

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

INTAS PHARMACEUTICALS LTD.
Petitioner,

v.

ATOSSA THERAPEUTICS, INC.
Patent Owner.

PGR2023-00043

PATENT OWNER'S UPDATED EXHIBIT LIST

Patent Owner's Updated Exhibit List
PGR2023-00043
U.S. Patent No. 11,572,334

EXHIBIT	DESCRIPTION
2001	Expert Declaration of Stephen Graham Davies, D. Phil. (“Davies Decl.”)
2002	Elkins et al., “Characterization of the isomeric configuration and impurities of (Z)-endoxifen by 2D NMR, high resolution LCMS, and quantitative HPLC analysis,” J. Pharmaceutical and Biomedical Analysis, 88:174-179 (2014) (“Elkins”)
2003	U.S. Patent No. 11,261,151 (“’151 patent”)
2004	Excerpt of ’151 Patent File History - IDS Filings, Receipts, List Considered (“’985 File History 1”)
2005	Excerpt of ’151 Patent File History - Liu (“’985 File History 2”)
2006	Excerpt of ’151 Patent File History - FOA and NOA (“’985 File History 3”)
2007	Intl. Pub. No. WO 2010/135703A2 by Ahmad et al.
2008	Intl. Pub. No. WO 2009/032699A1 by Bortz et al.
2009	Intl. Pub. No. WO 2009/120999A2 by Kushner et al.
2010	Excerpt of File History for U.S. Patent 9,333,190 - Office Actions, Responses, Declarations, and Allowance (“Ahmad File History”)
2011	Ali et al., “Endoxifen is a new potent inhibitor of PKC: A potential therapeutic agent for bipolar disorder,” Bioorganic & Medicinal Chem. Letters, 20:2665-2667 (2010) (“Ali”)
2012	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use, “Impurities: Guideline for Residual Solvents,” Step 4 Version (2021) (“ICH Guidelines”)
2013	Stephen Graham Davies, D. Phil. <i>Curriculum Vitae</i>
2014	Center for Drug Evaluation and Research, FDA Guidance Document, “Development of New Stereoisomeric Drugs,” (1992) (“FDA Guidance”)

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EXHIBIT	DESCRIPTION
2015	Lv et al., “Synthesis of mixed (E,Z)-, (E)-, and (Z)-norendoxifen with dual aromatase inhibitory and estrogen receptor modulatory activities,” J. Med. Chem., 56: 4611-4618 (2013) (“Lv”)
2016	Buchanan et al., “Solubilization and Dissolution of Tamoxifen-Hydroxybutenyl Cyclodextrin Complexes,” J. Pharm. Sciences, 95(10):2246-2255 (2006) (“Buchanan”)
2017	Gupta et al., “Salts of Therapeutic Agents: Chemical, Physicochemical, and Biological Considerations,” Molecules, 23:1719 (2018) (“Gupta”)
2018	Jacques et al., <i>Enantiomers, Racemates, and Resolutions</i> (1981) (“Jacques”)
2019	Declaration of Susan M. Krumplitsch in Support of Motion to Appear <i>Pro Hac Vice</i>
2020	Expert Declaration of Stephen Graham Davies, D. Phil. in Support of Patent Owner’s Response (“Davies POR Decl.”)
2021	Deposition Transcript of Jason T. McConville, Ph.D. taken on April 12, 2024, in <i>Intas Pharmaceuticals Ltd. v. Atossa Therapeutics, Inc.</i> , PGR2023-00043 (“McConville Tr.”)
2022	Excerpt of File History for U.S. Patent 9,333,190 – Original Filed Application, Office Actions, Responses, Appeal of Examiner’s Decision, Declarations, and Allowance (“Ahmad File History Excerpt 2”)
2023	Prescribing Information for Nolvadex® (tamoxifen citrate tablets)
2024	Prescribing Information for Soltamox® (tamoxifen citrate solution)
2025	Prescribing Information for Evista® (raloxifene hydrochloride tablets)
2026	Prescribing Information for Fareston® (toremifene citrate tablets)
2027	Deposition Transcript of Ron Bihovsky, Pd.D. taken on August 14, 2024, in <i>Intas Pharmaceuticals Ltd. v. Atossa Therapeutics, Inc.</i> , PGR2023-00043

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EXHIBIT	DESCRIPTION
2028	Deposition Transcript of Jason T. McConville, Ph.D. taken on August 15, 2024, in <i>Intas Pharmaceuticals Ltd. v. Atossa Therapeutics, Inc.</i> , PGR2023-00043
2029	Supplemental Declaration of Stephen Graham Davies, D. Phil. in Support of Patent Owner's Sur-Reply
2030	Patent Owner's Hearing Demonstratives

Dated: October 30, 2024

Respectfully Submitted,

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on this 30th day of October 2024, a true copy of the foregoing was served on Petitioner INTAS PHARMACEUTICALS LTD. by emailing a copy to counsel of record for Petitioner at the email addresses listed below:

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