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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

IMPERATIVE CARE, INC.,
Petitioner,

v.

INARI MEDICAL INC.,
Patent Owner.

Case No. IPR2025-00289
Patent No. 11,554,005

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

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LIST OF EXHIBITS

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1001	U.S. Patent No. 11,554,005 (“the ’005 patent”)
1002	Excerpts from the prosecution history of the ’005 patent
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 No. 2003/0116731 A1 to Hartley (“Hartley”)
1007	U.S. Patent No. 9,980,813 B1 to Eller (“Eller”)
1008	Drawings Submitted During Prosecution of U.S. Patent Application No. 10/371,190 dated June 18, 2003
1009	U.S. Patent No. 5,429,616 to Schaffer (“Schaffer ’616”)
1010	U.S. Patent Publication US 2011/0144592 A1 to Wong et al. (“Wong”)
1011	U.S. Patent Publication No. 2015/0173782 A1 to Garrison et al. (“Garrison”)
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1014	U.S. Patent No. 4,723,550 to Bales et al.
1015	U.S. Patent No. 5,895,376 to Schwartz et al.
1016	U.S. Patent No. 12,109,384 B2 to Merritt et al.
1017	U.S. Patent Application No. 16/117,519 (the “’519 application”)

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1018	U.S. Patent No. 7,775,501 B2 to Kees (“Kees”)
1019	U.S. Patent Publication No. 2016/022041 A1 to Garrison et al. (“Garrison ’741”)
1020	U.S. Patent No. 6,776,770 B2 to Treretola
1021	U.S. Patent Publication No. 2010/0042118 A1 to Garrison et al.
1022	U.S. Patent No. 5,938,645 to Gordon (“Gordon”)
1023	U.S. Patent Publication No. 2014/0296868 A1 to Garrison et al.
1024	WIPO Publication No. WO 2006/124307 A2 to Goff et al.
1025	Decision Granting Institution of <i>Inter Partes</i> Review for U.S. Patent No. 11,697,011 (Paper 7) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2024-01157 (P.T.A.B. Jan. 23, 2025)
1026	Decision Granting Institution of <i>Inter Partes</i> Review for U.S. Patent No. 11,697,012 (Paper 6) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-00156 (P.T.A.B. Apr. 22, 2025)
1027	United States District Courts – National Judicial Caseload Profile (Dec. 2024)
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1029	Imperative Care’s Reply in Support of Motion to Stay Pending <i>Inter Partes</i> Review (Dkt. #108) in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 24-cv-03117-EKL (N.D. Cal.) (filed May 7, 2025)
1030	Decision Denying Institution of <i>Inter Partes</i> Review for U.S. Patent No. 11,744,691 (Paper 10) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2024-01257 (P.T.A.B. Feb. 7, 2025)

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1031	Standing Order for Patent Cases Before Judge Eumi K. Lee (Aug. 16, 2024)
1032	<i>Yangtze Memory Techs. Co., Ltd. v. Micron Tech., Inc.</i> , No. 23-cv-05792-RFL, Dkt. 243 (N.D. Cal. Mar. 14, 2025)
1033	<i>Jawbone Innovations, LLC v. Google LLC</i> , No. 23-cv-00466-TLT, Dkt. 137 (N.D. Cal. Apr. 27, 2023)
1034	Joint Claim Construction and Prehearing Statement Pursuant to Patent Local Rule 4-3 (Dkt. #107) in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 24-cv-03117-EKL (N.D. Cal.) (filed Apr. 28, 2025)

I. INTRODUCTION

The Director should deny Patent Owner’s (“PO’s”) Request for Discretionary Denial (“Request”) under 35 U.S.C. §314(a) for several reasons. First, the co-pending litigation in the Northern District of California is still in its early stages and nowhere near trial. The Court has not scheduled a trial date, or any dates beyond the claim construction hearing currently set for late July 2025. (Ex. 2016.) As PO concedes, the pleadings are not even closed. On May 28, 2025, PO obtained leave from the Court to file a **third** amended complaint to assert another patent, and the Court has ordered the parties to meet and confer regarding extensions of the *Markman* schedule to accommodate new claim terms in the new patent. Moreover, the parties agree that discovery is in its infancy. PO recently argued to the Court in support of its motion for leave to file a third amended complaint that “discovery is at an early stage” and emphasized that the Court has “not even set a date for the close of fact discovery.” (Ex. 2025 at 6.) Against this backdrop, PO’s speculation that “[i]t is fully possible” the Court will set trial date before a final written decision in this IPR (which would be due in June 2026) is unsupported and fanciful.

Second, Petitioner has moved the Court to stay the litigation pending the outcome of the IPRs filed by Petitioner against PO’s patents, including two instituted IPRs against U.S. Patent No. 11,697,011 (“the ’011 patent”) and 11,697,012 (“the ’012 patent”). (Ex. 2008; Ex. 1025; Ex. 1026.) The Court has scheduled a hearing on the

Motion to Stay for July 16, 2025. (Ex. 2009.) Statistics for the Northern District of California indicate that the Court is likely to grant Petitioner's motion to stay. Given this pending motion, PO's speculation that the Court may schedule trial before this Board issues a final written decision is even more improbable.

Third, the merits of this IPR are particularly strong. The Board has already instituted two IPRs on PO's '011 and '012 patents, which contain similar limitations to those in the challenged '005 patent claims. (Ex. 1025; Ex. 1026). And Petitioner asserts the same prior art against the '005 patent that the Board relied on in instituting those IPRs. Moreover, in those IPRs, the Board addressed and preliminarily rejected the very arguments that PO raised in its PO Preliminary Response ("POPR") to this IPR and in the current Request.

The institution decisions in the '011 and '012 patent IPRs highlight the strength of Petitioner's invalidity grounds for the '005 patent and demonstrate the inefficiency that would result from discretionary denial. The Board is currently addressing the very arguments Petitioner and PO have raised in this IPR. A discretionary denial of this IPR would force the parties and Court to relitigate these same issues, leading to a significant waste of judicial and party resources and possibly inconsistent outcomes.

For these reasons, and the additional reasons provided below, Petitioner respectfully requests that the Director deny PO's Request for Discretionary Denial and allow this IPR to proceed to an institution determination on the merits.

II. CLARIFICATION OF THE FACTS

PO currently asserts ten patents in the co-pending district court litigation and recently obtained leave to file a third amended complaint to add an eleventh patent. (Paper 6 (Request) at 1.) Petitioner has already filed IPR petitions against all **eight** patents asserted in PO's original complaint. See (1) *Imperative Care, Inc. v. Inari Medical, Inc.*, IPR2024-01157 requesting review of U.S. Patent No. 11,697,011; (2) *Imperative Care, Inc. v. Inari Medical, Inc.*, IPR2024-01257 requesting review of U.S. Patent No. 11,744,691; (3) *Imperative Care, Inc. v. Inari Medical, Inc.*, IPR2025-00156 requesting review of U.S. Patent No. 11,697,012; (4) *Imperative Care, Inc. v. Inari Medical, Inc.*, IPR2025-00289 requesting review of U.S. Patent No. 11,554,005; (5) *Imperative Care, Inc. v. Inari Medical, Inc.*, IPR2025-00728 requesting review of U.S. Patent No. 11,844,921; (6) *Imperative Care, Inc. v. Inari Medical, Inc.*, IPR2025-00989 requesting review of U.S. Patent No. 11,865,291; (7) *Imperative Care, Inc. v. Inari Medical, Inc.*, IPR2025-01021 requesting review of U.S. Patent No. 11,969,333; and (8) *Imperative Care, Inc. v. Inari Medical, Inc.*, IPR2025-01025 requesting review of U.S. Patent No. 11,974,910.

As mentioned above, the Board has already granted institution of two IPRs challenging the validity of the '011 and '012 patents. (Ex. 1025; Ex. 1026.) Shortly after the Board instituted the '011 patent IPR, PO dropped the '011 patent from the district court litigation, demonstrating the narrowing effect of the IPRs. (Ex. 1028 at 3,

7.) The parties are currently awaiting institution decisions on five of the pending IPRs, including this IPR challenging the validity of the '005 patent. The Board denied institution of one IPR challenging the validity of the '691 patent. (Ex. 1030 at 22-29.) However, the Board premised its denial on a claim limitation in the '691 patent requiring a specific orientation of two “chambers” that is not found in any of the other patents subject to IPR. (*Id.*)

Petitioner intends to file IPRs on the four patents PO has added, or will add, to the litigation through its first, second, and third amended complaints. One of those patents, U.S. Patent No. 12,016,580, became eligible for IPR only recently, while the other three other patents, U.S. Patent Nos. 12,109,384; 12,156,669; and 12,239,333, are not yet eligible for IPR because the patents issued so recently.

III. THE DIRECTOR SHOULD NOT DENY INSTITUTION UNDER § 314(a)

PO fails to show that discretionary denial under Section 314(a) is warranted. Each of the *Fintiv* factors are either neutral or weigh against discretionary denial, as summarized below:

- Factor 1 – Petitioner has moved for a stay of the district court litigation, which the court will likely grant given the early stage of the case and the common practice of courts in the district (weighs against discretionary denial);

- Factor 2 – The Court set no trial date in the litigation, and evidence indicates that any trial would take place years after the Board’s statutory deadline (weighs against discretionary denial);
- Factor 3 – PO agrees that the district court litigation is in its “early stages” with document production just beginning, no party depositions outside of the narrow preliminary injunction depositions, no dispositive motions, and no date set for the close of fact discovery (weighs against discretionary denial);
- Factor 4 – Petitioner submitted a *Sotera* stipulation that will minimize any overlap of issues addressed in the district court litigation and this IPR (weighs against discretionary denial);
- Factor 5 – Petitioner and PO are the same parties in the district court litigation (neutral);
- Factor 6 – Petitioner’s IPR is strong on the merits as demonstrated by the Board’s institution of two other IPRs asserting the same prior art against claims reciting every limitation contested by PO here (weighs against discretionary denial).

The Director has recently denied requests for discretionary denial in similar factual circumstances under the March 26, 2025 Interim Processes for PTAB Workload

Management. Petitioner believes that the facts outlined below warrant a similar denial here.

A. The *Fintiv* Factors Weigh Against Discretionary Denial

1. The Co-Pending Litigation Is Nowhere Near Trial

PO concedes that the proximity of the Court’s trial date to the final written decision at least “slightly favors institution.” (Paper 6 (Request) at 5.) PO speculates, however, that the “Board’s written decision deadline may come after a judgment on the merits.” (*Id.*) PO cites no facts to support this assertion, nor do any exist. (*Id.*) The Court set a case schedule only through the claim construction hearing, which had been set for July 24, 2025. (Ex. 2016.) But on May 28, the Court ordered the parties to submit a new schedule to delay those dates. The Court never set any case deadlines after the claim construction hearing, and refrained from setting a trial date. (*Id.*) Further, the Court’s Standing Order explains that the Court will hold a subsequent case management conference to discuss a future schedule only *after* it issues its claim construction ruling. (Ex. 1031 at § VI.) Thus, any trial date is still a long way off and highly speculative.

Moreover, statistics for the Northern District of California show that the median time to trial in civil cases last year was 48.9 months. (Ex. 1027 at 66.) PO correctly notes that it filed the co-pending litigation in May 2024. (Paper 6 (Request) at 5 (citing Ex. 2013).) Thus, even assuming that the Court does not stay the litigation pending the

outcome of the IPRs, a trial is unlikely to occur before May 2028, which would be **long** after the Board’s statutory deadline here (which would fall in June 2026).

Importantly, the Director recently denied a request for discretionary denial under similar circumstances. *See Twitch Interactive, Inc. v. Razdog Holdings LLC*, IPR 2025-00307, Paper 18 (P.T.A.B. May 16, 2025). Like PO’s Request in this IPR, the request in *Twitch* was “primarily based on a parallel district court proceeding in the Northern District of California.” *Id.* at 2. In denying the request for discretionary denial, the Director emphasized that there was “no currently scheduled trial date in the co-pending district court litigation” and that “the median time-to-trial statistics [for the district court] suggest trial will begin in February 2027, which would be significantly after the projected final written decision (July 30, 2026).” *Id.* Those same circumstances are present here and warrant the same outcome – denial of PO’s Request.

Accordingly, the proximity of the district court’s trial date (which will not be set for a long while) to the Board’s statutory deadline weighs strongly against discretionary denial.

2. Petitioner Has Moved For A Stay, Which Courts In The Northern District Of California Frequently Grant

Petitioner recently filed a Motion to Stay the district court litigation pending resolution of the IPRs challenging PO’s patents, including the instituted ’011 and ’012 IPRs. (Ex. 2008; Ex. 1025; Ex. 1026.) A hearing is scheduled for Petitioner’s Motion to Stay on July 16, 2025. (Ex. 2009.) Prior decisions and statistics from the Northern

District of California indicate that the Court is likely to grant Petitioner's Motion to Stay.

For example, courts in the Northern District of California frequently grant stays pending IPRs, even when less than all asserted patents have instituted IPRs, and even before the Board has issued its institution decisions on all filed IPRs. *See, e.g., Google LLC v. EcoFactor, Inc.*, No. 21-cv-03220-HSG, 2022 WL 6837715, at *2-3 (N.D. Cal. Oct. 11, 2022) (granting stay where IPRs were instituted on three asserted patents but institution was denied for fourth asserted patent); *Ex. 1032 (Yangtze Memory Techs. Co., Ltd. v. Micron Tech., Inc.)*, No. 23-cv-05792-RFL, Dkt. 243 (N.D. Cal. Mar. 14, 2025) (granting stay where IPR was instituted for 23 asserted claims, but institution was denied for 11 other asserted claims)); *Dialect, LLC v. Google LLC*, No. 24-cv-04388-JSC, 2024 WL 4314206 (N.D. Cal. Sept. 26, 2024) (granting stay even though Board had not yet issued institution decisions on any of the filed IPRs); *Apple Inc. v. Alivecor, Inc.*, No. 22-cv-07608-HSG, 2023 WL 9187388 (N.D. Cal. Dec. 29, 2023) (granting stay where one IPR had been instituted and institution decisions for remaining IPRs were pending); *Ex. 1033 (Jawbone Innovations, LLC v. Google LLC)*, No. 23-cv-00466-TLT, Dkt. 137 (N.D. Cal. Apr. 27, 2023) (granting stay where IPR was instituted for eight asserted patents, but institution was denied for ninth asserted patent)).

In fact, in the Director's recent decision in *Twitch* denying discretionary denial, the Director acknowledged that "[o]ver the past twelve years, judges in the [Northern

District of California] have granted or partially granted 76% of all post-institution motions to stay pending *inter partes* review.” *Twitch Interactive Inc.*, IPR2025-00307, Paper 18 at 2. The Director concluded this statistic offered “persuasive evidence that ‘[t]here is good reason to believe that a stay will be granted’” in the district court litigation. *Id.* The same statistics and conclusion apply here. Thus, PO’s argument that “there is no evidence that [the Court] will grant” a stay is incorrect. (Paper 6 (Request) at 4.)

PO also accuses Petitioner of delaying to file its Motion to Stay. (*Id.*) Not so. Petitioner recognized that the Court would need to resolve PO’s pending motion for preliminary injunction before it could stay the litigation. Yet, due to the Court’s heavy docket and the schedule of the parties, the Court was unable to schedule a hearing on the motion for preliminary injunction until May 28, 2025, roughly ***ten months*** after the motion was filed. (Ex. 2015.) Petitioner filed its motion for stay as soon as the hearing date for the preliminary injunction motion was set for May 28. The briefing on the Motion to Stay is complete and the Court has set a hearing for the motion on July 16, 2025. (Ex. 2009.) If anything, the scheduling of the preliminary injunction motion illustrates the Court’s congested docket and further suggests that the parties will not reach trial before the Board issues a final written decision on this IPR.

Accordingly, the likelihood that the Court will stay the litigation following institution of this IPR also weighs strongly against discretionary denial.

3. The Board Has Already Instituted IPRs On Similar Claims Based On The Same Prior Art

PO argues that “the merits favor denial.” (Paper 6 (Request) at 12.) But PO conspicuously omits any mention of the ’011 and ’012 patent IPRs in which the Board instituted IPRs on similar claims based on the same prior art raised in this IPR. PO also ignores that in the ’011 and ’012 IPRs, the the Board expressly considered and found unconvincing PO’s arguments for patentability raised in this Request and its POPR.

PO’s arguments for patentability in its Request and POPR focus exclusively on limitations relating to the “filament” of the hemostasis valve recited in the claims of the challenged ’005 patent. (See Paper 6 (Request) at 12-17; Paper 5 (POPR) at 26-72.) Specifically, PO argues that the prior art raised in the Petition does not render the following limitations obvious:

- a “filament” that is “flexible” (see Paper 5 (POPR), 28-31);
- a “filament” having two ends extending in different directions and coupled to different members of an actuator (see *id.*, 31-35, 43-47, 67-68); and
- a “filament” formed in a loop that reduces in diameter (see *id.*, 35-38).

Each of the limitations that PO contests in its POPR and Request are also recited in the claims of the ’011 and/or ’012 patents, as illustrated in the charts below:

'005 Patent – Claim 1	'011 Patent – Claim 1
1. A vacuum aspiration system, comprising: ... a hemostasis valve in the housing configured to receive a second catheter and direct the second catheter through the first catheter, wherein the hemostasis valve comprises: a tubular member defining a lumen configured to slidably receive the second catheter; a constricting mechanism including a filament and an actuator coupled to the filament, the filament comprising a first portion extending around at least a portion of the tubular member and a second portion having a first end extending from the first portion in one direction and a second end extending from the first portion in another direction, and the actuator comprises a first member coupled to the first end of the filament and a second member coupled to the second end of the filament, wherein the first member and the second member of the actuator are moveable between (a) a first position wherein the filament circumferentially constricts the lumen to create a seal and (b) a second position wherein the filament is moved to at least partially open the lumen; and a biasing system configured to bias the first member and the second member to the first position.	1. A valve, comprising: a tubular member defining a lumen configured to slidably receive a catheter; a constricting mechanism including at least one filament and an actuator coupled to the filament, the filament comprising a first portion extending around at least a portion of the tubular member and a second portion having a first end extending from the first portion in one direction and a second end extending from the first portion in another direction, and the actuator comprises a first member coupled to the first end of the filament and a second member coupled to the second end of the filament, wherein the first member and the second member of the actuator are moveable between (a) a first position wherein the filament circumferentially constricts the lumen to create a seal and (b) a second position wherein the filament is moved to at least partially open the lumen; and a biasing system configured to bias the first member and the second member to the first position.

'005 Patent – Claim 10	'012 Patent – Claim 1
10. A vacuum aspiration system, comprising: ... a hemostasis valve in the housing configured to receive a second catheter and direct the second catheter through the first catheter, wherein the hemostasis valve comprises (a) a support; (b) an actuator having a least a first member movably coupled to the support; (c) a collapsible tubular sidewall defining a lumen carried by the support; (d) a filament formed in a loop around the tubular sidewall, the filament having at least a first end portion extending away from the loop to the first member; and (e) a first spring configured to move the first member in a direction that pulls the first end portion such that a diameter of the lumen decreases in response to reducing a diameter of the loop.	1. An aspiration catheter, comprising: an elongate, flexible tubular body, having a proximal end, a distal end and a central lumen; a hemostasis valve on the proximal end of the catheter, the hemostasis valve comprising (a) a collapsible tubular sidewall defining a valve lumen in communication with the central lumen; and (b) a constricting mechanism having at least a first actuator, a first filament formed into a loop around the collapsible tubular sidewall, the filament having at least a first end portion extending away from the loop and connected to the first actuator, and a first spring configured to move the first actuator in a direction that pulls the first end portion such that a diameter of the valve lumen decreases in response to reducing a diameter of the loop.

(Ex. 1001 ('005 patent) at Claims 1, 10; Ex. 1025 at 8; Ex. 1026 at 8.)

The Petition explains that each of the above “filament” limitations would have been obvious to a person of ordinary skill in view of: Schaffer (Ground 1); Schaffer combined with Hartley (Ground 2); Schaffer combined with Eller (Ground 3); and

Hartley combined with Eller (Ground 4). (Paper 1 (Petition) at 20.)¹ Petitioner relied upon **the same** prior art references and combinations (i.e., Schaffer, Hartley, and Eller) for these same limitations in the '011 and '012 IPRs. (Ex. 1025 at 9, 30-35; Ex. 1026 at 9, 30-38.) In each of the '011 and '012 IPRs, the Board preliminarily agreed with Petitioner's arguments and found PO's counterarguments "unavailing." (Ex. 1025 at 35; Ex. 1026 at 38.)

For example, in the '011 IPR, the Board found that "Petitioner provides evidence-backed argument, sufficient at this stage, to explain where each of claim 1's limitations is taught or suggested in the combination of Schaffer and Hartley." (Ex. 1025 at 35.) The Board noted that PO "provide[d] no argument that any limitation is missing in the combination of Schaffer and Hartley" and instead argued that "a skilled artisan would not have been motivated to combine Schaffer and Hartley with a reasonable expectation of success." (*Id.* at 36.) The Board analyzed PO's counterarguments in detail and found them "unavailing." (*Id.* at 35-41.) The Board specifically considered and rejected PO's arguments that a skilled artisan would not have combined Schaffer and Hartley because: (1) Schaffer's U-shaped actuating members do not create gaps; (2) modifying Schaffer to include Hartley's flexible string "would change Schaffer's principle of operation";

¹ Petitioner relies upon the Garrison prior art reference for other limitations recited in the claims of the '005 patent, but Petitioner does not rely on Garrison for the "filament" limitations. (See Paper 1 (Petition) at 20.) PO does not contest that Garrison discloses the limitations of the '005 patent claims as asserted by Petitioner. (See Paper 5 (POPR); Paper 6 (Request) at 16-17.)

and (3) incorporating Hartley's flexible string into Schaffer's valve would "introduce manufacturing difficulties and reduce the durability of Schaffer's valve." (*Id.*)

In the '012 IPR, the Board again found that "Petitioner's argument and evidence [were] sufficient, at this stage, to support the rationale for modifying Schaffer in view of Hartley as proposed with a reasonable expectation of success, and to explain where each of claim 1's limitations is taught or suggested in the combination of Schaffer and Hartley." (Ex. 1026 at 38.) Notably, in the '012 IPR, the Board agreed with PO that the claimed "filament" must be flexible, but the Board nonetheless concluded that the combination of Schaffer with Hartley or Eller likely renders the claimed "filament" obvious. (*Id.* at 21, 38.) The Board also addressed each of PO's counterarguments regarding the combination of Schaffer with Hartley or Eller and again found them unpersuasive. (*Id.* at 38-48.) In addition to the arguments that PO had presented in the '011 IPR, the Board also considered and rejected PO's additional arguments that: (1) combination of Schaffer and Hartley is not a "simple substitution" because Hartley does not disclose "'any [single] element' that is attached to separate actuators" and (2) Hartley's string would "'render[] Schaffer's valve inoperable by inhibiting or even preventing' movement of the seal module from the closed to the open position." (*Id.*)

PO raises the same arguments against Petitioner's invalidity grounds for the '005 patent here that the Board previously considered and rejected in the '011 and '012 IPRs. (See Paper 5 (POPR) at 47-63; Paper 6 (Request) at 16-17.) For example, in its Request,

PO asserts that “a POSA would not have been motivated to replace Schaffer’s rigid U-shaped actuating members with a flexible string or wire as disclosed in Hartley or Eller” because it “requires that a POSA first remove the features of Schaffer that Petitioner itself asserts form a complete seal.” (Paper 6 (Request) at 16.) The Board considered and rejected this very argument in its institution decisions for the ’011 and ’012 IPRs. (Ex. 1025 at 37-38; *see also* Ex. 1026 at 40-42.) The Board noted that the portion of Schaffer that PO relies upon “concerns only ‘one embodiment’ of Schaffer’s valve and the ‘sticky’ or ‘selfclosing’ material appears to be simply one optional feature,” but “Schaffer more broadly discloses that its seal member can be made of highly elastic, deformable, and compliant materials” which “overlap with materials suitable for forming the ’011 patent’s ‘elongate member.’” (Ex. 1025 at 37-38; *see also* Ex. 1026 at 40-42.) The Board further found that “even if the optional ‘sticky’ material described in Schaffer can help to avoid gaps as suggested by [PO], it is not evident why that would discourage the POSA from considering *other* known features in the field to mitigate potential gaps or leaks around inserted tools, such as suggested with Hartley’s flexible member/string.” (Ex. 1025 at 38 (emphasis in original); *see also* Ex. 1026 at 40-42.)

Tellingly, PO’s Request fails to mention that the Board rejected the same arguments it presents for the ’005 patent in prior IPRs, and PO does not even attempt to address the Board’s decisions instituting the ’011 and ’012 IPRs. (See Paper 6 (Request) at 12-17.) That the Board has twice considered the same prior art and

arguments for nearly identical claims and twice concluded that Petitioner’s grounds warranted institution demonstrates that Petitioner presents a “particularly strong” challenge to the patentability of the ’005 patent which strongly weighs against discretionary denial. *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11, at 14-15 (P.T.A.B. Mar. 20, 2020).

4. The District Court Proceedings Are Still In Early Stages

PO also overstates the investment of time and resources by the Court and parties in the co-pending litigation. (Paper 6 (Request) at 5-8.) In fact, PO’s arguments in the Request directly conflict with arguments it recently made to the Court regarding the stage of the litigation. As explained above, PO filed a Motion for Leave to File a Third Amended Complaint in the district court, seeking to add yet another patent to the litigation. (Ex. 2025.) In an effort to get the Court to grant the motion, PO argued that “discovery is at an early stage” and emphasized that the parties were just beginning document production. (*Id.* at 2, 6.) PO also emphasized that the district court “has not even set a date for the close of fact discovery.” (*Id.*) PO further argued that the litigation “has not yet come anywhere close to the point where a patent owner would typically be required to narrow the number of asserted patents and claims.” (*Id.* at 2.) Thus, at least when it suits its interests, PO apparently agrees that the co-pending litigation is “at an early stage,” which weighs against discretionary denial.

PO's representation to the Court that the case is at an early stage is correct. The parties only recently began document production. No party depositions or 30(b)(6) depositions have been scheduled, let alone completed. Outside of limited discovery related to PO's preliminary injunction motion and claim construction, the parties have not engaged in any expert discovery or filed dispositive motions (nor has the Court set any deadlines for expert discovery or dispositive motions).

The events that PO identifies at pages 6-7 of its Request exemplify the early stage of the litigation. (See Paper 6 (Request) at 6-7.) Those events reflect standard discovery that occurs at the beginning of every patent infringement litigation, most of which is required by the Federal Rules (e.g., initial disclosures) and/or the Court's local rules (e.g., preliminary contentions). (*Id.*) PO also relies upon third-party subpoenas served by each party in the litigation, but PO does not identify any investment or expenses by the parties related to the subpoenas beyond the fact that they have been served. (*Id.*) Moreover, the parties and the Court have not yet expended any resources addressing the validity of '005 patent, other than Petitioner's mandatory invalidity contentions, the expense of which was entirely born by Petitioner. (See *id.*) If the Board cancels any of the challenged claims of the '005 patent in this IPR, the parties and the Court will never need to expend resources addressing those claims in the district court, providing the exact cost-saving efficiency IPRs were created for.

PO's request also relies upon the limited claim construction proceedings that have occurred in the district court, but the parties only just recently began claim construction proceedings. (*See id.* at 8.) The Court just ordered the parties to meet and confer regarding extending the claim construction schedule based on the Court's decision to allow PO's third amended complaint. Thus, the schedule for claim construction in the district court is in flux. However, even under the now old schedule, claim construction briefing would not have been due until July 3, 2025, and the Court would not have had a claim construction hearing until July 24, 2025, nearly a month after the deadline for the Board's institution decision in this IPR, and after the hearing on the Motion to Stay. (Ex. 2016.) Because the claim construction hearing is not set until after the hearing on the Motion to Stay, there is a high likelihood that the Court will not devote any resources to claim construction because the litigation will be stayed. In addition, there is minimal overlap between the issues that will be addressed during the district court claim construction proceedings and this IPR. There is only one term from the '005 patent proposed for construction by either party – "filament." (Ex. 1034 at 2, Exhibit A pg. 1.) As noted above, the Board addressed the construction of "filament" in its institution decisions in the '011 and '012 IPRs and will continue to address that issue as those IPRs proceed. (*Supra* §III.A.3.)

The early stage of the co-pending litigation is further illustrated by the fact that the pleadings have not yet closed. As noted above, PO recently sought leave from the

district court to amend its complaint for a third time to add yet another patent to the case. (Ex. 2025.) From the bench, the district court granted PO's request during a hearing that took place the same day as this filing, May 28, 2025 (thus, the formal Order is not yet available). The Court also ordered the parties to meet and confer to extend the schedule for the litigation that will be required by PO's amendment and the new patent. PO's addition of the new patent will further delay the case schedule by at least requiring the parties to serve additional invalidity contentions and lodge new claim construction positions to account for the new patent. (See Ex. 1028 at 2, 9-10.) Thus, claim construction will not proceed according to the Court's prior schedule and it is even more unlikely that a trial will occur in the litigation before the Board issues its final written decision in this IPR.

For at least these reasons, the investment in the parallel proceeding by the Court and the parties, which has been minimal to-date due to the early stage of the litigation, weighs against discretionary denial of institution in this IPR.

5. **There Will Be Minimal Overlap Between Issues Addressed In The District Court Litigation And This IPR Following Institution**

PO argues that there will be "substantial overlap between the issues raised" in this IPR and the co-pending litigation. (Paper 6 (Request) at 9.) But PO ignores that the IPRs have already successfully *reduced* overlap between the Board and Court. Shortly after the Board granted institution of the '011 patent IPR, PO filed an amended

complaint **dropping** the '011 patent from the co-pending litigation. (Ex. 2008 at 7-8.) Thus, Petitioner's IPRs have minimized overlap between the Board and Court.

PO's arguments regarding the overlap between this IPR and the district court litigation focus on PO's assertion of the '005 patent in the litigation and Petitioner's reliance on some of the same grounds of invalidity in its preliminary invalidity contentions. (See Paper 6 (Request) at 9.) However, Petitioner has stipulated that it will not pursue any invalidity grounds in the district court that are raised or reasonably could have been raised in the Petition if the Board institutes this IPR. (See Paper 1 (Petition) at 107.) Petitioner's stipulation "mitigates any concerns of duplicative efforts between the district court and the Board, as well as concerns of potentially conflicting decisions." *Sotera Wireless, Inc. v. Masimo Corp.*, IPR2020-01019, Paper 12, at 19 (P.T.A.B. Dec. 1, 2020). Thus, if the Board institutes Petitioner's IPR of the '005 patent, there will be little, if any, overlap between the issues addressed during the IPR and the district court litigation, which also weighs against discretionary denial. *See id.*

PO incorrectly argues that Petitioner's stipulation does not mitigate the potential overlap of issues because PO has asserted patents related to the '005 patent in the district court. (See Paper 6 (Request) at 9-11.) PO's argument regarding the related patents fails for several reasons.

First, PO fails to mention or address the Board's institution of the '011 and '012 patent IPRs. (See *id.*) As explained above, the '011 and '012 IPRs involve the same

prior art and the same “filament” limitations that PO raises in its Preliminary Response and Request here. (*Supra* §III.A.3.) Therefore, the Board will already address similar, if not identical, invalidity issues in the instituted ’011 and ’012 IPRs, including the proper construction of “filament” and whether the prior art renders the claimed “filament” obvious. Given the similarity between the claims of the ’005, ’011, and ’012 patents and Petitioner’s prior art challenges asserted across the three IPRs, discretionary denial of institution in this case would lead to inefficiency and potentially inconsistent outcomes. If discretionary denial is applied here, the parties would have to simultaneously litigate the same invalidity issues in the district court litigation and the instituted ’011 and ’012 IPRs. This would be costly, inefficient, and contrary to Congress’s purpose for creating IPRs – to provide a cost-effective alternative to district court litigation.

Second, Petitioner has filed IPRs challenging two of the additional related patents that PO raises in its Request – U.S. Patent Nos. 11,969,333 and 11,974,910. *See Imperative Care, Inc. v. Inari Medical, Inc.*, IPR2025-01021 requesting review of U.S. Patent No. 11,969,333 (Filed May 19, 2025); *Imperative Care, Inc. v. Inari Medical, Inc.*, IPR2025-01025 requesting review of U.S. Patent No. 11,974,910 (Filed May 20, 2025). Petitioner also intends to file IPRs challenging the remaining two patents raised in PO’s Request – U.S. Patent Nos. 12,016,580 and 12,156,669. The nine month deadline from issuance for the ’580 patent only recently expired, and the deadline has

not passed for the '669 patent. *See* 35 U.S.C. §311(c)(1). Petitioner has submitted similar *Sotera* stipulations in each of its IPR Petitions challenging PO's patents – confirming that Petitioner will not pursue grounds in the district court that are raised or reasonably could have been raised in the Petitions if the IPRs are instituted. These stipulations will similarly minimize overlap of issues between the IPRs of the related patents and the district court litigation following institution.

Third, PO's reliance on the Board's denial of Petitioner's IPR for U.S. Patent No. 11,744,691 is misplaced. PO fails to mention that the Board denied institution of the '691 IPR based on a limitation that is ***not*** recited in the '005 patent claims. (Ex. 1030, 22-29.) That limitation is also absent from the claims of the other related patents raised in PO's Request. Thus, the invalidity issues that will be addressed in the district court for the '691 patent will have minimal overlap with the issues in this IPR or the IPRs challenging PO's related patents.

Accordingly, the Board, not the district court, will be the forum adjudicating the invalidity issues raised in the Petition following institution. The minimal overlap between issues raised in this IPR and the district court litigation also weighs against discretionary denial.

B. The Additional Considerations Raised By PO Do Not Warrant Discretionary Denial

1. The Preliminary Injunction Proceedings Do Not Warrant Discretionary Denial

PO's motion for a preliminary injunction in the district court does not warrant or weigh in favor of discretionary denial of this IPR. PO did not rely on the challenged '005 patent in its PI Motion. Therefore, the '005 patent was not addressed by either party during any of the PI proceedings. PO does not explain why PI proceedings that relied on and addressed different patents somehow weigh in favor of discretionary denial for an IPR challenging the '005 patent. They do not. PO also fails to identify any additional investment of time or resources by the Court or the parties regarding the '005 patent caused by the PI Motion.

2. The Timing Of Petitioner's IPRs Do Not Warrant Discretionary Denial

PO also incorrectly asserts that the timing of Petitioner's IPRs for the asserted patents weigh in favor of discretionary denial. To date, Petitioner has filed IPRs challenging 8 of the 11 patents that have been asserted in the district court, including both patents PO relied upon for its PI Motion.² All of those IPRs were timely filed within the one-year statutory deadline under 35 U.S.C. §315(b). As noted above, the nine-month deadline from issuance only recently passed for one of the three remaining

² PO dropped the '011 patent from the district court litigation following institution of the '011 IPR.

patents asserted in the district court (the '580 patent), and Petitioner intends to promptly file an IPR petition challenging the '580 patent. (*Supra* §III.A.5). The nine-month deadline has not yet passed for the other two asserted patents or the additional patent that PO will likely add in its third amended complaint, but Petitioner plans to promptly file IPR petitions challenging those patents as well after the 9-month statutory period expires. Thus, Petitioner has acted diligently and promptly in filing IPRs challenging every one of the eligible patents asserted in the district court litigation. There has been no delay that warrants discretionary denial.

3. Mr. Thornton's Expert Declaration Does Not Warrant Discretionary Denial

PO incorrectly asserts that Petitioner's expert, Troy Thornton, presents "unfocused testimony" to support Petitioner's grounds and that Mr. Thornton's declaration weighs in favor of discretionary denial. (See Paper 6 (Request) at 18.) However, PO's argument is premised exclusively on the length of Mr. Thornton's expert declaration. (*Id.*) The Director recently rejected similar arguments from the patent owner in *Twitch*, noting that they were not "sufficiently explained." *Twitch Interactive Inc.*, IPR2025-00307, Paper 18 at 3. PO presents even less explanation for its arguments than presented in *Twitch*. Aside from noting the length of Mr. Thornton's declaration, PO does not explain how or why it believes Mr. Thornton's declaration presents any issues that would be better addressed by an Article III court than the Board. (See Paper 6 (Request) at 18.)

Mr. Thornton’s declaration provides proper evidentiary support for the invalidity grounds set forth in the Petition, including explanations for how a person of ordinary skill in the art would have understood and applied the teachings of the prior art. This is consistent with the Board’s repeated admonitions against unsupported attorney argument. *See, e.g., Eve Energy Co., Ltd. V. VARTA Microbattery GmbH*, IPR2022-01487, 2023 WL 2604644, at *8 (P.T.A.B. Mar. 14, 2023); *Dyson Tech. Ltd. V. Omachron Intellectual Prop. Inc.*, IPR2024-00938, 2024 WL 4828116, at *7 (P.T.A.B. Nov. 19, 2024). Moreover, given that PO raises only issues concerning certain “filament” limitations in its Preliminary Response, the vast majority of issues and claim limitations that Mr. Thornton addresses in his declaration are ***undisputed***. Accordingly, Mr. Thornton’s expert declaration does not warrant or weigh in favor of discretionary denial.

4. The Office Did Not Previously Consider Petitioner’s Prior Art Or Invalidity Grounds

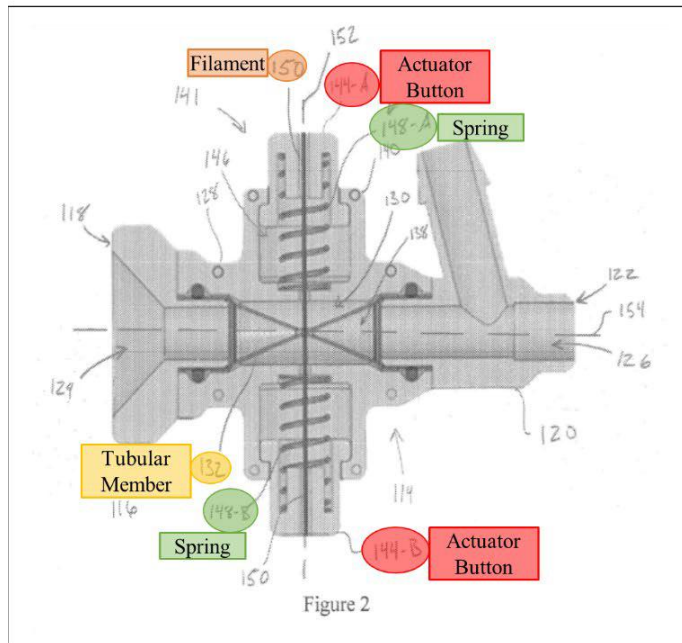
As explained in the Petition, Schaffer, which forms the basis for three of Petitioner’s four invalidity grounds, was not of-record during prosecution of the ’005 patent. *See* Paper 1 (Petition) at 108. Because Schaffer was not before the Examiner during prosecution, the Director should not deny institution under Section 325(d). *See Advanced Bionics, LLC v. MED-EL Elektromedizinische Gertite GmbH*, IPR2019-01469, Paper 6 at 7 (P.T.A.B. Feb. 13, 2020) (precedential) (“Under § 325(d), the art

and arguments must have been previously presented to the Office during proceedings pertaining to the challenged patent.”).

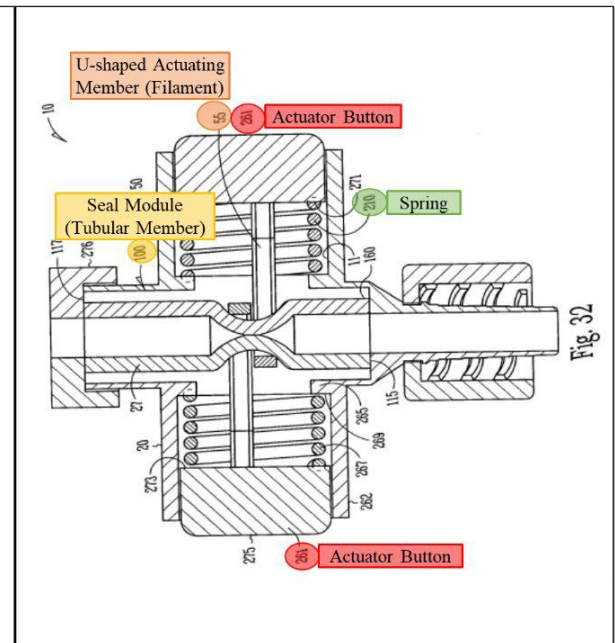
The fact that the Examiner did not consider Schaffer during prosecution of the ’005 patent is critical here because Schaffer supplies all the limitations of the challenged claims that the Examiner allegedly found missing from the prior art. During prosecution, the Examiner found that Hartley disclosed all the hemostasis-valve limitations of the pending claims except an “actuator having a first member movable [SIC] coupled to the support and the first spring configured to move the first member.” (Ex. 1002, 212-215.) Schaffer discloses those limitations the Examiner found lacking in Hartley. (See Paper 1 (Petition) at 40-43, 60-61.) PO does not contest that Schaffer discloses those limitations. Instead, PO challenges only whether a person of ordinary skill would have been motivated to combine Hartley’s filament with Schaffer’s hemostasis valve. (See Paper 6 (Request) at 12-17; Paper 5 (POPR) at 26-72.) However, as explained above, the Board has already twice concluded, at least preliminarily, that a skilled artisan would have been motivated to make this combination with a reasonable expectation of success in the ’011 and ’012 IPRs. (*Supra* §III.A.3.)

The Board’s conclusion that Schaffer likely anticipates or renders the ’011 and ’012 patent claims obvious is unsurprising given the immediately apparent similarities between Schaffer’s hemostasis valve and the valve described and claimed in the ’011, ’012, and ’005 patents:

'005 Patent ('519 Application)



Schaffer



(Ex. 1017 at Fig. 2³; Ex. 1005 at Fig. 32.) Thus, contrary to PO's representations, the Examiner did not consider the same prior art or invalidity arguments raised in the Petition during prosecution of the '005 patent. But the Board has considered this prior art and similar arguments in the '011 and '012 IPRs, and in both instances the Board concluded that there was a reasonable likelihood that the hemostasis valves claimed in those patents are invalid in view of Schaffer. (Ex. 1025; Ex. 1026.)

PO also incorrectly asserts that Schaffer is similar to Wong, a reference that was before the Examiner. (Paper 6 (Request) at 19-20.) In the Notice of Allowance for the '005 patent, the Examiner concluded that a person of ordinary skill would not combine

³ The specification of the '005 patent does not describe the structure of any hemostasis valve but rather relies on alleged incorporation of U.S. patent application Ser. No. 16/117,519 (the "'519 application" (Ex. 1017)).

Wong with the filament from Hartley because doing so “would conflict with the operation of the [Wong] device[],” which uses two plastic “sliders” to press on and close an elastic tube. (Ex. 1002 at 174.) However, in both the ’011 and ’012 IPRs, PO argued that combining Hartley’s filament with Schaffer would also conflict with the operation of Schaffer’s hemostasis valve, but the Board disagreed and found PO’s arguments unpersuasive. (Ex. 1025 at 39-40; Ex. 1026 at 40-45.) Thus, Schaffer is not similar to Wong at least because combining Schaffer’s hemostasis valve with Hartley’s filament would not conflict with the operation of Schaffer’s valve.

PO’s reliance on the fact that the Garrison prior art reference was before the Examiner during prosecution is also misplaced. Although Garrison is asserted in each of Petitioner’s invalidity grounds, PO does not contest that Garrison discloses the claimed limitations as explained in the Petition. (*See* Paper 5 (POPR).) In other words, Petitioner’s arguments regarding Garrison are undisputed. Thus, the fact that Garrison was before the Examiner during prosecution does not warrant denying institution under Section 325(d), particularly given that Schaffer was not of-record during prosecution.

IV. CONCLUSION

For the foregoing reasons, Petitioner respectfully requests that the Director deny PO’s Request for Discretionary Denial and allow this IPR to proceed to an institution determination on the merits.

CERTIFICATE OF COMPLIANCE

Pursuant to 37 C.F.R. § 42.24(d), the undersigned certifies that this **PETITIONER’S OPPOSITION TO PATENT OWNER’S REQUEST FOR DISCRETIONARY DENIAL** contains 7,003 words according to the word-processing program used to prepare this paper. The foregoing word count complies with the 14,000-word type-volume limit specified by the Interim Processes for PTAB Workload Management and 37 C.F.R. § 42.24.

Dated: May 28, 2025

By: /Joshua J. Stowell /

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

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*Attorneys for Petitioner,
Imperative Care, Inc.*

CERTIFICATE OF SERVICE

I hereby certify that, pursuant to 37 C.F.R. § 42.6(e), a true and correct copy of **PETITIONER'S OPPOSITION TO PATENT OWNER'S REQUEST FOR DISCRETIONARY DENIAL and Exhibit 1025 – Exhibit 1034** are being served electronically on May 28, 2025, to the e-mail addresses shown below:

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Dated: May 28, 2025

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