

Filed on behalf of Intas Pharmaceuticals Ltd.

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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 No. 12,071,391

**PETITIONER'S AMENDED OPPOSITION TO PATENT OWNER'S
MOTION FOR DISCOVERY**

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37 C.F.R. § 42.55

37 C.F.R. § 42.85

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PETITIONER'S EXHIBIT LIST

EX.	DESCRIPTION
1001	USPN 12,071,391 ("391 patent")
1002	File history of USPN 12,071,391
1003	USPN 9,333,190 ("Ahmad")
1004	WO2017/70651 ("Liu")
1005	EXCERPT OF HANDBOOK OF PHARMACEUTICAL SALTS: PROPERTIES, SELECTION, & USE (P. Heinrich Stahl & Camille G. Wermuth eds., 1st ed., 2002) ("Stahl")
1006	Benameur, H., Capsule Technology, Enteric Capsule Drug Delivery Technology – Achieving Protection Without Coating, 15(5) DRUG DEV. & DELIVERY 34-37 (2015) ("Benameur")
1007	Melgardt de Villiers, <i>Pharmaceutical Solvents & Solubilizing Agents, in A Practical Guide to Contemporary Pharmacy Practice</i> (3d ed., 2009) ("de Villiers")
1008	Stegemann, S., Hard gelatin capsules today – and tomorrow, CAPSUGEL LIBRARY (2002) ("Stegemann")
1009	Excerpts OF HANDBOOK OF PHARMACEUTICAL EXCIPIENTS (Rowe, R., Sheskey, J. & Owen, S., eds., 5th ed., 2006) (The "HPE")
1010	Cole, E., et al., <i>Enteric coated HPMC capsules designed to achieve intestinal targeting</i> , 231 INTL J. PHARMACEUTICS 83-95 (2002) ("Cole")
1011	Ahmad, A. et al., <i>Endoxifen, a New Cornerstone of Breast Cancer Therapy: Demonstration of Safety, Tolerability and Systemic Bioavailability in Healthy Human Subjects</i> , 88(6) CLIN. PHARMACOLOGY & THERAPEUTICS 814-817 (2010) ("Ahmad 2010")
1012	Ahmad, A. et al., <i>Endoxifen for breast cancer: Multiple-dose, dose-escalation study characterizing pharmacokinetics and safety in metastatic breast cancer patients</i> , ASCO Meeting Library, presented June 4, 2012 ("Ahmad 2012")
1013	Fauq, A.H., et al., <i>A convenient synthesis of (Z)-4-hydroxy-N-desmethyltamoxifen (endoxifen)</i> , 20 BIOORGANIC MED. CHEM. LETT. 3036-38 (2010) ("Fauq")

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EX.	DESCRIPTION
1014	Milroy, L. et al., <i>A multi-gram-scale stereoselective synthesis of Z-endoxifen</i> , 28 BIOORGANIC MED. CHEM. LETT. 1352-56 (2018) ("Milroy")
1015	Krahn, F. et al., <i>Effect of type and extent of crystalline order on chemical and physical stability of carbamazepine</i> , 53(1) INT'L J. OF PHARMACEUTICS 25-34 (1989) ("Krahn")
1016	A FOCUS ON CRYSTALLOGRAPHY (FIZ KARLSRUHE 2005)
1017	Fan, J. et al., <i>Pharmacokinetics</i> , 81 BIOCHEM. PHARMACOLOGY 93-120 (2014) ("Fan")
1018	Urso, R. et al., <i>A short introduction to pharmacokinetics</i> , 6 EUR. REV. FOR MED. & PHARMACOLOGICAL SCIS., 33-44 (2002) ("Urso")
1019	<i>Endoxifen</i> , PUB CHEM: COMPOUND SUMMARY (2024)
1020	Ansel, H., et al, PHARMACEUTICAL DOSAGE FORMS AND DRUG DELIVERY SYSTEMS, SEVENTH EDITION (1999) ("Ansel")
1021	Beasley, D. et al, <i>The Evolution of Stomach Acidity and Its Relevance to the Human Microbiome</i> , 10(7) PLOS ONE 1-12 (2015) ("Beasley")
1022	WO 2011/107855 ("Gandhi")
1023	USPN 11,572,334 ("334 patent")
1024	Supporting information to Milroy, L. et al., <i>A multi-gram-scale stereoselective synthesis of Z-endoxifen</i> , 28 BIOORGANIC MED. CHEM. LETT. 1352-56 (2018)
1025	Ali et al., <i>Endoxifen is a new potent inhibitor of PKC: A potential therapeutic agent for bipolar disorder</i> , 20 BIOORGANIC & MEDICINAL CHEM. LETTERS 2665-67 (2010) ("Ali")
1026	Supporting information to Fauq, A.H., et al., <i>A convenient synthesis of (Z)-4-hydroxy-N-desmethyltamoxifen (endoxifen)</i> , 20 BIOORGANIC MED. CHEM. LETT. 3036-38 (2010)
1027	Elkins et al., <i>Characterization of the isomeric configuration and impurities of (Z)-endoxifen by 2D NMR, high resolution LCMS, and quantitative HPLC analysis</i> , 88 J. PHARMACEUTICAL AND BIOMEDICAL ANALYSIS 174-79 (2014) ("Elkins")

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EX.	DESCRIPTION
1028	Reid et al., <i>Pharmacokinetics of endoxifen and tamoxifen in female mice: implications for comparative in vivo activity studies</i> , 74(6) CANCER CHEMOTHERAPY PHARMACOLOGY 1271-78 (2014) (“Reid”)
1029	SHARGEL, LEON & YU, ANDREW, APPLIED BIOPHARMACEUTICS & PHARMACOKINETICS (7th ed. 2016) (“Shargel”)
1030	ALLEN & ANSEL, ANSEL’S PHARMACEUTICAL DOSAGE FORMS & DRUG DELIVERY SYSTEMS (10th ed. 2013) (“Ansel”)
1031	Wieckhusen, D., <i>The Development of API Manufacturing Processes – Targets and Strategies</i> , 60(9) CHIMIA INT’L J. FOR CHEM. 598-604 (2006) (“Wieckhusen”)
1032	COULSON & RICHARDSON, COULSON & RICHARDSON’S CHEMICAL ENGINEERING (5th ed. 2002) (“Coulson & Richardson”)
1033	Expert Declaration of Jason McConville, Ph.D.
1034	Expert Declaration of Ron Bihovsky, Ph.D.
1035	Chen P. et al, <i>Orally administered endoxifen inhibits tumor growth in melanoma-bearing mice</i> , 23:3 CELLULAR & MOLECULAR BIOLOGY LETTERS (2018)
1036	Goetz MP et al, <i>First-in-Human Phase I Study of the Tamoxifen Metabolite Z-Endoxifen in Women With Endocrine-Refractory Metastatic Breast Cancer</i> , 35(30) J CLIN ONCOLOGY 3391 (2017)
1037	Takebe N et al, <i>Phase I study of Z-endoxifen in patients with advanced gynecologic, desmoid, and hormone receptor-positive solid tumors</i> , 12(4) ONCOTARGET 267-277 (2021)

I. INTRODUCTION

While Intas maintains that it is the proper RPI and Jina was properly identified as only a party who may have an interest, Jina will agree to be added explicitly as an RPI to resolve any need for further discovery and briefing.

Atossa's real goal is to terminate this proceeding. But Atossa cites no authority that Intas's identification of Jina was insufficient, nor any case authorizing discovery once a party has agreed to add the allegedly missing RPI (especially one who was identified in the Petition). Nor can Patent Owner explain why it waited months to seek discovery. Indeed, it sought discovery not because of any concern about identification of Jina for conflicts (as Jina was identified) or any estoppel (as Jina has agreed to be estopped) but because it sought the windfall of termination. But it cites no case in which a non-315 time-barred Petition was terminated, let alone where discovery was permitted to seek termination.

Board decisions including *Corning* and the Rules make clear that the Board may waive its Rule about according a filing date (37 C.F.R. § 42.206). Waiver here would be appropriate as (1) Jina was identified in the Petition as a party having an interest Petitioner reasonably believed and maintains was more accurate than naming Jina an RPI; (2) Patent Owner waited months to seek discovery and present its RPI arguments and did so only to seek termination; and (3) neither Petitioner nor Jina is time-barred.

Requiring discovery and further briefing where the case would not be time-barred and at worst could be refiled as an IPR is directly contrary to the Board's goals to have a speedy and just resolution of the issues and the Board's stated preference for early challenges to patents through PGR. To the contrary, it would simply cause delay and expense and limit the Board's review of the patent. Intas submits that the Board's time is better spent assessing patentability.

II. BACKGROUND

Intas Pharmaceuticals and its wholly owned subsidiary Accord are a manufacturer and seller of pharmaceuticals throughout the world, including the United States. Intas currently sells an endoxifen product in India under the trade name Zonalta®. Jina Pharmaceuticals is a pharmaceutical development company who partnered with Intas to develop Zonalta. *See Ex. 2020; see also Ex. 1011; Ex. 1012.* Jina and Intas have also partnered in bringing endoxifen to the United States market and are working together conducting clinical trials. *See Ex. 2019 at 3.*

Intas has never hidden Jina in this proceeding, identifying Jina as a party who may have an interest. *See Paper 2 and 2; Paper 13 at 3; see also PGR2023-00043 Paper 2* (doing same in previous proceeding challenging related patent). Indeed, Intas had no reason to hide Jina as Jina is not time-barred or subject to estoppel.

Intas did not identify Jina as the real party in interest because Intas does not believe Jina is the real party in interest—Intas has funded and controlled this petition

and stands to benefit from it, as it would be Intas that markets endoxifen in the United States (through its subsidiary, Accord, which is identified as a real party in interest) if the collaboration is successful. Nevertheless, to avoid any further dispute and waste of the parties' and Board's resources, Intas is willing to modify its mandatory notices to explicitly identify Jina as a real party in interest and Jina is willing to assume the estoppel effects of being named.

III. DISCOVERY IS UNNECESSARY AS PETITIONER WILL AGREE TO ADD JINA AS AN RPI AND WAIVER OF THE FILING DATE RULES IS APPROPRIATE

While discovery would show only that Intas has reasonably communicated with its development partner about the ongoing proceedings that serve Intas's own interests, which Intas submits does not render Jina an RPI,¹ Petitioner has agreed to

¹ Intas's and Jina's agreement to name Jina as an RPI is meant only to avoid unnecessary discovery and further briefing. If the Board rules that it must resolve the RPI dispute and terminate if Jina is to be added, then Intas will agree to discovery and prove that Jina is not a missing RPI because the parties have their own independent interests and Intas is the party directing, controlling, and funding this proceeding. *See, e.g., Wi-Fi One, LLC v. Broadcom Corp.*, 887 F.3d 1329, 1340 (Fed. Cir. 2018) (affirming that D-link was not an unnamed RPI because “[w]hile

explicitly add Jina as an RPI to moot any need for discovery and further use of the Board's resources resolving this "highly-fact dependent" inquiry.

Patent Owner does not cite any authority that Intas's identification of Jina was insufficient. Nor does Patent Owner cite a *single case* terminating a PGR where a party has agreed to add the allegedly missing RPI who is not time-barred, let alone a case compelling discovery to seek such termination. And to the best of Petitioner's knowledge, no case has terminated an IPR or PGR absent a 315 time bar.

Patent Owner references *Corning Optical Commc'ns RF, LLC v. PPC Broadband Inc.*, IPR2014-00440, Paper 68 (P.T.A.B. Aug. 18, 2015) for the proposition that "a petition must identify all real parties-in-interest as a condition of institution." Paper 20 at 2. However, *Corning* does not address discovery, a situation in which a Petitioner agrees to add the RPI, or whether a non-time-barred Petition must be terminated. Rather, *Corning* addressed a final decision on RPI (after discovery) in an IPR where the completely unidentified party was 315 time-barred.

Wi-Fi has speculated that Broadcom may have been serving the interests of the D-Link defendants when it sought inter partes review, Broadcom clearly has an interest of its own in challenging the '215 patent, based on its manufacture of the assertedly infringing chips").

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Moreover, *Corning* also confirmed that pursuant to Rule 42.5(b) the Board may waive the Rules implicated in connection with according a filing date only upon identifying all Real Parties in Interest—Rules 42.8 and 42.206—“where sufficient reason exists to do so.” *Id.* at 25 (citing 37 C.F.R. § 42.5(b)).

Intas submits that to the extent it is needed, sufficient reason exists to waive the application of Rule 42.206 to avoid further discovery and briefing.

First, Intas identified Jina as a party potentially interested in the proceeding. The core functions of identifying a “real party-in-interest” are “to assist members of the Board in identifying potential conflicts, and to assure proper application of the statutory estoppel provisions.” Patent Trial and Appeal Board Consolidated Trial Practice Guide November 2019 at 12. Intas’s identification of Jina in the very paragraph of its Petition titled “Real parties-in-interest” satisfied those core functions enabling the Board to identify potential conflicts and the Parties to address any future questions of estoppel.

Second, Patent Owner has long known of the development relationship between Intas and Jina, identifying that relationship in its Request for Discretionary Denial (and likely being aware of the development relationship years earlier), yet never asking Jina to be named as an RPI or seeking such discovery until it could seek termination. To the contrary, Patent Owner admits it waited until the Director designated *Corning* and then sought the windfall of termination. That weighs against

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discovery and in favor of allowing the amendment. *See College Prods., Inc. v. Intirion Corp.*, PGR2024-00003, PGR2024-00004, Paper 26, at *5 (P.T.A.B. Sept. 4, 2024) (“we deny Petitioner’s Motion because Petitioner has not shown sufficiently why the additional discovery and subpoena it seeks in this proceeding could not have been requested earlier and that there is good cause to consider this information.”).

Third, not only was Jina not time-barred at the time of filing of the Petition, but there is also no ongoing litigation and Jina is not time-barred now either. Conducting discovery, motion practices, and even terminating and requiring Intas to refile the Petition naming Jina as an RPI would not “secure the just, speedy, and inexpensive resolution of every proceeding.” 37 C.F.R. § 42.1(b). It would only delay the proceedings and add unnecessary costs for the parties to end up in the same position as they are currently in (absent a few 112 defenses). That simply wastes time and money and limits the ability of the Board to fully reevaluate the patent’s validity—undermining the very purpose of PGR. *See LifeVac LLC v. DCSTAR Inc.*, IPR2025-00454, Paper 11, at *2 (P.T.A.B. July 11, 2025) (“petitions for post-grant review are favored because they must be filed no later than nine months from the grant of the patent (35 U.S.C. § 321(c)), are close in time to examination, and occur before expectations in the patent rights are strongly settled.”). In short, there is simply no practical reason to terminate when Intas and Jina have agreed to include Jina as an RPI, and thus no reason to conduct discovery.

To the extent the Board disagrees, then Intas will agree to the discovery and prove that Jina is not an RPI – a process that will simply require the Board to spend resources evaluating “a highly fact-dependent question” with no “bright-line test”. (PTAB Consolidated Trial Practice Guide at 13, 16) that at most could require refiling. Intas submits that the Board’s time is better spent assessing patentability. *See College Products*, PGR2024-0003, Paper 26, at *9 (“The statutory provisions for inter partes reviews, post-grant reviews, and covered-business method patent reviews ... provide the same considerations, including efficient administration of the Office and the ability of the Office to complete the proceeding timely.”).

IV. CONCLUSION

For the above reasons, Patent Owner’s Motion for Additional Discovery should be denied.

Respectfully submitted,

McANDREWS, HELD & MALLOY, LTD.

Dated: February 25, 2026

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CERTIFICATE OF SERVICE

Under 37 C.F.R. §§ 42.6(e)(4) and 42.105, the undersigned certifies on this date, a true and correct copy of **Petitioner's Amended Opposition to Patent Owner's Motion for Additional Discovery** was served by electronic mail to:

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CERTIFICATE OF PAGE COUNT

The undersigned attorney certifies that the above paper complies with the Board's November 26, 2025 Order (Paper 16) limiting this paper to 10 pages.

Dated: February 25, 2026

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