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On behalf of **Imperative Care, Inc.**

By: Joshua J. Stowell (Reg. No. 64,096)  
Joseph R. Re (Reg. No. 31,291)  
Brian C. Barnes (Reg. No. 75,805)  
KNOBBE, MARTENS, OLSON & BEAR, LLP  
2040 Main Street, 14th Floor  
Irvine, CA 92614  
Tel.: (949) 760-0404  
Fax: (949) 760-9502  
Email: BoxImperative921@knobbe.com

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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IMPERATIVE CARE, INC.,  
Petitioner,

v.

INARI MEDICAL INC.,  
Patent Owner.

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Case No. IPR2025-00728  
Patent No. 11,844,921

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

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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”
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1016	U.S. Patent No. 12,109,384 B2 to Merritt et al.

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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
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1032	U.S. Patent No. 11,697,012 B2 to Merritt et al. (“’012 patent”)
1033	U.S. Patent No. 11,554,005 B2 to Merritt et al. (“’005 patent”)
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)
1035	Transcript of Proceedings Before the Honorable Eumi K. Lee on March 28, 2025 (Dkt. #119) in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 24-cv-03117-EKL (N.D. Cal.) (filed June 8, 2025)
1036	Notice of Allowance for U.S. Patent App. No. 17/865,280

## **I. INTRODUCTION**

Five weeks ago the Director denied a nearly identical request for discretionary denial involving the same parties and a related patent with similar claims. (Ex. 1022, “the ’005 Patent IPR”.) PO does not identify any change in circumstances since that denial that would warrant a different outcome here. To the contrary, recent developments in the co-pending Litigation and related IPRs make discretionary denial even more inappropriate.

For example, the Court recently vacated all previously scheduled case deadlines except for a hearing on Petitioner’s motion to stay the Litigation pending resolution of the IPRs. (Ex. 1023.) The hearing is scheduled for the same day as this filing. (*Id.*) Thus, not only is there no scheduled trial date, but there is also no claim construction schedule or any discovery deadlines. Moreover, statistics for the Northern District of California indicate that the Court is likely to grant Petitioner’s motion to stay, particularly now that the Board has instituted IPRs on three asserted patents. (*See id.* (recognizing that “circumstances have changed since briefing concluded [because] Imperative Care has filed IPR petitions on all eight patents that Inari asserted in the original complaint, and the PTAB has instituted IPR on three of four petitions to date”).) Against this backdrop, PO’s speculation that “[i]t is fully possible” the Court will set a trial date before a final written decision in this IPR (which would be due in October 2026) is unsupported and fanciful.

Events since the Director's prior denial have also reinforced the strength of Petitioner's invalidity grounds. Shortly after the Director denied PO's request for discretionary denial, the Board instituted the '005 Patent IPR, marking the third time the Board has found that the prior art likely renders claims in PO's related patents invalid. (Ex. 1024; *see also* Ex. 1017, "'011 Patent IPR"; Ex. 1025, "'012 Patent IPR".) Petitioner asserts the same prior art against the '921 patent here that the Board relied on in instituting the related IPRs, and the challenged claims of the '921 patent are very similar to those the Board found to be likely invalid. (*Infra* §III.A.3.)

The institution decisions in the '011, '012, and '005 Patent IPRs highlight the strength of Petitioner's invalidity grounds for the '921 patent and demonstrate the inefficiency that would result from discretionary denial. The Board is currently addressing the same invalidity issues raised in this IPR. A discretionary denial of this IPR would force the parties and Court to relitigate the same issues, wasting judicial and party resources and possibly resulting in inconsistent outcomes.

The institution decisions in the '011, '012, and '005 Patent IPRs also expose the critical flaw in PO's Section 325(d) argument. In each of those IPRs, the Board relied upon the Schaffer prior art reference in concluding that the challenged claims were likely anticipated or obvious. (Ex. 1017; Ex. 1024; Ex. 1025.) It is undisputed that Schaffer was not before the Examiner during prosecution of the '921 patent. Thus, the Examiner did not have the opportunity to consider the patentability of the

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claims in view of Schaffer. But the Board has had that opportunity three times now, and in each instance concluded that the claims are likely unpatentable in view of Schaffer.

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 eleven patents in the co-pending district court litigation. (Paper 5 (Request) at 2.) Petitioner has already filed IPR petitions against all eight patents asserted in PO's original complaint and the additional patent PO added in its first amended 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

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No. 11,969,333; (8) *Imperative Care, Inc. v. Inari Medical, Inc.*, IPR2025-01025 requesting review of U.S. Patent No. 11,974,910; and (9) *Imperative Care, Inc. v. Inari Medical, Inc.*, IPR2025-01264 requesting review of U.S. Patent No. 12,016,580.

As mentioned above, the Board has already granted institution of three IPRs challenging the validity of the '011, '012, and '005 patents. (Ex. 1024; Ex. 1017; Ex. 1025.) Shortly after the Board instituted the '011 Patent IPR, PO dropped the '011 patent from the Litigation, demonstrating the narrowing effect of the IPRs. (Ex. 1026 at 3, 7.) The parties are currently awaiting institution decisions on five of the pending IPRs, including this IPR challenging the validity of the '921 patent. The Board denied institution of one IPR challenging the validity of the '691 patent. (Ex. 1027 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 three patents PO has added to the litigation through its second and third amended complaints, U.S. Patent Nos. 12,109,384; 12,156,669; and 12,239,333, in the near future and once they become eligible for IPR after expiration of the 9-month statutory waiting period.

**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 dates set for claim construction or 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 three other IPRs asserting the same prior art against claims reciting very similar limitations as the ’921 patent (weighs against discretionary denial).

Further, the ’921 patent recently issued on December 19, 2023, so PO does not allege it had settled expectations. Accordingly, Petitioner believes that the facts outlined below warrant a denial of PO’s request.

**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 5 (Request) at 8.) PO speculates, however, that “[i]t is possible that the district court will, after the Markman hearing, set a trial date before the projected statutory deadline in this or future IPRs.” (*Id.*) PO cites no facts to support this assertion, nor do any exist. (*Id.*)

The Court initially set a case schedule through only the claim construction hearing (initially set for July 24, 2025) and never set a trial date. (Ex. 1021.) However, on July 3, the Court vacated the case schedule and told the parties that it “will address the case schedule after the July 16 hearing on Imperative Care’s motion

to stay the case in its entirety pending *inter partes* review (‘IPR’) proceedings before the Patent Trial and Appeal Board (the ‘PTAB’).” (Ex. 1023.) The Court’s order observed that “circumstances have changed since briefing concluded” because “Imperative Care has filed IPR petitions on all eight patents that Inari asserted in the original complaint, and the PTAB has instituted IPR on three of four petitions to date.” (*Id.*) Thus, there are currently *no deadlines* set in the Litigation besides the July 16 hearing on Petitioner’s motion to stay.

Moreover, even under the original case schedule, which has been vacated, the Court never set any case deadlines after the claim construction hearing and would not set a trial date. (Ex. 1021.) 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. 1028 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. 1029 at 66.) PO filed the co-pending litigation in May 2024. (Ex. 2001.) 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 October 2026).

Importantly, in its recent decision denying PO's request for discretionary denial in the related '005 Patent IPR, the Director emphasized that "there is no trial date scheduled in the district court." (Ex. 1022.) That remains true, and the recent events in the Litigation have made PO's speculation that a trial may take place before the statutory deadline in this IPR even less likely.

Accordingly, as the Director found in the related '005 Patent IPR, 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 filed a Motion to Stay the district court litigation pending resolution of the IPRs challenging PO's patents, including the instituted '011, '012, and '005 Patent IPRs. (Ex. 2005.) A hearing is scheduled for Petitioner's Motion to Stay on July 16, 2025. (*See* Ex. 1023.) As explained above, the district court recently issued an order emphasizing that "circumstances have changed since briefing concluded" on Petitioner's motion because Petitioner "has filed IPR petitions on all eight patents that [PO] asserted in the original complaint, and the PTAB has instituted IPR on three of four petitions to date." (*Id.*)

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. 1030 (*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. Alivacor, 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. 1031 (*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. v. Razdog Holdings LLC*, IPR2025-00307, Paper 18 at 2 (P.T.A.B. May 16, 2025).

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 Director’s recent decision denying PO’s request in the related ’005 Patent IPR also credited this evidence, finding that “Petitioner also provides evidence that the district court is likely to grant a stay if this proceeding is instituted.” (Ex. 1022.)

Thus, PO’s argument that “there is no evidence that [the Court] will grant” a stay is incorrect. (Paper 5 (Request) at 5.)

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. 2006.) 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 held a hearing on the motion the same day as this Opposition was filed. (*See* Ex. 1023.) 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, as the Director found in the related '005 Patent IPR, 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's request does not even attempt to address the merits of the Petition, which are particularly strong here. (*See* Paper 5 (Request).) PO glaringly omits any mention of the '011, '012, and '005 Patent IPRs in which the Board granted institution on similar claims based on the same prior art raised in this IPR. For example, as illustrated in the chart below, the '011 patent recites the same or similar limitations as each of the challenged independent claims of the '921 patent:<sup>1</sup>

'921 Patent – Claim 1	'011 Patent – Claim 1
1. A valve, comprising: an elongate member defining a lumen; an active tensioning mechanism including an actuator coupled to the elongate member via a filament extending at least partially around the elongate member,	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

<sup>1</sup> The '012 and '005 patents also recite similar limitations as the challenged '921 patent (*See* Ex. 1032; Ex. 1033).

'921 Patent – Claim 1	'011 Patent – Claim 1
<p>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</p> <p>a biasing member configured to bias the actuator to the first position.</p>	<p>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</p> <p>a biasing system configured to bias the first member and the second member to the first position.</p>

'921 Patent – Claim 15	'011 Patent – Claim 1
<p>15. A valve, comprising:  an elongate member defining a lumen;  a filament coupled to the elongate member;  an actuator coupled to the filament, 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</p>	<p>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</p>

’921 Patent – Claim 15	’011 Patent – Claim 1
<p>a biasing member configured to bias the actuator to the first position.</p>	<p>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</p> <p>a biasing system configured to bias the first member and the second member to the first position.</p>

’921 Patent – Claim 21	’011 Patent – Claim 1
<p>21. A valve, comprising:  an elongate member defining a lumen;  a filament coupled to the elongate member; and  an actuator coupled to the elongate member, wherein the actuator is moveable between (a) a first position in which the actuator pulls the filament to collapse the elongate member such that the lumen is constricted and sealed and (b) a second position wherein the lumen is at least partially open;  a biasing member configured to bias the actuator to the first position.</p>	<p>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</p>

'921 Patent – Claim 21	'011 Patent – Claim 1
	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.

(Ex. 1001 ('921 patent) at Claims 1, 15, 21; Ex. 1012 ('011 patent) at Claim 1.) The '921 Patent Petition explains that each of the above claims are anticipated by Schaffer, a prior art reference that was *not* considered by the Examiner during prosecution, and would have been obvious to a person of ordinary skill in view of: Schaffer (Ground 2); Schaffer combined with Hartley (Ground 3); Schaffer combined with Eller (Ground 4); and Hartley combined with Eller (Ground 5). (Paper 1 (Petition) at 20.) Petitioner relied upon *the same* prior art references and combinations (i.e., Schaffer, Hartley, and Eller) for these same limitations in the '011, '012, and '005 Patent IPRs. (Ex. 1017 at 9, 30-35; Ex. 1024 at 12, 29-36; Ex. 1025 at 9, 30-38.) In each of the '011, '012, and '005 Patent IPRs, the Board preliminarily agreed with Petitioner's arguments and found PO's counterarguments "unavailing." (Ex. 1017 at 35; Ex. 1025 at 38; Ex. 1024 at 36.)

For example, in the '011 Patent IPR, the Board found that “Petitioner has established a reasonable likelihood that it will prevail in showing that at least claim 1 [of the '011 patent] is anticipated by Schaffer.” (Ex. 1017 at 33.) Importantly, as illustrated in the table above, the independent claims of the challenged '921 patent are even broader than the claims of the '011 patent that the Board found are likely anticipated by Schaffer.

The Board in the '011 Patent IPR also preliminarily 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. 1017 at 35.) The Board observed 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”; and (3) incorporating Hartley’s flexible string into Schaffer’s valve would “introduce manufacturing difficulties and reduce the

durability of Schaffer's valve." (*Id.*) The Board conducted a similar analysis, and made similar preliminary findings, in each of the '012 and '005 Patent IPRs as well, concluding in each case that Petitioner had shown a reasonable likelihood that at least one of the challenged claims was obvious in view of Schaffer combined with Hartley. (Ex. 1025 at 38; Ex. 1024 at 36, 45.)

Moreover, in both the '012 and '005 Patent IPRs, the Board agreed with PO that the claimed "filament" must be flexible where the claims recite that the filament forms a "loop," but the Board nonetheless concluded that the combination of Schaffer with Hartley or Eller likely renders the looped "filament" obvious. (Ex. 1025 at 21, 38; Ex. 1024 at 18, 45.) The Board also addressed and found unpersuasive PO's additional counterarguments beyond those presented in the '011 Patent IPR, including that: (1) the 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." (Ex. 1025 at 38-48; Ex. 1024 at 36-42.)

Tellingly, PO's Request fails to mention that the Board has now considered the same prior art asserted in the Petition for similar claims as those recited in the challenged '921 patent and each time concluded that Petitioner's grounds warranted institution. The consistent and repeated preliminary findings by the Board in the

related IPRs demonstrates that Petitioner presents a “particularly strong” challenge to the patentability of the ’921 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 5 (Request) at 9-12.) In fact, PO’s arguments in the Request directly conflict with arguments it recently made to the Court regarding the stage of the Litigation. PO recently filed a Motion for Leave to File a Third Amended Complaint in the district court, which sought to add yet another patent to the litigation. (Ex. 1019.) 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 Court has not set a deadline for fact discovery. Document discovery remains in its infancy and neither party has scheduled, much less completed, any 30(b)(6) depositions. The parties have not engaged in expert discovery (aside from limited discovery related to PO's preliminary injunction motion and claim construction), and the parties have not filed dispositive motions. The Court has not set any deadlines for expert discovery or dispositive motions.

The events that PO identifies at pages 10-11 of its Request exemplify the early stage of the Litigation. (*See* Paper 5 (Request) at 10-11.) 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 the only investment or expenses by the parties related to the subpoenas identified by PO are two depositions of Petitioner's former employees. (*Id.*)

PO's request also relies upon the limited claim construction proceedings that have occurred in the district court, but the Court vacated the July 24 date for the claim construction hearing and has explained that it "will address the case schedule after the July 16 hearing on Imperative Care's motion to stay." (Ex. 1023.) Thus, there is currently no schedule for claim construction. It is therefore even more

unlikely that any trial will occur in the litigation before the Board issues its final written decision in this IPR.

Moreover, because any claim construction hearing will not take place 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 '921 patent proposed for construction by either party – “filament.” (Ex. 1034 at Exhibit A pg. 1-4.) As discussed above, the Board addressed the construction of “filament” in its institution decisions in the '011, '012, and '005 Patent IPRs and will continue to address that issue as those IPRs proceed. (*Supra* §III.A.3.)

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 “significant overlap between the issues raised” in this IPR and the co-pending litigation. (Paper 5 (Request) at 12.) 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. 2005 at 7-8.) Thus, Petitioner's IPRs have already 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 '921 patent in the Litigation and Petitioner's reliance on some of the same grounds of invalidity in its preliminary invalidity contentions. (See Paper 5 (Request) at 12-13.) 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 93.) 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 '921 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 '921 patent

in the district court. (*See* Paper 5 (Request) at 13-15.) 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, '012, and '005 Patent IPRs. (*See id.*) As explained above, the '011, '012, and '005 Patent IPRs involve the same prior art and nearly identical claim limitations as those at issue here. (*Supra* §III.A.3.) Therefore, the Board will already address similar, if not identical, invalidity issues in the instituted '011, '012, and '005 Patent IPRs, including the proper construction of "filament" and whether the prior art anticipates or renders the claimed "filament" obvious. Because of the similarity between the claims of the '921, '011, '012, and '005 patents and Petitioner's prior art challenges asserted across the four IPRs, 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, '012, and '005 Patent 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 three related patents that PO raises in its Request – U.S. Patent Nos. 11,697,012 and 11,865,291. *See Imperative Care, Inc. v. Inari Medical, Inc.*, IPR2025-00156 requesting review of U.S. Patent No. 11,697,012 (filed Nov. 8, 2024); *Imperative Care, Inc. v. Inari*

*Medical, Inc.*, IPR2025-00989 requesting review of U.S. Patent No. 11,865,291 (filed May 9, 2025). As discussed above, the Board has already granted institution in the '012 Patent IPR. (Ex. 1025.) Petitioner also intends to file an IPR challenging the third related patent raised in PO's Request – U.S. Patent No. 12,109,384. 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.

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 does not provide any explanation for why its PI motion supposedly warrants discretionary denial of this

IPR. Although the challenged '921 patent is one of the two patents PO asserted in its PI motion, the PI proceedings will not resolve the patentability of the '921 patent. The only issue for the district court in the PI proceedings relating to invalidity is whether Petitioner has presented a *substantial question* of invalidity for the '921 patent. *See, e.g., Amazon.com Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1350-51 (Fed. Cir. 2001). Thus, the district court's decision on the PI motion will not resolve the patentability issues presented in this IPR, which are the same issues that the Board will already be addressing in the instituted '011, '012, and '005 Patent IPRs.

PO also ignores that at the recent hearing on PO's preliminary injunction motion, the Court instructed the parties to focus their arguments on PO's '910 patent, not the '921 patent that is challenged here, because the "PTAB arguably may agree with [Petitioner]" that the '921 patent is anticipated or obvious, which was likely in recognition of the Board's findings in the '011 and '012 Patent IPRs for very similar claims. (Ex. 1035 at 16:7-16.) PO's counsel even acknowledged "the Court's concern that the PTAB ... decisions might suggest there's a substantial question of validity as to claim 10" of the '921 patent. (*Id.* at 19:4-8.)

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 9 of the 12 patents that have been asserted in the district court, including both patents PO relied upon for its PI Motion.<sup>2</sup> All of those IPRs were timely filed within the one-year statutory deadline under 35 U.S.C. §315(b). As discussed above, the nine-month deadline from issuance has not yet passed for two of the three remaining asserted patents, and Petitioner plans file IPR petitions challenging each patent at the appropriate time. 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 5 (Request) at 16.) However, PO’s argument is premised exclusively on the length of Mr. Thornton’s expert declaration and paragraphs of the declaration providing “general background

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<sup>2</sup> PO dropped the ’011 patent from the district court litigation following institution of the ’011 IPR.

on the references and prior art.” (*Id.*) 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 id.*) PO presented similarly conclusory and unexplained arguments in its request for discretionary denial for the ’005 Patent IPR, which the Director found unpersuasive. (Ex. 1022.)

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). Accordingly, Mr. Thornton’s expert declaration does not warrant or weigh in favor of discretionary denial.

#### **4. The Recent Issuance Of The ’921 Patent Favors Institution**

In the recent decision denying PO’s request for discretionary denial in the ’005 Patent IPR the Director held that “the challenged [’005] patent issued recently, in 2023. Early challenges to patents favor robust, predictable patent rights and weigh against discretionary denial.” (Ex. 1022.) The same is true for the ’921 patent challenged in this IPR, which issued on December 19, 2023. (Ex. 1001.) In fact,

the '921 patent issued 11 months *after* the '005 patent. Thus, there are no settled expectations that would warrant discretionary denial here.

PO attempts to rely on the Director's decision in *iRhythm* to suggest that there is an alleged delay that weighs in favor of discretionary denial here. (*See* Paper 5 (Request) at 18-20.) This case is nothing like *iRhythm*. There, the challenged patent issued in 2012 and the petitioner was aware of it as early as 2013, more than a decade before the petition was filed. *iRhythm Techs., Inc. v. Welch Allyn, Inc.*, IPR2025-00363, Paper 10, at 3 (P.T.A.B. June 6, 2025). Here, not even a year and half passed between the issuance of the '921 patent and Petitioner's filing of the Petition. (*See* Ex. 1001.) During that same period, Petitioner was defending itself in both the district court and filing IPR challenges of PO's related patents that it has also asserted against Petitioner, three of which have already been instituted. There has not been any delay in Petitioner's actions that could possibly warrant discretionary denial.

#### **IV. THE DIRECTOR SHOULD NOT DENY INSTITUTION UNDER § 325(d)**

In the twenty pages of its Request dedicated to Section 325(d), PO never once mentions that the Board has now concluded on three separate occasions that Schaffer, a reference that was *not* before the Examiner of the '921 patent, likely anticipates or renders obvious very similar claims of PO's related patents. Each of those institution decisions demonstrates that Schaffer is critical, invalidating prior

art. PO's failure to even attempt to address the decisions is telling. That Schaffer was never considered by the Examiner of the '921 patent is fatal to PO's Section 325(d) arguments.

**A. The Office Did Not Previously Consider Petitioner's Prior Art Or Invalidity Grounds**

It is undisputed that Schaffer, which forms the basis for four of Petitioner's five invalidity grounds, was not of-record during prosecution of the '921 patent. (*See* Paper 1 (Petition) at 94.) Because Schaffer was not before the Examiner during prosecution, PO's Section 325(d) arguments fail under the first step of the *Advanced Bionics* framework. *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."). Discretionary denial under Section 325(d) would therefore be inappropriate.

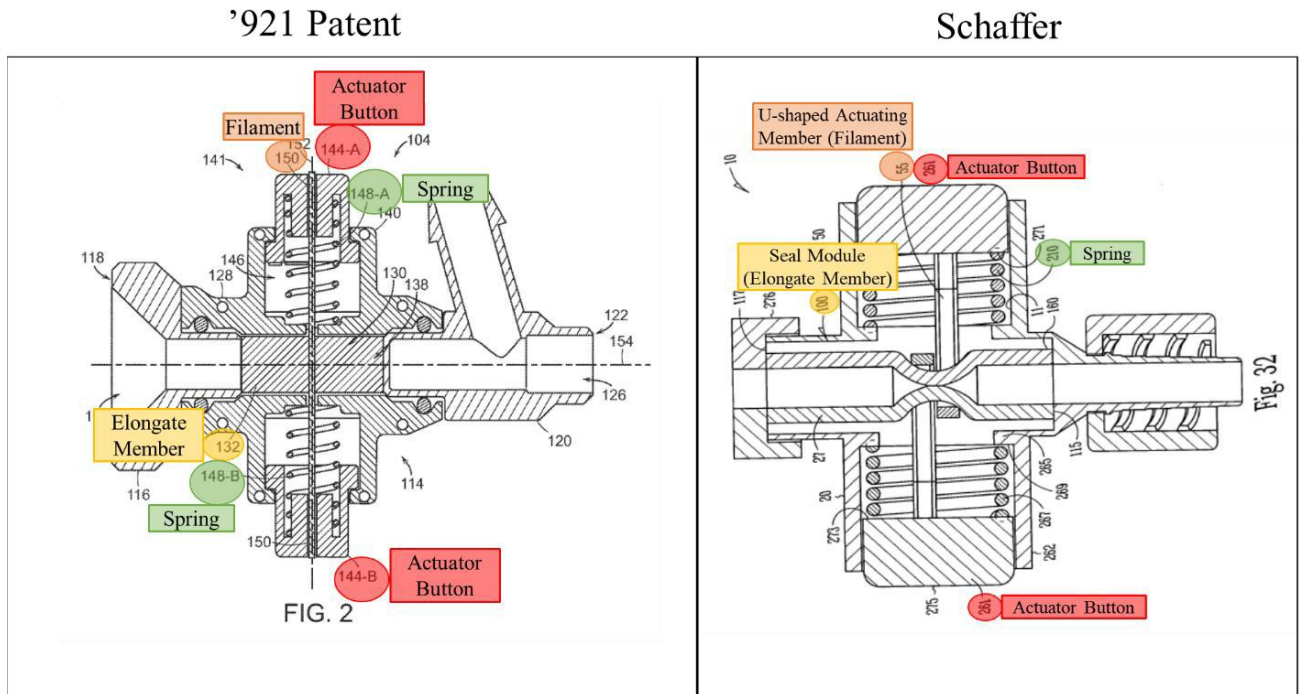
The fact that the Examiner did not consider Schaffer during prosecution of the '921 patent is critical here because the Board has already concluded that Schaffer likely anticipates at least claim 1 of the '011 and '005 patents, which are very similar to the challenged independent claims of the '921 patent. (*Supra* §III.A.3.) The Board has also found that the combination of Schaffer and Hartley or Eller likely

renders substantially similar claims obvious in each of the '011, '012, and '005 Patent IPRs. (*Id.*)

Schaffer supplies all the limitations of the challenged claims that the Examiner allegedly found missing from the prior art. The Examiner did not issue any rejections during prosecution of the '921 patent, but in the Notice of Allowance, the Examiner found that the Hartley prior art reference disclosed every limitation of several claims except “a biasing member configured to bias the actuator to the first position.” (Ex. 1002, 24.) Schaffer discloses a biasing member as claimed in the '921 patent. (*See* Paper 1 (Petition) at 46-47.) PO has not disputed that Schaffer discloses the claimed biasing member in any of the '011, '012, or '005 Patent IPRs. (Ex. 1017 at 31-32, 36; Ex. 1025 at 38-48; Ex. 1024 at 36-45.)

Instead, PO has only disputed only whether a person of ordinary skill would have been motivated to combine Hartley's filament with Schaffer's hemostasis valve. (Ex. 1017 at 31-32, 36; Ex. 1025 at 38-48; Ex. 1024 at 36-45.) However, as explained above, the Board has already concluded three times, at least preliminarily, that a skilled artisan would have been motivated to make this combination with a reasonable expectation of success in the '011, '012, and '005 Patent IPRs. (*Supra* §III.A.3.) The Board's conclusion that Schaffer likely anticipates or renders the '011, '012, and '005 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, ’005, and ’921 patents:



(Ex. 1001 at Fig. 2; Ex. 1005 at Fig. 32.)<sup>3</sup>

Thus, contrary to PO’s representations, the Examiner did not consider the same or similar prior art or invalidity arguments raised in the Petition during prosecution of the ’921 patent. But the Board has considered this prior art and similar arguments in the ’011, ’012, and ’005 Patent IPRs, and in all three instances the Board concluded that there was a reasonable likelihood that the hemostasis

<sup>3</sup> All coloring and annotations included in patent figures herein have been added by Petitioner.

valves claimed in those patents are invalid in view of Schaffer. (Ex. 1017 at 33, 35-36; Ex. 1025 at 38; Ex. 1024 at 29-30, 36.)

**1. None Of The Prior Art References Identified By PO Are Substantially The Same As Schaffer**

Because there is no dispute that Schaffer was *not* considered by the Examiner during prosecution of the '921 patent, PO instead attempts to show that Schaffer is “substantially the same” as the prior art that was of-record. PO points to three prior art references that are allegedly cumulative of Schaffer: (1) Wong, (2) Kees, and (3) Williams. (Paper 5 (Request) at 25-30.) None of those references are “substantially the same” as Schaffer.

**a. Wong Is Not The Same As Schaffer**

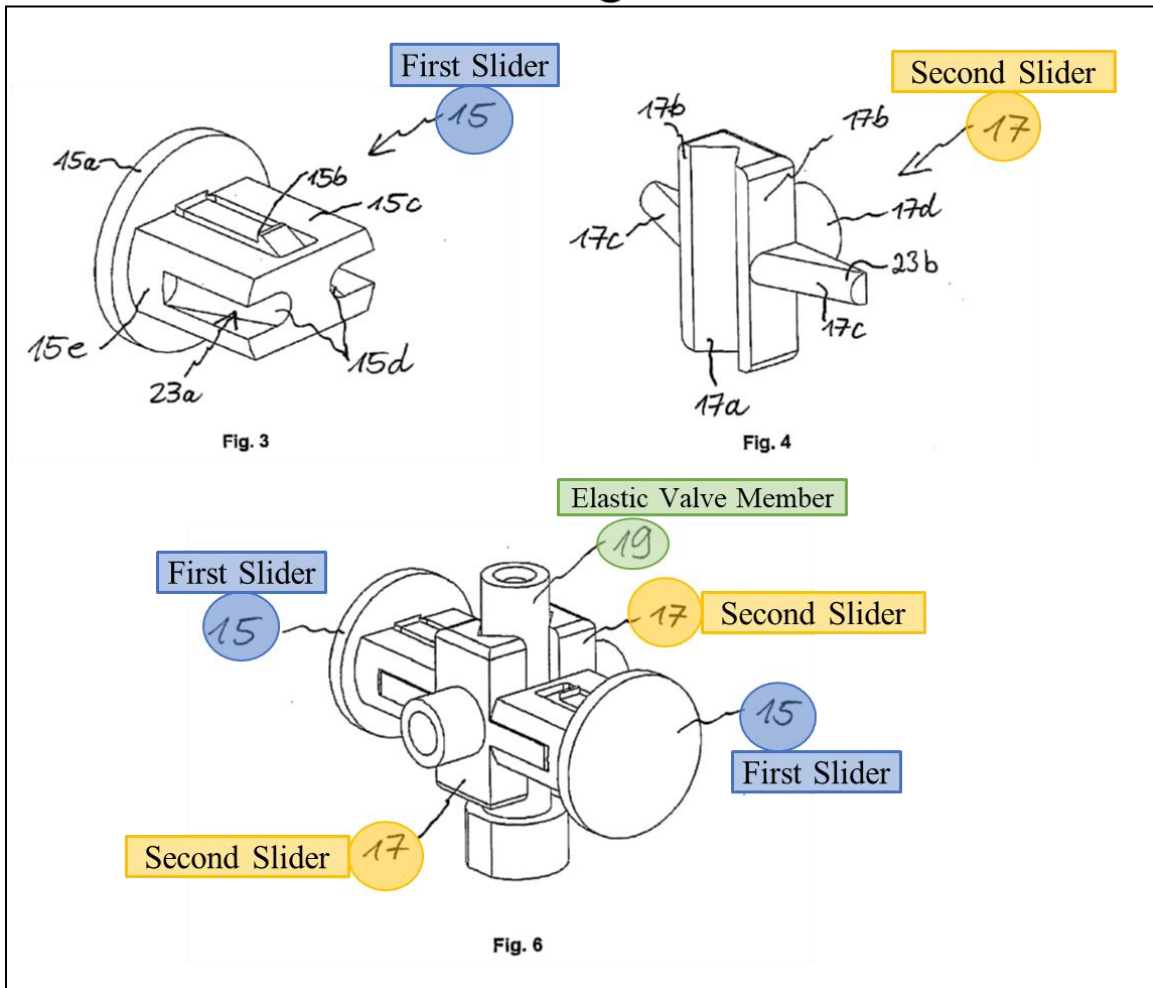
Although Wong was submitted to the Examiner during prosecution of the '921 patent, neither PO nor the Examiner substantively discussed Wong during prosecution. But Wong has been discussed during prosecution of PO's related patents, including the '005 patent subject to an instituted IPR that is based on Schaffer. (*See* Ex. 1036.)

In the Notice of Allowance for the '005 patent, the Examiner concluded that a person of ordinary skill would not combine 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. (*Id.* at 7.) However,

in all three of the '011, '012, and '005 Patent 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. 1017 at 39-40; Ex. 1025 at 40-45; Ex. 1024 at 40-43.) 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.

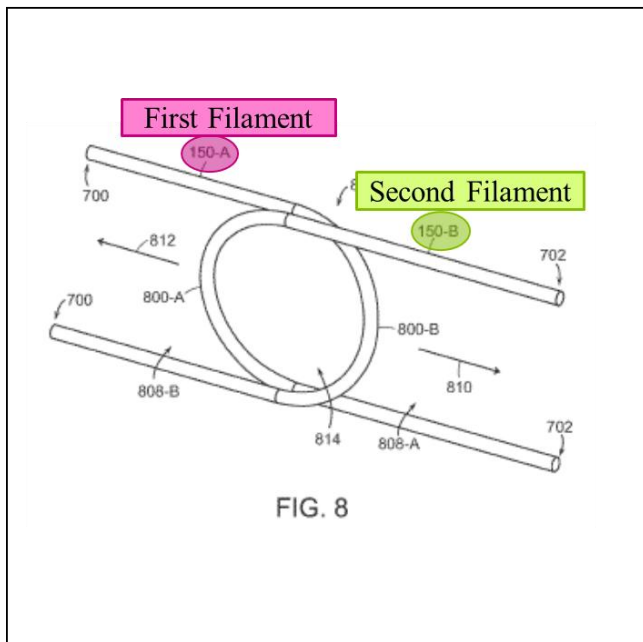
Schaffer is also not similar to Wong because Wong's valve uses distinct and dissimilar components and mechanisms of action to form a seal. Wong discloses a hemostasis valve that uses four "sliders" to pinch an elastic lumen and seal the valve – a pair of first sliders 15 and a pair of second sliders 17:

## Wong

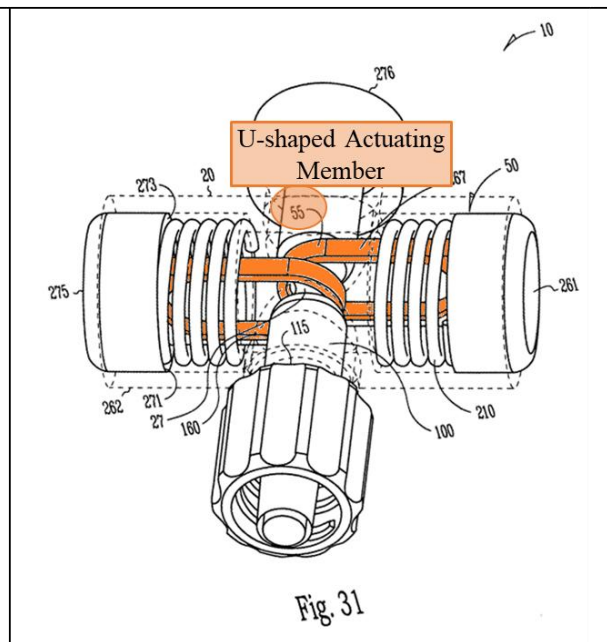


(Ex. 2019 (Wong) at [0042]-[0043], Figs. 3-4, 6.) Wong’s sliders are made from “suitable generally non-elastic synthetic material.” (*Id.* at [0053].) Each of the second sliders 17 is a “brake shoe-like element having a V-shaped groove 17a sandwiched between two opposing sidewalls 17b[.]” (*Id.* at [0052].) Wong’s sliders do not remotely resemble the U-shaped actuating members that Schaffer uses to seal its hemostasis valve, which are the same as the filaments disclosed in the ’921 patent:

## '921 Patent

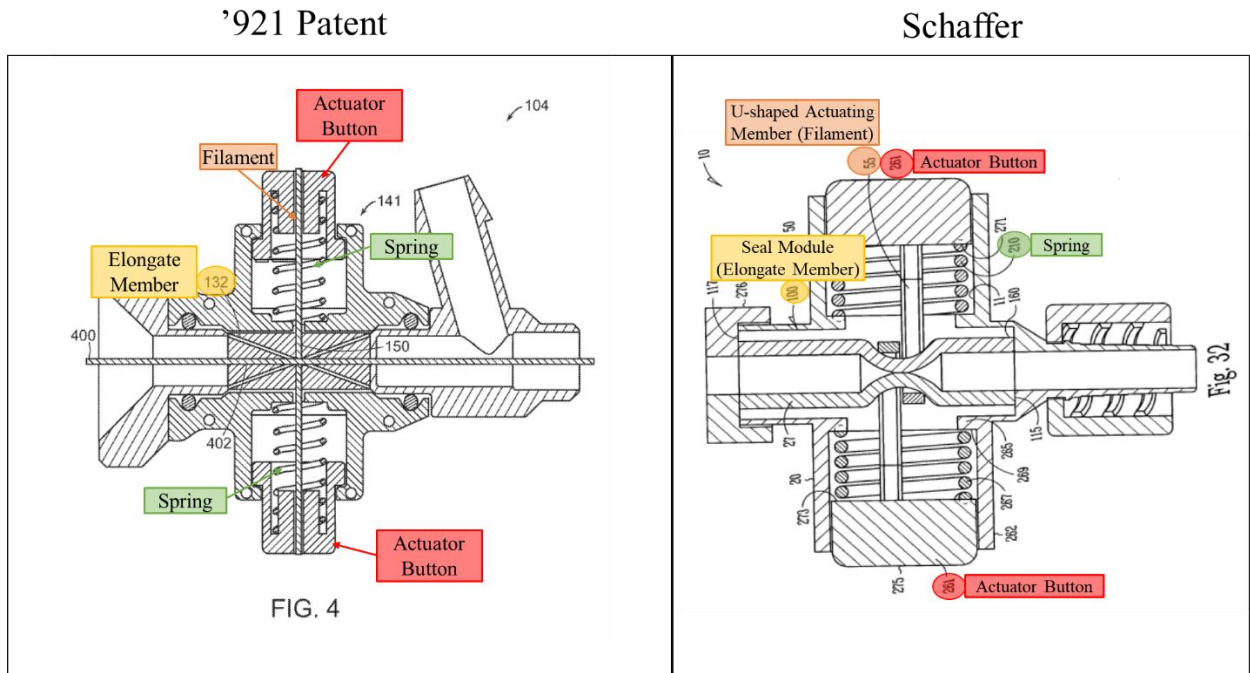


## Schaffer



(Ex. 1001 ('921 patent) at Fig. 8; Ex. 1005 (Schaffer) at Fig. 31.)

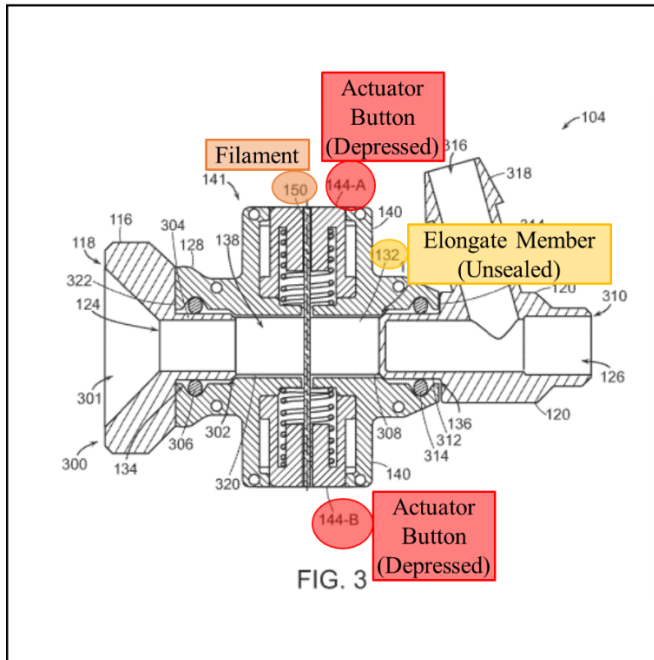
Wong's valve also does not function like Schaffer's valve or the valve disclosed in the challenged '921 patent. Both Schaffer and the '921 patent use the same mechanism to seal their hemostasis valves – actuator buttons attached to compression springs to pull their actuator members/filaments in opposite directions to constrict and seal the valve:



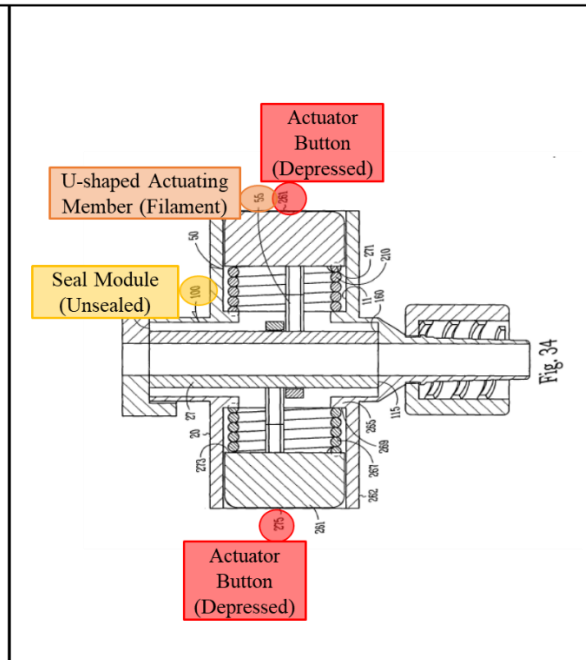
(Ex. 1001 ('921 patent) at 9:18-37, Fig. 4; Ex. 1005 (Schaffer) at [0077], Fig. 32.)

In Schaffer and the '921 patent, the valve is unsealed by depressing the actuator buttons, which removes the tensioning force on the actuator members/filaments:

## '921 Patent



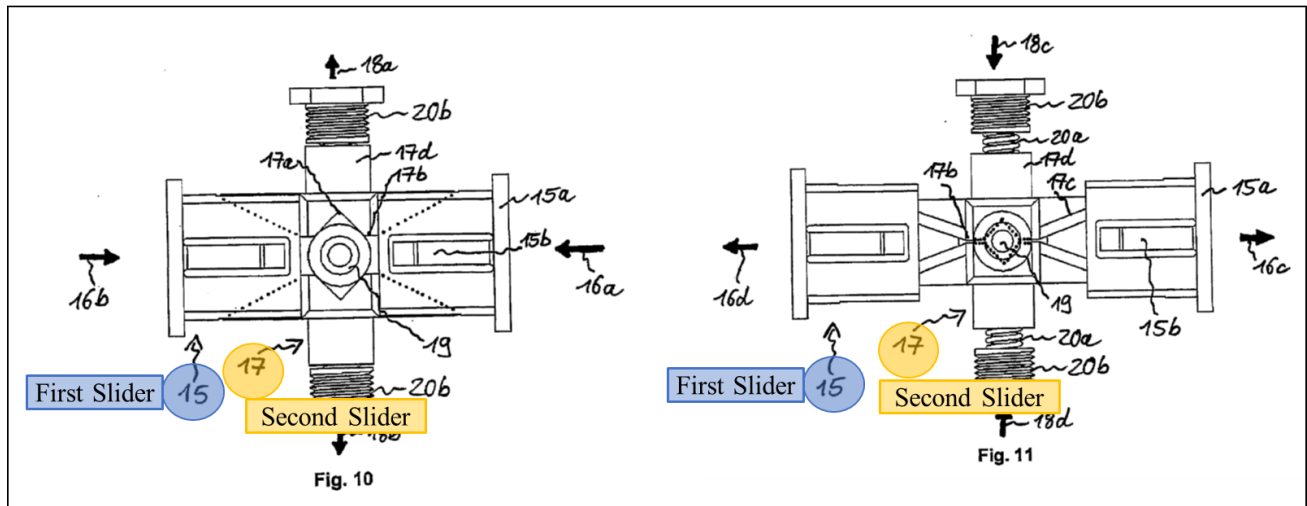
## Schaffer



(Ex. 1001 ('921 patent) at 9:18-37, Fig. 3; Ex. 1005 (Schaffer) at [0077], Fig. 32.)

In Wong's hemostasis valve, the first and second pairs of sliders are connected by a "transmission mechanism," so that movement of the first sliders 15 causes the second sliders 17 to move and pinch the valve. (Ex. 2019 (Wong) at [0046].) To unseal Wong's valve, the operator presses on the first sliders 15, which move toward each other and cause the second sliders 17 to move away from the elastic valve member:

## Wong



(*Id.* at [0060]-[0061].) Unlike the hemostasis valves in Schaffer and the '921 patent, Wong's first sliders, which are the depressible components, are not directly attached to the compression springs or biasing members. (*See id.*) Instead, Wong's springs are attached to the second sliders 17 and the housing of the valve or a nut 20b. (*Id.* at [0043].) Because of this arrangement, Wong's hemostasis valve relies upon its interlocking four-slider mechanism to function, which is unlike the mechanisms used by Schaffer and the '921 patent. (*Id.* at [0060]-[0061].) These differences led to the Examiner's conclusion in the '005 patent prosecution that Wong could not be combined with Hartley.

**b. Kees Is Not The Same As Schaffer**

Although Kees was submitted to the Examiner during prosecution of the '921 patent, neither PO nor the Examiner substantively discussed Kees during prosecution. But Kees has been discussed during prosecution of PO's related

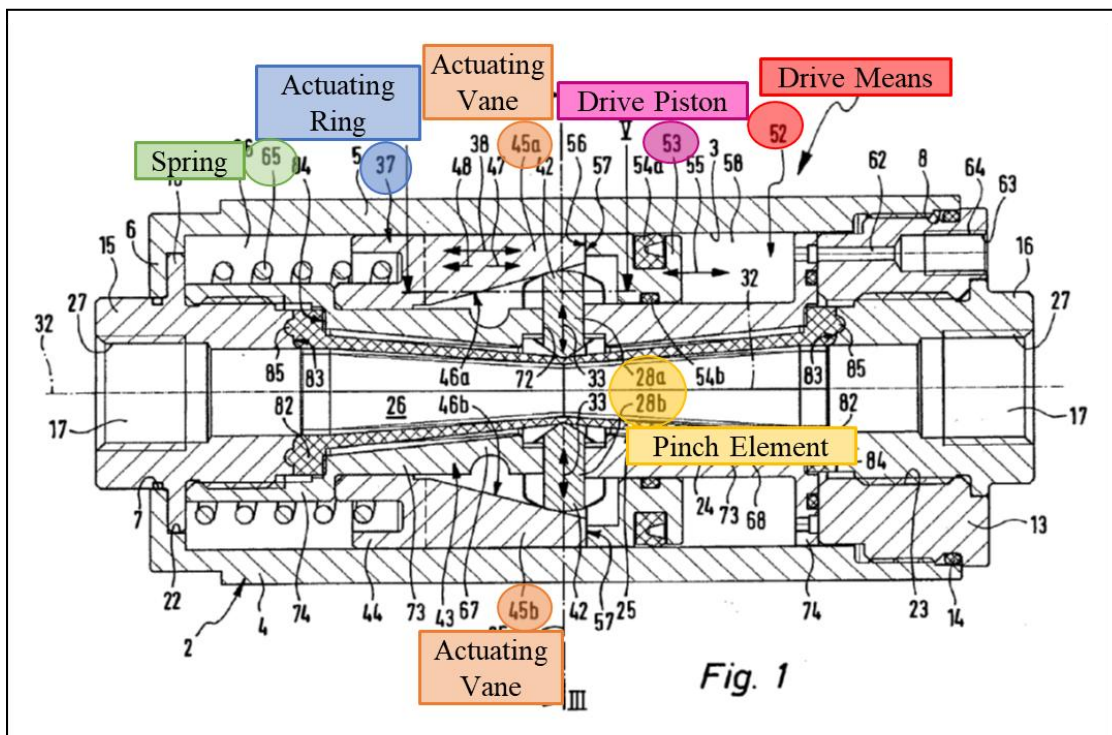
patents, including the '005 patent subject to an instituted IPR that is based on Schaffer. (*See* Ex. 1036.)

In the Notice of Allowance for the '005 patent, the Examiner concluded that a person of ordinary skill would not combine Kees with the filament from Hartley because doing so “would conflict with the operation of the [Kees] device[,],” which uses “pinch elements” to press on and close an elastic tube. (*Id.* at 7.) However, in all three of the '011, '012, and '005 Patent 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. 1017 at 39-40; Ex. 1025 at 40-45; Ex. 1024 at 40-43.) Thus, Schaffer is not similar to Kees at least because combining Schaffer’s hemostasis valve with Hartley’s filament would not conflict with the operation of Schaffer’s valve.

Schaffer is also not similar to Kees because Kees’s pinch valve uses distinct and dissimilar components and mechanisms of action to form a seal.

Kees’s pinch valve uses two “pinch elements” placed on opposing sides of a hose-like valve member. (Ex. 2018 (Kees) at [0048].) Kees’s valve includes an “actuating ring 37” that uses slanted “actuating vanes” to force the pinch elements toward each other to seal the valve:

## Kees



(*Id.* at [0057]-[0058], Fig. 1.) Kees’s actuating ring is moved via a “drive means 52 [that is] designed for the application of a fluid drive force, the fluid force preferably being supplied by compressed air at a suitable pressure.” (*Id.* at [0060].) The drive means preferably uses a drive piston to move the actuating ring in response to changes in fluid pressure (i.e., compressed air) in the drive means 52. (*Id.* at [0060]-[0063].) Because the drive means/drive piston can only exert pushing forces, Kees’s valve uses a spring 65 to exert force in the opposite direction to seal the valve when air pressure is removed from the drive means. (*Id.* at [0069]-[0072].)

Kees's compressed-air driven pinch valve uses a different mechanism to close the lumen of its valve than the actuator button arrangements used in Schaffer and the '921 patent. These differences led to the Examiner's conclusion in the '005 patent prosecution that Kees could not be combined with Hartley. For example, Kees's actuating vanes can only exert pushing forces on the pinch members to seal the valve. (*See id.* at [0057]-[0058], Figs. 1-2.) But creating tension on a string requires pulling forces, which are supplied in both Schaffer and the '921 patent by the compression springs and actuator buttons, which pull the actuating members/filaments in opposite directions. (Ex. 1003, ¶¶39-41, 148.) Thus, Kees's pinch valve is not substantially the same as Schaffer's hemostasis valve.

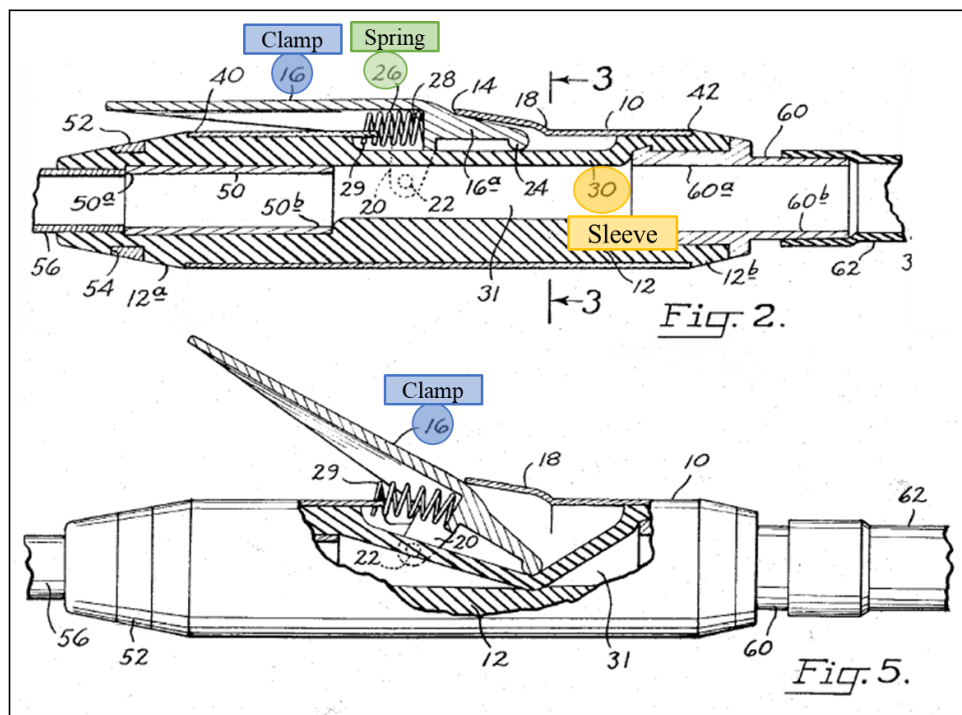
**c. Williams Is Not The Same As Schaffer**

In the Notice of Allowance for the '921 patent, the Examiner concluded that Williams disclosed every limitation of several claims except for a "filament extending around the elongate member." (Ex. 1002 at 26.) The Examiner also discussed Hartley in the Notice of Allowance and found that Hartley discloses a filament extending around the elongate member, but the Examiner did not discuss a possible combination of Williams with Hartley. (*Id.*) As discussed above, in all three of the '011, '012, and '005 Patent IPRs, the Board determined that there is a reasonable likelihood that a person of ordinary skill in the art would have been motivated to combine Schaffer and Hartley. (Ex. 1017 at 39-40; Ex. 1025 at 40-45;

Ex. 1024 at 40-43.) Thus, Schaffer is not similar to Williams at least because a person of ordinary skill in the art would have been motivated to combine Schaffer with Hartley and would have reasonably expected success in doing so.

Schaffer is also not similar to Williams because Williams's valve uses distinct and dissimilar components and mechanisms of action to form a seal. Williams is a prior art reference from 1969 that discloses a valve for a vacuum operated dental instrument that uses a spring-loaded clamp to pinch and seal a sleeve:

### Williams



(Ex. 1010 (Williams) at 2:48-3:2, Figs. 2, 5.)

Williams's dental valve uses a different mechanism to close the lumen of its valve than the actuator button arrangements used in Schaffer and the '921 patent.

For example, in contrast to Schaffer and the '921 patent, which pull two u-shaped members/bights in opposite directions to constrict the central lumen, Williams's clamp presses the lumen from a single side to pinch the valve closed. Williams's clamp presses against the lumen due to pushing force applied by the compression spring. But creating tension on a string requires pulling forces, which are supplied in both Schaffer and the '921 patent by the compression springs and actuator buttons, which pull the actuating members/filaments in opposite directions. (Ex. 1003, ¶¶39-41, 148.) Thus, Williams's dental valve is not substantially the same as Schaffer's hemostasis valve.

**B. It Would Have Been Material Error To Allow The Claims Of The '921 Patent Over Schaffer**

The institution decisions in each of the '011, '012, and '005 Patent IPRs, where the Board has concluded that Schaffer likely anticipates or renders nearly identical claims obvious, each demonstrate that it would have been material error for the Examiner of the '921 patent to allow the claims over Schaffer or Schaffer combined with Hartley. (*Supra* §III.A.3.) Thus, even if the first step of the *Advanced Bionics* framework was satisfied here, which it is not, discretionary denial under Section 325(d) would still be inappropriate because it would have been material error for the Examiner to issue the claims of the '921 patent over Schaffer. *See Advanced Bionics*, Paper 6 at 8.

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**V. CONCLUSION**

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

Dated: July 16, 2025

By: /Joshua J. Stowell /

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

Joseph R. Re (Reg. No. 31,291)

Brian C. Barnes (Reg. No. 75,805)

**KNOBBE MARTENS OLSON & BEAR, LLP**

*Attorneys for Petitioner,*

*Imperative Care, Inc.*

**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: July 16, 2025

By: /Joshua J. Stowell /

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

Joseph R. Re (Reg. No. 31,291)

Brian C. Barnes (Reg. No. 75,805)

**KNOBBE MARTENS OLSON & BEAR, LLP**

*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** is being served electronically on July 16, 2025, to the e-mail addresses shown below:

Joseph Hamilton  
Reg. No. 51,770  
hamilton-ptab@perkinscoie.com  
Inari-Imperative@perkinscoie.com  
PERKINS COIE LLP  
1888 Century Park East, Suite 1700  
Los Angeles, CA 90067-1721  
Tel: (310) 788-3271

Paul Parker  
Reg. No. 38,264  
parker-ptab@perkinscoie.com  
PERKINS COIE LLP  
1201 Third Avenue, Suite 4900  
Seattle, WA 98101-3099  
Tel: (206) 359-8000

Dated: July 16, 2025

By: /Joshua J. Stowell/  
Joshua J. Stowell (Reg. No. 64,096)  
**KNOBBE MARTENS OLSON & BEAR, LLP**