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and Axsome Therapeutics, Inc.*

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

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

**Plaintiffs,**

**v.**

**ALKEM LABORATORIES LTD.,  
AUROBINDO PHARMA USA, INC., and  
AUROBINDO PHARMA LIMITED,**

**Defendants.**

**Civil Action No. 24-10617 (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. 25-03721 (MCA) (LDW)**

**(Filed Electronically)**

**PLAINTIFFS' ANSWER TO AUROBINDO PHARMA USA, INC.  
AND AUROBINDO PHARMA LIMITED'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 No. 12,194,016 (“the ’016 patent”) by Defendants Aurobindo Pharma USA, Inc. and Aurobindo Pharma Limited (together, “Defendants” or “Aurobindo”), dated May 16, 2025 (the “Counterclaims”), as follows. Except as expressly admitted, all allegations are denied.

**PARTIES**

1. Aurobindo Pharma U.S.A., Inc. is a company organized and existing under the laws of the State of Delaware, having a principal place of business at 279 Princeton Hightstown Road, East Windsor, New Jersey 08520.

**ANSWER:** Axsome admits on information and belief the allegations of paragraph 1.

2. Aurobindo Pharma Limited is a corporation organized and existing under the laws of India, having a principal place of business at Galaxy Floors: 22-24, Plot No. 1, Survey No. 83/1, Hyderabad Knowledge City, Raidurg Pamkaktha, Ranga Reddy District, Hyderabad, Telangana, India, 500032.

**ANSWER:** Axsome admits on information and belief the allegations of paragraph 2.

3. Upon information and belief, Plaintiff 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 3.

4. Upon information and belief, Plaintiff 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, 29th Floor, New York, New York 10007.

**ANSWER:** Axsome admits the allegations of paragraph 4.

### **JURISDICTION AND VENUE**

5. These counterclaims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and under the patent laws of the United States, Title 35 of the United States Code.

**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 Aurobindo's counterclaims as to the '016 patent, but denies that Aurobindo 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 jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 1367, 2201, and 2202.

**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 subject matter jurisdiction over Aurobindo's counterclaims as to the '016 patent, but denies that Aurobindo is entitled to any of the relief that it seeks, and, except as so admitted, denies the allegations of paragraph 6.

7. Plaintiff/Counterclaim-Defendant Axsome Malta Ltd. and Axsome Therapeutics, Inc. (collectively, "Axsome") are subject to personal jurisdiction in this Judicial District because Plaintiff subjected itself to the jurisdiction of this Court by filing the Complaint here. Plaintiff Axsome is also subject to personal jurisdiction in this Judicial District because Axsome sells products here, regularly practices business here, and purposefully availed itself off the benefits of jurisdiction in the State of New Jersey.

**ANSWER:** Paragraph 7 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 Aurobindo is entitled to any of the relief that it seeks, and, except as so admitted, denies the allegations of paragraph 7.

8. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b) and by Counterclaim-Defendant's choice of forum in filing its Complaint against Aurobindo here.

**ANSWER:** Paragraph 8 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 8.

9. As a consequence of Plaintiff/Counterclaim-Defendant's complaint against Aurobindo, there is now an actual, substantial, continuing and justiciable controversy between the parties as to the infringement, validity, and enforceability of the '609 patent ("the patent-in-suit").

**ANSWER:** Paragraph 9 states legal conclusions for which no answer is required. To the extent that an answer is required, Axsome admits that there is an actual and justiciable controversy between Aurobindo and Axsome regarding the '016 patent, and that the submission of Aurobindo's ANDA No. 218725 to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of a generic version of Axsome's solriamfetol oral tablets ("Aurobindo's Proposed Product"), prior to the expiration of the '016 patent, infringes, has infringed, and/or will infringe at least one valid and enforceable claim of the '016 patent, and, except as so admitted, denies the allegations of paragraph 9.

### **THE CONTROVERSY**

10. On January 14, 2025, the United States Patent and Trademark Office ("USPTO") issued the '016 patent, entitled, "Methods of Providing Solriamfetol Therapy to Subjects with Impaired Renal Function." The face of the '016 patent identifies Katayoun Zomorodi as the inventor.

**ANSWER:** Axsome admits the allegations of paragraph 10.

11. Plaintiff Axsome Malta Ltd. purports to be the holder of the New Drug Application ("NDA") No. 211230 for the manufacture and sale of (solriamfetol HCl eq 75 mg base and eq 150 mg base) Oral Tablets, under the registered trademark SUNOSI® in the United States.

**ANSWER:** Axsome admits that it is the holder of NDA No. 211230 for solriamfetol oral tablets, Eq. 75 mg base and Eq. 150 mg base, which is sold under the trademark Sunosi®, and, except as so admitted, denies the allegations of paragraph 11.

12. The Federal Food, Drug, and Cosmetic Act (“FFDCA”), 21 U.S.C. § 301 *et seq.*, as amended by the Hatch-Waxman Amendments, sets forth the rules that the Food and Drug Administration (“FDA”) must follow when determining whether to approve for marketing brand and generic drugs.

**ANSWER:** Paragraph 12 states legal conclusions for which no answer is required. To the extent an answer is required, Axsome admits that 21 U.S.C. § 301, *et seq.* contains statutory provisions relating to food and drugs, refers to the statute for the terms thereof, and, except as so admitted, denies the allegations of paragraph 12.

13. Under the FFDCA, an applicant seeking to market a new brand drug must prepare a NDA for review by the FDA. See 21 U.S.C. § 355.

**ANSWER:** Paragraph 13 states a legal conclusion for which no answer is required. To the extent an answer is required, Axsome admits that 21 U.S.C. § 301, *et seq.* contains statutory provisions relating to food and drugs, refers to the statute for the terms thereof, and, except as so admitted, denies the allegations of paragraph 13.

14. An NDA may include the patent number of any patent that claims the “drug” or a “method of using [the] drug” for which the NDA was submitted and for which a claim of patent infringement could reasonably be asserted against an authorized party. See 21 U.S.C. § 355(b)(1), (c)(2); 21 C.F.R. § 314.53(b), (c)(2).

**ANSWER:** Paragraph 14 states legal conclusions for which no answer is required. To the extent that an answer is required, Axsome admits that 21 U.S.C. § 301, *et seq.* and 21 C.F.R. § 314.53 contain statutory provisions and/or regulations relating to the filing, contents, and/or approval of New Drug Applications, refers to the statute and regulations for the terms thereof, and, except as so admitted, denies the allegations of paragraph 14.

15. An NDA holder is required to submit to the FDA the patent number of each patent relevant to the drug for which the NDA was submitted to the FDA. The FDA automatically lists the NDA holder’s disclosed patents pursuant to 21 U.S.C. §§ 355(b)(1) and (c)(2) in the Orange Book.

**ANSWER:** Paragraph 15 states legal conclusions for which no answer is required. To the extent that an answer is required, Axsome admits that 21 U.S.C. §§ 355(b)(1) and (c)(2)

contain statutory provisions relating to the filing, contents, and/or approval of New Drug Applications, refers to the statute for the terms thereof, and, except as so admitted, denies the allegations of paragraph 15.

16. Upon information and belief, Plaintiffs caused the patent-in-suit to be listed in the Orange Book in connection with NDA No. 211230.

**ANSWER:** Axsome admits that it submitted the '016 patent to the FDA for listing in the Orange Book in connection with NDA No. 211230, and, except as so admitted, denies the allegations of paragraph 16.

17. Aurobindo submitted ANDA No. 218725 (Aurobindo's ANDA) to the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Aurobindo's ANDA Product within the United States at some time after approval by the FDA and referenced NDA No. 211230. As part of Aurobindo's ANDA, Aurobindo submitted a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV), commonly called a "paragraph IV certification," that the patent-in-suit is invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, or sale of Aurobindo's ANDA Product.

**ANSWER:** Axsome admits on information and belief that Aurobindo submitted Abbreviated New Drug Application ("ANDA") No. 218725 ("Aurobindo's ANDA") to the United States Food and Drug Administration ("FDA") seeking approval to engage in the commercial manufacture, use, sale, or offer for sale in, or importation into, the United States of a generic version of Axsome's solriamfetol oral tablets drug products prior to the expiration of the '016 patent. Axsome further admits on information and belief that, in connection with the submission of its ANDA as described above, Aurobindo provided a written certification to the FDA, as called for by Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Aurobindo's Paragraph IV Certification"), alleging that the claims of the '016 patent are invalid and/or will not be infringed by the activities described in Aurobindo's ANDA, but Axsome denies the legitimacy of Aurobindo's allegations. Except as so admitted, Axsome denies the allegations of paragraph 17.

18. On August 10, 2023, Aurobindo sent Axsome written notice that Aurobindo had filed ANDA No. 218725 seeking approval to market Aurobindo's ANDA Product prior to the expiration of the '715 patent, the '151 patent, the '609 patent, the '597 patent, the '976 patent, the '779 patent, the '354 patent and the '232 patent, pursuant to FFD&C Act, 21 U.S.C. § 355(j)(2)(B) (the "August Paragraph IV notice letter"). The August Paragraph IV notice letter included Aurobindo's allegations that the patents are invalid and/or not infringed by Aurobindo's ANDA Product.

**ANSWER:** Paragraph 18 states legal conclusions for which no answer is required. To the extent that an answer is required, Axsome admits that no earlier than August 10, 2023, Aurobindo sent a written notice of Aurobindo's Paragraph IV Certification to Axsome ("Aurobindo's August 10 Notice Letter") alleging that the claims of United States Patent Nos. Nos. 8,440,715 ("the '715 patent"), 10,195,151 ("the '151 patent"), 10,512,609 ("the '609 patent"), 10,959,976 ("the '976 patent"), 11,160,779 ("the '779 patent"), 11,439,597 ("the '597 patent"), 11,560,354 ("the '354 patent"), and 11,648,232 ("the '232 patent") are invalid and/or will not be infringed by the activities described in Aurobindo's ANDA, but Axsome denies the legitimacy of Aurobindo's arguments in Aurobindo's August 10 Notice Letter, and, except as so admitted, denies the allegations of paragraph 18.

19. On or about September 18, 2023, Plaintiff/Counterclaim-Defendant Axsome sued Aurobindo, alleging infringement of the '715 patent, the '151 patent, the '609 patent, the '597 patent, the '976 patent, the '779 patent, the '354 patent and the '232 patent. There has been and is now an actual and justiciable controversy between Aurobindo and Axsome as to whether the drug products described in ANDA No. 218725 infringe, induce infringement, or contribute to the infringement of any valid, enforceable claims of the '715 patent, the '151 patent, the '609 patent, the '597 patent, the '976 patent, the '779 patent, the '354 patent and the '232 patent.

**ANSWER:** Paragraph 19 states legal conclusions for which no answer is required. To the extent that an answer is required, Axsome admits that, on September 13, 2023, it filed a Complaint in the litigation captioned Civil Action No. 23-20354 alleging, *inter alia*, Aurobindo's infringement of the '715 patent, the '151 patent, the '609 patent, the '976 patent, the '779 patent, the '597 patent, the '354 patent, and the '232 patent, including that Aurobindo has infringed and will infringe those patents by submitting ANDA No. 218725 and by making, using, offering to

sell, selling, and/or importing into the United States Aurobindo's Proposed Product, and, except as so admitted, denies the allegations of paragraph 19.

20. On December 8, 2023, Aurobindo sent Axsome written notice that Aurobindo had amended its ANDA No. 218725 to seek approval to market Aurobindo's ANDA Product prior to the expiration of the '666 patent, the '667 patent, the '554 patent and the '776 patent, pursuant to FFD&C Act, 21 U.S.C. § 355(j)(2)(B) (the "December Paragraph IV notice letter"). The December Paragraph IV notice letter included Aurobindo's allegations that the patents are invalid and/or not infringed by Aurobindo's ANDA Product.

**ANSWER:** Paragraph 20 states legal conclusions for which no answer is required. To the extent that an answer is required, Axsome admits that no earlier than December 8, 2023, Aurobindo sent a written notice of Aurobindo's Paragraph IV Certification to Axsome ("Aurobindo's December 8 Notice Letter") alleging that the claims U.S. Patent Nos. 11,771,666 ("the '666 patent"); 11,771,667 ("the '667 patent"); 11,779,554 ("the '554 patent"); and 11,793,776 ("the '776 patent") are invalid and/or will not be infringed by the activities described in Aurobindo's ANDA, but Axsome denies the legitimacy of Aurobindo's arguments in Aurobindo's December 8 Notice Letter, and, except as so admitted, denies the allegations of paragraph 20.

21. On or about January 18, 2024, Plaintiff/Counterclaim-Defendant Axsome sued Aurobindo, alleging infringement of the '666 patent, the '667 patent, the '554 patent and the '776 patent. There has been and is now an actual and justiciable controversy between Aurobindo and Axsome as to whether the drug products described in ANDA No. 218725 infringe, induce infringement, or contribute to the infringement of any valid, enforceable claims of the '666 patent, the '667 patent, the '554 patent and the '776 patent.

**ANSWER:** Paragraph 21 states legal conclusions for which no answer is required. To the extent that an answer is required, Axsome admits that, on January 18, 2024, it filed the Complaint in Civil Action No. 24-00309, which has now been consolidated into the litigation captioned Civil Action No. 23-20354, alleging, *inter alia*, Aurobindo's infringement of the '666 patent, the '667 patent, the '554 patent, and the '776 patent, including that Aurobindo has infringed and will infringe those patents by submitting ANDA No. 218725 and by making,



using, offering to sell, selling, and/or importing into the United States Aurobindo's Proposed Product, and, except as so admitted, denies the allegations of paragraph 21.

22. On February 13, 2024, Aurobindo sent Axsome written notice that Aurobindo had amended its ANDA No. 218725 to seek approval to market Aurobindo's ANDA Product prior to the expiration of the '598 patent, the '226 patent, the '227 patent, the '228 patent, the '528 patent, the '203 patent and the '204 patent, pursuant to FFD&C Act, 21 U.S.C. § 355(j)(2)(B)(the "February 13 Paragraph IV notice letter"). The February 13 Paragraph IV notice letter included Aurobindo's allegations that the patents are invalid and/or not infringed by Aurobindo's ANDA Product.

**ANSWER:** Paragraph 22 states legal conclusions for which no answer is required. To the extent that an answer is required, Axsome admits that no earlier than February 13, 2024, Aurobindo sent a written notice of Aurobindo's Paragraph IV Certification to Axsome ("Aurobindo's February 13 Notice Letter") alleging that the claims of United States Patent Nos. 11,839,598 ("the '598 patent"), 11,850,226 ("the '226 patent"), 11,850,227 ("the '227 patent"), 11,850,228 ("the '228 patent"), 11,857,528 ("the '528 patent"), 11,872,203 ("the '203 patent"), and 11,872,204 ("the '204 patent") are invalid and/or will not be infringed by the activities described in Aurobindo's ANDA, but Axsome denies the legitimacy of Aurobindo's arguments in Aurobindo's February 13 Notice Letter, and, except as so admitted, denies the allegations of paragraph 22.

23. On February 27, 2024, Aurobindo sent Axsome written notice that Aurobindo had amended its ANDA No. 218725 to seek approval to market Aurobindo's ANDA Product prior to the expiration of the '098 patent, pursuant to FFD&C Act, 21 U.S.C. § 355(j)(2)(B)(the "February 27 Paragraph IV notice letter"). The February 27 Paragraph IV notice letter included Aurobindo's allegations that the '098 patent is invalid and/or not infringed by Aurobindo's ANDA Product.

**ANSWER:** Paragraph 23 states legal conclusions for which no answer is required. To the extent that an answer is required, Axsome admits that no earlier than February 27, 2024, Aurobindo sent a written notice of Aurobindo's Paragraph IV Certification to Axsome ("Aurobindo's February 27 Notice Letter") alleging that the claims of United States Patent No.

11,865,098 (“the ’098 patent”) are invalid and/or will not be infringed by the activities described in Aurobindo’s ANDA, but Axsome denies the legitimacy of Aurobindo’s arguments in Aurobindo’s February 27 Notice Letter, and, except as so admitted, denies the allegations of paragraph 23.

24. On or about March 19, 2024, Plaintiff/Counterclaim-Defendant Axsome sued Aurobindo, alleging infringement of the ’598 patent, the ’226 patent, the ’227 patent, the ’228 patent, the ’528 patent, the ’203 patent, the ’204 patent and the ’098 patent. There has been and is now an actual and justiciable controversy between Aurobindo and Axsome as to whether the drug products described in ANDA No. 218725 infringe, induce infringement, or contribute to the infringement of any valid, enforceable claims of the patents.

**ANSWER:** Paragraph 24 states legal conclusions for which no answer is required. To the extent that an answer is required, Axsome admits that, on March 19, 2024, it filed the Complaint in Civil Action No. 24-04002, which has now been consolidated into the litigation captioned Civil Action No. 23-20354, alleging, *inter alia*, Aurobindo’s infringement of the ’598 patent, the ’226 patent, the ’227 patent, the ’228 patent, the ’528 patent, the ’203 patent, the ’204 patent, and the ’098 patent, including that Aurobindo has infringed and will infringe those patents by submitting ANDA No. 218725 and by making, using, offering to sell, selling, and/or importing into the United States Aurobindo’s Proposed Product, and, except as so admitted, denies the allegations of paragraph 24.

25. On May 21, 2024, Aurobindo sent Axsome written notice that Aurobindo had amended its ANDA No. 218725 to seek approval to market Aurobindo’s ANDA Product prior to the expiration of the ’404 patent, pursuant to FFD&C Act, 21 U.S.C. § 355(j)(2)(B)(the “May Paragraph IV notice letter”). The May Paragraph IV notice letter included Aurobindo’s allegations that the ’404 patent is invalid and/or not infringed by Aurobindo’s ANDA Product.

**ANSWER:** Paragraph 25 states legal conclusions for which no answer is required. To the extent that an answer is required, Axsome admits that no earlier than May 21, 2024, Aurobindo sent a written notice of Aurobindo’s Paragraph IV Certification to Axsome (“Aurobindo’s May 21 Notice Letter”) alleging that the claims of United States Patent No.

11,969,404 (“the ’404 patent”) are invalid and/or will not be infringed by the activities described in Aurobindo’s ANDA, but Axsome denies the legitimacy of Aurobindo’s arguments in Aurobindo’s May 21 Notice Letter, and, except as so admitted, denies the allegations of paragraph 25.

26. On or about July 2, 2024, Plaintiff/Counterclaim-Defendant Axsome sued Aurobindo, alleging infringement of the ’404 patent. There has been and is now an actual and justiciable controversy between Aurobindo and Axsome as to whether the drug products described in ANDA No. 218725 infringe, induce infringement, or contribute to the infringement of any valid, enforceable claims of the patent.

**ANSWER:** Paragraph 26 states legal conclusions for which no answer is required. To the extent that an answer is required, Axsome admits that, on July 2, 2024, it filed the Complaint in Civil Action No. 24-07511, which has now been consolidated into the litigation captioned Civil Action No. 23-20354, alleging, *inter alia*, Aurobindo’s infringement of the ’404 patent, including that Aurobindo has infringed and will infringe that patent by submitting ANDA No. 218725 and by making, using, offering to sell, selling, and/or importing into the United States Aurobindo’s Proposed Product, and, except as so admitted, denies the allegations of paragraph 26.

27. On July 9, 2024, Aurobindo sent Axsome written notice that Aurobindo had amended its ANDA No. 218725 to seek approval to market Aurobindo’s ANDA Product prior to the expiration of the ’454 patent, the ’455 patent, the ’639 patent, and the ’036 patent, pursuant to FFD&C Act, 21 U.S.C. § 355(j)(2)(B)(the “July Paragraph IV notice letter”). The July Paragraph IV notice letter included Aurobindo’s allegations that the ’454 patent, the ’455 patent, the ’639 patent, and the ’036 patent are invalid and/or not infringed by Aurobindo’s ANDA Product.

**ANSWER:** Paragraph 27 states legal conclusions for which no answer is required. To the extent that an answer is required, Axsome admits that no earlier than July 9, 2024, Aurobindo sent a written notice of Aurobindo’s Paragraph IV Certification to Axsome (“Aurobindo’s July 9 Notice Letter”) alleging that the claims of United States Patent Nos. 11,986,454 (“the ’454 patent”), 11,986,455 (“the ’455 patent”), 11,998,639 (“the ’639 patent”), and 12,005,036 (“the

'036 patent") are invalid and/or will not be infringed by the activities described in Aurobindo's ANDA, but Axsome denies the legitimacy of Aurobindo's arguments in Aurobindo's July 9 Notice Letter, and, except as so admitted, denies the allegations of paragraph 27.

28. On or about August 21, 2024, Plaintiff/Counterclaim-Defendant Axsome sued Aurobindo, alleging infringement of the '454 patent, the '455 patent, the '639 patent, and the '036 patent. There has been and is now an actual and justiciable controversy between Aurobindo and Axsome as to whether the drug products described in ANDA No. 218725 infringe, induce infringement, or contribute to the infringement of any valid, enforceable claims of the patents.

**ANSWER:** Paragraph 28 states legal conclusions for which no answer is required. To the extent that an answer is required, Axsome admits that, on August 21, 2024, it filed the Complaint in Civil Action No. 24-08624, which has now been consolidated into the litigation captioned Civil Action No. 23-20354, alleging, *inter alia*, Aurobindo's infringement of the '454 patent, the '455 patent, the '639 patent, and the '036 patent, including that Aurobindo has infringed and will infringe those patents by submitting ANDA No. 218725 and by making, using, offering to sell, selling, and/or importing into the United States Aurobindo's Proposed Product, and, except as so admitted, denies the allegations of paragraph 28.

29. On or about September 16, 2024, Plaintiff/Counterclaim-Defendant Axsome sued Aurobindo, alleging infringement of the '194 and '411 patents. There has been and is now an actual and justiciable controversy between Aurobindo and Axsome as to whether the drug products described in ANDA No. 218725 infringe, induce infringement, or contribute to the infringement of any valid, enforceable claims of the patents.

**ANSWER:** Paragraph 29 states legal conclusions for which no answer is required. To the extent that an answer is required, Axsome admits that, on September 16, 2024, it filed the Complaint in Civil Action No. 24-09209, which has now been consolidated into the litigation captioned Civil Action No. 23-20354, alleging, *inter alia*, Aurobindo's infringement of United States Patent Nos. 12,036,194 ("the '194 patent") and 12,064,411 ("the '411 patent"), including that Aurobindo has infringed and will infringe those patents by submitting ANDA No. 218725 and by making, using, offering to sell, selling, and/or importing into the United States

Aurobindo's Proposed Product, and, except as so admitted, denies the allegations of paragraph 29.

30. On or about October 8, 2024, Aurobindo sent Axsome written notice that Aurobindo had amended its ANDA No. 218725 to seek approval to market Aurobindo's ANDA Product prior to the expiration of the '194 patent, the '411 patent and the '126 patent, pursuant to FFD&C Act, 21 U.S.C. § 355(j)(2)(B) (the "October Paragraph IV notice letter"). The October Paragraph IV notice letter included Aurobindo's allegations that the '194 patent, the '411 patent and the '126 patent are invalid and/or not infringed by Aurobindo's ANDA Product.

**ANSWER:** Paragraph 30 states legal conclusions for which no answer is required. To the extent that an answer is required, Axsome admits that no earlier than October 8, 2024, Aurobindo sent a written notice of Aurobindo's Paragraph IV Certification to Axsome ("Aurobindo's October 8 Notice Letter") alleging that the claims of the '194 patent, '411 patent, and United States Patent No. 12,090,126 ("the '126 patent") are invalid and/or will not be infringed by the activities described in Aurobindo's ANDA, but Axsome denies the legitimacy of Aurobindo's arguments in Aurobindo's October 8 Notice Letter, and, except as so admitted, denies the allegations of paragraph 30.

31. On or about November 20, 2024, Plaintiff/Counterclaim-Defendant Axsome sued Aurobindo, alleging infringement of the '126 patent. There has been and is now an actual and justiciable controversy between Aurobindo and Axsome as to whether the drug products described in ANDA No. 218725 infringe, induce infringement, or contribute to the infringement of any valid, enforceable claims of the '126 patent.

**ANSWER:** Paragraph 31 states legal conclusions for which no answer is required. To the extent that an answer is required, Axsome admits that, on November 20, 2024, it filed the Complaint in Civil Action No. 24-10619, alleging, *inter alia*, Aurobindo's infringement of the '126 patent, including that Aurobindo has infringed and will infringe that patent by submitting ANDA No. 218725 and by making, using, offering to sell, selling, and/or importing into the United States Aurobindo's Proposed Product, and, except as so admitted, denies the allegations of paragraph 31.

32. On or about December 10, 2024, Aurobindo sent Axsome written notice that Aurobindo had amended its ANDA No. 218725 to seek approval to market Aurobindo's ANDA Product prior to the expiration of the '609 patent, pursuant to FFD&C Act, 21 U.S.C. § 355(j)(2)(B) (the "December Paragraph IV notice letter"). The December Paragraph IV notice letter included Aurobindo's allegations that the '609 patent are invalid and/or not infringed by Aurobindo's ANDA Product.

**ANSWER:** Paragraph 32 states legal conclusions for which no answer is required. To the extent that an answer is required, Axsome admits that no earlier than December 10, 2024, Aurobindo sent a written notice of Aurobindo's Paragraph IV Certification to Axsome ("Aurobindo's December 10 Notice Letter") alleging that the claims of United States Patent No. 12,102,609 ("the '609 patent") are invalid and/or will not be infringed by the activities described in Aurobindo's ANDA, but Axsome denies the legitimacy of Aurobindo's arguments in Aurobindo's December 10 Notice Letter, and, except as so admitted, denies the allegations of paragraph 32.

33. On or about January 21, 2025, Plaintiff/Counterclaim-Defendant Axsome sued Aurobindo, alleging infringement of the '609 patent. There has been and is now an actual and justiciable controversy between Aurobindo and Axsome as to whether the drug products described in ANDA No. 218725 infringe, induce infringement, or contribute to the infringement of any valid, enforceable claims of the '609 patent.

**ANSWER:** Paragraph 33 states legal conclusions for which no answer is required. To the extent that an answer is required, Axsome admits that, on January 21, 2025, it filed the Complaint in Civil Action No. 25-643, alleging, *inter alia*, Aurobindo's infringement of the '609 patent, including that Aurobindo has infringed and will infringe that patent by submitting ANDA No. 218725 and by making, using, offering to sell, selling, and/or importing into the United States Aurobindo's Proposed Product, and, except as so admitted, denies the allegations of paragraph 33.

34. On or about March 19, 2025, Aurobindo sent Axsome written notice that Aurobindo had amended its ANDA No. 218725 to seek approval to market Aurobindo's ANDA Product prior to the expiration of the '016 patent, pursuant to FFD&C Act, 21 U.S.C. § 355(j)(2)(B) (the "December Paragraph IV notice letter"). The December Paragraph IV notice

letter included Aurobindo's allegations that the '016 patent are invalid and/or not infringed by Aurobindo's ANDA Product.

**ANSWER:** Paragraph 34 states legal conclusions for which no answer is required. To the extent that an answer is required, Axsome admits that no earlier than March 19, 2025, Aurobindo sent a written notice of Aurobindo's Paragraph IV Certification to Axsome ("Aurobindo's March 19 Notice Letter") alleging that the claims of the '016 are invalid and/or will not be infringed by the activities described in Aurobindo's ANDA, but Axsome denies the legitimacy of Aurobindo's arguments in Aurobindo's March 19 Notice Letter, and, except as so admitted, denies the allegations of paragraph 34.

35. Aurobindo and Plaintiff/Counterclaim-Defendant Axsome have adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment with respect to the patent-in-suit. The patent-in-suit effectively delays FDA approval of the drug products described in ANDA No. 218725.

**ANSWER:** Paragraph 35 states legal conclusions for which no answer is required. To the extent that an answer is required, Axsome admits that there is an actual and justiciable controversy between Aurobindo and Axsome regarding the '016 patent, and, except as so admitted, denies the allegations of paragraph 35.

## **COUNT I**

### **(Declaratory Judgment of Alleged Non-Infringement of the '016 Patent by Aurobindo's ANDA Product and Declaratory Judgment of Alleged Invalidity of the '016 Patent)**

36. Aurobindo repeats and incorporates by reference Paragraphs 1-35 of its Counterclaims as if fully set forth herein.

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

37. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 et seq. and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that no valid claim of the '016 patent will be infringed by the manufacture, use, sale, offer for sale, or importation into the United States of Aurobindo's ANDA Product described by ANDA No. 218725 and that all claims of the '016 patent are invalid for failure to comply with

the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, and/or 112, or other judicially-created bases for invalidation and unenforceability.

**ANSWER:** Paragraph 37 states legal conclusions for which no answer is required. To the extent that an answer is required, Axsome admits that Aurobindo's counterclaim purports to seek declarations of non-infringement and invalidity for the '016 patent, but Axsome denies the legal sufficiency of Aurobindo's counterclaim, denies that Aurobindo is entitled to the declarations it seeks, and, except as so admitted, denies the allegations of paragraph 37.

38. In Aurobindo's various Paragraph IV notice letters, Aurobindo provided reasons sufficient to show that Aurobindo's ANDA Product described by ANDA No. 218725 does not infringe any valid claim of the '016 patent.

**ANSWER:** Axsome denies the allegations of paragraph 38.

39. There is an actual, substantial, and continuing justiciable case or controversy between the parties having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment concerning whether the manufacture, use, sale, offering for sale, or importation of Aurobindo's ANDA Product described by ANDA No. 218725 will infringe any valid and enforceable claim of the '016 patent.

**ANSWER:** Paragraph 39 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 Aurobindo regarding the '016 patent, and, except as so admitted, denies the allegations of paragraph 39.

40. Aurobindo is entitled to a judicial declaration that the manufacture, use, sale, offering for sale, or importation of Aurobindo's ANDA Product described by ANDA No. 218725 will not infringe, directly or indirectly, any valid claim of the '016 patent.

**ANSWER:** Axsome denies the allegations of paragraph 40.

#### **AUROBINDO'S PRAYER FOR RELIEF**

Axsome denies that Aurobindo 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 Aurobindo’s Counterclaims:

**Failure to State a Claim**

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

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