

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 SUR-REPLY IN OPPOSITION TO PATENT OWNER'S
MOTION FOR DISCOVERY**

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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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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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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 1 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

Patent Owner repeatedly suggests Patent Owner (i) “made a deliberate decision to not name Jina as an RPI in the Petition,” (ii) that this was objectively unreasonable (without explanation), and (iii) that it is somehow indicative of gamesmanship. But Intas did not name Jina as an RPI because Intas continues to believe Jina is not a real party in interest (as Intas is funding and controlling this proceeding) but will add Jina to avoid unnecessary dispute—just as the Board found proper in *Proppant*.

Patent Owner does not cite a *single case* in which discovery was granted into RPI status once a Petitioner agreed to simply add the allegedly missing RPI, nor does Patent Owner rebut the numerous cases Petitioner cited where such discovery was denied as moot. Nor does Patent Owner cite a *single case* in which a proceeding was terminated absent a 315 time-bar issue. Yet, Patent Owner argues that the Board should permit discovery so that Patent Owner can later file a motion to terminate, which *at best* would merely require Petitioner to refile the Petition as an IPR as neither Petitioner nor Jina would be time-barred or otherwise estopped. Such a sideshow has no benefit and is directly contrary to the goals of post-grant proceedings to “secure the just, speedy, and inexpensive resolution of every proceeding.” 37 C.F.R. § 42.1(b). The Board denied such discovery in the precedential *Adello* decision and it should deny it here as well.

II. PATENT OWNER'S REQUESTED DISCOVERY SHOULD BE DENIED

A. The Board's Precedential decisions allow addition of an alleged RPI

As explained in Petitioner's opposition brief, the Board's *precedential* decision in *Proppant Express Investments, LLC v. Oren Techs., LLC*, expressly states that 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." IPR2017-01917, Paper 86, at *7 (P.T.A.B. Feb. 13, 2019) (precedential). And as Petitioner further explained, the Board's *precedential* decision in *Adello Biologics LLC v. Amgen Inc.*, denied leave to file a motion for discovery because such discovery was moot once the party disclosed the allegedly missing RPI. PGR2019-00001, Paper 11, at *5 (P.T.A.B. Feb. 14, 2019) (precedential).

Patent Owner attempts to sidestep *Proppant* and *Adello* by saying they are "no longer good law." Reply at 6. But it gives no reason for why they are not "good law" as both remain precedential decisions and were not somehow implicitly de-designated by the designation of *Corning*.¹ As Petitioner explained, *Corning*

¹ Further, if the Director intended for *Proppant* and *Adello* to no longer be "good law," then he would have de-designated them, as he did for *Shark Ninja*.

“recognize[d] that the above-mentioned rules are regulatory, not statutory, and, therefore, may be waived by the Board.” *Corning Optical Commc'ns RF, LLC v. PPC Broadband, Inc.*, IPR2015-00550, Paper 68, at *25 (P.T.A.B. Aug. 18, 2015) (citing 37 C.F.R. § 42.5(b)). That is consistent with *Proppant* and *Adello*.

B. The Board should allow the addition of Jina as an RPI rather than engage in unnecessary discovery and motion practice

In *Proppant*, to determine whether to accept updated mandatory notices without changing the filing date, the Board considered “whether there have been (1) attempts to circumvent the § 315(b) bar or estoppel rules, (2) bad faith by the petitioner, (3) prejudice to the patent owner caused by the delay, or (4) gamesmanship by the petitioner.” *Id.* at *6-7. All of those factors favor allowing Petitioner to add Jina as an RPI to avoid unnecessary discovery and motion practice.²

(1) There were no attempts to circumvent the § 315(b) bar or estoppel rules

There was no attempt to “circumvent” time-bar or estoppel rules by hiding Jina. On the contrary— there were no time-bars or estoppels to evade. *See Adello*, at

² Moreover, as explained above Patent Owner chose not to raise any RPI issue in its POPR despite being aware of all of the facts it presently asserts. *See* Paper 9, Paper 7. Patent Owner should not be rewarded with delaying the case further by waiting to raise the issue.

*5; see also *Banilla Games, Inc. v. Savvy Dog Sys., LLC*, CBM2020-00014, 2020 WL 6685563 (P.T.A.B. Nov. 10, 2020) (rejecting “speculative possibility” party was trying to evade unstated future estoppels); *One World Techs., Inc. v. Chervon (Hk) Ltd.*, No. IPR2020-00884, 2021 WL 5192891, at *18 (PTAB Nov. 3, 2021) (granting motion to add RPI where it was undisputed they were not time barred or estopped). In any event, Jina was identified as a party who may have an interest, allowing the Board to check for conflicts and identifying Jina to the extent there had been or would be any future estoppel or time-bar issues.

(2) There is no evidence of bad faith

Petitioner exhibited no bad faith. Again, to the contrary, Petitioner identified Jina, only as having an interest only because Intas did not believe under the “highly fact-dependent” assessment with “no bright-line test” that Jina is an RPI. For example, as Petitioner noted in opposition, merely having a relationship does not make a party an RPI. Paper 22 at 2 n.1 citing *Wi-Fi One, LLC v. Broadcom Corp.*, 887 F.3d 1329, 1340 (Fed. Cir. 2018). And this proceeding has been funded, controlled, and directed by Intas, not Jina, as any commercial product that arises out of the development by Intas and Jina will be sold by Intas through its subsidiary Accord (which was identified explicitly as a real party in interest). Thus, Intas reasonably believes (and continues to believe) that it and Accord are the proper real parties in interest. See *Banilla*, 2020 WL 6685563, at *2 (“we do not think it was

unreasonable that Petitioner initially considered only Banilla to be the RPI of this proceeding”).

Further, Jina's development work with Intas was not hidden as the Petition (like the Petition in the earlier PGR) relied on prior art clearly showing that Intas and Jina had partnered in investigating endoxifen. *See, e.g.*, Ex. 1006:

A Ahmad¹, S Shahabuddin¹, S Sheikh¹, P Kale², M Krishnappa², RC Rane³ and I Ahmad¹

¹Jina Pharmaceuticals, Inc., Libertyville, Illinois, USA; ²Lambda Therapeutic Research Ltd., Ahmedabad, India; ³Intas Pharmaceuticals Ltd., Ahmedabad, India.
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And there was no reason to “hide” Jina (which Petitioner did not) as Jina is not estopped or time-barred. *See One World*, 2021 WL 5192891, at *19 (“Patent Owner does not identify any way that Petitioner may benefit from not naming the Disputed Entities as real parties-in-interest”). Further, Petitioner affirms its understanding of duty of candor and good faith to the Office during the course of a proceeding and represents that there was no intentional concealment or bad faith as Intas continues to believe that Jina is not an RPI. *See Adello*, at *5; *Proppant*, at *14-15.

(3) Patent Owner is not prejudiced

There is no prejudice to Patent Owner. To the contrary, Patent Owner has long known about the co-development work with Intas and Jina, and only recently moved for discovery to raise an RPI issue, shortly before institution. *See Heil Co. v. Advanced Custom Eng'd Sys. & Equip Co.*, IPR2018-00139, Paper 17, at *7 (P.T.A.B. Oct. 9, 2018) (“Patent Owner could not provide a reason as to why it did

not request this discovery sooner”). Patent Owner admits that only as of late October it sought RPI discovery to seek termination, despite knowing about Jina for months. See Paper 20 at 1-2 (noting Patent Owner waited until October to seek discovery despite basing its allegations on correspondence from May). “But neither the statute nor the rule governing RPI disclosures is designed to award a patent owner such a windfall.” *Adello*, at *3-4. Instead, the rule’s purpose is “to assist members of the Board in identifying potential conflicts, and to assure proper application of the statutory estoppel provisions.” *Id.* (citing Patent Trial Practice Guide). As Jina was identified the Board was able to assess potential conflicts, and Jina will agree to be estopped to avoid unnecessary discovery and motion practice, there is no prejudice to Patent Owner. See *Banilla*, 2020 WL 6685563, at *2.

(4) Petitioner did not engage in gamesmanship

Patent Owner erroneously states that Intas only agreed to add Jina after “the Board granted Atossa discovery into RPI...” Reply at 3. The Board did not do so, it permitted Atossa to request discovery. See Paper 16. And in doing so, it also directed the parties to *Adello*. *Id.* at *4. Petitioner then promptly followed that direction and agreed to add Jina as an RPI consistent with *Adello* and *Proppant* to avoid unnecessary dispute. See Ex. 2024. That is the opposite of gamesmanship. See *Banilla*, 2020 WL 6685563, at *2. Indeed, it is not even clear that such a modification is necessary, as Intas expressly identified Jina as a potentially interested

party, flagging Jina for the Board while not asserting a fact that Intas does not believe to be true. *See Proppant*, at *14-15 (rejecting argument that identifying party “without admitting they are in fact real parties-in-interest”—is evidence of gamesmanship” because “we see nothing wrong with this approach as the identification fulfills the key purposes of identifying the real parties in interest—namely, ‘identifying potential conflicts, and to assure proper application of the statutory estoppel provisions’”) (citation omitted); *see also Adello*, at *4 (noting “the Board was able to check for conflicts”). And rather than requiring the parties to engage in discovery and the Board to resolve this dispute (which Intas maintains would be resolved in its favor), Intas and Jina promptly agreed Jina would be estopped, accomplishing the “key purposes” of the requirement. *Proppant*, at *16; *see also One-World*, 2021 WL 5192891, at *19. Indeed, this case is remarkably similar to *Proppant*, *Banilla*, and *One-World*, where the petitioner had a good faith belief the allegedly missing RPI was not an RPI, but agreed to add it anyway to avoid unnecessary dispute.

C. Patent Owner's cases are readily distinguishable

Unlike here, *Proppant*, *Banilla*, and *One-World*, all of Patent Owner's cases involve situations where a party had no reasonable basis for not naming the allegedly missing RPI and the petitioner or its RPI was then time-barred. Further, in none of

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the cited cases by Patent Owner did the petitioner agree to add the allegedly missing RPI without the need for discovery or a Board determination on the matter.

For example, in *Corning*, discovery revealed that a related but unnamed corporate entity “hired outside counsel to handle these IPR proceedings” “paid for the proceedings,” and “provided direction to outside counsel in relation to these proceedings.” *Corning*, at *19-23. The *Corning* petitioner did not voluntarily add the missing RPIs. Rather, it forced the patent owner to go through discovery and motion practice leading to a Board determination *and only then* asked to add the missing RPIs *if* the Board disagreed. *See* Reply at 7 quoting *Corning Optical*, Paper 54, at *25. On the facts before it, the Board was “not persuaded sufficient reason exists” to allow the petitioner to amend the petition without changing the filing date and the parties were time-barred. *Corning*, at *25.

In *Reflectix*, it was not simply that the petitioner's view of RPI was a mistake of law and not a mistake of fact, as Patent Owner asserts (Reply at 4-5), but that “Reflectix's incorrect RPI determination was not objectively reasonable, and cannot support good cause justifying late action” because the “facts overwhelmingly lead to the determination that SAC-US is an RPI that should have been named in the Petitions.” *Reflectix, Inc. v. Promethean Insulation Tech. LLC*, IPR2015-00039, Paper 18, at *15 (P.T.A.B. April 24, 2015). That was because it was undisputed that the unnamed alleged RPI (SAC-US) paid for, prepared and drafted the petition

without input from the actual petitioner. *Id.*, at *10. Even then, the Board terminated the proceeding because the petitioner was now time barred but noted the petitioner “could have corrected its RPI identifications without encountering a § 315(b) bar until January 10, 2015.” *Id.* at 15 n.7.

Finally, in *GEA Process*, GEA and the missing RPI (Procomac) were “related companies, with a common parent, GEA Group” and “GEA and Procomac were so closely aligned in relation to these proceedings that even the entities themselves did not fully appreciate they were separate and distinct entities.” *GEA Process Eng'g. Inc. v. Steuben Foods, Inc.*, IPR2014-00041, Paper 140, at *19-20 (P.T.A.B. Feb. 11, 2015). In fact, the missing “Procomoc funded the significant costs of these proceedings until May 2015, approximately a month and a half after Steuben foods first raised the RPI issue.” *Id.* at *20-21.

Patent Owner does not cite a *single case* suggesting that the identification of Jina as a party who has an interest was insufficient. Further, Patent Owner does not cite a *single case* in which a case was terminated absent a 315 time-bar. Rather, it asserts that the time for a PGR would have expired if the filing date is changed. *See* Reply at 6 citing § 321(c). But *Adello specifically rejected* such an argument as a basis for terminating the proceeding, citing 37 C.F.R. § 42.1's mandate to secure a “just, speedy, and inexpensive resolution” of the proceeding. *Adello*, at *3-4. And

Petitioners could simply refile the PGR as an IPR – simply delaying resolution and increasing costs on everyone.

Thus, Patent Owner cannot show that it will obtain something “favorable in substantive value to a contention of the party moving for discovery.” *Garmin Int’l, Inc. v. Cuozzo Speed Techs. LLC*, IPR2012-00001, Paper 26, at *3 (P.T.A.B. Mar. 5, 2013) (precedential).

Indeed, Patent Owner does not cite a single case permitting discovery for a fishing expedition to obtain the “windfall” of termination despite a petitioner agreeing to add the alleged RPI. And it simply ignores Petitioner’s cited cases (*Adello, BlueCatBio, Dispersive*) finding such discovery moot. *See* Paper 22 at *5-6. It is simply a waste of resources to permit discovery and motion practice that would, at best, cause only delay.

III. CONCLUSION

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

Respectfully submitted,

McANDREWS, HELD & MALLOY, LTD.

Dated: January 12, 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 Sur-Reply in Opposition to Patent Owner's Motion for Additional Discovery** was served by electronic mail to:

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