

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

AZURITY PHARMACEUTICALS, INC.,	)	
	)	
	)	
Plaintiff,	)	
	)	
v.	)	Case No. 8:21-cv-2515
	)	
CORERX, INC.,	)	
	)	<b>JURY TRIAL DEMANDED</b>
Defendant.	)	

**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<sup>®</sup> 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.

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