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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. 24-6489 (MEF) (LDW)  
Civil Action No. 24-9535 (MEF) (LDW)  
(consolidated)**

**(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.<sup>1</sup> 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).

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<sup>1</sup> Teva answers the Complaint originally filed in Civil Action No. 24-9535. On October 23, 2024, this Court consolidated Civil Action No. 24-9535 with Civil Action No. 24-6489 (D.I. 10).

### **Nature of the Action<sup>2</sup>**

**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. 11,986,444 (the "'444 patent"), 12,036,191 (the "'191 patent"), and 12,042,473 (the "'473 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 the 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.

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<sup>2</sup> 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 May 21, 2024, the United States Patent and Trademark Office (“USPTO”) duly and lawfully issued the ‘444 patent, entitled, “Treatment of Poor Metabolizers of Dextromethorphan with a Combination of Bupropion and Dextromethorphan.” The face of the ‘444 patent identifies Dr. Herriot Tabuteau as the inventor. Antecip is the present assignee of the ‘444 patent; the assignment is recorded with the USPTO at Reel: 066116, Frame: 0656. Axsome is the exclusive licensee of the ‘444 patent. A copy of the ‘444 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. 11,986,444 (“the ‘444 patent”). Teva admits that the face of the ‘444 patent lists the title as “Treatment of Poor Metabolizers of Dextromethorphan with a Combination of Bupropion and Dextromethorphan,” and May 21, 2024, as the issue date. Teva also admits that the face of the ‘444 patent lists Dr. Herriot Tabuteau as the inventor and Antecip as the assignee of the ‘444 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 July 16, 2024, the USPTO duly and lawfully issued the ‘191 patent, entitled, “Treatment of Poor Metabolizers of Dextromethorphan with a Combination of Bupropion and Dextromethorphan.” The face of the ‘191 patent identifies Dr. Herriot Tabuteau as the inventor. Antecip is the present assignee of the ‘191 patent; the assignment is recorded with the USPTO at Reel: 063524, Frame: 0142. Axsome is the exclusive licensee of the ‘191 patent. A copy of the ‘191 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. 12,036,191 (“the ‘191 patent”). Teva admits that the face of the ‘191 patent lists the title as “Treatment of Poor Metabolizers of Dextromethorphan with a Combination of Bupropion and Dextromethorphan,” and July 16, 2024, as the issue date. Teva also admits that the face of the ‘191 patent lists Dr. Herriot Tabuteau as the inventor and Antecip as the assignee of the ‘191 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 July 23, 2024, the USPTO duly and lawfully issued the ‘473 patent, entitled, “Compounds and Combinations Thereof for Treating Neurological and Psychiatric Conditions.” The face of the ‘473 patent identifies Dr. Herriot Tabuteau as the inventor. Antecip is the present assignee of the ‘473 patent; the assignment is recorded with the USPTO at Reel: 064894, Frame: 0543. Axsome is the exclusive licensee of the ‘473 patent. A copy of the ‘473 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. 12,042,473 (“the ‘473 patent”). Teva admits that the face of the ‘473 patent lists the title as “Compounds and Combinations Thereof for Treating Neurological and Psychiatric Conditions,” and July 23, 2024 as the issue date. Teva also admits that the face of the ‘473 patent lists Dr. Herriot Tabuteau as the inventor and Antecip as the assignee of the ‘473

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 hydrochloride; 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 ’444 patent, the ’191 patent, and the ’473 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 in 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 in 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, Sept. 11, 2024). Teva has admitted that it has a "a principal place of business" in Parsippany, New Jersey in related action *Axsome Therapeutics, Inc., et al. v. Teva Pharmaceuticals, Inc.*, Civil Action No. 23-1695 (MEF)(LDW) (D.N.J) (consolidated).

**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").<sup>1</sup> 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.

<sup>1</sup> The '064, '842, '124, and '942 patents are subject to an existing lawsuit, *Axsome Therapeutics, Inc., et al. v. Teva Pharmaceuticals, Inc.*, Civil Action No. 23-1695 (MEF)(LDW) (D.N.J.) (consolidated).

**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 First Notice Letter"). Teva admits that the '064, '842, '124, and '942 patents are the subject to Civil Action No. 23-1695 in this District. 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 Axxsome. 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 United States Patent Nos. 11,717,518 (the “’518 patent”), 11,730,706 (the “’706 patent”), and 11,752,144 (the “’144 patent”).<sup>2</sup> 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.

<sup>2</sup> The ‘518, ‘706, and ‘144 patents are subject to an existing lawsuit, *Axxsome Therapeutics, Inc., et al. v. Teva Pharmaceuticals, Inc.*, Civil Action No. 23-1695 (MEF)(LDW) (D.N.J.) (consolidated).

**ANSWER:** Teva admits that it sent written notice pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act to Axxsome on November 2, 2023 (“Teva’s Second Notice Letter”). Teva admits that the ‘518, ‘706, and ‘144 patents are subject to Civil Action No. 23-1695 in this District. 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.** No earlier than April 10, 2024, Teva sent written notice of its third Paragraph IV Certification (“Teva’s Third Notice Letter”) to Axxsome. According to Teva’s Third 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 United States Patent Nos. 11,839,612 (the “’612 patent”) and 11,883,373 (the “’373 patent”).<sup>3</sup> Teva’s Third Notice Letter alleged that the claims of the ‘612 and ‘373 patents are invalid, unenforceable, and/or will not be infringed by the activities described in Teva’s ANDA.

<sup>3</sup> The ‘612 and ‘373 patents are subject to an existing lawsuit, *Axxsome Therapeutics, Inc., et al. v. Teva Pharmaceuticals, Inc.*, Civil Action No. 24-6489 (MEF)(LDW) (D.N.J.).

**ANSWER:** Teva admits that it sent written notice pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act to Axxsome on April 10, 2024 (“Teva’s Third Notice Letter”). Teva admits that the ‘612 and ‘373 patents are subject to Civil Action No. 24-6489 in this District. To the extent a further response is required, Teva’s Third Notice Letter speaks for itself and is the best source for its content. Teva denies any remaining allegations in Paragraph 22.

**Complaint ¶ 23.** No earlier than May 1, 2024, Teva sent written notice of its fourth Paragraph IV Certification (“Teva’s Fourth Notice Letter”) to Axsome. According to Teva’s Fourth 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 United States Patent Nos. 11,844,797 (the “’797 patent”), 11,896,563 (the “’563 patent”), and 11,925,636 (the “’636 patent”).<sup>4</sup> Teva’s Fourth Notice Letter alleged that the claims of the ‘797, ‘563, and ‘636 patents are invalid, unenforceable, and/or will not be infringed by the activities described in Teva’s ANDA.

<sup>4</sup> The ‘797, ‘563, and ‘636 patents are subject to an existing lawsuit, *Axsome Therapeutics, Inc., et al. v. Teva Pharmaceuticals, Inc.*, Civil Action No. 24-6489 (MEF)(LDW) (D.N.J.).

**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 May 1, 2024 (“Teva’s Fourth Notice Letter”). Teva admits that the ‘797, ‘563, and ‘636 patents are subject to Civil Action No. 24-6489. To the extent a further response is required, Teva’s Fourth Notice Letter speaks for itself and is the best source for its content. Teva denies any remaining allegations in Paragraph 23.

**Complaint ¶ 24.** No earlier than August 30, 2024, Teva sent written notice of its fifth Paragraph IV Certification (“Teva’s Fifth Notice Letter”) to Axsome. According to Teva’s Fifth 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 ‘444, ‘191, and ‘473 patents. Teva’s Fifth Notice Letter alleged that the claims of the ‘444, ‘191, and ‘473 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 or about August 30, 2024 (“Teva’s Fifth Notice Letter”). To the extent a further response is required, Teva’s Fifth Notice Letter speaks for itself and is the best source for its content. Teva denies any remaining allegations in Paragraph 24.

**Complaint ¶ 25.** 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, ‘144, ‘612, ‘797, ‘373, ‘563, ‘636, ‘444, ‘191, and ‘473 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 speak for themselves and are the best source for their contents. Teva denies any remaining allegations in Paragraph 25.

**Complaint ¶ 26.** 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 26 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 27, and therefore denies them.

**Count I: Infringement of the ‘444 Patent by Teva**

**Complaint ¶ 27.** 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 ¶ 28.** 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 ‘444 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 18.

**ANSWER:** Paragraph 28 states legal conclusions to which no response is required. To the extent a response is required, denied.

**Complaint ¶ 29.** A justiciable controversy exists between the parties hereto as to the infringement of the ‘444 patent.

**ANSWER:** Paragraph 29 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 ‘444 patent.

**Complaint ¶ 30.** Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will infringe one or more claims of the '444 patent under 35 U.S.C. § 271(a), including at least claims 1 and 18, by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in the United States.

**ANSWER:** Paragraph 30 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 '444 patent.

**Complaint ¶ 31.** Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will induce infringement of one or more claims of the '444 patent under 35 U.S.C. § 271(b), including at least claims 1 and 18, 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 '444 patent and knowledge that its acts are encouraging infringement.

**ANSWER:** Paragraph 31 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 '444 patent.

**Complaint ¶ 32.** Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will contributorily infringe one or more claims of the '444 patent under 35 U.S.C. § 271(c), including at least claims 1 and 18, 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 '444 patent, and Teva's Proposed Product lacks a substantial non-infringing use.

**ANSWER:** Paragraph 32 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 '444 patent.

**Complaint ¶ 33.** Failure to enjoin Teva's infringement of the '444 patent will substantially and irreparably damage Plaintiffs.

**ANSWER:** Paragraph 33 states legal conclusions to which no response is required. To the extent a response is required, Teva denies the allegations in Paragraph 33.

**Complaint ¶ 34.** Plaintiffs do not have an adequate remedy at law.

**ANSWER:** Paragraph 34 states legal conclusions to which no response is required. To the extent a response is required, Teva denies the allegations in Paragraph 34.

**Complaint ¶ 35.** This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

**ANSWER:** Paragraph 35 states legal conclusions to which no response is required. To the extent a response is required, Teva denies the allegations in Paragraph 35.

**Count II: Infringement of the '191 Patent by Teva**

**Complaint ¶ 36.** 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 ¶ 37.** 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 '191 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 26.

**ANSWER:** Paragraph 37 states legal conclusions to which no response is required. To the extent a response is required, denied.

**Complaint ¶ 38.** A justiciable controversy exists between the parties hereto as to the infringement of the '191 patent.

**ANSWER:** Paragraph 38 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 '191 patent.

**Complaint ¶ 39.** Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will infringe one or more claims of the '191 patent under 35 U.S.C. § 271(a), including at least claims 1 and 26, by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in the United States.

**ANSWER:** Paragraph 39 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 '191 patent.

**Complaint ¶ 40.** Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will induce infringement of one or more claims of the '191 patent under 35 U.S.C. § 271(b), including at least claims 1 and 26, 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 '191 patent and knowledge that its acts are encouraging infringement.

**ANSWER:** Paragraph 40 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 '191 patent.

**Complaint ¶ 41.** Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will contributorily infringe one or more claims of the '191 patent under 35 U.S.C. § 271(c), including at least claims 1 and 26, 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 '191 patent, and Teva's Proposed Product lacks a substantial non-infringing use.

**ANSWER:** Paragraph 41 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 '191 patent.

**Complaint ¶ 42.** Failure to enjoin Teva's infringement of the '191 patent will substantially and irreparably damage Plaintiffs.

**ANSWER:** Paragraph 42 states legal conclusions to which no response is required. To the extent a response is required, Teva denies the allegations in Paragraph 42.

**Complaint ¶ 43.** Plaintiffs do not have an adequate remedy at law.

**ANSWER:** Paragraph 43 states legal conclusions to which no response is required. To the extent a response is required, Teva denies the allegations in Paragraph 43.

**Complaint ¶ 44.** This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

**ANSWER:** Paragraph 44 states legal conclusions to which no response is required. To the extent a response is required, Teva denies the allegations in Paragraph 44.

**Count III: Infringement of the '473 Patent by Teva**

**Complaint ¶ 45.** 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 ¶ 46.** 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 '473 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including claims 1-9.

**ANSWER:** Paragraph 46 states legal conclusions to which no response is required. To the extent a response is required, denied.

**Complaint ¶ 47.** A justiciable controversy exists between the parties hereto as to the infringement of the '473 patent.

**ANSWER:** Paragraph 48 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 '473 patent.

**Complaint ¶ 48.** Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will infringe one or more claims of the '473 patent under 35 U.S.C. § 271(a), including claims 1-9, by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in the United States.

**ANSWER:** Paragraph 48 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 '473 patent.

**Complaint ¶ 49.** Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will induce infringement of one or more claims of the '473 patent under 35 U.S.C. § 271(b), including claims 1-9, 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 '473 patent and knowledge that its acts are encouraging infringement.

**ANSWER:** Paragraph 49 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 '473 patent.

**Complaint ¶ 50.** Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will contributorily infringe one or more claims of the '473 patent under 35 U.S.C. § 271(c), including claims 1-9, 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 '473 patent, and Teva's Proposed Product lacks a substantial non-infringing use.

**ANSWER:** Paragraph 50 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 '473 patent.

**Complaint ¶ 51.** Failure to enjoin Teva's infringement of the '473 patent will substantially and irreparably damage Plaintiffs.

**ANSWER:** Paragraph 51 states legal conclusions to which no response is required. To the extent a response is required, Teva denies the allegations in Paragraph 51.

**Complaint ¶ 52.** Plaintiffs do not have an adequate remedy at law.

**ANSWER:** Paragraph 52 states legal conclusions to which no response is required. To the extent a response is required, Teva denies the allegations in Paragraph 52.

**Complaint ¶ 53.** This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

**ANSWER:** Paragraph 53 states legal conclusions to which no response is required. To the extent a response is required, Teva denies the allegations in Paragraph 53.



### **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, 115, 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 One World Trade Center, 22nd 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 hydrochloride.

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 October 29, 2024, the Orange Book entry for Auvelity® lists 120 patents. Three of these patents include United States Patent 11,986,444 (“the ’444 patent”), 12,036,191 (“the ’191 patent”), and 12,042,473 (“the ’473 patent”), (collectively, “the patents-in-suit”).

11. The face of the '444 patent lists the title as "Treatment of Poor Metabolizers of Dextromethorphan with a Combination of Bupropion and Dextromethorphan," the issue date as May 21, 2024, and the assignee as Antecip.

12. The face of the '191 patent lists the title as "Treatment of Poor Metabolizers of Dextromethorphan with a Combination of Bupropion and Dextromethorphan," the issue date as July 16, 2024, and the assignee as Antecip.

13. The face of the '473 patent lists the title as "Compounds and Combinations Thereof for Treating Neurological and Psychiatric Conditions," the issue date as July 23, 2024, 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 August 30, 2024 ("Teva's Fifth Notice Letter"). On information and belief, and as Counterclaim-Defendants allege in the Complaint, Counterclaim-Defendants received Teva's Fifth Notice Letter.

18. On September 30, 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 '444 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 '444 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 '444 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 judgment regarding Teva's non-infringement of the '444 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 '444 patent, either directly or indirectly.

### **SECOND COUNTERCLAIM**

#### **Declaratory Judgment of Invalidity or Unenforceability of the '444 Patent**

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

25. The claims of the '444 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, 115, 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 '444 patent.

27. Teva is entitled to a judicial declaration that the claims of the '444 patent are invalid and/or unenforceable.

### **THIRD COUNTERCLAIM**

#### **Declaratory Judgment of Noninfringement of the '191 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 '191 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 '191 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 '191 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 '191 patent, either directly or indirectly.

#### **FOURTH COUNTERCLAIM**

##### **Declaratory Judgment of Invalidity or Unenforceability of the '191 Patent**

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

34. The claims of the '191 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, 115, 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 '191 patent.

36. Teva is entitled to a judicial declaration that the claims of the '191 patent are invalid and/or unenforceable.

#### **FIFTH COUNTERCLAIM**

##### **Declaratory Judgment of Noninfringement of the '473 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 '473 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 '473 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 '473 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 '473 patent, either directly or indirectly.

### **SIXTH COUNTERCLAIM**

#### **Declaratory Judgment of Invalidity or Unenforceability of the '473 Patent**

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

43. The claims of the '473 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, 115, 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 '473 patent.

45. Teva is entitled to a judicial declaration that the claims of the '473 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: October 29, 2024

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**CERTIFICATION PURSUANT TO LOCAL CIVIL RULES 11.2 AND 40.1**

Pursuant to Local Civil Rule 11.2 and 40.1, Defendant Teva Pharmaceuticals USA, Inc., by its undersigned counsel, hereby certifies that to the best of their knowledge, this matter in controversy is the subject of the following pending matter involving United States Patent Nos. 10,780,064, 10,925,842, 10,940,124, 10,966,942, 11,717,518, 11,730,706, and 11,752,144:

- *Axsome Therapeutics, Inc., et al. v. Teva Pharmaceuticals, Inc.*, Civil Action No. 23-1695 (MEF)(LDW) (D.N.J.) (consolidated).

The undersigned counsel further certifies that to the best of their knowledge, this matter in controversy is also the subject of the following pending matter involving United States Patent Nos. 11,839,612, 11,883,373, 11,844,797, 11,896,563, and 11,925,636, which the Court consolidated with this matter:

- *Axsome Therapeutics, Inc., et al. v. Teva Pharmaceuticals, Inc.*, Civil Action No. 24-6489 (MEF)(LDW) (D.N.J.).

Other than the above-listed matters, the undersigned counsel hereby certifies that to the best of their knowledge, this matter is not the subject of any other pending matters in any court, or of any pending arbitration or administrative proceeding.

Dated: October 29, 2024

Respectfully submitted,

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**CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 201.1**

Pursuant to Local Civil Rule 201.1, Defendant Teva Pharmaceuticals USA, Inc., by its undersigned counsel, hereby certifies that this action seeks declaratory and injunctive relief, and therefore this action is not appropriate for compulsory arbitration.

Dated: October 29, 2024

Respectfully submitted,

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