Gregory D. Miller
Gene Y. Kang
Timothy P. Gonzalez
RIVKIN RADLER LLP
25 Main Street
Court Plaza North, Suite 501
Hackensack, New Jersey 07601
Telephone: (201) 287-2460
Facsimile: (201) 489-0495
Gregory.miller@rivkin.com
Gene.kang@rivkin.com
Timothy.Gonzalez@rivkin.com

Of Counsel:
Samuel T. Lockner (to be admitted *pro hac vice*)
Caroline L Marsili (to be admitted *pro hac vice*)
Harpreet S. Mahal (to be admitted *pro hac vice*)
CARLSON, CASPERS, VANDENBURGH & LINDQUIST
225 South Sixth Street, Suite 4200
Minneapolis, Minnesota 55402
Telephone: (612) 436-9600
Facsimile: (612) 436-9605
SLockner@carlsoncaspers.com
CMarsili@carlsoncaspers.com
HMahal@carlsoncaspers.com

Attorneys for Alkem Laboratories Ltd.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

AZURITY PHARMACEUTICALS, INC. ET AL, Plaintiffs, v. ALKEM LABORATORIES LTD., Defendant.	C.A. No.: 1:23-cv-00079 (KMW)(MJS)

ALKEM LABORATORIES, LTD.'S ANSWER, SEPARATE DEFENSES, AND COUNTERCLAIMS TO COMPLAINT

Alkem Laboratories Ltd. ("Alkem"), by and through its attorneys, hereby answers and counterclaims to the Complaint of Plaintiffs Azurity Pharmaceuticals, Inc. and Tulex Pharmaceuticals Inc. ("Azurity" or "Plaintiffs") as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement of United States Patent No. 11,433,046 ("the '046 patent" or the "Patent-in-Suit") under the patent laws of the United States of America, Title 35, United States Code, arising out of the submission by Alkem of

Abbreviated New Drug Application ("ANDA") No. 217795 to the United States Food and Drug Administration ("FDA") seeking approval of a generic version of Azurity's topiramate oral solution formulation that is the subject of New Drug Application ("NDA") No. 214679, hereinafter referred to as Azurity's "Eprontia® Product" or "Eprontia®." Plaintiffs seek all available relief under the patent laws of the United States, 35 U.S.C. § 100 *et seq.,* and other applicable laws for Alkem's infringement of the Patent-in-Suit.

ANSWER: Paragraph 1 contains conclusions of law for which no response is required. To the extent a response is required, Alkem admits that the Complaint purports to set forth claims for patent infringement of U.S. Patent No. 11,433,046 ("the '046 patent"). Alkem further admits that it submitted Alkem's ANDA No. 217795 ("Alkem's ANDA") to obtain approval from the FDA to engage in the commercial manufacture, use, offer for sale, and/or sale of Alkem's topiramate in a 25 mg/mL oral solution drug product ("Alkem's ANDA Product"). Alkem further admits that Alkem's ANDA identifies Eprontia® (topiramate) oral solution, 25 mg/mL, as the reference listed drug product, which is the subject of New Drug Application ("NDA") No. 214679. Except as expressly admitted, Alkem denies the allegations of Paragraph 1 of the Complaint.

THE PARTIES

2. Azurity is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 8 Cabot Road, Suite 2000, Woburn, MA 01801.

ANSWER: Alkem is without sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 2 of the Complaint, and therefore, Alkem denies the allegations in Paragraph 2.

3. Tulex is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 5 Cedar Brook Drive, Cranbury, NJ 08512.

ANSWER: Alkem is without sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 3 of the Complaint, and therefore, Alkem denies the allegations in Paragraph 3.

4. On information and belief, Alkem is an Indian corporation, having a principal place of business at Alkem House, Senapati Bapat Road, Lower Parel, Mumbai, Maharashtra 400013, India.

ANSWER: Alkem admits that Alkem is a company organized and existing under the laws of the Republic of India with a place of business at Alkem House, Senapati Bapat Road, Lower Parel, Mumbai, Maharashtra 400013, India.

5. On information and belief, Alkem is in the business of, among other things, developing, manufacturing, marketing, importing, and selling generic copies of branded pharmaceutical products for the United States market.

ANSWER: Paragraph 5 contains conclusions of law for which no response is required. To the extent a response is required, Alkem admits that it is in the business of developing, manufacturing, importing, and selling pharmaceutical products for the United States market that are the subject of Abbreviated New Drug Applications. Except as expressly admitted, Alkem denies the allegations of Paragraph 5 of the Complaint.

JURISDICTION AND VENUE

6. This action arises under the patent laws of the United States of America, 35 U.S.C. § 1 *et seq.*, and from Alkem's submission of ANDA No. 217795 ("Alkem's ANDA").

ANSWER: Alkem admits that this civil action of purported patent infringement arises under the patent laws of the United States and from Alkem's submission of ANDA No. 217795.

7. This Court has subject matter jurisdiction over the action under 28 U.S.C. §§ 1331 and 1338(a) (patent infringement). Relief is sought under 35 U.S.C. § 271(e).

ANSWER Paragraph 7 of the Complaint contains legal conclusions to which no answer is required. To the extent a response is required, Alkem admits that this Court has subject matter jurisdiction for Plaintiffs' patent infringement counts under 28 U.S.C. §§ 1331 and 1338(a). Alkem admits that Plaintiffs seek relief under 35 U.S.C. § 271(e)(2). Otherwise, denied.

8. On information and belief, this Court has personal jurisdiction over Alkem because of, among other things, Alkem's persistent and continuous contacts with New Jersey. Alkem has purposefully availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here. On information and belief, Alkem regularly and continuously transacts business in New Jersey, including by directly or indirectly developing, manufacturing, marketing, and selling generic pharmaceutical products in New Jersey. On

information and belief, Alkem derives substantial revenue from the sale of those products in New Jersey, and has availed itself of the privilege of conducting business within New Jersey. Alkem has regularly engaged in patent litigation concerning FDA-approved products in this judicial district, has not contested personal jurisdiction in such litigation in this judicial district, and has purposefully availed itself of the rights and benefits of this court by asserting claims and/or counterclaims in this Court. *See, e.g., Celgene Corp. v. Alkem Labs. Ltd.*, C.A. No. 3:18-cv-11265 (D.N.J.); *Valeant Pharm. N. Am. LLC v. Alkem Labs. Ltd.*, C.A. No. 3:18-cv-13905 (D.N.J.); *Sumitomo Dainippon Pharma Co. v. Alkem Labs. Ltd.*, C.A. No. 2:18-cv-14787 (D.N.J.); *Arbor Pharmaceuticals, LLC v. Alkem Laboratories Ltd.*, C.A. No. 1:22-cv-00143 (D.N.J.).

ANSWER: Paragraph 8 of the Complaint contains legal conclusions to which no answer is required. To the extent a response is required, Alkem admits that Alkem is in the business of developing, manufacturing, marketing, and selling pharmaceutical products for the United States market that are the subject of Abbreviated New Drug Applications. Alkem admits that it did not contest personal jurisdiction in the litigations identified in Paragraph 8 of the Complaint and asserted counterclaims in them. Except as expressly admitted, Alkem denies the allegations of Paragraph 8. For the purposes of this action only, Alkem does not contest personal jurisdiction in this Court.

9. Alternatively, this Court has personal jurisdiction over Alkem pursuant to Federal Rule of Civil Procedure 4(k)(2) because (a) Plaintiffs' claims arise under federal law; (b) Alkem is a foreign defendant not subject to personal jurisdiction in the courts of any state; and (c) Alkem has sufficient contacts with the United States as a whole, including, but not limited to, preparing and submitting ANDA No. 217795 to FDA and/or manufacturing, importing, offering to sell, and/or selling generic pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Alkem satisfies due process.

ANSWER: Paragraph 9 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Alkem admits that it prepared and submitted Alkem's ANDA to the FDA and manufactures, imports, offers to sell, and sells pharmaceutical products that are the subject of Abbreviated New Drug Applications that are distributed in the United States. Alkem further admits that it has a place of business at Alkem House, Senapati Bapat Road, Lower

Parel, Mumbai, Maharashtra 400013, India. Except as expressly admitted, Alkem denies the allegations of Paragraph 9. For the purposes of this action only, Alkem does not contest personal jurisdiction in this Court.

10. On information and belief, this judicial district is a likely destination of the product that is the subject of Alkem's ANDA.

ANSWER: Paragraph 10 of the Complaint contains legal conclusions to which no answer is required. To the extent a further response is required, Alkem denies the allegations of Paragraph 10 of the Complaint or lacks sufficient information to respond, particularly given it is forward looking and speculative, and therefore denies such allegations. For the purposes of this action only, Alkem does not contest personal jurisdiction in this Court.

11. Venue is proper in this Court under 28 U.S.C. §§ 1391(b) and (c) and 1400(b).

ANSWER: Paragraph 11 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Alkem does not contest venue in this Court for purposes of this action only.

AZURITY'S EPRONTIA® PRODUCT

12. Azurity holds approved NDA No. 214679 for an oral solution of topiramate, which is prescribed and sold under the trade name Eprontia®.

ANSWER: Alkem admits that the U.S. Food and Drug Administration website identifies Azurity Pharmaceuticals, Inc. as the applicant holder of NDA No. 214679 for an oral solution of topiramate under the trademarked name Eprontia®. To the extent a further response is required, Alkem is without sufficient knowledge or information to form a belief as to the truth of the allegations set forth in Paragraph 12 of the Complaint, and therefore, Alkem denies the allegations in Paragraph 12.

13. Azurity's Eprontia® product is an FDA approved and labeled monotherapy indicated for epilepsy and related seizures in patients 2 years of age and older and migraine in patients 12 years of age and older.

ANSWER: Alkem admits that the FDA-approved label for Eprontia® dated October 2022 states that it is an initial monotherapy for the treatment of partial-onset or primary generalized tonic-clonic seizures in patients 2 years of age and older and that it is a preventive treatment of migraine in patients 12 years of age and older. Alkem is without sufficient knowledge or information to form a belief as to the truth of the remaining allegations set forth in Paragraph 13 of the Complaint, and therefore, Alkem denies the allegations in Paragraph 13.

PATENT-IN-SUIT

14. The ’046 patent, entitled “Compositions and Methods for Treating Epilepsy, Seizures and Other Conditions,” was duly and legally issued on September 6, 2022, from the United States Patent Application No. 17/308,910. A true and correct copy of the ’046 patent is attached to this Complaint as Exhibit A.

ANSWER: Paragraph 14 of the Complaint contains legal conclusions to which no answer is required. To the extent a further response is required, Alkem admits that the face of U.S. Patent No. 11,433,046 (“the ’046 patent”) specifies the date of patent as September 6, 2022 and that the ’046 patent is titled “Compositions and Methods for Treating Epilepsy, Seizures and Other Conditions”. Alkem further admits that Exhibit A to the Complaint purports to be a copy of the ’046 patent. Alkem denies that the ’046 patent was duly and legally issued.

15. The face of the ’046 patent names Yu-Hsing Tu, Ashok Perumal, Kalyan Kathala, and Romona Bhattacharya as inventors and Tulex as assignee. Azurity, as exclusive licensee, has the right to enforce the ’046 patent.

ANSWER: Alkem admits that the face of the ’046 patent names Yu-Hsing Tu, Ashok Perumal, Kalyan Kathala, and Romona Bhattacharya as inventors and Tulex Pharmaceuticals Inc. as assignee. Alkem is without sufficient knowledge or information to form a belief as to the truth of the remaining allegations set forth in Paragraph 15 of the Complaint, and therefore, Alkem denies the allegations in Paragraph 15.

16. Pursuant to 21 U.S.C. § 355, the ’046 patent is listed in the Approved Drug Products with Therapeutic Equivalence Evaluations (“the Orange Book”) in connection with NDA No. 214679 and Azurity’s Eprontia® Product.

ANSWER: Alkem admits that upon information and belief, Azurity caused the ’046 patent to be listed in the Approved Drug Products with Therapeutic Equivalence Evaluations (“the Orange Book”) in connection with Eprontia®, which is subject to NDA No. 214679. Otherwise, denied.

17. The use of Azurity’s Eprontia® Product is covered by at least one claim of the ’046 patent.

ANSWER: Paragraph 17 of the Complaint contains legal conclusions to which no answer is required. To the extent a response is required, Alkem is without sufficient knowledge or

information to form a belief as to the truth of the remaining allegations set forth in Paragraph 17 of the Complaint, and therefore, Alkem denies the allegations in Paragraph 17.

INFRINGEMENT BY ALKEM

18. By letter dated November 21, 2022 (the "Notice Letter"), Alkem notified Plaintiffs that it had submitted ANDA No. 217795 to FDA under Section 505(j)(2)(B) of the Federal Food, Drug, and Cosmetic Act ("FDCA") (21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95 seeking approval to engage in the commercial manufacture, use, and sale of a generic version of Azurity's Eprontia® Product (the "Alkem ANDA Product") before the expiration of the '046 patent.

ANSWER: Alkem admits that Alkem sent a letter to Plaintiffs dated November 21, 2022 ("the Notice Letter"), notifying Plaintiffs that pursuant to 21 U.S.C. § 505(j)(2)(B)(iv) and 21 C.F.R. § 314.95, Alkem submitted, and the FDA has received, an Abbreviated New Drug Application (as amended and/or supplemented) under 21 U.S.C. § 355(j) seeking to engage in the commercial manufacture, use, importation, offer for sale or sale of Alkem's proposed drug product containing topiramate oral solution, 25 mg/mL, prior to the expiration of the '046 patent. Alkem further admits that the '046 patent is listed in the Orange Book in association with NDA No. 214679. Except as expressly admitted, Alkem denies the allegations of Paragraph 18 of the Complaint.

19. The '046 patent expires on August 21, 2040.

ANSWER: Paragraph 19 of the Complaint contains legal conclusions to which no answer is required. To the extent a response is required, Alkem admits that the Orange Book identifies the '046 patent as expiring on August 21, 2040. Except as expressly admitted, Alkem denies the allegations of Paragraph 19 of the Complaint.

20. On information and belief, the proposed labeling for Alkem's ANDA Product directs a method for treating a disease or disorder, or symptom thereof selected from: epilepsy, onset seizures, primary generalized tonic-clonic seizures, seizures associated with Lennox-Gastaut syndrome, and migraine.

ANSWER: Paragraph 20 of the Complaint contains legal conclusions to which no answer is required. To the extent a response is required, Alkem admits that its proposed label will set forth indications of usage and Alkem's proposed label speaks for itself. Alkem denies the remaining allegations set forth in Paragraph 20 of the Complaint.

21. On information and belief, Alkem is seeking FDA approval to engage in the commercial manufacture, use, and sale of the Alkem ANDA Product with its proposed labeling before the expiration of the '046 patent.

ANSWER: Admitted.

22. On information and belief, Alkem intends to engage in commercial manufacture, use, offer for sale, and/or sale of the Alkem ANDA Product with its proposed labeling promptly upon receiving FDA approval of its ANDA.

ANSWER: Alkem admits that Alkem submitted ANDA No. 217795 to obtain approval from the FDA to engage in the commercial manufacture, use, importation, offer for sale, or sale of Alkem's proposed drug product containing topiramate oral solution, 25 mg/mL, prior to the expiration of the '046 patent. Alkem is without sufficient knowledge or information to form a belief as to the truth of the remaining allegations set forth in Paragraph 22 of the Complaint, and therefore, Alkem denies the allegations in Paragraph 22.

23. By submitting ANDA No. 217795, Alkem has represented to FDA that the Alkem ANDA Product has the same active ingredients as Azurity's Eprontia® Product; has the same route of administration, dosage form, use, and strength as Azurity's Eprontia® Product; and is bioequivalent to Azurity's Eprontia® Product.

ANSWER: Alkem admits that the Alkem ANDA Product has the same active pharmaceutical ingredient, topiramate, as Azurity's Eprontia® Product. Alkem further admits that Alkem's proposed drug product that is subject to ANDA No. 217795 is an oral solution with 25 mg of topiramate per mL. Alkem further admits that Alkem's proposed drug label will set forth indications of usage, and Alkem's proposed label speaks for itself. Otherwise, denied.

24. This action is being filed within forty-five (45) days of Plaintiffs' receipt of Alkem's Notice Letter.

ANSWER: Alkem admits that it sent Alkem's Notice Letter to Azurity Pharmaceuticals, Inc. and Tulex Pharmaceuticals Inc. on November 21, 2022. Alkem further admits that Plaintiffs filed their Complaint in this Court on January 6, 2023. To the extent a further response is required, Alkem is without sufficient knowledge or information to form a belief as to the truth of the allegations of Paragraph 24, and therefore, Alkem denies the allegations in Paragraph 24.

CLAIMS FOR RELIEF

Count I—Infringement of the '046 patent Under 35 U.S.C. § 271(e)(2)

25. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

ANSWER: Alkem incorporates each of the preceding paragraphs as if fully set forth herein.

26. Alkem submitted ANDA No. 217795 to FDA under Section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Alkem ANDA Product with its proposed labeling throughout the United States before the expiration of the '046 patent. By submitting their ANDA, Alkem has committed an act of infringement of one or more claims of the '046 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Alkem admits it submitted its ANDA No. 217795 to FDA under 21 U.S.C. § 355(j) seeking to engage in the commercial manufacture, use, importation, offer for sale or sale of Alkem's ANDA Product containing topiramate oral solution, 25 mg/mL, prior to the expiration of the '046 patent. Except as expressly admitted, Alkem denies the allegations of Paragraph 26 of the Complaint.

27. On information and belief, if Alkem's ANDA is approved by FDA, the commercial manufacture, use (including in accordance with and as directed by Alkem's proposed labeling for Alkem's ANDA Product), offer to sell, or sale within the United States, and/or importation into the United States of the Alkem ANDA Product will constitute acts of infringement, either literally or under the doctrine of equivalents, of the '046 patent under 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

ANSWER: Denied.

28. On information and belief, Alkem has actual and constructive knowledge of the '046 patent, and is aware that submission of ANDA No. 217795 to FDA constituted an act of infringement of the '046 patent.

ANSWER: Paragraph 28 of the Complaint contains legal conclusions to which no answer is required. To the extent a further response is required, Alkem admits Alkem submitted ANDA No.

217795 to obtain approval from the FDA to engage in the commercial manufacture, use importation, offer for sale or sale of Alkem's proposed drug product containing topiramate oral solution, 25 mg/mL, prior to the expiration of the '046 patent. Except as expressly admitted, Alkem denies the allegations of Paragraph 28 of the Complaint.

29. On information and belief, Alkem had specific intent to infringe the '046 patent when it filed ANDA No. 217795. Moreover, there are no substantial non-infringing uses for the Alkem ANDA Product other than the methods claimed in the 046 patent.

ANSWER: Paragraph 29 of the Complaint contains legal conclusions to which no answer is required. To the extent a further response is required, Alkem denies the allegations of Paragraph 29 of the Complaint.

30. On information and belief, Alkem plans and intends to, and will, actively induce infringement of the '046 patent by another, at least including physicians, healthcare professionals, healthcare providers, and patients, when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

ANSWER: Denied.

31. On information and belief, Alkem knows that Alkem's ANDA Product with its proposed labeling is especially made or adapted for use in infringing the '046 patent, and that Alkem's ANDA Product with its proposed labeling is not suitable for substantial noninfringing use. On information and belief, Alkem plans and intends to, and will, contribute to infringement of the '046 patent immediately and imminently upon approval of the Alkem ANDA.

ANSWER: Denied.

32. The commercial manufacture, use (including in accordance with and as directed by Alkem's proposed labeling for Alkem's ANDA Product), offer for sale, sale, and/or importation of the Alkem ANDA Product in violation of Plaintiffs' patent rights will cause substantial and irreparable harm to Plaintiffs for which damages are inadequate.

ANSWER: Denied.

ANSWER TO PLAINTIFFS' PRAYER FOR RELIEF

Alkem denies that Plaintiffs are entitled to the relief sought against Alkem in Paragraphs (a)-(f) of the Complaint or any relief at all for the allegations relating to Alkem made in the Complaint.

SEPARATE DEFENSES

Without prejudice to the denials set forth in its Answer to the Complaint, and without admitting any allegations of the Complaint not expressly admitted, on information and belief, Alkem asserts the following separate defenses to Plaintiffs' Complaint without assuming the burden of proof on any such defense that would otherwise rest on Plaintiffs.

FIRST DEFENSE

The submission of ANDA No. 217795 and/or manufacture, use, sale, offer for sale and/or importation into the United States of Alkem's proposed product that is subject to ANDA No. 217795 does not and will not directly infringe, indirectly infringe, induce infringement of, or contribute to the infringement of, either literally or under the Doctrine of Equivalents, any valid and enforceable claim of U.S. Patent No. 11,433,046.

SECOND DEFENSE

Based on information and belief, each of the claims of the '046 patent is invalid for failing to satisfy one or more requirements for patentability of Title 35 of the United States Code, including 35 U.S.C. §§ 101, 102, 103, and/or 112, or other judicially-created bases for invalidity or unenforceability, for example, for at least the reasons set forth in Alkem's Notice Letter dated November 21, 2022.

THIRD DEFENSE

The Complaint fails to state a cause of action under 35 U.S.C. §§ 271 (a)-(c) against Alkem because Plaintiffs have not pleaded with particularity facts regarding any post-ANDA-approval activities.

FOURTH DEFENSE

The Court lacks subject matter jurisdiction over any and all claims asserted under 35 U.S.C. §§ 271 (a)-(c).

FIFTH DEFENSE

Any claims of infringement of the '046 patent are precluded by the doctrine of prosecution history estoppel.

SIXTH DEFENSE

Plaintiffs have failed to state a proper claim for exceptional case.

RESERVATION OF ADDITIONAL SEPARATE AND/OR AFFIRMATIVE DEFENSES

Alkem reserves the right to assert additional defenses in the event that discovery or other analysis indicates that additional separate and/or affirmative defenses are appropriate, including, but not limited to, defense of unenforceability.

COUNTERCLAIMS FOR DECLARATORY JUDGMENT

Pursuant to Rule 13 of the Federal Rules of Civil Procedure, Defendant/Counterclaimant Plaintiff Alkem Laboratories Ltd. ("Alkem"), by and through their undersigned attorneys, counterclaim against Plaintiff/Counterclaim Defendants Azurity Pharmaceuticals, Inc. and Tulex Pharmaceuticals Inc. ("Azurity" or "Counterclaim Defendants") for declaratory judgment that no valid and enforceable claim of U.S. Patent No. 11,433,046 ("the '046 patent") is infringed or will be infringed under 35 U.S.C. § 271 *et seq*. by the submission of abbreviated New Drug Application

("ANDA") No. 217795 ("Alkem's ANDA") or by the making, using, selling, offering for sale or importing of the drug product subject to ANDA No. 217795.

THE PARTIES

1. Counterclaimant Alkem is the owner of Alkem's ANDA and is an Indian corporation with a place of business at Alkem House, Senapati Bapat Road, Lower Parel, Mumbai, Maharashtra 400013, India.

2. Counterclaim Defendant Azurity Pharmaceuticals, Inc. is a plaintiff in the underlying action and, upon information and belief, is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 8 Cabot Road, Suite 2000, Woburn, MA 01801.

3. Counterclaim Defendant Tulex Pharmaceuticals Inc. is a plaintiff in the underlying action and, upon information and belief, is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 5 Cedar Brook Drive, Cranbury, NJ 08512.

4. Upon information and belief, Counterclaim Defendant Tulex Pharmaceuticals Inc. is the assignee of the '046 patent and Counterclaim Defendant Azurity Pharmaceuticals, Inc. alleges having an exclusive license to the '046 patent, and therefore would have the rights to enforce the '046 patent.

NATURE OF ACTION

5. This action arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq*.; the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; and the Hatch-Waxman Act, 21 U.S.C. § 355(j) *et seq*. The Hatch-Waxman Act governs the U.S. Food and Drug Administration's ("FDA") approval of both new and generic drugs. Alkem seeks FDA approval for the commercial

manufacture, use, importation, offer for sale, and sale of a version of topiramate oral solution, 25 mg/mL as described in Alkem's ANDA. Alkem's ANDA contains a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '046 patent.

6. In accordance with 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95, Alkem sent to Counterclaim Defendants a letter dated November 21, 2022, detailing the legal and factual basis for its Paragraph IV certifications that Alkem's ANDA would not infringe any valid claim of the '046 patent, specifically detailing at least one basis for Alkem's certification as to each claim of the '046 patent, and including an Offer of Confidential Access with reasonable terms to its ANDA No. 217795 in accordance with 21 U.S.C. § 355(j)(5)(C)(i)(III) ("Alkem's Notice Letter and Detailed Statement"). Counterclaim Defendants received Alkem's Notice Letter and Detailed Statement on November 22, 2022.

7. Counterclaim Defendants did not seek access to Alkem's ANDA, did not contact Alkem with any proposed counter terms, and deliberately did not perform an investigation into the bases of noninfringement and invalidity of the '046 patent disclosed in Alkem's Notice Letter and Detailed Statement. Instead, Counterclaim Defendants filed the aforementioned lawsuit for patent infringement as it relates to the '046 patent.

8. Alkem seeks declaratory judgment that no valid and enforceable claim of the '046 patent is infringed by Alkem's ANDA and the products described therein.

JURISDICTION AND VENUE

9. This is an action for declaratory judgments that Alkem has not, does not, and will not infringe the claims of the '046 patent, which arises under the patent laws of the United States, 35 U.S.C. §§ 1 *et seq.*; the Hatch-Waxman Act, 21 U.S.C. §§ 355(j) *et seq.*; and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

10. This Court has subject matter jurisdiction over these counterclaims under 28 U.S.C. §§ 1331 and 1338(a) because the counterclaims involve substantial claims arising under the United States Patent Act (35 U.S.C. §§ 1 *et seq.*), and the Declaratory Judgment Act (28 U.S.C. §§ 2201 and 2202).

11. This Court has personal jurisdiction over Counterclaim Defendants due to, *inter alia*, Counterclaim Defendants having availed themselves of the jurisdiction of this Court by filing the underlying action.

12. An actual controversy exists between Alkem and Counterclaim Defendants by virtue of Counterclaim Defendants' listing of the '046 patent in the FDA's Approved Products with Therapeutic Equivalence Evaluations ("the Orange Book") for Eprontia®, Alkem's filing of ANDA No. 217795 with the FDA under § 505(j) of the Federal Food Drug and Cosmetic Act, 21 U.S.C. § 355(j), for topiramate oral solution, 25 mg/mL, with a certification as to the '046 patent, and Counterclaim Defendants' assertion of the '046 patent against Alkem.

13. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b), and because Counterclaim Defendants commenced the underlying action in this venue.

14. An actual and justiciable controversy exists between Alkem and Counterclaim Defendants as to whether Alkem's ANDA or the products described therein infringe any valid claims of the '046 patent of sufficient immediacy and reality to warrant the issuance of declaratory judgments.

15. This Court may declare the rights and legal relation of the parties pursuant to §§ 2201 and 2202 of Title 28 of the United States Code and §271(e)(5) of Title 35 of the United States Code because Counterclaims present an actual controversy within the Court's jurisdiction

concerning the alleged infringement of the patents asserted by Counterclaim Defendants against Alkem.

COUNT I

(Declaratory Judgment of Non-Infringement of the '046 Patent)

16. Alkem re-alleges and incorporates by reference the allegations in Paragraphs 1 through 15 of its Counterclaims as though fully set forth herein.

17. This claim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the Hatch-Waxman Act, 21 U.S.C. § 355(j)(5)(C).

18. Counterclaim Defendants allege that Tulex Pharmaceuticals Inc. is the assignee of the '046 patent and that Azurity Pharmaceuticals, Inc. is an exclusive licensee of the '046 patent, and have brought claims against Alkem alleging infringement of the '046 patent.

19. Alkem filed an ANDA with a Paragraph IV certification stating the '046 patent is not and will not be infringed by Alkem's ANDA or the products described therein.

20. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the commercial manufacture, marketing, and/or sale of Alkem's product infringe, have infringed, and/or will infringe a valid and enforceable claim of the '046 patent.

21. Alkem's ANDA and the products described therein do not infringe any claim of the '046 patent either directly or indirectly as set forth in more detail in Alkem's Notice Letter and Detailed Statement.

22. Alkem is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the products that are subject to Alkem's ANDA would not infringe any valid or enforceable claim of the '046 patent either directly or indirectly.

COUNT II

(Declaratory Judgment of Invalidity or Unenforceability of the '046 Patent)

23. Alkem re-alleges and incorporates by reference the allegations of Paragraphs 1 through 22 of its Counterclaims as though fully set forth herein.

24. This claim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the Hatch-Waxman Act, 21 U.S.C. § 355(j)(5)(C).

25. Counterclaim Defendants allege that Tulex Pharmaceuticals Inc. is the assignee of the '046 patent and that Azurity Pharmaceuticals, Inc. is an exclusive licensee of the '046 patent, and have brought claims against Alkem alleging infringement of the '046 patent.

26. One or more of the claims of the '046 patent is invalid for failure to comply with one or more of the conditions of patentability set forth in Title 35 of the United States Code as set forth in more detail in Alkem's Notice Letter and Detailed Statement.

27. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the commercial manufacture, marketing, and/or sale of Alkem's product infringe, have infringed, and/or will infringe a valid and enforceable claim of the '046 patent.

28. Alkem is entitled to a judicial declaration that all claims of the '046 patent are invalid.

PRAYER FOR RELIEF

WHEREFORE, Alkem prays for declaratory judgments against Plaintiffs as follows:

(a) Judgment against Plaintiffs declaring that the claims of the '046 patent are not and will not be infringed by Alkem's submission of ANDA No. 217795, directly or indirectly;

(b) Judgment against Plaintiffs declaring that the manufacture, use, sale, offer for sale, and/or importation of products subject to Alkem's ANDA do not infringe and will not, if marketed, used, offered for sale, or sold, infringe or induce or contribute to the infringement of any valid claim of the '046 patent;

(c) Judgment against Plaintiffs declaring that the claims of the '046 patent are invalid;

(d) Awarding Plaintiffs its costs, expenses, and reasonable attorneys' fees pursuant to 35 U.S.C. § 285; and

(e) Awarding Alkem such other further relief as the Court deems just and proper.

Respectfully submitted,

Dated: March 27, 2023

s/ Gregory D. Miller

Gregory D. Miller
Gene Y. Kang
Timothy P. Gonzalez
RIVKIN RADLER LLP
25 Main Street
Court Plaza North, Suite 501
Hackensack, New Jersey 07601
Telephone: (201) 287-2460
Facsimile: (201) 489-0495

Of Counsel:
Samuel T. Lockner (to be admitted *pro hac vice*)
Caroline L Marsili (to be admitted *pro hac vice*)
Harpreet S. Mahal (to be admitted *pro hac vice*)
CARLSON, CASPERS, VANDENBURGH & LINDQUIST
225 South Sixth Street, Suite 4200
Minneapolis, Minnesota 55402
Telephone: (612) 436-9600
Facsimile: (612) 436-9605
SLockner@carlsoncaspers.com
CMarsili@carlsoncaspers.com
HMahal@carlsoncaspers.com

Attorneys for Alkem Laboratories Ltd.

LOCAL CIVIL RULE 11.2 CERTIFICATION

Pursuant to Local Civil Rule 11.2, I hereby certify that 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: March 27, 2023

s/ Gregory D. Miller
Gregory D. Miller

LOCAL CIVIL RULE 201.1 CERTIFICATION

I hereby certify that the above-captioned matter is not subject to compulsory arbitration in that the parties seek, *inter alia*, declaratory relief in their respective pleadings.

I hereby certify under penalty of perjury that the foregoing is true and correct.

Dated: March 27, 2023

s/ Gregory D. Miller
Gregory D. Miller

CERTIFICATE OF SERVICE

The undersigned attorney certifies that a copy of Alkem's foregoing Answer, Separate Defenses, and Counterclaims was filed via ECF and served on all counsel of record by electronic mail on March 27, 2023.

Dated: March 27, 2023

s/ Gregory D. Miller
Gregory D. Miller