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

AZURITY PHARMACEUTICALS, INC., Plaintiff, v. BIONPHARMA INC., Defendant.	C.A. No. _____ *Document Filed Electronically*

COMPLAINT FOR PATENT INFRINGEMENT

For its Complaint against Defendant Bionpharma Inc. ("Bionpharma" 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 declaratory judgement of patent infringement of United States Patent No. 11,040,023 (the "'023 patent") under the patent laws of the United States, Title 35, United States Code, and the Declaratory Judgement Act, Title 28 United States Code, that arises out of the filing by Defendant Bionpharma of Abbreviated New Drug Application ("ANDA") No. 212408 with the U.S. Food and Drug Administration ("FDA") seeking approval of a generic version of Azurity's oral solution that is the subject of New Drug Application ("NDA") No.

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208686, hereinafter referred to as Azurity's "Epaned® product," and Bionpharma's decision to launch that product. Azurity seeks all available relief under the patent laws of the United States, 35 U.S.C. § 100 *et. seq.*, and the Declaratory Judgment Act, 28 U.S.C. § 2201, and any other applicable laws for Defendant's infringement of the '023 Patent.

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. Azurity is the successor-in-interest to Silvergate Pharmaceuticals, Inc. ("Silvergate").[1]

4. On information and belief, Bionpharma is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 600 Alexander Rd., #2-4B, Princeton, NJ 08540. On information and belief, Bionpharma 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

5. This action arises under the patent laws of the United States of America, 35 U.S.C. § 1, *et seq.*, and from Bionpharma's submission of ANDA No. 212408.

6. This Court has subject matter jurisdiction over the action under 28 U.S.C. §§ 1331, 1338(a) (patent infringement) and 28 U.S.C. §2201. Relief is sought under 35 U.S.C. §§ 271(a)-(c) and 35 U.S.C. § 271(e).

7. This Court has personal jurisdiction over Bionpharma because, among other things, on information and belief, Bionpharma is a corporation with its principal place of business in New Jersey.

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

[1] For simplicity, both Azurity and Silvergate are referred to herein as "Azurity."

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AZURITY'S EPANED® PRODUCT

9. 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®.

10. Azurity's Epaned® product is the only FDA approved and labeled ace inhibitor treatment that is a ready-to-use oral solution for hypertension in children. Epaned® is also indicated to treat hypertension in adults, heart failure, and asymptomatic left ventricular dysfunction.

PATENTS-IN-SUIT

11. 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.

12. 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.

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

INFRINGEMENT BY BIONPHARMA

14. By letter dated October 30, 2018, Bionpharma notified Azurity that it had submitted ANDA No. 212408 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 Epaned® product ("Bionpharma ANDA Product") before the expiration of United States Patent Nos. 9,669,008 (the "'008 Patent"), 9,808,442 (the "'442 Patent"), and 10,039,745 (the "'745 Patent").[2]

15. By letter dated April 25, 2019, Bionpharma notified Azurity that it had submitted ANDA No. 212408 to FDA under Section 505(j)(2)(B) of the 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

[2] On December 12, 2018, Azurity brought an action against Bionpharma for infringement of the '008 Patent, '442 Patent, and '745 Patent in the District of Delaware. That case was captioned *Silvergate Pharmaceuticals, Inc. v. Bionpharma Inc*. C.A. No. 18-1962 (D. Del). A final judgment, dated April 29, 2021, is currently on appeal at the Federal Circuit.

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of the Bionpharma ANDA Product before the expiration of United States Patent No. 10,154,987 (the "'987 Patent").[3]

16. By two separate letters both dated December 4, 2020, Bionpharma notified Azurity that it had submitted ANDA No. 212408 to FDA under Section 505(j)(2)(B) of the 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 Bionpharma ANDA Product before the expiration of United States Patent Nos. 10,772,868 (the "'868 Patent") and 10,786,482 (the "'482 Patent").[4]

17. Each of the '008, '442, '987, '868, '481, and '023 Patents expire on March 25, 2036.

18. On information and belief, Bionpharma intends to engage in commercial manufacture, use, and sale of the Bionpharma ANDA Product promptly upon receiving FDA approval to do so.

19. On information and belief, Bionpharma is seeking approval to engage in the commercial manufacture, use, and sale of the Bionpharma ANDA Product before the expiration of the '023 Patent.

20. On information and belief, Bionpharma's proposed generic version of Azurity's Epaned® brand product, if approved and marketed, will infringe, either literally or under the doctrine of equivalents, at least one claim, including at least claim 1 of the '023 Patent, under at least one of 35 U.S.C. § 271(a), (b), and/or (c).

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[3] On June 7, 2019, Azurity brought an action against Bionpharma for infringement of the '987 Patent in the District of Delaware. That case was captioned *Silvergate Pharmaceuticals, Inc. v. Bionpharma Inc*. C.A. No. 19-1067 (D. Del) and proceeded on the same schedule as C.A. No. 18-1962. A final judgment, dated April 29, 2021, is currently on appeal at the Federal Circuit.

[4] On September 18, 2020, Azurity brought an action against Bionpharma for infringement of the '868 Patent and the '482 Patent in the District of Delaware. That case was captioned *Silvergate Pharmaceuticals, Inc. v. Bionpharma Inc*. C.A. No. 20-1256 (D. Del). The Parties filed a Stipulation of Dismissal on May 17, 2021 pending the outcome of the decision on appeal in C.A. No. 18-1962 (D. Del.) and No. 19-1067.

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21. On information and belief, under 35 U.S.C. § 271(e)(2)(A), Bionpharma has infringed at least one claim, including at least claim 1, of the '023 Patent by submitting, or causing to be submitted, to FDA ANDA No. 212408 seeking approval to manufacture, use, import, offer to sell or sell Bionpharma's proposed generic version of Azurity's Epaned® brand product before the expiration date of the '023 Patent. Upon information and belief, the product described in ANDA No. 212408 would infringe, either literally or under the doctrine of equivalents, at least one claim, including at least claim 1 of the '023 Patent under 35 U.S.C. § 271(e)(2)(A).

CLAIM FOR RELIEF

Count I
(Infringement of the '023 Patent Under 35 U.S.C. § 271(e)(2)(A))

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

23. Bionpharma submitted ANDA No. 212408 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 Bionpharma ANDA Product throughout the United States prior to the expiration of the '023 patent. By submitting the ANDA, Bionpharma has committed an act of infringement of the '023 Patent under 35 U.S.C. § 271(e)(2)(A).

24. There is a definite and concrete, real and substantial, justiciable, and continuing case or controversy existing between Azurity and Bionpharma as to the infringement of the '023 Patent.

25. If Bionpharma's ANDA is approved by FDA, the commercial manufacture, use, offer for sale, sale, and/or importation of the product that is the subject of Bionpharma's ANDA No. 212408 will constitute an act of direct or indirect infringement of one or more claims of the '023 patent under 35 U.S.C. § 271(a)-(c).

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

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