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Arbor Pharmaceuticals, LLC,
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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ARBOR PHARMACEUTICALS, LLC, AZURITY PHARMACEUTICALS, INC., and COMAR, LLC, Plaintiffs, v. AMNEAL PHARMACEUTICALS, LLC, Defendant.	Civil Action No.: COMPLAINT FOR PATENT INFRINGEMENT *Document Electronically Filed*

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Arbor Pharmaceuticals, LLC ("Arbor"), Azurity Pharmaceuticals, Inc. ("Azurity"), and Comar, LLC ("Comar") (collectively, "Plaintiffs"), by and through their attorneys, bring this Complaint against Defendant Amneal Pharmaceuticals, LLC ("Amneal" or "Defendant"), and hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement of United States Patent Nos. 7,070,581, ("the '581 patent"), 8,517,997 ("the '997 patent"), 10,342,787 ("the '787 patent"), 10,576,070 ("the '070 patent"), and 11,207,306 ("the '306 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 Amneal of Abbreviated New Drug Application ("ANDA") No. 216256 to the United States Food and Drug Administration ("FDA") seeking approval of a generic version of Arbor's oral solution formulation and dispenser for the oral solution formulation (the "Nymalize® Product") which are the subject of New Drug Application ("NDA") No. 203340. 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 Amneal's infringement of the Nymalize® Patents.

THE PARTIES

2. Arbor is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at Six Concourse Parkway, Suite 1800, Atlanta, Georgia. Arbor is a wholly owned subsidiary of Arbor Pharmaceuticals, Inc., which is a wholly-owned subsidiary of Azurity.

3. 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.

4. Comar is a limited liability company organized and existing under the laws of the State of Delaware, with a principal place of business at 220 Laurel Road, Suite 201, Voorhees, New Jersey.

5. On information and belief, Amneal is a limited liability company organized under the laws of the State of Delaware, with a principal place of business at 400 Crossing Boulevard, Third Floor, Bridgewater, New Jersey.

6. On information and belief, Amneal is in the business of, among other things, developing, manufacturing, and selling generic copies of branded pharmaceutical products for distribution and sale within the United States.

JURISDICTION AND VENUE

7. This action arises under the patent laws of the United States of America, 35 U.S.C. § 1 *et seq*., and from Amneal's submission of ANDA No. 216256 ("Amneal's ANDA").

8. 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).

9. This Court has personal jurisdiction over Amneal because, on information and belief, Amneal is a limited liability company operating a principal place of business within this judicial district, including at 400 Crossing Boulevard, Third Floor, Bridgewater, New Jersey.

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

11. Upon information and belief, Amneal has a regular and established place of business at 400 Crossing Boulevard, Third Floor, Bridgewater, New Jersey.

12. Upon information and belief, Amneal has committed acts of infringement in this judicial district by, among other things, submitting ANDA No. 216256 from within this judicial district and/or engaging in activities related to the submission of ANDA No. 216256 within this judicial district, and/or directing some or all of the ANDA submission-related from within the judicial district.

THE NYMALIZE® PRODUCT

13. The Nymalize® Product includes both 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) and a dispenser assembly for liquid products.

14. Azurity is the holder of approved NDA No. 203340.

PATENTS-IN-SUIT

15. The ’581 patent, entitled “Dispenser for Medicaments and Method and Apparatus for Making Same,” was duly and legally issued on July 4, 2006, from the United States Patent Application No. 10/407,360. A true and correct copy of the ’581 patent is attached to this Complaint as Exhibit A.

16. The face of the ’581 patent names David A. Manera and John D. Buehler as inventors and Comar, Inc. as assignee. Comar, Inc. assigned all interest in the ’581 patent to Comar. Comar owns all rights, title, and interest in the ’581 patent.

17. Arbor and Azurity are exclusive licensees of the ’581 patent.

18. Pursuant to 21 U.S.C. § 355, the ’581 patent is listed in the Approved Drug Products with Therapeutic Equivalence Evaluations (“the Orange Book”) in connection with NDA No. 203340 and the Nymalize® Product.

19. The Nymalize® Product is covered by at least one claim of the ’581 patent.

20. The ’997 patent, entitled “Dispenser for Medicaments and Method and Apparatus for Making Same,” was duly and legally issued on August 27, 2013, from the United States Patent Application No. 12/029,925. A true and correct copy of the ’997 patent is attached to this Complaint as Exhibit B.

21. The face of the ’997 patent names David A. Manera and John D. Buehler as inventors and Comar, Inc. as assignee. Comar, Inc. assigned all interest in the ’997 patent to Comar. Comar owns all rights, title, and interest in the ’997 patent.

22. Arbor and Azurity are exclusive licensees of the ’997 patent.

23. Pursuant to 21 U.S.C. § 355, the ’997 patent is listed in the Orange Book in connection with NDA No. 203340 and the Nymalize® Product.

24. The Nymalize® Product is covered by at least one claim of the '997 patent.

25. 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 Complaint as Exhibit C.

26. The face of the '787 patent names Hugh Greg Thomas as inventor and Arbor as assignee. Arbor owns all rights, title, and interest in the '787 patent.

27. Pursuant to 21 U.S.C. § 355, the '787 patent is listed in the Orange Book in connection with NDA No. 203340 and the Nymalize® Product.

28. The Nymalize® Product is covered by at least one claim of the '787 patent.

29. 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 Complaint as Exhibit D.

30. The face of the '070 patent names Hugh Greg Thomas as inventor and Arbor as assignee. Arbor owns all rights, title, and interest in the '070 patent.

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

32. The Nymalize® Product is covered by at least one claim of the '070 patent.

33. 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 Complaint as Exhibit E.

34. The face of the '306 patent names Hugh Greg Thomas as inventor and Arbor as assignee. Arbor owns all rights, title, and interest in the '306 patent.

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

36. The Nymalize® Product is covered by at least one claim of the ’306 patent.

INFRINGEMENT BY AMNEAL

37. By letter dated March 10, 2022 (the “Notice Letter”), Amneal notified Plaintiffs that it had submitted ANDA No. 216256 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 the Nymalize® Product (the “Amneal ANDA Product”) before the expiration of the ’581, ’997, ’787, and ’070 patents.

38. By letter dated March 17, 2022 (the “Second Notice Letter”), Amneal notified Arbor that it had submitted ANDA No. 216256 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 the Amneal ANDA Product before the expiration of the ’306 patent.

39. The ’581 patent expires on June 23, 2023.

40. The ’997 patent expires on May 14, 2024.

41. Each of the ’787, ’070, and ’306 patents expire on April 16, 2038.

42. 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 ’581, ’997, ’787, ’070, and ’306 patents.

43. 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.

44. By submitting ANDA No. 216256, Amneal represented to FDA that the Amneal ANDA Product has the same active ingredients as the Nymalize® Product; has the same route of administration, dosage form, use, and strength as the Nymalize® Product; and is bioequivalent to the Nymalize® Product.

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

CLAIMS FOR RELIEF

Count I—Infringement of the '581 Patent Under 35 U.S.C. § 271(e)(2)

46. Plaintiffs incorporate each of the preceding paragraphs 1-45 as if fully set forth herein.

47. Amneal submitted ANDA No. 216256 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 Amneal ANDA Product throughout the United States before the expiration of the '581 patent. By submitting its ANDA, Amneal has committed an act of infringement of one or more claims of the '581 patent under 35 U.S.C. § 271(e)(2)(A).

48. 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, either literally or under the doctrine of equivalents, of the '581 patent under 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

49. On information and belief, Amneal has actual and constructive knowledge of the '581 patent and is aware that submission of ANDA No. 216256 to FDA constituted an act of infringement of the '581 patent. In addition, upon information and belief, Amneal had specific intent to infringe the '581 patent when it filed ANDA No. 216256. Moreover, there are no substantial non-infringing uses for the dispenser of the Amneal ANDA Product other than as the dispenser claimed in the '581 patent.

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

Count II—Infringement of the '997 Patent Under 35 U.S.C. § 271(e)(2)

51. Plaintiffs incorporate each of the preceding paragraphs 1-50 as if fully set forth herein.

52. Amneal submitted ANDA No. 216256 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 Amneal ANDA Product throughout the United States before the expiration of the '997 patent. By submitting its ANDA, Amneal has committed an act of infringement of one or more claims of the '997 patent under 35 U.S.C. § 271(e)(2)(A).

53. 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, either literally or under the doctrine of equivalents, of the '997 patent under 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

54. On information and belief, Amneal has actual and constructive knowledge of the '997 patent and is aware that submission of ANDA No. 216256 to FDA constituted an act of

infringement of the ’997 patent. In addition, upon information and belief, Amneal had specific intent to infringe the ’997 patent when it filed ANDA No. 216256. Moreover, there are no substantial non-infringing uses for the dispenser of the Amneal ANDA Product other than as the dispenser claimed in the ’997 patent.

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

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

56. Plaintiffs incorporate each of the preceding paragraphs 1-55 as if fully set forth herein.

57. Amneal submitted ANDA No. 216256 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 Amneal ANDA Product throughout the United States before the expiration of the ’787 patent. By submitting its ANDA, Amneal has committed an act of infringement of one or more claims of the ’787 patent under 35 U.S.C. § 271(e)(2)(A).

58. 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, 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.

59. On information and belief, Amneal has actual and constructive knowledge of the ’787 patent and is aware that submission of ANDA No. 216256 to FDA constituted an act of infringement of the ’787 patent. In addition, upon information and belief, Amneal had specific intent to infringe the ’787 patent when it filed ANDA No. 216256. Moreover, there are no

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

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

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

61. Plaintiffs incorporate each of the preceding paragraphs 1-60 as if fully set forth herein.

62. Amneal submitted ANDA No. 216256 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 Amneal ANDA Product throughout the United States before the expiration of the '070 patent. By submitting its ANDA, Amneal has committed an act of infringement of one or more claims of the '070 patent under 35 U.S.C. § 271(e)(2)(A).

63. 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, 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.

64. On information and belief, Amneal has actual and constructive knowledge of the '070 patent and is aware that submission of ANDA No. 216256 to FDA constituted an act of infringement of the '070 patent. In addition, upon information and belief, Amneal had specific intent to infringe the '070 patent when it filed ANDA No. 216256. Moreover, there are no substantial non-infringing uses for the Amneal ANDA Product other than as the pharmaceutical claimed in the '070 patent.

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

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

66. Plaintiffs incorporate each of the preceding paragraphs 1-65 as if fully set forth herein.

67. Amneal submitted ANDA No. 216256 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 Amneal ANDA Product throughout the United States before the expiration of the '306 patent. By submitting its ANDA, Amneal has committed an act of infringement of one or more claims of the '306 patent under 35 U.S.C. § 271(e)(2)(A).

68. 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, 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.

69. On information and belief, Amneal has actual and constructive knowledge of the '306 patent and is aware that submission of ANDA No. 216256 to FDA constituted an act of infringement of the '306 patent. In addition, upon information and belief, Amneal had specific intent to infringe the '306 patent when it filed ANDA No. 216256. Moreover, there are no substantial non-infringing uses for the Amneal ANDA Product other than as the pharmaceutical claimed in the '306 patent.

70. The commercial manufacture, use, offer for sale, sale, and/or importation of the Amneal 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 Amneal has infringed the '581, '997, '787, '070, and '306 patents under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 216256 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 '581, '997, '787, '070, and '306 patents;

b) A finding that the '581, '997, '787, '070, and '306 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. 216256 shall be a date which is not earlier than the latest expiration date of the '581, '997, '787, '070, and '306 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, sale, and/or importation into the United States, of any drug product the use of which is covered by the '581, '997, '787, '070, and '306 patents, including the Amneal 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: April 21, 2022

Respectfully submitted,

SAIBER LLC

/s/ *Arnold 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 is the subject of the following matter pending in this Court:

- *Arbor Pharms., LLC v. Alkem Labs. Ltd.*, Civil Action No. 22-143 (D.N.J.) (KMW) (AMD)

Dated: April 21, 2022

Respectfully submitted,

SAIBER LLC

/s/ *Arnold Calmann*

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Attorneys for Plaintiffs Arbor Pharmaceuticals, LLC, Azurity Pharmaceuticals, Inc., and Comar, LLC

LOCAL CIVIL RULE 201.1 CERTIFICATION

Under Local Civil Rule 201.1, the undersigned counsel hereby certifies that the within Complaint seeks injunctive and other equitable relief, and therefore this action is not appropriate for compulsory arbitration.

Dated: April 21, 2022

Respectfully submitted,

SAIBER LLC

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