials in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 5:24-cv-03117-EKL (N.D. Cal.), Dkt. 105
2012	Imperative Care, Inc.’s Preliminary Invalidity Contentions and Document Production Accompanying Invalidity Contentions Pursuant to Patent Local Rules 3-3 and 3-4 (omitting accompanying claim charts) in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 5:24-cv-03117-EKL (N.D. Cal.)
2013	Imperative Care, Inc.’s Preliminary Invalidity Contentions and Document Production Regarding U.S. Patent Nos. 12,109,384 and 12,156,669 Pursuant to Patent Local Rules 3-3 and 3-4 (omitting accompanying claim charts) in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 5:24-cv-03117-EKL (N.D. Cal.)
2014	Al-Salam Letter to Truvic (September 29, 2023)
2015	Declaration of Joseph P. Hamilton (April 28, 2025)
2016	Minute Entry for Proceedings Held Before Judge Eumi K Lee in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 5:24-cv-03117-EKL (N.D. Cal.), Dkt. 110
2017	Minute Entry for Proceedings Held Before Judge Eumi K Lee in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 5:24-cv-03117-EKL (N.D. Cal.), Dkt. 111
2018	U.S. Patent Publication US 2008/0087853 A1 to Kees (“Kees”)
2019	U.S. Patent Publication US 2011/0144592 A1 to Wong et al. (“Wong”)
2020	Notice of Allowance Issued in U.S. Patent Application No. 16/117,519 (January 27, 2021)
2021	Inari's Reply in Support of Motion for Preliminary Injunction in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 5:24-cv-03117-EKL (N.D. Cal.), Dkt. 46
2022	Inari's Report Regarding Claim Construction Schedule and Claim Narrowing in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 5:24-cv-03117-EKL (N.D. Cal.), Dkt. 116
2023	Imperative Care, Inc.'s Proposed Schedule for Claim Construction and Narrowing Asserted Patents and Claims in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 5:24-cv-03117-EKL (N.D. Cal.). Dkt. 117

I. INTRODUCTION

Patent Owner requests that the Office exercise its discretion to deny the above-referenced petition for IPR of U.S. Patent No. 11,844,921 (Paper 1) (hereinafter “Petition”) under 35 U.S.C. § 314(a) in view of a parallel district court litigation, and under 35 U.S.C. § 325(d), because “the same or substantially the same prior art or arguments” were previously presented to the Office.

In the parallel district court proceeding, the merits of validity issues relating to the ’921 Patent have already been extensively presented to the district court in the context of a preliminary injunction motion that is fully briefed, argued, and awaiting a decision. Institution here will necessarily result in duplication of much of that effort, including deposition of the same experts from both parties. And in addition to the work already complete related to the preliminary injunction motion, in the parallel district court proceeding Petitioner has raised the same invalidity challenges to US11,844,921 (“the ’921 Patent”) based on Schaffer, Hartley and/or Eller, and also asserted those same and additional invalidity challenges for several patents related to the ’921 Patent. Thus, there is near complete overlap between issues raised in the Petition and in the parallel district court proceeding, including the same and substantially similar claims and arguments. The district court and parties may be forced to address these issues regardless of the outcome here. In view of that overlap, both the district court and the parties have and will continue to invest substantial

time and resources in the parallel district court proceeding, including on the same or similar issues.

Moreover, in the parallel proceeding Patent Owner currently asserts eleven patents, including the '921 Patent. EX2004, ¶5. Petitioner waited almost a year to file most of its IPR petitions and, even today, has filed such petitions for only seven of the eleven asserted patents (EX2005, p.4), with one of those IPR petitions having already been denied. *See* IPR2024-01257, Paper 10, p.31 (P.T.A.B. Feb. 7, 2025) (denying institution because “Petitioner has not demonstrated a reasonable likelihood that it will prevail in establishing the unpatentability of any of the challenged claims....”). So, of the eleven patents currently at issue in the district court litigation, there is only one instituted IPR.¹

Second, the same or substantially the same prior art or arguments set forth in the Petition were previously presented to the Office. Specifically, of the three references relied upon in the Petition, the Office considered both references for grounds 5 to 7, namely, Hartley and Eller, during prosecution. And for the third

¹ IPR have been instituted on two patents: U.S. Patent Nos. 11,697,011 and 11,697,012. The '011 Patent is, however, no longer at issue in the district court proceeding, leaving only the '012 Patent as the sole overlapping patent for which IPR has been instituted.

reference, Schaffer, relied upon in grounds 1-4 either alone or in combination with Hartley and Eller, although Schaffer was not specifically considered by the Office, multiple other references that teach substantially the same as Schaffer were considered. And, all three references (Schaffer, Hartley, and Eller) have been considered in a continuation application related to the '921 Patent, with that continuation patent issuing over that art.

While the Board recently did not exercise its discretion to deny a petition for IPR of a different Patent Owner patent, U.S. Patent No. 11,554,005 (*see* IPR2025-00289, Paper 9 (P.T.A.B. June 12, 2025)), the Board should take a different approach here. This Petition involves a patent (the '921 Patent) that is the subject of Patent Owner's pending preliminary injunction motion for which Petitioner delayed far longer (an additional four months, despite the pending preliminary injunction motion) to file its Petition.

Accordingly, Patent Owner requests that the Board deny the Petition in the interest of efficiency and fairness under either Section 314(a) or Section 325(d).

II. PARALLEL DISTRICT COURT LITIGATION FAVORS DENIAL UNDER 35 U.S.C. § 314(a)

The Office considers numerous factors when analyzing whether to discretionarily deny a petition under Section 314(a) in view of a parallel proceeding. *See Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11, p.6, 2020 WL 2126495, at

*2 (P.T.A.B. Mar. 20, 2020) (precedential) (considering (a) “whether the court granted a stay or evidence exists that one may be granted if a proceeding is instituted;” (b) “proximity of the court’s trial date to the Board’s projected statutory deadline for a final written decision;” (c) “investment in the parallel proceeding by the court and the parties;” (d) “overlap between issues raised in the petition and in the parallel proceeding;” (e) “whether the petitioner and the defendant in the parallel proceeding are the same party;” and (f) “other circumstances that impact the Board’s exercise of discretion, including the merits.”). Those factors, on balance, weigh heavily in favor of denial.

Additionally, the Office’s recent guidance identifies other considerations relevant to discretionary denial beyond those traditionally considered. *See, e.g.*, FAQs for Interim Processes for PTAB Workload Management, at No. 20 (<<
https://www.uspto.gov/patents/ptab/faqs/interim-processes-workload-management?utm_campaign=subscriptioncenter&utm_content=&utm_medium=email&utm_name=&utm_source=govdelivery&utm_term=>>>) (last visited June 16, 2025) (“Parties are encouraged to address any fact or circumstance they believe bears on whether the Office should or should not institute trial, including reasons not discussed in current Board precedent or the Process Memorandum.”) (hereinafter “FAQs for Interim Processes for PTAB Workload Management”). On balance, the *Fintiv* factors and these additional considerations favor discretionary denial.

A. No Stay of the Parallel District Court Litigation.

The first *Fintiv* factor is neutral. “[A]bsent a stay of the related litigation and no indication based on evidence in the record that it will be stayed, this factor is neutral.” *U.S. Venture, Inc. v. Sunoco Partners Mktg. & Terminals L.P.*, No. IPR2020-00728, Paper 10, p.8, 2020 WL 5848121, at *3 (P.T.A.B. Oct. 1, 2020).

Here, the district court has not granted a stay, and there is no evidence that it will grant one. In fact, Petitioner made a tactical decision to wait almost a year after the litigation was filed to only recently move for a stay on April 2, 2025, based upon this and other IPR petitions, including Petitions that Petitioner waited until the end of the period it could statutorily file and others that it has not yet filed. *See* EX2005, p.1 (“Imperative Care has filed or will file IPRs against all asserted claims”); *id.* at p.4 (Petitions filed for seven of eleven asserted patents). Petitioner noticed the motion to stay for a hearing for July 16, 2025, so that motion will not even be heard for another month. *See id.*, caption page.

Courts, including in the Northern District of California, are particularly reluctant to grant stays where, as is the case here, the parties are direct competitors or where the plaintiff is seeking a preliminary injunction. *See Verinata Health, Inc. v. Ariosa Diagnostics, Inc.*, No. 12-cv-05501 SI, 2014 WL 121640, at *3 (N.D. Cal. Jan. 13, 2014) (denying motion for stay, despite institution of IPRs on both patents, because, in part, “[c]ourts are generally reluctant to stay proceedings where the

parties are direct competitors”) (quoting *Boston Sci. Corp. v. Cordis Corp.*, 777 F. Supp. 2d 783, 789 (D. Del. 2011)); *Avago Techs. Fiber IP (Sing.) Pte. Ltd. v. IPtronics Inc.*, No. 10-cv-2863-EJD, 2011 WL 3267768, at *5 (N.D. Cal. July 28, 2011) (“Staying a case while [infringement among competitors] is ongoing usually prejudices the patentee that seeks timely enforcement of its right to exclude.”); *Tric Tools, Inc. v. TT Techs., Inc.*, No. 12-cv-3490-YGR, 2012 WL 5289409, at *2-3 (N.D. Cal. Oct. 25, 2012) (where parties are direct competitors, courts presume a stay will prejudice the non-movant; collecting cases); *Skillz Platform Inc. v. Aviagames Inc.*, No. 21-cv-02436-BLF, 2022 WL 1189882, at *5-7 (N.D. Cal. Apr. 21, 2022) (finding that parties’ status as competitors weighs against granting a stay; failure to seek injunctive relief undermines prejudice argument, but not dispositive).

And here, although an IPR has been instituted for U.S. Patent No. 11,697,012, the absence of instituted IPRs on the remaining ten of the eleven patents-in-suit indicates that a stay is unlikely, particularly given that institution has been denied on one patent. *E.g.*, *Wildseed Mobile LLC v. Google LLC*, No. 3:22-cv-04928-WHO (N.D. Cal. Apr. 10, 2023), ECF No. 100 (denying motion to stay because “the PTAB has not yet decided whether to institute review, so at this point any simplification of the issues is speculative”); *Int’l Test Sols., Inc. v. Mipox Int’l Corp.*, No. 16-CV-00791-RS, 2017 WL 1316549, at *3 (N.D. Cal. Apr. 10, 2017) (“Ultimately, the

uncertainty surrounding whether the PTO will elect to institute IPR proceedings weighs against a finding of likelihood of simplification of issues.”); *Novitaz, Inc. v. Shopkick, Inc.*, No. 14-CV-05077-WHO, 2015 WL 12966286, at *1 (N.D. Cal. Mar. 18, 2015) (“The mere requests for review do not simplify this matter.”); *SAGE Electrochromics, Inc. v. View, Inc.*, No. 12-CV-06441-JST, 2015 WL 66415, at *2 (N.D. Cal. Jan. 5, 2015) (“[An] IPR, if granted, would increase the likelihood of simplification, but this argument is largely undercut by the reality that IPR has not yet been instituted.”).

Accordingly, under circumstances like those present here—the parties are direct competitors with a preliminary injunction motion pending and where no IPR has been instituted on the vast majority of asserted patents and—the district court is unlikely to grant a stay.

Further, as explained below, there has and will continue to be substantial duplication of efforts, including both claim construction and discovery before the motion for a stay is even considered, much less resolved. And, because one petition has already been denied on the merits (*see* IPR2024-01257, Paper 10, p.31), the district court proceeding will not be resolved by any filed or yet-to-be-filed IPR, such that the district court and the parties will exert substantial investment of time and resources and duplicate efforts regardless of the outcome of the motion to stay.

B. The Board’s Written Decision Deadline May Come After a Judgment on the Merits.

The second *Fintiv* factor is neutral or slightly favors institution. Although the schedule in the district court only extends through the Markman hearing, the current hearing date is in July and any extension based on the addition of another patent should not delay proceeding more than two months², with initial claim construction activities and discovery already completed. It is possible that the district court will, after the Markman hearing, set a trial date before the projected statutory deadline for a final written decision in this or future IPRs that Petitioner has promised to file. Here, depending on the date of a decision on institution, the statutory deadline will likely be in October 2026,³ which is more than 24 months from the initial filing of the district court action in May 2024. *See* EX2001. Even if trial were not to take place prior to the statutory deadline, the parties will have made substantial investment in moving the parallel litigation far towards trial before the Board’s statutory deadline as explained below. And, if the preliminary injunction motion is

² Petitioner proposed a delay of less than two months to September, while Patent Owner proposed that the Court maintain the current hearing date. EX2023, pp.1-2.

³ *See* 35 U.S.C. § 316(a)(11) (2018) (requiring issuance of a final written decision within one year of institution, absent extension up to six months for good cause).

granted, Patent Owner intends to request an expedited schedule. Therefore, this factor is neutral or slightly favors institution.

C. Substantial Investment of Time and Resources.

The third *Fintiv* factor strongly favors denial. Both the district court and the parties have already and will continue to invest substantial time and resources in the parallel district court litigation, including on the same or similar issues raised in the Petition here.

For example, Patent Owner has filed, and the parties have fully briefed, a preliminary injunction motion that addresses claim construction and patentability for the '921 Patent. *See* EX2006; EX2007; EX2008. For that motion, both parties have already conducted significant discovery with multiple depositions, including depositions of each party's expert here. *See, e.g.*, EX2021 at i.v. The district court held a tutorial related to the preliminary injunction motion on May 15, 2025 (*see* EX2016) and a hearing for the preliminary injunction motion on May 28, 2025 (*see* EX2017).

Moreover, and in addition to the significant investment of substantial time and resources related to the preliminary injunction motion, the district court and the parties have invested and will continue to invest substantial time and resources advancing the litigation through July 2025. The district court held a scheduling conference on December 19, 2024, entering a scheduling order that same day. *See*

EX1021. Pursuant to that schedule, the district court and the parties have made significant investment in the district court litigation.

First, the parties have conducted substantial and expensive discovery, including:

- The parties exchanged initial disclosures on January 13, 2025. *See* EX2015, ¶3.
- The district court entered a protective order on February 19, 2025. *See* EX2009.
- Both parties have propounded and responded to discovery requests including interrogatories and requests for production. *See* EX2015, ¶4.
- Patent Owner has now produced almost 300,000 pages of documents, including in response to email search requests, and Petitioner has produced almost 50,000 pages of documents.
- Patent Owner has served multiple third-party subpoenas requesting both documents and depositions, including from Petitioner's contractors and former employees. *See* EX2015, ¶5.
- Patent Owner has begun depositions and has now deposed two former Petitioner employees and is attempting to set a date for depositions of Petitioner's contract design firm. *Id.*

- Patent Owner moved to compel discovery on certain issues on March 14, 2025 (*see* EX2010), and the district court considered and granted that motion in part (*see* EX2011).
- And, for its part, Petitioner has served several subpoenas, including on other competitors, apparently directed to third-party system prior art that will not be mitigated by any *Sotera* stipulation. *See* EX2015, ¶6.

Additionally, the parties have prepared and served contentions related to the issues of infringement, validity, and damages, including:

- Patent Owner served infringement contentions and produced tens of thousands of pages of documents with those contentions on January 13, 2025, and supplemented those contentions on February 7, 2025, and on March 5, 2025. *See* EX2015, ¶7.
- Petitioner served invalidity contentions and produced documents with those contentions on February 27, 2025, and supplemented those contentions on March 24, 2025. *See* EX2012; EX2013.
- Patent Owner served damages contentions on April 18, 2025. *See* EX2015, ¶8.
- And Petitioner served responsive damages contentions on May 19, 2025.

Third, the parties have proceeded with claim construction discovery, including exchanging proposed terms, proposed constructions, extrinsic evidence, filing a Joint Claim Construction and Prehearing Statement, and exchanging claim construction expert reports. *See* EX1021, pp.2-3. The district court currently has scheduled a claim construction hearing for July 24, 2025, which Patent Owner has proposed to keep. *Id.*; EX2022, p.4. And, while Imperative has moved to delay that hearing to September 18, 2025 (*see* EX2023, p.3), the district court has not yet ruled on that request. All of the above investment of substantial time and resources in the parallel district court proceeding by the parties and the district court has occurred or is currently scheduled to be completed within a week of the scheduled hearing for Petitioner's request for a stay on July 16, 2025. There has and will continue to be investment of substantial time and resources in the parallel district court proceeding by both the district court and the parties before the motion for a stay is scheduled for a hearing. Moreover, even if the district court delays the Markman hearing as much as Petitioner requested, the parties will still exert significant time and resources in the parallel proceeding by September 2025.

For those reasons, the third *Fintiv* factor weighs strongly in favor of denial.

D. Substantial Overlap Between Issues Raised.

The fourth *Fintiv* factor strongly favors denial because there is significant overlap between issues raised in the Petition and in the parallel district court

proceeding. In that proceeding, Patent Owner asserts that Petitioner infringes the '921 Patent and several other patents, many of them related to the '921 Patent. *See* EX2004, ¶5; EX2003, ¶5. For its part, Petitioner asserts that the '921 Patent and several other patents, including patents related to the '921 Patent, are invalid based on the same prior art combinations advanced in the Petition here. *See* EX2012, pp. 21-22. As such, there is almost complete overlap between issues raised in the Petition and in the parallel proceeding.

Moreover, Petitioner's stipulation limiting issues it will pursue in the district court does not mitigate the substantial overlap of issues in both proceedings. Here, the Petition recites "that if the Board institutes this IPR based on the grounds and claims raised in the Petition, Petitioner will not pursue in district court the grounds asserted in the IPR Petition or any other ground that could have been reasonably raised in this IPR." Petition, p.93. But even accepting Petitioner's stipulation, the district court will still have to address similar grounds with respect to related patents asserted in the parallel district court proceeding. In other words, in the related litigation, Petitioner has asserted that patents related by priority to the '921 Patent are invalid over the same references and combinations asserted here. So Petitioner's proposed stipulation does not change the substantial overlap in the issues between the parallel district court proceeding and the Petition.

Here, in grounds 1 to 4, Petitioner asserts unpatentability of claims of the '921 Patent based upon Schaffer alone (grounds 1 and 2), Schaffer combined with Hartley (ground 3), and Schaffer combined with Eller (ground 4). Petition, p.20. Moreover, in ground 5, Petitioner asserts unpatentability based upon Hartley combined with Eller. *Id.* Similarly, in the co-pending litigation, Petitioner relies upon those same references in the same combinations to assert invalidity for the claims of several patents that are related to the '921 Patent. For example, in the parallel district court proceeding:

- For related U.S. Patent No. 11,697,012, Petitioner asserts that various claims are invalid under 35 U.S.C. § 102 in view of Schaffer and under 35 U.S.C. §103 in view of “Schaffer alone or in combination with Hartley, Eler, and/or Garrison.” EX2012, p.21.
- For related U.S. Patent No. 11,865,291, Petitioner asserts that various claims are invalid under 35 U.S.C. § 102 in view of Schaffer and under 35 U.S.C. § 103 in view of “Schaffer alone or in combination with Hartley and/or Eller.” *Id.*
- For related U.S. Patent No 12,109,384, Petitioner asserts that various claims are invalid under 35 U.S.C. § 102 in view of Schaffer and under 35 U.S.C. § 103 in view of “Schaffer alone or in combination with Hartley and/or Eller.” EX2013, pp.25-26.

Accordingly, even accepting Petitioner’s proposed stipulation, there will most likely still be significant overlap between issues raised in the Petition and in the parallel district court proceeding that has and will continue to require substantial investment by both the district court and the parties. In other words, Petitioner’s stipulation does not meaningfully mitigate duplication of effort and resources in the parallel district court proceeding for the ’921 Patent and certainly not for the family of patents including the ’921 Patent. Despite Petitioner’s stipulation to not assert various grounds, the parties and district court will still most likely consider the same references and combination of those references with respect to related patents such that there will be, and already has been, significant overlap between issues raised in the Petition and in the parallel proceeding. Accordingly, Factor 4 strongly favors denial.

E. Identity of Parties.

The fifth *Fintiv* factor favors denial. The same parties are before the district court as here. *See, e.g.*, EX2002 (identifying the Plaintiff as “Inari Medical, Inc.” and the Defendant as “Imperative Care, Inc.”).

F. Other Circumstances.

The sixth *Fintiv* factor favors denial.

1. Petitioner’s extensive reliance on expert testimony.

“While the Board may consider expert testimony, as a matter of efficiency, extensive reliance on expert testimony and/or reasonable disputes between experts on dispositive issues may suggest that the questions are better resolved in an Article III court.” FAQs for Interim Processes for PTAB Workload Management at No. 21. “As the judges have technical and legal expertise, it is not necessary for an expert to explain every aspect of the prior art. It is most helpful if an expert is providing focused testimony, for example to provide helpful context or to explain terms of art.”

Id.

Here, Petitioner’s failure to provide focused expert testimony weighs against institution. The expert declaration accompanying the Petition includes 224 paragraphs spread over 141 pages. *See* EX1003. For example, paragraphs 62-63, 67-69, 71, 73-84, 95-98, 108-109, 111, 113, 125-127, 130-137, 139-141, 148, 150-151, 155-159, 161, 179-186, 195, 197, 199, 201, 203, 206, and 208 of the expert testimony only provide general background on the references and prior art, without offering analysis relevant to the asserted grounds of unpatentability. That unfocused testimony is better resolved in an Article III court and thus weighs against institution.

2. Patent Owner's request for injunctive relief and Petitioner's delay in petitioning for IPR or moving for a stay.

This Petition and the '921 Patent is one small piece of a much larger competitor dispute between the parties that involves the assertion of eleven patents, many of which will not be resolved through IPR. There is already a preliminary injunction motion pending, fully briefed, argued, and awaiting decision that involves the patent that is the subject of this Petition (and another patent from a family that has not had a single IPR instituted and for which Petitioner waited the full year to file its Petition). Regardless of the outcome of this Petition, this wider dispute can and will have to be resolved by the district court and will take up resources accordingly. It does not make sense for the PTAB to take issues piecemeal that the district court can take at once—or for the institution of a small number of petitions (only one so far) to become the basis for delaying resolution of the wider dispute. What's more, the district court has signaled that it will require the parties to reduce their claims and patents at issue and the prior art references at issue, making the district court litigation more efficient.

As explained above, Patent Owner and Petitioner are competitors such that the injunctive relief in the district court is particularly important. The first notice of Imperative Care's alleged infringement of the '921 Patent was provided in a September 29, 2023, letter specifically identifying the allowed claims of the

application that would issue as the '921 Patent three months later, thus putting Imperative Care on notice of the infringement. EX2014, pp.1-2. Subsequently, Patent Owner moved for preliminary injunctive relief in the parallel district court proceeding. *See* EX2006, p.1 (July 24, 2024 motion for preliminary injunction based upon infringement of US11,844,921 and US11,974,910). In response, Petitioner waited over eight months to request a stay in the district court. *See* EX2005 (April 2, 2025 motion for stay). And, for the two patents at issue in Patent Owner's request for preliminary injunction, Petitioner waited until March 13, 2025 to petition for IPR of U.S. Patent No. 11,844,921 here, and waited until May 20, 2025 to petition for IPR of the other patent, U.S. Patent No. 11,974,910 (*see* IPR2025-01025).

That the parallel district court litigation involves competitors and a request for preliminary injunction, yet Petitioner delayed to petition for IPR for the majority of the asserted patents, including the two patents at issue in Patent Owner's preliminary injunction motion, or request a stay in the district court weighs in favor of discretionary denial.

3. Petitioner's delay in filing petition for IPR.

The Director has recognized that a “[p]etitioner’s awareness of Patent Owner’s applications and failure to seek early review of the patents favors denial.” *iRhythm Technologies, Inc. v. Welch Allyn, Inc.*, IPR2025-00363, -374, -376, -377, -378, Paper 10, p.3 (P.T.A.B. June 6, 2025).

Here, Petitioner was put on notice of the imminent issue of the '921 Patent on September 29, 2023, when Patent Owner sent a letter identifying the application and publication numbers corresponding to the '921 Patent and its pending but allowed claims. *See* EX2014. The '921 Patent issued less than three months later on December 19, 2023. On January 15, 2024, Petitioner responded to that letter citing the same references that now form the basis of its IPR petition here, demonstrating Petitioner's awareness of both the '921 Patent and the art. Despite this notice, Petitioner declined to file a Post-Grant Review petition and waited until March 13, 2025—nearly fifteen months after the '921 Patent issued—to file the present petition for *inter partes* review. Petitioner made these tactical choices, including to avoid the wider estoppel of Post-Grant Review by waiting rather than asserting the same art that it now asserts, but it should not be rewarded for doing so.

Consistent with the Director's reasoning in *iRhythm*, Petitioner's notice of the '921 Patent and its delay in seeking review despite already having identified the same prior art strongly favors discretionary denial. In summary, given the balance of the above factors, Patent Owner requests that the Office exercise its discretion under Section 314(a) to deny institution because proceeding would not be consistent with the objective of the AIA to “provide an effective and efficient alternative to district court litigation.” *NHK Spring Co. v. Intri-Plex Techs., Inc.*, IPR2018-00752, Paper 8, p.20 (P.T.A.B. Sept. 12, 2018) (quoting *Gen. Plastic Indus. Co. v. Canon*

Kabushiki Kaisha, IPR2016-01357, Paper 19, pp.16-17, 2017 WL 3917706, at *7 (P.T.A.B. Sept. 6, 2017) (precedential)).

III. THE PETITION SHOULD BE DENIED UNDER 35 U.S.C. § 325(d)

The Board should exercise its discretion to deny the Petition because “the same or substantially the same prior art or arguments” were previously presented to the Patent Office. 35 U.S.C. § 325(d). Here, the Patent Office considered both Hartley and Eller during prosecution and, although Schaffer was not specifically considered, multiple other references that are substantially the same as Schaffer and that involve the same issues were considered and overcome.⁴

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

⁴ Notably, the Office did consider Schaffer during prosecution of US12,109,384, which is related to the '921 patent. *See* EX1016 at 5 (listing US2003/0225379 (Schaffer) as a referenced cited). US12,109,384 is also asserted in the parallel district court litigation identified above, and as of this filing, Petitioner has not petitioned for IPR of that related patent.

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 challenged claims.

Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH, IPR2019-01469, Paper 6, 2020 WL 740292 (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*”).⁵

⁵ 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

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.

B. 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 Patent Office.

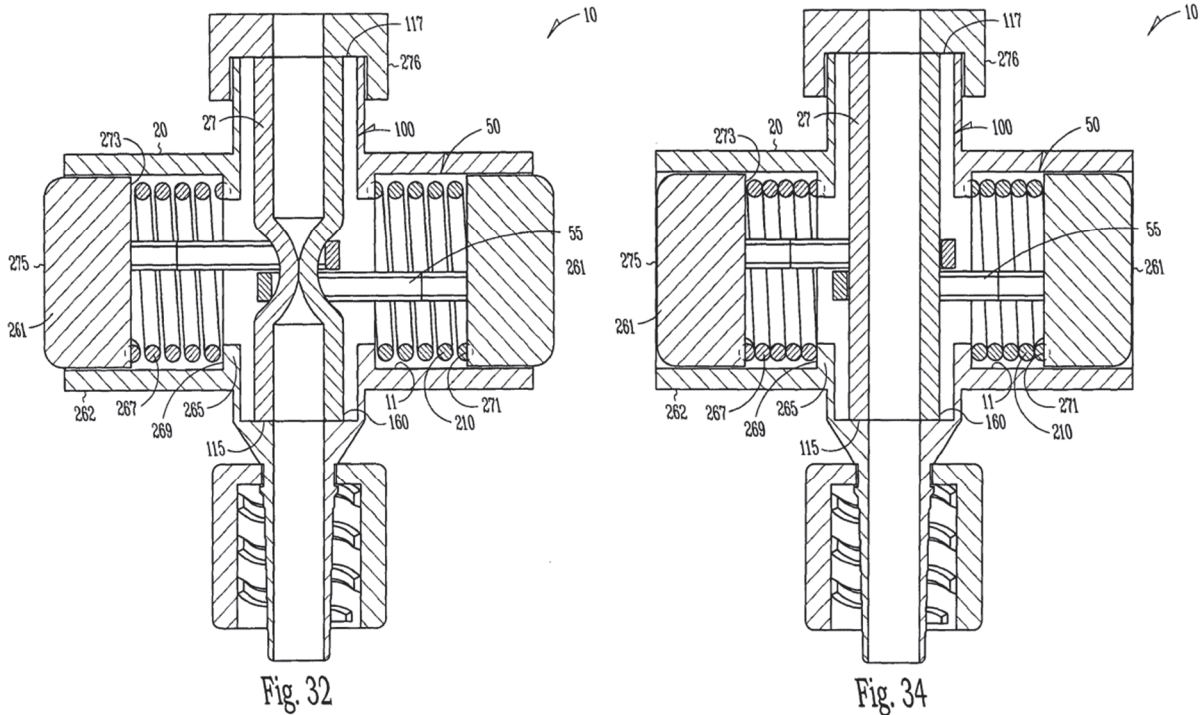
- 1. The first (a) and second (b) *Becton, Dickinson* factors weigh in favor of denial because Petitioner’s asserted art is the same or substantially the same and cumulative to the prior art previously considered by the Patent Office.**

Petitioner relies on Schaffer alone for grounds 1 and 2, Schaffer in combination with Hartley or Eller for grounds 3 and 4, and Hartley in combination with Eller for ground 5. Petition, p.20. Hartley and Eller were both cited by the Examiner in a Notice of References Cited and appear on the face of the '921 Patent with an “*” next to the patent document number. EX1002, p.29 (citing Hartley), p.30 (citing Eller); EX1001, p.4 (citing Hartley and Eller). In the Notice of Allowance,

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 Examiner further identified that the “closest prior art of record is Hartley (US2003/0116731),” finding that Hartley discloses a valve, an actuator, and a filament, but that the “spring 29 in Hartley is not configured to bias the actuator to the first position.” EX1002, p.25. Therefore, the Office closely considered each of Hartley and Eller during prosecution. The Board regularly denies institution where examiners substantively address 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, 2019 WL 762295 (P.T.A.B. Feb. 19, 2019).

And, although Schaffer was not specifically considered during prosecution, substantially the same prior art was. Schaffer is therefore wholly cumulative of art considered by the Office. The primary embodiment relied upon by Petitioner shown in Figures 30-34 of Schaffer discloses a stasis valve 10 having a seal module 100 and two actuators 50 each attached to a rigid actuating member 55 that is disposed about the seal module 100:

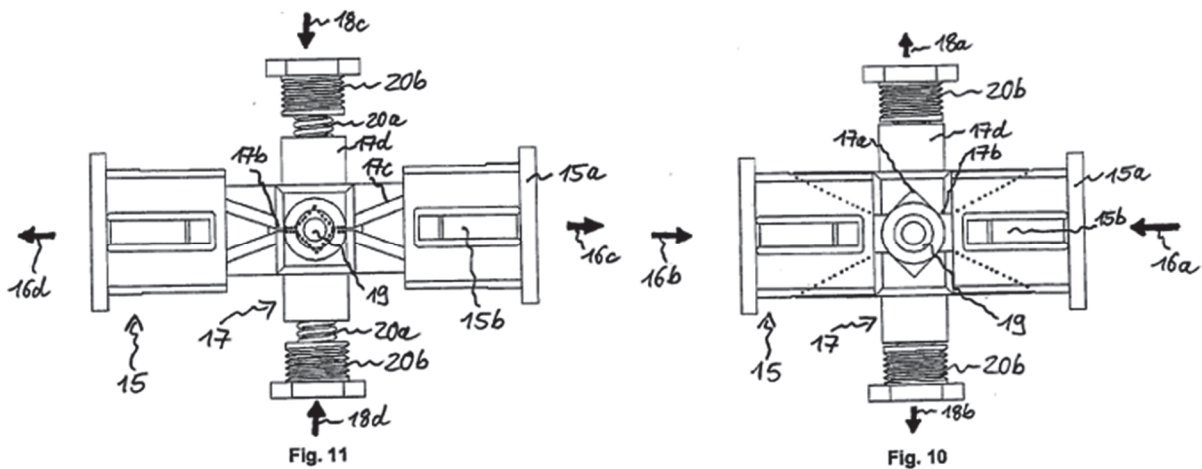


EX1005, ¶¶[0075]-[0077]. Two resilient members 267 (e.g., springs 210) bias the actuators 50 such that the actuating members 55 compress and collapse the seal module 100 in a sealed first position shown in Figure 32. *Id.* at ¶¶[0076]-[0077]. Actuating the actuators 50 moves the actuating members 55 against the biasing force of the resilient members 267 to permit the seal module 100 to move to an unsealed second position such that gases and fluids can pass therethrough as shown in Figure 34. *Id.* at ¶[0077].

But, as set forth below, the Patent Office expressly considered multiple references like Schaffer having rigid members that are biased to compress and seal a resilient/expandable tubular member including, for example, Wong (EX2019), Kees (EX2018), and Williams (EX1010).

a) Wong was considered by the Patent Office and discloses a valve that is substantially the same as and cumulative of Schaffer.

Wong was cited by the Examiner in the Notice of References Cited and appears on the face of the '921 Patent with a "*" next to its patent publication number. EX1002, p.29; EX1001, p.5. Like Schaffer, Wong discloses a hemostatic 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].

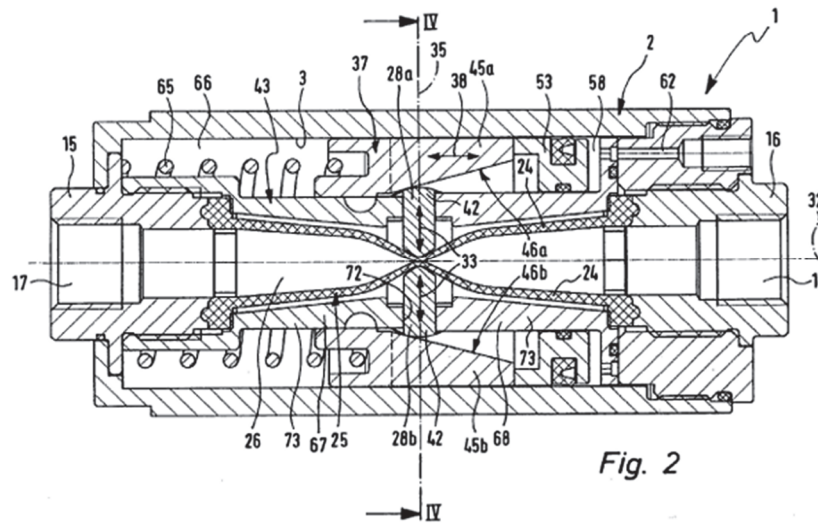
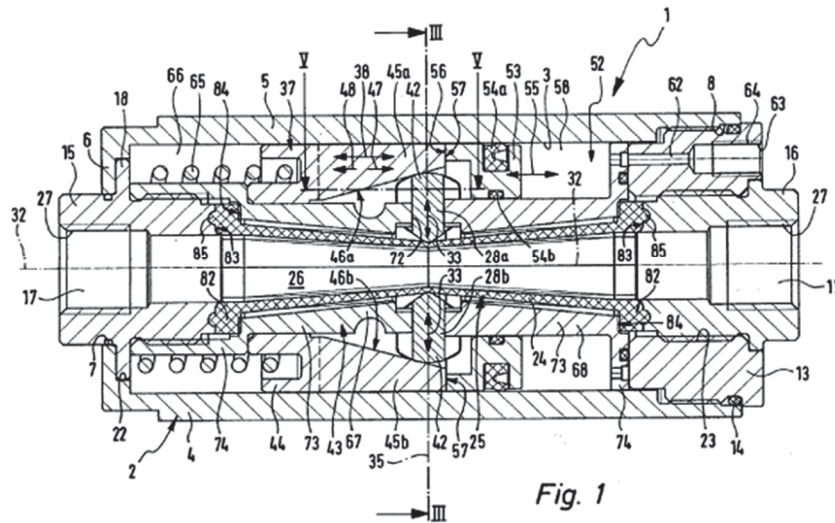
Accordingly, Wong is substantially the same as and cumulative of Schaffer:

<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

b) Kees was considered by the Patent Office and discloses a valve that is substantially the same as and cumulative of Schaffer.

Kees was cited by the Examiner in the Notice of References Cited and appears on the face of the '921 Patent with a "*" next to its patent publication number. EX1002, p.29; EX1001, p.5. Like Schaffer, Kees discloses a pinch valve 1 having a

hose-like valve member 25 with a flexible peripheral wall 24, an actuating ring 37, and a pair of rigid pinch elements 28a and 28b disposed about the valve member 25:



EX2018, ¶¶[0046], [0048], [0055]. Spring means 65 bias the actuating ring 37 such that the pinch elements 28a and 28b compress and seal the valve member 25 in a sealed first position shown in Figure 2. *Id.* at ¶¶[0053], [0071]. Actuating the actuating ring 37 moves the actuating ring 37 against the biasing force of the spring

means 65 to permit the valve member 25 to move to an unsealed second position such that gases and fluids can pass therethrough as shown in Figure 10. *Id.* at ¶¶[0054], [0072].

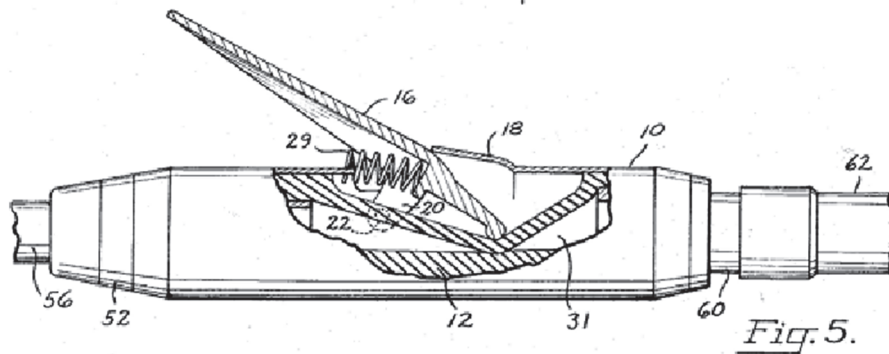
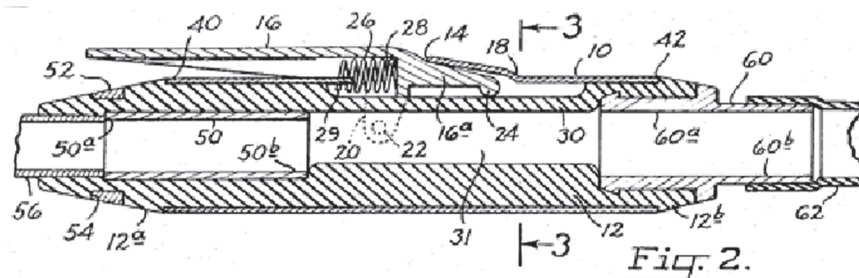
Accordingly, Kees is substantially the same as and cumulative of Schaffer:

<u>Disclosure of Schaffer</u>	<u>Substantially the Same Disclosure of Kees</u>
Stasis valve 10	Pinch valve 1
Seal module 100	Hose-like valve member 25
Actuators 50	Actuating ring 37
Actuating members 55	Pinch elements 28a and 28b
Resilient members 267	Spring means 54
Biased, sealed first position of the stasis valve 10 shown in Figure 32	Biased, sealed first position of the pinch valve 1 shown in Figure 2
Unsealed second position of the stasis valve 10 shown in Figure 34	Unsealed second position of the pinch valve 1 shown in Figure 1

c) Williams was considered by the Office and Discloses a Valve that is Substantially the Same as Schaffer.

Williams was cited by the Examiner in the Notice of References Cited and appears on the face of the '921 Patent with a "*" next to its patent number. EX1002, p.29; EX1001, p.2. In the Notice of Allowance, the Examiner identified that the "closest prior art of record is Hartley (US2003/0116731) ... [and] Williams et al. (US 3,438,607)" finding that Williams discloses a valve, an active tensioning

mechanism including an actuator, and a biasing spring, but that “Williams fails to discloses [sic] a filament extending around the elongate member.” EX1002, p.26. Like Schaffer, Williams discloses a valve having an elongated hollow element 12 of elastomeric material and a rigid actuating clamp 16 having a transversely extending rib 24 disposed about the elongated hollow element 12:



EX1010, 2:39-44, 2:63-65. A coil compression spring 26 biases the actuating clamp 26 in a clockwise direction such that the transversely extending rib 24 compresses and seals the elongated hollow element 12 in a sealed first position shown in Figure 5. *Id.* at 2:66-3:2, 4:17-29. Actuating the clamp 16 (e.g., when the “clamp is gripped and swung in a counterclockwise direction from the position shown in FIG. 5”) moves the clamp 16 against the biasing force of the coil compression spring 26 to

permit the elongated hollow element 12 to move to an unsealed second position such that gases and fluids can pass therethrough as shown in Figure 5. *Id.* at 4:29-39.

Accordingly, Williams is substantially the same as and cumulative of Schaffer:

<u>Disclosure of Schaffer</u>	<u>Substantially the Same Disclosure of Williams</u>
Stasis valve 10	Valve
Seal module 100	Elongated hollow element 12
Actuators 50	Clamp 16
Actuating members 55	Transversely extending rib 24
Resilient members 267	Coil compression spring 26
Biased, sealed first position of the stasis valve 10 shown in Figure 32	Biased, sealed first position of the valve shown in Figure 5
Unsealed second position of the stasis valve 10 shown in Figure 34	Unsealed second position of the pinch valve 1 shown in Figure 2

Therefore, Petitioner's references for each ground are substantially the same as and cumulative of the references cited and considered by the Patent Office such that the first and second *Becton, Dickinson* factors weigh in favor of denial, and support a finding that the first part of the *Advanced Bionics* framework is satisfied.

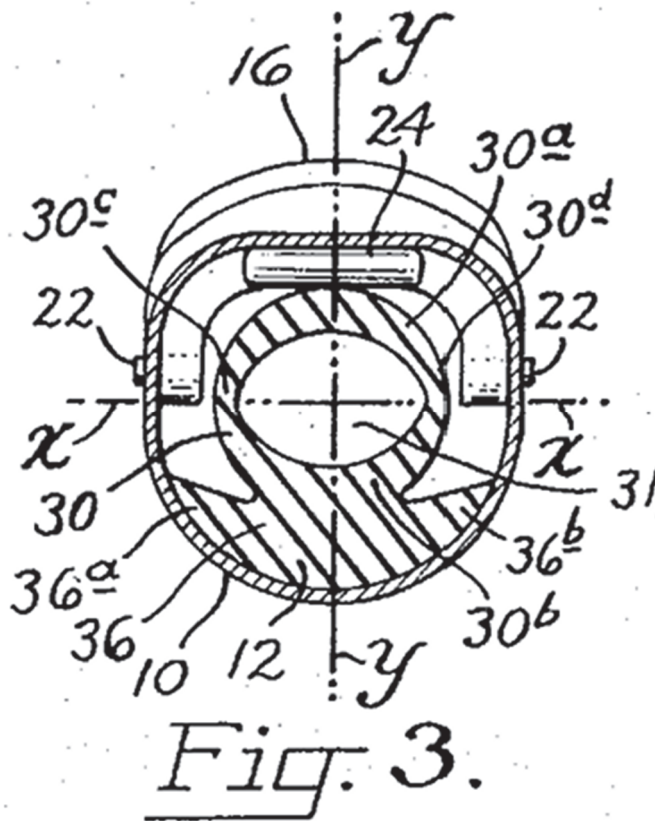
2. The fourth (d) *Becton, Dickinson* factor weighs in favor of denial because there is substantial overlap between Petitioner’s arguments related to Schaffer and the positions considered by the Patent Office when finding patentability.

a) Grounds 1 and 2 (Schaffer alone).

As set forth above, the Patent Office considered Wong, Kees, and Williams which disclose substantially similar valves to Schaffer that each include one or more rigid members (i.e., the second sliders 17 of Wong, the pinch elements 28a and 28b of Kees, and the transversely extending rib 24 of Williams) that are biased to compress and seal an elongate member. But, the Patent Office allowed the claims of the '921 Patent over Wong, Kees, and Williams despite considering those references in the Notice of References Cited and, for Williams, in the Notice of Allowance where the Patent Office found that “Williams fails to disclose a filament extending around the elongate member.” EX1002, pp.26, 29.

Nevertheless, according to Petitioner, Schaffer’s actuating members 55 are “filaments” because the term “filament” in the challenged claims means “at least one or more threads, lines, cords, ropes, ribbons, flat wires, sheets, or tapes.” Petition, pp.17, 30. Petitioner further alleges that if the foregoing structures are rigid “they would still form a ‘filament’ under the correct construction of that term.” *Id.* at pp.18, 30-31.

The Patent Office got it right—the rigid compression members of Wong, Kees, and Williams are not a “filament” as recited in the challenged claims. Petitioner’s overly-broad construction of “filament” to include rigid members overlaps with the Patent Office’s finding that Williams (and Wong and Kees) do not disclose a “filament.” For example, under Petitioner’s proposed construction, the rigid transversely extending rib 24 of Williams is a filament because it is at least a “line,” “cord, or “ribbon” as best seen in Figure 3:



But, the Patent Office expressly found that Williams does not disclose the claimed “filament.” EX1002, p.26.

Likewise, the Patent Office found that Wong and Kees do not disclose a “filament” during prosecution of the parent application to the ’921 Patent, U.S. Patent Application No. 16/117,519 (“the Parent ’519 Application”). The claims allowed in the Parent ’519 Application are similar to the challenged claims here:

Claim 1 of the Parent ’519 Application	Claim 1 of the ’921 Patent
1. A hemostatic valve for sealing a medical device, the hemostatic valve comprising:	1. A valve, comprising:
an elongate member having a first end, a second end, and a central lumen extending therebetween, wherein the elongate member is pliable;	an elongate member defining a lumen;
a reinforcement structure extending along at least a portion of the elongate member, wherein the reinforcement structure is coupled to the elongate member;	
an active tensioning mechanism including an actuator coupled to the elongate member, wherein the actuator is moveable between (a) a first position wherein the central lumen is constricted and sealed and (b) a second position wherein the central lumen is open, and wherein the tensioning mechanism comprises at least one filament extending at least partially around the elongate member; and	an active tensioning mechanism including an actuator coupled to the elongate member via a filament extending at least partially around the elongate member, wherein the actuator is moveable between (a) a first position wherein the lumen is constricted and sealed and (b) a second position wherein the lumen is at least partially open; and
a biasing member configured to bias the actuator to the first position.	a biasing member configured to bias the actuator to the first position.

In a Notice of Allowance in the Parent '519 Application, the same Examiner that considered and allowed the '921 Patent identified Wong (EX2019), U.S. Patent No. 7,775,501 (the issued patent corresponding to the publication of Kees (EX2018)), and Hartley (EX1006) as the “closest prior art of record” but that “these references do not disclose the device as claimed.” EX2020, p.4. In particular, the Examiner concluded that “the prior arts Wong and Kees are missing the filament.” *Id.* at p.5. Again, the Examiner correctly concluded that the rigid actuating members of Wong and Kees (like those of Schaffer) are not a “filament.”

Accordingly, Petitioner’s arguments with respect to grounds 1 and 2 over Schaffer alone are substantially similar to the art already considered by the Office and conflict with the Office’s finding of patentability that devices like Schaffer having rigid actuating members do not include a “filament.”

b) Grounds 3 and 4 (Schaffer in combination with Hartley or Eller).

As set forth above, the Patent Office considered (1) Wong, Kees, and Williams which disclose substantially similar valves to Schaffer that each include one or more rigid members that are biased to compress and seal an elongate member and (2) Hartley and Eller. But the Office Action did not reject the claims of the '921 Patent based on a combination of any of Wong, Kees, or Williams with Hartley or Eller. That is, the Examiner did not conclude, as Petitioner asserts, that it would have

been obvious to modify a valve like Schaffer (i.e., the valves of Wong, Kees, or Williams having rigid actuating members) to somehow include a filament (e.g., Hartley's string). Such a potential combination was insufficient to support a Section 103 rejection.

Moreover, during prosecution of the Parent '519 Application, the same Examiner that considered and allowed the '921 Patent identified Wong, Kees, and Hartley as the "closest prior art of record," and stated that "[a]lthough Hartley disclose [sic] a filament, while the prior arts Wong and Kees are missing the filament." EX2020, pp.4-5. The Examiner continued that despite Hartley disclosing a filament, a "person skilled in the art would recognize that it is improper to add the filament of Hartley in either the device of Wong or Kees." *Id.* at p.5. Again, the Examiner correctly concluded that modifying a valve like Schaffer (i.e., the valves of Wong, Kees, or Williams having rigid actuating members) to somehow include a filament (e.g., Hartley's string) was insufficient to support a Section 103 rejection.

Accordingly, Petitioner's arguments with respect to grounds 3 and 4 relying upon Schaffer in combination with Hartley or Eller are substantially similar to art and positions already considered and rejected by the Office.

c) Ground 5 (Hartley in combination with Eller).

As set forth above, the Patent Office considered both Hartley and Eller, finding Hartley to be the "closest prior art of record," disclosing a valve, an actuator,

and a filament, but not the claimed “biasing member configured to bias the actuator to the first position.” EX1002, p.25. Petitioner asserts that the Examiner of the ’921 Patent “overlooked ... that such biasing members were well known in the prior art and would have been obvious to combine with Hartley in September 2017,” relying on Eller for disclosing a biasing member. Petition, p.76.

Petitioner’s assertion is incorrect—the Examiner did not overlook valves having a biasing member and their potential combination with Hartley. Notably, in the Notice of Allowance the Examiner found that Williams disclosed a valve including a “biasing/spring member 26 configured to bias the actuator to the first position.” EX1002, p.4. Despite this finding, by allowing the claims of the ’921 Patent the Examiner did not find that it would have been obvious to modify Hartley to include the biasing/spring member 26 of Williams.

Moreover, during prosecution of the Parent ’519 Application, the same Examiner that considered and allowed the ’921 Patent identified Wong, Kees, and Hartley as the “closest prior art of record,” finding that “Wong discloses a hemostatic valve comprising ... a biasing member 20a-20b configured to bias the actuator to the first position.” EX2020, p.4. Again, the Examiner was aware of a hemostatic valve including a biasing member but did not find that it would have been obvious to modify Hartley to include the biasing member 20a-20b of Wong.

Accordingly, Petitioner's arguments with respect to ground 5 overlap with positions already considered and rejected by the Office when it found that a person of ordinary skill in the art would not modify Hartley's valve to include a "biasing member configured to bias the actuator to the first position."

For the foregoing reasons, Petitioner's arguments for each ground overlap with the Office's findings of patentability 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. 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 Patent Office substantively evaluated Hartley, Eller, and multiple references substantially the same as Schaffer.

As set forth above, Hartley and Eller were both cited by the Examiner in a Notice of References Cited and appear on the face of the '921 Patent with a * next to the patent document number. EX1002, p.29 (citing Hartley), p.30 (citing Eller); EX1001, p.4 (citing Hartley and Eller). In the Notice of Allowance, the Examiner even identified that the "closest prior art of record is Hartley (US2003/0116731). *Id.* at p.25. Likewise, the Patent Office expressly considered multiple references like Schaffer having rigid members that are biased to compress and seal a resilient/expandable tubular member including, for example, Wong (EX2019, Kees

(EX2018), and Williams (EX1010). *Id.* at p.29. Moreover, during prosecution of the related Parent '519 Application, the same Examiner that considered and allowed the '921 Patent identified Wong, Kees, and Hartley as the “closest prior art of record.” EX2020, p.5. Thus, the Patent Office substantively considered Hartley and Eller, along with multiple references (Wong, Kees, and Williams) 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.

Indeed, for grounds 1 and 2, as explained in § C.2.a above, Petitioner ignores the substantial similarities between Schaffer and the prior art considered during prosecution including Wong, Kees, and Williams. Petitioner fails to make any showing as to how its overly-broad construction of “filament” excludes the rigid compression members of Wong, Kees, and Williams that the Examiner found were not a “filament” as recited in the challenged claims.

For grounds 3 and 4, as explained in § C.2.b above, Petitioner fails to address how the Patent Office materially erred in concluding that a person of ordinary skill in the art would not have modified a valve like Schaffer (i.e., the valves of Wong, Kees, or Williams) having rigid actuating members to somehow include a filament (e.g., Hartley's string).

For ground 5, as explained in § C.2.c. above, Petitioner misleadingly argues that the Examiner of the '921 Patent "overlooked ... that such biasing members were well known in the prior art and would have been obvious to combine with Hartley in September 2017." Petition, p.76. But in the Notice of Allowance the Examiner found that Williams discloses a valve including a "biasing/spring member 26 configured to bias the actuator to the first position." EX1002, p.26. And, the same Examiner identified Hartley and Wong as the "closest prior art of record" despite the Examiner finding that "Wong discloses a hemostatic valve comprising ... a biasing member 20a-20b configured to bias the actuator to the first position." EX2020, p.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.

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 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.”).

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

IV. CONCLUSION

For the forgoing reasons Patent Owner requests that that the Office exercise its discretion under Sections 314(a) and 325(d) and deny institution.

Respectfully submitted,

Dated: June 16, 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 8,267 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: June 16, 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 June 16, 2025, a copy of **Patent Owner's Request for Discretionary Denial, and Exhibits 2001-2023** were served upon the below-listed counsel by electronic mail:

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