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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** *Document Electronically Filed*

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. 10,493,028 ("'028 Patent"); 10,688,046 ("'046 Patent"); 10,959,946 ("'946 Patent"); 10,959,947 ("'947 Patent"); 10,959,948 ("'948 Patent"); 10,959,949 ("'949 Patent"); and 11,638,692 ("'692 Patent") (collectively, the "Asserted Patents"), arising under the patent laws of the United States, Title 35, United States Code.

2. By letter dated July 15, 2024 (the "Notice Letter"), Annora notified Azurity that it had submitted Abbreviated New Drug Application ("ANDA") No. 218168 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 FIRVANQ® product (the "Annora ANDA Product") before the expiration of the Asserted Patents.

3. This action arises out of the filing by Defendant Annora of ANDA No. 218168 with FDA seeking approval of a generic version of Azurity's vancomycin hydrochloride oral solution that is the subject of New Drug Application ("NDA") No. 208910, hereinafter referred to as "Azurity's FIRVANQ® 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 Asserted 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. 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. 218168.

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 FIRVANQ® Product

13. Azurity's FIRVANQ® product is an FDA approved antibacterial indicated in adults and pediatric patients less than 18 years of age for treatment of *Clostridium difficile*-associated diarrhea. FIRVANQ® is also indicated for the treatment of enterocolitis caused by *Staphylococcus aureus* (including methicillin-resistant strains).

14. Azurity is the holder of NDA No. 208910.

Asserted Patents

15. The '028 Patent, entitled "Composition and Method for Vancomycin Oral Liquid," was duly and legally issued on December 3, 2019, from U.S. Patent Application No. 15/791,717. A true and correct copy of the '028 Patent is attached to this Complaint as Exhibit A.

16. The face of the '028 Patent names Indu Muni, Peter Mione, Anisa Gandhi, and Cristina LeChiara as inventors and CutisPharma as assignee, which assigned the '028 Patent to Azurity. Azurity, as assignee, owns all rights, title, and interest in the '028 Patent.

17. Pursuant to 21 U.S.C. § 355, the '028 Patent is listed in the Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book"), in connection with

Azurity's FIRVANQ® product. Azurity's FIRVANQ® product is covered by at least one claim of the '028 Patent.

18. The '046 Patent, entitled "Composition and Method for Vancomycin Oral Liquid," was duly and legally issued on June 23, 2020, from U.S. Patent Application No. 16/676,325. A true and correct copy of the '046 Patent is attached to this Complaint as Exhibit B.

19. The face of the '046 Patent names Indu Muni, Peter Mione, Anisa Gandhi, and Cristina LeChiara as inventors and CutisPharma as assignee, which assigned the '046 Patent to Azurity. Azurity, as assignee, owns all rights, title, and interest in the '046 Patent.

20. Pursuant to 21 U.S.C. § 355, the '046 Patent is listed in the Orange Book in connection with Azurity's FIRVANQ® product. The use of Azurity's FIRVANQ® product is covered by at least one claim of the '046 Patent.

21. The '946 Patent, entitled "Composition and Method for Vancomycin Oral Liquid," was duly and legally issued on March 30, 2021, from U.S. Patent Application No. 15/126,059. A true and correct copy of the '946 Patent is attached to this Complaint as Exhibit C.

22. The face of the '946 Patent names Indu Muni, Peter Mione, Anisa Gandhi, and Cristina LeChiara as inventors and Azurity as assignee. Azurity, as assignee, owns all rights, title, and interest in the '946 Patent.

23. Pursuant to 21 U.S.C. § 355, the '946 Patent is listed in the Orange Book in connection with Azurity's FIRVANQ® product. Azurity's FIRVANQ® product is covered by at least one claim of the '946 Patent.

24. The '947 Patent, entitled "Composition and Method for Vancomycin Oral Liquid," was duly and legally issued on March 30, 2021, from U.S. Patent Application No.

16/892,421. A true and correct copy of the '947 Patent is attached to this Complaint as Exhibit D.

25. The face of the '947 Patent names Indu Muni, Peter Mione, Anisa Gandhi, and Cristina LeChiara as inventors and Azurity as assignee. Azurity, as assignee, owns all rights, title, and interest in the '947 Patent.

26. Pursuant to 21 U.S.C. § 355, the '947 Patent is listed in the Orange Book in connection with Azurity's FIRVANQ® product. The use of Azurity's FIRVANQ® product is covered by at least one claim of the '947 Patent.

27. The '948 Patent, entitled "Composition and Method for Vancomycin Oral Liquid," was duly and legally issued on March 30, 2021, from U.S. Patent Application No. 16/941,400. A true and correct copy of the '948 Patent is attached to this Complaint as Exhibit E.

28. The face of the '948 Patent names Indu Muni, Peter Mione, Anisa Gandhi, and Cristina LeChiara as inventors and Azurity as assignee. Azurity, as assignee, owns all rights, title, and interest in the '948 Patent.

29. Pursuant to 21 U.S.C. § 355, the '948 Patent is listed in the Orange Book in connection with Azurity's FIRVANQ® product. Azurity's FIRVANQ® product is covered by at least one claim of the '948 Patent.

30. The '949 Patent, entitled "Composition and Method for Vancomycin Oral Liquid," was duly and legally issued on March 30, 2021, from U.S. Patent Application No. 16/941,414. A true and correct copy of the '949 Patent is attached to this Complaint as Exhibit F.

31. The face of the '949 Patent names Indu Muni, Peter Mione, Anisa Gandhi, and Cristina LeChiara as inventors and Azurity as assignee. Azurity, as assignee, owns all rights, title, and interest in the '949 Patent.

32. Pursuant to 21 U.S.C. § 355, the ’949 Patent is listed in the Orange Book in connection with Azurity’s FIRVANQ® product. The use of Azurity’s FIRVANQ® product is covered by at least one claim of the ’949 Patent.

33. The ’692 Patent, entitled “Composition and Method for Vancomycin Oral Liquid,” was duly and legally issued on May 2, 2023, from U.S. Patent Application No. 17/965,253. A true and correct copy of the ’692 Patent is attached to this Complaint as Exhibit G.

34. The face of the ’692 Patent names Indu Muni, Peter Mione, Anisa Gandhi, and Cristina LeChiara as inventors and Azurity as assignee. Azurity, as assignee, owns all rights, title, and interest in the ’692 Patent.

35. Pursuant to 21 U.S.C. § 355, the ’692 Patent is listed in the Orange Book in connection with Azurity’s FIRVANQ® product. Azurity’s FIRVANQ® product is covered by at least one claim of the ’692 Patent.

Infringement by Annora

36. By the Notice Letter, Annora notified Azurity that it had submitted ANDA No. 218168 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 Asserted Patents.

37. 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.

38. By filing ANDA No. 218168, Annora has necessarily represented to FDA that the Annora ANDA Product has the same active ingredients as Azurity’s FIRVANQ® product, has

the same route of administration, dosage form, use, and strength as Azurity's FIRVANQ® product, and is bioequivalent to Azurity's FIRVANQ® product.

39. In the Notice Letter, Annora offered confidential access to portions of ANDA No. 218168 on the terms and conditions set forth in Section II of the Notice Letter ("Annora Offer"). Annora requested that Azurity accept the Annora Offer before receiving access to any portion of the Annora ANDA. The Annora Offer contained unreasonable restrictions that differ materially from restrictions found under protective orders.

40. Under 21 U.S.C. § 355(j)(5)(c)(i)(III), an "offer of confidential access shall contain such restrictions . . . on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information."

41. Azurity attempted to negotiate with Annora to obtain relevant information from ANDA No. 218168 under restrictions "as would apply had a protective order been issued." On August 16, 2024, counsel for Azurity proposed an amended Offer of Confidential Access seeking access to relevant sections of ANDA No. 218168. As of the filing of this Complaint, Annora has informed Azurity that Annora is represented by outside counsel, but neither Annora nor its counsel has provided any substantive response to Azurity's amended Offer of Confidential Access.

FIRST COUNT

Infringement of the '028 Patent Under 35 U.S.C. § 271 (e)(2)(A)

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

43. Annora submitted ANDA No. 218168 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 '028 Patent under 35 U.S.C. § 271(e)(2)(A).

44. 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 '028 Patent under 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

45. Upon information and belief, Annora had actual and constructive knowledge of the '028 Patent prior to filing ANDA No. 218168 and was aware that filing this ANDA with FDA constituted an act of infringement of the '028 Patent. In addition, upon information and belief, Annora had specific intent to infringe the '028 Patent when it filed ANDA No. 218168. Moreover, there are no substantial non-infringing uses for the Annora ANDA Product other than as the pharmaceutical claimed in the '028 Patent.

46. 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 '046 Patent Under 35 U.S.C. § 271(e)(2)(A)

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

48. Annora submitted ANDA No. 218168 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 '046 Patent under 35 U.S.C. § 271(e)(2)(A).

49. 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 '046 Patent under 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

50. Upon information and belief, Annora had actual and constructive knowledge of the '046 Patent prior to filing ANDA No. 218168 and was aware that filing this ANDA with FDA constituted an act of infringement of the '046 Patent. In addition, upon information and belief, Annora had specific intent to infringe the '046 Patent when it filed ANDA No. 218168. Moreover, there are no substantial non-infringing uses for the Annora ANDA Product other than as the pharmaceutical claimed in the '046 Patent.

51. 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 '946 Patent Under 35 U.S.C. § 271(e)(2)(A)

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

53. Annora submitted ANDA No. 218168 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 '946 Patent under 35 U.S.C. § 271(e)(2)(A).

54. 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 '946 Patent under 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

55. Upon information and belief, Annora had actual and constructive knowledge of the '946 Patent prior to filing ANDA No. 218168 and was aware that filing this ANDA with FDA constituted an act of infringement of the '946 Patent. In addition, upon information and belief, Annora had specific intent to infringe the '946 Patent when it filed ANDA No. 218168. Moreover, there are no substantial non-infringing uses for the Annora ANDA Product other than as the pharmaceutical claimed in the '946 Patent.

56. 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 '947 Patent Under 35 U.S.C. § 271(e)(2)(A)

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

58. Annora submitted ANDA No. 218168 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 '947 Patent under 35 U.S.C. § 271(e)(2)(A).

59. 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 '947 Patent under 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

60. Upon information and belief, Annora had actual and constructive knowledge of the '947 Patent prior to filing ANDA No. 218168 and was aware that filing this ANDA with FDA constituted an act of infringement of the '947 Patent. In addition, upon information and belief, Annora had specific intent to infringe the '947 Patent when it filed ANDA No. 218168. Moreover, there are no substantial non-infringing uses for the Annora ANDA Product other than as the pharmaceutical claimed in the '947 Patent.

61. 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 '948 Patent Under 35 U.S.C. § 271(e)(2)(A)

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

63. Annora submitted ANDA No. 218168 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 '948 Patent under 35 U.S.C. § 271(e)(2)(A).

64. 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 '948 Patent under 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

65. Upon information and belief, Annora had actual and constructive knowledge of the '948 Patent prior to filing ANDA No. 218168 and was aware that filing this ANDA with FDA constituted an act of infringement of the '948 Patent. In addition, upon information and belief, Annora had specific intent to infringe the '948 Patent when it filed ANDA No. 218168. Moreover, there are no substantial non-infringing uses for the Annora ANDA Product other than as the pharmaceutical claimed in the '948 Patent.

66. 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 '949 Patent Under 35 U.S.C. § 271(e)(2)(A)

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

68. Annora submitted ANDA No. 218168 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 '949 Patent under 35 U.S.C. § 271(e)(2)(A).

69. 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 '949 Patent under 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

70. Upon information and belief, Annora had actual and constructive knowledge of the '949 Patent prior to filing ANDA No. 218168 and was aware that filing this ANDA with FDA constituted an act of infringement of the '949 Patent. In addition, upon information and belief, Annora had specific intent to infringe the '949 Patent when it filed ANDA No. 218168. Moreover, there are no substantial non-infringing uses for the Annora ANDA Product other than as the pharmaceutical claimed in the '949 Patent.

71. 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 '692 Patent Under 35 U.S.C. § 271(e)(2)(A)

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

73. Annora submitted ANDA No. 218168 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 '692 Patent under 35 U.S.C. § 271(e)(2)(A).

74. 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 '692 Patent under 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

75. Upon information and belief, Annora has actual and constructive knowledge of the '692 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 '692 Patent. Moreover, there are no substantial non-infringing uses for the Annora ANDA Product other than as the pharmaceutical claimed in the '692 Patent.

76. 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 '028, '046, '946, '947, '948, '949, and '692 Patents;

b) A judgment ordering that the effective date of any FDA approval of ANDA No. 218168 shall be a date which is not earlier than the latest expiration date of the '028, '046, '946, '947, '948, '949, or '692 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 ’028, ’046, ’946, ’947, ’948, ’949, or ’692 Patent, including the Annora ANDA Product;

d) A judgment that the ’028, ’046, ’946, ’947, ’948, ’949, and ’692 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: August 28, 2024

Respectfully submitted,

SAIBER LLC

Arnold B. Calmann

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Attorneys for Plaintiff Azurity Pharmaceuticals, Inc.

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: August 28, 2024

Respectfully submitted,

SAIBER LLC

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Attorneys for Plaintiff Azurity Pharmaceuticals, Inc.

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: August 28, 2024

Respectfully submitted,

SAIBER LLC

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