



United States, 35 U.S.C. § 100 *et. seq.*, and any other applicable laws for CoreRx's infringement of the Patents-in-Suit. This is also an action for breach of contract arising out of the Litigation Settlement Agreement by and between Azurity and CoreRx, dated November 24, 2021 (the "Settlement Agreement").

### **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 supplemental jurisdiction over Azurity's breach of contract claim pursuant to 28 U.S.C. § 1367. The federal and state claims alleged herein are so related that they form part of the same case or controversy. Judicial economy, convenience, and fairness to the parties will result if this Court asserts jurisdiction over the breach of contract claims.

7. In the alternative, this Court has subject matter jurisdiction over Azurity's breach of contract claim pursuant to 28 U.S.C. § 1332. The matter in controversy exceeds the sum or value of \$75,000, exclusive of interest and costs.

8. 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.

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

#### **AZURITY'S EPANED® PRODUCT**

10. 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®.

11. 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**

12. 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.

13. 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.

14. 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<sup>®</sup> product.

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

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

17. 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.

18. 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.

19. 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.

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

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

### INFRINGEMENT BY CORERX

22. On information and belief, CoreRx developed, manufactures, and sells the CoreRx 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 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”).

24. 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).

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

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. 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

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