

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SILVERGATE PHARMACEUTICALS,
INC.,

Plaintiff,

v.

ANNORA PHARMA PRIVATE LIMITED,

Defendant.

C.A. No.: 1:20-00753-LPS

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

Defendant Annora Pharma Private Limited (“Defendant” or “Annora”), by and through its attorneys, hereby answers the Complaint of Plaintiff, Silvergate Pharmaceuticals, Inc. (“Plaintiff” or “Silvergate”) (D.I. 1), with each numbered paragraph below corresponding to the same numbered paragraph in the Complaint (*id.*), and assert its affirmative defenses and counterclaims as follows. Except as otherwise specifically stated in this Answer, Annora denies each and every allegation of Plaintiff’s Complaint (*id.*).

NATURE OF THE ACTION

1. Annora admits that this purports to be an action for patent infringement related to the referenced ANDA and the referenced patents. Otherwise, denied.

THE PARTIES

2. Annora is without information sufficient to form a belief as to the truth or falsity of the allegations in paragraph 2 of the Complaint; therefore, denied.

3. Admitted.

4. Admitted that Annora is an Indian company involved in the development of generic pharmaceutical products. Otherwise, denied.

JURISDICTION AND VENUE

5. Admitted that this purports to be an action for patent infringement under the patent laws of the United states of America, 35 U.S.C. § 100, *et. seq.*, and that Annora submitted ANDA No. 214667. Otherwise, denied.

6. 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). Otherwise, denied.

7. Annora does not contest personal jurisdiction for purposes of this action only. Otherwise, denied.

8. Annora does not contest personal jurisdiction for purposes of this action only. Otherwise, denied.

9. Annora does not contest personal jurisdiction for purposes of this action only. Otherwise, denied.

10. Admitted that Annora is a foreign corporation, and that Annora does not contest venue for purposes of this action only. Otherwise, denied.

SILVERGATE'S EPANED® PRODUCT

11. Admitted that the labeling for Epaned® lists indications of “treatment of hypertension in adults and children older than one month, to lower blood pressure,” “treatment of symptomatic heart failure,” and “treatment of asymptomatic left ventricular dysfunction, to decrease the rate of development of overt heart failure and reduce hospitalization for heart failure” . Annora either denies, or is without sufficient information to admit or deny and therefore denies, all remaining allegations of paragraph 11.

12. Admitted that the Orange Book identifies Silvergate as the holder of NDA No. 208686 for Epaned[®]. Otherwise, denied.

PATENTS-IN-SUIT

13. Admitted that what purports to be the '008 Patent is entitled "Enalapril Formulations," issued on June 6, 2017, and lists Gerold L. Mosher and David W. Miles as inventors. Otherwise, denied.

14. Admitted that Silvergate is listed as an assignee on what purports to be the '008 Patent. Annora denies all remaining allegations of paragraph 14.

15. Admitted that the '008 Patent is listed in the Orange Book in connection with the Epaned[®] product.

16. Paragraph 16 contains legal conclusions to which no answer is required. To the extent an answer is required, Annora either denies, or is without sufficient information to admit or deny and therefore denies, the allegations of paragraph 16.

17. Admitted that what purports to be the '442 Patent is entitled "Enalapril Formulations," issued on November 7, 2017, and lists Gerold L. Mosher and David W. Miles as inventors. Otherwise, denied.

18. Admitted that Silvergate is listed as an assignee on what purports to be the '442 Patent. Annora denies all remaining allegations of paragraph 18.

19. Admitted that the '442 Patent is listed in the Orange Book in connection with the Epaned[®] product.

20. Paragraph 20 contains legal conclusions to which no answer is required. To the extent an answer is required, Annora either denies, or is without sufficient information to admit or deny, and therefore denies, the allegations of paragraph 20.

21. Paragraph 21 contains legal conclusions to which no answer is required. To the extent an answer is required, Annora either denies, or is without sufficient information to admit or deny and therefore denies, the allegations of paragraph 21.

22. Admitted that what purports to be the '745 Patent is entitled "Enalapril Formulations," issued on August 7, 2018, and lists Gerold L. Mosher and David W. Miles as inventors. Otherwise, denied.

23. Admitted that Silvergate is listed as an assignee on what purports to be the '745 Patent. Annora denies all remaining allegations of paragraph 23.

24. Admitted that the '745 Patent is listed in the Orange Book in connection with the Epaned[®] product.

25. Paragraph 25 contains legal conclusions to which no answer is required. To the extent an answer is required, Annora either denies, or is without sufficient information to admit or deny and therefore denies, the allegations of paragraph 25.

26. Admitted that what purports to be the '987 Patent is entitled "Enalapril Formulations," issued on December 18, 2018, and lists Gerold L. Mosher and David W. Miles as inventors. Otherwise, denied.

27. Admitted that Silvergate is listed as an assignee on what purports to be the '987 Patent. Annora denies all remaining allegations of paragraph 27.

28. Admitted the '987 Patent is listed in the Orange Book in connection with the Epaned[®] product.

29. Paragraph 29 contains legal conclusions to which no answer is required. To the extent an answer is required, Annora either denies, or is without sufficient information to admit or deny and therefore denies, the allegations of paragraph 29.

30. Paragraph 30 contains legal conclusions to which no answer is required. To the extent an answer is required, Annora either denies, or is without sufficient information to admit or deny and therefore denies, the allegations of paragraph 30.

INFRINGEMENT BY ANNORA

31. Annora admits that it submitted ANDA No. 214467 to the FDA. Otherwise, denied.

32. Annora admits that the FDA has not yet granted final approval to ANDA No. 214667.

33. Admitted.

34. Paragraph 34 contains allegations about future events that have not occurred, and Annora therefore denies the allegations of paragraph 34.

35. Admitted that Annora submitted an ANDA directed to an enalapril maleate (1 mg/mL) oral solution that it believes is bioequivalent to Epaned® oral solution. Annora denies any remaining allegations of paragraph 35.

36. Admitted.

CLAIMS FOR RELIEF

Count I – Infringement of the '008 Patent

37. Paragraph 37 contains no allegations to which a response is not required.

38. Annora admits that it submitted ANDA No. 214467 to the FDA. Otherwise, denied.

39. Denied.

40. Admitted that Annora was aware of the '008 patent before it filed its ANDA, otherwise denied.

41. Denied.

Count II – Infringement of the '442 Patent

42. Paragraph 42 contains allegations to which a response is not required.

43. Annora admits that it submitted ANDA No. 214467 to the FDA. Otherwise, denied.

44. Denied.

45. Admitted that Annora was aware of the '442 patent before it filed its ANDA, otherwise denied.

46. Denied.

Count III – Infringement of the '745 Patent

47. Paragraph 47 contains allegations to which a response is not required.

48. Annora admits that it submitted ANDA No. 214467 to the FDA. Otherwise, denied.

49. Denied.

50. Admitted that Annora was aware of the '745 patent before it filed its ANDA, otherwise denied.

51. Denied.

Count IV – Infringement of the '987 Patent

52. Paragraph 52 contains allegations to which a response is not required.

53. Annora admits that it submitted ANDA No. 214467 to the FDA. Otherwise, denied.

54. Denied.

55. Admitted that Annora was aware of the '008 patent before it filed its ANDA, otherwise denied.

56. Denied.

RESPONSE TO PLAINTIFFS' REQUEST FOR RELIEF

Annora denies that Plaintiffs are entitled to the relief as requested in ¶¶ (a) - (f) of the Complaint's Request 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. 9,669,008)

The manufacture, use, sale, offer for sale, or importation of Enalapril Maleate oral solution, 1 mg/ml that is the subject of ANDA No. 214467 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 the patent-in-suit, either literally or under the doctrine of equivalents.

SECOND AFFIRMATIVE DEFENSE

(Invalidity of U.S. Patent No. 9,669,008)

The claims of the patent-in-suit 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. 9,808,442)

The manufacture, use, sale, offer for sale, or importation of Enalapril Maleate oral solution, 1 mg/ml that is the subject of ANDA No. 214467 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 the patent-in-suit, either literally or under the doctrine of equivalents.

FOURTH AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 9,808,442)

The claims of the patent-in-suit 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. 10,039,745)

The manufacture, use, sale, offer for sale, or importation of Enalapril Maleate oral solution, 1 mg/ml that is the subject of ANDA No. 214467 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 the patent-in-suit, either literally or under the doctrine of equivalents.

SIXTH AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 10,039,745)

The claims of the patent-in-suit 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. 10,154,987)

The manufacture, use, sale, offer for sale, or importation of Enalapril Maleate oral solution, 1 mg/ml that is the subject of ANDA No. 214467 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 the patent-in-suit, either literally or under the doctrine of equivalents.

EIGHTH AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 10,154,987)

The claims of the patent-in-suit 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
(Subject Matter Jurisdiction)

The Court lacks subject matter jurisdiction over any and all claims asserted under 35 U.S.C § 271(a), (b), and/or (c).

ANNORA COUNTERCLAIMS FOR DECLARATORY JUDGMENT

Annora Pharma Private Limited, by way of counterclaim against Silvergate Pharmaceuticals, Inc. (“Counterclaim-Defendant”), alleges as follows:

1. Counterclaim-Plaintiff Annora Pharma Private Limited (“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 Silvergate Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware, with a

principal place of business at 6251 Greenwood Plaza Blvd., Suite 101, Greenwood Village, CO 80111.

3. As alleged in the Complaint, Silvergate Pharmaceuticals, Inc. purports to be the owner of U.S. Patent Nos. 9,669,008 (“the ’008 Patent”); 9,808,442 (“the ’442 Patent”); 10,039,745 (“the ’745 Patent”); and 10,154,987 (“the ’987 Patent”).

4. As alleged in Counterclaim-Defendant’ Complaint, Silvergate Pharmaceuticals, Inc. purports to be the holder of New Drug Application (“NDA”) No. 208686.

5. On information and belief, Counterclaim-Defendant caused the ’008 Patent, the ’442 Patent, ’745 Patent, and ’987 Patent to be listed in the publication *Approved Drug Products with Therapeutic Equivalence Evaluations* (“The Orange Book”) as patents that cover the Epaned[®] product to which NDA No. 208686 is directed.

6. Annora submitted Abbreviated New Drug Application (“ANDA”) No. 214467 for an enalapril maleate oral solution, 1 mg/ml (“Annora’s Proposed Product”) to the Food and Drug Administration (“FDA”).

7. Annora’s ANDA No. 214467 contains a “Paragraph IV” certification under 21 U.S.C. § 505(j)(2)(A)(vii)(IV) that the ’008 Patent, the ’442 Patent, ’745 Patent, and ’987 Patent 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 April 21, 2020 Annora sent Counterclaim-Defendant notice of Annora’s Paragraph IV certification with ANDA No. 214467 (“Annora’s Notice Letter”).

9. Annora’s Notice Letter contained an offer of confidential access to relevant portions of ANDA No. 214467 to the Counterclaim-Defendant so that they could determine

whether Annora's Proposed Product would infringe any valid claim of the Orange Book-listed patents, 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 Counterclaim-Defendant had the opportunity to file an action for patent infringement.

11. On June 4, 2020, Counterclaim-Defendant filed this instant suit alleging that Annora infringes the '008 Patent, the '442 Patent, '745 Patent, and '987 Patent by filing ANDA No. 214467 with the FDA and/or commercially selling, offering for sale, using, and/or manufacturing Annora's Proposed Product.

12. There has been and now is an actual and justiciable controversy between Annora and Counterclaim-Defendant as to whether Annora's Proposed Product infringes, induces infringement, or contributes to the infringement of any valid and enforceable claim of the '008 Patent, the '442 Patent, '745 Patent, and '987 Patent.

13. As a consequence of the foregoing, there is an actual and justiciable controversy between Annora and Counterclaim-Defendant as to whether the claims of the '008 Patent, the '442 Patent, '745 Patent, and '987 Patent have been, are being or will be infringed by filing of ANDA No. 214467 and/or the use, sale, offer for sale, or manufacture of Annora's Proposed Product.

14. As a consequence of the foregoing, there is an actual and justiciable controversy between Annora and the Counterclaim-Defendant as to whether the claims of the '008 Patent, the '442 Patent, '745 Patent, and '987 Patent are valid and enforceable.

JURISDICTION

15. 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.

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

17. Counterclaim-Defendant, by bringing this action in this district, have consented to and are subject to personal jurisdiction in this district.

FIRST COUNTERCLAIM
(Declaration of Non-Infringement of U.S. Patent No. 9,669,008)

18. Annora repeats and realleges its responses to the Complaint and the allegations in paragraphs 1 through 17 above as if fully set forth herein.

19. Counterclaim-Defendant has asserted the '008 Patent against Annora based on the filing of ANDA No. 214467. Counterclaim-Defendant alleges—and Annora denies—that the claims of the '008 Patent cover Annora's Proposed Product.

20. The claims of the '008 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 '008 Patent by making, using, selling, offering for sale, marketing or importing Annora's Proposed Product.

21. Annora and Counterclaim-Defendant have adverse legal interests, and there is a substantial controversy between Counterclaim-Defendant and Annora of sufficient immediacy and reality to warrant the issuance of a declaratory judgment that Annora, by virtue of filing ANDA No. 214467, neither has nor will in the future infringe any valid and enforceable claim of the '008 Patent.

22. Annora is entitled to a judicial declaration that Annora has not infringed and will not infringe any valid and enforceable claim of the '008 Patent by virtue of filing ANDA No. 214467 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. 9,669,008)

23. Annora repeats and realleges its responses to the Complaint and the allegations in paragraphs 1 through 22 above as if fully set forth herein.

24. Counterclaim-Defendant alleges—and Annora denies—that the '008 Patent is valid.

25. The claims of the '008 Patent are invalid for failure to comply with one or more of the conditions of patentability set forth in Title 35 of the United States Code.

26. Annora and Counterclaim-Defendant have adverse legal interests, and there is a substantial controversy between Counterclaim-Defendant and Annora of sufficient immediacy and reality to warrant the issuance of a declaratory judgment of invalidity of the claims of the '008 Patent.

27. Annora is entitled to a judicial declaration that the claims of the '008 Patent are invalid.

THIRD COUNTERCLAIM
(Declaration of Non-Infringement of U.S. Patent No. 9,808,442)

28. Annora repeats and realleges its responses to the Complaint and the allegations in paragraphs 1 through 27 above as if fully set forth herein.

29. Counterclaim-Defendant has asserted the '442 Patent against Annora based on the filing of ANDA No. 214467. Counterclaim-Defendant alleges—and Annora denies—that the claims of the '442 Patent cover Annora's Proposed Product.

30. The claims of the '442 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 '442 Patent by making, using, selling, offering for sale, marketing or importing Annora's Proposed Product.

31. Annora and Counterclaim-Defendant have adverse legal interests, and there is a substantial controversy between Counterclaim-Defendant and Annora of sufficient immediacy and reality to warrant the issuance of a declaratory judgment that Annora, by virtue of filing ANDA No. 214467, neither has nor will in the future infringe any valid and enforceable claim of the '442 Patent.

32. Annora is entitled to a judicial declaration that Annora has not infringed and will not infringe any valid and enforceable claim of the '442 Patent by virtue of filing ANDA No. 214467 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. 9,808,442)

33. Annora repeats and realleges its responses to the Complaint and the allegations in paragraphs 1 through 32 above as if fully set forth herein.

34. Counterclaim-Defendant alleges—and Annora denies—that the '442 Patent is valid.

35. The claims of the '442 Patent are invalid for failure to comply with one or more of the conditions of patentability set forth in Title 35 of the United States Code.

36. Annora and Counterclaim-Defendant have adverse legal interests, and there is a substantial controversy between Counterclaim-Defendant and Annora of sufficient immediacy and reality to warrant the issuance of a declaratory judgment of invalidity of the claims of the '442 Patent.

37. Annora is entitled to a judicial declaration that the claims of the '442 Patent are invalid.

FIFTH COUNTERCLAIM
(Declaration of Non-Infringement of U.S. Patent No. 10,039,745)

38. Annora repeats and realleges its responses to the Complaint and the allegations in paragraphs 1 through 37 above as if fully set forth herein.

39. Counterclaim-Defendant has asserted the '745 Patent against Annora based on the filing of ANDA No. 214467. Counterclaim-Defendant alleges—and Annora denies—that the claims of the '745 Patent cover Annora's Proposed Product.

40. The claims of the '745 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 '745 Patent by making, using, selling, offering for sale, marketing or importing Annora's Proposed Product.

41. Annora and Counterclaim-Defendant have adverse legal interests, and there is a substantial controversy between Counterclaim-Defendant and Annora of sufficient immediacy and reality to warrant the issuance of a declaratory judgment that Annora, by virtue of filing ANDA No. 214467, neither has nor will in the future infringe any valid and enforceable claim of the '745 Patent.

42. Annora is entitled to a judicial declaration that Annora has not infringed and will not infringe any valid and enforceable claim of the '745 Patent by virtue of filing ANDA No. 214467 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. 10,039,745)

43. Annora repeats and realleges its responses to the Complaint and the allegations in paragraphs 1 through 42 above as if fully set forth herein.

44. Counterclaim-Defendant alleges—and Annora denies—that the '745 Patent is valid.

45. The claims of the '745 Patent are invalid for failure to comply with one or more of the conditions of patentability set forth in Title 35 of the United States Code.

46. Annora and Counterclaim-Defendant have adverse legal interests, and there is a substantial controversy between Counterclaim-Defendant and Annora of sufficient immediacy and reality to warrant the issuance of a declaratory judgment of invalidity of the claims of the '745 Patent.

47. Annora is entitled to a judicial declaration that the claims of the '745 Patent are invalid.

SEVENTH COUNTERCLAIM
(Declaration of Non-Infringement of U.S. Patent No. 10,154,987)

48. Annora repeats and realleges its responses to the Complaint and the allegations in paragraphs 1 through 47 above as if fully set forth herein.

49. Counterclaim-Defendant has asserted the '987 Patent against Annora based on the filing of ANDA No. 214467. Counterclaim-Defendant alleges—and Annora denies—that the claims of the '987 Patent cover Annora's Proposed Product.

50. The claims of the '987 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 '987 Patent by making, using, selling, offering for sale, marketing or importing Annora's Proposed Product.

51. Annora and Counterclaim-Defendant have adverse legal interests, and there is a substantial controversy between Counterclaim-Defendant and Annora of sufficient immediacy and reality to warrant the issuance of a declaratory judgment that Annora, by virtue of filing ANDA No. 214467, neither has nor will in the future infringe any valid and enforceable claim of the '987 Patent.

52. Annora is entitled to a judicial declaration that Annora has not infringed and will not infringe any valid and enforceable claim of the '987 Patent by virtue of filing ANDA No. 214467 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. 10,154,987)

53. Annora repeats and realleges its responses to the Complaint and the allegations in paragraphs 1 through 52 above as if fully set forth herein.

54. Counterclaim-Defendant alleges—and Annora denies—that the '987 Patent is valid.

55. The claims of the '987 Patent are invalid for failure to comply with one or more of the conditions of patentability set forth in Title 35 of the United States Code.

56. Annora and Counterclaim-Defendant have adverse legal interests, and there is a substantial controversy between Counterclaim-Defendant and Annora of sufficient immediacy and reality to warrant the issuance of a declaratory judgment of invalidity of the claims of the '987 Patent.

57. Annora is entitled to a judicial declaration that the claims of the '987 Patent are invalid.

PRAYER FOR RELIEF

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

A. Dismissing Counterclaim-Defendant/Plaintiff's Complaint with prejudice and denying each and every request for relief made therein by Counterclaim-Defendant/Plaintiff;

B. Declaring that ANDA No. 214467 has not infringed any valid and enforceable claim of the '008 Patent;

C. Declaring that the manufacture, use, sale, offer for sale, or importation of the Proposed Product that is the subject of ANDA No. 214467 has not infringed, does not infringe, and would not infringe any valid and enforceable claim of the '008 Patent;

D. Declaring that the claims of the '008 Patent are invalid;

E. Declaring that ANDA No. 214467 has not infringed any valid and enforceable claim of the '442 Patent;

F. Declaring that the manufacture, use, sale, offer for sale, or importation of the Proposed Product that is the subject of ANDA No. 214467 has not infringed, does not infringe, and would not infringe any valid and enforceable claim of the '442 Patent;

G. Declaring that the claims of the '442 Patent are invalid;

H. Declaring that ANDA No. 214467 has not infringed any valid and enforceable claim of the '745 Patent;

I. Declaring that the manufacture, use, sale, offer for sale, or importation of the Proposed Product that is the subject of ANDA No. 214467 has not infringed, does not infringe, and would not infringe any valid and enforceable claim of the '745 Patent;

J. Declaring that the claims of the '745 Patent are invalid;

K. Declaring that ANDA No. 214467 has not infringed any valid and enforceable claim of the '987 Patent;

L. Declaring that the manufacture, use, sale, offer for sale, or importation of the Proposed Product that is the subject of ANDA No. 214467 has not infringed, does not infringe, and would not infringe any valid and enforceable claim of the '987 Patent;

M. Declaring that the claims of the '987 Patent are invalid;

N. Declaring this case exceptional and awarding Annora reasonable attorneys' fees and costs under 35 U.S.C. § 285; and

O. Awarding Annora such other and further relief as the Court may deem just and proper.

Respectfully submitted,

BAYARD, P.A.

Date: October 19, 2020

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