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**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

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

**Plaintiffs,
v.**

**ALKEM LABORATORIES LTD.,
Defendant.**

**Civil Action No. 23-20354 (MCA)(LDW)
(CONSOLIDATED)**
(Filed Electronically)

**PLAINTIFFS' ANSWER TO
ALKEM'S COUNTERCLAIMS**

Plaintiffs Axsome Malta Ltd. and Axsome Therapeutics, Inc. (together, “Axsome”), by their undersigned attorneys, hereby answer the Counterclaims to their Complaint for Patent Infringement of United States Patent Nos. 12,036,194 (“the ‘194 patent”) and 12,064,411 (“the ‘411 patent”) (together, “the second set of additional patents-in-suit against Alkem”) by Defendant Alkem Laboratories Ltd. (“Alkem” or “Defendant”), dated September 23, 2024 (the “Counterclaims”), as follows. Except as expressly admitted, all allegations are denied.

ALKEM'S COUNTERCLAIMS

PARTIES

1. On information and belief, Axsome Malta Ltd. is a corporation organized and existing under the laws of the Republic of Malta, having a principal place of business at Pinto Business Centre, Level 4, Office 4, Mill Street, Qormi, Triq il-Mithna Hal, Malta, QRM 3104.

ANSWER: Axsome admits the allegations of paragraph 1.

2. On information and belief, Axsome Therapeutics, Inc., is a corporation organized and existing under the laws of Delaware, having a principal place of business at One World Trade Center, 22nd Floor, New York, New York 10007.

ANSWER: Axsome admits the allegations of paragraph 2.

3. Alkem Laboratories Ltd. is a corporation organized and existing under the laws of India, having a principal place of business at Devashish Building, Alkem House, Senapati Bapat Road, Lower Parel, Mumbai, 400 013, Maharashtra, India.

ANSWER: Axsome admits, on information and belief, the allegations of paragraph 3.

NATURE OF THE ACTION

4. Alkem seeks declaratory judgment under the patent laws of the United States, 35 U.S.C. § 100, *et seq.* and the Declaratory Judgment Act, 28 U.S.C. § 2201, *et seq.*, that United States Patent Nos. 12,036,194 (“the ‘194 patent”) and 12,064,411 (“the ‘411 patent”) (collectively, “the patents-in-suit”) are invalid and/or not infringed.

ANSWER: Paragraph 4 states legal conclusions for which no answer is required. To the extent that an answer is required, Axsome admits that this Court has subject matter jurisdiction over Alkem’s counterclaims as to the second set of additional patents-in-suit against Alkem, but denies that Alkem is entitled to any of the relief that it seeks, and, except as so admitted, denies the allegations of paragraph 4.

JURISDICTION AND VENUE

5. This Court has jurisdiction over these counterclaims under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

ANSWER: Paragraph 5 states legal conclusions for which no answer is required. To the extent that an answer is required, Axsome admits that this Court has subject matter jurisdiction

over Alkem's counterclaims as to the second set of additional patents-in-suit against Alkem, but denies that Alkem is entitled to any of the relief that it seeks, and, except as so admitted, denies the allegations of paragraph 5.

6. This Court has personal jurisdiction over Axsome because, among other reasons, Axsome subjected itself to the jurisdiction of this Court by filing its complaint here.

ANSWER: Paragraph 6 states legal conclusions for which no answer is required. To the extent that an answer is required, Axsome admits that this Court has personal jurisdiction over Axsome for purposes of this action only, but denies that Alkem is entitled to any of the relief that it seeks, and, except as so admitted, denies the allegations of paragraph 6.

7. Venue is proper in this Court under 28 U.S.C. §§ 1391(b) and 1400(b), and by Axsome's choice of forum.

ANSWER: Paragraph 7 states legal conclusions for which no answer is required. To the extent that an answer is required, Axsome admits that venue is proper to adjudicate this action and, except as so admitted, denies the allegations of paragraph 7.

8. There is an actual and justiciable controversy between the parties as to the infringement and invalidity of the patents-in-suit.

ANSWER: Paragraph 8 states legal conclusions for which no answer is required. To the extent that an answer is required, Axsome admits that there is a justiciable controversy between Axsome and Alkem regarding the second set of additional patents-in-suit against Alkem, and, except as so admitted, denies the allegations of paragraph 8.

THE CONTROVERSY

9. Alkem holds Abbreviated New Drug Application ("ANDA") No. 218722 for solriamfetol oral tablets.

ANSWER: Axsome admits, on information and belief, the allegations of paragraph 9.

10. On or about September 16, 2024, Axsome filed the present action against Alkem alleging infringement of the patents-in-suit. Accordingly, there is a real, substantial, and continuing justiciable controversy between the parties concerning the patents-in-suit.

ANSWER: Axsome admits that, on September 16, 2024, it filed the Complaint in Civil Action No. 24-09209, which has now been consolidated into the above-captioned litigation, alleging, inter alia, Alkem's infringement of the second set of additional patents-in-suit against Alkem, including that Alkem has infringed and will infringe the second set of additional patents-in-suit against Alkem by submitting ANDA No. 218722 and by making, using, offering to sell, selling, and/or importing into the United States a generic version of Axsome's solriamfetol oral tablets ("Alkem's Proposed Product"), and, except as so admitted, denies the allegations of paragraph 10.

11. Alkem and Axsome have adverse legal interests with respect to the patents-in-suit of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

ANSWER: Paragraph 11 states legal conclusions for which no answer is required. To the extent that an answer is required, Axsome admits that there is a justiciable controversy between Axsome and Alkem regarding the second set of additional patents-in-suit against Alkem, and, except as so admitted, denies the allegations of paragraph 11.

Count I: Declaratory Judgment of Alleged Invalidity of the '194 Patent

12. Alkem repeats and incorporates by reference the preceding paragraphs of its Counterclaims as if fully set forth herein.

ANSWER: Axsome incorporates its answers to the preceding paragraphs as if fully set forth herein.

13. Each and every asserted claim of United States Patent No. 12,036,194 is invalid for failing to satisfy one or more conditions of patentability set forth in Title 35, United States Code, including without limitation, §§ 101, 102, 103, 112 and/or 116, and/or is invalid under any other ground provided by 35 U.S.C. § 282 and/or based on other judicially-created bases for invalidity.

ANSWER: Axsome denies the allegations of paragraph 13.

Count II: Declaratory Judgment of Alleged Noninfringement of the '194 Patent

14. Alkem repeats and incorporates by reference the preceding paragraphs of its Counterclaims as if fully set forth herein.

ANSWER: Axsome incorporates its answers to the preceding paragraphs as if fully set forth herein.

15. Alkem has not infringed, induced infringement, or contributed to the infringement, and Alkem will not infringe, induce infringement, or contribute to the infringement, either literally or under the doctrine of equivalents, of any valid and enforceable asserted claim of U.S. Patent No. 12,036,194.

ANSWER: Axsome denies the allegations of paragraph 15.

Count III: Declaratory Judgment of Alleged Invalidity of the '411 Patent

16. Alkem repeats and incorporates by reference the preceding paragraphs of its Counterclaims as if fully set forth herein.

ANSWER: Axsome incorporates its answers to the preceding paragraphs as if fully set forth herein.

17. Each and every asserted claim of United States Patent No. 12,064,411 is invalid for failing to satisfy one or more conditions of patentability set forth in Title 35, United States Code, including without limitation, §§ 101, 102, 103, 112 and/or 116, and/or is invalid under any other ground provided by 35 U.S.C. § 282 and/or based on other judicially-created bases for invalidity.

ANSWER: Axsome denies the allegations of paragraph 17.

Count IV: Declaratory Judgment of Alleged Noninfringement of the '411 Patent

18. Alkem repeats and incorporates by reference the preceding paragraphs of its Counterclaims as if fully set forth herein.

ANSWER: Axsome incorporates its answers to the preceding paragraphs as if fully set forth herein.

19. Alkem has not infringed, induced infringement, or contributed to the infringement, and Alkem will not infringe, induce infringement, or contribute to the infringement, either literally or under the doctrine of equivalents, of any valid and enforceable asserted claim of U.S. Patent No. 12,064,411.

ANSWER: Axsome denies the allegations of paragraph 19.

ALKEM'S REQUEST FOR RELIEF

Axsome denies that Alkem is entitled to any relief on its Counterclaims, either as prayed for in its pleading or otherwise.

AXSOME'S AFFIRMATIVE DEFENSE

Without prejudice to the denials set forth in this Answer and to the ability to amend this Answer to seek and allege any and all defenses not presently known or that are revealed during the course of discovery or otherwise, Axsome asserts the following affirmative defense in response to Alkem's Counterclaims:

Failure to State a Claim

The Counterclaims fail to state any claim for which relief may be granted.

Dated: October 11, 2024

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