

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

INTAS PHARMACEUTICALS LTD.,

Petitioner,

v.

ATOSSA THERAPEUTICS, INC.,

Patent Owner.

Case No. PGR2023-00043

Patent 11,572,334

PETITIONER'S UPDATED EXHIBIT LIST

PETITIONER'S EXHIBIT LIST

EX.	DESCRIPTION
1001	USPN 11,572,334 ("334 patent")
1002	File history of USPN 11,572,334
1003	USPN 9,333,190 ("Ahmad")
1004	WO2017/70651 ("Liu")
1005	WO 2012/050263 ("Song")
1006	Ahmad, A. et al., Endoxifen, a New Cornerstone of Breast Cancer Therapy: Demonstration of Safety, Tolerability and Systemic Bioavailability in Healthy Human Subjects, 88(6) CLIN. PHARMACOLOGY & THERAPEUTICS 814-817 (2010) ("Ahmad 2010")
1007	Ahmad, A. et al., Endoxifen for breast cancer: Multiple-dose, dose-escalation study characterizing pharmacokinetics and safety in metastatic breast cancer patients, ASCO MEETING LIBRARY, presented June 4, 2012 ("Ahmad 2012")
1008	Cole, E., et al., Enteric coated HPMC capsules designed to achieve intestinal targeting, 231 INTL J. PHARMACEUTICS 83-95 (2002) ("Cole")
1009	Ku, M., et al., Performance qualification of a new hypromellose capsule: Part I. Comparative evaluation of physical, mechanical, and processability quality attributes of Vcaps Plus®, Quali-V® and gelatin capsules, 386 INTL J. PHARMACEUTICS 30-41 (2010) ("Ku")
1010	Benameur, H., Capsule Technology, Enteric Capsule Drug Delivery Technology – Achieving Protection Without Coating, 15(5) DRUG DEV. & DELIVERY 34-37 (2015) ("Benameur")
1011	Stegemann, S., Hard gelatin capsules today – and tomorrow, CAPSUGEL LIBRARY (2002) ("Stegemann")
1012	Excerpts of HANDBOOK OF PHARMACEUTICAL EXCIPIENTS FIFTH EDITION (Rowe, R., Sheskey, J. & Owen, S., eds., 2006) (The "HPE")
1013	Office Action dated 2/25/2020 from prosecution of Application No. 16/641,985

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U.S. Patent No. 11,572,334

EX.	DESCRIPTION
1014	Prescribing Information for Zonalta
1015	USP 711
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).
1017	Evans, D. et al, <i>Measurement of gastrointestinal pH profiles in normal ambulant human subjects</i> , 29 GUT 1035-41 (1988)
1018	Ahmad, A. et al., <i>Endoxifen, a New Treatment Option for Mania: A Double-Blind, Active-Controlled Trial Demonstrates the Antimanic Efficacy of Endoxifen</i> , Clin Transl Sci (2016) 9, 252–259 (“Ahmad 2016”)
1019	Milroy, L. et al., <i>A multi-gram-scale stereoselective synthesis of Z-endoxifen</i> , Bioorganic Med. Chem. Lett. 28 (2018) 1352-1356 (“Milroy”)
1020	Expert Declaration of Jason McConville, Ph.D.
1021	Ansel, H., et al, PHARMACEUTICAL DOSAGE FORMS AND DRUG DELIVERY SYSTEMS, Seventh Edition (1999)
1022	Fauq, A.H., et al., <i>A convenient synthesis of (Z)-4-hydroxy-N-desmethyltamoxifen (endoxifen)</i> , Bioorganic Med. Chem. Lett. 20 (2010) 3036-3038 (“Fauq”)
1023	Supporting information to Fauq, A.H., et al., <i>A convenient synthesis of (Z)-4-hydroxy-N-desmethyltamoxifen (endoxifen)</i> , Bioorganic Med. Chem. Lett. 20 (2010) 3036-3038
1024	NMR Spectra obtained by Dr. Bihovsky
1025	Supporting information to Milroy, L. et al., <i>A multi-gram-scale stereoselective synthesis of Z-endoxifen</i> , Bioorganic Med. Chem. Lett. 28 (2018) 1352-1356
1026	Majee, S.B. et al., <i>HPMC as Capsule Shell Material: Physicochemical, Pharmaceutical and Biopharmaceutical Properties</i> , 9(10) INT’L J. PHARMACY & PHARMACEUTICAL SCI. 2 (2017)

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1027	Marzorati, M. et al., <i>A novel Hypromellose capsule, with acid resistance properties, permits the targeted delivery of acid-sensitive products to the intestine</i> , 60 LWT – FOOD SCI. & TECH. 544-551 (2015)
1028	Al-Tabakha, M.M., <i>HPMC Capsules: Current Status and Future Prospects</i> , 13(3) J PHARM PHARMACEUTC SCI. 428-442 (2010)
1029	Honkanen, O, <i>Biopharmaceutical Evaluation of Orally and Rectally Administered Hard Hydroxypropyl Methylcellulose Capsules</i> , Division of Biopharmaceutics & Pharmacokinetics, Faculty of Pharmacy, University of Helsinki (March 2004)
1030	Expert Declaration of Ron Bihovsky, Ph.D.
1031	Reply Expert Declaration of Jason McConville, Ph.D.
1032	Additional excerpts of HANDBOOK OF PHARMACEUTICAL EXCIPIENTS FIFTH EDITION (Rowe, R., Sheskey, J. & Owen, S., eds., 2006) (The “HPE”)
1033	Dr. Davies Cross-Examination Transcript, September 18, 2024
1034	Petitioner's Oral Argument Demonstratives

Respectfully submitted,

Date: October 30, 2024

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CERTIFICATE OF SERVICE

The undersigned certifies that on October 30, 2024, a copy of **Petitioner's Updated Exhibit List** was served via email to the Patent Owner's counsel at the following:

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