

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 IPR2025-00799
Patent No. 11,261,151

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

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<i>Corning Optical Commc’ns RF, LLC v. PPC Broadband Inc.</i> , IPR2014-00440, Paper 68 (P.T.A.B. Aug. 18, 2015).....	3, 5
<i>Garmin Int’l, Inc. v. Cuozzo Speed Techs. LLC</i> , IPR2012-00001, Paper 26 (P.T.A.B. Mar. 5, 2013) (Precedential)	3
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PETITIONER'S EXHIBIT LIST

EX.	DESCRIPTION
1001	USPN 11,261,151
1002	File history of USPN 11,261,151
1003	WO 2017/070651 (“Liu”)
1004	USPN 9,333,190 (“Ahmad”)
1005	Fauq, A.H., et al., <i>A convenient synthesis of (Z)-4-hydroxy-N-desmethyltamoxifen (endoxifen)</i> , 20 BIOORGANIC MED. CHEM. LETT. 3036-3038 (2010) (“Fauq”)
1006	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”)
1007	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”)
1008	Cole, E., et al., <i>Enteric coated HPMC capsules designed to achieve intestinal targeting</i> , 231 INTL J. PHARMACEUTICS 83-95 (2002) (“Cole”)
1009	Fan, J. et al., <i>Pharmacokinetics</i> , 87 BIOCHEM. PHARMACOLOGY 93-120 (2014) (“Fan”)
1010	Urso, R. et al., <i>A short introduction to pharmacokinetics</i> , 6 EUR. REV. FOR MED. & PHARMACOLOGICAL SCIS., 33-44 (2002) (“Urso”)
1011	Bunaciu, A. et al., <i>X-ray Diffraction: Instrumentation and Applications</i> , 45 CRITICAL REVIEWS IN ANALYTICAL CHEM. 289-99 (May 21, 2015) (“Bunaciu”)
1012	Excerpts of HANDBOOK OF PHARMACEUTICAL EXCIPIENTS FIFTH EDITION (Rowe, R., Sheskey, J. & Owen, S., eds., 2006) (The “HPE”)
1013	Stegemann, S., <i>Hard gelatin capsules today – and tomorrow</i> , CAPSUGEL LIBRARY (2002) (“Stegemann”)

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EX.	DESCRIPTION
1014	Benameur, H., <i>Capsule Technology, Enteric Capsule Drug Delivery Technology – Achieving Protection Without Coating</i> , 15(5) DRUG DEV. & DELIVERY 34-37 (2015) (“Benameur”)
1015	Prescribing Information for Zonalta
1016	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”)
1017	Evans, D. et al, <i>Measurement of gastrointestinal pH profiles in normal ambulant human subjects</i> , 29 GUT 1035-41 (1988) (“Evans”)
1018	Goel, R. et al, <i>Clinical Significance of Half Life of Drugs</i> , 4(1) INT’L J. OF PHARMACOTHERAPY 6-7 (2014) (“Goel”)
1019	<i>Endoxifen</i> , PUB CHEM: COMPOUND SUMMARY (2024)
1020	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”)
1021	A FOCUS ON CRYSTALLOGRAPHY (FIZ KARLSRUHE 2005)
1022	Milroy, L. et al., <i>A multi-gram-scale stereoselective synthesis of Z-endoxifen</i> , 28 BIOORGANIC MED. CHEM. LETT. 1352-1356 (2018) (“Milroy”)
1023	Supporting information to Milroy, L. et al., <i>A multi-gram-scale stereoselective synthesis of Z-endoxifen</i> , 28 BIOORGANIC MED. CHEM. LETT. 1352-1356 (2018)
1024	Ali et al., <i>Endoxifen is a new potent inhibitor of PKC: A potential therapeutic agent for bipolar disorder</i> , 20 BIOORGANIC & MEDICINAL CHEM. LETT. 2665-2667 (2010) (“Ali”)
1025	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. 3036-3038 (2010)
1026	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 174-179 (2014) (“Elkins”)

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EX.	DESCRIPTION
1027	SHARGEL, LEON & YU, ANDREW, APPLIED BIOPHARMACEUTICS & PHARMACOKINETICS (7th ed. 2016) (“Shargel”)
1028	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”)
1029	COULSON & RICHARDSON, COULSON & RICHARDSON’S CHEMICAL ENGINEERING (5th ed. 2002) (“Richardson”)
1030	ALLEN & ANSEL, ANSEL’S PHARMACEUTICAL DOSAGE FORMS & DRUG DELIVERY SYSTEMS (10th ed. 2013) (“Ansel”)
1031	USP 941
1032	Expert Declaration of Jason McConville, Ph.D. (“McConville”)
1033	Expert Declaration of Ron Bihovsky, Ph.D. (“Bihovsky”)
1034	Expert Declaration of Steven Miller, Ph.D. (“Miller”)
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 M. 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 3391-3400 (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 268-277 (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 has agreed to be added as an RPI to resolve any dispute or need for further discovery and Intas has agreed to add Jina. Thus, there is no need for further discovery, as Intas has already agreed to the relief any such discovery could lead to.

Atossa's real goal is to file a motion to terminate this proceeding. But there is no dispute or allegation that neither Intas nor Jina is time-barred and that the Petition remains eligible for IPR. Thus, there is no basis for termination or unnecessary discovery. Indeed, Atossa has not even attempted to identify what practical impact affording this IPR a new filing date would have. There is simply no basis to engage in unnecessary discovery that would have no effect on the outcome of this proceeding.

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®. *See* Ex. 1015. Jina Pharmaceuticals is a pharmaceutical development company who partnered with Intas to develop Zonalta. *See* Ex. 2020;

see also Ex. 1006; Ex. 1007. Jina and Intas have also partnered in bringing endoxifen to the United States market and 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, 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 THERE IS NO TIME-BAR

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 add Jina as an RPI, which moots any need for discovery.

Patent Owner does not cite a contention for which such discovery would be useful given that Intas has agreed to add Jina, as Patent Owner acknowledges. Paper 20 at 3, 5; *see Garmin Int'l, Inc. v. Cuozzo Speed Techs. LLC*, IPR2012-00001, Paper 26, at *3 (P.T.A.B. Mar. 5, 2013) (Precedential) (“the requester of information” must show “that something useful will be uncovered... ‘Useful’ in that context does not mean merely ‘relevant’ and/or ‘admissible....’ ‘useful’ means favorable in substantive value to a contention of the party moving for discovery.”).

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

¹ *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 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”).

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.

Even assuming *arguendo* a new filing date must be given here, Atossa does not identify any practical effect it would have, as there is no time-bar whatsoever for considering the Petition. Atossa simply assumes, without legal support, that the Board would then terminate. But *every* termination case it has cited is based on a 315 time-bar—which indisputably does not apply here. The Petition remains eligible for IPR, and thus at best a new filing date would cause only delay in resolution of the proceedings.

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 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 (and the Petition is still eligible for IPR). Conducting discovery and motion practice would *at most* simply delay the proceeding, the opposite of the stated goals to "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. In short, there is simply no basis for termination 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 would have no effect other than delay. 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.

Petitioner's Amended Opposition to Patent Owner's Motion for Discovery

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 18) limiting this paper to 10 pages.

Dated: February 25, 2026

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