IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AZURITY PHARMACEUTICALS, INC.,	)	
	)	
Plaintiff,	)	C.A. No. 21-1286 (MSG)
	)	CONSOLIDATED
v.	)	
	)	**JURY TRIAL DEMANDED**
BIONPHARMA INC., et al.,	)	
	)	
Defendants.	)	
	)	

FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT

For its First Amended Complaint against Defendant Novitium Pharma, LLC ("Novitium"), 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") under the patent laws of the United States, Title 35, United States Code, that arises out of Novitium'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 Defendant Bionpharma Inc.'s ("Bionpharma") ANDA No. 212408 (the "Novitium 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 Novitium'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, Novitium is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 70 Lake Drive, East Windsor, NJ 08520. On information and belief, Novitium 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 Novitium'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 Novitium 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 and 1338(a) (patent infringement). Relief is sought under 35 U.S.C. §§ 271(a)-(c).

6. This Court has personal jurisdiction over Novitium because, among other things, on information and belief, Novitium is a corporation organized and existing under the laws of the State of Delaware.

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. Epaned® is approved for hypertension in children one month of age

and older and is also indicated to treat hypertension, heart failure, and asymptomatic left ventricular dysfunction in adults.

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 NOVITIUM

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

21. Novitium has represented through an official disclosure to the National Institute of Health that it is the manufacturer of the Novitium Formulation for Bionpharma. Ex. C at 14.[1]

22. On information and belief, the Novitium Formulation is the same formulation as the previous formulation sold by Bionpharma and its previous manufacturer, CoreRx, Inc. ("CoreRx") ("the ANDA Formulation").

23. 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 ANDA Formulation, and thus the Novitium 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-MSG (D. Del.) ("the '023 Bionpharma Action").

24. On information and belief, Novitium is aware of the '023 Bionpharma Action.

25. On information and belief, Novitium was aware of the '023 Bionpharma Action when it engaged in the commercial manufacture, offer for sale, and sale of the Novitium Formulation.

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-MSG (D. Del.) ("the '405 Bionpharma Action").

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

28. On information and belief, Novitium was aware of the '405 Bionpharma Action when it engaged in the commercial manufacture, offer for sale, and sale of the Novitium Formulation.

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[1] This information is available through the National Institute of Health's website at: https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=9391b8d8-2217-4838-8976-1a5ad90ef4ca&type=display.

29. On April 1, 2022, Azurity brought an action against CoreRx for infringement of the '023 and '405 patents. That case is captioned *Azurity Pharmaceuticals, Inc. v. CoreRx, Inc.*, C.A. No. 22-784-SDM-AAS (M.D. Fla.) ("the CoreRx Action").

30. On information and belief, Novitium is aware of the CoreRx Action.

31. On information and belief, Novitium was aware of the CoreRx Action when it engaged in the commercial manufacture, offer for sale, and sale of the Novitium Formulation.

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

33. On August 10, 2021, several weeks after the '023 patent legally issued from the United States Patent and Trademark Office and after Azurity brought suit for infringement of the '023 patent against Bionpharma, ANDA No. 212408 was approved by FDA and Bionpharma and CoreRx began selling the ANDA Formulation.

34. Over a year after the '023 patent issued and nearly a year after the '405 patent issued, on information and belief, in June 2022, in blatant disregard for Azurity's patent rights, Novitium listed itself as the manufacturer of the Novitium Formulation.

35. The Novitium Formulation has been approved by FDA, and Novitium has begun manufacturing, offering to sell, and selling the Novitium Formulation to Bionpharma.

36. On or about December 1, 2021, CoreRx stopped supplying the ANDA Formulation to Bionpharma. Ex. D. On December 13, 2021, Bionpharma's President and CEO, Venkat Krishnan, stated in a declaration signed under penalty of perjury that it would take at least nine months for Bionpharma to obtain a new supplier and transfer the product to a new manufacturer. Ex. E at ¶ 34. At the time, Bionpharma was "currently engaged" in obtaining a new supplier. *Id.* Novitium is that new supplier. *See* Ex. C at 14.

37. On information and belief, Bionpharma is no longer selling the ANDA Formulation previously supplied by CoreRx and is now selling the Novitium Formulation instead.

Bionpharma's President and CEO, Venkat Krishnan stated in a declaration signed under penalty of perjury, "Bionpharma will exhaust its inventory of [the ANDA Formulation] before" it obtains a new supplier. Ex. F at ¶ 3. Bionpharma requested a preliminary injunction against CoreRx to get it "over the hump" from one supplier to the next. Ex. G at 3:25-4:1, 4:6-13, 5:4-8. On information and belief, Bionpharma has sold through its CoreRx supply of the ANDA Formulation and Novitium is currently manufacturing, offering to sell, and selling to Bionpharma the Novitium Formulation.

38. On information and belief, the Novitium 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).

39. On information and belief, under 35 U.S.C. § 271(a)-(c), Novitium 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 Novitium 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))

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

41. On information and belief, Novitium is engaged in and/or is inducing another, including Bionpharma, to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Novitium Formulation.

42. The commercial manufacture, use, offer for sale, sale, and/or importation of the Novitium Formulation in the United States 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.

43. On information and belief, Novitium 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 Novitium Formulation in the United States. On information and belief, Novitium is intentionally encouraging such acts of direct infringement with knowledge of the ’023 patent and knowledge that its acts are encouraging infringement.

44. On information and belief, Novitium 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 Novitium Formulation in the United States. On information and belief, Novitium, through offering to sell or selling the Novitium 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, Novitium is conducting 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.

45. The foregoing actions by Novitium constitute infringement of the ’023 patent.

46. Novitium is committing those acts of infringement without license or authorization.

47. Novitium is committing those acts of infringement despite its knowledge of the ’023 patent, the ’023 Bionpharma Action, and the CoreRx Action.

48. Azurity is entitled to a judgment that Novitium's commercial manufacture, use, offer for sale, sale, and/or importation of the Novitium Formulation infringes the '023 patent under 35 U.S.C. § 271(a), (b) and/or (c).

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

50. The commercial manufacture, use, offer for sale, sale, and/or importation of the Novitium 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.

51. Azurity is entitled to monetary damages, but because the infringement by Novitium of the '023 patent will continue to cause Azurity irreparable injury and damage for which there is no adequate remedy at law, Azurity is entitled to injunctive relief.

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

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

53. On information and belief, Novitium is engaged in and/or is inducing another, including Bionpharma, to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Novitium Formulation.

54. The commercial manufacture, use, offer for sale, sale, and/or importation of the Novitium Formulation in the United States 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.

55. On information and belief, Novitium is inducing infringement of one or more claims of the '405 patent under 35 U.S.C. § 271(b) by inducing the making, using, offering to sell, selling, and/or importation of the Novitium Formulation in the United States. On information and

belief, Novitium is intentionally encouraging such acts of direct infringement with knowledge of the ’405 patent and knowledge that its acts are encouraging infringement.

56. On information and belief, Novitium 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 Novitium Formulation in the United States. On information and belief, Novitium, through offering to sell or selling the Novitium 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, Novitium is conducting 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.

57. The foregoing actions by Novitium constitute infringement of the ’405 patent.

58. Novitium is committing those acts of infringement without license or authorization.

59. Novitium is committing those acts of infringement despite its knowledge of the ’405 patent, the ’405 Bionpharma Action, and the CoreRx Action.

60. Azurity is entitled to a judgment that Novitium’s commercial manufacture, use, offer for sale, sale, and/or importation of the Novitium Formulation infringes the ’405 patent under 35 U.S.C. § 271(a), (b) and/or (c).

61. Azurity has suffered and will continue to suffer financial harm as a result of Novitium’s infringing activities.

62. The commercial manufacture, use, offer for sale, sale, and/or importation of the Novitium 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.

63. Azurity is entitled to monetary damages, but because the infringement by Novitium of the '405 patent will continue to cause Azurity irreparable injury and damage for which there is no adequate remedy at law, Azurity is entitled to injunctive relief.

PRAYER FOR RELIEF

Azurity respectfully requests the following relief:

a) A judgment that Novitium's making, using, offering to sell, or selling in the United States, or importing into the United States of the Novitium Formulation infringes one or more claims of the Patents-in-Suit and/or induces or contributes to the infringement of one or more claims of the Patents-in-Suit under 35 U.S.C. § 271(a)-(c);

b) A finding that the Patents-in-Suit are valid and enforceable;

c) A finding that Azurity be awarded all damages adequate to compensate it for Novitium's past and any continuing or future infringement of the Patents-in-Suit (and in any event, no less than the reasonable royalty), up to and until any permanent injunction;

d) A permanent injunction enjoining Novitium, 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 Novitium Formulation, until the expiration of the Patents-in-Suit;

e) A finding that Novitium's infringement was and 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;

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

g) An award of the costs and expenses Azurity has incurred in this action; and

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

Dated: July 27, 2023

MORRIS, NICHOLS, ARSHT & TUNNEL LLP

/s/ *Megan E. Dellinger*

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