

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

PETITIONER’S REPLY TO PATENT OWNER’S PRELIMINARY RESPONSE

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 Tetramethylenedisulfotetramine (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 MUTUAT 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. 786 (2009) (“ <u>Yang</u> ”)
1020	Sotera Stipulation by Petitioner’s counsel

Petitioner submits the following reply to address Patent Owner's request for discretionary denial under 35 U.S.C. § 314(a). Under former Director Vidal's Interim Procedure, "the PTAB will not discretionarily deny institution in view of parallel district court litigation where a petitioner presents a stipulation not to pursue in a parallel proceeding the same grounds or any grounds that could have reasonably been raised before the PTAB." Interim Procedure, 3. Petitioner (and Defendant in the parallel district court litigation) has stipulated that if the Board institutes an IPR on this Petition, it will not pursue in the related district court proceeding "any ground that [Petitioner] raised or reasonably could have raised" during this proceeding. *Sotera Wireless, Inc. v. Masimo Corp.*, IPR2020-01019, Paper 12 at 18-19 (PTAB Dec. 1, 2020); 35 U.S.C. § 315(d); Ex.1020.

Dated: February 13, 2025

Respectfully Submitted,
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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), I hereby certify that on this 13th day of February, 2025, I caused to be served a true and correct copy of the foregoing Reply to Patent Owner's Preliminary Response by email on the following counsel for patent owner:

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