

**IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION**

AZURITY PHARMACEUTICALS,
INC.,

Plaintiff,

V.

CORERX, INC.,

Defendant.

Case No. 8:21-cv-2515

JURY TRIAL DEMANDED

COMPLAINT FOR PATENT INFRINGEMENT

For its Complaint against Defendant CoreRx, Inc. (“CoreRx” or “Defendant”), Plaintiff Azurity Pharmaceuticals, Inc. (“Azurity” or “Plaintiff”), by and through its attorneys, alleges as follows:

THE NATURE OF THE ACTION

1. This is an action for patent infringement of United States Patent Nos. 11,040,023 (the “’023 patent”) and 11,141,405 (the “’405 patent”) (collectively the “Patents-in-Suit”) and damages under the patent laws of the United States, Title 35, United States Code, that arises out of CoreRx’s manufacture, use, sale, importation, and/or offer to sell and/or inducement of or contributing to others to do the foregoing within the United States of the product that is the subject of Bionpharma Inc.’s (“Bionpharma”) ANDA No. 212408 (“CoreRx Formulation”) prior to the expiration of the Patents-in-Suit. Azurity seeks all available relief under the patent laws of the

United States, 35 U.S.C. § 100 *et. seq.*, and any other applicable laws for CoreRx's infringement of the Patents-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. On information and belief, CoreRx is a corporation organized and existing under the laws of the State of Florida, with its principal place of business at 14205 Myerlake Cir., Clearwater, FL 33760. On information and belief, CoreRx 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.*, and from CoreRx's manufacture, use, sale, importation, and/or offer to sell and/or inducement of or contributing to others to do the foregoing within the United States of the CoreRx Formulation before the expiration of the Patents-in-Suit.

5. 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(a)-(c).

6. This Court has personal jurisdiction over CoreRx because, among other things, on information and belief, CoreRx is a corporation formed under the laws of the State of Florida that maintains a principal place of business in Florida.

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

AZURITY'S EPANED® PRODUCT

8. Azurity holds approved NDA No. 208686 for a ready-to-use oral solution of enalapril maleate, which is prescribed and sold under the trade name Epaned®.

9. Azurity's Epaned® product is the first FDA approved ace inhibitor treatment that is a ready-to-use oral solution for hypertension in children under six years of age. Epaned® is also indicated to treat hypertension in adults, heart failure, and asymptomatic left ventricular dysfunction.

PATENTS-IN-SUIT

10. The '023 patent, entitled "Enalapril Formulations," issued on June 22, 2021. A true and correct copy of the '023 patent is attached to this Complaint as Exhibit A.

11. The '023 patent was duly and legally issued to Azurity as the assignee and Azurity owns all rights, title, and interest in the '023 patent.

12. Pursuant to 21 U.S.C. § 355, the '023 patent is listed in the Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") in connection with Azurity's Epaned® product.

13. The '023 patent describes stable, oral liquid formulations of enalapril.

14. The '023 patent expires on March 25, 2036.

15. The '405 patent, entitled "Enalapril Formulations," issued on October 12, 2021. A true and correct copy of the '405 patent is attached to this Complaint as Exhibit B.

16. The '405 patent was duly and legally issued to Azurity as the assignee and Azurity owns all rights, title, and interest in the '405 patent.

17. Pursuant to 21 U.S.C. § 355, the '405 patent is listed in the Orange Book in connection with Azurity's Epaned[®] product.

18. The '405 patent describes stable, oral liquid formulations of enalapril.

19. The '405 patent expires on March 25, 2036.

INFRINGEMENT BY CORERX

20. On information and belief, CoreRx developed, manufactures, and sells the CoreRx Formulation.

21. On June 22, 2021, Azurity brought an action against Bionpharma alleging that the filing of ANDA No. 212408 was an act of infringement of the '023 patent because the CoreRx Formulation is covered by one or more claims in the '023 patent. That case is captioned *Azurity Pharmaceuticals, Inc. v. Bionpharma Inc.*, C.A. No. 21-1286-LPS (D. Del.) ("the '023 Bionpharma Action").

22. During prior litigation regarding ANDA No. 212408, CoreRx was represented by the same counsel that represented Bionpharma. *See Silvergate Pharmaceuticals, Inc. v. Bionpharma Inc.*, C.A. No. 18-1962-LPS, D.I. 56 (D. Del. Mar. 13, 2020) & C.A. No. 19-1067-LPS, D.I. 68 (D. Del. Mar. 13, 2020).

23. On information and belief, CoreRx is aware of the '023 Bionpharma Action.

24. On information and belief, CoreRx is aware that Azurity, in the '023 Bionpharma Action, filed a motion for preliminary injunction ("Azurity's PI Motion") seeking to enjoin the sale of the CoreRx Formulation.

25. On information and belief, CoreRx is aware that Bionpharma, in response to Azurity's PI Motion, does not deny that the CoreRx Formulation infringes several claims of the '023 patent.

26. On October 15, 2021, Azurity brought an action against Bionpharma for infringement of the '405 patent. That case is captioned *Azurity Pharmaceuticals, Inc. v. Bionpharma Inc.*, C.A. No. 21-1455-LPS (D. Del.) ("the '405 Bionpharma Action").

27. On information and belief, CoreRx is aware of the '405 Bionpharma Action.

28. The Patents-in-Suit expire on March 25, 2036.

29. On information and belief, on August 10, 2021, several weeks after the '023 patent legally issued from the United States Patent and Trademark Office and Azurity brought suit for infringement of the '023 patent against Bionpharma, ANDA No. 212408 was approved by FDA. Thereafter, in blatant disregard for Azurity's patent rights, Bionpharma began offering for sale and selling the CoreRx Formulation which, on information and belief, was manufactured by CoreRx.

30. On information and belief, CoreRx has and continues to engage in the commercial manufacture and sale of the CoreRx Formulation before the expiration of the Patents-in-Suit with the knowledge and intent to infringe the Patents-in-Suit.

31. On information and belief, the CoreRx Formulation infringes at least one claim of the Patents-in-Suit, including at least claim 1 of the '023 patent and claim 1 of the '405 patent, under at least one of 35 U.S.C. § 271(a), (b), and/or (c).

32. On information and belief, under 35 U.S.C. § 271(a)-(c), CoreRx has knowingly, willfully, repeatedly, and continually infringed at least one claim of the Patents-in-Suit, including at least claim 1 of the '023 patent and claim 1 of the '405 patent, by manufacturing, using, offering for sale, selling, and/or importing the CoreRx Formulation, and/or inducement of or contributing to others to do the foregoing in the United States before the expiration date of the Patents-in-Suit.

CLAIMS FOR RELIEF

Count I

(Infringement of the '023 Patent Under 35 U.S.C. § 271(a)-(c))

33. Azurity realleges and incorporates paragraphs 1 through 32 as if fully set forth herein.

34. On information and belief, the CoreRx Formulation has received final approval from FDA.

35. On information and belief, CoreRx has engaged in and/or induced and continues to induce another, including Bionpharma, to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the CoreRx Formulation.

CoreRx's acts of infringement have irreparably injured and damaged and continue to irreparably injure and damage Azurity.

36. The commercial manufacture, use, offer for sale, sale, and/or importation of the CoreRx Formulation is an act of direct infringement of one or more claims of the '023 patent under 35 U.S.C. § 271(a), including at least claim 1 of the '023 patent.

37. On information and belief, CoreRx is inducing infringement of one or more claims of the '023 patent under 35 U.S.C. § 271(b) by inducing the making, using, offering to sell, selling, and/or importation of the CoreRx Formulation in the United States. On information and belief, CoreRx is intentionally encouraging acts of direct infringement with knowledge of the '023 patent and knowledge that its acts are encouraging infringement.

38. On information and belief, CoreRx is contributorily infringing one or more claims of the '023 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing the CoreRx Formulation in the United States. On information and belief, CoreRx, through offering to sell or selling the CoreRx Formulation, has offered to sell or sold, and continues to do so, within the United States or import into the United States a component of a composition or material for use in practicing one or more claims of the '023 patent. On information and belief, CoreRx conducts and has conducted such activities knowing such component of a composition or material to be especially adapted for a use that infringes one or more

claims of the '023 patent and is not a staple article or commodity of commerce suitable for substantial noninfringing use.

39. The foregoing actions by CoreRx constitute infringement of the '023 patent.

40. CoreRx is committing those acts of infringement without license or authorization.

41. CoreRx is committing those acts of infringement despite its knowledge of both the '023 patent and the '023 Bionpharma Action.

42. Azurity is entitled to a judgement that the commercial manufacture, use, offer for sale, sale, and/or importation of the CoreRx Formulation infringes the '023 patent.

43. Azurity has suffered and will continue to suffer financial harm as a result of CoreRx's infringing activities.

44. The commercial manufacture, use, offer for sale, sale, and/or importation of the CoreRx Formulation in violation of Azurity's patent rights has caused and is continuing to cause substantial and irreparable harm to Azurity for which damages are inadequate.

45. Azurity is entitled to monetary damages but, because the infringement by CoreRx of the '023 patent will continue to cause Azurity irreparable injury and damage for which there is no adequate remedy at law unless and until CoreRx is enjoined from infringing the '023 patent, Azurity has no complete, adequate remedy at law and, therefore, is entitled to injunctive relief.

Count II

(Infringement of the '405 Patent Under 35 U.S.C. § 271(a)-(c))

46. Azurity realleges and incorporates paragraphs 1 through 32 as if fully set forth herein.

47. On information and belief, the CoreRx Formulation has received final approval from FDA.

48. On information and belief, CoreRx has engaged in and/or induced and continues to induce another, including Bionpharma, to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the CoreRx Formulation. CoreRx's acts of infringement have irreparably injured and damaged and continue to irreparably injure and damage Azurity.

49. The commercial manufacture, use, offer for sale, sale, and/or importation of the CoreRx Formulation is an act of direct infringement of one or more claims of the '405 patent under 35 U.S.C. § 271(a), including at least claim 1 of the '405 patent.

50. On information and belief, CoreRx is inducing infringement of one or more claims of the '405 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing the CoreRx Formulation in the United States. On information and belief, CoreRx is intentionally encouraging acts of direct infringement with knowledge of the '405 patent and knowledge that its acts are encouraging infringement.

51. On information and belief, CoreRx is contributorily infringing one or more claims of the '405 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing the CoreRx Formulation in the United States. On information and belief, CoreRx, through offering to sell or selling the CoreRx Formulation, has offered to sell or sold, and continues to do so, within the United States or import into the United States a component of a composition or material for use in practicing one or more claims of the '405 patent. On information and belief, CoreRx conducts and has conducted such activities knowing such component of a composition or material to be especially adapted for a use that infringes one or more claims of the '405 patent and is not a staple article or commodity of commerce suitable for substantial noninfringing use.

52. The foregoing actions by CoreRx constitute infringement of the '405 patent.

53. CoreRx is committing those acts of infringement without license or authorization.

54. CoreRx is committing those acts of infringement despite its knowledge of both the '405 patent and the '405 Bionpharma Action Azurity is entitled to a judgement that the commercial manufacture, use, offer for sale, sale, and/or importation of the CoreRx Formulation infringes the '405 patent.

55. Azurity has suffered and will continue to suffer financial harm as a result of CoreRx's infringing activities.

56. The commercial manufacture, use, offer for sale, sale, and/or importation of the CoreRx Formulation in violation of Azurity's patent rights has caused and is continuing to cause substantial and irreparable harm to Azurity for which damages are inadequate.

57. Azurity is entitled to monetary damages but, because the infringement by CoreRx of the '405 patent will continue to cause Azurity irreparable injury and damage for which there is no adequate remedy at law unless and until CoreRx is enjoined from infringing the '405 patent, Azurity has no complete, adequate remedy at law and, therefore, is entitled to injunctive relief.

PRAYER FOR RELIEF

Azurity respectfully requests the following relief:

- a) A finding that the Patents-in-Suit are valid and enforceable;
- b) A judgment that CoreRx's making, using, offering to sell, or selling in the United States, or importing into the United States of the CoreRx Formulation directly infringes one or more claims of the Patents-in-Suit;
- c) A judgment that CoreRx has induced infringement of the Patents-in-Suit by encouraging others to use, sell, offer for sale, and/or import the CoreRx Formulation in the United States before the expiration of the Patents-in-Suit;
- d) A judgment that CoreRx has contributorily infringed the Patents-in-Suit by offering to sell or selling the CoreRx Formulation in the United States before the expiration of the Patents-in-Suit, knowing the same is especially adapted for a use that

directly infringes the Patents-in-Suit and that there is no substantial non-infringing use for the CoreRx Formulation;

e) A judgment that CoreRx's infringement was and is willful;

f) A finding that Azurity be awarded all damages adequate to compensate it for CoreRx's past infringement and any continuing or future infringement of the Patents-in-Suit in addition to interest and costs;

g) A permanent injunction enjoining CoreRx, and 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 the Patents-in-Suit, including the CoreRx Formulation, until the expiration of the Patents-in-Suit;

h) A finding that CoreRx's infringement is willful and that the monetary damages awarded to Azurity be trebled and include pre- and post-judgment interest, costs, and disbursements pursuant to 35 U.S.C. § 284;

i) A finding that this action for infringement is an exceptional case under 35 U.S.C. § 285, and that CoreRx is responsible for payment of Azurity's attorneys' fees and costs;

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

DEMAND FOR JURY TRIAL

Plaintiff Azurity hereby demands a trial by jury on all issues so triable

October 26, 2021

/Woodrow H. Pollack/

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Motions for Special Admission Forthcoming

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