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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

AXSOME THERAPEUTICS, INC. and ANTECIP BIOVENTURES II LLC, **Plaintiffs,** **v.** **TEVA PHARMACEUTICALS, INC.** **Defendant.**	**Civil Action No. 2:23-cv-23142 (MEF-LDW)** **(Filed Electronically)**

DEFENDANT TEVA PHARMACEUTICALS, INC.'S ANSWER TO COMPLAINT, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS

Defendant Teva Pharmaceuticals, Inc. ("Teva" or "Defendant") hereby answers the Complaint for Patent Infringement of Plaintiffs Axsome Therapeutics, Inc. ("Axsome") and Antecip Bioventures II LLC ("Antecip") (collectively, "Plaintiffs"), as set forth below. This pleading is based upon Teva's knowledge as to its own activities, and upon information and belief as to the activities of others. Teva denies all allegations except those specifically admitted below. *See* Fed. R. Civ. P. 8(b)(3).

Nature Of The Action[1]

Complaint ¶ 1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. §100, *et seq*., arising from the Defendant's filing of its Abbreviated New Drug Application ("ANDA") No. 218147 ("Teva's ANDA") with the United States Food and Drug Administration ("FDA") seeking approval to commercially market a generic version of Plaintiffs' dextromethorphan hydrobromide and bupropion hydrochloride extended-release tablets prior to the expiration of United States Patent Nos. 11,717,518 ("the '518 patent"), 11,730,706 ("the '706 patent"), and 11,752,144 ("the '144 patent") (collectively, "the patents-in-suit"), all owned by Antecip and exclusively licensed to Axsome.

ANSWER: Paragraph 1 states legal conclusions to which no response is required. To the extent a response is required, Teva admits that Plaintiffs purport to bring an action for patent infringement under patent laws of the United States. Teva further admits that Teva submitted Abbreviated New Drug Application ("ANDA") No. 218147 ("Teva's ANDA") to the U.S. Food and Drug Administration ("FDA") seeking approval for generic dextromethorphan hydrobromide and bupropion hydrochloride extended-release tablets ("the Teva ANDA Product"). Except as expressly admitted, Teva denies the remaining allegations of Paragraph 1.

The Parties

Complaint ¶ 2. Axsome is a biopharmaceutical company focused on discovering, developing, and commercializing novel therapeutics for central nervous system ("CNS") conditions that have limited treatment options.

ANSWER: Teva lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 2, and therefore denies them.

Complaint ¶ 3. Axsome is a corporation existing under the laws of Delaware, having a principal place of business at One World Trade Center, 22nd Floor, New York, NY 10007.

[1] For ease of reference, Teva includes the headings contained in Plaintiffs' Complaint. Although Teva believes that no response is necessary for each of those headings, to the extent a response is required and that the headings could be construed to contain factual allegations, Teva denies the allegations.

ANSWER: Teva lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 3, and therefore denies them.

Complaint ¶ 4. Antecip is a limited liability corporation existing under the laws of Delaware, having a principal place of business at 630 Fifth Avenue, Suite 200, New York, NY 10111.

ANSWER: Teva lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 4, and therefore denies them.

Complaint ¶ 5. On information and belief, Teva is a corporation organized and existing under the laws of Delaware, having a principal place of business at 400 Interpace Parkway, Suite A1, Parsippany, New Jersey 07054.

ANSWER: Teva admits that it is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 400 Interpace Parkway, Parsippany, NJ 07054.

The Patents-in-Suit

Complaint ¶ 6. On August 8, 2023, the United States Patent and Trademark Office ("USPTO") duly and lawfully issued the '518 patent, entitled, "Bupropion Dosage Forms with Reduced Food and Alcohol Dosing Effects." The face of the '518 patent identifies Dr. Herriot Tabuteau as the inventor. Antecip is the present assignee of the '518 patent; the assignment is recorded with the USPTO at Reel: 063524, Frame: 0142. Axsome is the exclusive licensee of the '518 patent. A copy of the '518 patent is attached hereto as Exhibit A.

ANSWER: Paragraph 6 states legal conclusions to which no response is required. To the extent a response is required, Teva admits that Exhibit A of the Complaint purports to be a copy of United States Patent No. 11,717,518 ("the '518 patent"). Teva admits that the face of the '518 patent lists the title as "Bupropion Dosage Forms with Reduced Food and Alcohol Dosing Effects," and August 8, 2023 as the issue date. Teva also admits that the face of the '518 patent lists Dr. Herriot Tabuteau as the inventor and Antecip as the assignee of the '518 patent. To the extent a further response is required, Teva lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 6, and therefore denies them.

Complaint ¶ 7. On August 22, 2023, the USPTO duly and lawfully issued the '706 patent, entitled, "Treatment of Depression in Certain Patient Populations." The face of the '706 patent identifies Dr. Herriot Tabuteau as the inventor. Antecip is the present assignee of the '706 patent; the assignment is recorded with the USPTO at Reel: 063524, Frame: 0142. Axsome is the exclusive licensee of the '706 patent. A copy of the '706 patent is attached hereto as Exhibit B.

ANSWER: Paragraph 7 states legal conclusions to which no response is required. To the extent a response is required, Teva admits that Exhibit B of the Complaint purports to be a copy of United States Patent No. 11,730,706 ("the '706 patent"). Teva admits that the face of the '706 patent lists the title as "Treatment of Depression in Certain Patient Populations," and August 22, 2023 as the issue date. Teva also admits that the face of the '706 patent lists Dr. Herriot Tabuteau as the inventor and Antecip as the assignee of the '706 patent. To the extent a further response is required, Teva lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 7, and therefore denies them.

Complaint ¶ 8. On September 12, 2023, the USPTO duly and lawfully issued the '144 patent, entitled, "Compounds and Combinations Thereof for Treating Neurological and Psychiatric Conditions." The face of the '144 patent identifies Dr. Herriot Tabuteau as the inventor. Antecip is the present assignee of the '144 patent; the assignment is recorded with the USPTO at Reel: 063524, Frame: 0142. Axsome is the exclusive licensee of the '144 patent. A copy of the '144 patent is attached hereto as Exhibit C.

ANSWER: Paragraph 8 states legal conclusions to which no response is required. To the extent a response is required, Teva admits that Exhibit C of the Complaint purports to be a copy of United States Patent No. 11,752,144 ("the '144 patent"). Teva admits that the face of the '144 patent lists the title as "Bupropion as a Modulator of Drug Activity" and February 23, 2021 as the issue date. Teva also admits that the face of the '144 patent lists Dr. Herriot Tabuteau as the inventor and Antecip as the assignee of the '144 patent. To the extent a further response is required, Teva lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 8, and therefore denies them.

The Auvelity® Drug Product

Complaint ¶ 9. Axsome holds an approved New Drug Application ("NDA") under Section 505(a) of the Federal Food Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 355(a), for dextromethorphan hydrobromide and bupropion hydrochloride extended-release tablets ("NDA No. 215430"), which is sold under the trade name Auvelity®. Auvelity® is a combination of dextromethorphan, an uncompetitive N-methyl D-aspartate ("NMDA") receptor antagonist and sigma-1 receptor agonist, and bupropion, an aminoketone and CYP450 2D6 inhibitor, approved in adult patients for the treatment of major depressive disorder ("MDD"). The claims of the patents-in-suit cover, *inter alia*, methods of using dextromethorphan and bupropion to treat MDD.

ANSWER: Teva admits that the Orange Book entry for NDA No. 215430 for dextromethorphan hydrobromide and bupropion hydrochloride extended-release tablets, sold under the trade name Auvelity®, lists Axsome Therapeutics, Inc. as the applicant holder. Teva admits that the Orange Book lists the "active ingredients" for Auvelity® as "bupropion hydrocholoride; dextromethorphan hydrobromide." To the extent a further response is required, Teva lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 9, and therefore denies them.

Complaint ¶ 10. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the patents-in-suit are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to Auvelity®.

ANSWER: Teva admits that the Orange Book entry for NDA No. 215430 for dextromethorphan hydrobromide and bupropion hydrochloride extended-release tablets, sold under the trade name Auvelity®, identifies the '518 patent, the '706 patent, and the '144 patent, among other patents. To the extent a further response is required, Teva lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 10, and therefore denies them.

Jurisdiction and Venue

Complaint ¶ 11. This Court has jurisdiction over the subject matter of Counts I through III against Teva pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

ANSWER: Paragraph 11 states legal conclusions to which no response is required. To the extent a response is deemed required, for purposes of this case only, Teva does not contest that this Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202. Teva denies any remaining allegations in Paragraph 11.

Complaint ¶ 12. As set forth in Paragraphs 13-17 below, the Court has personal jurisdiction over Teva by virtue of, *inter alia*, its systematic and continuous contacts with the State of New Jersey.

ANSWER: Paragraph 12 states legal conclusions to which no response is required. To the extent a response is required, for the purposes of this case only, solely to conserve the resources of the parties and the Court, Teva does not contest personal jurisdiction in this Judicial District. Teva denies any remaining allegations Paragraph 12.

Complaint ¶ 13. On information and belief, Teva purposefully has conducted and continues to conduct business in this Judicial District.

ANSWER: Paragraph 13 states legal conclusions to which no response is required. To the extent a response is required, for the purposes of this case only, solely to conserve the resources of the parties and the Court, Teva does not contest personal jurisdiction in this Judicial District. Teva denies any remaining allegations Paragraph 13.

Complaint ¶ 14. On information and belief, Teva is in the business of, among other things, manufacturing, marketing, importing, offering for sale, and selling pharmaceutical products, including generic drug products, throughout the United States, including in this Judicial District.

ANSWER: Teva admits that it develops, manufactures, and sells pharmaceutical products in the United States. For the purposes of this case only, solely to conserve the resources of the parties and the Court, Teva does not contest personal jurisdiction in this Judicial District. Teva denies any remaining allegations in Paragraph 14.

Complaint ¶ 15. On information and belief, this Judicial District will be a destination for the generic version of Plaintiffs' dextromethorphan hydrobromide and bupropion hydrochloride extended-release tablets for which Teva seeks FDA approval to manufacture,

market, import, offer for sale, and/or sell pursuant to ANDA No. 218147 ("Teva's Proposed Product").

ANSWER: Paragraph 15 states legal conclusions to which no response is required. For the purposes of this case only, solely to conserve the resources of the parties and the Court, Teva does not contest personal jurisdiction in this Judicial District. Teva denies any remaining allegations in Paragraph 15.

Complaint ¶ 16. On information and belief, Teva maintains a physical place of business in this Judicial District, in at least Parsippany, New Jersey. Teva's website states that its "US Headquarters" is located in Parsippany, New Jersey. *See* https://www.tevausa.com/contact-us/ (last visited, December 14, 2023). In recent court filings, Teva has admitted that it has a "a principal place of business" in Parsippany, New Jersey. *See, e.g., Neurocrine Biosci., Inc. v. Teva Pharms., Inc., et al.*, No. 22-cv-965, ECF No. 14 at ¶ 12 (D. Del. Nov. 1, 2022).

ANSWER: Teva admits that it has a principal place of business in Parsippany, New Jersey. The website available at https://www.tevausa.com/contact-us/ speaks for itself and is the best source for its content. To the extent a further response is required, Teva denies any remaining allegations in Paragraph 16.

Complaint ¶ 17. On information and belief, Teva is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business ID No. 0450614134.

ANSWER: Teva admits that it is registered as a business operating in New Jersey with Entity ID No. 0450614134. To the extent any further response is required, the State of New Jersey's Division of Revenue and Enterprise Services record speaks for itself and is the best source of information. Teva denies any remaining allegations in Paragraph 17.

Complaint ¶ 18. For at least the foregoing reasons set forth above in Paragraphs 13-17 above, venue is proper in this Judicial District with respect to Teva pursuant to 28 U.S.C. § 1400(b).

ANSWER: Paragraph 18 states legal conclusions to which no response is required. To the extent a response is required, for the purposes of this case only, solely to conserve the resources of the parties and the Court, Teva does not contest venue in this Judicial District.

Acts Giving Rise To Counts I-III

Complaint ¶ 19. Pursuant to Section 505 of the FFDCA, Teva filed ANDA No. 218147 seeking approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of Teva's Proposed Product, before the patents-in-suit expire.

ANSWER: Teva admits that it submitted Teva's ANDA to the FDA. To the extent a further response is required, Teva's ANDA speaks for itself and is the best source for its content. Teva denies any remaining allegations in Paragraph 19.

Complaint ¶ 20. No earlier than February 9, 2023, Teva sent written notice of its first Paragraph IV Certification ("Teva's First Notice Letter") to Axsome. According to Teva's First Notice Letter, Teva filed an ANDA pursuant to Section 505 of the FFDCA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Teva's Proposed Product before expiration of United States Patent Nos. 10,780,064 (the "'064 patent"), 10,925,842 (the "'842 patent"), 10,940,124 (the "'124 patent"), and 10,966,942 (the "'942 patent"). Teva's First Notice Letter alleged that the claims of '064, '842, '124, and '942 patents are invalid, unenforceable, and/or will not be infringed by the activities described in Teva's ANDA.

ANSWER: Teva admits that it sent written notice pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act to Axsome on February 9, 2023 ("Teva's Notice Letter"). To the extent a further response is required, Teva's First Notice Letter speaks for itself and is the best source for its content. Teva denies any remaining allegations in Paragraph 20.

Complaint ¶ 21. No earlier than November 2, 2023, Teva sent written notice of its second Paragraph IV Certification ("Teva's Second Notice Letter") to Axsome. According to Teva's Second Notice Letter, Teva seeks approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Teva's Proposed Product before expiration of the '518, '706, and '144 patents. Teva's Second Notice Letter alleged that the claims of the '518, '706, and '144 patents are invalid, unenforceable, and/or will not be infringed by the activities described in Teva's ANDA.

ANSWER: Teva admits that it sent written notice pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act to Axsome on November 2, 2023 ("Teva's Second Notice Letter"). To the extent a further response is required, Teva's Second Notice Letter speaks for itself and is the best source for its content. Teva denies any remaining allegations in Paragraph 21.

Complaint ¶ 22. On information and belief, in connection with the filing of its ANDA as described above, Teva provided written certifications to the FDA, as called for by Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Teva's Paragraph IV Certifications"), alleging that the claims of the '064, '842, '124, '942, '518, '706, and '144 patents are invalid, unenforceable, and/or will not be infringed by the activities described in Teva's ANDA.

ANSWER: Teva admits that it sent written certifications to the FDA pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Teva's Paragraph IV Certifications"). To the extent any further response is required, Teva's Paragraph IV Certifications speaks for itself and is the best source for its content. Teva denies any remaining allegations in Paragraph 22.

Complaint ¶ 23. On information and belief, following FDA approval of Teva's ANDA, unless enjoined by the Court, Teva will make, use, offer to sell, or sell Teva's Proposed Product throughout the United States, or import such a generic product into the United States.

ANSWER: Paragraph 23 states legal conclusions to which no response is required. To the extent a response is required, Teva lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 23, and therefore denies them.

Count I: Infringement of the '518 Patent by Teva

Complaint ¶ 24. Plaintiffs repeat and reallege the allegations of the preceding paragraphs as if fully set forth herein.

ANSWER: Teva repeats and incorporates here by reference its responses to the preceding paragraphs.

Complaint ¶ 25. Teva's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Teva's Proposed Product, prior to the expiration of the '518 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claims 1 and 4.

ANSWER: Paragraph 25 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 26. A justiciable controversy exists between the parties hereto as to the infringement of the '518 patent.

ANSWER: Paragraph 26 states legal conclusions to which no response is required. To the extent a response is required, Teva admits that because of Plaintiffs' Complaint against Teva, there is an actual, substantial, and justiciable controversy between the parties as to the infringement, validity, and enforceability of the '518 patent.

Complaint ¶ 27. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will infringe one or more claims of the '518 patent under 35 U.S.C. § 271(a), including at least claims 1 and 4, by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in the United States.

ANSWER: Paragraph 27 states legal conclusions to which no response is required. To the extent a response is required, Teva denies that the Teva ANDA Product will infringe any valid or enforceable claim of the '518 patent.

Complaint ¶ 28. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will induce infringement of one or more claims of the '518 patent under 35 U.S.C. § 271(b), including at least claims 1 and 4, by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in the United States. On information and belief, upon FDA approval of Teva's ANDA, Teva will intentionally encourage acts of direct infringement with knowledge of the '518 patent and knowledge that its acts are encouraging infringement.

ANSWER: Paragraph 28 states legal conclusions to which no response is required. To the extent a response is required, Teva denies that Teva will induce infringement of any valid or enforceable claim of the '518 patent

Complaint ¶ 29. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will contributorily infringe one or more claims of the '518 patent under 35 U.S.C. § 271(c), including at least claims 1 and 4, by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in the United States. On information and belief, Teva knew and knows that Teva's Proposed Product is designed for a use that infringes one or more claims of the '518 patent, and Teva's Proposed Product lacks a substantial non-infringing use.

ANSWER: Paragraph 29 states legal conclusions to which no response is required. To the extent a response is required, Teva denies that Teva will contributorily infringe any valid or enforceable claim of the '518 patent.

Complaint ¶ 30. Failure to enjoin Teva's infringement of the '518 patent will substantially and irreparably damage Plaintiffs.

ANSWER: Paragraph 30 states legal conclusions to which no response is required. To the extent a response is required, Teva denies the allegations in Paragraph 30.

Complaint ¶ 31. Plaintiffs do not have an adequate remedy at law.

ANSWER: Paragraph 31 states legal conclusions to which no response is required. To the extent a response is required, Teva denies the allegations in Paragraph 31.

Count II: Infringement of the '706 Patent by Teva

Complaint ¶ 32. Plaintiffs repeat and reallege the allegations of the preceding paragraphs as if fully set forth herein.

ANSWER: Teva repeats and incorporates here by reference its responses to the preceding paragraphs.

Complaint ¶ 33. Teva's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Teva's Proposed Product, prior to the expiration of the '706 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claims 1 and 9.

ANSWER: Paragraph 33 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 34. A justiciable controversy exists between the parties hereto as to the infringement of the '706 patent.

ANSWER: Paragraph 34 states legal conclusions to which no response is required. To the extent a response is required, Teva admits that because of Plaintiffs' Complaint against Teva, there is an actual, substantial, and justiciable controversy between the parties as to the infringement, validity, and enforceability of the '706 patent.

Complaint ¶ 35. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will infringe one or more claims of the '706 patent under 35 U.S.C. § 271(a), including at least claims 1 and 9, by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in the United States.

ANSWER: Paragraph 35 states legal conclusions to which no response is required. To the extent a response is required, Teva denies that the Teva ANDA Product will infringe any valid or enforceable claim of the '706 patent.

Complaint ¶ 36. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will induce infringement of one or more claims of the '706 patent under 35 U.S.C. § 271(b), including at least claims 1 and 9, by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in the United States. On information and belief, upon FDA approval of Teva's ANDA, Teva will intentionally encourage acts of direct infringement with knowledge of the '706 patent and knowledge that its acts are encouraging infringement.

ANSWER: Paragraph 36 states legal conclusions to which no response is required. To the extent a response is required, Teva denies that Teva will induce infringement of any valid or enforceable claim of the '706 patent.

Complaint ¶ 37. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will contributorily infringe one or more claims of the '706 patent under 35 U.S.C. § 271(c), including at least claims 1 and 9, by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in the United States. On information and belief, Teva knew and knows that Teva's Proposed Product is designed for a use that infringes one or more claims of the '706 patent, and Teva's Proposed Product lacks a substantial non-infringing use.

ANSWER: Paragraph 37 states legal conclusions to which no response is required. To the extent a response is required, Teva denies that Teva will contributorily infringe any valid or enforceable claim of the '706 patent.

Complaint ¶ 38. Failure to enjoin Teva's infringement of the '706 patent will substantially and irreparably damage Plaintiffs.

ANSWER: Paragraph 38 states legal conclusions to which no response is required. To the extent a response is required, Teva denies the allegations in Paragraph 38.

Complaint ¶ 39. Plaintiffs do not have an adequate remedy at law.

ANSWER: Paragraph 39 states legal conclusions to which no response is required. To the extent a response is required, Teva denies the allegations in Paragraph 39.

Count III: Infringement of the '144 Patent by Teva

Complaint ¶ 40. Plaintiffs repeat and reallege the allegations of the preceding paragraphs as if fully set forth herein.

ANSWER: Teva repeats and incorporates here by reference its responses to the preceding paragraphs

Complaint ¶ 41. Teva's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Teva's Proposed Product, prior to the expiration of the '144 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

ANSWER: Paragraph 41 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 42. A justiciable controversy exists between the parties hereto as to the infringement of the '144 patent.

ANSWER: Paragraph 42 states legal conclusions to which no response is required. To the extent a response is required, Teva admits that because of Plaintiffs' Complaint against Teva, there is an actual, substantial, and justiciable controversy between the parties as to the infringement, validity, and enforceability of the '144 patent.

Complaint ¶ 43. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will infringe one or more claims of the '144 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in the United States.

ANSWER: Paragraph 43 states legal conclusions to which no response is required. To the extent a response is required, Teva denies that the Teva ANDA Product will infringe any valid or enforceable claim of the '144 patent

Complaint ¶ 44. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will induce infringement of one or more claims of the '144 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in the United States. On information and belief, upon FDA approval of Teva's ANDA, Teva will intentionally encourage acts of direct infringement with knowledge of the '144 patent and knowledge that its acts are encouraging infringement.

ANSWER: Paragraph 44 states legal conclusions to which no response is required. To the extent a response is required, Teva denies that Teva will induce infringement of any valid or enforceable claim of the '144 patent.

Complaint ¶ 45. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will contributorily infringe one or more claims of the '144 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in the United States. On information and belief, Teva knew and knows that Teva's Proposed Product is designed for a use that infringes one or more claims of the '144 patent, and Teva's Proposed Product lacks a substantial non-infringing use.

ANSWER: Paragraph 45 states legal conclusions to which no response is required. To the extent a response is required, Teva denies that Teva will contributorily infringe any valid or enforceable claim of the '144 patent.

Complaint ¶ 46: Failure to enjoin Teva's infringement of the '144 patent will substantially and irreparably damage Plaintiffs.

ANSWER: Paragraph 46 states legal conclusions to which no response is required. To the extent a response is required, Teva denies the allegations in Paragraph 46.

Complaint ¶ 47. Plaintiffs do not have an adequate remedy at law.

ANSWER: Paragraph 47 states legal conclusions to which no response is required. To the extent a response is required, Teva denies the allegations in Paragraph 47.

PLAINTIFFS' PRAYER FOR RELIEF

The remainder of Plaintiffs' Complaint recites a prayer for relief to which no response is required. To the extent a response is required, Teva denies that Plaintiffs are entitled to any remedy or relief, including those requested.

AFFIRMATIVE DEFENSES

Without any admission as to the burden of proof, burden of persuasion, or the truth of any allegation in Plaintiffs' Complaint, and expressly reserving its right to assert additional defenses, Teva states the following affirmative defenses:

First Affirmative Defense

The manufacture, use, sale, offer for sale, or importation of the Teva ANDA Product will not infringe, directly or indirectly, any valid or enforceable claim of the patents-in-suit.

Second Affirmative Defense

The filing of Teva's ANDA has not infringed, and will not infringe, directly or indirectly, any valid or enforceable claim of the patents-in-suit.

Third Affirmative Defense

The claims of the patents-in-suit are invalid and/or unenforceable for failure to satisfy the statutory provisions of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, 111, 112, 116, 135, 251, 256, and 287, and/or the doctrine of obviousness-type double patenting, and/or judicially created doctrines of invalidity or unenforceability.

Fourth Affirmative Defense

The Complaint fails to state a claim for willful infringement.

Fifth Affirmative Defense

The relief requested in the Complaint is barred by the doctrines of res judicata, estoppel, laches, unclean hands, and/or waiver.

Sixth Affirmative Defense

Teva's actions in defending this case do not give rise to an exceptional case under 35 U.S.C. § 285.

Seventh Affirmative Defense

Any additional defenses or counterclaims that discovery may reveal.

* * *

COUNTERCLAIMS

Without admitting any of Plaintiffs' allegations other than those expressly admitted herein, and without prejudice to the rights of Defendant to plead additional Counterclaims as the facts of the matter warrant, Defendant Teva Pharmaceuticals, Inc. ("Teva" or "Counterclaim-Plaintiff") hereby asserts the following Counterclaims against Axsome Therapeutics, Inc. ("Axsome") and Antecip Bioventures II LLC ("Antecip") (collectively, "Counterclaim-Defendants").

PARTIES

1. Teva is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 400 Interpace Parkway, Parsippany, NJ 07054.

2. On information and belief, Axsome is a corporation existing under the laws of Delaware, having a principal place of business at 22 Cortland Street, 16th Floor, New York, NY 10007.

3. On information and belief, Antecip is a limited liability corporation existing under the laws of Delaware, having a principal place of business at 630 Fifth Avenue, Suite 200, New York, NY 10111.

JURISDICTION AND VENUE

4. These Counterclaims arise 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.

5. The Court has original jurisdiction over the subject matter of these Counterclaims pursuant to 28 U.S.C. §§ 1331 and 1338(a).

6. This Court has personal jurisdiction over Counterclaim-Defendants because Counterclaim-Defendants have availed themselves of the rights and privileges, and have subjected themselves to the jurisdiction, of this Court by filing this action and/or because Counterclaim-

Defendants conduct substantial business in, and have regular and systematic contacts with, this District.

7. Venue is proper in this District under 28 U.S.C. §§ 1391(b) and 1400(b).

FACTUAL BACKGROUND

8. According to the United States Food and Drug Administration ("FDA") publication entitled Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book"), Axsome is the holder of New Drug Application ("NDA") No. 215430 for Auvelity®, a combination of dextromethorphan hydrobromide and bupropion hydrocholoride.

9. NDA holders are required to disclose to the FDA the patent numbers of patents claiming the drug or method of using such drug for which the NDA is submitted. The FDA lists these patents in the Orange Book.

10. As of January 18,2024, the Orange Book entry for Auvelity® lists 106 patents. Three of these patents include United States Patent Nos. 11,717,518 ("the '0518 patent"), 11,730,706 ("the '706 patent"), and 11,752,144 ("the '144 patent") (collectively, "the patents-in-suit").

11. The face of the '518 patent lists the title as "Bupropion Dosage Forms with Reduced Food and Alcohol Dosing Effects," the issue date as August 8, 2023, and the assignee as Antecip.

12. The face of the '706 patent lists the title as "Treatment of Depression in Certain Patient Populations," the issue date as August 22, 2023, and the assignee as Antecip.

13. The face of the '144 patent lists the title as "Compounds and Combinations Thereof for Treating Neurological and Psychiatric Conditions," the issue date as September 12, 2023, and the assignee as Antecip.

14. Antecip purports to own, and to have the right to enforce, the patents-in-suit.

15. Axsome purports to be an exclusive licensee of the patents-in-suit and to have the right to enforce the patents in-suit.

16. Teva submitted Abbreviated New Drug Application ("ANDA") No. 218147 ("Teva's ANDA") to the FDA under 21 U.S.C. § 355(j) seeking approval to market Teva's proposed Dextromethorphan Hydrobromide and Bupropion Hydrochloride Extended-release Tablets, 45 mg/105 mg ("the Teva ANDA Product"). Teva submitted Teva's ANDA to the FDA with a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the patents-in-suit.

17. Teva sent notice of this certification to Counterclaim-Defendants on or about November 2, 2023 ("Teva's Notice Letter"). On information and belief, and as Counterclaim-Defendants allege in the Complaint, Counterclaim-Defendants received Teva's Notice Letter.

18. On December 15, 2024, Counterclaim-Defendants filed suit in this Judicial District against Teva in connection with Teva's ANDA, alleging Teva's infringement of the patents-in-suit.

FIRST COUNTERCLAIM

Declaratory Judgment of Noninfringement of the '518 Patent

19. Teva repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

20. The manufacture, use, sale, offer for sale, and/or importation of the Teva ANDA Product has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '518 patent, either directly or indirectly.

21. Teva has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the '518 patent.

22. There is an actual, substantial, and continuing justiciable controversy between Teva and Counterclaim-Defendants of sufficient immediacy and reality to warrant the issuance of a declaratory judgement regarding Teva's non-infringement of the '518 patent.

23. Teva is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the Teva ANDA Product has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '518 patent, either directly or indirectly.

SECOND COUNTERCLAIM

Declaratory Judgment of Invalidity or Unenforceability of the '518 Patent

24. Teva repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

25. The claims of the '518 patent are invalid and/or unenforceable for failure to comply with one or more of the conditions of patentability set forth in Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, 111, 112, 116, 135, 251, 256, and 287, and/or the doctrine of obviousness-type double patenting, and/or judicially created doctrines of invalidity or unenforceability.

26. There is an actual, substantial, and continuing justiciable case or controversy between Teva and Counterclaim-Defendants of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding the invalidity and/or unenforceability of the '518 patent.

27. Teva is entitled to a judicial declaration that the claims of the '518 patent are invalid and/or unenforceable.

THIRD COUNTERCLAIM

Declaratory Judgment of Noninfringement of the '706 Patent

28. Teva repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

29. The manufacture, use, sale, offer for sale, and/or importation of the Teva ANDA Product has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '706 patent, either directly or indirectly.

30. Teva has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the '706 patent.

31. There is an actual, substantial, and continuing justiciable controversy between Teva and Counterclaim-Defendants of sufficient immediacy and reality to warrant the issuance of a declaratory judgement regarding Teva's non-infringement of the '706 patent.

32. Teva is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the Teva ANDA Product has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '706 patent, either directly or indirectly.

FOURTH COUNTERCLAIM

Declaratory Judgment of Invalidity or Unenforceability of the '706 Patent

33. Teva repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

34. The claims of the '706 patent are invalid and/or unenforceable for failure to comply with one or more of the conditions of patentability set forth in Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, 111, 112, 116, 135, 251, 256, and

287, and/or the doctrine of obviousness-type double patenting, and/or judicially created doctrines of invalidity or unenforceability.

35. There is an actual, substantial, and continuing justiciable case or controversy between Teva and Counterclaim-Defendants of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding the invalidity and/or unenforceability of the '706 patent.

36. Teva is entitled to a judicial declaration that the claims of the '706 patent are invalid and/or unenforceable.

FIFTH COUNTERCLAIM

Declaratory Judgment of Noninfringement of the '144 Patent

37. Teva repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

38. The manufacture, use, sale, offer for sale, and/or importation of the Teva ANDA Product has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '144 patent, either directly or indirectly.

39. Teva has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the '144 patent.

40. There is an actual, substantial, and continuing justiciable controversy between Teva and Counterclaim-Defendants of sufficient immediacy and reality to warrant the issuance of a declaratory judgement regarding Teva's non-infringement of the '144 patent.

41. Teva is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the Teva ANDA Product has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '144 patent, either directly or indirectly.

SIXTH COUNTERCLAIM

Declaratory Judgment of Invalidity or Unenforceability of the '144 Patent

42. Teva repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

43. The claims of the '144 patent are invalid and/or unenforceable for failure to comply with one or more of the conditions of patentability set forth in Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, 111, 112, 116, 135, 251, 256, and 287, and/or the doctrine of obviousness-type double patenting, and/or judicially created doctrines of invalidity or unenforceability.

44. There is an actual, substantial, and continuing justiciable case or controversy between Teva and Counterclaim-Defendants of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding the invalidity and/or unenforceability of the '144 patent.

45. Teva is entitled to a judicial declaration that the claims of the '144 patent are invalid and/or unenforceable.

PRAYER FOR RELIEF

WHEREFORE, Teva requests judgment in its favor and against Counterclaim-Defendants:

A. declaring that the manufacture, use, sale, offer for sale, and/or importation of the Teva ANDA Product, that is the subject of ANDA No. 218147, has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the patents-in-suit, either directly or indirectly;

B. declaring that the claims of the patents-in-suit are invalid and/or unenforceable;

C. ordering that judgment be entered in favor of Teva and that Counterclaim-Defendants' Complaint be dismissed with prejudice;

D. declaring this case exceptional and awarding Teva its reasonable attorneys' fees and costs of defending this action and prosecuting its counterclaims under 35 U.S.C. § 285; and

E. awarding Teva such other and further relief as the Court may deem just and proper.

Dated: January 18, 2024

Respectfully submitted,

/s/ Liza M. Walsh

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CERTIFICATION PURSUANT TO LOCAL CIVIL RULES 11.2 AND 40.1

Pursuant to Local Civil Rules 11.2 and 40.1, I hereby certify that, to the best of my knowledge, the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

Dated: January 18, 2024

Respectfully submitted,

/s/ Liza M. Walsh

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CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 201.1

Pursuant to Local Civil Rule 201.1, I hereby certify that this action seeks declaratory and injunctive relief, and therefore this action is not appropriate for compulsory arbitration.

Dated: January 18, 2024

Respectfully submitted,

/s/ Liza M. Walsh
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