

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 UPDATED 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”)
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”)

EX.	DESCRIPTION
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”)
1027	SHARGEL, LEON & YU, ANDREW, APPLIED BIOPHARMACEUTICS & PHARMACOKINETICS (7th ed. 2016) (“Shargel”)

EX.	DESCRIPTION
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)
1038	Expert Declaration of William Mayo, Ph.D. Adopting the Opinions of Steven Miller, Ph.D.
1039	Confidential Settlement Agreement [Under Seal]

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 Updated Exhibit List** was served by electronic mail to:

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