

Filed December 22, 2025

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

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

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

# TABLE OF CONTENTS

	<b>Page No.</b>
I. INTRODUCTION .....	1
II. SUMMARY OF PROSECUTION HISTORY .....	3
III. ARGUMENT .....	4
A. The Office Did Not Previously Consider Petitioner’s Prior Art Or Invalidity Grounds .....	4
1. Hermann Was Not Of Record During Prosecution .....	5
2. The Office Did Not Previously Consider Petitioner’s Prior Art Combinations Or Arguments.....	5
B. The Examiner Materially Erred In Allowing The Challenged Claims .....	8
1. The Examiner Did Not Expressly Evaluate Or Assert Schaffer Or Any Of Petitioner’s Prior Art Combinations .....	9
2. The Examiner Materially Erred In Assessing The Prior Art .....	14
3. Additional Evidence And Facts Presented In The Petition Warrant Denial Of PO’s Request .....	16
IV. CONCLUSION.....	18

## TABLE OF AUTHORITIES

	Page No(s).
<p><i>10X Genomics, Inc. v. Univ. of Chicago</i>, IPR2015-01157, 2015 WL 7304561 (P.T.A.B. Nov. 16, 2015).....</p>	16
<p><i>Advanced Bionics, LLC v. MED-EL Elektromedizinische Gerate GmbH</i>, IPR2019- 01469, 2020 WL 740292 (P.T.A.B. Feb. 13, 2020) .....</p>	<i>passim</i>
<p><i>Atlas Copco Tools and Assembly Sys. LLC v. Wildcat Licensing WI LLC</i>, IPR2020-00891, 2020 WL 6470316 (P.T.A.B. Nov. 3, 2020).....</p>	8
<p><i>Becton, Dickinson and Co. v. B. Braun Melsungen AG</i>, IPR2017-01586, 2017 WL 6405100 (P.T.A.B. Dec. 15, 2017).....</p>	9, 14, 16
<p><i>Bowtech, Inc. v. Mcp IP, LLC</i>, IPR2019-00382, 2019 WL 3714325 (P.T.A.B. Aug. 6, 2019).....</p>	8
<p><i>Celltrion, Inc. v. Genentech, Inc.</i>, IPR2017-01140, 2018 WL 576158 (P.T.A.B. Jan. 25, 2018) .....</p>	16
<p><i>CSPV Pharm. Grp. Ltd. v. Ipsen Biopharm Ltd.</i>, IPR2025-00505, Paper 11 (P.T.A.B. July 16, 2025).....</p>	15
<p><i>Fasteners for Retail, Inc. v. RTC Indus., Inc.</i>, IPR2019-00994, 2019 WL 5777769 (P.T.A.B. Nov. 5, 2019).....</p>	9
<p><i>H-E-b, Lp v. Digital Retail Apps, Inc.</i>, IPR2020-00347, 2020 WL 3669643 (P.T.A.B. July 6, 2020).....</p>	7
<p><i>Microsoft Corp. v. ParTec Cluster Competence Ctr. GMBH</i>, IPR2025-00318, Paper 9 (P.T.A.B. June 12, 2025) .....</p>	15
<p><i>Microsoft Corp. v. XI Discovery, Inc.</i>, IPR2025-00253, Paper 13 (P.T.A.B. June 25, 2025) .....</p>	16

**TABLE OF AUTHORITIES**  
**(cont'd)**

	<b>Page No(s).</b>
<i>Prollenium US Inc. v. Allergan Industrie, SAS</i> , IPR2019-01617, 2020 WL 1491363 (P.T.A.B. Mar. 20, 2020).....	17
<i>REG Synthetic Fuels v. Neste Oil, OYJ</i> , IPR2018-01375, 2019 WL 845658 (P.T.A.B. Feb. 19, 2019) .....	8
<i>Tesla, Inc. v. Charge Fusion Techs., LLC</i> , IPR2025-00152, Paper 11 (P.T.A.B. June 12, 2025) .....	16
<i>Xencor, Inc. v. Merus N.V.</i> , IPR2025-00604, Paper 12 (P.T.A.B. July 17, 2025).....	9, 10, 16

## TABLE OF EXHIBITS

Exhibit No.	Description
1001	U.S. Patent No. 12,109,384 (“the ’384 patent”)
1002	Prosecution History of the ’384 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 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. 5,599,305 to Hermann (“Hermann”)
1010	U.S. Patent Publication US 2011/0144592 A1 to Wong et al. (“Wong”)
1011	RESERVED
1012	RESERVED
1013	Inari’s Supplemental Infringement Contentions (without claim charts) from <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , No. 24-cv-3117 (N.D. Cal.) (served February 7, 2025).
1014	Google Dictionary Definition of “String”
1015	Cambridge Dictionary Definition of “String”
1016	Deposition Transcript of PO’s Expert Paul Zalesky, Ph.D. dated June 23, 2025

**TABLE OF EXHIBITS**  
(*cont'd*)

Exhibit No.	Description
1017	Deposition Transcript of PO's Expert Paul Zalesky, Ph.D. dated August 27, 2025
1018	Deposition Transcript of Troy Thornton dated March 19, 2025
1019	RESERVED
1020	Case Management & Scheduling Order (Dkt. #54) in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 24-cv-03117-EKL (N.D. Cal.) (issued December 19, 2024)
1021	RESERVED
1022	U.S. Patent No. 11,697,011 ("the '011 patent")
1023	U.S. Patent No. 11,697,012 ("the '012 patent")
1024	RESERVED
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	Imperative Care, Inc.'s Notice of Motion and Motion to Stay Pending <i>Inter Partes</i> Review in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 5:24-cv-03117-EKL (N.D. Cal.)
1028	Order Regarding Case Schedule and Motion to Stay in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 5:24-cv-03117-EKL (N.D. Cal.)

**TABLE OF EXHIBITS**  
(*cont'd*)

Exhibit No.	Description
1029	Decision Granting Institution of <i>Inter Partes</i> Review for U.S. Patent No. 11,554,005 (Paper 10) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-00289 (P.T.A.B. June 18, 2025)
1030	Patent Owner Response for <i>Inter Partes</i> Review for U.S. Patent No. 11,697,011 (Paper 3) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2024-01157 (P.T.A.B. Apr. 18, 2025)
1031	Supplemental Declaration of Paul J. Zalesky submitted in IPR2024-01157
1032	Robert C. Allen, <i>The Gore DrySeal Sheath</i> , Supp. Endovascular Today (Feb. 2011) (“Allen”)
1033	Cara M. Michelson, et al., <i>Use of a Modified Cardiopulmonary Bypass Circuit for Suction Embolectomy with the Angiovac Device</i> , 49 J. Extra Corpor. Tech., 299-303 (2017) (“Michelson”)
1034	Jacques Kpodonu, <i>Manual of Thoracic Endoaortic Surgery</i> (2010) (“Kpodonu”)
1035	510(k) Summary – K123990, Sentrant Introducer Sheath with Hydrophilic Coating (Apr. 26, 2013) (“Sentrant”)
1036	Matthew Kruse, <i>Thoracic Endovascular Aortic Repair (TEVAR) Sheaths</i> , CTSNet (Jan. 18, 2011) (“Kruse”)
1037	Cook Medical, <i>Endovascular Aortic Repair – Abdominal: Zenith Endovascular Grafts</i> (2012) (“Zenith Brochure”)
1038	U.S. Patent No. 8,137,321 B2 to Argentine (“Argentine”)
1039	U.S. Patent Pub. No. 2017/0080200 A1 (“Bickhart”)
1040	U.S. Patent No. 11,730,942 B2 to Fantuzzi (“Fantuzzi”)
1041	U.S. Patent No. 8,777,893 B2 to Malewicz (“Malewicz”)

**TABLE OF EXHIBITS**  
(*cont'd*)

Exhibit No.	Description
1042	U.S. Patent No. 5,125,903 to McLaughlin (“McLaughlin”)
1043	U.S. Patent No. 8,808,350 B2 to Schreck (“Schreck”)
1044	Order Denying Motion for Preliminary Injunction (Dkt. #136) in <i>Inari Medical, Inc. v. Imperative Care, Inc.</i> , 24-cv-03117-EKL (N.D. Cal.) (issued September 29, 2025)
1045	Decision Granting Institution of <i>Inter Partes</i> Review for U.S. Patent No. 11,844,921 (Paper 13) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-00728 (P.T.A.B. Oct. 10, 2025)
1046	Decision Granting Institution of <i>Inter Partes</i> Review for U.S. Patent No. 11,865,291 (Paper 10) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-00989 (P.T.A.B. Oct. 23, 2025)
1047	Decision Granting Institution of <i>Inter Partes</i> Review for U.S. Patent No. 11,969,333 (Paper 15) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-01021 (P.T.A.B. Dec. 11, 2025)
1048	Decision Granting Institution of <i>Inter Partes</i> Review for U.S. Patent No. 11,974,910 (Paper 15) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-01025 (P.T.A.B. Dec. 11, 2025)
1049	Notice of Decision Granting Institution of <i>Inter Partes</i> Review for U.S. Patent No. 12,016,580 (Paper 11) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-01264 (P.T.A.B. Dec. 11, 2025)
1050	Decision Denying Patent Owner’s Request for Discretionary Denial (Paper 9) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-00289 (P.T.A.B. June 12, 2025)
1051	Decision Referring the Petition to the Board (Paper 9) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-00728 (P.T.A.B. July 31, 2025)
1052	Decision Referring the Petitions to the Board (Paper 11) in

**TABLE OF EXHIBITS**  
*(cont'd)*

<b>Exhibit No.</b>	<b>Description</b>
	<i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-01021 (P.T.A.B. Oct. 10, 2025)
1053	Decision Referring the Petitions to the Board (Paper 11) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-01025 (P.T.A.B. Oct. 10, 2025)
1054	Notice of Decisions on Institution (Paper 10) in <i>Imperative Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-01264 (P.T.A.B. Nov. 20, 2025)
1055	Patent Owner's Request for Discretionary Denial of <i>Inter Partes</i> Review for U.S. Patent No. 11,844,921 (Paper 5) in <i>Imperative</i> <i>Care, Inc. v. Inari Medical, Inc.</i> , IPR2025-00728 (P.T.A.B. June 16, 2025)

## **I. INTRODUCTION**

This is Patent Owner’s (“PO’s”) sixth Request for Discretionary Denial in these related IPRs. The Director has denied the previous five Requests. (Exs. 1050-1054.) In its first two Requests, PO sought discretionary denial under § 314(a). (Exs. 1050-1051.) The Director denied those Requests because “there is no trial date scheduled in the district court” and the “challenged patent issued recently,” among other reasons. (*Id.*) Those facts apply here with even more force because the Court stayed the litigation in view of Petitioner’s IPRs. (Ex. 1028.) In its next three Requests, PO abandoned its § 314(a) arguments and requested discretionary denial under § 325(d) as it has done in this IPR. (Exs. 1052-1054.) The Director denied PO’s Requests because they “present[ed] the same discretionary [denial] considerations” as those in PO’s first two Requests. (Ex. 1052, 2; *see also* Ex. 1053, 2; Ex. 1054.) The same is true here.

Like PO’s recently denied Requests in IPR2025-01021 (the ’333 Patent IPR), IPR2025-01025 (the ’910 Patent IPR), and IPR2025-01264 (the ’580 Patent IPR), PO’s current § 325(d) arguments fail under both prongs of *Advanced Bionics*.

During prosecution of the ’384 patent, the Examiner did not substantively discuss **Schaffer**, a prior art reference describing hemostasis valves that Petitioner relies on for each unpatentability ground. Importantly, the Board has preliminarily found that Schaffer anticipates or renders obvious similar patent claims in *seven*

instituted IPRs involving patents related to the '384 patent. (Ex. 1025, 28-41; Ex. 1026, 34-48; Ex. 1029, 28-45; Ex. 1045, 28-33; Ex. 1046, 34-39; Ex. 1047, 9-10, 39-40; Ex. 1049, 2 (collectively, the “Instituted IPRs”).) Further, **Hermann**, which discloses a hemostasis valve having the sizes recited in several of the challenged claims, was never disclosed to the Examiner during prosecution.

Moreover, even if PO met the first prong of *Advanced Bionics* (it did not), PO's Request still fails under the second prong of *Advanced Bionics* because the Examiner materially erred in allowing the challenged claims over the prior art, particularly Schaffer. The Examiner allowed the challenged claims because two other prior-art references, Hartley and Eller, purportedly do not disclose a pair of actuators. However, as shown in the Petition, Schaffer discloses a hemostasis valve with a pair of actuators (two buttons). (Petition (Paper 1), 25-53; *see also* Ex. 1025, 8, 28-33 (Board preliminarily finding that Schaffer discloses an actuator that “comprises a first member coupled to the first end of the filament and a second member coupled to the second end of the filament”); Ex. 1029, 10, 28-32 (similar).)

The Board and the Director have also now preliminarily agreed with Petitioner that a POSITA would have been motivated to combine Schaffer with Hartley or Eller in *seven* IPRs challenging PO's related patents claiming a hemostasis valve with a “filament.” (Ex. 1025, 36-41; Ex. 1026, 34-48; Ex. 1029, 33-45; Ex. 1045, 28-33; Ex. 1046, 34-39; Ex. 1047, 9-10, 39-40; Ex. 1049, 2.) The Examiner of the '384

patent, however, did not issue a single prior art-based rejection and never mentioned Schaffer or combined it with other references, likely because it was buried on an IDS form among hundreds of other references. The Examiner's failure to apply Schaffer during prosecution was material error that warrants reconsideration of the challenged claims, making discretionary denial inappropriate under *Advanced Bionics's* second prong.

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. SUMMARY OF PROSECUTION HISTORY**

The Examiner did not issue any office actions or make any prior-art-based rejections during prosecution of the '384 patent. In the Notice of Allowance, the Examiner identified three references as the "closest prior art of record": (1) Hartley, (2) Eller, and (3) Wong. (Ex. 1002, 20.) The Examiner stated that Hartley disclosed every limitation of the independent claims except "that the actuator is as [sic] a pair of actuators; [and] a second filament." (*Id.*) The Examiner stated that Eller disclosed every limitation of the independent claims except "that the actuator is as [sic] a pair of the actuator." (*Id.*, 21.) The Examiner did not address the combination of Hartley or Eller with any other prior art reference. (*Id.*, 20-21.)

Neither PO nor the Examiner substantively discussed Schaffer during prosecution of the '384 patent.

### **III. ARGUMENT**

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

Under the first prong of *Advanced Bionics*, the Director evaluates whether the same or substantially the same prior art or arguments presented in the Petition were previously presented to the Office during prosecution of the challenged patent. *Advanced Bionics, LLC v. MED-EL Elektromedizinische Gerate GmbH*, IPR2019-01469, 2020 WL 740292, at \*3 (P.T.A.B. Feb. 13, 2020) (precedential). If those conditions are not met, discretionary denial under § 325(d) is inappropriate, and the Director does not need to address the second prong—whether the Petitioner has demonstrated that the Office erred in a manner material to the patentability of the challenged claims. *Id.*

Whether the same or substantially the same prior art or arguments were previously presented to the Office is a highly factual inquiry that is guided by *Becton, Dickinson* factors (a), (b), and (d):

(a) the similarities and material differences between the asserted art and the prior art involved during examination; (b) the cumulative nature of the asserted art and the prior art evaluated during examination; ... (d) the extent of the overlap between the arguments made during examination and the manner in which petitioner relies on the prior art.

*Id.* at \*4. Here, the factors demonstrate that the prior art and arguments presented in the Petition were not previously presented to the Office. Thus, PO's Request fails under the first prong of *Advanced Bionics* and should be denied.

**1. Hermann Was Not Of Record During Prosecution**

PO's Request ignores that Hermann (Ex. 1009), which Petitioner relies upon for Grounds 4-6, was not of record during prosecution of the '384 patent. Hermann discloses a large-diameter catheter system that includes a hemostasis valve for "sealing against catheters having a wide range of outside diameters ... often as large as 26 F, and preferably as large as 22 F." (Ex. 1009, 7:28-39.) Thus, Hermann discloses a hemostasis valve with a lumen having an opened diameter ranging from at least 14 French to at least 24 French as recited in challenged claims 11-14, 20-22, and 28-30 of the '384 patent. (Petition (Paper 1), 80-85.) Because Hermann was not of record during prosecution, PO cannot satisfy the first prong of *Advanced Bionics* and this Request should be denied.

**2. The Office Did Not Previously Consider Petitioner's Prior Art Combinations Or Arguments**

The Examiner also did not consider the prior art combinations or arguments presented in the Petition, providing further basis to deny PO's request. *See Advanced Bionics*, 2020 WL 740292 at \*4 n. 10 (noting that *Becton, Dickinson* factor (d) looks

to “the extent of the overlap between the arguments made during examination and the manner in which petitioner relies on the prior art”).

Although Schaffer was listed on an IDS form during prosecution, amongst hundreds of other references, neither PO nor the Examiner ever substantively discussed Schaffer, much less the combinations of Schaffer with Hartley, Eller, or Hermann asserted in the Petition. Critically, Schaffer supplies 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 '384 patent, but in the Notice of Allowance, the Examiner found that Eller disclosed every limitation of the independent claims except a pair of actuators. (Ex. 1002, 21.) Schaffer discloses two actuator buttons (i.e., a “pair of actuators”) as claimed in the '384 patent. (Petition (Paper 1), 50-53; *see also* Ex. 1025, 8, 28-33 (Board preliminarily finding that Schaffer discloses an actuator that “comprises a first member coupled to the first end of the filament and a second member coupled to the second end of the filament”); Ex. 1029, 10, 28-32 (similar).) PO has not disputed that Schaffer discloses a pair of actuator buttons in any of the Instituted IPRs. (*See* Ex. 1025, 31 (identifying PO’s arguments regarding Schaffer); Ex. 1029, 29-32 (similar).) And as explained above, the Board and the Director have already concluded seven times, at least preliminarily, that a skilled artisan would have been motivated to combine Schaffer and Eller with a reasonable expectation of success. (*Supra* §I.)

PO also fails to show that the Examiner considered Petitioner's arguments regarding Hartley. In the Notice of Allowance, the Examiner stated that Hartley fails to disclose a second filament. (Ex. 1002, 20.) However, the Petition explains that Hartley's string is comprised of at least two filaments and therefore constitutes both a "first filament" and a "second filament" as claimed in the '384 patent. (Petition (Paper 1), 28-29.) The Petition also explains that a POSITA would have found it obvious to substitute two of Hartley's strings for Schaffer's U-shaped actuating members, thus resulting in a "first filament" and a "second filament." (*Id.*, 37-40.) As Petitioner and its expert, Mr. Thorton, explain, a POSITA would have recognized that using two of Hartley's strings in Schaffer's valve would have provided several benefits, such as a larger sealing area around inserted tools and redundancy to ensure the valve seals even if one string fails to tighten around the tubular member. (*Id.*) PO identifies no evidence that the Examiner considered either argument. In fact, PO's Request ignores Petitioner's argument to use two of Hartley's strings.

Because the Office has not previously considered Petitioner's invalidity arguments or the prior art combinations asserted in the Petition, *Becton, Dickinson* factor (d) weighs against discretionary denial, and the Director should therefore deny PO's request for this additional reason. *See, e.g., H-E-b, Lp v. Digital Retail Apps, Inc.*, IPR2020-00347, 2020 WL 3669643, at \*4-5 (P.T.A.B. July 6, 2020) (finding that the office had not previously considered petitioner's prior art or arguments

where reference was identified on an IDS but never asserted or discussed by the examiner); *Atlas Copco Tools and Assembly Sys. LLC v. Wildcat Licensing WI LLC*, IPR2020-00891, 2020 WL 6470316, at \*12 (P.T.A.B. Nov. 3, 2020) (“Patent Owner also does not show where the Office previously considered Gass applied to a reference like Stimpson or Fredrick, even if Gass and references similar to Stimpson and Fredrick were individually considered. ... We, thus, determine that Petitioner’s arguments were not previously presented to the Office.”); *Bowtech, Inc. v. Mcp IP, LLC*, IPR2019-00382, 2019 WL 3714325, at \*4 (P.T.A.B. Aug. 6, 2019) (“Regardless of whether [t]he Examiner was aware of the *possible* combination of [prior art references], Patent Owner points to no evidence that the Examiner actually considered such a combination.” (internal quotations omitted)); *REG Synthetic Fuels v. Neste Oil, OYJ*, IPR2018-01375, 2019 WL 845658, at \*5 (P.T.A.B. Feb. 19, 2019) (“Patent Owner, however, does not show that the Examiner considered the *combination* of Jakkula and Monnier or the *combination* of Jakkula and Oldrich such that there is substantial overlap between the arguments made during examination and the arguments made in the Petition.”).

**B. The Examiner Materially Erred In Allowing The Challenged Claims**

Even if PO satisfied the first prong of *Advanced Bionics* (it did not), the Director should still deny the Request for discretionary denial because the Examiner materially erred in allowing the challenged claims of the '384 patent over the prior

art, particularly Schaffer. The Examiner's material error is illustrated by *Becton, Dickinson* factors (c), (e), and (f), each of which strongly weighs against discretionary denial. See *Advanced Bionics*, 2020 WL 740292 at \*4.

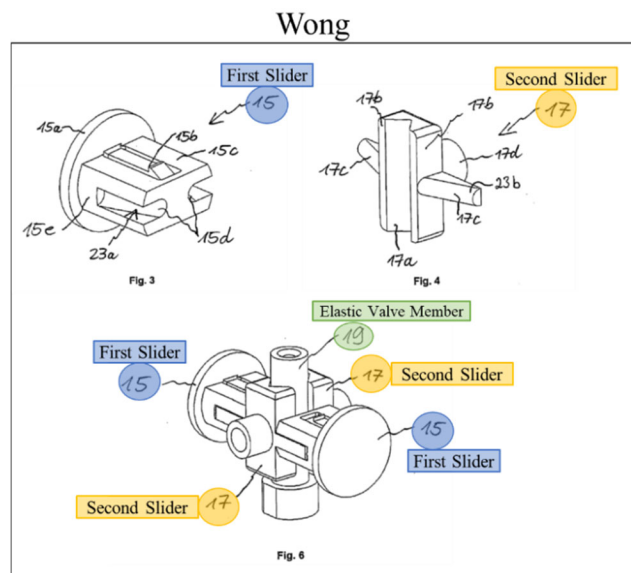
**1. The Examiner Did Not Expressly Evaluate Or Assert Schaffer Or Any Of Petitioner's Prior Art Combinations**

Schaffer was never mentioned by the Examiner during prosecution, much less asserted in a rejection. See *Becton, Dickinson and Co. v. B. Braun Melsungen AG*, IPR2017-01586, 2017 WL 6405100, at \*6 (P.T.A.B. Dec. 15, 2017) (factor (c)). And while the Examiner discussed Hartley and Eller in the Notice of Allowance, the Examiner did not evaluate the combination of Hartley or Eller with Schaffer or any other prior art reference. Thus, if the Examiner considered Schaffer, the Examiner overlooked its teachings, and *Becton, Dickinson* factor (c) strongly weighs against discretionary denial. See, e.g., *Fasteners for Retail, Inc. v. RTC Indus., Inc.*, IPR2019-00994, 2019 WL 5777769, at \*3 (P.T.A.B. Nov. 5, 2019) ("Based on the voluminous number of prior art documents before the examiner, we are skeptical that the examiner was able to devote sufficient time to evaluate all of the asserted art in detail during prosecution. *Becton Dickinson* expressly distinguished the situation 'where the prior art was simply listed in an IDS during prosecution' from actual examiner consideration."); *Xencor, Inc. v. Merus N.V.*, IPR2025-00604, Paper 12, at 2-3 (P.T.A.B. July 17, 2025) (finding that the "Office erred in a manner material to

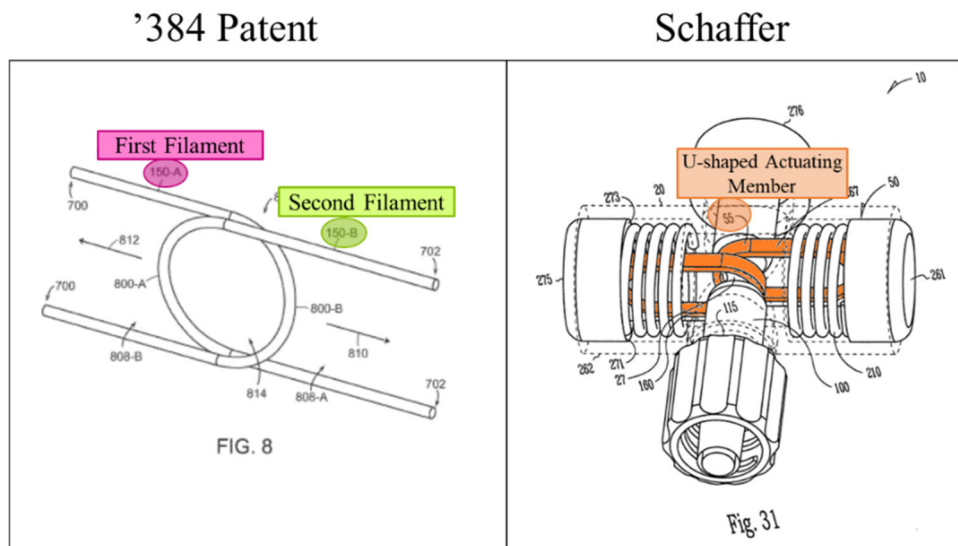
the patentability of the challenged claims by overlooking the teachings of Lazar,” which was cited on an IDS during prosecution).

PO does not contest that the Examiner never mentioned or applied Schaffer during prosecution of the '384 patent. (*See* Request (Paper 6), 11-12.) Instead, PO argues that Wong, the third reference discussed in the Notice of Allowance, “discloses a substantially similar valve to Schaffer.” (*Id.*, 8.) PO is wrong. Wong’s hemostasis valve is dissimilar in both design and function to Schaffer’s valve. Indeed, the Office has already rejected PO’s arguments concerning the similarity between Wong and Schaffer when it denied PO’s Request for discretionary denial of the '921 Patent IPR. (Ex. 1055, 25-26 (PO presenting argument); Ex. 1051 (Director denying PO’s Request).)

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:

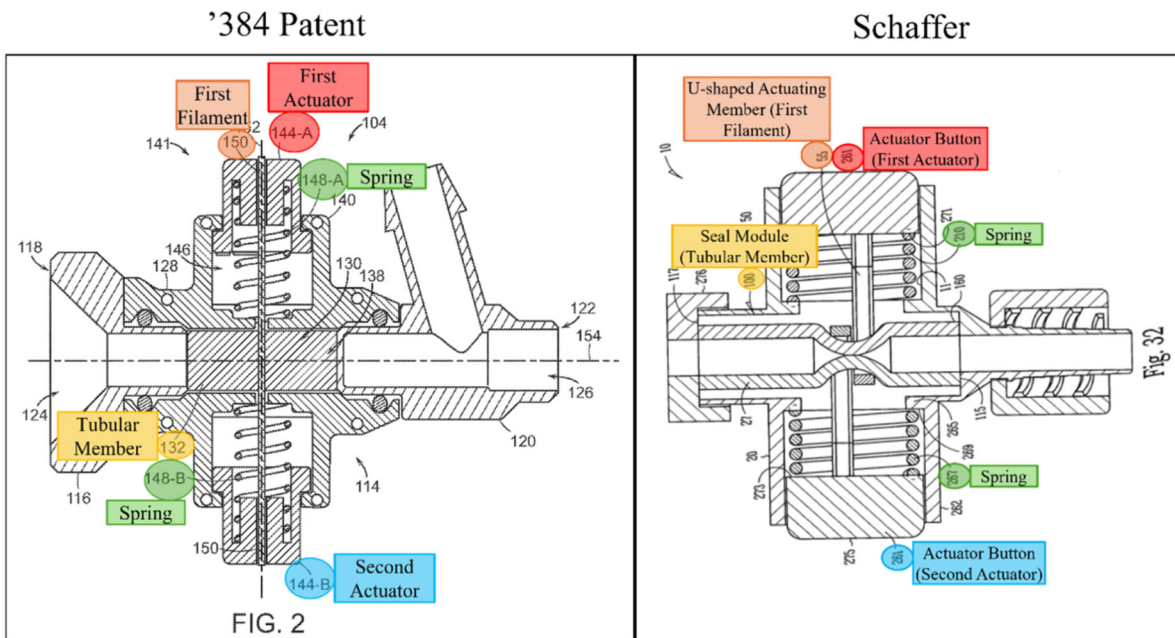


(Ex. 1010, [0042]-[0043], Figs. 3-4, 6.) Wong’s sliders are made from “suitable generally non-elastic synthetic material.” (*Id.* at [0053].) Each of the second sliders 17 is a “brake shoe-like element having a V-shaped groove 17a sandwiched between two opposing sidewalls 17b[.]” (*Id.* at [0052].) Wong’s sliders do not remotely resemble the U-shaped actuating members that Schaffer uses to seal its hemostasis valve, which are similar to the filaments disclosed in the ’384 patent:

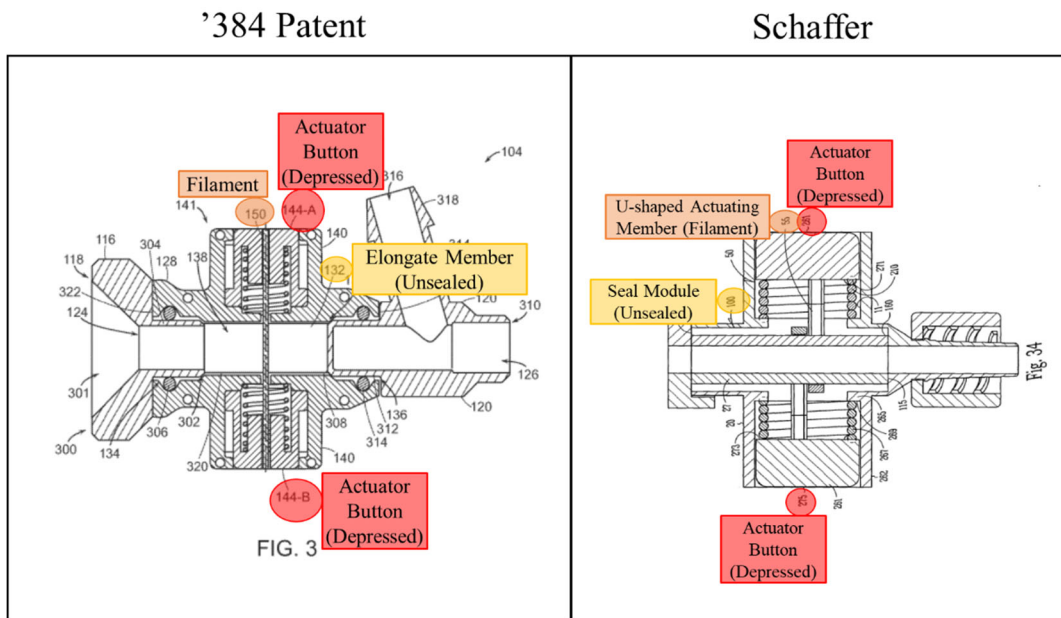


(Ex. 1001, Fig. 8; Ex. 1005, Fig. 31.)

Wong’s valve also does not function like Schaffer’s valve or the valve disclosed in the challenged ’384 patent. Schaffer and the ’384 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:



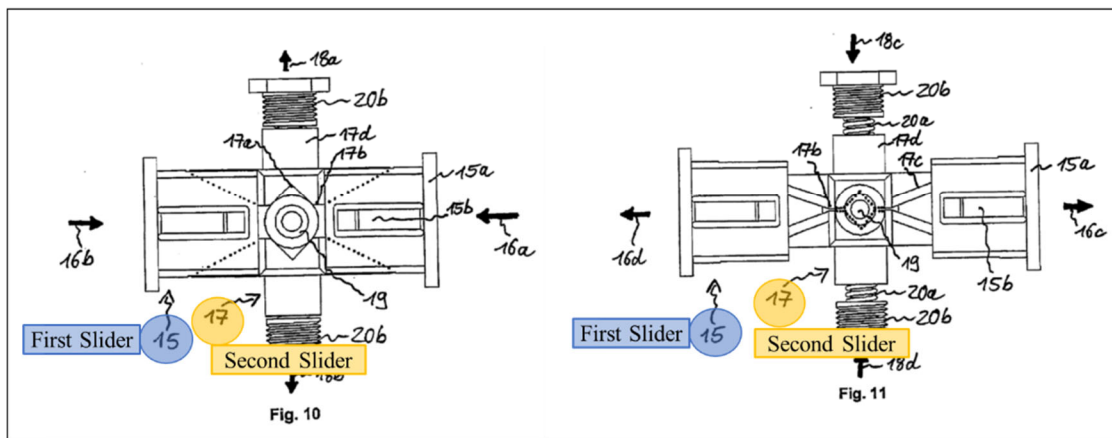
(Ex. 1001, 9:24-43, Fig. 4; Ex. 1005, [0077], Fig. 32.) In Schaffer and the '384 patent, the valve is unsealed by depressing the actuator buttons, which removes the tensioning force on the actuator members/filaments:



(Ex. 1001, 9:24-43, Fig. 3; Ex. 1005, [0077], Fig. 34.)

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. 1010, [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.*, [0060]-[0061].) Unlike the hemostasis valves in Schaffer and the '384 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.*, [0043].) Due to 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 '384 patent. (*Id.*, [0060]-[0061].)

Accordingly, the Examiner's discussion of Wong does not show that the Examiner evaluated Schaffer during prosecution of the '384 patent, and it does not support denying institution under § 325(d).

**2. The Examiner Materially Erred In Assessing The Prior Art**

The Board's and Director's decision to institute each of the '011, '012, '005, '921, '291, '333, and '580 Patent IPRs based on Schaffer and Hartley or Eller demonstrates that the Examiner of the '384 patent materially erred in allowing the claims over those references. (Ex. 1025, 36-41; Ex. 1026, 34-48; Ex. 1029, 33-45; Ex. 1045, 28-33; Ex. 1046, 34-39; Ex. 1047, 9-10, 39-40; Ex. 1049, 2.) Thus, *Becton, Dickinson* factor (e) also weighs heavily against discretionary denial.

As explained above, the Examiner allowed the challenged claims of the '384 patent based on a finding that Hartley did not disclose a "second filament" and that Hartley and Eller each failed to disclose a pair of actuators. (Ex. 1002, 20-21.) Yet, the Petition demonstrates that Schaffer discloses a pair of actuator buttons, and that it would have been obvious to substitute Schaffer's U-shaped actuating members with Hartley's strings or Eller's wires. (Petition (Paper 1), 25-53.) The Board and Director have agreed on seven occasions, at least preliminarily, that these combinations would have been obvious. (Ex. 1025, 36-41; Ex. 1026, 34-48; Ex. 1029, 33-45; Ex. 1045, 28-33; Ex. 1046, 34-39; Ex. 1047, 9-10, 39-40; Ex. 1049, 2.) Yet, the Examiner failed to consider these combinations. That was material error.

The only distinction PO attempts to draw between the challenged claims of the '384 patent and the claims in the Instituted IPRs is that the challenged claims recite a “first filament” and a “second filament.” (Request (Paper 6), 2.) However, PO does not dispute the Examiner’s finding that Eller discloses both first and second filaments as claimed in the '384 patent. (Ex. 1002, 21; Petition (Paper 1), 40-50.) Thus, PO’s only possible dispute is whether a POSITA would have found it obvious to replace Schaffer’s U-shaped actuating members with Eller’s first and second filaments. The Board and Director have repeatedly found (at least preliminarily) that a POSITA would have found it obvious to combine Schaffer with Eller’s filaments, confirming that the Examiner materially erred by not considering it for the claims of the '384 patent. (Ex. 1025, 36-41; Ex. 1026, 34-48; Ex. 1029, 33-45; Ex. 1045, 28-33; Ex. 1046, 34-39; Ex. 1047, 9-10, 39-40; Ex. 1049, 2.)

Due to the Examiner’s material error during prosecution of the '384 patent demonstrated in the Petition and above, *Becton, Dickinson* factor (e) strongly weighs against discretionary denial. *See, e.g., CSPV Pharm. Grp. Ltd. v. Ipsen Biopharm Ltd.*, IPR2025-00505, Paper 11, at 2-3 (P.T.A.B. July 16, 2025) (declining to exercise discretion under § 325(d) because “Petitioner provides persuasive reasoning, supported by evidence, that ... the Office materially erred during prosecution of the challenged patent.”); *Microsoft Corp. v. ParTec Cluster Competence Ctr. GMBH*, IPR2025-00318, Paper 9, at 2-3 (P.T.A.B. June 12, 2025)

IPR2025-01562

*Imperative Care, Inc. v. Inari Medical, Inc.*

(similar); *Microsoft Corp. v. XI Discovery, Inc.*, IPR2025-00253, Paper 13, at 2 (P.T.A.B. June 25, 2025) (similar); *Tesla, Inc. v. Charge Fusion Techs., LLC*, IPR2025-00152, Paper 11, at 2-3 (P.T.A.B. June 12, 2025) (similar); *Xencor, Inc.*, IPR2025-00604, Paper 12, at 2-3 (similar).

**3. Additional Evidence And Facts Presented In The Petition Warrant Denial Of PO's Request**

Additional facts and evidence presented in the Petition that were not before the Examiner also warrant the Office's reconsideration of the patentability of the '384 patent. Therefore, *Becton, Dickinson* factor (f) also strongly weighs against discretionary denial.

Petitioner supplies additional material evidence in the form of the expert declaration of Troy Thornton, an engineering expert, that was not previously considered by the Examiner during prosecution of the '384 patent. (*See Ex. 1003.*) Petitioner's new testimonial evidence provides another reason to deny PO's Request. *See, e.g., Celltrion, Inc. v. Genentech, Inc.*, IPR2017-01140, 2018 WL 576158, at \*6 (P.T.A.B. Jan. 25, 2018) (declining to exercise discretion under § 325(d) because "Petitioner's testimonial evidence presents the prior art in a new light."); *10X Genomics, Inc. v. Univ. of Chicago*, IPR2015-01157, 2015 WL 7304561, at \*5 (P.T.A.B. Nov. 16, 2015) (declining to exercise discretion under § 325(d) where

expert “testifies directly on the ... the limitation Patent Owner indicates was the basis for the Examiner’s allowance of the claims”).

Mr. Thornton directly addresses the Examiner’s mistaken conclusion that the prior art did not disclose or render obvious a hemostasis valve having a pair of actuators as claimed. The Board has credited similar testimony from Mr. Thornton in the Instituted IPRs. (*See* Ex. 1025, 36-41; Ex. 1026, 34-48; Ex. 1029, 33-45; Ex. 1045, 28-33; Ex. 1046, 34-39.) Mr. Thornton’s expert declaration is material evidence that was not available to the Examiner during prosecution, and that directly rebuts the reasons for allowance. The Examiner’s reasons for allowance suggest “that, had the evidence in the [Thornton] Declaration been presented to the Examiner during prosecution of the [’384] patent, there is a reasonable likelihood that the Examiner would have maintained the rejection of the claims of the [’384 patent], and that the [’384] patent would not have issued.” *Prollenium US Inc. v. Allergan Industrie, SAS*, IPR2019-01617, 2020 WL 1491363, at \*24 (P.T.A.B. Mar. 20, 2020).

Accordingly, Petitioner’s additional evidence beyond just Hermann warrants reconsideration of the patentability of the ’384 patent and weighs against discretionary denial under *Becton, Dickinson* factor (f).

**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.

Dated: December 22, 2025

By: /Joshua J. Stowell/

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**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 EXHIBITS 1045-1055** was served electronically on December 22, 2025, to the e-mail addresses shown below:

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