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

AZURITY PHARMACEUTICALS, INC., Plaintiff, v. AMNEAL PHARMACEUTICALS, LLC, Defendant.	CIVIL ACTION NO.: _____

COMPLAINT FOR PATENT INFRINGEMENT

For its Complaint against Defendant Amneal Pharmaceuticals LLC ("Amneal"), Plaintiff Azurity Pharmaceuticals, Inc. ("Azurity"), by and through its attorneys, alleges as follows:

The Nature of the Action

1. This is an action for infringement of United States Patent Nos. 10,695,329 ("the '329 patent"), 10,799,453 ("the '453 patent"), 10,894,039 ("the '039 patent"), and 10,952,998 ("the '998 patent") (collectively, the "Katerzia Patents"), arising under the patent laws of the United States, Title 35, United States Code. This action arises out of the filing by Amneal of Abbreviated New Drug Application ("ANDA") No. 215035 with the U.S. Food and Drug Administration ("FDA") seeking approval of a generic version of Azurity's oral liquid formulation that is the subject of New Drug Application ("NDA") No. 211340, hereinafter referred to as Azurity's "Katerzia® product." 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 Amneal's infringement of the Katerzia 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, 01801.

3. On information and belief, Amneal is a limited liability company organized and existing under the laws of the State of Delaware, with a principal place of business at 400 Crossing Boulevard, Third Floor, Bridgewater, NJ 08807-2863. On information and belief, Amneal is in the business of, among other things, developing, manufacturing, and selling generic copies of branded pharmaceutical products for the U.S. market.

Jurisdiction and Venue

4. This action arises under the patent laws of the United States of America, 35 U.S.C. § 1, *et seq*. This Court has subject matter jurisdiction over the action under 28 U.S.C. §§ 1331, 1338(a) (patent infringement). Relief is sought under 35 U.S.C. § 271(e).

5. This Court has personal jurisdiction over Amneal because, on information and belief, Amneal is a limited liability company operating a principal place of business at 400 Crossing Boulevard, Third Floor, Bridgewater, NJ 08807-2863.

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

Azurity's Katerzia® Product

7. Azurity's Katerzia® product is an FDA approved and labeled calcium channel blocker indicated for treatment of hypertension in adults and pediatric patients 6 years of age and older. Katerzia® is also indicated for treatment of coronary artery disease, including chronic

stable angina, vasospastic angina, and angiographically documented coronary artery disease in patients without heart failure or an ejection fraction < 40%.

8. Azurity is the holder of approved NDA No. 211340.

Patents-In-Suit

9. The ’329 patent, entitled “Amlodipine Formulations,” was duly and legally issued on June 30, 2020. A true and correct copy of the ’329 patent is attached to this Complaint as Exhibit A.

10. The face of the ’329 patent names Scott Brauer and Gerold L. Mosher as inventors and Silvergate Pharmaceuticals, Inc. (“Silvergate”) as assignee. Silvergate assigned all interest in the ’329 patent to Azurity. Azurity, as assignee, holds all rights to sue and to recover for infringement of the ’329 patent.

11. Pursuant to 21 U.S.C. § 355, the ’329 patent is listed in the Approved Drug Products with Therapeutic Equivalence Evaluations (“the Orange Book”), in connection with Azurity’s Katerzia® product.

12. Azurity’s Katerzia® product is covered by at least one claim of the ’329 patent.

13. The ’453 patent, entitled “Amlodipine Formulations,” was duly and legally issued on October 13, 2020. A true and correct copy of the ’453 patent is attached to this Complaint as Exhibit B.

14. The face of the ’453 patent names Scott Brauer and Gerold L. Mosher as inventors and Silvergate as assignee. Silvergate assigned all interest in the ’453 patent to Azurity. Azurity, as assignee, holds all rights to sue and to recover for infringement of the ’453 patent.

15. Pursuant to 21 U.S.C. § 355, the ’453 patent is listed in the Orange Book in connection with Azurity’s Katerzia® product.

16. Azurity’s Katerzia® product is covered by at least one claim of the ’453 patent.

17. The ’039 patent, entitled “Amlodipine Formulations,” was duly and legally issued on January 19, 2021. A true and correct copy of the ’039 patent is attached to this Complaint as Exhibit C.

18. The face of the ’039 patent names Scott Brauer and Gerold L. Mosher as inventors and Silvergate as assignee. Silvergate assigned all interest in the ’039 patent to Azurity. Azurity, as assignee, holds all rights to sue and to recover for infringement of the ’039 patent.

19. Pursuant to 21 U.S.C. § 355, the ’039 patent is listed in the Orange Book in connection with Azurity’s Katerzia® product.

20. The use of Azurity’s Katerzia® product is covered by at least one claim of the ’039 patent.

21. The ’998 patent, entitled “Amlodipine Formulations,” was duly and legally issued on March 23, 2021. A true and correct copy of the ’998 patent is attached to this Complaint as Exhibit D.

22. The face of the ’998 patent names Scott Brauer and Gerold L. Mosher as inventors and Silvergate as assignee. Silvergate assigned all interest in the ’998 patent to Azurity. Azurity, as assignee, holds all rights to sue and to recover for infringement of the ’998 patent.

23. Pursuant to 21 U.S.C. § 355, the ’998 patent is listed in the Orange Book in connection with Azurity’s Katerzia® product.

24. Azurity's Katerzia® product is covered by at least one claim of the '998 patent.

Infringement by Amneal

25. By letter dated February 23, 2021 (the "Notice Letter"), Amneal notified Azurity that it had submitted ANDA No. 215035 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)(iv)(I) and 21 C.F.R. §314.95(c)(1)) seeking approval to engage in the commercial manufacture, use, and sale of a generic version of Azurity's Katerzia® product (the "Amneal ANDA Product") before the expiration of the '329 and '453 patents.

26. On information and belief, Amneal is seeking FDA approval to engage in the commercial manufacture, use, and sale of the Amneal ANDA Product before the expiration of the '329. '453, '039 and '998 patents.

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

28. By filing ANDA No. 215035, Amneal has necessarily represented to FDA that the Amneal ANDA Product has the same active ingredient as Azurity's Katerzia® product, as well as the same dosage form, route of administration, use, and strength as Azurity's Katerzia® product, and that it is bioequivalent to Azurity's Katerzia® product.

FIRST COUNT

Infringement of the '329 Patent Under 35 U.S.C. § 271 (e)(2)(A)

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

30. Amneal submitted ANDA No. 215035 to FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or

importation of the Amneal ANDA Product throughout the United States. By submitting their ANDA, Amneal has committed an act of infringement of the '329 patent under 35 U.S.C. § 271 (e)(2)(A).

31. If Amneal'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 Amneal ANDA Product will constitute acts of infringement of the '329 patent under 35 U.S.C. § 271(a)-(c).

32. On information and belief, Amneal had actual and constructive knowledge of the '329 patent prior to filing ANDA No. 215035 and was aware that filing this ANDA with FDA constituted an act of infringement of the '329 patent. Further, on information and belief, Amneal had specific intent to infringe the '329 patent when it filed ANDA No. 215035. Moreover, there are no substantial non-infringing uses for the Amneal ANDA Product other than as the formulation claimed in the '329 patent.

33. The commercial manufacture, use, offer for sale, sale, and/or importation of the Amneal ANDA Product in violation of Azurity's patent rights will cause irreparable harm to Azurity if Amneal's infringement of the '329 patent is not enjoined by this Court. Azurity does not have an adequate remedy at law.

SECOND COUNT

Infringement of the '453 Patent Under 35 U.S.C. § 271 (e)(2)(A)

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

35. Amneal submitted ANDA No. 215035 to FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of the Amneal ANDA Product throughout the United States. By submitting the

ANDA, Amneal has committed an act of infringement of the '453 patent under 35 U.S.C. § 271 (e)(2)(A).

36. If Amneal'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 Amneal ANDA Product will constitute acts of infringement of the '453 patent under 35 U.S.C. § 271(a)-(c).

37. On information and belief, Amneal had actual and constructive knowledge of the '453 patent prior to filing ANDA No. 215035 and was aware that filing this ANDA with FDA constituted an act of infringement of the '453 patent. Further, on information and belief, Amneal had specific intent to infringe the '453 patent when it filed ANDA No. 215035. Moreover, there are no substantial non-infringing uses for the Amneal ANDA Product other than as the product claimed in the '453 patent.

38. The commercial manufacture, use, offer for sale, sale, and/or importation of the Amneal ANDA Product in violation of Azurity's patent rights will cause irreparable harm to Azurity if Amneal's infringement of the '453 patent is not enjoined by this Court. Azurity does not have an adequate remedy at law.

THIRD COUNT

Infringement of the '039 Patent Under 35 U.S.C. § 271 (e)(2)(A)

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

40. Amneal submitted ANDA No. 215035 to FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of the Amneal ANDA Product throughout the United States. By submitting the

ANDA, Amneal has committed an act of infringement of the '039 patent under 35 U.S.C. § 271 (e)(2)(A).

41. If Amneal'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 Amneal ANDA Product will constitute acts of infringement of the '039 patent under 35 U.S.C. § 271(a)-(c).

42. On information and belief, upon FDA approval of Amneal's ANDA, Amneal will intentionally encourage acts of direct infringement with knowledge of the '039 patent and with knowledge that its acts are encouraging infringement.

43. On information and belief, if Amneal's ANDA is approved by FDA, Amneal will contributorily infringe one or more claims of the '039 patent by making, using offering to sell, selling, and/or importing Amneal's ANDA Product in the United states. On information and belief, Amneal has had and continues to have knowledge that Amneal's ANDA Product is especially adapted for a use that infringes one or more claims of the '039 patent and there is no substantial non-infringing use for Amneal's ANDA Product.

44. The commercial manufacture, use, offer for sale, sale, and/or importation of the Amneal ANDA Product in violation of Azurity's patent rights will cause irreparable harm to Azurity if Amneal's infringement of the '039 patent is not enjoined by this Court. Azurity does not have an adequate remedy at law.

FOURTH COUNT

Infringement of the '998 Patent Under 35 U.S.C. § 271 (e)(2)(A)

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

46. Amneal submitted ANDA No. 215035 to FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of the Amneal ANDA Product throughout the United States. By submitting the ANDA, Amneal has committed an act of infringement of the '998 patent under 35 U.S.C. § 271 (e)(2)(A).

47. If Amneal'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 Amneal ANDA Product will constitute acts of infringement of the '998 patent under 35 U.S.C. § 271(a)-(c).

48. On information and belief, upon FDA approval of Amneal's ANDA, Amneal will intentionally encourage acts of direct infringement with knowledge of the '998 patent and with knowledge that its acts are encouraging infringement.

49. On information and belief, if Amneal's ANDA is approved by FDA, Amneal will contributorily infringe one or more claims of the '998 patent by making, using offering to sell, selling, and/or importing Amneal's ANDA Product in the United states. On information and belief, Amneal has had and continues to have knowledge that Amneal's ANDA Product is especially adapted for a use that infringes one or more claims of the '998 patent and there is no substantial non-infringing use for Amneal's ANDA Product.

50. The commercial manufacture, use, offer for sale, sale, and/or importation of the Amneal ANDA Product in violation of Azurity's patent rights will cause irreparable harm to Azurity if Amneal's infringement of the '998 patent is not enjoined by this Court. Azurity does not have an adequate remedy at law.

Prayer for Relief

Azurity respectfully requests the following relief:

a) A judgment that Amneal has infringed the ’329, ’453, ’039, and ’998 patents under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 215035 under Section 505(j) of the FDCA, and that Amneal’s making, using, offering to sell, or selling in the United States, or importing into the United States of the Amneal ANDA Product will infringe one or more claims of the ’329, ’453, ’039, and ’998 patents;

b) A finding that the ’329, ’453, ’039, and ’998 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. 215035 shall be a date which is not earlier than the latest expiration date of the ’329, ’453, ’039, and ’998 patents, as extended by any applicable periods of exclusivity;

d) An order under 35 U.S.C. § 27l(e)(4)(B) permanently enjoining Amneal, 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, or importation into the United States, of any drug product covered by, or any drug product for which the use of the drug product is covered by the ’329, ’453, ’039, or ’998 patent, including the Amneal ANDA Product;

e) A finding that this action for infringement 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: April 8, 2021 Respectfully submitted,

SAIBER LLC

/s/ Arnold B. Calmann

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LOCAL CIVIL RULE 11.2 CERTIFICATION

Pursuant to Local Civil Rule 11.2, the undersigned counsel hereby certifies that this matter in controversy not is the subject of any other action in any other court, or of any pending arbitration or administrative proceeding.

Dated: April 8, 2021

Respectfully submitted,

SAIBER LLC
Attorneys for Plaintiff Azurity Pharmaceuticals, Inc.

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LOCAL CIVIL RULE 201.1 CERTIFICATION

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

Dated: April 8, 2021

Respectfully submitted,

SAIBER LLC
Attorneys for Plaintiff Azurity Pharmaceuticals, Inc.

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