

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

INTAS PHARMACEUTICALS LTD.,
Petitioner

v.

ATOSSA THERAPEUTICS, INC.,
Patent Owner

Case PGR2025-00043
Patent 12,071,391

**PATENT OWNER'S AUTHORIZED REPLY TO PETITIONER'S
RESPONSE TO PATENT OWNER'S REQUEST FOR DISCRE-
TIONARY DENIAL UNDER 35 U.S.C. § 314(a)¹**

¹ Reply authorized by EX3101. Emphases herein are added, and abbrevia-
tions/references are as in Pap.7.

LIST OF EXHIBITS

Exhibit	Description
EX2001	ATOSSA THERAPEUTICS, INC. QUARTERLY REPORT FORM 10-Q (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., http://www.intas-pharma.com/financials/
EX2005	Atossa Therapeutics Announces Issuance of Key U.S. Patent Covering Endoxifen (March 08, 2022)
EX2006	Efficacy and Safety of Endoxifen in Bipolar I Disorder Patients, NCT06608641 (Last Updated March 17, 2025), https://clinicaltrials.gov/study/NCT06608641
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> 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
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)

Exhibit	Description
EX2016	Default Protective Order
EX2017	<i>Intas Pharmaceuticals, Limited v. Atossa Therapeutics, Inc.</i> , IPR2025-00799, Pap.1 (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?, https://zonalta.in/
EX2021	Atossa Therapeutics Granted Additional Patent Protection for Endoxifen (August 28, 2024)
EX2022	Declaration of Megan Raymond
EX2023	Corrected Covenant Not To Sue

Petitioner’s Generic Competition Argument Fails. The Response (Pap.10

(“Resp.”)) doesn’t dispute that Petitioner’s current commercial use of (Z)-endoxifen is for bipolar disorder (in India), not breast cancer in the U.S. Despite its vague suggestions, Petitioner provides no *evidence* supporting any suggestion that it is today pursuing or investing in any ongoing clinical breast cancer trials using (Z)-endoxifen. Resp.7-8.² Any future impact on hypothetical generic competition is speculative, but the harm from derailing PO’s work by undermining the investments needed to continue and complete clinical trials is immediate. *See* Pap.7, 10-14 (“Br., Brief”)); *Amgen Inc. v. Bristol-Myers Squibb Co.*, IPR2025-00601, Pap.9 at 2 (July 24, 2025) (noting “extraordinary... investment, time, and resources dedicated to research, development, trials, and regulatory approval” could give rise to settled expectations). Petitioner also offers no evidence of “threaten[ing of] other parties” (Resp.3), and Petitioner’s claim that invalidating the ’391 would hasten generic entry is also pure speculation: if PO can’t secure investments to complete its trials (including Phase III trials (EX2002)) and secure FDA approval, PO won’t have an approved reference drug for generics like Petitioner to rely on; they would instead need to begin their own clinical trials, an uncertain and time-consuming process.

² The only other breast cancer work Petitioner identifies involves endoxifen salts. *See* Resp.7-8. But PO’s trials use free base (Z)-endoxifen. *See e.g.*, EX2002.

PO's Covenant Is Not Illusory. While Petitioner claims PO's covenant (which constrains PO, not Petitioner), EX2023 (corrected to address an acknowledged typo), does not align with its commercial interests or alleged claim scope, Petitioner failed to provide evidence of any having concrete commercial interest *not* covered by the covenant (*e.g.*, investments in ongoing breast cancer trials). Coupled with Petitioner's simultaneous failure to identify any Petitioner-owned patent that could give even arguable cover to *Petitioner's royalty demand*, this confirms the Petitioner's purpose is leverage against a small innovator.

The merits are weak. *See* Pap.9. The claim language is unambiguous: "A composition comprising an *endoxifen and an enteric material*" describes a formulation where the enteric material is an ingredient *within* the composition itself, alongside endoxifen. Petitioner ignores this plain language and the distinction between the structure of claim 1 of this patent and the '334 Patent. The specification describes two distinct embodiments. It describes, for example, tablets and caplets that comprise an endoxifen and an enteric *material* but lack any enteric *coating*—explaining, *e.g.*, that "the *enteric tablets, enteric caplets...may be uncoated.*" EX1001, 40:1-2; *see id.* at 54:37-42. In these examples, the enteric material is part of the composition itself, as in claim 1 of the '391 Patent. But *in contrast*, consistent with the composition claimed in the '334 Patent, the specification describes an *endoxifen* "composition" (*without* enteric material) that is formulated as, *e.g.*, a tablet

or caplet or capsule and *then* encapsulated by an outer enteric material. *Id.* at 38:56-67; *see also* Pap.9, 8-9. Petitioner’s selective specification quoting only reinforces this distinction. Resp.12-13. Indeed, the same passages Petitioner relies on describe different ways to achieve enteric behavior: (a) pH-dependent *polymers* as a component of the composition (internal) (which would, *e.g.*, coat the (Z)-endoxifen within the mixture) and (b) *encapsulating coatings* used “for enteric coating of capsules, caplets, and tablets” (external). EX1001, 38:56–68, 39:22–57, 40:1-7.

Petitioner misinterprets dependent claims 6 and 8 to argue claim 1’s “composition” including “enteric material” encompasses purely *external* enteric coatings. Resp.13. But claim 6 merely specifies the composition is in capsule form, which doesn’t imply an enteric coating. EX1001, 40:1-2. And claim 8, consistent with properly interpreted claim 1, simply requires that the enteric material *coat the endoxifen within the composition, not an external* enteric coating (*e.g.*, an “enteric coating *of capsules*”) over/on top of a tablet or capsule.³ Resp.12-14 (citing, *e.g.*, EX1001, 39:52-57). Petitioner also ignores the context in which “enteric coating” is

³ To convey Petitioner’s apparent meaning (Resp.13), claim 8 would recite that “the enteric material [of claim 1] comprises an outer external enteric coating.” *See also* Resp. 2 (arguing “enteric *coating* as the claimed ‘enteric *material*”). But instead, claim 8 recites “the composition comprises an enteric coating.”

used and assumes, without support, that an enteric coating must be an *external* one (Resp.13-14), ignoring, *e.g.*, explicit examples of *uncoated* enteric *tablets* (EX1001, 40:1-7) (in which, *e.g.*, the enteric coating would coat the endoxifen molecules within the composition). And in agreeing with PO that claim 9 is consistent with claim 1, Petitioner does not dispute that its Ground 8 reading (Pet.74) requires the enteric material of the claimed composition be “suspended ... with the endoxifen.”

Petitioner’s interpretation renders the distinction between the ’391 and ’334 claim structures illogical and meaningless, and violates claim differentiation. *See Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1326 (Fed. Cir. 2003). More importantly, however the dependent claims are construed, none can broaden or rewrite claim 1’s plain-language requirement that *the composition itself* includes “an enteric material.” *See Multilayer Stretch Cling Film Holdings, Inc. v. Berry Plastics Corp.*, 831 F.3d 1350, 1360 (Fed. Cir. 2016) (“dependent claim [language] cannot change the scope of an independent claim whose meaning is clear on its face.”).

Petitioner’s terminal disclaimer arguments are also misplaced, and Petitioner’s own cases disprove its suggestion that a terminal disclaimer is an admission of claim scope or patentable indistinctness: “[O]ur cases *foreclose* the inference that filing a terminal disclaimer functions as an admission regarding the patentability of the resulting claims.” *SimpleAir, Inc. v. Google LLC*, 884 F.3d 1160, 1171 (Fed. Cir. 2018); *see also Quad Env'tl. Techs. Corp. v. Union Sanitary Dist.*, 946 F.2d 870, 874

(Fed. Cir. 1991) (terminal disclaimer “simply serves the statutory function of removing the rejection of double patenting, and *raises neither presumption nor estoppel on the merits of the rejection.*”). Petitioner’s cases do not support converting an Examiner’s double-patenting rejection into disclaimer. Resp.15-16. *SandBox* involved claim amendment not terminal disclaimers. *Ventana* relied on reasons reflecting both Examiner’s *and applicant’s* understanding relating to restriction and prior art rejections, and rejected the argument that a terminal disclaimer represents an admission. And *Biogen* (which does not relate to terminal disclaimers) found disavowal where applicant explicitly adopted the examiner’s narrow characterization to overcome a rejection, distinguishing the facts from an “acquiescence case[.]”

Petitioner’s Estoppel Arguments Are Hypothetical. ’391’s claims differ materially from the ’334’s. Because the issues are not identical, collateral estoppel does not apply in *any* forum, including the Board, itself. Petitioner’s imagined loss of an estoppel to which it is not entitled provides no basis for institution. Even if it were to apply, Petitioner is effectively asking the Board to institute a PGR for the sole purpose of preserving a procedural advantage for Petitioner in a future, hypothetical case that, given the stipulated covenant not to sue, is remote at best. This is the very definition of an inefficient use of Board resources and an abuse of the AIA process.

Respectfully submitted,
By: /s/ Megan Raymond

Dated: August 26, 2025

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of Patent Owner’s Authorized Reply to Petitioner’s Response to Patent Owner’s Request For Discretionary Denial Under 35 U.S.C. § 314(a) and the accompanying exhibit have been served in their entirety on August 26, 2025, by causing the aforementioned documents to be electronically mailed to the following attorneys of record for the Petitioner listed below.

Lead Counsel:	Alejandro Menchaca Registration No.: 34,389 Email: amenchaca@mcandrews-ip.com McAndrews, Held & Malloy, Ltd. 500 West Madison Street, 34th Floor Chicago, Illinois 60661 Tel: (312) 775-8000 Fax: (312) 775-8100 By Electronic Mail
Backup Counsel:	Ben J. Mahon Registration No.: 78,178 Email: bmahon@mcandrews-ip.com Amanda C. Jackson Registration No.: 77,549 Email: ajackson@mcandrews-ip.com McAndrews, Held & Malloy, Ltd. 500 West Madison Street, 34th Floor Chicago, Illinois 60661 Tel: (312) 775-8000 By Electronic Mail

Dated: August 26, 2025

Respectfully submitted,

By: /Sayem Osman /
Sayem Osman