

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 OPPOSITION TO PATENT OWNER'S MOTION FOR
DISCOVERY**

TABLE OF CONTENTS

I. Introduction.....1

II. Background.....1

III. Discovery is unnecessary as Petitioner has agreed to add Jina as an RPI2

IV. Conclusion6

TABLE OF AUTHORITIES

Cases

Adello Biologics LLC v. Amgen Inc.,
PGR2019-00001, Paper 11 (P.T.A.B. Feb. 14, 2019) (precedential).....6

Banilla Games, Inc. v. Savvy Dog Sys., LLC,
CBM2020-00014, 2020 WL 6685563 (P.T.A.B. Nov. 10, 2020).....5

BlueCatBio MA Inc. v. Yantai Ausbio Labs. Co.,
PGR2020-00051, Paper 21 (P.T.A.B. Sep. 30, 2020).....6

Corning Optical Commc’ns RF, LLC v. PPC Broadband Inc.,
IPR2014-00440, Paper 68 (P.T.A.B. Aug. 18, 2015).....3

Dispersive Networks, Inc. v. Nicira, Inc.,
PGR2018-00063, 2018 WL 4191543 (P.T.A.B. Aug. 30, 2018).....6

Garmin Int’l, Inc. v. Cuozzo Speed Techs. LLC,
IPR2012-00001, Paper 26 (P.T.A.B. Mar. 5, 2013) (Precedential)3

Lifecore Fitness, LLC v. Woodway Usa, Inc.,
IPR2024-00083, 2024 WL 2242665 (P.T.A.B. May 17, 2024)5

One World Techs., Inc. v. Chervon (Hk) Ltd.,
No. IPR2020-00884, 2021 WL 5192891 (P.T.A.B. Nov. 3, 2021).....5

Proppant Express Investments, LLC v. Oren Techs., LLC,
IPR2017-01917, Paper 86 (P.T.A.B. Feb. 13, 2019) (precedential)4

Wi-Fi One, LLC v. Broadcom Corp.,
878 F.3d 1364 (Fed. Cir. 2018) (en banc)4

Wi-Fi One, LLC v. Broadcom Corp.,
887 F.3d 1329 (Fed. Cir. 2018)3

Zte (Usa) Inc. v. Fundamental Innovation Sys. Int’l LLC,
IPR2018-00425, 2019 WL 469486 (P.T.A.B. Feb. 6, 2019)4

Regulations

37 C.F.R. § 42.1(b)5

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")

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

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”)

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

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 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 precedential Board decisions make clear that a party cannot continue to insist on RPI discovery and seek termination once a party has agreed to add the alleged RPI if the RPI does not implicate time-bar issues. There is no dispute or allegation that Jina is time barred, and thus no basis for unnecessary discovery.

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 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 HAS AGREED TO ADD JINA AS AN RPI

While discovery would show only that Intas has reasonably communicated with its development partner about the ongoing proceedings that serve Intas' 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.

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

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

Notably, Patent Owner does not allege any relevance to RPI discovery given that Petitioner has agreed to add Jina. *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 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

Patent Owner references *Corning Optical Commc'ns RF, LLC v. PPC Broadband Inc.*, IPR2014-00440, Paper 68 (P.T.A.B. Aug. 18, 2015) but provides no explanation of how it applies here, noting only that it was recently granted Precedential status. *See* Paper 20, at *2-3. *Corning* terminated a proceeding because the missing RPI was time-barred and the party had refused to add it as an RPI. *Corning*, at *25.

Though Patent Owner never acknowledges it, it is clear its only interest in seeking discovery is to file a motion to terminate. However, precedential decisions of the Board make clear that where a party agrees to add a non-time barred RPI, the

its own in challenging the '215 patent, based on its manufacture of the assertedly infringing chips”).

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

Board may retain the original filing date without terminating the proceeding. *See Proppant Express Investments, LLC v. Oren Techs., LLC*, IPR2017-01917, Paper 86, at *7 (P.T.A.B. Feb. 13, 2019) (precedential) (denying motion to terminate post-institution based on updated mandatory notices because the “Board may, under 35 U.S.C. § 312(a), accept updated mandatory notices as long as the petition would not have been time-barred under 35 U.S.C. § 315(b) if it had included the real party in interest.”).²

This was not a new practice. *See id.* at *8 (citing eight decisions accepting updated mandatory notices); *see also Zte (Usa) Inc. v. Fundamental Innovation Sys. Int'l LLC*, IPR2018-00425, 2019 WL 469486, at *2 (P.T.A.B. Feb. 6, 2019) (distinguishing *Corning*). And it has been approved of by the Federal Circuit. *Wi-Fi One, LLC v. Broadcom Corp.*, 878 F.3d 1364, 1374 n. 9 (Fed. Cir. 2018) (en banc) (“the Director can, and does, allow the petitioner to add a real party in interest”) (citing cases).

Several panels since have applied *Proppant* to deny motions to terminate where there is no time bar issue. *See, e.g., One World Techs., Inc. v. Chervon (Hk) Ltd.*, No. IPR2020-00884, 2021 WL 5192891, at *19 (P.T.A.B. Nov. 3, 2021) (“Because we grant this motion, we need not determine if Techtronic Industries Co.

² Petitioner identified the *Proppant* decision to Patent Owner in the parties' discussions, yet Patent Owner chose to ignore it in filing its motion. Ex. 2024 at 1.

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

Ltd., Techtronic Industries North America, Inc., and Homelite Consumer Products, Inc. are actually real parties-in-interest.”); *Banilla Games, Inc. v. Savvy Dog Sys., LLC*, CBM2020-00014, 2020 WL 6685563, at *2-3 (P.T.A.B. Nov. 10, 2020); *Lifecore Fitness, LLC v. Woodway Usa, Inc.*, IPR2024-00083, 2024 WL 2242665, at *5 (P.T.A.B. May 17, 2024).

To the extent good cause is required,³ Intas submits that the Board has good cause to maintain the filing date. Not only was Jina not time barred at the time of filing of the Petition, there is 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.

Because there is no basis to terminate even if Jina were an RPI, and Petitioner has agreed to add Jina as an RPI, such discovery is unwarranted. *See Adello Biologics LLC v. Amgen Inc.*, PGR2019-00001, Paper 11, at *5 (P.T.A.B. Feb. 14, 2019) (precedential) (denying leave to file a motion for discovery because “Given

³ Even *Corning* acknowledges that the Board was not *required* to terminate as it could have waived the requirements for good cause. *Id.*, at *25.

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

that Amneal LLC is now disclosed as an RPI and is subject to the relevant statutory restrictions, such discovery appears to have little, if any, substantive relevance...”); *BlueCatBio MA Inc. v. Yantai Ausbio Labs. Co.*, PGR2020-00051, Paper 21, at *11 (P.T.A.B. Sep. 30, 2020) (“We agree with Petitioner that adding the identified parties (Mann, Heimberg, BCB GmbH, HTI, and Micronix) as RPIs moots Patent Owner’s motion for additional discovery.”); *Dispersive Networks, Inc. v. Nicira, Inc.*, PGR2018-00063, 2018 WL 4191543, at *2 (P.T.A.B. Aug. 30, 2018) (“In light of our decision to allow Petitioner to amend its RPI disclosure to add Dispersive Technologies without changing the filing date, we deny as moot the Motion for Additional Discovery.”).

IV. CONCLUSION

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

Respectfully submitted,

McANDREWS, HELD & MALLOY, LTD.

Dated: December 16, 2025

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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 Opposition to Patent Owner's Motion for Additional Discovery** was served by electronic mail to:

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