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

AZURITY PHARMACEUTICALS, INC., Plaintiff, v. ALKEM LABORATORIES LTD., Defendant.	Civil Action No.: 1:22-00143 (KMW-EAP) SECOND AMENDED COMPLAINT FOR PATENT INFRINGEMENT *Document Electronically Filed*

SECOND AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Azurity Pharmaceuticals, Inc. ("Azurity" or "Plaintiff"), by and through its attorneys, brings this Second Amended 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. 10,342,787 ("the '787 patent"), 10,576,070 ("the '070 patent"), 11,207,306 ("the '306 patent"), and 11,413,277 ("the '277 patent") (collectively, the "Nymalize® Patents") 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. 213409 to the United States Food and Drug

Administration ("FDA") seeking approval of a generic version of Azurity's oral solution formulation that is the subject of New Drug Application ("NDA") No. 203340, hereinafter referred to as Azurity's "Nymalize® Product" or "Nymalize®." Azurity seeks 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 Nymalize® Patents.

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, Massachusetts.

3. 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.

4. 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

5. 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. No. 213409 ("Alkem's ANDA").

6. 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)(2).

7. 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.).

8. Alternatively, this Court has personal jurisdiction over Alkem pursuant to Federal Rule of Civil Procedure 4(k)(2) because (a) Azurity's 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. 213409 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.

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

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

AZURITY'S NYMALIZE® PRODUCT

11. Azurity holds approved NDA No. 203340 for an oral solution of nimodipine, which is prescribed and sold under the trade name Nymalize®.

12. Azurity's Nymalize® product is an FDA approved and labeled dihydropyridine calcium channel blocker indicated for the improvement of neurological outcome by reducing the incidence and severity of ischemic deficits in adult patients with subarachnoid hemorrhage from ruptured intracranial berry aneurysms regardless of their post-ictus neurological condition (i.e., Hunt and Hess Grades I-V).

PATENTS-IN-SUIT

13. The '787 patent, entitled "Non-Aqueous Liquid Nimodipine Compositions," was duly and legally issued on July 9, 2019, from the United States Patent Application No. 15/954,357. A true and correct copy of the '787 patent is attached to this Second Amended Complaint as Exhibit A.

14. The face of the '787 patent names Hugh Greg Thomas as inventor and Arbor Pharmaceuticals, LLC ("Arbor") as assignee. Arbor assigned its rights, title, and interest in the '787 patent to Azurity. Azurity, as assignee, owns all rights, title, and interest in the '787 patent.

15. Pursuant to 21 U.S.C. § 355, the '787 patent is listed in the Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") in connection with NDA No. 203340 and Azurity's Nymalize® Product.

16. Azurity's Nymalize® Product is covered by at least one claim of the '787 patent.

17. The '070 patent, entitled "Non-Aqueous Liquid Nimodipine Compositions," was duly and legally issued on March 3, 2020, from the United States Patent Application No. 16/407,980. A true and correct copy of the '070 patent is attached to this Second Amended Complaint as Exhibit B.

18. The face of the ’070 patent names Hugh Greg Thomas as inventor and Arbor as assignee. Arbor assigned its rights, title, and interest in the ’070 patent to Azurity. Azurity , as assignee, owns all rights, title, and interest in the ’070 patent.

19. Pursuant to 21 U.S.C. § 355, the ’070 patent is listed in the Orange Book in connection with NDA No. 203340 and Azurity’s Nymalize® Product.

20. Azurity’s Nymalize® Product is covered by at least one claim of the ’070 patent.

21. The ’306 patent, entitled “Non-Aqueous Liquid Nimodipine Compositions,” was duly and legally issued on December 28, 2021, from the United States Patent Application No. 16/722,513. A true and correct copy of the ’306 patent is attached to this Second Amended Complaint as Exhibit C.

22. The face of the ’306 patent names Hugh Greg Thomas as inventor and Arbor as assignee. Arbor assigned its rights, title, and interest in the ’306 patent to Azurity. Azurity, as assignee, owns all rights, title, and interest in the ’306 patent.

23. Pursuant to 21 U.S.C. § 355, the ’306 patent is listed in the Orange Book in connection with NDA No. 203340 and Azurity’s Nymalize® Product.

24. Azurity’s Nymalize® Product is covered by at least one claim of the ’306 patent.

25. The ’277 patent, entitled “Non-Aqueous Liquid Nimodipine Compositions,” was duly and legally issued on August 16, 2022, from the United States Patent Application No. 17/558,924. A true and correct copy of the ’277 patent is attached to this Second Amended Complaint as Exhibit D.

26. The face of the ’277 patent names Hugh Greg Thomas as inventor and Arbor as assignee. Arbor assigned its rights, title, and interest in the ’277 patent to Azurity. Azurity, as assignee, owns all rights, title, and interest in the ’277 patent.

27. Pursuant to 21 U.S.C. § 355, the '277 patent is listed in the Orange Book in connection with NDA No. 203340 and Azurity's Nymalize® Product.

28. Azurity's Nymalize® Product is covered by at least one claim of the '277 patent.

INFRINGEMENT BY ALKEM

29. By letter dated November 29, 2021 (the "Notice Letter"), Alkem notified Arbor, the holder of NDA No. 203340 at the time of the Notice Letter, that it had submitted ANDA No. 213409 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 Nymalize® Product (the "Alkem ANDA Product") before the expiration of the '787 and '070 patents.

30. By letter dated February 15, 2021 (the "Second Notice Letter"), Alkem notified Arbor, the holder of NDA No. 203340 at the time of the Second Notice Letter, that it had submitted ANDA No. 213409 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 Nymalize® Product (the "Alkem ANDA Product") before the expiration of the '306 patent.

31. Each of the '787, '070, '306, and '277 patents expire on April 16, 2038.

32. On information and belief, Alkem is seeking FDA approval to engage in the commercial manufacture, use, and sale of the Alkem ANDA Product before the expiration of the '787, '070, '306, and '277 patents.

33. On information and belief, Alkem intends to engage in commercial manufacture, use, and sale of the Alkem ANDA Product promptly upon receiving FDA approval of its ANDA.

34. By submitting ANDA No. 213409, Alkem has represented to FDA that the Alkem ANDA Product has the same active ingredients as Azurity's Nymalize® Product; has the same route of administration, dosage form, use, and strength as Azurity's Nymalize® Product; and is bioequivalent to Azurity's Nymalize® Product.

35. A thirty-month stay of approval is already in place with respect to the accused ANDA because the original Complaint in this action was filed within forty-five (45) days of Arbor's receipt of Alkem's initial Notice Letter.

CLAIMS FOR RELIEF

Count I—Infringement of the '787 Patent Under 35 U.S.C. § 271(e)(2)

36. Azurity incorporates each of the preceding paragraphs as if fully set forth herein.

37. Alkem submitted ANDA No. 213409 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 throughout the United States before the expiration of the '787 patent. By submitting its ANDA, Alkem has committed an act of infringement of one or more claims of the '787 patent under 35 U.S.C. § 271(e)(2)(A).

38. If Alkem's ANDA is approved by FDA, the commercial manufacture, use, 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 '787 patent under 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

39. On information and belief, Alkem has actual and constructive knowledge of the '787 patent, and is aware that submission of ANDA No. 213409 to FDA constituted an act of infringement of the '787 patent. In addition, upon information and belief, Alkem has specific intent to infringe the '787 patent when it filed ANDA No. 213409. Moreover, there are no

substantial non-infringing uses for the Alkem ANDA Product other than as the pharmaceutical claimed in the '787 patent.

40. The commercial manufacture, use, offer for sale, sale, and/or importation of the Alkem ANDA Product in violation of Azurity's patent rights will cause substantial and irreparable harm to Azurity for which damages are inadequate.

Count II—Infringement of the '070 Patent Under 35 U.S.C. § 271(e)(2)

41. Azurity incorporates each of the preceding paragraphs as if fully set forth herein.

42. Alkem submitted ANDA No. 213409 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 throughout the United States before the expiration of the '070 patent. By submitting its ANDA, Alkem has committed an act of infringement of one or more claims of the '070 patent under 35 U.S.C. § 271(e)(2)(A).

43. If Alkem's ANDA is approved by FDA, the commercial manufacture, use, 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 '070 patent under 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

44. On information and belief, Alkem has actual and constructive knowledge of the '070 patent, and is aware that submission of ANDA No. 213409 to FDA constituted an act of infringement of the '070 patent. In addition, upon information and belief, Alkem has specific intent to infringe the '070 patent when it filed ANDA No. 213409. Moreover, there are no substantial non-infringing uses for the Alkem ANDA Product other than as the pharmaceutical claimed in the '070 patent.

45. The commercial manufacture, use, offer for sale, sale, and/or importation of the Alkem ANDA Product in violation of Azurity's patent rights will cause substantial and irreparable harm to Azurity for which damages are inadequate.

Count III—Infringement of the '306 Patent Under 35 U.S.C. § 271(e)(2)

46. Azurity incorporates each of the preceding paragraphs as if fully set forth herein.

47. Alkem submitted ANDA No. 213409 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 throughout the United States before the expiration of the '306 patent. By submitting its ANDA, Alkem has committed an act of infringement of one or more claims of the '306 patent under 35 U.S.C. § 271(e)(2)(A).

48. If Alkem's ANDA is approved by FDA, the commercial manufacture, use, 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 '306 patent under 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

49. On information and belief, Alkem has actual and constructive knowledge of the '306 patent, and is aware that submission of ANDA No. 213409 to FDA constituted an act of infringement of the '306 patent. In addition, upon information and belief, Alkem has specific intent to infringe the '306 patent when it filed ANDA No. 213409. Moreover, there are no substantial non-infringing uses for the Alkem ANDA Product other than as the pharmaceutical claimed in the '306 patent.

50. The commercial manufacture, use, offer for sale, sale, and/or importation of the Alkem ANDA Product in violation of Azurity's patent rights will cause substantial and irreparable harm to Azurity for which damages are inadequate.

Count IV—Infringement of the '277 Patent Under 35 U.S.C. § 271(e)(2)

51. Azurity incorporates each of the preceding paragraphs as if fully set forth herein.

52. Alkem submitted ANDA No. 213409 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 throughout the United States before the expiration of the '277 patent. By submitting its ANDA, Alkem has committed an act of infringement of one or more claims of the '277 patent under 35 U.S.C. § 271(e)(2)(A).

53. If Alkem's ANDA is approved by FDA, the commercial manufacture, use, 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 '277 patent under 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

54. On information and belief, Alkem has actual and constructive knowledge of the '277 patent, and is aware that submission of ANDA No. 213409 to FDA constituted an act of infringement of the '277 patent. In addition, upon information and belief, Alkem has specific intent to infringe the '277 patent when it filed ANDA No. 213409. Moreover, there are no substantial non-infringing uses for the Alkem ANDA Product other than as the pharmaceutical claimed in the '277 patent.

55. The commercial manufacture, use, offer for sale, sale, and/or importation of the Alkem ANDA Product in violation of Azurity's patent rights will cause substantial and irreparable harm to Azurity for which damages are inadequate.

PRAYER FOR RELIEF

Azurity respectfully requests the following relief:

a) A judgment that Alkem has infringed the '787, '070, '306, and '277 patents under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 213409 under Section 505(j) of the FDCA, and that Alkem's making, using, 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 '787, '070,'306, and '277 patents;

b) A finding that the '787, '070, '306, and '277 patents are 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. 213409 shall be a date which is not earlier than the latest expiration date of the '787, '070, '306, and '277 patents, 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 '787, '070, '306, and '277 patents, including the Alkem ANDA Product;

e) A finding that this is an exceptional case under 35 U.S.C. § 285, and that Azurity 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: August 30, 2022

Respectfully submitted,

SAIBER LLC

/s/ *Arnold B. Calmann*

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