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Attorneys for Plaintiff Azurity Pharmaceuticals, Inc.

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

AZURITY PHARMACEUTICALS, INC. Plaintiff, v. ANNORA PHARMA PRIVATE LTD., Defendant.	)	C.A. No. _____

COMPLAINT FOR PATENT INFRINGEMENT

For its Complaint against Defendant Annora Pharma Private Ltd. ("Annora" 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. 9,463,183 (the "'183 patent"); 9,616,096 (the "'096 patent"); 9,814,751 (the "'751 patent"); 10,039,800 (the "'800 patent"); 10,265,370 (the "'370 patent"); 10,406,199 (the "'199 patent"); 10,940,177 (the "'177 patent"); and 11,179,434 (the "'434 patent") (collectively, the "Qbrelis Patents"), arising under the patent laws of the United States, Title 35, United States Code.

2. By letter dated July 24, 2023 (the "Notice Letter"), Annora notified Azurity that it had submitted Abbreviated New Drug Application ("ANDA") No. 218419 to the U.S. Food and Drug Administration ("FDA") under § 505(j)(2)(B) of the Federal Food, Drug and Cosmetic Act ("FDCA") (21 U.S.C. § 355(j)(2)(B)(iv)(I) and 21 C.F.R. § 314.95(c)(1)) seeking approval to engage in the commercial manufacture, use, and sale of a generic version of Azurity's QBRELIS® product (the Annora "ANDA Product") before the expiration of the Qbrelis Patents.

3. This action arises out of the filing by Defendant Annora of ANDA No. 218419 with FDA seeking approval of a generic version of Azurity's oral liquid formulation that is the subject of New Drug Application ("NDA") No. 208401, hereinafter referred to as Azurity's "QBRELIS® product." Azurity seeks all available relief under the patent laws of the United States, 35 U.S.C. § 100 *et. seq.*, and other applicable laws for Defendant's infringement of the Qbrelis Patents.

The Parties

4. 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, Massachusetts 01801.

5. On information and belief, Annora is a corporation organized and existing under the laws of the Republic of India, having a principal place of business at Sy. No. 261, Annaram Village, Gummadidala Mandal, Sangareddy Dist., Telangana State, 502313, India.

6. Upon information and belief, Annora is in the business of, among other things, developing, manufacturing, and selling generic copies of branded pharmaceutical products for the United States market.

7. On information and belief, Annora has designated Somaraju Indukuri, Ph.D., as the agent for service of process in the United States for Annora. On information and belief, Dr. Somaraju Indukuri acts at the direction of, under the control of, and/or for the benefit of Annora Pharma. The address for Dr. Somaraju Indukuri is provided in Annora's Notice Letter as 121 New England Avenue, Piscataway, New Jersey 08854. On information and belief, Dr. Somaraju Indukuri is the Vice President, Regulatory Affairs, U.S. Agent for Hetero USA Inc., and Annora Pharma Private Limited's parent corporation is Hetero Labs Ltd. *Catalyst Pharmaceuticals, Inc. et al. v. Annora Pharma Private Ltd. et al.*, C.A. No. 2:23-cv-01194-MEF-JRA, D.I. 8 (March 13, 2023) (Defendants Annora Pharma Private Limited, Grace Consulting Services, Inc., Hetero Labs, Ltd. and Hetero USA, Inc.'s Rule 7.1 Corporate Disclosure Statement and Certification Pursuant to L. Civ. R. 11.2). On information and belief, Hetero USA Inc.'s parent corporations are Hetero Labs Ltd. and Hetero Drugs Ltd. *Id.*

Jurisdiction and Venue

8. This action arises under the patent laws of the United States of America, 35 U.S.C. § 1, *et seq*. and from Annora's submission of ANDA No. 218419.

9. 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(e)(2).

10. On information and belief, this Court has personal jurisdiction over Annora because of, among other things, Annora's persistent and continuous contacts with New Jersey. Annora has purposefully availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here. On information and belief, Annora regularly and continuously transacts business in New Jersey, including by directly or indirectly through one or more agents, developing, manufacturing, marketing, and selling generic pharmaceutical products in New Jersey. On information and belief, Annora derives substantial revenue from the sale of those products in New Jersey and has availed itself of the privilege of conducting business within New Jersey. Annora has regularly engaged in patent litigation concerning FDA-approved products in this judicial district, has not contested personal jurisdiction in such litigation in this judicial district, and has purposefully availed itself of the rights and benefits of this Court by asserting claims and/or counterclaims in this Court. *E.g.*, *Rigel Pharmaceuticals, Inc. v. Annora Pharma Private, Ltd. et al.*, C.A. No. 3:22-cv-04732 (D.I. 7) (September 21, 2022); *Celgene Corp. v. Annora Pharma Private Limited et al.*, C.A. No. 18-cv-11220 (MAS/DEA) (D.I. 11) (September 10, 2018).

11. In the alternative, this Court has personal jurisdiction over Annora because the requirements of Federal Rule of Civil Procedure 4(k)(2) are met as (a) Azurity's claims arise under federal law; (b) Annora is a foreign defendant not subject to general personal jurisdiction

in the courts of any state; and (c) Annora has sufficient contacts with the United States as a whole, including, but not limited to, preparing and submitting ANDAs to FDA and/or manufacturing, importing, offering to sell, or selling pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Annora satisfies due process.

12. At least because, on information and belief, Annora is a foreign corporation, venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b).

Azurity's QBRELIS® Product

13. Azurity's QBRELIS® product is an FDA approved angiotensin converting enzyme ("ACE") inhibitor indicated for treatment of hypertension in adults and pediatric patients 6 years of age and older. QBRELIS® is also indicated for adjunct therapy for heart failure and treatment of acute myocardial infarction.

14. Azurity is the holder of NDA No. 208401.

Patents-In-Suit

15. The '183 patent, entitled "Lisinopril Formulations," was duly and legally issued on October 11, 2016. A true and correct copy of the '183 patent is attached to this Complaint as Exhibit A. Azurity is the assignee of the '183 patent.

16. Pursuant to 21 U.S.C. § 355, the '183 patent is listed in the Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book"), in connection with Azurity's QBRELIS® product. Azurity's QBRELIS® product is covered by at least one claim of the '183 patent.

17. The ’096 patent, entitled “Lisinopril Formulations,” was duly and legally issued on April 11, 2017. A true and correct copy of the ’096 patent is attached to this Complaint as Exhibit B. Azurity is the assignee the ’096 patent.

18. Pursuant to 21 U.S.C. § 355, the ’096 patent is listed in the Orange Book in connection with Azurity’s QBRELIS® product. The use of Azurity’s QBRELIS® product is covered by at least one claim of the ’096 patent.

19. The ’751 patent, entitled “Lisinopril Formulations,” was duly and legally issued on November 14, 2017. A true and correct copy of the ’751 patent is attached to this Complaint as Exhibit C. Azurity is the assignee the ’751 patent.

20. Pursuant to 21 U.S.C. § 355, the ’751 patent is listed in the Orange Book in connection with Azurity’s QBRELIS® product. Azurity’s QBRELIS® product is covered by at least one claim of the ’751 patent.

21. The ’800 patent, entitled “Lisinopril Formulations,” was duly and legally issued on August 7, 2018. A true and correct copy of the ’800 patent is attached to this Complaint as Exhibit D. Azurity is the assignee the ’800 patent.

22. Pursuant to 21 U.S.C. § 355, the ’800 patent is listed in the Orange Book in connection with Azurity’s QBRELIS® product. The use of Azurity’s QBRELIS® product is covered by at least one claim of the ’800 patent.

23. The ’370 patent, entitled “Lisinopril Formulations,” was duly and legally issued on April 23, 2019. A true and correct copy of the ’370 patent is attached to this Complaint as Exhibit E. Azurity is the assignee the ’370 patent.

24. Pursuant to 21 U.S.C. § 355, the ’370 patent is listed in the Orange Book in connection with Azurity’s QBRELIS® product. Azurity’s QBRELIS® product is covered by at least one claim of the ’370 patent.

25. The ’199 patent, entitled “Lisinopril Formulations,” was duly and legally issued on September 10, 2019. A true and correct copy of the ’199 patent is attached to this Complaint as Exhibit F. Azurity is the assignee the ’199 patent.

26. Pursuant to 21 U.S.C. § 355, the ’199 patent is listed in the Orange Book in connection with Azurity’s QBRELIS® product. The use of Azurity’s QBRELIS® product is covered by at least one claim of the ’199 patent.

27. The ’177 patent, entitled “Lisinopril Formulations,” was duly and legally issued on March 9, 2021. A true and correct copy of the ’177 patent is attached to this Complaint as Exhibit G. Azurity is the assignee the ’177 patent.

28. Pursuant to 21 U.S.C. § 355, the ’177 patent is listed in the Orange Book in connection with Azurity’s QBRELIS® product. Azurity’s QBRELIS® product is covered by at least one claim of the ’177 patent.

29. The ’434 patent, entitled “Lisinopril Formulations,” was duly and legally issued on November 23, 2021. A true and correct copy of the ’434 patent is attached to this Complaint as Exhibit H. Azurity is the assignee the ’434 patent.

30. Pursuant to 21 U.S.C. § 355, the ’434 patent is listed in the Orange Book in connection with Azurity’s QBRELIS® product. Azurity’s QBRELIS® product is covered by at least one claim of the ’434 patent.

Infringement by Annora

31. By the Notice Letter, Annora notified Azurity that it had submitted ANDA No. 218419 to FDA under Section 505(j)(2)(B) of the FDCA (21 U.S.C. § 355(j)(2)(B)(iv)(I) and 21 C.F.R. §314.95(c)(1)) seeking approval to engage in the commercial manufacture, use, and sale of the Annora "ANDA Product") before the expiration of the Qbrelis Patents.

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

33. By filing ANDA No. 218419, Annora has necessarily represented to FDA that the Annora ANDA Product has the same active ingredients as Azurity's QBRELIS® product, has the same route of administration, dosage form, use, and strength as Azurity's QBRELIS® product, and is bioequivalent to Azurity's QBRELIS® product.

FIRST COUNT

Infringement of the '183 Patent Under 35 U.S.C. § 271 (e)(2)(A)

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

35. Annora submitted ANDA No. 218419 to FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of the Annora ANDA Product throughout the United States. By submitting the ANDA, Annora has committed an act of infringement of the '183 patent under 35 U.S.C. § 271(e)(2)(A).

36. On information and belief, if Annora's ANDA is approved by FDA, the commercial manufacture, use (in accordance with and as directed by Annora's proposed labeling for Annora's ANDA Product), offer to sell, or sale within the United States, and/or importation into the United States of the Annora ANDA Product will constitute acts of infringement, either

literally or under the doctrine of equivalents, of the '183 patent under 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

37. Upon information and belief, Annora had actual and constructive knowledge of the '183 patent prior to filing ANDA No. 218419 and was aware that filing this ANDA with FDA constituted an act of infringement of the '183 patent. In addition, upon information and belief, Annora had specific intent to infringe the '183 patent when it filed ANDA No. 218419. Moreover, there are no substantial non-infringing uses for the Annora ANDA Product other than as the pharmaceutical claimed in the '183 patent.

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

SECOND COUNT

Infringement of the '096 Patent Under 35 U.S.C. § 271(e)(2)(A)

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

40. Annora submitted ANDA No. 218419 to FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of the Annora ANDA Product throughout the United States. By submitting the ANDA, Annora has committed an act of infringement of the '096 patent under 35 U.S.C. § 271(e)(2)(A).

41. On information and belief, if Annora's ANDA is approved by FDA, the commercial manufacture, use (in accordance with and as directed by Annora's proposed labeling for Annora's ANDA Product), offer to sell, or sale within the United States, and/or importation into the United States of the Annora ANDA Product will constitute acts of infringement, either

literally or under the doctrine of equivalents, of the '096 patent under 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

42. Upon information and belief, Annora had actual and constructive knowledge of the '096 patent prior to filing ANDA No. 218419 and was aware that filing this ANDA with FDA constituted an act of infringement of the '096 patent. In addition, upon information and belief, Annora had specific intent to infringe the '096 patent when it filed ANDA No. 218419. Moreover, there are no substantial non-infringing uses for the Annora ANDA Product other than as the pharmaceutical claimed in the '096 patent.

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

THIRD COUNT

Infringement of the '751 Patent Under 35 U.S.C. § 271(e)(2)(A)

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

45. Annora submitted ANDA No. 218419 to FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of the Annora ANDA Product throughout the United States. By submitting the ANDA, Annora has committed an act of infringement of the '751 patent under 35 U.S.C. § 271(e)(2)(A).

46. On information and belief, if Annora's ANDA is approved by FDA, the commercial manufacture, use (in accordance with and as directed by Annora's proposed labeling for Annora's ANDA Product), offer to sell, or sale within the United States, and/or importation into the United States of the Annora ANDA Product will constitute acts of infringement, either

literally or under the doctrine of equivalents, of the '751 patent under 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

47. Upon information and belief, Annora had actual and constructive knowledge of the '751 patent prior to filing ANDA No. 218419 and was aware that filing this ANDA with FDA constituted an act of infringement of the '751 patent. In addition, upon information and belief, Annora had specific intent to infringe the '751 patent when it filed ANDA No. 218419. Moreover, there are no substantial non-infringing uses for the Annora ANDA Product other than as the pharmaceutical claimed in the '751 patent.

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

FOURTH COUNT

Infringement of the '800 Patent Under 35 U.S.C. § 271(e)(2)(A)

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

50. Annora submitted ANDA No. 218419 to FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of the Annora ANDA Product throughout the United States. By submitting the ANDA, Annora has committed an act of infringement of the '800 patent under 35 U.S.C. § 271(e)(2)(A).

51. On information and belief, if Annora's ANDA is approved by FDA, the commercial manufacture, use (in accordance with and as directed by Annora's proposed labeling for Annora's ANDA Product), offer to sell, or sale within the United States, and/or importation into the United States of the Annora ANDA Product will constitute acts of infringement, either

literally or under the doctrine of equivalents, of the '800 patent under 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

52. Upon information and belief, Annora had actual and constructive knowledge of the '800 patent prior to filing ANDA No. 218419 and was aware that filing this ANDA with FDA constituted an act of infringement of the '800 patent. In addition, upon information and belief, Annora had specific intent to infringe the '800 patent when it filed ANDA No. 218419. Moreover, there are no substantial non-infringing uses for the Annora ANDA Product other than as the pharmaceutical claimed in the '800 patent.

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

FIFTH COUNT

Infringement of the '370 Patent Under 35 U.S.C. § 271(e)(2)(A)

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

55. Annora submitted ANDA No. 218419 to FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of the Annora ANDA Product throughout the United States. By submitting the ANDA, Annora has committed an act of infringement of the '370 patent under 35 U.S.C. § 271(e)(2)(A).

56. On information and belief, if Annora's ANDA is approved by FDA, the commercial manufacture, use (in accordance with and as directed by Annora's proposed labeling for Annora's ANDA Product), offer to sell, or sale within the United States, and/or importation into the United States of the Annora ANDA Product will constitute acts of infringement, either

literally or under the doctrine of equivalents, of the '370 patent under 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

57. Upon information and belief, Annora had actual and constructive knowledge of the '370 patent prior to filing ANDA No. 218419 and was aware that filing this ANDA with FDA constituted an act of infringement of the '370 patent. In addition, upon information and belief, Annora had specific intent to infringe the '370 patent when it filed ANDA No. 218419. Moreover, there are no substantial non-infringing uses for the Annora ANDA Product other than as the pharmaceutical claimed in the '370 patent.

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

SIXTH COUNT

Infringement of the '199 Patent Under 35 U.S.C. § 271(e)(2)(A)

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

60. Annora submitted ANDA No. 218419 to FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of the Annora ANDA Product throughout the United States. By submitting the ANDA, Annora has committed an act of infringement of the '199 patent under 35 U.S.C. § 271(e)(2)(A).

61. On information and belief, if Annora's ANDA is approved by FDA, the commercial manufacture, use (in accordance with and as directed by Annora's proposed labeling for Annora's ANDA Product), offer to sell, or sale within the United States, and/or importation into the United States of the Annora ANDA Product will constitute acts of infringement, either

literally or under the doctrine of equivalents, of the '199 patent under 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

62. Upon information and belief, Annora had actual and constructive knowledge of the '199 patent prior to filing ANDA No. 218419 and was aware that filing this ANDA with FDA constituted an act of infringement of the '199 patent. In addition, upon information and belief, Annora had specific intent to infringe the '199 patent when it filed ANDA No. 218419. Moreover, there are no substantial non-infringing uses for the Annora ANDA Product other than as the pharmaceutical claimed in the '199 patent.

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

SEVENTH COUNT

Infringement of the '177 Patent Under 35 U.S.C. § 271(e)(2)(A)

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

65. Annora submitted ANDA No. 218419 to FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of the Annora ANDA Product throughout the United States. By submitting the ANDA, Annora has committed an act of infringement of the '177 patent under 35 U.S.C. § 271(e)(2)(A).

66. On information and belief, if Annora's ANDA is approved by FDA, the commercial manufacture, use (in accordance with and as directed by Annora's proposed labeling for Annora's ANDA Product), offer to sell, or sale within the United States, and/or importation into the United States of the Annora ANDA Product will constitute acts of infringement, either

literally or under the doctrine of equivalents, of the '177 patent under 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

67. Upon information and belief, Annora has actual and constructive knowledge of the '177 patent and the application from which it issued (U.S. Patent App. No. 16/822,412). In addition, upon information and belief, Annora has specific intent to infringe the '177 patent. Moreover, there are no substantial non-infringing uses for the Annora ANDA Product other than as the pharmaceutical claimed in the '177 patent.

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

EIGHTH COUNT

Infringement of the '434 Patent Under 35 U.S.C. § 271(e)(2)(A)

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

70. Annora submitted ANDA No. 218419 to FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of the Annora ANDA Product throughout the United States. By submitting the ANDA, Annora has committed an act of infringement of the '434 patent under 35 U.S.C. § 271(e)(2)(A).

71. On information and belief, if Annora's ANDA is approved by FDA, the commercial manufacture, use (in accordance with and as directed by Annora's proposed labeling for Annora's ANDA Product), offer to sell, or sale within the United States, and/or importation into the United States of the Annora ANDA Product will constitute acts of infringement, either

literally or under the doctrine of equivalents, of the '434 patent under 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

72. Upon information and belief, Annora has actual and constructive knowledge of the '434 patent and the application from which it issued (U.S. Patent App. No. 17/194,021). In addition, upon information and belief, Annora has specific intent to infringe the '434 patent. Moreover, there are no substantial non-infringing uses for the Annora ANDA Product other than as the pharmaceutical claimed in the '434 patent.

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

Prayer for Relief

Azurity respectfully requests the following relief:

a) A judgment that Annora has infringed the '183, '096, '751, '800, '370, '199, '177, and '434 patents;

b) A judgment ordering that the effective date of any FDA approval of ANDA No. 218419 shall be a date which is not earlier than the latest expiration date of the '183, '096, '751, '800, '370, '199, '177, or '434 patent, as extended by any applicable periods of exclusivity;

c) A preliminary and permanent injunction enjoining Annora, 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, or any drug product for which the use of the drug

product is covered by the '183, '096, '751, '800, '370, '199, '177, or '434 patent, including the Annora ANDA Product;

d) A judgment that the '183, '096, '751, '800, '370, '199, '177, and '434 patents are valid and enforceable;

e) A finding that this is an exceptional case under 35 U.S.C. § 285, and that Azurity be awarded reasonable attorneys' fees and costs; and

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

DATED: September 7, 2023

Respectfully submitted,

SAIBER LLC
Attorneys for Plaintiff Azurity Pharmaceuticals, Inc.

s/ Arnold B. Calmann

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LOCAL CIVIL RULE 11.2 CERTIFICATION

Pursuant to Local Civil Rule 11.2, the undersigned counsel for Plaintiff Azurity Pharmaceuticals, Inc. hereby certify that this matter in controversy is not the subject of any other action in any other court, or of any pending arbitration or administrative proceeding.

Dated: September 7, 2023

Respectfully submitted,

SAIBER LLC

Attorneys for Plaintiff Azurity Pharmaceuticals, Inc.

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LOCAL CIVIL RULE 201.1 CERTIFICATION

Under Local Civil Rule 201.1, the undersigned counsel for Plaintiff Azurity Pharmaceuticals, Inc. hereby certify that they seek both monetary damages greater than $150,000 and injunctive and other equitable relief, and therefore this action is not appropriate for compulsory arbitration.

Dated: September 7, 2023

Respectfully submitted,

SAIBER LLC

Attorneys for Plaintiff Azurity Pharmaceuticals, Inc.

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