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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.	Civil Action No. 2:24-cv-08809-SDW-JRA

DEFENDANT ANNORA PHARMA PRIVATE LTD.'S ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS TO PLAINTIFF'S COMPLAINT

Defendant Annora Pharma Private Ltd. ("Annora" or "Defendant"), by and through its undersigned counsel, file this Answer, Affirmative Defenses, and Counterclaims to Plaintiff Azurity Pharmaceuticals, Inc.'s ("Azurity" or "Plaintiff") Complaint, and states as follows:

GENERAL DENIAL

Pursuant to Fed. R. Civ. P. 8(b)(3), Annora denies all allegations in Azurity's Complaint except those specifically admitted below.

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.

ANSWER: Annora admits that Azurity filed a civil action alleging Annora infringed U.S. 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") under the patent laws of the United States, Title 35, United States Code. Except as expressly admitted, Annora is without knowledge or information sufficient to form a belief about the truth of the allegations of Paragraph 1, and on that basis denies these allegations.

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.

ANSWER: Annora admits that it sent a notice letter to Azurity, notifying Azurity that it had submitted Abbreviated New Drug Application ("ANDA") No. 218168 to the U.S. Food and Drug Administration ("FDA") 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. The content of Annora's Notice Letter speaks for itself. Except as expressly admitted, Annora is without knowledge or information sufficient to form a belief about the truth of the allegations of Paragraph 2, and on that basis denies these allegations.

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.

ANSWER: Annora admits that it filed 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." Except as expressly admitted, Annora is without knowledge or information sufficient to form a belief about the truth of the allegations of Paragraph 3, and on that basis denies these allegations.

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.

ANSWER: Paragraph 4 contains legal conclusions to which no answer is required. To the extent that Annora is required to answer, on information and belief, Annora admits 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. Except as expressly admitted, Annora is without knowledge or information sufficient to form a belief about the truth of the allegations of Paragraph 4, and on that basis denies these allegations.

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.

ANSWER: Annora admits that it 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.

ANSWER: Paragraph 6 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Annora admits that it develops and manufactures high-quality generic pharmaceutical products that are ultimately used by consumers in the United States. Except as expressly admitted, Annora denies the remaining allegations of Paragraph 6.

> 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*.

ANSWER: Annora admits that it has designated Somaraju Indukuri, Ph.D., as the agent for service of process in the United States, and that 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. Except as expressly admitted, Annora is without knowledge or information sufficient to form a belief about the truth of the allegations of Paragraph 7, and on that basis denies these allegations.

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.

ANSWER: Annora admits that Azurity filed a civil action alleging Annora infringed the Asserted Patents under the patent laws of the United States, Title 35, United States Code. Except as expressly admitted, Annora is without knowledge or information sufficient to form a belief about the truth of the allegations of Paragraph 8, and on that basis denies these allegations.

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).

ANSWER: Paragraph 9 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Annora does not contest subject matter jurisdiction in this Court for the limited purposes of this action only. Except as expressly admitted, Annora denies the remaining allegations of Paragraph 9.

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).

ANSWER: Paragraph 10 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Annora does not contest personal jurisdiction in this Court for the limited purposes of this action only. Prior consent to personal jurisdiction in this Court has no bearing on this action. Except as expressly admitted, Annora denies the remaining allegations of Paragraph 10.

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.

ANSWER: Paragraph 11 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Annora does not contest personal jurisdiction in this Court for the limited purposes of this action only. Except as expressly admitted, Annora denies the remaining allegations of Paragraph 11.

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).

ANSWER: Paragraph 12 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Annora does not contest venue in this Court for the limited purposes of this action only. Except as expressly admitted, Annora denies the remaining allegations of Paragraph 12.

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).

ANSWER: The FDA-approved label for Azurity's FIRVANQ® product states that it is a glycopeptide antibacterial indicated in adults and pediatric patients less than 18 years of age for the treatment of *Clostridium difficile*-associated diarrhea and Enterocolitis caused by *Staphylococcus aureus* (including methicillin-resistant strains). Except as expressly admitted, Annora denies the remaining allegations of Paragraph 13.

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

ANSWER: The Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") lists Azurity Pharmaceuticals Inc. as the holder for NDA No. 208910. Except as expressly admitted, Annora denies the remaining allegations of Paragraph 14.

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.

ANSWER: Annora admits that the ’028 Patent is titled “Composition and Method for Vancomycin Oral Liquid,” and that the ’028 Patent was issued by the USPTO on or about December 3, 2019. What appears to be an uncertified copy of the ’028 Patent was attached to Azurity’s Complaint as Exhibit A. Except as expressly admitted, Annora is without knowledge or information sufficient to form a belief about the truth of the allegations of Paragraph 15, and on that basis denies these allegations.

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.

ANSWER: Annora admits that the face of the ’028 Patent identifies Indu Muni, Peter Mione, Anisa Gandhi, and Cristina LeChiara as inventors and CutisPharma, Inc. as the assignee. Except as expressly admitted, Annora is without knowledge or information sufficient to form a belief about the truth of the allegations of Paragraph 16, and on that basis denies these allegations.

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.

ANSWER: Paragraph 17 contains legal conclusions and allegations to which no answer is required. Annora admits that, according to the FDA publication, “Approved Drug Products with Therapeutic Equivalence Evaluations” (the “Orange Book”), the ’028 Patent is listed in connection with Azurity’s FIRVANQ® product. Except as expressly admitted, Annora is without knowledge

or information sufficient to form a belief about the truth of the allegations of Paragraph 17, and on that basis denies these allegations.

> 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.

ANSWER: Annora admits that the ’046 Patent is titled “Composition and Method for Vancomycin Oral Liquid,” and that the ’046 Patent was issued by the USPTO on or about June 23, 2020. What appears to be an uncertified copy of the ’046 Patent was attached to Azurity’s Complaint as Exhibit B. Except as expressly admitted, Annora is without knowledge or information sufficient to form a belief about the truth of the allegations of Paragraph 18, and on that basis denies these allegations.

> 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.

ANSWER: Annora admits that the face of the ’046 Patent identifies Indu Muni, Peter Mione, Anisa Gandhi, and Cristina LeChiara as inventors and CutisPharma, Inc. as the assignee. Except as expressly admitted, Annora is without knowledge or information sufficient to form a belief about the truth of the allegations of Paragraph 19, and on that basis denies these allegations.

> 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.

ANSWER: Paragraph 20 contains legal conclusions and allegations to which no answer is required. Annora admits that, according to the Orange Book, the ’046 Patent is listed in connection with Azurity’s FIRVANQ® product. Except as expressly admitted, Annora is without knowledge or information sufficient to form a belief about the truth of the allegations of Paragraph 20, and on that basis denies these allegations.

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.

ANSWER: Annora admits that the ’946 Patent is titled “Composition and Method for Vancomycin Oral Liquid,” and that the ’946 Patent was issued by the USPTO on or about March 30, 2021. What appears to be an uncertified copy of the ’946 Patent was attached to Azurity’s Complaint as Exhibit C. Except as expressly admitted, Annora is without knowledge or information sufficient to form a belief about the truth of the allegations of Paragraph 21, and on that basis denies these allegations.

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.

ANSWER: Annora admits that the face of the ’946 Patent identifies Indu Muni, Peter Mione, Anisa Gandhi, and Cristina LeChiara as inventors and Azurity as the assignee. Except as expressly admitted, Annora is without knowledge or information sufficient to form a belief about the truth of the allegations of Paragraph 22, and on that basis denies these allegations.

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.

ANSWER: Paragraph 23 contains legal conclusions and allegations to which no answer is required. Annora admits that, according to the Orange Book, the ’946 Patent is listed in connection with Azurity’s FIRVANQ® product. Except as expressly admitted, Annora is without knowledge or information sufficient to form a belief about the truth of the allegations of Paragraph 23, and on that basis denies these allegations.

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.

ANSWER: Annora admits that the '947 Patent is titled "Composition and Method for Vancomycin Oral Liquid," and that the '947 Patent was issued by the USPTO on or about March 30, 2021. What appears to be an uncertified copy of the '947 Patent was attached to Azurity's Complaint as Exhibit D. Except as expressly admitted, Annora is without knowledge or information sufficient to form a belief about the truth of the allegations of Paragraph 24, and on that basis denies these allegations.

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.

ANSWER: Annora admits that the face of the '947 Patent identifies Indu Muni, Peter Mione, Anisa Gandhi, and Cristina LeChiara as inventors and Azurity as the assignee. Except as expressly admitted, Annora is without knowledge or information sufficient to form a belief about the truth of the allegations of Paragraph 25, and on that basis denies these allegations.

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.

ANSWER: Paragraph 26 contains legal conclusions and allegations to which no answer is required. Annora admits that, according to the Orange Book, the '947 Patent is listed in connection with Azurity's FIRVANQ® product. Except as expressly admitted, Annora is without knowledge or information sufficient to form a belief about the truth of the allegations of Paragraph 26, and on that basis denies these allegations.

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.

ANSWER: Annora admits that the '948 Patent is titled "Composition and Method for Vancomycin Oral Liquid," and that the '948 Patent was issued by the USPTO on or about March

30, 2021. What appears to be an uncertified copy of the '948 Patent was attached to Azurity's Complaint as Exhibit E. Except as expressly admitted, Annora is without knowledge or information sufficient to form a belief about the truth of the allegations of Paragraph 27, and on that basis denies these allegations.

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.

ANSWER: Annora admits that the face of the '948 Patent identifies Indu Muni, Peter Mione, Anisa Gandhi, and Cristina LeChiara as inventors and Azurity as the assignee. Except as expressly admitted, Annora is without knowledge or information sufficient to form a belief about the truth of the allegations of Paragraph 28, and on that basis denies these allegations.

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.

ANSWER: Paragraph 29 contains legal conclusions and allegations to which no answer is required. Annora admits that, according to the Orange Book, the '948 Patent is listed in connection with Azurity's FIRVANQ® product. Except as expressly admitted, Annora is without knowledge or information sufficient to form a belief about the truth of the allegations of Paragraph 29, and on that basis denies these allegations.

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.

ANSWER: Annora admits that the '949 Patent is titled "Composition and Method for Vancomycin Oral Liquid," and that the '949 Patent was issued by the USPTO on or about March 30, 2021. What appears to be an uncertified copy of the '949 Patent was attached to Azurity's Complaint as Exhibit F. Except as expressly admitted, Annora is without knowledge or

information sufficient to form a belief about the truth of the allegations of Paragraph 30, and on that basis denies these allegations.

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.

ANSWER: Annora admits that the face of the '949 Patent identifies Indu Muni, Peter Mione, Anisa Gandhi, and Cristina LeChiara as inventors and Azurity as the assignee. Except as expressly admitted, Annora is without knowledge or information sufficient to form a belief about the truth of the allegations of Paragraph 31, and on that basis denies these allegations.

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.

ANSWER: Paragraph 32 contains legal conclusions and allegations to which no answer is required. Annora admits that, according to the Orange Book, the '949 Patent is listed in connection with Azurity's FIRVANQ® product. Except as expressly admitted, Annora is without knowledge or information sufficient to form a belief about the truth of the allegations of Paragraph 32, and on that basis denies these allegations.

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.

ANSWER: Annora admits that the '692 Patent is titled "Composition and Method for Vancomycin Oral Liquid," and that the '692 Patent was issued by the USPTO on or about May 2, 2023. What appears to be an uncertified copy of the '692 Patent was attached to Azurity's Complaint as Exhibit G. Except as expressly admitted, Annora is without knowledge or information sufficient to form a belief about the truth of the allegations of Paragraph 33, and on that basis denies these allegations.

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.

ANSWER: Annora admits that the face of the '692 Patent identifies Indu Muni, Peter Mione, Anisa Gandhi, and Cristina LeChiara as inventors and Azurity as the assignee. Except as expressly admitted, Annora is without knowledge or information sufficient to form a belief about the truth of the allegations of Paragraph 34, and on that basis denies these allegations.

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.

ANSWER: Paragraph 35 contains legal conclusions and allegations to which no answer is required. Annora admits that, according to the Orange Book, the '692 Patent is listed in connection with Azurity's FIRVANQ® product. Except as expressly admitted, Annora is without knowledge or information sufficient to form a belief about the truth of the allegations of Paragraph 35, and on that basis denies these allegations.

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.

ANSWER: Annora admits that it sent a notice letter to Azurity, notifying Azurity that it had submitted Abbreviated New Drug Application ("ANDA") No. 218168 to the FDA seeking approval to engage in the commercial manufacture, use, and sale of a generic version of the Annora ANDA Product before the expiration of the Asserted Patents. The content of Annora's Notice Letter speaks for itself. Except as expressly admitted, Annora is without knowledge or information sufficient to form a belief about the truth of the allegations of Paragraph 36, and on that basis denies these allegations.

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.

ANSWER: Paragraph 37 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Annora denies the allegations of Paragraph 37.

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.

ANSWER: Paragraph 38 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Annora denies the allegations of Paragraph 38.

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.

ANSWER: Paragraph 39 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Annora denies the allegations of Paragraph 39.

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."

ANSWER: Paragraph 40 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Annora denies the allegations of Paragraph 40.

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.

ANSWER: Paragraph 41 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Annora denies the allegations of Paragraph 41.

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.

ANSWER: Annora incorporates its responses to 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).

ANSWER: Paragraph 43 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Annora denies the allegations of Paragraph 43.

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.

ANSWER: Paragraph 44 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Annora denies the allegations of Paragraph 44.

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.

ANSWER: Paragraph 45 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Annora denies the allegations of Paragraph 45.

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.

ANSWER: Paragraph 46 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Annora denies the allegations of Paragraph 46.

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.

ANSWER: Annora incorporates its responses to 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).

ANSWER: Paragraph 48 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Annora denies the allegations of Paragraph 48.

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.

ANSWER: Paragraph 49 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Annora denies the allegations of Paragraph 49.

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.

ANSWER: Paragraph 50 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Annora denies the allegations of Paragraph 50.

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.

ANSWER: Paragraph 51 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Annora denies the allegations of Paragraph 51.

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.

ANSWER: Annora incorporates its responses to 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).

ANSWER: Paragraph 53 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Annora denies the allegations of Paragraph 53.

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.

ANSWER: Paragraph 54 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Annora denies the allegations of Paragraph 54.

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.

ANSWER: Paragraph 55 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Annora denies the allegations of Paragraph 55.

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.

ANSWER: Paragraph 56 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Annora denies the allegations of Paragraph 56.

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.

ANSWER: Annora incorporates its responses to 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).

ANSWER: Paragraph 58 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Annora denies the allegations of Paragraph 58.

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.

ANSWER: Paragraph 59 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Annora denies the allegations of Paragraph 59.

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.

ANSWER: Paragraph 60 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Annora denies the allegations of Paragraph 60.

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.

ANSWER: Paragraph 61 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Annora denies the allegations of Paragraph 61.

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.

ANSWER: Annora incorporates its responses to 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).

ANSWER: Paragraph 63 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Annora denies the allegations of Paragraph 63.

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.

ANSWER: Paragraph 64 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Annora denies the allegations of Paragraph 64.

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.

ANSWER: Paragraph 65 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Annora denies the allegations of Paragraph 65.

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.

ANSWER: Paragraph 66 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Annora denies the allegations of Paragraph 66.

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.

ANSWER: Annora incorporates its responses to 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).

ANSWER: Paragraph 68 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Annora denies the allegations of Paragraph 68.

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.

ANSWER: Paragraph 69 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Annora denies the allegations of Paragraph 69.

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.

ANSWER: Paragraph 70 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Annora denies the allegations of Paragraph 70.

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.

ANSWER: Paragraph 71 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Annora denies the allegations of Paragraph 71.

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.

ANSWER: Annora incorporates its responses to 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).

ANSWER: Paragraph 73 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Annora denies the allegations of Paragraph 73.

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.

ANSWER: Paragraph 74 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Annora denies the allegations of Paragraph 74.

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.

ANSWER: Paragraph 75 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Annora denies the allegations of Paragraph 75.

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.

ANSWER: Paragraph 76 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Annora denies the allegations of Paragraph 76.

Azurity's Prayer for Relief

All allegations in Azurity's Complaint that are not expressly admitted by Annora are denied. Annora denies that Azurity is entitled to any of the relief sought in its Prayer for Relief.

ANNORA'S AFFIRMATIVE DEFENSES

Without prejudice to the denials in this Answer, and without admitting any allegations of the Complaint not expressly admitted, Annora asserts the following Affirmative Defenses to Azurity's Complaint without assuming the burden of proof on any defense that would otherwise rest on Azurity. Annora reserves the right to assert additional defenses, as warranted by facts learned through investigation and discovery.

FIRST DEFENSE

The manufacture, use, or sale, offer for sale, or importation of the products that are the subject of Annora's ANDA No. 218168 has not infringed, does not infringe, and would not, if marketed, manufactured, used, sold, offered for sale, or imported into the United States, infringe any valid or enforceable claim of the Asserted Patents.

SECOND DEFENSE

Each of the claims of each of the Asserted Patents is invalid for failure to satisfy one or more of the conditions for patentability set forth in 35 U.S.C. §§ 101, 102, 103, and/or 112, or for failure to satisfy other judicially created bases for invalidation or unenforceability.

THIRD DEFENSE

Azurity's Complaint fails to state a claim for exceptional case under 35 U.S.C. § 285 and/or willful infringement. Annora's actions in defending this case do not give rise to an exceptional case under 35 U.S.C. § 285.

RESERVATION OF DEFENSES

Annora reserves any and all defenses available under the Federal Rules of Civil Procedure and the U.S. Patent Laws and any other defenses, at law or in equity, that may now exist or become available later as a result of discovery and further factual investigation during this litigation.

ANNORA'S COUNTERCLAIMS

Defendant Annora Pharma Private Ltd. ("Annora" or "Defendant"), by and through its undersigned counsel, pleads the following counterclaims against Plaintiff Azurity Pharmaceuticals, Inc.'s ("Azurity" or "Plaintiff"):

PARTIES

1. 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.

2. On information and belief, 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.

JURISDICTION AND VENUE

3. This Court has subject matter jurisdiction over these Counterclaims for declaratory judgment pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202; based on an actual controversy between Annora, on the one hand, and Azurity on the other hand, arising under the Patent Laws of the United States, 35 U.S.C. §§ 1 *et seq.*

4. This Court has personal jurisdiction over Azurity because, *inter alia*, Azurity subjected itself to the jurisdiction of this Court by filing its Complaint here.

5. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b), and/or by Azurity's choice of forum.

FACTUAL BACKGROUND

6. On information and belief, and based on the allegations in the Complaint, Azurity is the holder of New Drug Application ("NDA") No. 208910 for vancomycin hydrochloride oral solution, which is sold under trademark FIRVANQ®.

7. On information and belief, and based on the allegations in the Complaint, Azurity caused the Food and Drug Administration ("FDA") to list U.S. 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") in the FDA's publication Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") in connection with NDA No. 208910.

8. The '028 patent lists the title as "Composition and Method for Vancomycin Oral Liquid," and the issue date as December 3, 2019.

9. The '046 patent lists the title as "Composition and Method for Vancomycin Oral Liquid," and the issue date as June 23, 2020.

10. The '946 patent lists the title as "Composition and Method for Vancomycin Oral Liquid," and the issue date as March 30, 2021.

11. The '947 patent lists the title as "Composition and Method for Vancomycin Oral Liquid," and the issue date as March 30, 2021.

12. The '948 patent lists the title as "Composition and Method for Vancomycin Oral Liquid," and the issue date as March 30, 2021.

13. The ’949 patent lists the title as “Composition and Method for Vancomycin Oral Liquid,” and the issue date as March 30, 2021.

14. The ’692 patent lists the title as “Composition and Method for Vancomycin Oral Liquid,” and the issue date as May 2, 2023.

15. Azurity purports and claims to be the assignee and owner of all rights, title and interest in the Asserted Patents.

16. Annora submitted Abbreviated New Drug Application (“ANDA”) No. 218168 to the FDA under 21 U.S.C. § 355(j) seeking approval to engage in the commercial manufacture, use, importation, offer for sale or sale of Annora’s proposed drug product containing vancomycin hydrochloride oral solution (“Annora’s ANDA product”).

17. On August 28, 2024, Azurity filed suit in this Judicial District against Annora in connection with ANDA No. 218168 alleging infringement of the Asserted Patents.

18. In view of the foregoing, there has been, and is now, an actual, substantial, and continuing, justiciable controversy between Annora and Azurity having sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court with respect to noninfringement and/or invalidity of the Asserted Patents, and as to Annora’s right to obtain FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Annora’s ANDA product.

COUNT I
(Declaratory Judgment of Noninfringement of U.S. Patent No. 10,493,028)

19. Annora incorporates by reference and re-alleges each of the foregoing paragraphs of Annora’s Answer and Affirmative Defenses to the Complaint and these Counterclaims as if fully set forth herein.

20. Annora has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the '028 patent.

21. A present, genuine, and justiciable controversy exists between Annora, on the one hand, and Azurity, on the other hand, regarding, *inter alia*, the issue of whether the manufacture, use, sale, offer for sale and/or importation of Annora's ANDA Product would infringe any valid or enforceable claim of the '028 patent.

22. The Court should declare that Annora has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the '028 patent.

COUNT II
(Declaratory Judgment of Invalidity of U.S. Patent No. 10,493,028)

23. Annora incorporates by reference and re-alleges each of the foregoing paragraphs of Annora's Answer and Affirmative Defenses to the Complaint and these Counterclaims as if fully set forth herein.

24. Upon information and belief, the claims of the '028 patent are invalid for failure to comply with one or more of the requirements of at least 35 U.S.C. §§ 101, 102, 103, 112, and/or 251 *et seq.*, and/or are invalid under the doctrine of obviousness-type double patenting, and/or for any other judicially created and/or non-statutory basis for invalidity or unenforceability.

25. There is a real, substantial, and justiciable controversy between Annora and Azurity concerning whether the claims of the '028 patent are invalid and/or unenforceable for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, 251, and/or pursuant to common law and/or equitable doctrines.

26. The Court should declare that the claims of the ’028 patent are invalid and/or unenforceable.

COUNT III
(Declaratory Judgment of Noninfringement of U.S. Patent No. 10,688,046)

27. Annora incorporates by reference and re-alleges each of the foregoing paragraphs of Annora’s Answer and Affirmative Defenses to the Complaint and these Counterclaims as if fully set forth herein.

28. Annora has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the ’046 patent.

29. A present, genuine, and justiciable controversy exists between Annora, on the one hand, and Azurity, on the other hand, regarding, *inter alia*, the issue of whether the manufacture, use, sale, offer for sale and/or importation of Annora’s ANDA Product would infringe any valid or enforceable claim of the ’046 patent.

30. The Court should declare that Annora has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the ’046 patent.

COUNT IV
(Declaratory Judgment of Invalidity of U.S. Patent No. 10,688,046)

31. Annora incorporates by reference and re-alleges each of the foregoing paragraphs of Annora’s Answer and Affirmative Defenses to the Complaint and these Counterclaims as if fully set forth herein.

32. Upon information and belief, the claims of the ’046 patent are invalid for failure to comply with one or more of the requirements of at least 35 U.S.C. §§ 101, 102, 103, 112, and/or

251 *et seq.*, and/or are invalid under the doctrine of obviousness-type double patenting, and/or for any other judicially created and/or non-statutory basis for invalidity or unenforceability.

33. There is a real, substantial, and justiciable controversy between Annora and Azurity concerning whether the claims of the '046 patent are invalid and/or unenforceable for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, 251, and/or pursuant to common law and/or equitable doctrines.

34. The Court should declare that the claims of the '046 patent are invalid and/or unenforceable.

COUNT V
(Declaratory Judgment of Noninfringement of U.S. Patent No. 10,959,946)

35. Annora incorporates by reference and re-alleges each of the foregoing paragraphs of Annora's Answer and Affirmative Defenses to the Complaint and these Counterclaims as if fully set forth herein.

36. Annora has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the '946 patent.

37. A present, genuine, and justiciable controversy exists between Annora, on the one hand, and Azurity, on the other hand, regarding, *inter alia*, the issue of whether the manufacture, use, sale, offer for sale and/or importation of Annora's ANDA Product would infringe any valid or enforceable claim of the '946 patent.

38. The Court should declare that Annora has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the '946 patent.

COUNT VI
(Declaratory Judgment of Invalidity of U.S. Patent No. 10,959,946)

39. Annora incorporates by reference and re-alleges each of the foregoing paragraphs of Annora's Answer and Affirmative Defenses to the Complaint and these Counterclaims as if fully set forth herein.

40. Upon information and belief, the claims of the '946 patent are invalid for failure to comply with one or more of the requirements of at least 35 U.S.C. §§ 101, 102, 103, 112, and/or 251 *et seq.*, and/or are invalid under the doctrine of obviousness-type double patenting, and/or for any other judicially created and/or non-statutory basis for invalidity or unenforceability.

41. There is a real, substantial, and justiciable controversy between Annora and Azurity concerning whether the claims of the '946 patent are invalid and/or unenforceable for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, 251, and/or pursuant to common law and/or equitable doctrines.

42. The Court should declare that the claims of the '946 patent are invalid and/or unenforceable.

COUNT VII
(Declaratory Judgment of Noninfringement of U.S. Patent No. 10,959,947)

43. Annora incorporates by reference and re-alleges each of the foregoing paragraphs of Annora's Answer and Affirmative Defenses to the Complaint and these Counterclaims as if fully set forth herein.

44. Annora has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the '947 patent.

45. A present, genuine, and justiciable controversy exists between Annora, on the one hand, and Azurity, on the other hand, regarding, *inter alia*, the issue of whether the manufacture, use, sale, offer for sale and/or importation of Annora's ANDA Product would infringe any valid or enforceable claim of the '947 patent.

46. The Court should declare that Annora has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the '947 patent.

COUNT VIII
(Declaratory Judgment of Invalidity of U.S. Patent No. 10,959,947)

47. Annora incorporates by reference and re-alleges each of the foregoing paragraphs of Annora's Answer and Affirmative Defenses to the Complaint and these Counterclaims as if fully set forth herein.

48. Upon information and belief, the claims of the '947 patent are invalid for failure to comply with one or more of the requirements of at least 35 U.S.C. §§ 101, 102, 103, 112, and/or 251 *et seq.*, and/or are invalid under the doctrine of obviousness-type double patenting, and/or for any other judicially created and/or non-statutory basis for invalidity or unenforceability.

49. There is a real, substantial, and justiciable controversy between Annora and Azurity concerning whether the claims of the '947 patent are invalid and/or unenforceable for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, 251, and/or pursuant to common law and/or equitable doctrines.

50. The Court should declare that the claims of the '947 patent are invalid and/or unenforceable.

COUNT IX
(Declaratory Judgment of Noninfringement of U.S. Patent No. 10,959,948)

51. Annora incorporates by reference and re-alleges each of the foregoing paragraphs of Annora's Answer and Affirmative Defenses to the Complaint and these Counterclaims as if fully set forth herein.

52. Annora has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the '948 patent.

53. A present, genuine, and justiciable controversy exists between Annora, on the one hand, and Azurity, on the other hand, regarding, *inter alia*, the issue of whether the manufacture, use, sale, offer for sale and/or importation of Annora's ANDA Product would infringe any valid or enforceable claim of the '948 patent.

54. The Court should declare that Annora has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the '948 patent.

COUNT X
(Declaratory Judgment of Invalidity of U.S. Patent No. 10,959,948)

55. Annora incorporates by reference and re-alleges each of the foregoing paragraphs of Annora's Answer and Affirmative Defenses to the Complaint and these Counterclaims as if fully set forth herein.

56. Upon information and belief, the claims of the '948 patent are invalid for failure to comply with one or more of the requirements of at least 35 U.S.C. §§ 101, 102, 103, 112, and/or 251 *et seq.*, and/or are invalid under the doctrine of obviousness-type double patenting, and/or for any other judicially created and/or non-statutory basis for invalidity or unenforceability.

57. There is a real, substantial, and justiciable controversy between Annora and Azurity concerning whether the claims of the ’948 patent are invalid and/or unenforceable for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, 251, and/or pursuant to common law and/or equitable doctrines.

58. The Court should declare that the claims of the ’948 patent are invalid and/or unenforceable.

COUNT XI
(Declaratory Judgment of Noninfringement of U.S. Patent No. 10,959,949)

59. Annora incorporates by reference and re-alleges each of the foregoing paragraphs of Annora’s Answer and Affirmative Defenses to the Complaint and these Counterclaims as if fully set forth herein.

60. Annora has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the ’949 patent.

61. A present, genuine, and justiciable controversy exists between Annora, on the one hand, and Azurity, on the other hand, regarding, *inter alia*, the issue of whether the manufacture, use, sale, offer for sale and/or importation of Annora’s ANDA Product would infringe any valid or enforceable claim of the ’949 patent.

62. The Court should declare that Annora has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the ’949 patent.

COUNT XII
(Declaratory Judgment of Invalidity of U.S. Patent No. 10,959,949)

63. Annora incorporates by reference and re-alleges each of the foregoing paragraphs of Annora's Answer and Affirmative Defenses to the Complaint and these Counterclaims as if fully set forth herein.

64. Upon information and belief, the claims of the '949 patent are invalid for failure to comply with one or more of the requirements of at least 35 U.S.C. §§ 101, 102, 103, 112, and/or 251 *et seq.*, and/or are invalid under the doctrine of obviousness-type double patenting, and/or for any other judicially created and/or non-statutory basis for invalidity or unenforceability.

65. There is a real, substantial, and justiciable controversy between Annora and Azurity concerning whether the claims of the '949 patent are invalid and/or unenforceable for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, 251, and/or pursuant to common law and/or equitable doctrines.

66. The Court should declare that the claims of the '949 patent are invalid and/or unenforceable.

COUNT XIII
(Declaratory Judgment of Noninfringement of U.S. Patent No. 11,638,692)

67. Annora incorporates by reference and re-alleges each of the foregoing paragraphs of Annora's Answer and Affirmative Defenses to the Complaint and these Counterclaims as if fully set forth herein.

68. Annora has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the '692 patent.

69. A present, genuine, and justiciable controversy exists between Annora, on the one hand, and Azurity, on the other hand, regarding, *inter alia*, the issue of whether the manufacture, use, sale, offer for sale and/or importation of Annora's ANDA Product would infringe any valid or enforceable claim of the '692 patent.

70. The Court should declare that Annora has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the '692 patent.

COUNT XIV
(Declaratory Judgment of Invalidity of U.S. Patent No. 11,638,692)

71. Annora incorporates by reference and re-alleges each of the foregoing paragraphs of Annora's Answer and Affirmative Defenses to the Complaint and these Counterclaims as if fully set forth herein.

72. Upon information and belief, the claims of the '692 patent are invalid for failure to comply with one or more of the requirements of at least 35 U.S.C. §§ 101, 102, 103, 112, and/or 251 *et seq.*, and/or are invalid under the doctrine of obviousness-type double patenting, and/or for any other judicially created and/or non-statutory basis for invalidity or unenforceability.

73. There is a real, substantial, and justiciable controversy between Annora and Azurity concerning whether the claims of the '692 patent are invalid and/or unenforceable for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, 251, and/or pursuant to common law and/or equitable doctrines.

74. The Court should declare that the claims of the '692 patent are invalid and/or unenforceable.

PRAYER FOR RELIEF

WHEREFORE, Annora prays that the Court enter judgment in its favor and against Azurity as follows:

A. Declaring that the filing of Annora's ANDA No. 218168 has not and does not directly or indirectly infringe any valid claim of any of the Asserted Patents;

B. Declaring that the commercial manufacture, use, offer to sell, sale within the United States, and/or importation into the United States of Annora's vancomycin hydrochloride oral solution product described in ANDA No. 218168 does not, and would not, if marketed, directly or indirectly infringe any valid claim of any of the Asserted Patents;

C. Declaring that the claims of the Asserted Patents are invalid;

D. Ordering that judgment be entered in favor of Annora and that Azurity's Complaint be dismissed with prejudice;

E. Declaring this case exceptional and awarding Annora its reasonable attorney fees and costs of defending this action and prosecuting their counterclaims under 35 U.S.C. § 285; and

F. Awarding Annora such other and further relief as this Court deems just and proper.

Dated: February 3, 2025

Respectfully submitted,

s/ Kaan Ekiner

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CERTIFICATION PURSUANT TO LOCAL CIVIL RULES 11.2 AND 40.1

Pursuant to Local Civil Rules 11.2 and 40.1, I hereby certify that, to the best of my knowledge, the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

Dated: February 3, 2025

s/ Kaan Ekiner
Kaan Ekiner

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 201.1

Pursuant to Local Civil Rule 201.1, Defendant/Counterclaimant Annora Pharma Private Ltd., by its undersigned counsel, hereby certify that this action seeks declaratory and injunctive relief and therefore, this action is not appropriate for compulsory arbitration.

Dated: February 3, 2025

s/ Kaan Ekiner
Kaan Ekiner

CERTIFICATE OF SERVICE

I, Kaan Ekiner, hereby certify that on February 3, 2025, a true and correct copy of the foregoing **DEFENDANT ANNORA PHARMA PRIVATE LTD.'S ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS TO PLAINTIFF'S COMPLAINT** was filed electronically with the Clerk of Court using the CM/ECF system, which will send notification of such filing to all counsel of record.

s/ Kaan Ekiner
Kaan Ekiner