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Attorneys for Defendant Annora Pharma Private Ltd.

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

AZURITY PHARMACEUTICALS, INC.)	
)	
Plaintiff,)	C.A. No. 2:23-cv-18420-CPO
)	
v.)	
)	
ANNORA PHARMA PRIVATE LTD.,)	
)	
Defendant.)	

**ANNORA PHARMA PRIVATE LIMITED'S ANSWER, DEFENSES, AND
COUNTERCLAIMS TO AZURITY PHARMACEUTICALS, INC.'S COMPLAINT**

Defendant Annora Pharma Private Ltd. (“Annora” or “Defendant”), by and through its attorneys answers the Complaint of Plaintiff Azurity Pharmaceuticals, Inc. (“Azurity” or “Plaintiff”), responding in each numbered paragraph below to correspond to the same numbered paragraph in the Complaint, and asserts its affirmative defenses and counterclaims as follows. Except as otherwise specifically stated in this Answer, Defendant denies each and every allegation of Plaintiff in the Complaint.

THE NATURE OF THE ACTION

1. Annora admits that this purports to be an action for patent infringement relating to the referenced ANDA and the referenced patents. Otherwise, denied.
2. Annora admits that it sent a Notice Letter on about July 24, 2023 (the “Notice Letter”) in which it notified Azurity that it had submitted ANDA No. 218419 to FDA under 21 U.S.C. § 355(j)(2)(B)(iv)(I) seeking approval to sell lisinopril oral solution before the expiration of the patents listed by Azurity in FDA Orange Book for that product. Otherwise, denied.
3. Annora admits that this purports to be an action for patent infringement under 35 U.S.C. § 271(e)(2)(A) relating to ANDA No. 218419 which identifies NDA No. 208401 as the reference listed drug. Otherwise, denied.

THE PARTIES

4. Annora is without information sufficient to form a belief as to the truth or falsity of the allegations in paragraph 4 of the Complaint; therefore, denied.
5. Admitted.
6. Annora admits that it is a business that, among other activities, is in the business of developing and manufacturing pharmaceutical products. Otherwise, denied.
7. Annora admits that its July 24, 2023 letter to Azurity identifies Somaraju Indukuri, Ph.D at 121 New England Avenue, Piscataway, NJ 08854 as a person “authorized to

accept service of process for any patent infringement complaint that may result from this notification (and limited to such a complaint only)” and that the letter states that “Somaraju Indukuri is a U.S. Agent for Grace Consulting Services, Inc., and Grace Consulting Services, Inc., is an Agent for Annora Pharma Private Limited.” Annora also admits that Annora Pharma Private Limited’s is a subsidiary of Hetero Labs Ltd. Otherwise, denied.

JURISDICTION AND VENUE

8. Annora admits that this purports to be an action for patent infringement under the patent laws of the United States of America, 35 U.S.C. § 271(e)(2)(A) and that it submitted ANDA No. 218419. Otherwise, denied.

9. Annora does not contest that this Court has subject matter jurisdiction over Plaintiff’s claims for infringement under 35 U.S.C. § 271(e)(2)(A).

10. Annora does not contest personal jurisdiction for purposes of this action only.

11. Annora does not contest personal jurisdiction for purposes of this action only.

12. Annora does not contest venue for purposes of this action only.

AZURITY’S QBRELIS® PRODUCT

13. Admitted that QBRELIS® has received FDA approval for the specified indications by demonstrating bioequivalence to preexisting drug products.

14. Admitted that the Orange Book identifies Azurity Pharmaceuticals Inc. as the holder of NDA No. 208401. Annora is otherwise without information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 14 of the Complaint; therefore, denied.

PATENTS-IN-SUIT

15. Annora admits that what purports to be the ’183 patent is entitled “Lisinopril Formulations,” issued on October 11, 2016, and lists Silvergate Pharmaceuticals, Inc. as the assignee. Otherwise, denied.

16. Annora admits that the '183 patent is listed in the Orange Book in connection with the QBRELIS® product. Otherwise, denied.

17. Annora admits that what purports to be the '096 patent is entitled "Lisinopril Formulations," issued on April 11, 2017, and lists Silvergate Pharmaceuticals, Inc. as the assignee. Otherwise, denied.

18. Annora admits that the '096 patent is listed in the Orange Book in connection with the QBRELIS® product. Otherwise, denied.

19. Annora admits that what purports to be the '751 patent is entitled "Lisinopril Formulations," issued on November 14, 2017, and lists Silvergate Pharmaceuticals, Inc. as the assignee. Otherwise, denied.

20. Annora admits that the '751 patent is listed in the Orange Book in connection with the QBRELIS® product. Otherwise, denied.

21. Annora admits that what purports to be the '800 patent is entitled "Lisinopril Formulations," issued on August 7, 2018, and lists Silvergate Pharmaceuticals, Inc. as the assignee. Otherwise, denied.

22. Annora admits that the '800 patent is listed in the Orange Book in connection with the QBRELIS® product. Otherwise, denied.

23. Annora admits that what purports to be the '370 patent is entitled "Lisinopril Formulations," issued on April 23, 2019, and lists Silvergate Pharmaceuticals, Inc. as the assignee. Otherwise, denied.

24. Annora admits that the '370 patent is listed in the Orange Book in connection with the QBRELIS® product. Otherwise, denied.

25. Annora admits that what purports to be the '199 patent is entitled "Lisinopril Formulations," issued on September 10, 2019, and lists Silvergate Pharmaceuticals, Inc. as the assignee. Otherwise, denied.

26. Annora admits that the '199 patent is listed in the Orange Book in connection with the QBRELIS® product. Otherwise, denied.

27. Annora admits that what purports to be the '177 patent is entitled "Lisinopril Formulations," issued on March 9, 2021, and lists Silvergate Pharmaceuticals, Inc. as the assignee. Otherwise, denied.

28. Annora admits that the '177 patent is listed in the Orange Book in connection with the QBRELIS® product. Otherwise, denied.

29. Annora admits that what purports to be the '434 patent is entitled "Lisinopril Formulations," issued on November 23, 2021, and lists Silvergate Pharmaceuticals, Inc. as the assignee. Otherwise, denied.

30. Annora admits that the '434 patent is listed in the Orange Book in connection with the QBRELIS® product. Otherwise, denied.

INFRINGEMENT BY ANNORA

31. Admitted.

32. Annora admits that it filed an ANDA seeking FDA permission to manufacture and sell the product identified therein. Paragraph 32 otherwise contains allegations about future events that have not occurred, and Annora therefore denies the remaining allegations of Paragraph 32.

33. Annora admits that it submitted an ANDA directed to lisinopril oral solution (1 mg/mL) that it believes to be bioequivalent to QBRELIS®. Annora denies any remaining allegations of Paragraph 33.

FIRST COUNT

34. Annora incorporates by reference its responses to Paragraphs 1-33 as if fully set forth herein.

35. Annora admits that it submitted ANDA No. 218419 to the FDA under Section 505(j) of the FDCA. Otherwise, denied.

36. Denied.

37. Annora admits that it was aware of the '183 patent before filing its ANDA. Otherwise, denied.

38. Denied.

SECOND COUNT

39. Annora incorporates by reference its responses to Paragraphs 1-38 as if fully set forth herein.

40. Annora admits that it submitted ANDA No. 218419 to the FDA under Section 505(j) of the FDCA. Otherwise, denied.

41. Denied.

42. Annora admits that it was aware of the '096 patent before filing its ANDA. Otherwise, denied.

43. Denied.

THIRD COUNT

44. Annora incorporates by reference its responses to Paragraphs 1-43 as if fully set forth herein.

45. Annora admits that it submitted ANDA No. 218419 to the FDA under Section 505(j) of the FDCA. Otherwise, denied.

46. Denied.

47. Annora admits that it was aware of the '751 patent before filing its ANDA.

Otherwise, denied.

48. Denied.

FOURTH COUNT

49. Annora incorporates by reference its responses to Paragraphs 1-48 as if fully set forth herein.

50. Annora admits that it submitted ANDA No. 218419 to the FDA under Section 505(j) of the FDCA. Otherwise, denied.

51. Denied.

52. Annora admits that it was aware of the '800 patent before filing its ANDA.

Otherwise, denied.

53. Denied.

FIFTH COUNT

54. Annora incorporates by reference its responses to Paragraphs 1-53 as if fully set forth herein.

55. Annora admits that it submitted ANDA No. 218419 to the FDA under Section 505(j) of the FDCA. Otherwise, denied.

56. Denied.

57. Annora admits that it was aware of the '370 patent before filing its ANDA.

Otherwise, denied.

58. Denied.

SIXTH COUNT

59. Annora incorporates by reference its responses to Paragraphs 1-58 as if fully set forth herein.

60. Annora admits that it submitted ANDA No. 218419 to the FDA under Section 505(j) of the FDCA. Otherwise, denied.

61. Denied.

62. Annora admits that it was aware of the '199 patent before filing its ANDA. Otherwise, denied.

63. Denied.

SEVENTH COUNT

64. Annora incorporates by reference its responses to Paragraphs 1-63 as if fully set forth herein.

65. Annora admits that it submitted ANDA No. 218419 to the FDA under Section 505(j) of the FDCA. Otherwise, denied.

66. Denied.

67. Annora admits that it was aware of the '177 patent before filing its ANDA. Otherwise, denied.

68. Denied.

EIGHTH COUNT

69. Annora incorporates by reference its responses to Paragraphs 1-68 as if fully set forth herein.

70. Annora admits that it submitted ANDA No. 218419 to the FDA under Section 505(j) of the FDCA. Otherwise, denied.

71. Denied.

72. Annora admits that it was aware of the '434 patent before filing its ANDA. Otherwise, denied.

73. Denied.

RESPONSE TO PLAINTIFF'S REQUEST FOR RELIEF

Defendant denies that Plaintiff is entitled to any of the relief requested in ¶¶ a-f of the Complaint's Prayer for Relief or to any relief whatsoever.

AFFIRMATIVE DEFENSES

Without prejudice to the denials set forth in the Answer, without admitting any allegation in the Complaint not otherwise admitted, and without undertaking any of the burdens imposed by law on Plaintiffs, Annora asserts the following affirmative defenses:

FIRST AFFIRMATIVE DEFENSE

(Non-infringement of U.S. Patent No. 9,463,183)

The manufacture, use, sale, offer for sale, or importation of lisinopril oral solution, 1 mg/mL that is the subject of ANDA No. 218419 has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported, or marketed—infringe, directly or indirectly, any valid and enforceable claim of U.S. Patent No. 9,463,183, either literally or under the doctrine of equivalents.

SECOND AFFIRMATIVE DEFENSE

(Invalidity of U.S. Patent No. 9,463,183)

The claims of U.S. Patent No. 9,463,183 are invalid and/or unenforceable for failure to comply with the requirements for patentability, including but not limited to the requirements set forth in 35 U.S.C. §§ 101, 102, 103, and/or 112.

THIRD AFFIRMATIVE DEFENSE

(Non-infringement of U.S. Patent No. 9,616,096)

The manufacture, use, sale, offer for sale, or importation of lisinopril oral solution, 1 mg/mL that is the subject of ANDA No. 218419 has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported, or marketed—infringe, directly or indirectly,

any valid and enforceable claim of U.S. Patent No. 9,616,096, either literally or under the doctrine of equivalents.

FOURTH AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 9,616,096)

The claims of U.S. Patent No. 9,616,096 are invalid and/or unenforceable for failure to comply with the requirements for patentability, including but not limited to the requirements set forth in 35 U.S.C. §§ 101, 102, 103, and/or 112.

FIFTH AFFIRMATIVE DEFENSE
(Non-infringement of U.S. Patent No. 9,814,751)

The manufacture, use, sale, offer for sale, or importation of lisinopril oral solution, 1 mg/mL that is the subject of ANDA No. 218419 has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported, or marketed—infringe, directly or indirectly, any valid and enforceable claim of U.S. Patent No. 9,814,751, either literally or under the doctrine of equivalents.

SIXTH AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 9,814,751)

The claims of U.S. Patent No. 9,814,751 are invalid and/or unenforceable for failure to comply with the requirements for patentability, including but not limited to the requirements set forth in 35 U.S.C. §§ 101, 102, 103, and/or 112.

SEVENTH AFFIRMATIVE DEFENSE
(Non-infringement of U.S. Patent No. 10,039,800)

The manufacture, use, sale, offer for sale, or importation of lisinopril oral solution, 1 mg/mL that is the subject of ANDA No. 218419 has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported, or marketed—infringe, directly or indirectly, any valid and enforceable claim of U.S. Patent No. 10,039,800, either literally or under the doctrine of equivalents.

EIGHTH AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 10,039,800)

The claims of U.S. Patent No. 10,039,800 are invalid and/or unenforceable for failure to comply with the requirements for patentability, including but not limited to the requirements set forth in 35 U.S.C. §§ 101, 102, 103, and/or 112.

NINTH AFFIRMATIVE DEFENSE
(Non-infringement of U.S. Patent No. 10,265,370)

The manufacture, use, sale, offer for sale, or importation of lisinopril oral solution, 1 mg/mL that is the subject of ANDA No. 218419 has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported, or marketed—infringe, directly or indirectly, any valid and enforceable claim of U.S. Patent No. 10,265,370, either literally or under the doctrine of equivalents.

TENTH AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 10,265,370)

The claims of U.S. Patent No. 10,265,370 are invalid and/or unenforceable for failure to comply with the requirements for patentability, including but not limited to the requirements set forth in 35 U.S.C. §§ 101, 102, 103, and/or 112.

ELEVENTH AFFIRMATIVE DEFENSE
(Non-infringement of U.S. Patent No. 10,406,199)

The manufacture, use, sale, offer for sale, or importation of lisinopril oral solution, 1 mg/mL that is the subject of ANDA No. 218419 has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported, or marketed—infringe, directly or indirectly, any valid and enforceable claim of U.S. Patent No. 10,406,199, either literally or under the doctrine of equivalents.

TWELFTH AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 10,406,199)

The claims of U.S. Patent No. 10,406,199 are invalid and/or unenforceable for failure to comply with the requirements for patentability, including but not limited to the requirements set forth in 35 U.S.C. §§ 101, 102, 103, and/or 112.

THIRTEENTH AFFIRMATIVE DEFENSE
(Non-infringement of U.S. Patent No. 10,940,177)

The manufacture, use, sale, offer for sale, or importation of lisinopril oral solution, 1 mg/mL that is the subject of ANDA No. 218419 has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported, or marketed—infringe, directly or indirectly, any valid and enforceable claim of U.S. Patent No. 10,940,177, either literally or under the doctrine of equivalents.

FOURTEENTH AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 10,940,177)

The claims of U.S. Patent No. 10,940,177 are invalid and/or unenforceable for failure to comply with the requirements for patentability, including but not limited to the requirements set forth in 35 U.S.C. §§ 101, 102, 103, and/or 112.

FIFTEENTH AFFIRMATIVE DEFENSE
(Non-infringement of U.S. Patent No. 11,179,434)

The manufacture, use, sale, offer for sale, or importation of lisinopril oral solution, 1 mg/mL that is the subject of ANDA No. 218419 has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported, or marketed—infringe, directly or indirectly, any valid and enforceable claim of U.S. Patent No. 11,179,434, either literally or under the doctrine of equivalents.

SIXTEENTH AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 11,179,434)

The claims of U.S. Patent No. 11,179,434 are invalid and/or unenforceable for failure to comply with the requirements for patentability, including but not limited to the requirements set forth in 35 U.S.C. §§ 101, 102, 103, and/or 112.

SEVENTEENTH AFFIRMATIVE DEFENSE
(No Exceptional Case)

Annora's actions in defending this case do not give rise to an exceptional case under 35 U.S.C. § 285.

RESERVATION OF ADDITIONAL SEPARATE DEFENSES

Annora reserves the right to plead additional separate defenses in accordance with the scheduling order to be entered in this matter or in the event that discovery or other analysis indicates that additional separate and/or affirmative defenses are appropriate, including, but not limited to, defenses of unenforceability.

ANNORA PHARMA PRIVATE LIMITED'S COUNTERCLAIMS FOR DECLARATORY JUDGMENT

Annora Pharma Private Limited ("Counterclaim-Plaintiff" or "Annora"), by way of counterclaim against Azurity Pharmaceuticals, Inc. ("Counterclaim-Defendant" or "Azurity"), alleges as follows:

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, Counterclaim-Defendant Azurity Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the state of Delaware, with a principal place of business at 8 Cabot Road, Suite 2000, Woburn, MA 01801.

3. As alleged in the Complaint, Azurity purports to be the owner of U.S. Patent Nos. 9,463,183 (the “183 patent”); 9,616,096 (the “096 patent”); 9,814,751 (the “751 patent”); 10,039,800 (the “800 patent”); 10,265,370 (the “370 patent”); 10,406,199 (the “199 patent”); 10,940,177 (the “177 patent”); and 11,179,434 (the “434 patent”) (collectively, the “patents-in-suit”).

4. As alleged in the Complaint, Azurity purports to be the holder of the New Drug Application (“NDA”) No. 208401.

5. On information and belief, Azurity caused the patents-in-suit to be listed in the publication *Approved Drug Products with Therapeutic Equivalence Evaluations* (“the Orange Book”) as patents that claim the drug and/or claim a method of using such a drug for which Azurity submitted NDA No. 208401.

6. Annora submitted Abbreviated New Drug Application No. 218419 (“Annora’s ANDA”) lisinopril oral solution, 1 mg/mL (“Annora’s Proposed Product”) to the Food and Drug Administration (“FDA”).

7. Annora’s ANDA contains a “Paragraph IV” certification under 21 U.S.C. § 505(j)(2)(A)(vii)(IV) that the patents-in-suit are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, or sale of Annora’s Proposed Product.

8. Pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) and C.F.R. § 314.95(c) on July 24, 2023, Annora sent Azurity notice of Annora’s Paragraph IV certification with Annora’s ANDA (“Annora’s Notice Letter”).

9. Annora’s Notice Letter contained an offer of confidential access to relevant portions of Annora’s ANDA to Azurity so that Azurity could evaluate whether the filing of

Annora's ANDA infringed any valid claim of the Orange Book listed patent, pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III).

10. Annora's Notice Letter initiated a 45-day statutory period during which Azurity had the opportunity to file an action for patent infringement.

11. On September 7, 2023, Azurity filed this instant suit alleging that Annora infringes the patents-in-suit by filing Annora's ANDA the FDA.

12. There has been and now is an actual and justiciable controversy between Annora and Azurity as to whether Annora's ANDA infringes, induces infringement, or contributes to the infringement of any valid and enforceable claim of the patents-in-suit.

13. As a consequence of the foregoing, there is an actual and justiciable controversy between Annora and Azurity as to whether the claims of the patents-in-suit were infringed by the filing Annora's ANDA.

14. As a consequence of the foregoing, there is an actual and justiciable controversy between Annora and Azurity as to whether the claims of the patents-in-suit are valid and enforceable.

15. The filing of this Complaint against Annora alleging infringement of the patents-in-suit shows that Azurity is willing to assert its patents against companies for the filing of ANDAs referencing NDA No. 208401.

JURISDICTION

16. These counterclaims arise under the Patent Laws of the United States, 35 U.S.C. §§ 1 *et seq.*, and under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

17. This Court has jurisdiction over the subject matter of Annora's counterclaims pursuant to 28 U.S.C. §§ 1331, 1338, 1367, 2201, and 2202.

18. Azurity, by bringing this action in this district, has consented to and is subject to personal jurisdiction in this district.

FIRST COUNTERCLAIM
(Declaration of Non-Infringement of U.S. Patent No. 9,463,183)

19. Annora repeats and realleges its responses to the Complaint and the allegations in Paragraphs 1-18 above as if fully set forth herein.

20. Azurity has asserted the '183 patent against Annora based on the filing of Annora's ANDA. Azurity alleges—and Annora denies—that the claims of the '183 patent cover Annora's Proposed Product.

21. The claims of the '183 patent do not, either literally or under the doctrine of equivalents, cover Annora's Proposed Product. Thus, Annora has not infringed and will not infringe the claims of the '183 patent by making, using, selling, offering or sale, marketing, or importing Annora's Proposed Product.

22. Annora and Azurity have adverse legal interests, and there is a substantial controversy between Azurity and Annora of sufficient immediacy and reality to warrant the issuance of a declaratory judgment that Annora, by virtue of filing Annora's ANDA, neither has nor will in the future infringe any valid and enforceable claim of the '183 patent.

23. Annora is entitled to a judicial declaration that Annora has not infringed and will not infringe any valid and enforceable claim of the '183 patent by virtue of filing Annora's ANDA or by making, using, selling, offering for sale, marketing, or importing Annora's Proposed Product.

SECOND COUNTERCLAIM
(Declaration of Invalidity of U.S. Patent No. 9,463,183)

24. Annora repeats and realleges its responses to the Complaint and the allegations in Paragraphs 1-23 above as if fully set forth herein.

25. Azurity alleges—and Annora denies—that the '183 patent is valid.

26. Claims 1-13 of the '183 patent are invalid for failure to comply with one or more of the conditions of patentability set forth in 35 U.S.C. §§ 101, 102, 103, and 112.

27. Annora and Azurity have adverse legal interests, and there is a substantial controversy between Azurity and Annora of sufficient immediacy and reality to warrant the issuance of a declaratory judgement of invalidity of claims 1-13 of the '183 patent.

28. Annora is entitled to a judicial declaration of the invalidity of claims 1-13 of the '183 patent.

THIRD COUNTERCLAIM
(Declaration of Non-Infringement of U.S. Patent No. 9,616,096)

29. Annora repeats and realleges its responses to the Complaint and the allegations in Paragraphs 1-28 above as if fully set forth herein.

30. Azurity has asserted the '096 patent against Annora based on the filing of Annora's ANDA. Azurity alleges—and Annora denies—that the claims of the '096 patent cover Annora's Proposed Product.

31. The claims of the '096 patent do not, either literally or under the doctrine of equivalents, cover Annora's Proposed Product. Thus, Annora has not infringed and will not infringe the claims of the '096 patent by making, using, selling, offering or sale, marketing, or importing Annora's Proposed Product.

32. Annora and Azurity have adverse legal interests, and there is a substantial controversy between Azurity and Annora of sufficient immediacy and reality to warrant the issuance of a declaratory judgment that Annora, by virtue of filing Annora's ANDA, neither has nor will in the future infringe any valid and enforceable claim of the '096 patent.

33. Annora is entitled to a judicial declaration that Annora has not infringed and will not infringe any valid and enforceable claim of the '096 patent by virtue of filing ANDA No. 218419 or by making, using, selling, offering for sale, marketing, or importing Annora's Proposed Product.

FOURTH COUNTERCLAIM
(Declaration of Invalidity of U.S. Patent No. 9,616,096)

34. Annora repeats and realleges its responses to the Complaint and the allegations in Paragraphs 1-33 above as if fully set forth herein.

35. Azurity alleges—and Annora denies—that the '096 patent is valid.

36. Claims 1-20 of the '096 patent are invalid for failure to comply with one or more of the conditions of patentability set forth in 35 U.S.C. §§ 101, 102, 103, and 112.

37. Annora and Azurity have adverse legal interests, and there is a substantial controversy between Azurity and Annora of sufficient immediacy and reality to warrant the issuance of a declaratory judgement of invalidity of claims 1-20 of the '096 patent.

38. Annora is entitled to a judicial declaration of the invalidity of claims 1-20 of the '096 patent.

FIFTH COUNTERCLAIM
(Declaration of Non-Infringement of U.S. Patent No. 9,814,751)

39. Annora repeats and realleges its responses to the Complaint and the allegations in Paragraphs 1-38 above as if fully set forth herein.

40. Azurity has asserted the '751 patent against Annora based on the filing of Annora's ANDA. Azurity alleges—and Annora denies—that the claims of the '751 patent cover Annora's Proposed Product.

41. The claims of the '751 patent do not, either literally or under the doctrine of equivalents, cover Annora's Proposed Product. Thus, Annora has not infringed and will not

infringe the claims of the '751 patent by making, using, selling, offering or sale, marketing, or importing Annora's Proposed Product.

42. Annora and Azurity have adverse legal interests, and there is a substantial controversy between Azurity and Annora of sufficient immediacy and reality to warrant the issuance of a declaratory judgment that Annora, by virtue of filing Annora's ANDA, neither has nor will in the future infringe any valid and enforceable claim of the '751 patent.

43. Annora is entitled to a judicial declaration that Annora has not infringed and will not infringe any valid and enforceable claim of the '751 patent by virtue of filing Annora's ANDA or by making, using, selling, offering for sale, marketing, or importing Annora's Proposed Product.

SIXTH COUNTERCLAIM
(Declaration of Invalidity of U.S. Patent No. 9,814,751)

44. Annora repeats and realleges its responses to the Complaint and the allegations in Paragraphs 1-43 above as if fully set forth herein.

45. Azurity alleges—and Annora denies—that the '751 patent is valid.

46. Claims 1-20 of the '751 patent are invalid for failure to comply with one or more of the conditions of patentability set forth in 35 U.S.C. §§ 101, 102, 103, and 112.

47. Annora and Azurity have adverse legal interests, and there is a substantial controversy between Azurity and Annora of sufficient immediacy and reality to warrant the issuance of a declaratory judgement of invalidity of claims 1-20 of the '751 patent.

48. Annora is entitled to a judicial declaration of the invalidity of claims 1-20 of the '751 patent.

SEVENTH COUNTERCLAIM
(Declaration of Non-Infringement of U.S. Patent No. 10,039,800)

49. Annora repeats and realleges its responses to the Complaint and the allegations in Paragraphs 1-48 above as if fully set forth herein.

50. Azurity has asserted the '800 patent against Annora based on the filing of Annora's ANDA. Azurity alleges—and Annora denies—that the claims of the '800 patent cover Annora's Proposed Product.

51. The claims of the '800 patent do not, either literally or under the doctrine of equivalents, cover Annora's Proposed Product. Thus, Annora has not infringed and will not infringe the claims of the '800 patent by making, using, selling, offering or sale, marketing, or importing Annora's Proposed Product.

52. Annora and Azurity have adverse legal interests, and there is a substantial controversy between Azurity and Annora of sufficient immediacy and reality to warrant the issuance of a declaratory judgment that Annora, by virtue of filing Annora's ANDA, neither has nor will in the future infringe any valid and enforceable claim of the '800 patent.

53. Annora is entitled to a judicial declaration that Annora has not infringed and will not infringe any valid and enforceable claim of the '800 patent by virtue of filing Annora's ANDA or by making, using, selling, offering for sale, marketing, or importing Annora's Proposed Product.

EIGHTH COUNTERCLAIM
(Declaration of Invalidity of U.S. Patent No. 10,039,800)

54. Annora repeats and realleges its responses to the Complaint and the allegations in Paragraphs 1-53 above as if fully set forth herein.

55. Azurity alleges—and Annora denies—that the '800 patent is valid.

56. Claims 1-20 of the '800 patent are invalid for failure to comply with one or more of the conditions of patentability set forth in 35 U.S.C. §§ 101, 102, 103, and 112.

57. Annora and Azurity have adverse legal interests, and there is a substantial controversy between Azurity and Annora of sufficient immediacy and reality to warrant the issuance of a declaratory judgement of invalidity of claims 1-20 of the '800 patent.

58. Annora is entitled to a judicial declaration of the invalidity of claims 1-20 of the '800 patent.

NINTH COUNTERCLAIM
(Declaration of Non-Infringement of U.S. Patent No. 10,265,370)

59. Annora repeats and realleges its responses to the Complaint and the allegations in Paragraphs 1-58 above as if fully set forth herein.

60. Azurity has asserted the '370 patent against Annora based on the filing of Annora's ANDA. Azurity alleges—and Annora denies—that the claims of the '370 patent cover Annora's Proposed Product.

61. The claims of the '370 patent do not, either literally or under the doctrine of equivalents, cover Annora's Proposed Product. Thus, Annora has not infringed and will not infringe the claims of the '370 patent by making, using, selling, offering or sale, marketing, or importing Annora's Proposed Product.

62. Annora and Azurity have adverse legal interests, and there is a substantial controversy between Azurity and Annora of sufficient immediacy and reality to warrant the issuance of a declaratory judgment that Annora, by virtue of filing Annora's ANDA, neither has nor will in the future infringe any valid and enforceable claim of the '370 patent.

63. Annora is entitled to a judicial declaration that Annora has not infringed and will not infringe any valid and enforceable claim of the '370 patent by virtue of filing Annora's

ANDA or by making, using, selling, offering for sale, marketing, or importing Annora's Proposed Product.

TENTH COUNTERCLAIM
(Declaration of Invalidity of U.S. Patent No. 10,265,370)

64. Annora repeats and realleges its responses to the Complaint and the allegations in Paragraphs 1-63 above as if fully set forth herein.

65. Azurity alleges—and Annora denies—that the '370 patent is valid.

66. Claims 1-20 of the '370 patent are invalid for failure to comply with one or more of the conditions of patentability set forth in 35 U.S.C. §§ 101, 102, 103, and 112.

67. Annora and Azurity have adverse legal interests, and there is a substantial controversy between Azurity and Annora of sufficient immediacy and reality to warrant the issuance of a declaratory judgement of invalidity of claims 1-20 of the '370 patent.

68. Annora is entitled to a judicial declaration of the invalidity of claims 1-20 of the '370 patent.

ELEVENTH COUNTERCLAIM
(Declaration of Non-Infringement of U.S. Patent No. 10,406,199)

69. Annora repeats and realleges its responses to the Complaint and the allegations in Paragraphs 1-68 above as if fully set forth herein.

70. Azurity has asserted the '199 patent against Annora based on the filing of Annora's ANDA. Azurity alleges—and Annora denies—that the claims of the '199 patent cover Annora's Proposed Product.

71. The claims of the '199 patent do not, either literally or under the doctrine of equivalents, cover Annora's Proposed Product. Thus, Annora has not infringed and will not infringe the claims of the '199 patent by making, using, selling, offering or sale, marketing, or importing Annora's Proposed Product.

72. Annora and Azurity have adverse legal interests, and there is a substantial controversy between Azurity and Annora of sufficient immediacy and reality to warrant the issuance of a declaratory judgment that Annora, by virtue of filing Annora's ANDA, neither has nor will in the future infringe any valid and enforceable claim of the '199 patent.

73. Annora is entitled to a judicial declaration that Annora has not infringed and will not infringe any valid and enforceable claim of the '199 patent by virtue of filing Annora's ANDA or by making, using, selling, offering for sale, marketing, or importing Annora's Proposed Product.

TWELFTH COUNTERCLAIM
(Declaration of Invalidity of U.S. Patent No. 10,406,199)

74. Annora repeats and realleges its responses to the Complaint and the allegations in Paragraphs 1-73 above as if fully set forth herein.

75. Azurity alleges—and Annora denies—that the '199 patent is valid.

76. Claims 1-20 of the '199 patent are invalid for failure to comply with one or more of the conditions of patentability set forth in 35 U.S.C. §§ 101, 102, 103, and 112.

77. Annora and Azurity have adverse legal interests, and there is a substantial controversy between Azurity and Annora of sufficient immediacy and reality to warrant the issuance of a declaratory judgement of invalidity of claims 1-20 of the '199 patent.

78. Annora is entitled to a judicial declaration of the invalidity of claims 1-20 of the '199 patent.

THIRTEENTH COUNTERCLAIM
(Declaration of Non-Infringement of U.S. Patent No. 10,940,177)

79. Annora repeats and realleges its responses to the Complaint and the allegations in Paragraphs 1-78 above as if fully set forth herein.

80. Azurity has asserted the '177 patent against Annora based on the filing of Annora's ANDA. Azurity alleges—and Annora denies—that the claims of the '177 patent cover Annora's Proposed Product.

81. The claims of the '177 patent do not, either literally or under the doctrine of equivalents, cover Annora's Proposed Product. Thus, Annora has not infringed and will not infringe the claims of the '177 patent by making, using, selling, offering or sale, marketing, or importing Annora's Proposed Product.

82. Annora and Azurity have adverse legal interests, and there is a substantial controversy between Azurity and Annora of sufficient immediacy and reality to warrant the issuance of a declaratory judgment that Annora, by virtue of filing Annora's ANDA, neither has nor will in the future infringe any valid and enforceable claim of the '177 patent.

83. Annora is entitled to a judicial declaration that Annora has not infringed and will not infringe any valid and enforceable claim of the '177 patent by virtue of filing Annora's ANDA or by making, using, selling, offering for sale, marketing, or importing Annora's Proposed Product.

FOURTEENTH COUNTERCLAIM
(Declaration of Invalidity of U.S. Patent No. 10,940,177)

84. Annora repeats and realleges its responses to the Complaint and the allegations in Paragraphs 1-83 above as if fully set forth herein.

85. Azurity alleges—and Annora denies—that the '177 patent is valid.

86. Claims 1-19 of the '177 patent are invalid for failure to comply with one or more of the conditions of patentability set forth in 35 U.S.C. §§ 101, 102, 103, and 112.

87. Annora and Azurity have adverse legal interests, and there is a substantial controversy between Azurity and Annora of sufficient immediacy and reality to warrant the issuance of a declaratory judgement of invalidity of claims 1-19 of the '177 patent.

88. Annora is entitled to a judicial declaration of the invalidity of claims 1-19 of the '177 patent.

FIFTEENTH COUNTERCLAIM
(Declaration of Non-Infringement of U.S. Patent No. 11,179,434)

89. Annora repeats and realleges its responses to the Complaint and the allegations in Paragraphs 1-88 above as if fully set forth herein.

90. Azurity has asserted the '434 patent against Annora based on the filing of Annora's ANDA. Azurity alleges—and Annora denies—that the claims of the '434 patent cover Annora's Proposed Product.

91. The claims of the '434 patent do not, either literally or under the doctrine of equivalents, cover Annora's Proposed Product. Thus, Annora has not infringed and will not infringe the claims of the '434 patent by making, using, selling, offering or sale, marketing, or importing Annora's Proposed Product.

92. Annora and Azurity have adverse legal interests, and there is a substantial controversy between Azurity and Annora of sufficient immediacy and reality to warrant the issuance of a declaratory judgment that Annora, by virtue of filing Annora's ANDA, neither has nor will in the future infringe any valid and enforceable claim of the '434 patent.

93. Annora is entitled to a judicial declaration that Annora has not infringed and will not infringe any valid and enforceable claim of the '434 patent by virtue of filing Annora's ANDA or by making, using, selling, offering for sale, marketing, or importing Annora's Proposed Product.

SIXTEENTH COUNTERCLAIM
(Declaration of Invalidity of U.S. Patent No. 11,179,434)

94. Annora repeats and realleges its responses to the Complaint and the allegations in Paragraphs 1-93 above as if fully set forth herein.

95. Azurity alleges—and Annora denies—that the '434 patent is valid.

96. Claims 1-18 of the '434 patent are invalid for failure to comply with one or more of the conditions of patentability set forth in 35 U.S.C. §§ 101, 102, 103, and 112.

97. Annora and Azurity have adverse legal interests, and there is a substantial controversy between Azurity and Annora of sufficient immediacy and reality to warrant the issuance of a declaratory judgement of invalidity of claims 1-18 of the '434 patent.

98. Annora is entitled to a judicial declaration of the invalidity of claims 1-18 of the '434 patent.

PRAYER FOR RELIEF

WHEREFORE Annora respectfully prays for judgment in its favor and against Azurity, including the following specific relief:

A. Dismissing Azurity's Complaint with prejudice and denying each and every request for relief made therein by Azurity;

B. Declaring that the filing of Annora's ANDA did not infringe any valid and enforceable claim of the '183 patent;

C. Declaring that the manufacture, use, sale, offer for sale, or importation of Annora's Proposed Product would not infringe any valid and enforceable claim of the '183 patent;

D. Declaring that claims 1-13 of the '183 patent are invalid;

E. Declaring that the filing of Annora's ANDA did not infringe any valid and enforceable claim of the '096 patent;

F. Declaring that the manufacture, use, sale, offer for sale, or importation of Annora's Proposed Product would not infringe any valid and enforceable claim of the '096 patent;

G. Declaring that claims 1-20 of the '096 patent are invalid;

H. Declaring that the filing of Annora's ANDA did not infringe any valid and enforceable claim of the '751 patent;

I. Declaring that the manufacture, use, sale, offer for sale, or importation of Annora's Proposed Product would not infringe any valid and enforceable claim of the '751 patent;

J. Declaring that claims 1-20 of the '751 patent are invalid;

K. Declaring that the filing of Annora's ANDA did not infringe any valid and enforceable claim of the '800 patent;

L. Declaring that the manufacture, use, sale, offer for sale, or importation of Annora's Proposed Product would not infringe any valid and enforceable claim of the '800 patent;

M. Declaring that claims 1-20 of the '800 patent are invalid;

N. Declaring that the filing of Annora's ANDA did not infringe any valid and enforceable claim of the '370 patent;

O. Declaring that the manufacture, use, sale, offer for sale, or importation of Annora's Proposed Product would not infringe any valid and enforceable claim of the '370 patent;

- P. Declaring that claims 1-20 of the '370 patent are invalid;
- Q. Declaring that the filing of Annora's ANDA did not infringe any valid and enforceable claim of the '199 patent;
- R. Declaring that the manufacture, use, sale, offer for sale, or importation of Annora's Proposed Product would not infringe any valid and enforceable claim of the '199 patent;
- S. Declaring that claims 1-20 of the '199 patent are invalid;
- T. Declaring that the filing of Annora's ANDA did not infringe any valid and enforceable claim of the '177 patent;
- U. Declaring that the manufacture, use, sale, offer for sale, or importation of Annora's Proposed Product would not infringe any valid and enforceable claim of the '177 patent;
- V. Declaring that claims 1-19 of the '177 patent are invalid;
- W. Declaring that the filing of Annora's ANDA did not infringe any valid and enforceable claim of the '434 patent;
- X. Declaring that the manufacture, use, sale, offer for sale, or importation of Annora's Proposed Product would not infringe any valid and enforceable claim of the '434 patent;
- Y. Declaring that claims 1-18 of the '434 patent are invalid;
- Z. Declaring this case exceptional and awarding Annora reasonable attorneys' fees and costs under 35 U.S.C. § 285; and
- AA. Awarding Annora such other and further relief as the Court may deem just and proper.

Dated: November 6, 2023

Respectfully submitted,

HILL WALLACK, LLP

By: /s/ Eric I. Abraham

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