

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 UPDATED 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”)

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”)

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 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	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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Dated: April 23, 2026

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