

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SOLVENTUM CORPORATION,
Petitioner,

v.

WOUND HEALING TECHNOLOGIES, LLC,
Patent Owner.

IPR2025-01042
Patent 10,639,404

**PETITIONER’S OPPOSITION TO PATENT OWNER’S REQUEST FOR
DISCRETIONARY DENIAL OF INSTITUTION**

TABLE OF CONTENTS

	Page
I. Introduction	1
II. Petitioner and its Life Saving Wound Care Technology.....	2
III. The Facts of This Case Overwhelmingly Support Institution	4
A. The Co-Pending Litigation is Stayed and the <i>Fintiv</i> Factors Weigh Heavily in Favor of Institution	5
B. The '404 Patent is Only Five Years Old and PO's Conduct Belies Any Claim of Settled Expectations.....	7
1. The '404 Patent is Only Five Years Old	7
2. PO's Shifting Claim Interpretations Undermine Any Settled Expectations	7
C. Section 325(d) Weighs in Favor of Institution.....	10
IV. PO Fails to Show That It Had Settled Expectations or That the PTAB Has Already Adjudicated These Issues.....	13
A. PO Could Not Have Developed Settled Expectations Based on Petitioner's Conduct.....	13
B. The PTAB has Not Adjudicated the Validity of the Challenged Claims	17
1. Argenta 2008 is Not Cumulative of Any Argenta Reference Identified During Prosecution.....	18
2. Hu (EX1005) is Not Cumulative of Biggie (EX1008).....	19
C. The Petition Accurately Describes Argenta 2010	19
V. Petitioner Is Likely To Prevail In This IPR	20
VI. Conclusion.....	20

TABLE OF AUTHORITIES

	Page(s)
Cases	
<i>Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH,</i> IPR2019-01469, Paper 6 (PTAB Feb. 13, 2020)	11
<i>Amazon.com, Inc. v. Audio Pod IP, LLC,</i> IPR2025-00757, Paper 15 (Director Aug. 14, 2025)	15
<i>Apple Inc. v. Fintiv, Inc.,</i> IPR2020-00019, Paper 11 (PTAB Mar. 20, 2020)	5
<i>Becton, Dickinson & Co. v. B. Braun Melsungen AG,</i> IPR2017-01586, Paper 8 (PTAB Dec. 15, 2017)	11
<i>Cambridge Indus. USA, Inc. v. Applied Optoelectronics, Inc.,</i> IPR2025-00434, Paper 11 (Director June 26, 2025)	5, 13
<i>CSPC Megalith BioPharma Co. v. Shanghai Miracogen, Inc.,</i> IPR2025-00685, Paper 9 (Director July 31, 2025)	13
<i>Fleet Engineers, Inc. v. Mudguard Techs., LLC,</i> No. 22-2001, 2023 WL 5219773 (Fed. Cir. Aug 15, 2023)	14
<i>Microsoft Corp v. Edge Networking Sys., LLC,</i> IPR2025-00619, Paper 12 (Director July 31, 2025)	16
<i>Mim Software, Inc. v. Progenics Pharms., Inc.,</i> IPR2025-00630, Paper 13 (Director July 24, 2025)	13
<i>State Indus., Inc. v. A.O. Snith Corp.,</i> 751 F.2d 1226 (Fed. Cir. 1985)	14
<i>Tanklogix, LLC v. SitePro, Inc.,</i> IPR2025-00650, Paper 10 (Director July 31, 2025)	13
Statutes	
35 U.S.C. § 325(d)	10

LIST OF EXHIBITS

Exhibit No.	Description
1001	U.S. Patent No. 10,639,404 (the “’404 Patent”)
1002	Declaration of Dr. Morten O. Jensen, Ph.D., DrMed
1003	Morten Jensen <i>curriculum vitae</i>
1004	U.S. Publication No. 2008/0208147 (“Argenta”)
1005	U.S. Publication No. 2010/0042021 (“Hu”)
1006	U.S. Patent No. 10,639,404 File History
1007	U.S. Patent No. 6,071,267 (“Zamierowski”)
1008	U.S. Patent No. 7,520,872 (“Biggie”)
1009	U.S. Publication No. 2005/0131327 (“Lockwood”)
1010	U.S. Publication No. 2010/0137775 (“Hu775”)
1011	U.S. Publication 2007/0027414 (“Hoffman”)
1012	RESERVED
1013	Okan D., et al., <i>The Role of Moisture Balance in Wound Healing</i> , Advances in Skin and Wound Care, Vol. 20, No. 1 at 39 (Jan. 2007)
1014	U.S. Publication No. 2009/0234306 (“Vitaris”)
1015	U.S. Publication No. 2004/0073151 (“Weston”)
1016	Chariker, M.E., et al., <i>Effective management of incisional and cutaneous fistulae with closed suction wound drainage</i> , Contemporary Surgery, Vol. 34 at 59 (June 1989)
1017	Jerome, D., <i>Advances in Negative Pressure Wound Therapy The VAC Instill</i> , J. of Wound, Ostomy and Continence Nursing, 34(2) at 191 (March 2007)
1018	Thomas, S., <i>Hydrocolloid Dressings in the Management of Acute Wounds: a review of the literature</i> , Int’l. Wound J., 5(5) at 602 (2008)

1019	Bui, T.D., et al., <i>Negative Pressure Wound Therapy with Off-The-Shelf components</i> , Am. J. of Surgery, 192 at 235 (2006)
1020	Reserved
1021	Orgill D.P., et al., <i>The Mechanism of Action of Vacuum Assisted Closure: More to Learn</i> , Surgery 146(1) at 40 (2009)
1022	Miller-Mikolajczyk C., et al. <i>The Evolution of Commercial Negative Pressure Wound Therapy Systems over the Past Three Decades</i> , Adv. In Wound Care, 13(8) at 375 (2024)
1023	Argenta L.C. & Morykwas, M.J., <i>Vacuum-assisted Closure: A New Method for Wound Control and Treatment: Clinical Experience</i> , Annals Plastic Surgery, 38(6) at 563-576 (1997)
1024	Morykwas, M.J., et. al., <i>Vacuum-assisted Closure: A New Method for Wound Control and Treatment: Animal Studies and Basic Foundation</i> , Annals Plastic Surgery, 38(6) at 553 (1997)
1025	The Theory and Practice of Vacuum Therapy (Christian Willy, ed.) (2006)
1026	Williams, C. <i>Granuflex</i> , Br. J. Nurs., 3(14) at 730 (1994)
1027	Williams, C. <i>Hydrocoll: A ‘New Breed’ of Hydrocolloid Wound Dressing</i> , Br. J. Nurs., 7(21) at 1337 (1998)
1028	RESERVED
1029	Gabriel, A., et al., <i>A Clinical Review of Infected Wound Treatment with Vacuum Assisted Closure® (V.A.C.®) Therapy: Experience and Case Series</i> , Int’l Wound J., 6 (suppl. 2) at 1 (2009)
1030	Eaglestein, W.H., <i>Moist Wound Healing with Occlusive Dressings: A Clinical Focus</i> , Dermatologic Surgery 27 at 175-181 (2001)
1031	Field, C.K. & Kerstein, M.D., <i>Overview of Wound Healing in a Moist Environment</i> , Am. J. of Surgery, 167(1A(Suppl)) at 1S (Jan. 1994)
1032	<i>Wound Healing Technologies Corp. v. Solventum Corp.</i> , No. 6:24-cv-589 (W.D. Tex filed Nov. 15, 2024)
1033	Assignment of U.S. Application No. 13/152,446 from Isaac Lichtenstein to Wound Healing Technologies, LLC (June 3, 2011)

1034	Declaration of Michael P. Kahn in Support of Petitioner Solventum's Notice of Intent to Designate Michael P. Kahn as a Provisionally Recognized PTAB Attorney Eligible for Automatic <i>Pro Hac Vice</i> Admission as Backup Counsel Pursuant to 37 C.F.R. § 42.10
1035	Declaration of Caitlin Olwell, Esq. in Support of Petitioner's Opposition to Patent Owner's Request for Discretionary Denial of Institution
1036	December 30, 2021 Letter from FDA to Lightstone Medical Products (Ningbo) Co. Ltd. <i>available at</i> : https://www.accessdata.fda.gov/cdrh_docs/pdf20/K202898.pdf
1037	<i>Wound Healing Techs. Corp. v. Solventum Corp.</i> , No 6:24-cv-589 (W.D. Tex) (Dkt. 30) (Order granting motion to stay)
1038	June 11, 2010, 510(k) Summary: Prevena™ Incision Management System, <i>available at</i> https://www.accessdata.fda.gov/cdrh_docs/pdf10/K100821.pdf
1039	September 16, 2025 PTO Memorandum Regarding PTAB Consideration of Prior Findings of Fact and Conclusions of Law
1040	3M United States Securities and Exchange Commission Form 10 (Jan. 26, 2024), <i>available at</i> https://www.sec.gov/Archives/edgar/data/1964738/000162827924000036/filename1.htm
1041	3M United States Securities and Exchange Commission Form 10 Exhibit 99.1 (Jan. 26, 2024), <i>available at</i> https://www.sec.gov/Archives/edgar/data/1964738/000162827924000036/filename14.htm

I. Introduction

The Petition challenges a young patent asserted against Petitioner Solventum in district court approximately 4.5 years after it issued. The district court promptly stayed the litigation so the Board could address patentability. The challenged claims issued based upon a single limitation that the applicant argued was missing from the art before the Patent Office during examination—a narrow limitation directed to a specific type of material (a “hydrocolloid”) used for a conventional component (a “cover”). The Petition presents a straightforward combination, including one reference that teaches everything but that single limitation and a second reference that teaches the hydrocolloid cover. Despite Patent Owner’s (“PO’s”) attempt to sow confusion, neither reference was before the Patent Office during prosecution. This is precisely the sort of case that should be resolved efficiently by the Board.

Petitioner Solventum is a pioneer in negative pressure wound therapy (“NPT”) and provides products that save lives in hospitals, VA facilities, and other health care settings throughout the United States. EX1040; EX1041 at 10, 22. Petitioner was first-to-market an NPT device and based on market share data reported in July 2023 is now one of the leading providers of NPT devices in the world, including to the U.S. military. EX1041 at 101, 106-107. Petitioner’s NPT solutions are backed by over 2,000 peer-reviewed publications, accounting for more than 70% of all published NPT clinical trials. EX1041 at 101, 107. PO does not

manufacture any products, does not appear to practice its own technology, and simply imports products made by others in China to try to disrupt the US market.

PO filed a discretionary denial brief trying to retrofit the facts of this case to recent Director decisions that have denied institution under very different circumstances. PO exaggerates and misrepresents the operative facts in this dispute in an attempt to apply inapplicable theories of “settled expectations.” The record reveals, however, that PO has shifted its view of the scope of its young patent’s claims repeatedly, rendering any arguments about its “settled” expectations hollow.

II. Petitioner and its Life Saving Wound Care Technology

Two scientists, Dr. Louis Argenta and Dr. Michael Morykwas, conducted the pioneering work that led to modern NPT. Pet. at 16. Shortly after Drs. Argenta and Morykwas tested the first NPT system, a company named Kinetic Concepts, Inc. (“KCI”) licensed the technology and commercialized the V.A.C.® therapy device. EX1022 at 376; EX1029 at 2. For nearly three decades Petitioner and its predecessors (including 3M and KCI) have invested in developing cutting edge wound therapy devices—now selling to more than 100,000 channel partners and customers globally. EX1041 at 101, 106-107.

In 2023, a company named “Wound Healing Technologies Inc.” (“WHTI”)¹ sent a half-page letter to 3M Co., Petitioner’s immediate predecessor, to provide “notice of the issuance of the ’404 Patent” and to accuse 3M’s Prevena™ brand of products of embodying the “subject matter claimed in the ’404 Patent”—with no further analysis. EX2006. A month after receiving WHTI’s letter, 3M promptly informed WHTI that “[n]one of the Prevena™ products fall within the scope of the claims of this patent for at least the reason that none of the Prevena™ products include ‘a hydrocolloid vapor sealant’ as is required by the claims,” and that 3M therefore “consider[s] this matter closed.” Neither WHTI nor PO responded. *Id.*

The next communication was when PO sued Petitioner over 20 months later and accused Petitioner’s “Prevena” and “Snap” product lines of infringing the ’404 Patent. EX1032 ¶ 14. Shortly after filing its Complaint, PO provided Petitioner with a sample product allegedly embodying the ’404 Patent. EX1035 ¶ 3. The product provided by PO bore the name “Tzoar Negative Pressure Wound Therapy One Piece Dressing” and is apparently for use with the “Tzoar Negative Pressure Wound Therapy System,” which, based on public FDA documents, appears to be a NPT pump marketed by a Chinese company. EX1035 at 7; EX1036.

¹ PO has thus far not explained how WHTI relates to the PO, Wound Healing Technologies, LLC, nor identified WHTI in its Mandatory Notices.

PO's motivation in seeking discretionary denial is simple—district court litigation over the '404 Patent will cost Petitioner more money and PO can increase its settlement demand. PO even seeks to use the '404 Patent to enjoin Petitioner's sales of its lifesaving products. EX1032 at 9. As a major provider of NPT devices in the U.S., Petitioner would either have to pay PO its demand or risk prolonged litigation with the potential outcome that many U.S. consumers would lose access to necessary NPT therapy pending an appeal. Every dollar Petitioner spends to litigate this case in district court instead of in this IPR is a dollar taken away from U.S. R&D and patient support. Proceeding with this IPR is in the best interest of the citizens of the United States for both public health and economic reasons.

III. The Facts of This Case Overwhelmingly Support Institution

The Petition presents three Grounds, each identifying Argenta 2008 (EX1004) and Hu (EX1005).² Argenta 2008 discloses a wound dressing for NPT and teaches every claim limitation except that the vapor sealant sheet is formed from a hydrocolloid material. The vapor sealant sheet is a sheet that overlies the drain and drain-surrounding materials to create an air-tight seal. Argenta 2008 discloses a cover that performs that function, but its cover is made of a standard surgical drape. Hu also addresses NPT wound dressings with a cover and expressly discloses that

² Grounds 2 and 3 each cite an additional reference for dependent claim limitations.

the cover may be “made of a hydrocolloid material.” EX1005 ¶ 59. The Board is rarely presented with an IPR petition as straightforward as this one. The district court litigation is stayed. The challenged patent is young. Neither key reference was before the Examiner during prosecution and if this combination had been considered, the claims would not have issued. Accordingly, it is in the interest of the Patent Office, the District Court, the parties, and the public for the PTAB to assess the patentability of the ’404 Patent claims. *See e.g. Cambridge Indus. USA, Inc. v. Applied Optoelectronics, Inc.*, IPR2025-00434, Paper 11 at 2-3 (Director June 26, 2025) (one of many decisions rejecting requests for denial where co-pending litigation is stayed, the challenged patent issued in 2019 or later, and denial under § 325(d) is inappropriate).

A. The Co-Pending Litigation is Stayed and the *Fintiv* Factors Weigh Heavily in Favor of Institution

PO fails to mention the *Fintiv* factors, but those factors weigh strongly in favor of institution. *See Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11 at 5-6 (PTAB Mar. 20, 2020) (precedential). First, the district court has ***already stayed*** the co-pending litigation filed in November 2024 to allow this IPR to proceed. EX1037 at 3. The district court concluded that, among other things, the litigation could be greatly simplified if the PTAB institutes review, and if any claims survive the court will benefit from the PTAB’s analysis. *Id.* at 2. Second, there is no trial date set in

the litigation. Third, the Court and parties have invested very little time in the litigation. At the time of the stay the court had not yet entered a scheduling order. *Id.* at 2-3. Thus there has been no discovery, no claim construction efforts, and no exchange of contentions other than the claim scope positions set forth in the district court Complaint. Fourth, in view of the stay there is no evidence of any overlapping positions. Fifth, while PO contends that it and the district court plaintiff are one and the same, publicly available information shows they are different entities, as noted in the Petition. Pet. at 2-3. Finally, the merits of the petition are strong. The petition provides evidence supporting a simple combination of a primary reference that teaches every limitation except the limitation that led to allowance of certain claims, and a secondary reference that expressly discloses that “missing” limitation. PO’s argument to the contrary is confusing and directly contradicts its district court Complaint. Paper 8 at 26-31; *infra* § III.B.2.³

³ PO filed an over-length brief on September 3, 2025 (Paper 8). The PTO permitted PO to re-file a compliant brief on September 19, 2025 (Paper 9) (“DD Br.”). Where PO made admissions relevant to the issues here, citations to Paper 8 are included.

B. The '404 Patent is Only Five Years Old and PO's Conduct Belies Any Claim of Settled Expectations

1. The '404 Patent is Only Five Years Old

The '404 Patent issued on May 5, 2020. Petitioner filed its petition on June 13, 2025. Although PO suggests otherwise, it is indisputable that the patent was five-years and one-month old when Petitioner challenged it. Moreover, the petition here is the first post-issuance challenge to the claims of the '404 Patent. *See infra* § IV.B.

In an effort to make its patent sound older than it is, PO makes several misleading statements about its age. First, PO claims that Petitioner was aware of the '404 Patent for “more than eleven years.” DD Br. at 3, 9. That is obviously false. The Patent did not exist eleven years ago. And if that were true, WHTI would have had little reason to send a letter to “provide notice” of the patent in 2023. Moreover, PO's faulty premise leads to the absurd argument about a 2020 patent, that “Petitioner waited *over a decade* before filing (in June 2025) its Petition.” DD Br. at 6. Petitioner did not and could not have had “actual knowledge” of the claims of the '404 patent for eleven years, or challenged those claims over a decade ago, when the patent issued in mid-2020. *Id.*

2. PO's Shifting Claim Interpretations Undermine Any Settled Expectations

The unique facts of this case show that PO could ***not*** have developed settled expectations. First, PO is aware that its express disagreement with the Examiner's

reasoning in the Notice of Allowance created uncertainty regarding claim scope. During prosecution the Examiner withdrew an obviousness rejection of many of the claims because she reconstrued certain terms to be means-plus-function terms, and PO disputed that new construction. EX1006 at 108-111. In her Notice of Allowance, the Examiner maintained that interpretation and instructed PO either to amend the claims or to “present a sufficient showing that the claim limitation(s) recite(s) sufficient structure to perform the claimed function.” EX1006 at 20-22. PO did neither and simply maintained its disagreement, shifting the burden back to the Examiner while leaving the construction of those terms unsettled. EX1006 at 7.

Second, in 2023 WHTI sent Petitioner a letter suggesting that the Prevena™ line of products “embodies” claims of the ’404 Patent. EX2006. Every claim of the ’404 patent requires “a vapor sealant sheet formed from a hydrocolloid material.” It is not clear how WHTI interpreted the claims—none of the Prevena™ products include this feature. 3M informed WHTI that the claims did not embody the product “for at least” the reason that the products do not include this feature. PO never responded, thus Petitioner had no reason to also explain that parts of the Prevena™ line of products pre-date the ’404 Patent (EX1038) or identify invalidity positions.

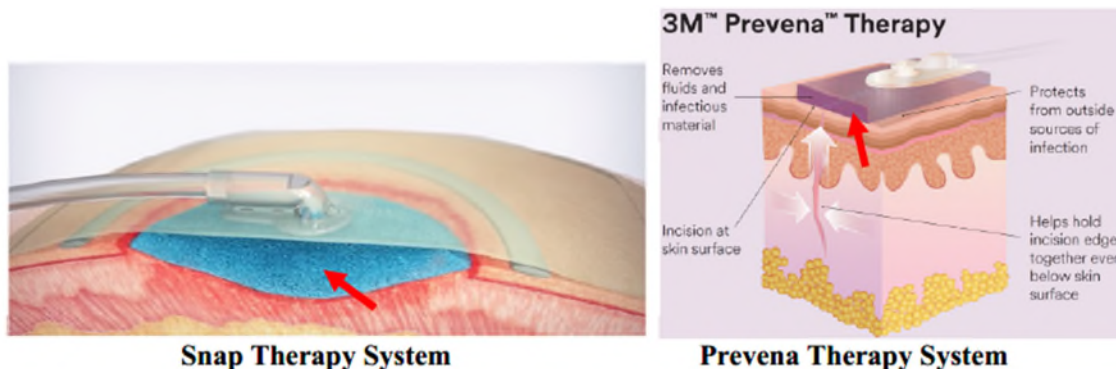
Third, PO’s claim interpretation in this IPR presents a new proposed interpretation of its claims—one that directly contradicts the allegations in its district

court Complaint. In this IPR, PO insists that the claims do not read on a device where foam is first cut and placed in the wound (like the device in the prior art), but in the district court it has accused products where foam is first cut and placed in the wound. Specifically, in its initial brief, PO argued that the “fluid absorbing/transferring layer” in the claimed dressing “cannot be cut, further shaped, or used to then fill a wound.” Paper 8 at 27. Allegedly it would change the principle of operation of the references in the Petition to arrive at the claimed dressing because those references use “a screen that can be cut, shaped to fit and used to fill the wound.” *Id.* at 29-30.

In direct contrast, the products that PO accused in its district court Complaint are built in or on a wound just like the prior art device. PO even depicted images of the accused devices in its district court Complaint, showing that Snap devices have an absorbing/transferring layer in the form of a foam filler ***that is cut to fill the wound***. EX1032 ¶¶ 14, 20. The Prevena™ dressing similarly has a separate foam component that is ***cut to size and placed on the wound***. *Id.*



Id. at ¶ 14. In both cases, the vacuum tube, which is a separate component, is added overtop of the foam that is already placed in or on the wound.



Id. at ¶¶ 22-23. PO cannot reasonably have developed “settled expectations” in its young patent when it has not even settled on a consistent interpretation of the claims.

C. Section 325(d) Weighs in Favor of Institution

Each Ground of the Petition relies on references and prior art combinations that were not previously presented to the Office, further weighing against discretionary denial. Although PO does not cite to or rely on 35 U.S.C. § 325(d), the provision and related decisions are instructive for analyzing the lack of overlap in prior arguments. In applying § 325(d), the Board asks: (1) whether the same or substantially the same art or arguments were previously presented to the Office and (2) if so, whether the petitioner has demonstrated that the Office erred in a manner

material to the patentability of the challenged claims.⁴ *Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 at 8 (PTAB Feb. 13, 2020) (precedential). The factors set forth in *Becton, Dickinson* explain how to apply the *Advanced Bionics* framework. *Becton, Dickinson & Co. v. B. Braun Melsungen AG*, IPR2017-01586, Paper 8 (PTAB Dec. 15, 2017) (precedential as to § III.C.5, first paragraph).

In the first prong of the *Advanced Bionics* test, the Board considers the similarities and material differences between the asserted art and the prior art involved during examination, the cumulative nature of the asserted art and the prior art evaluated during examination, and the extent of the overlap between the arguments made during examination and the manner in which petitioner relies on the prior art or patent owner distinguishes the prior art. *Advanced Bionics*, IPR2019-01469, Paper 6 at 9-10; *Becton*, IPR2017-01586, Paper 8 at 17-18.

⁴ PO faults Petitioner for not identifying Examiner error in its Petition. DD Br. at 17-18. That argument is meritless. None of the references were considered or are cumulative of any prosecution reference. Moreover, Petitioners should **not** address discretionary considerations in the Petition. See Interim Director Discretionary Process at § I.C (available at <https://www.uspto.gov/patents/ptab/interim-director-discretionary-process>).

Here, PO must concede that neither of the primary references that the Petition relies on, Argenta 2008 (EX1004) and Hu (EX1005), was before the Examiner during prosecution. Instead PO makes the superficial argument that another patent application by the same inventor (Argenta) renders Argenta 2008 cumulative. DD Br. at 13-15. As explained further below, unlike the reference with the same named inventor considered during prosecution, Argenta 2008 expressly teaches that the vapor sealant sheet includes adhesive that maintains placement of the sheet relative to the fluid-absorbing/transferring layer. *See infra*, § IV.B.1. PO admits that limitation is not disclosed by any Argenta reference cited during prosecution. *Id.*

PO also argues that Hu is cumulative of Biggie (EX1008). DD Br. at 14-15. Hu discloses a NPT dressing with a sheet that is “made of a hydrocolloid material”—exactly the limitation, “a vapor sealant sheet formed from a hydrocolloid material,” that overcame the prior art during prosecution. In contrast, the art before the Board included “a vapor sealant sheet made of a different material . . . having a hydrocolloid adhesive disposed along the periphery of the sheet,” which was not sufficient. EX1006 at 59. But Hu teaches a sheet that is itself made of a hydrocolloid material. Hu is not cumulative of any reference cited during prosecution. Moreover, during prosecution the Office did not consider the combination identified in the Petition, or any of the evidence supporting that combination. In any event, even if substantially

the same art or arguments were considered by the Examiner, which they were not, the Examiner erred in allowing the claims for the reasons set forth in the Petition. *See, e.g.*, Pet. at 31-55 (Ground 1). Accordingly, § 325(d) favors institution.

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The Director routinely rejects requests for discretionary denial where: (1) any co-pending litigation is stayed, (2) the challenged patent issued in 2019 or later, and (3) discretionary denial under § 325(d) is inappropriate. *See, e.g., Cambridge Indus. USA, Inc. v. Applied Optoelectronics, Inc.*, IPR2025-00434, Paper 11 at 2-3 (Director June 26, 2025); *Mim Software, Inc. v. Progenics Pharms., Inc.*, IPR2025-00630, Paper 13 at 2 (Director July 24, 2025); *Tanklogix, LLC v. SitePro, Inc.*, IPR2025-00650, Paper 10 at 2-3 (Director July 31, 2025); *CSPC Megalith BioPharma Co. v. Shanghai Miracogen, Inc.*, IPR2025-00685, Paper 9 at 2 (Director July 31, 2025). Those are exactly the facts here. The Director should not deny consideration of the grounds set forth in the Petition.

IV. PO Fails to Show That It Had Settled Expectations or That the PTAB Has Already Adjudicated These Issues

A. PO Could Not Have Developed Settled Expectations Based on Petitioner's Conduct

Despite the issuance of the '404 Patent in mid-2020, 4.5 years before the PO initiated litigation, PO suggests it developed settled expectations based on Petitioner's conduct. There is no evidence that Petitioner's conduct affected PO's

understanding of its own patent—and the 2023 letter to the Petitioner undermines any suggestion that WHTI or PO considered or relied upon Petitioner’s conduct prior to that time.

Petitioner did not and could not have had “actual knowledge” of the ’404 Patent for eleven years as PO alleges. DD Br. at 6. PO argues that Petitioner was aware of a published **application** (not the ’404 Patent) in 2014. DD Br. at 5-7. PO fails to explain how that allegation, if true, is probative of PO’s mental state. For example, PO neither argues nor suggests that it was aware of and relied on the citation of a pending application by the Petitioner’s predecessor in interest in 2014, or any time thereafter. PO’s argument is particularly off base because the claims materially changed during prosecution. As PO is undoubtedly aware, “an application is no guarantee any patent will issue. . . . What the scope of claims in patents that do issue will be is something totally unforeseeable.” *Fleet Engineers, Inc. v. Mudguard Techs., LLC*, No. 22-2001, 2023 WL 5219773, at *7 (Fed. Cir. Aug 15, 2023) (nonprecedential) (quoting *State Indus., Inc. v. A.O. Snith Corp.*, 751 F.2d 1226, 1236 (Fed. Cir. 1985).

PO appears to have found discretionary denial decisions it liked and then worked backwards to try to make them fit the circumstances of this case. But they do not. None of those cases suggest that a petitioner’s mere knowledge of an

application, without more, is sufficient for a patent owner to develop settled expectations shortly after issuance. In each of the cases PO cites for Petitioner's alleged knowledge of applications, the Director considered multiple IPRs challenging families of related patents, where each family included one or more challenged patents that were well over a decade old (warranting denial on their own). For example, in *Amazon.com, Inc. v. Audio Pod IP, LLC*, the Director denied institution of a patent issued in late-2020 because the Director was already denying institution of five related patents that had each been in force for between seven and eleven years. IPR2025-00757, Paper 15 at 2-3 (Director Aug. 14, 2025). Because the district court would address all five of those patents anyway, it would not have been an efficient use of Office resources to institute review on only the sixth patent, even though ***ordinarily the circumstances might counsel against discretionary denial***. PO's other cases similarly include multi-patent families that included patents that had been in force for over a decade. DD Br. at 5-7.

Here, the '404 Patent is the only member of its family and issued in mid-2020. No district court will be addressing any related patents (there are none) for which the Board otherwise has reason to deny institution. In other words, there is no efficiency to be gained by denying institution. Indeed, the Director has rejected the same argument PO makes when other factors counsel against discretionary denial.

In *Microsoft Corp. v. Edge Networking Sys., LLC*, the patent owner argued petitioner knew of the patent's family because its parent was cited during prosecution of petitioner's own patent. IPR2025-00619, Paper 8 at 44-46 (DD Br. June 15, 2025). Nonetheless, because the patent issued in 2020 and § 325(d) did not support discretionary denial, the Director referred the Petition to the Board. *Microsoft Corp v. Edge Networking Sys., LLC*, IPR2025-00619, Paper 12 (Director July 31, 2025).

Second, the 2023 letter that WHTI sent to Petitioner states that “[i]t has come to the attention of [WHTI] that [Petitioner’s predecessor] is offering at least one product . . . under the Prevena brand that embodies subject matter claimed in the ’404 Patent.” EX2006. PO did not identify any specific allegedly infringing product among the Prevena™ brand—a brand of products that has been marketed since 2010, long before the ’404 Patent’s priority date. EX1038. If anything, the long-term marketing of the Prevena™ brand of products evidences *Petitioner’s* settled expectations in selling these products. Nonetheless, PO apparently did not become aware of Petitioner’s conduct until several years **after** the ’404 Patent issued. PO could not have developed settled expectations based on conduct it did not know about. Moreover, Petitioner explained that Prevena™ products do not use a hydrocolloid vapor sealant sheet and neither WHTI nor PO ever followed up on that letter. EX2006. These are not the type of facts that show “settled expectations.”

Finally, after informing PO that Prevena™ products cannot infringe, Petitioner continued to invest and innovate in the NPT space and in 2023 the FDA expanded the approved indications for the Prevena™ product. EX1041 at 108. Again, this conduct demonstrates *Petitioner's* settled expectations that it need not challenge the '404 Patent. In contrast, nothing in Petitioner's conduct provided reason for PO to develop settled expectations and PO has not shown that it did so.

B. The PTAB has Not Adjudicated the Validity of the Challenged Claims

PO next incorrectly suggests that the PTAB has already adjudicated the patentability of the challenged claims. It has not. PO's argument is based on an obviousness rejection of a small subset of the issued claims that was appealed to the Board during prosecution. Patentability of the claims has *never* been evaluated in any post-issuance proceeding and PO identifies no case where a routine Board appeal during prosecution supported discretionary denial. Instead, PO relies on cases where a patent had been subject to a post-issuance challenge, either in previous IPRs, or a previous court case. DD Br. at 11, n.7. The Director's recent memorandum regarding consistency with prior adjudications confirms that the relevant inquiry is whether the claims have been challenged in "post-issuance" proceedings, not in connection with mere prosecution. EX1039.

PO then accuses Petitioner of “rehashing” the substance of the Examiner’s obviousness rejection of a subset of claims. That argument is facially incorrect—the Petition explains why using a vapor sealant sheet made of a hydrocolloid material would have been obvious to a skilled artisan, and how that feature is expressly disclosed in Hu (EX1005 ¶ 59). That is the exact limitation that was determined to be missing during prosecution conducted without the benefit of Argenta 2008 and Hu. EX1006 at 59. And for the reasons below, the Petition references are not cumulative of those considered during prosecution.

1. Argenta 2008 is Not Cumulative of Any Argenta Reference Identified During Prosecution

PO’s “cumulative” argument amounts to irrelevant name games. Argenta 2008 is not cumulative of any Argenta reference considered during prosecution. Every claim in the ’404 Patent requires that the vapor sealant sheet have an adhesive for adhering it to the fluid-absorbing/transferring layer, and that adhesive maintains the placement and orientation of that layer relative to the vapor sealant sheet. *E.g.*, Pet. at 42. Argenta 2008 discloses that “[t]he screen 20 may be held in place by contacting an adhesive coated under surface 12 of the cover 10 to assist in securing the screen 20 in a fixed position.” *Id.* (citing EX1004 ¶ 19). In its initially-filed brief, PO took the position that none of the Argenta references identified during prosecution meet this limitation. Paper 8 at 19 (representing that this limitation is

“neither shown nor suggested by Argenta 2010 or any of the cited references”). PO’s suggestion that every patent having the same inventor includes the same disclosure is wrong. PO’s admission confirms Argenta 2008 is **not** cumulative of the prosecution references.

2. Hu (EX1005) is Not Cumulative of Biggie (EX1008)

As explained above, Hu was not before the Examiner during prosecution. Hu expressly discloses a cover sheet (the claimed “vapor sealant sheet”) that may be made of a hydrocolloid material. Pet. at 27; EX1005 ¶ 59. Biggie, in contrast, depicts filling a wound with a hydrocolloid gel that is covered by a sheet made of a different material. EX1008 at 7:37-44, Figs. 3-5. Hu is not cumulative of Biggie. In any event, PO is incorrect that Biggie discloses an embodiment where the gel is used without a protective cover. DD Br. at 15. Figure 4 is not a separate embodiment. Figures 3-5 depict individual steps in building the preferred embodiment. See EX1008 at 7:37-44. Thus, PO’s reading of Biggie, which was not relied on in any rejection, is wrong.

C. The Petition Accurately Describes Argenta 2010

Finally, PO boldly accuses Petitioner of trying to mislead the Board by referring to Argenta 2010 as “an apparatus for cardiac tissue modulation.” DD Br. 15-17. But Petitioner’s characterization is accurate: Argenta 2010, which PO admits refers to “cardiac tissue modulation” in the title (DD Br. at 16) **is** indisputably related to cardiac tissue modulation. The device is not a negative pressure wound therapy

device for an external wound, it is a vacuum device implanted in a patient's body directly on the heart to increase blood flow to damaged cardiac tissue. EX2007 ¶¶ 2, 7, 19. PO described that reference similarly to the Board during prosecution and distinguished it from the technology of its patent claims. EX1006 at 92 ("Argenta is directed specifically to internal organ damage . . ."). Petitioner did not try to mislead the Board. In any event, Argenta 2010 is irrelevant—PO admits it does not disclose a limitation that *is* expressly disclosed in Argenta 2008. *See supra*, § IV.B.1.

V. Petitioner Is Likely To Prevail In This IPR

PO offers a final three-sentence argument alleging that Petitioner "omits direct treatment" of a lengthy claim limitation. DD Br. at 18-19. Petitioner did not omit anything. The Petition explains in detail how the combination of prior art renders obvious limitations related to placement of the vapor sealant sheet. Pet. at 38-42.

VI. Conclusion

A holistic review of the factors here strongly favors institution of IPR. The Director should deny PO's request for discretionary denial.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned hereby certifies pursuant to 37 C.F.R. §§ 42.6(e) that the above-captioned Petitioner's Opposition to Patent Owner's Request for Discretionary Denial of Institution, as well as new exhibits filed with that document, was served in its entirety on October 3, 2025, via electronic mail upon the following counsel of record for Patent Owner at:

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Dated: October 3, 2025

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