

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

HIKMA PHARMACEUTICALS USA INC.,
Petitioner,

v.

SK BIOPHARMACEUTICALS CO., LTD., and AXSOME MALTA LTD,
Patent Owners.

IPR2024-01418
U.S. Patent No. 11,560,354

**JOINT REQUEST THAT SETTLEMENT AGREEMENT BE TREATED AS
BUSINESS CONFIDENTIAL INFORMATION AND BE KEPT SEPARATE
PURSUANT TO 35 U.S.C. § 317(b) AND 37 C.F.R. § 42.74(c)**

PETITIONER’S UPDATED EXHIBIT LIST

No.	Exhibit Description
1001	U.S. Patent No. 11,560,354
1002	U.S. Patent No. 11,560,354 File History
1003	Declaration of Dr. Salvatore Lepore, Ph.D.
1004	CV of Dr. Salvatore Lepore, Ph.D.
1005	US Pub. No. 2009/0312416 (“ <u>Ahnaou</u> ”)
1006	US 2005/0080268 (“ <u>Choi268</u> ”)
1007	S. Kim, <i>Pharmaceutical Industry Practices on Genotoxic Impurities</i> , Chapter 14 “Salt Formation of Pharmaceutical Compounds and Associated Genotoxic Risks” 385–426 (Kim Lee ed., CRC Press 2015) (“ <u>Kim</u> ”)
1008	C.G. Fraga, <i>Profiling of Volatile Impurities in Tetramethylenedisulfate tramine (TETS) for Synthetic-Route Determination</i> 210 FORENSIC SCI. INT’L 164 (2011) (“ <u>Fraga</u> ”)
1009	Z. Sobol, <i>Genotoxicity Profiles of Common Alkyl Halides and Esters with Alkylating Activity</i> 633 MUTAT RES. 80 (2007) (“ <u>Sobol</u> ”)
1010	Wayback Machine webpage – T. Kaleemullah et al., <i>Development and Validation of Gas Chromatography Method for Low Level Detection of Residual Methyl Chloride, Ethyl Chloride and Isopropyl Chloride in Ziprasidone Hydrochloride</i> 3(6) DER PHARM. CHEMICA 390 (2011) (https://web.archive.org/web/20160203013049/http://derpharmachemica.com/vol3-iss6/DPC-2011-3-6-390-399.pdf) (captured September 19, 2024)
1011	Declaration of Dr. Sylvia Hall-Ellis certifying the publication date of Ex. 1016
1012	Unichem Dismissal, Docket No. 103, June 14, 2024
1013	Stipulated Consolidation and Scheduling Order, Docket No. 110, September 24, 2024

1014	David Liu et al., <i>Recent Advances in Trace Analysis of Pharmaceutical Genotoxic Impurities</i> 51 J. PHARM. BIOMED. ANALYSIS 999 (2010) (“ <u>Liu</u> ”)
1015	Zadeo Cimarosti et al., <i>Application of Quality by Design Principles to Support Development of a Control Strategy for the Control of Genotoxic Impurities in the Manufacturing Process of a Drug Substance</i> 14 ORGANIC PROCESS RSCH. & DEV. 993 (2010) (“ <u>Cimarosti</u> ”)
1016	T. Kaleemullah et al., <i>Development and Validation of Gas Chromatography Method for Low Level Detection of Residual Methyl Chloride, Ethyl Chloride and Isopropyl Chloride in Ziprasidone Hydrochloride</i> 3(6) DER PHARM. CHEMICA 390 (2011) (“ <u>Kaleemullah</u> ”)
1017	Courtney M. Callis et al., <i>Risk Assessment of Genotoxic Impurities in Marketed Compounds Administered Over a Short-Term Duration: Applications to Oncology Products and Implications for Impurity Control Limits</i> 14(4) ORGANIC PROCESS RSCH. & DEV. 986 (2010) (“ <u>Callis</u> ”)
1018	<i>Guideline on the Limits of Genotoxic Impurities</i> , Committee for Medicinal Products for Human Use (CHMP), European Medicines Agency (Jun. 28, 2006) (“ <u>CHMP</u> ”)
1019	Q. Yang et al., <i>Controlling the Genotoxins Ethyl Chloride and Methyl Chloride Formed During the Preparation of Amine Hydrochloride Salts from Solutions of Ethanol and Methanol</i> 13 ORGANIC PROCESS RSCH. & DEV.
1020	Board’s Decision in <i>Sotera Wireless, Inc. v. Masimo Corp.</i> , IPR2020-01019, Paper 12 at 18-19 (PTAB Dec. 1, 2020)
1021 NEW	Confidential Settlement Agreement Between Parties [FILED UNDER SEAL]

Pursuant to 35 U.S.C. § 317(b) and 37 C.F.R. § 42.74(c), Petitioner Hikma Pharmaceuticals USA Inc. and Patent Owners SK Biopharmaceuticals Co., Ltd. and Axsome Malta Ltd. jointly request to file the Settlement Agreement (Ex. 1021) between the parties, as referenced in Petitioner's Unopposed Motion To Dismiss Petition For Inter Partes Review, as business confidential information, which shall be kept separate from the file of the patent at issue, and only made available to Federal Government agencies upon written request.

The requested relief is appropriate because the terms of the Settlement Agreement are confidential business information and require Patent Owners and Petitioner to treat the Settlement Agreement as confidential information and limit their respective abilities to share the Settlement Agreement with or disclose its contents to third parties. Patent Owners and Petitioner have filed a copy of the Settlement Agreement (Ex. 1021) with the Board, as required by 35 U.S.C. § 317(b) and 37 C.F.R. § 42.74. The confidential Settlement Agreement was filed in the PTAB P-TACTS system to provide availability only to the Board.

Dated: March 6, 2025

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on March 6, 2025, I caused a true and correct copy of
The foregoing to be served on the following counsel for Patent Owner by
electronic mail to the following email addresses:

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