

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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INTAS PHARMACEUTICALS LTD.,  
Petitioner

v.

ATOSSA THERAPEUTICS, INC.,  
Patent Owner

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Case PGR2025-00043  
Patent 12,071,391

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

**PROTECTIVE ORDER MATERIAL**

**LIST OF EXHIBITS**

<b>Exhibit</b>	<b>Description</b>
EX2001	ATOSSA THERAPEUTICS, INC. QUARTERLY REPORT FORM 10-Q for the Quarterly Period Ended March 31, 2025
EX2002	Atossa Therapeutics Proposes Potentially Groundbreaking Study Aimed at Reducing Interval Breast Cancer in High-Risk Women at AACR 2025 (April 29, 2025)
EX2003	Atossa Therapeutics Announces Plans to Pursue Metastatic Breast Cancer Indication for (Z)-Endoxifen and Continued Engagement with FDA on Additional Indications (March 11, 2025)
EX2004	Financials – Intas Pharmaceuticals Ltd., <a href="http://www.intaspharma.com/financials/">http://www.intaspharma.com/financials/</a>
EX2005	Atossa Therapeutics Announces Issuance of Key U.S. Patent Covering Endoxifen (March 8, 2022)
EX2006	Efficacy and Safety of Endoxifen in Bipolar I Disorder Patients, NCT06608641 (Last Updated March 17, 2025), <a href="https://clinicaltrials.gov/study/NCT06608641">https://clinicaltrials.gov/study/NCT06608641</a>
EX2007	Declaration of Sayem Osman
EX2008	Atossa Covenant Not to Sue
EX2009	Atossa Therapeutics Announces Full Results from Phase 2 KARISMA-Endoxifen Study Demonstrating Statistically Significant Reductions in Mammographic Breast Density (Dec. 11, 2024)
EX2010	Atossa Therapeutics Announces First Quarter 2025 Financial Results and Provides a Corporate Update (May 13, 2025)
EX2011	INTENTIONALLY OMITTED
EX2012	Breast Center Year in Review, An Unmet Need in HR-Positive Endocrine-Resistant Breast Cancer, <i>available at</i> <a href="https://jons-online.com/special-issues-and-supplements/2021/2021-year-in-review-breast-cancer/an-unmet-need-in-hr-positive-endocrine-resistant-breast-cancer">https://jons-online.com/special-issues-and-supplements/2021/2021-year-in-review-breast-cancer/an-unmet-need-in-hr-positive-endocrine-resistant-breast-cancer</a>
EX2013	ATOSSA THERAPEUTICS, INC. ANNUAL REPORT FORM 10-K for the Fiscal Year Ended December 31, 2024
EX2014	U.S. Patent No. 11,572,334
EX2015	Intas Requirements For Resolving Disputes With Atossa (FILED UNDER SEAL)

<b>Exhibit</b>	<b>Description</b>
EX2016	Default Protective Order
EX2017	<i>Intas Pharmaceuticals, Limited v. Atossa Therapeutics, Inc.</i> , IPR2025-00799, Pap.2 (Apr. 3, 2025)
EX2018	<i>Intas Pharmaceuticals, Limited v. Atossa Therapeutics, Inc.</i> , PGR2023-00043, Pap.1 (Aug. 18, 2023)
EX2019	Rishab Gupta & Swarndeeep Singh, <i>Endoxifen Approval for Bipolar in India, A Premature or a Pragmatic Decision?</i> , 43(1) J. CLINICAL PSYCHOPHARMACOLOGY 3 (2023)
EX2020	Zonalta, Why Zonalta?, available at <a href="https://zonalta.in/">https://zonalta.in/</a>
EX2021	Atossa Therapeutics Granted Additional Patent Protection for Endoxifen (August 28, 2024)
EX2022	Declaration of Megan Raymond

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## I. Introduction

The Petition challenging U.S. Patent No. 12,071,391 (“the ’391 Patent”; EX1001), a foundational patent owned by Atossa Therapeutics (“Atossa” or “Patent Owner”) covering highly pure (Z)-endoxifen compositions, represents precisely the type of inefficient and unduly burdensome proceeding that the USPTO’s current policies seek to prevent. The ’391 Patent and its patent family relate to novel (Z)-endoxifen compositions, and include claims directed to, *e.g.*, the treatment of hormone-dependent and tamoxifen-resistant breast cancer. This patent family is an important asset of Atossa and reflects years of focused research and clinical investment by a small American biopharmaceutical company to develop a stable, purified form of (Z)-endoxifen and to address a critical unmet need in hormone-sensitive breast cancer therapy. As explained below, discretionary denial is appropriate here pursuant to 35 U.S.C. §§ 314(a) and 325(d).

The challenged claims are directed to pharmaceutical compositions comprising (Z)-endoxifen and an enteric material, as well as methods for making and administering such compositions, including to treat hormone-dependent breast cancer. Unlike the claims of the previously adjudicated related patent, U.S. Patent No. 11,572,334 (“the ’334 Patent”), the ’391 Patent’s claims require *the composition itself comprise both an endoxifen and an enteric material*. EX1001, cl.1. By contrast, the ’334 Patent’s claims require an endoxifen composition to be

“encapsulated in an enteric capsule.” EX2014, cl.1. The (Z)-endoxifen claimed in the '391 Patent provides a direct and reliable therapeutic alternative to tamoxifen, a decades-old standard of care that fails many patients due to metabolic limitations, and is combined with an enteric material to prevent degradation in the stomach. As discussed below, Patent Owner is currently pursuing clinical trials on the use of a free base form of its (Z)-endoxifen to treat breast cancer. Petitioner, in contrast, is apparently involved in clinical trials using a salt form of (Z)-endoxifen to treat bipolar disorder.

This PGR is not an isolated event. Instead, it is the latest in a series of coordinated attacks by Petitioner against Patent Owner’s intellectual property related to (Z)-endoxifen. Patent Owner is demonstrably a small entity, and relies almost entirely on external investment to fund its extensive research and clinical programs.

As discussed below, the relevant factors under the USPTO’s March 26, 2025 Memorandum on Interim Processes for PTAB Workload Management (“March 26 Guidance”) demonstrate that discretionary denial is the proper outcome here.

*First*, the public health implications are profound: Patent Owner’s business is focused on the treatment and prevention of breast cancer. Patent Owner is conducting multiple Phase 2 and 3 clinical trials targeting hormone-dependent and metastatic breast cancers using its (Z)-endoxifen, and institution could disrupt and jeopardize access to these therapies for patients with few alternatives, particularly as

Petitioner's filing is part of a serial attack designed to burden and destabilize a small clinical-stage innovator.

*Second*, institution here would be a needless waste of Patent Office and party resources. As discussed in more detail below and as reflected by the attached covenant, ***Patent Owner has provided a covenant not to sue Petitioner*** (or its affiliates or commercial partners) in the event Petitioner is able to bring its use of (Z)-endoxifen for treating bipolar disease to market. In light of this covenant, which eliminates any arguably legitimate commercial interest of Petitioner in challenging the '391 Patent, this proceeding would be a waste of resources for the Board and Patent Owner.

*Third*, discretionary denial is warranted under 35 U.S.C. § 325(d). Petitioner seeks to invalidate the '391 Patent by rehashing the same old art (*i.e.*, the Ahmad reference) that the USPTO already considered, and Petitioner fails to show any material error by the Examiner. The key reference that Petitioner relies on to disclose the claimed composition, Ahmad, was already before the Examiner, and the "new" secondary references cited only for certain dependent claims do not alter the analysis. There was also no material error in allowing the claims over Ahmad.

*Fourth*, the merits are exceptionally weak: each of the seven asserted prior art grounds (Grounds 1-7) relies on Ahmad as the base reference and fails because Ahmad's alleged disclosure of an enteric-coated capsule is fundamentally different

from the claimed composition that itself must contain an enteric material. The issues and claims presented also differ from the previous PGR such that collateral estoppel does not apply. Petitioner’s Ground 8, a § 112 challenge directed to certain dependent claims, fares no better. The brief argument—spanning less than two pages—is unsupported by expert testimony and does not provide any explanation whatsoever regarding enablement.

Finally, *fifth*, the Petition’s excessive reliance on expert testimony to fill gaps and also to allege inherency through benchtop testing confirms that the factual issues raised here are ill-suited for an PGR.

For the reasons above, taken individually or based on a holistic assessment, the Board should grant Patent Owner’s request for discretionary denial.

## **II. The ’391 Patent: A Lifeline for Breast Cancer Patients**

Breast cancer continues to be a formidable public health challenge, remaining as the most common form of cancer in women and second leading cause of cancer death in humans. *See, e.g.*, EX1001, 1:25-28. Hormone-dependent breast cancer represents the most prevalent subtype. EX2001, 18 (“ER+ breast cancer which comprises approximately...78% of all breast cancers.”). Tamoxifen has been a first-line treatment for hormone-dependent breast cancer, but many patients, due to genetic factors or drug interactions, cannot adequately metabolize tamoxifen into its active metabolite, endoxifen, rendering such treatment ineffective for those

individuals. *See* EX1001, 2:1-2:28; 43:62-44:17. Tamoxifen is also known to have severe side effects. *See id.* at 2:1-2:28. (Z)-endoxifen is the “main active metabolite responsible for the clinical efficacy of tamoxifen” and provides more consistent efficacy, regardless of patient genotype. *See id.* at 2:41-43.

Obtaining relatively pure and stable forms of (Z)-endoxifen proved a challenge until the filing of the '391 patent family. *See id.* at 27:40-55. The inventors of the '391 Patent developed a novel synthesis process that avoids the inefficiencies and instabilities of prior methods, yielding a crystalized form of (Z)-endoxifen (at least 90% by weight) with superior stability and commercial-scale feasibility. *See id.*

The '391 Patent teaches a synthetic pathway and purification process to create this highly pure (Z)-endoxifen. EX1001 at Examples 1, 4-9. The starting isomeric mixture of (E)/(Z)-endoxifen is first subjected to crystallization. *Id.* Because the inventors observed that (E)-endoxifen is much less soluble than (Z)-endoxifen in a variety of solvents, this initial crystallization step results in an enriched (Z)-endoxifen component (*e.g.*, a mother liquor or filtrate). *See id.* at 68:51-59 (“(Z)-endoxifen was seen to be more soluble than (E)-endoxifen in EtOAc....Serial enrichment of Z-endoxifen by adding filtrates back to the first filtrate (first mother liquor) can also be performed.”). The enriched (Z)-endoxifen component is then subjected to further crystallization to obtain pure (Z)-endoxifen solid in a free base

composition. *See id.* at 68:55-57 (“Both solids and filtrates are useful for the preparation of (Z)-endoxifen free base.”). The (Z)-endoxifen free-base solid composition obtained is shown to have increased stability in ambient conditions, with reduced isomeric conversion to the (E)-isomer. *See id.* at 83:19-28 (“Results show that solid Z-endoxifen free base is stable for at least 9 months at 5° C. and 25° C./60% RH.... (Z)-to-(E) endoxifen interconversion is minimal at the storage conditions studied.”).

The stable, highly pure form of (Z)-endoxifen claimed in the '391 Patent aims to address the urgent need for a safer and more effective treatment and has improved bioavailability, bypassing metabolic limitations and providing consistent therapeutic benefit across diverse patient populations. *Id.* at 2:1-58, 2:60-11:15, 96:20-98:66. Moreover, unlike existing synthetic methods and purification strategies, the process disclosed in the '391 Patent to synthesize the claimed composition achieves higher yield, greater purity, and improved stability, and is more economical and scalable for commercial production. *Id.* at 24:16-20, 27:40-55, 30:25-52, 81:3-18.

The '391 Patent's claims specifically are directed to a composition comprising endoxifen and an enteric material. *Id.* at cl.1.<sup>1</sup> The claimed composition is protected

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<sup>1</sup> Petitioner asserts that endoxifen is subject to degradation in the acidic conditions of the stomach and that enteric materials may be used to prevent release of the

from the acidic environment of the stomach and instead “target[s] upper small intestines and colon.” *See id.* at 39:27-28; cl.38 (“releasing no more than 10% of the (Z)-endoxifen in a stomach of the subject within 2 hours following the administering of the composition”).

### **III. The Parties**

Patent Owner Atossa is a small clinical-stage American biopharmaceutical innovator with “small entity” status at the USPTO. *See* EX2001, 16; EX1002, 2, 568. Atossa does not yet have any products on the market and therefore does not yet generate revenue sufficient to cover its operating costs. *See* EX2001, 6-7, 19 (“We are in the research and development phase and are not currently marketing any products. We do not anticipate generating revenue unless and until we develop and launch our pharmaceutical programs.”). For the time being, Atossa depends on investments in the company to fund its research and clinical efforts (*See* EX2001, 7) —as well as its defense of this dispute from Petitioner.

Atossa’s business is focused on developing its claimed (Z)-endoxifen treatment to help patients with or at high risk for breast cancer. *See* EX2001, 7, 16; EX2010 (Atossa’s “focus remains firmly on advancing (Z)-endoxifen as a next-

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endoxifen in the stomach and instead release the active substance in the intestines.

Pet.6.

generation therapy for breast cancer patients across the full spectrum of care...”). Patent Owner is actively developing a free base form of (Z)-endoxifen and running several Phase 2 clinical trials using a free base form of its (Z)-endoxifen. *See* EX2001, 16-18. These trials include the EVANGELINE Trial, investigating it as a neoadjuvant treatment for premenopausal women; the I-SPY Trial, evaluating it in a Phase 2 sub-study for newly diagnosed ER+ invasive breast cancer; the RECAST-DCIS Study, assessing its suitability for neo-adjuvant endocrine therapy in women with Ductal Carcinoma In Situ; and the KARISMA Trial, demonstrating a statistically significant reduction in mammographic density, a major and under-addressed risk factor for breast cancer. *See id.*; EX2009. Additionally, Patent Owner is planning a Phase 3 trial, SMART 2.0, to investigate its potential in reducing interval breast cancer in high-risk women and is prioritizing its development for metastatic breast cancer. EX2002, 1.

Petitioner Intas is a large foreign manufacturer of generic drugs with billions in annual revenue and significantly greater resources. EX2004, 1. Intas appears to have a relationship with Jina Pharmaceuticals Inc.,<sup>2</sup> which Intas says “may be

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<sup>2</sup> Though Jina is not listed as an RPI in the Petition, Intas and Jina appear to have a relationship related to endoxifen and the treatment of bipolar disorder (*see, e.g.*,

interested” in the outcome of this PGR (Pet.1), and which is currently involved in Phase 3 trials using (Z)-endoxifen (in a salt form) to treat for Bipolar I Disorder (*see* EX2006).

**IV. The Board May Take Into Account All Relevant Considerations in Exercising its Discretion to Deny Institution**

The Board has discretion to deny institution under 35 U.S.C. §§ 314(a) and 325(d).<sup>3</sup> Pursuant to the Office’s March 26, 2025 Guidance, the Board may look to “all relevant considerations” in exercising discretionary denial, including: “whether the PTAB or another forum has already adjudicated the validity or patentability of the challenged patent claims;” “the strength of the unpatentability challenge;” “the extent of the petition’s reliance on expert testimony;” “settled expectations of the parties, such as the length of time the claims have been in force;” “compelling economic, public health, or national security interests;” and “any other considerations bearing on the Director's discretion.” *See* March 26 Guidance at 2-3. Each of the considerations addressed below, both taken independently and assessed together, supports discretionary denial.

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EX2019, 1; EX2020) [REDACTED]

[REDACTED]

<sup>3</sup> Unless stated, statutory and regulatory citations are to 35 U.S.C. or 37 C.F.R., as context indicates, internal citations omitted, and emphases/annotations are added.

**A. Compelling Public Health Interests Support Discretionary Denial**

Public health considerations here favor discretionary denial. Atossa has the potential to substantially improve patient outcomes, as suggested by Patent Owner’s ongoing clinical trials using its (Z)-endoxifen. Early results have shown that Atossa’s clinical trials “more than doubled the median [progression-free survival] compared to tamoxifen” in certain patients. *See* EX2003, 1. Its tolerability is a critical advantage, as it can lead to better patient adherence and an enhanced quality of life, especially for those with incurable metastatic breast cancer. *See id.*

Atossa’s clinical trial programs represent ongoing multi-year, multi-million-dollar investments. *See* EX2013, 8 (listing “Research and development” at \$14.1 million for 2024 and \$17.3 million for 2023). As a small innovative clinical-stage biopharmaceutical company, Patent Owner depends on external investment to fund these programs. *See* EX2001, 6, 7, 16, 19. Atossa’s IP, including the ’391 Patent and its patent family, helps Patent Owner build and maintain investor confidence, enabling the continued funding of these critical trials. *See* EX2001, 4, 21, 24, 33-34; EX2013, 8-9. Petitioner’s PGR undermines this confidence at a critical time of the development of (Z)-endoxifen for breast cancer, which could lead to delays, suspension, or even outright termination of ongoing and planned clinical trials, directly impacting patient enrollment and access to investigational therapies, and distracting management. *See* EX2001, 21 (“If we are unable to raise additional

capital when needed on reasonable terms, if at all, we could be forced to curtail or cease our operations. Our future capital uses and requirements will depend on the time and expenses needed to begin and continue clinical trials for our new drug developments.”), 34 (“Any litigation proceedings relating to our propriety technology... may result in substantial costs and distract our management and other employees”); EX2013, 8-9 (“Intellectual property is important to our business and future income streams will depend, in part, on our ability to obtain and maintain patents”); EX2021 (“this new patent will create long-term stockholder value as it further validates and expands Atossa’s patent protection beyond our previously issued composition of matter patents”); *see also* EX2005 (“[t]he ’151 Patent,’ with its estimated expiration in 2038, strengthens our intellectual property estate and should create long-term stockholder value”); *infra* §IV.(B) (providing covenant not to sue); EX2008.<sup>4</sup>

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<sup>4</sup> This PGR is not an isolated challenge, but instead is the latest in a series of coordinated attacks by Petitioner against Patent Owner’s intellectual property related to (Z)-endoxifen. *See* Pet.2 (acknowledging prior “PGR2023-00043” and noting “at the same time [Petitioner is] filing a petition for *inter partes* review challenging related U.S. Patent No. 11,261,151”).

Such disruption would not only harm Patent Owner but, more importantly, would directly undermine public health by delaying or preventing access to a promising new therapy for breast cancer—a disease with significant unmet medical needs. Individuals suffering from hormone-dependent breast cancer, especially those with metastatic or endocrine-resistant forms, eventually exhaust standard and/or older therapies and depend on newer and novel options to extend survival. Atossa is working to develop those options. The progression of their disease during such delays may render them ineligible for future treatment or diminish the effectiveness of any eventual therapy. The potential for increased progression-free survival using Patent Owner’s (Z)-endoxifen also represents a significant quality of life and economic benefit in reducing healthcare costs associated with more aggressive treatments. *See* EX2012, 2; EX2001, 18 (“(Z)-endoxifen for Neoadjuvant Treatment of Breast Cancer. We are also developing (Z)-endoxifen to treat estrogen receptor positive (ER+) / human epidermal growth factor receptor 2 negative (HER2-) breast cancer in the neoadjuvant setting, which is the administration of a therapy before the main treatment, which is usually surgery.”).

And while Intas uses a salt form of (Z)-endoxifen in India to treat bipolar disorder (EX2019, EX2020), and Intas (with Jina) appears to be involved in clinical trials using (Z)-endoxifen only to treat bipolar disorder, Intas has nevertheless chosen to include in its various PTAB challenges claims specifically limited to breast

disorders—claims not implicated by their very different work. *See* Pet.34-37 (challenging claim 42 (“treating a hormone-dependent breast disorder”), claim 43 (“wherein the hormone-dependent breast disorder... is... breast cancer”), claim 44 (“wherein the hormone-dependent breast disorder... is tamoxifen-refractory or tamoxifen resistant”)); EX2017, 35-37 (challenging claim 16 (“[a] method of treating a hormone-dependent breast disorder”), claim 18 (“wherein the subject has tamoxifen-refractory or tamoxifen resistant hormone-dependent breast disorder”)); EX2018, 33-35 (claim 20 (“treating a hormone-dependent breast disorder”), claim 21 (“wherein the hormone-dependent breast disorder... is... breast cancer”), claim 22 (“wherein the hormone-dependent breast disorder... is tamoxifen-refractory or tamoxifen resistant.”)). Intas’s goal is seemingly to interfere with Atossa’s clinical development of a treatment for breast cancer to the detriment of public health. *See also* §IV(B).

The threat posed by Petitioner’s PGR is not just to Patent Owner’s patent rights and clinical development, but to the patients who stand to benefit from a safer, more reliable breast cancer treatment. That potential harm to Patent Owner outweighs any arguable benefit to Petitioner in instituting this petition, particularly in view of Patent Owner’s stipulation discussed below, which leaves Intas and Jina free to pursue the use of (Z)-endoxifen salts for the treatment of bipolar disorders, consistent with their current trial.

The USPTO's recent guidance on its process for addressing discretionary denial explicitly identifies "compelling economic, public health, or national security interests" as a factor to be considered. *See* March 26 Guidance at 2. Given the critical unmet needs in breast cancer, the unique advantages of (Z)-endoxifen for treating breast cancer, Patent Owner's limited resources, and the advanced stage of Patent Owner's clinical development, the public health interest in ensuring the uninterrupted progress of this therapy is strong. Allowing institution here would not serve the goals of innovation or fairness; instead, it would enable a large foreign generic to exploit the machinery of the AIA to derail a small American innovator's efforts to bring a potentially critical breast cancer treatment to market.

**B. This Proceeding Would Waste the Board's Resources Given Patent Owner's Stipulation Not to Sue for Infringement**

As explained above, Intas's only commercial interest in (Z)-endoxifen appears to be in treating bipolar disorder using a salt form of (Z)-endoxifen. And Patent Owner attaches herein a covenant not to sue Petitioner Intas, Jina Pharmaceuticals Inc.,<sup>5</sup> or their respective affiliates, distributors, customers, and

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<sup>5</sup> For the avoidance of any related dispute, the covenant also covers Jina Pharmaceuticals Inc., which appears to have partnered with Intas on the clinical trials for treating bipolar disorder using a salt form of (Z)-endoxifen. *See* EX2019, 1; EX2008; EX2020.



[REDACTED]

*See generally OpenSky Indus. LLC, v. VLSI Tech. LLC, IPR2021-01064, Pap.102,* [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] *Patent Quality Assurance, LLC, et al. v. VLSI Tech. LLC, IPR2021-01229, Pap.102,* [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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[REDACTED]

[REDACTED] Even if they are subject to FRE 408, they are admissible here [REDACTED]

[REDACTED]

*See Blackbird Tech LLC v. Health in Motion LLC, 944 F.3d 910, 916 (Fed. Cir. 2019)* [REDACTED]

[REDACTED] The evidence here is not being used “to prove or disprove the validity or amount of a disputed claim or to impeach....” FRE408(a); *see also* FRE408(b) (“The court may admit this evidence for another purpose....”).

The March 26 Guidance confirms the Office’s case-by-case flexibility in considering arguments that may support discretionary denial. *See* March 26 Guidance at 3 (referring to “any other considerations bearing on the Director’s discretion”). In light of this covenant eliminating any arguably legitimate commercial interest of Petitioner in challenging the ’391 Patent, separately or together with the public health considerations, institution should be denied.

**C. The Board Should Additionally Deny Institution Under 35 U.S.C. §325(d) Because the Office Has Already Rejected the Same Art During Prosecution**

Section 325(d) provides that the Board may deny institution if “the same or substantially the same prior art or arguments previously were presented to the Office.” Part 1 of the *Advanced Bionics* test considers three factors, including “(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,” and “(d) the extent of the overlap between the arguments made during examination and the manner in which petitioner relies on the prior art.” *Advanced Bionics, LLC v. Med-El Elektromedizinische Gerate GmbH*, IPR2019-01469, Pap.6, 10 (Feb. 13, 2020) (precedential) (“*AB*”), *citing Becton, Dickinson & Co. v. B. Braun Melsungen AG*, IPR2017-01586, Pap.8 (Dec. 15, 2017). And Part 2 of *Advanced Bionics* considers “(c) the extent to which the asserted art was evaluated during examination, including whether the prior art was

the basis for rejection,” “(e) whether petitioner has pointed out sufficiently how the examiner erred in its evaluation of the asserted prior art,” and “(f) the extent to which additional evidence and facts presented in the petition warrant reconsideration of the prior art or arguments.” *Id.*

Here, the two-part *Advanced Bionics* test confirms that institution should be denied. First, the Ahmad reference (U.S. 9,333,190; EX1003), which is the linchpin of Petitioner’s entire challenge, was already presented during original prosecution. Second, there was no material error in the Office’s treatment of Ahmad or in its ultimate decision to allow the claims over Ahmad.

**AB Part 1.** As Petitioner acknowledges (Pet.16), Ahmad (the key prior art in Grounds 1-7), Liu (Ground 2), Ahmad 2010 (Ground 3), Ahmad 2012 (Ground 3), and Cole (used in Petitioner’s Ground 7 for certain dependent claims) were all before the Office during prosecution. *See* EX1002, 201, 206, 208, 259, 264, 266; EX1001, 84:64-65; *see AB*, 8, 9n.10, 10. The Ahmad references were cited in an IDS (EX1002, 201, 208, 259, 266) and explicitly discussed in the ’391 Patent’s specification (EX1001, 18:22-35 (addressing U.S. Pat. No. 9,333,190), 94:21-24 (addressing Ahmad 2010, Ahmad 2012)). Thus, all of the art recited in Grounds 1-3 and 7 was before the examiner and the first condition of the AB framework is satisfied for at least Grounds 1, 2, 3, and 7.

Moreover, with respect to Grounds 4-6, Petitioner relies primarily on Ahmad in its unpatentability contentions, and cites Benameur (EX1006, Ground 4), de Villiers (EX1007, Ground 5), Ghandi (EX1022, Ground 5), Stegemann (EX1008, Ground 6), and HPE (EX1009, Ground 6) only for a subset of dependent claims. *See* Pet.3. Petitioner contends that because these references were not cited by the Examiner, the arguments presented in the Petition were not presented by the Examiner. Pet.16. But, with respect to Ground 4, and based on Petitioner's own assertions, the Benameur disclosures add nothing to the art already before the examiner. Petitioner asserts the limitations of claim 7 (the only claim challenged in Ground 4) would have been an "obvious modification...to instead use an uncoated enteric capsule, as had been developed in the art (*e.g.*, Capsugel)." Pet.54. But Capsugel was explicitly disclosed in the '391 specification itself. EX1001, 40:2-6, 16-21. Likewise, Petitioner relies on Villiers (Ground 5) for its disclosures of "a syrup (or an elixir), but asserts those are "common" liquid vehicles. Pet.55-56. Even with respect to the other secondary references cited for dependent claims, those references, when combined with primary reference that was previously presented to the Office, do not alter the Board's "analysis under Advanced Bionics" that "substantially the same prior art...was presented to the Office." *See Palo Alto Networks, Inc. v. Centripetal Networks, Inc.*, IPR2021-01270, Pap.10, 14 (Jan. 24, 2022) (finding "substantially the same prior art asserted in the Petition previously

was presented to the Office” where new secondary reference was cited “only for limitations in a few dependent claims”).<sup>7</sup>

**AB Part 2.** As further discussed in §IV.D.1-2 below, Ahmad fails to disclose the claimed '391 composition requiring *both* endoxifen *and* an enteric material. Instead, Ahmad discloses an endoxifen composition encapsulated in an enteric coating. See EX1003, 18:19-26; Pet.9 (“Thus, Ahmad teaches enteric coated formulations of highly pure (Z)-endoxifen”); EX1033, ¶¶ 29 (“Ahmad explains that the ‘term ‘enteric’ refers to the small intestine, and enteric coatings prevent release of medication before it reaches the small intestine.’ As such, Ahmad teaches that the ‘composition containing endoxifen or endoxifen-lipid complex can be encapsulated in enteric-coated capsules to protect it from acids in the stomach.”), 54. Accordingly, the Examiner did not err in its evaluation of the prior art, including Ahmad, and institution under §325(d) should be denied. See *Biocon Pharma Ltd. v. Novartis Pharms. Corp.*, IPR2020-01263, Pap.12, 9 (Feb. 16, 2021) (denying institution where reference was presented in an IDS and Petitioner had failed to show that the reference taught the feature that the Examiner allegedly overlooked).

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<sup>7</sup> While 44 claims are challenged in this PGR, only six claims in Grounds 5-6 (claims 10 and 21-25, and possibly claim 30) are not asserted in other prior art grounds. Ground 4 challenges only a single claim.

Indeed, Petitioner cannot avoid §325(d) with generalized statements as to Ahmad's alleged "strong evidence of unpatentability" (Pet.18). *See Ecto World, LLC v. RAI Strategic Holdings, Inc.*, IPR2024-01280, Pap.13, 5-6 (May 19, 2025) (precedential) (holding that "a petitioner must provide an analysis even when the asserted prior art is on an IDS, but the Examiner did not apply the reference" and that "**generalized statements as to the strength of its Petition fail to identify sufficiently a material error**").

Nor do any "new" secondary references in Grounds 4-6 alter the §325(d) analysis. Each is a generic formulation publication that the Examiner would have had no need to consult once the existing prior art, including Ahmad's encapsulation disclosure, was found insufficient. *See Palo Alto Networks*, IPR2021-01270, Pap.10, 13-18 (Jan. 24, 2022) (denying institution under §325(d) where primary reference was cited in an IDS and new secondary reference was cited "only for limitations in a few dependent claims"); *Google LLC v. Kewazinga Corp.*, IPR2021-00527, Pap.16, 20 (Aug. 24, 2021) (denying institution under §325(d) when two references were the same across eleven grounds such that "in addressing each of the eleven asserted grounds, [the Board] would need to consider art ... that is the same or substantially the same as art that previously was presented to the Office.").

**D. The Merits Are Weak: Petitioner’s Enteric-*Coated* Reference Does Not Teach Or Suggest the Claimed Endoxifen-Enteric Composition**

The “strength of the unpatentability challenge” is a factor explicitly identified in the Office’s March 26 Guidance as a consideration for discretionary denial. *See* March 26 Guidance at 2. Where, as here (and as PO’s forthcoming Preliminary Response will confirm), every prior art ground turns on misreading the prior art’s capsule coating as though it were part of the claimed drug composition and the Petition provides no reasoned motivation to modify that teaching, the Board should deny institution under §314(a) based on the weakness of the merits alone.

**1. The ’391 Claims Require Endoxifen-Enteric Composition, Not Endoxifen Composition Encapsulated In Enteric Coating**

Both independent claims of the ’391 Patent require a *composition with enteric material*, which cannot be fulfilled by a mere coating. Claim 1 recites “[a] *composition* comprising an *endoxifen and an enteric material*.” *See*, cl.1, cl.32. The claims thus plainly require that the two named components—endoxifen and enteric material—be part of the same composition itself (a composition which itself is, *e.g.*, encapsulated (claim 6) or formulated as, *e.g.*, part of a suspension (as in claim 30). The claims cannot be satisfied, for example, by a composition of endoxifen without an enteric material (*i.e.*, internal enteric content) even if the composition itself is encapsulated by an outer enteric coating.

The dependent claims of the '391 Patent are consistent with this understanding of the claim. For example, claim 9 recites the composition of claim 1 formulated as a “suspension,” and even more pointedly, claim 30 recites “[a] method of making the composition of claim 9, the method comprising *suspending the endoxifen and the enteric material in a fluid.*” See cl.9, cl.30. Indeed, a manufacturing step that combines both ingredients in a fluid would make no sense if the “enteric material” were merely a pre-formed capsule or exterior coating. The language of claim 30 makes clear that the endoxifen and the enteric material are combined together in a fluid vehicle to form a single, integrated suspension.

Petitioner appears to acknowledge this requirement in discussing claim 9 in Ground 8 (regarding §112), arguing that the “391 patent specification fails to describe a formulation in which *the enteric material is suspended in a fluid with the endoxifen.*” Pet.74. But, Petitioner’s arguments in Ground 8 are inconsistent with its obviousness argument for Ground 1 claim 9 in which Petitioner *does not acknowledge the requirement of that the composition be a suspension that includes enteric material* in addition to endoxifen. See Pet.28. However, as also discussed below, the specification expressly describes formulating endoxifen with an enteric material. See, e.g., EX1001, 36:9-16 (“Compositions intended for oral use may be prepared in solid or *fluid* unit dosage forms.”), 36:65-37:2 (“Examples of excipients that can be used in the compositions formulated for oral administration are provided

herein and can include...control release agents”), 39:1-21 (“Examples of control release agent suitable for use include, without limitation, pH-dependent polymers...”), 39:22-51; 39:56-68.<sup>8</sup>

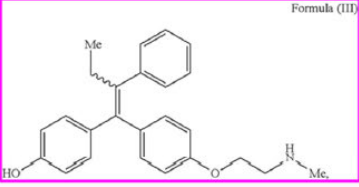
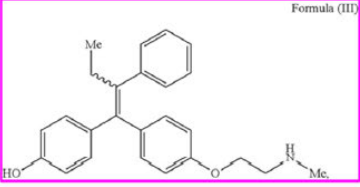
The '391 Patent's specification further confirms this requirement in the claims that both the endoxifen and enteric material be part of the composition by stating that “*compositions* may comprise one or more of pH-dependent [*i.e.*, enteric] polymers such as acid insoluble polymers.” *See, e.g.*, EX1001, 39:22-51, 36:9-16, 36:65-37:2, 39:1-21. This is expressly distinguished from embodiments where the endoxifen “composition” is put within, *e.g.*, a tablet or capsule then “coated” with enteric material: “Compositions formulated for oral delivery as disclosed herein, for

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<sup>8</sup> These inconsistencies in the interpretation of the claims and the arguments in different Grounds also merit discretionary denial. In addition, Petitioner, for example, asserts Ahmad anticipates claim 31 (which depends from claim 30). Pet.3, 29. This would require that claim 30 is also anticipated, though Petitioner failed to present explicit argument regarding Claim 30 in Ground 1. *See* Pet. §X.F; *see also* Pet.3 (listing claims 30-31 as included in Ground 1); Pet.28 (Ground 1 argument header listing Claims 9, 11-15, 30, and 31). But despite Petitioner's Ground 1 anticipation arguments, Petitioner later admits “Ahmad does not explicitly disclose the use of an enteric material in a suspension.” Pet.60.

example, tablets, caplets, and capsules, *may be coated* with one or more enteric coating agent, control release agent or film forming agent to control or delay disintegration and absorption *of the compositions comprising endoxifen or salts thereof* in the gastrointestinal tract and thereby provide a sustained action over a longer period of time.” *Id.* 38:56-68.

This understanding of the claims is further supported by contrasting claim 1 of the '391 Patent with claim 1 of the related '334 Patent, which the Board previously reviewed, that recited “[a]n oral formulation comprising an *endoxifen composition encapsulated in an enteric capsule...*” *See Intas Pharms. Ltd. v. Atossa Therapeutics, Inc.*, PGR2023-00043, Pap.37, 5 (Jan. 29, 2025).

391 Patent	334 Patent (Unpatentable)
<p>1. A composition comprising an endoxifen and an enteric material, wherein: the endoxifen comprises a compound of Formula (III):</p> <div style="text-align: center;">  <p>Formula (III)</p> </div> <p>or a pharmaceutically acceptable salt thereof, and at least 90% by weight of the compound of Formula (III) is (Z)-endoxifen.</p>	<p>1. An oral formulation comprising an endoxifen composition encapsulated in an enteric capsule, wherein the endoxifen composition comprises a compound of Formula (III):</p> <div style="text-align: center;">  <p>Formula (III)</p> </div> <p>wherein at least 90% by weight of the compound of Formula (III) is (Z)-endoxifen.</p>

Pet.20. The difference is dispositive.

**2. Collateral Estoppel Does Not Apply and Does Not Fix the  
Petition's Weakness**

No collateral estoppel applies including because of the significant difference between the claims in the '391 and in the '334 PGR. The issues here are not “identical” nor “actually litigated” in the '334 PGR.<sup>9</sup> Indeed, as discussed above, a “composition comprising an endoxifen and an enteric material,” as in claim 1 of the '391 is distinct from a composition that *is not required to include an enteric material*, as in claim 1 of the '334. As explain above, the requirement regarding something “enteric” in the '334 relates to the composition itself being “encapsulated in an enteric capsule.” EX2014 cl.1; *see also* cl.3 (“the enteric capsule is uncoated”), cl.4 (“the enteric capsule further comprises an enteric coating”), cl.8 (“the enteric capsule comprises hydroxypropylmethyl cellulose”), cl.14 (“the endoxifen composition comprises from 0.01 mg to 200 mg (Z)-endoxifen per enteric capsule”), cl.15 (“encapsulated in an enteric capsule”). Indeed, the '334 claims have no requirement that the composition itself contain an enteric material or even that there be an enteric material somewhere *within* the enteric capsule. *See VirnetX Inc. v. Apple, Inc.*, 909

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<sup>9</sup> The Ground 5 prior art combination (Ahmad in view of de Villiers (EX1007) and Ghandi (EX1022)) also differs from any prior art combination asserted in the '334 PGR. Ground 5. Further, Ground 8, which is directed towards written description and enablement, is a Ground unrelated to any ground raised in the '334 PGR.

F.3d 1375, 1377 (Fed. Cir. 2018) (requiring “a prior action present[ing] an identical issue” and that “the prior action actually [was] litigated” for collateral estoppel to apply); *Dr. Reddy’s Lab’ys., Ltd. v. Monosol RX, LLC*, IPR2016-01111, Pap.14, 17 (Dec. 5, 2016) (denying institution and finding collateral estoppel inapplicable where prior decision did not resolve the issue of whether the same prior art disclosed a different limitation in the challenged patents). The ’334 Patent claimed a dosage form where an enteric function had to be provided by the capsule coating. *See* EX2014, cl.1. The ’391 Patent claims the underlying composition itself, where the enteric material is an ingredient combined with the endoxifen. Petitioner’s attempt to conflate the two is the central flaw in its Petition.

**3. The Petition is Weak Because Petitioner Relies Only On Ahmad’s Teachings of Encapsulation, Not The Claimed Composition**

Petitioner’s entire prior art case rests on the Ahmad reference (*see* Pet.3), and its main ground, Ground 1, asserts anticipation based on Ahmad for the vast majority of claims challenged here. But Petitioner argues only that Ahmad teaches a composition of endoxifen that is *encapsulated in an enteric coating*. *See, e.g.*, Pet.9, 20, 27. Petitioner never even asserts (nor could it) that Ahmad teaches the claimed composition, which itself must include endoxifen and an enteric material.

Petitioner’s reliance on Ahmad’s disclosure is confined to an enteric *coating that encapsulates an endoxifen composition*. *See* EX1002, 18:19-29 (“[C]omposition containing endoxifen...can be *encapsulated in enteric-coated*

*capsules* to protect it from acids in the stomach.”). Petitioner’s own expert, Dr. McConville, repeatedly characterizes Ahmad’s disclosure in these same terms. *See, e.g.*, EX1033, ¶¶ 29, 54. These disclosures merely describe a two-part drug form: a pharmaceutical composition is prepared first, then the finished composition is encapsulated in a separate external enteric coating. *See* EX1002, 18:27-29 (“Enteric coating of capsules filled with composition containing endoxifen...can be done as *methods known in the art.*”). Petitioner identifies no teaching (or even suggestion) in Ahmad that the enteric material is a component *of the endoxifen composition*, as claimed. This alone is fatal to Petitioner’s anticipation Ground 1.

Petitioner’s attempt at a “genus–species” shortcut in relying on the Board’s earlier findings on the ’334 patent are inapposite. *See* Pet.19-23. The ’334 claims *expressly* recited “endoxifen composition encapsulated in an enteric capsule,” and the Board’s analysis hinged on that language. *See, e.g.*, EX2018, 5. In contrast, the ’391 Patent’s claims deliberately dispense with the capsule limitation and instead require a distinct composition, *i.e.*, combination of endoxifen and enteric material, which *Petitioner does not assert is disclosed by Ahmad.*

#### **4. Petitioner’s Failure in Ground 1 (Anticipation) Extends to All Prior Art Grounds (Obviousness Grounds 2-7)**

Because the Petition’s anticipation ground (Ground 1) and every obviousness ground (Grounds 2–7) relies on Ahmad for the claimed composition of the independent claims that requires both (Z)-endoxifen and an enteric material, the

fundamental failure of Ahmad Ground 1 extends to Grounds 2-7 and strongly weighs in favor of discretionary denial. *Azurity Pharms., Inc. v. Exelixis Inc.*, IPR2025-00210, Pap.11, 29 (June 4, 2025) (denying institution based on the merits, finding that “on the current record Petitioner has not shown that the combination of [the asserted art] would inherently result in [the claimed limitation] and Petitioner has not shown that it has a reasonable likelihood that it would prevail on the obviousness ground.”). The Board should not expend its resources on a Petition whose central premise is so legally and factually flawed. Patent Owner’s request for discretionary denial should be granted.

**5. Petitioner’s §112 Arguments Lack Analysis and Support (Ground 8)**

Petitioner’s one and half page throw-away Ground 8 arguments assert lack of written description and enablement for a small subset of ’391 claims. Pet.73-74. Petitioner provides no citations to expert support for this Ground, and does not appear to provide any analysis in the Petition directed to enablement. The weakness of this ground further supports discretionary denial. *See also* Pet.51n.**Error! Bookmark not defined..**

**E. Petitioner’s Excessive Reliance on Expert Testimony Highlights Factual Disputes Unsuitable for PGR**

The “extent of the petition’s reliance on expert testimony” is another consideration that supports discretionary denial. *See* March 26 Guidance at 2. As

the Board has recognized, “[w]hile the Board may consider expert testimony, as a matter of efficiency, extensive reliance on expert testimony and/or reasonable disputes between experts on dispositive issues may suggest that the questions are better resolved in an Article III court.” PTAB, FAQs for Interim Processes for PTAB Workload Management, <https://www.uspto.gov/patents/ptab/faqs/interim-processes-workload-management> (“FAQs for Interim Processes”). That concern is presented here with respect to Ground 2, for example.

First, Ground 2 is directed to single-reference obviousness based on Ahmad. But instead of relying on Ahmad for each limitation (*e.g.*, in a situation where a Petitioner might seek to mix and match embodiments via an obviousness argument), Petitioner asserts “each of the elements of these claims were also separately known and obvious in view of the knowledge of a POSA.” Pet.38. And while Petitioner identifies certain *other* references that it argues disclose discrete limitations of the claim, those references are not part of the Ground. Instead, Petitioner relies on extensive conclusory assertions from its experts to suggest that those non-asserted prior art disclosures represent the “view of the knowledge of a POSA.” *Id.*

Second, in addition to Dr. McConville (EX1033), Petitioner relies extensively on speculative and fact-intensive laboratory benchtop reconstruction experiments of Dr. Bihovsky on the *Liu* reference as a purported substitute for the actual teachings of *Ahmad* for dependent claim 16. *See, e.g.*, Pet.42-46; EX1034, ¶¶ 42-72 (modified

experiments of Liu), 73-76 (alleged inherency of Ahmad in view of Liu experiments) 77-85 (obviousness of Ahmad in view of Liu experiments). As discussed in detail in Patent Owner’s Request for Discretionary Denial in co-pending IPR2025-00799—where Petitioner relies on the *same* experiments to show alleged inherency in *Liu*—in performing those benchtop experiments, Petitioner’s expert added steps that were not disclosed in Liu’s method (in addition to altering steps that were). This use of the expert to fill in gaps supports discretionary denial. *See iRhythm Techs., Inc. v. Welch Allyn, Inc.* IPR2025-00363, -00374, -00376, -00377, -00378, Pap.10, 2 (June 6, 2025) (considering whether “Petitioner is using its expert to fill gaps in the prior art” in assessing discretionary denial). Further, while one effective way to prove the *lack* of inherency could be for Patent Owner’s expert to perform experiments of his own, such experiments here would be costly, impractical, and inefficient here—especially in the absence of any litigation or actual commercial dispute (*see* §IV.B, *supra*), and given the time constraints of the timeline for IPR proceedings. The burden of responding to these benchtop experiments with Patent Owners own benchtop experiments for this claim would be a disproportionate burden, especially in view of the covenant not to sue. The Board and Patent Owner should not be forced towards a fact-heavy expert-driven laboratory reconstruction exercise built around previously considered art as part of an AIA trial.

Discretionary denial is further supported by the conclusory and repetitive nature of Petitioner's expert's declarations. For example, Dr. McConville's "opinions" are largely verbatim or near-verbatim assertions merely parroted from the Petition without any independent analysis or supporting evidence. *Compare* Ex. 1032 ¶¶ 53-145 with Pet.19-72. Such conclusory testimony that merely echoes the Petition should be accorded little to no weight. *See cxLoyalty, Inc. v. Maritz Holdings Inc.*, 986 F.3d 1367, 1378 (Fed. Cir. 2021); *see also* 37 C.F.R. §42.65(a). Petitioner's "failure to provide focused expert testimony" further supports discretionary denial. FAQs for Interim Processes; *see generally Xerox Corp. v. ByteMark, Inc.*, IPR2022-00624, Pap.12, 4 (Feb. 10, 2023) (Director affirming Board's denial decision because "Petitioner's only evidence in support of its assertions was the declaration of its expert, which was unsupported by evidence or reasoning" and "merely repeats, verbatim, the conclusory assertion for which it is offered to support"); *TikTok Inc. v NTECH Properties Inc.*, IPR2024-01339, Pap.9, 16 (Feb. 25, 2025) (denying institution and noting Petitioner's expert testimony "repeats, almost verbatim, the language in the Petition without any further explanation or supporting reasoning or evidence").

Accordingly, the Petition's overreliance on expert testimony, particularly to manufacture inherency through extensive laboratory interventions and alterations, further supports discretionary denial.

## V. Conclusion

For the foregoing reasons, the Board should exercise its discretion to deny institution here. The public health implications of disrupting Patent Owner's clinical development of a promising new therapy for breast cancer are significant, particularly where Patent Owner has no products on the market and relies on its patent rights to sustain investor confidence and continue funding critical Phase 2 and 3 trials. The Petition presents no meaningful dispute to resolve, as Patent Owner has stipulated not to sue Petitioner and its related entities for any use of (Z)-endoxifen in the treatment of bipolar disorder—the only use at issue in clinical trials that Petitioner may have been involved in—rendering this proceeding an inefficient and unnecessary expenditure of Board and party resources. The Petition also fails under §325(d), as it merely repackages prior art already considered during prosecution without showing any material error by the Examiner. Critically, every one of Petitioner's prior art grounds hinges on misapplying Ahmad's enteric capsule coating as though it disclosed the claimed composition containing an enteric material. That the Petition relies so heavily on expert-driven reconstructions, conclusory testimony, and selective reporting of outcomes only reinforces that the factual disputes it raises are ill-suited to resolution in an PGR. The USPTO's guidance invites the Board to consider precisely these circumstances, and here, the relevant factors compel discretionary denial.

Respectfully submitted,

Dated: July 7, 2025

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**CERTIFICATE OF WORD COUNT**

The undersigned certifies that the foregoing Patent Owner’s Brief In Support Of Discretionary Denial Under 35 U.S.C. §314(a) complies with the type-volume limitation in 37 C.F.R. §42.24(c)(1) and the “Interim Processes for PTAB Workload Management” (Mar. 26, 2025). According to the word-processing system’s word count, the brief contains 7,329 words, excluding the parts of the brief exempted by 37 C.F.R. §42.24(a)(1).

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**CERTIFICATE OF SERVICE**

The undersigned hereby certifies that a copy of Patent Owner’s Brief In Support Of Discretionary Denial Under 35 U.S.C. §314(a) and the accompanying exhibits have been served in their entirety on July 7, 2025, by causing the aforementioned documents to be electronically mailed to the following attorneys of record for the Petitioner listed below.

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