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Attorneys for Plaintiffs Azurity Pharmaceuticals, Inc. and Tulex Pharmaceuticals Inc.

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

AZURITY PHARMACEUTICALS, INC., TULEX PHARMACEUTICALS INC., Plaintiffs, v. ALKEM LABORATORIES LTD., Defendant.	Civil Action No.: _____ COMPLAINT FOR PATENT INFRINGEMENT *Document Electronically Filed*

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Azurity Pharmaceuticals, Inc. ("Azurity") and Tulex Pharmaceuticals Inc. ("Tulex") (together, "Plaintiffs"), by and through their attorneys, bring this Complaint against Defendant Alkem Laboratories Ltd. ("Alkem" or "Defendant"), and hereby alleges as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement of United States Patent Nos. 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.

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.

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.

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.

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.

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").

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).

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.).

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.

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

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

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®.

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.

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.

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.

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.

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

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.

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

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.

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.

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.

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.

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

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.

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).

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.

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.

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.

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.

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.

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.

PRAYER FOR RELIEF

Plaintiffs respectfully request the following relief:

a) A judgment that Alkem has infringed the '046 patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 217795 under Section 505(j) of the FDCA, and that Alkem's making, using (including in accordance with and as directed by Alkem's proposed labeling for Alkem's ANDA Product), offering to sell, or selling in the United States or importing

into the United States of the Alkem ANDA Product will infringe one or more claims of the '046 patent;

b) A finding that the '046 patent is valid and enforceable;

c) An order under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of ANDA No. 217795 shall be a date which is not earlier than the latest expiration date of the '046 patent, as extended by any applicable periods of exclusivity;

d) An order under 35 U.S.C. § 27l(e)(4)(B) permanently enjoining Alkem, its subsidiaries, parents, officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with it or acting on its behalf, from engaging in the commercial manufacture, use, offer to sell, sale, and/or importation into the United States, of any drug product the use of which is covered by the '046 patent, including the Alkem ANDA Product;

e) A finding that this is an exceptional case under 35 U.S.C. § 285, and that Plaintiffs be awarded reasonable attorneys' fees and costs; and

f) An award of any such other and further relief as the Court may deem just and proper.

DATED: January 6, 2023

Respectfully submitted,

SAIBER LLC
Attorneys for Plaintiffs Azurity Pharmaceuticals, Inc. and Tulex Pharmaceuticals Inc.

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LOCAL CIVIL RULE 11.2 CERTIFICATION

Pursuant to Local Civil Rule 11.2, the undersigned counsel for Plaintiffs Azurity Pharmaceuticals, Inc. and Tulex Pharmaceuticals Inc. hereby certify that this matter in controversy is not the subject of any other action in any other court, or of any pending arbitration or administrative proceeding.

Dated: January 6, 2023

Respectfully submitted,

SAIBER LLC

Attorneys for Plaintiffs Azurity Pharmaceuticals, Inc. and Tulex Pharmaceuticals Inc.

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LOCAL CIVIL RULE 201.1 CERTIFICATION

Under Local Civil Rule 201.1, the undersigned counsel for Plaintiffs Azurity Pharmaceuticals, Inc. and Tulex Pharmaceuticals Inc. hereby certify that they seek both monetary damages greater than $150,000 and injunctive and other equitable relief, and therefore this action is not appropriate for compulsory arbitration.

Dated: January 6, 2023

Respectfully submitted,

SAIBER LLC

Attorneys for Plaintiffs Azurity Pharmaceuticals, Inc. and Tulex Pharmaceuticals Inc.

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