

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

**AXSOME MALTA LTD. and AXSOME
THERAPEUTICS, INC.,**

Plaintiffs,

v.

**ALKEM LABORATORIES LTD.,
AUROBINDO PHARMA USA, INC.,
AUROBINDO PHARMA LIMITED,
HETERO USA INC., HETERO LABS
LIMITED UNIT-V, HETERO LABS
LTD., HIKMA PHARMACEUTICALS
USA INC., SANDOZ INC., and UNICHEM
LABORATORIES LTD.,**

Defendants.

**Civil Action No. 23-20354 (MCA)(LDW)
Civil Action No. 23-23255 (MCA)(LDW)
Civil Action No. 24-196 (MCA)(LDW)
Civil Action No. 24-309 (MCA)(LDW)
Civil Action No. 24-860 (MCA)(LDW)
Civil Action No. 24-3999 (MCA)(LDW)
Civil Action No. 24-4002 (MCA)(LDW)
Civil Action No. 24-4608 (MCA)(LDW)
(consolidated)**

(Filed Electronically)

**AXSOME MALTA LTD. and AXSOME
THERAPEUTICS, INC.,**

Plaintiffs,

v.

**AUROBINDO PHARMA USA, INC. and
AUROBINDO PHARMA LIMITED,**

Defendants.

Civil Action No. 24-7511 (MCA)(LDW)

(Filed Electronically)

**AXSOME MALTA LTD. and AXSOME
THERAPEUTICS, INC.,**

Plaintiffs,

v.

ALKEM LABORATORIES LTD.,

Defendant.

Civil Action No. 24-8365 (MCA)(LDW)

(Filed Electronically)

**AXSOME MALTA LTD. and AXSOME
THERAPEUTICS, INC.,**

Plaintiffs,

v.

**AUROBINDO PHARMA USA, INC. and
AUROBINDO PHARMA LIMITED,**

Defendants.

Civil Action No. 24-8624 (MCA)(LDW)

(Filed Electronically)

**AXSOME MALTA LTD. and AXSOME
THERAPEUTICS, INC.,**

Plaintiffs,

v.

**ALKEM LABORATORIES LTD.,
AUROBINDO PHARMA USA, INC.,
AUROBINDO PHARMA LIMITED,
HETERO USA INC., HETERO LABS
LIMITED UNIT-V, HETERO LABS
LTD., and HIKMA
PHARMACEUTICALS USA INC.,**

Defendants.

Civil Action No. 24-9209

(Filed Electronically)

STIPULATED CONSOLIDATION AND SCHEDULING ORDER

WHEREAS, on September 13, 2023, Plaintiffs Axsome Malta Ltd. and Axsome Therapeutics, Inc. (together, “Axsome” or “Plaintiffs”) filed Civil Action No. 23-20354 (“Main Action”) in this Judicial District against Defendants Alkem Laboratories Ltd. (“Alkem”), Aurobindo Pharma USA, Inc. (“Aurobindo USA”), Hetero USA Inc., Hetero Labs Limited Unit-V, and Hetero Labs Ltd. (collectively, “Hetero”), Hikma Pharmaceuticals USA Inc. (“Hikma”), Sandoz Inc. (“Sandoz”), and Unichem Laboratories Ltd. (“Unichem”);

WHEREAS, on May 22, 2024, the Court consolidated related Civil Action Nos. 23-23255, 24-196, 24-309, 24-860, 24-3999, 24-4002, and 24-4608 into the Main Action (*see* ECF No. 99);

WHEREAS, on June 14, 2024, the Court dismissed Unichem from the Main Action (ECF No. 103);

WHEREAS, on July 2, 2024, Axsome filed related Civil Action No. 24-7511 in this Judicial District against Aurobindo USA and Aurobindo Pharma Limited (together, “Aurobindo,” and collectively with Alkem, Hetero, and Hikma, “Defendants”);

WHEREAS, on August 8, 2024, Axsome filed related Civil Action No. 24-8365 in this Judicial District against Alkem;

WHEREAS, on August 21, 2024, Axsome filed related Civil Action No. 24-8624 in this Judicial District against Aurobindo;

WHEREAS, on September 9, 2024, the Court dismissed Sandoz from the Main Action (ECF No. 108);

WHEREAS, on September 16, 2024, Axsome filed related Civil Action No. 24-9209 in this Judicial District against Defendants;

WHEREAS, each of the above-captioned actions relate to Axsome’s allegations of infringement of patents listed in the FDA’s publication entitled “Approved Drug Products with Therapeutics Equivalence Evaluations” (the “Orange Book”) for Axsome’s Sunosi® (solriamfetol) drug product; and

WHEREAS, Axsome and Defendants jointly request that the above-captioned actions be consolidated;

IT IS on this 24th day of September, 2024,

ORDERED that Civil Action Nos. 23-20354, 24-7511, 24-8365, 24-8624, and 24-9209 are consolidated for all purposes, including discovery, case management, and trial, subject to further order of the Court;

IT IS FURTHER ORDERED that all filings in the Main Action shall use the following caption:

**AXSOME MALTA LTD. and AXSOME
THERAPEUTICS, INC.,**

Plaintiffs,

v.

**ALKEM LABORATORIES LTD.,
AUROBINDO PHARMA USA, INC.,
AUROBINDO PHARMA LIMITED,
HETERO USA INC., HETERO LABS
LIMITED UNIT-V, HETERO LABS
LTD., and HIKMA
PHARMACEUTICALS USA INC.,**

Defendants.

**Civil Action No. 23-20354 (MCA)(LDW)
(consolidated)**

(Filed Electronically)

IT IS FURTHER ORDERED that all filings going forward shall be filed in the Main Action and that Civil Action Nos. 24-7511, 24-8365, 24-8624, and 24-9209 shall be administratively terminated by the Clerk's office;

IT IS FURTHER ORDERED that the Main Action shall proceed on the following amended schedule:

Event	Current Date (ECF No. 99)	Amended Date
Plaintiffs file Complaint to bring all currently-issued patents against relevant Defendants	N/A	09/16/2024

Defendants' Answers and Counterclaims to all outstanding Complaints	N/A	09/23/2024
Plaintiffs' Answer to Defendants' Answers and Counterclaims	N/A	10/11/2024
Plaintiffs to Provide Updated Disclosure of Asserted Claims	N/A	10/11/2024
Parties to Exchange Updated Rule 26(a)(1) Initial Disclosures	N/A	10/11/2024
Each Defendant Group to Provide Non-Infringement Contentions for Newly-Asserted Patents	N/A	10/25/2024
Defendants to Provide Joint Invalidity Contentions for Newly-Asserted Patents	N/A	10/25/2024
Plaintiffs to Provide Infringement Contentions to each Defendant Group for All Asserted Patents	10/28/2024	12/20/2024
Plaintiffs to Respond to Defendants' Joint Invalidity Contentions for All Asserted Patents	10/28/2024	12/20/2024
Parties to Exchange Proposed Claim Terms for Construction	11/8/2024	01/10/2025
Parties to Exchange Preliminary Claim Constructions	11/22/2024	01/24/2025
Parties to Exchange Evidence Opposing Claim Constructions	12/13/2024	02/14/2025
Joint Claim Construction and Prehearing Statement	12/20/2024	02/14/2025
Complete all non-expert <i>Markman</i> discovery	1/10/2025	03/07/2025

Opening <i>Markman</i> briefs	1/31/2025	03/28/2025
Complete all expert <i>Markman</i> discovery	2/21/2025	04/18/2025
Substantial Completion of Document Production	4/18/2025	4/18/2025
Responsive <i>Markman</i> briefs	5/9/2025	05/30/2025
Parties Jointly Propose <i>Markman</i> hearing schedule	5/16/2025	06/06/2025
<i>Markman</i> hearing	TBD	TBD
Deadline for Motions to Amend or to Add Parties	5/30/2025	06/13/2025
Close of Fact Discovery	9/19/2025	10/17/2025
Parties Exchange Opening Expert Reports on All Issues for which Party Bears Burden of Proof	TBD	TBD
Parties Exchange Responsive Expert Reports	TBD	TBD
Reply Expert Reports	TBD	TBD
Close of Expert Discovery	TBD	TBD
Submission of the Parties' Joint Pretrial Order	TBD	TBD
Final Pretrial Conference	TBD	TBD
Trial	TBD	TBD
30 Month Stay Expires	12/17/2026	12/17/2026

SO ORDERED.



Hon. Leda Dunn Wettre, U.S.M.J.

SO STIPULATED on September 17, 2024:

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