

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

**PATENT OWNER'S PRELIMINARY SUR-REPLY TO PETITIONER'S
PRELIMINARY REPLY**

LIST OF EXHIBITS

EX	Description
2001	Declaration of Dr. Leonard J. Chyall
2002	Sunosi Label 2023
2003	Sunosi Approval Letter
2004	Sunosi Treatment Guide
2005	Geodon Label 2022
2006	Risperdal Label 2022
2007	Uroxatrol Label 2020
2008	Valcyte Label 2021
2009	Prozac Label 2023
2010	U.S. Patent No. 5,955,499
2011	U.S. Patent No. 4,831,031
2012	Complaint, Docket No. 1, September 13, 2023
2013	Notice of Filing Date Accorded to Petition and Time for Filing Patent Owner Preliminary Response
2014	Excerpt from Defendants' Joint Invalidity Contentions, June 18, 2024
2015	Excerpts from Yuri Kazakevich & Rosario LoBrutto, HPLC for Pharmaceutical Scientists (2007)
2016	<i>Curriculum Vitae</i> of Dr. Leonard J. Chyall
2017	U.S. Patent No. 5,312,925
2018	U.S. Patent No. 8,178,674
2019	U.S. Patent Application Publication No. 2005/01433961
2020	Canadian Patent Application No. 2,549,244
2021	European Patent Application No. 0,380,924
2022	Board Email Authorizing Preliminary Reply Filing

As authorized by the Board via email dated February 7, 2025, Patent Owner submits this Preliminary Sur-Reply in response to Petitioner's Preliminary Reply.

The Board should not consider Petitioner's *Sotera* stipulation due to Petitioner's untimeliness. First, the Board granted Petitioner's request to file a *Sotera* stipulation "***on or before February 12, 2025.***" Ex. 2022 at 1. Petitioner missed its own requested deadline, filing its reply on February 13, 2025. Second, Petitioner has not shown good cause for why its *Sotera* stipulation was not filed with its Petition, which explicitly addressed *Fintiv*. See 37 C.F.R. § 42.108. Petitioner's untimely filing of a *Sotera* stipulation without re-addressing *Fintiv* deprived Patent Owner the opportunity to respond to Petitioner's § 314(a) arguments in full.

Even looking past these delays, PTAB guidance regarding *Sotera* stipulations is inapplicable here. Unlike in *Sotera Wireless, Inc. v. Masimo Corp.*, Petitioner did not name its co-defendants as real parties-in-interest. See IPR2020-01019, Paper 12 at 2. Petitioner thus has two opportunities to raise the same arguments—before the Board and in the district court through co-defendants. Moreover, Petitioner “already challenged the validity” of the '354 patent, relying on “two of the primary references relied on in this Petition.” *Shenzhen Waydoo Intel. Tech. Co., Ltd. v. MHL Custom, Inc.*, IPR2024-999, Paper 13 at 9. Petitioner's stipulation thus fails to “mitigate[] concerns of potentially conflicting decisions and duplicative efforts between the district court and the PTAB.” Guidance Memo at 7. Denial is thus warranted.

Date: February 19, 2025

Respectfully submitted,

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CERTIFICATE OF SERVICE

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Pursuant to 37 C.F.R. § 42.6(e), the undersigned hereby certify that
PATENT OWNER'S PRELIMINARY SUR-REPLY TO PETITIONER'S
PRELIMINARY REPLY and accompanying exhibit (Ex. 2022) were served on
February 19, 2025 by filing these documents through the Patent Review Processing
System, as well as e-mailing copies to sborder@winston.com and
jwong@winston.com.

Date: February 19, 2015

By: /F. Dominic Cerrito/
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