

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

BOEHRINGER INGELHEIM)
 PHARMACEUTICALS INC., BOEHRINGER)
 INGELHEIM INTERNATIONAL GMBH, and)
 BOEHRINGER INGELHEIM CORPORATION,)
)
 Plaintiffs,) C.A. No. 1:20-cv-277
 v.)
)
 ANNORA PHARMA PRIVATE LTD. and)
 HETERO USA INC.,)
)
 Defendants.)

DEFENDANTS ANNORA PHARMA PRIVATE LTD. AND HETERO USA, INC.'S
ANSWER TO PLAINTIFFS' COMPLAINT

Defendants Annora Pharma Private Ltd. (“Annora”) and Hetero USA Inc. (“Hetero USA”) (collectively, “Defendants”), by their attorneys, for their answer to Plaintiffs Boehringer Ingelheim Pharmaceuticals Inc.; Boehringer Ingelheim International GmbH; and Boehringer Ingelheim Corporation’s (collectively, “Plaintiffs”) Complaint (“Complaint”) state as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the Food and Drug Laws and Patent Laws of the United States, Titles 21 and 35 of the United States Code, respectively, arising from Defendants’ submission of an Abbreviated New Drug Application (“ANDA”) to the Food and Drug Administration (“FDA”) seeking approval to manufacture and sell a generic version of Plaintiffs’ GLYXAMBI® (empagliflozin/linagliptin) tablets prior to the expiration of United States Patent No. 10,258,637 (the “’637 patent”).

ANSWER: Defendants admit that Plaintiffs' Complaint purports to set forth an action for patent infringement arising under Titles 21 and 35 of the United States Code. Annora admits that it submitted an ANDA to the FDA seeking approval to manufacture and sell empagliflozin/linagliptin tablets before the expiration of the United States Patent No. 10,258,637 (the "637 patent"). Defendants deny the remaining allegations in Paragraph 1.

THE PARTIES

2. Plaintiff Boehringer Ingelheim Pharmaceuticals Inc. (“BIPI”) is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 900 Ridgebury Rd., Ridgefield, CT 06877.

ANSWER: Defendants lack sufficient information to form a belief as to the truth of the allegations in Paragraph 2, and therefore deny them.

3. Plaintiff Boehringer Ingelheim International GmbH (“BII”) is a private limited liability company organized and existing under the laws of Germany, having a principal place of business at Binger Strasse 173, 55216 Ingelheim, Germany.

ANSWER: Defendants lack sufficient information to form a belief as to the truth of the allegations in Paragraph 3, and therefore deny them.

4. Plaintiff Boehringer Ingelheim Corporation (“BIC”) is a corporation organized and existing under the laws of Nevada, having a principal place of business at 900 Ridgebury Road, Ridgefield, CT, 06877.

ANSWER: Defendants lack sufficient information to form a belief as to the truth of the allegations in Paragraph 4, and therefore deny them.

5. BIPI, BII, and BIC are collectively referred to hereinafter as “Boehringer” or “Plaintiffs.”

ANSWER: Paragraph 5 contains statements that do not require a response. To the extent a response is required, admitted.

6. On information and belief, Defendant Annora Pharma Private Limited (“Annora”) is a company organized and existing under the laws of India, having a principal place of business at Sy. No. 261, Annaram Village, Gummadidal Mandal, Sangareddy District, Telangana State, 502313, India.

ANSWER: Annora admits that it is a company organized and existing under the laws of India, having a principal place of business at Sy. No. 261, Annaram Village, Gummadidal Mandal,

Sangareddy District, Telangana State, 502313, India. Hetero USA lacks sufficient information to form a belief as to the truth of the allegations in Paragraph 6, and therefore denies them.

7. On information and belief, Annora is in the business of, among other things developing, preparing, manufacturing, selling, marketing, and distributing generic drugs, including distributing, selling, and marketing generic drugs throughout the United States, including within the state of Delaware.

ANSWER: Annora admits that it develops, prepares, manufactures, sells, markets and distributes generic drugs. Annora denies any remaining allegations in paragraph 7 as phrased. Hetero USA lacks sufficient information to form a belief as to the truth of the allegations in Paragraph 7, and therefore denies them.

8. On information and belief, Annora prepared and submitted ANDA No. 212364 (the “Annora ANDA”) for Annora’s 10 mg/5 mg and 25 mg/5 mg empagliflozin and linagliptin tablets (the “Annora ANDA Products”).

ANSWER: Annora admits that it prepared and submitted ANDA No. 212364 (the “Annora ANDA”) for Annora’s 10 mg/5 mg and 25 mg/5 mg empagliflozin and linagliptin tablets (the “Annora ANDA Products”). Hetero USA lacks sufficient information to form a belief as to the truth of the allegations in Paragraph 8, and therefore denies them.

9. On information and belief, Annora will market and sell the Annora ANDA Products throughout the United States, including within the state of Delaware.

ANSWER: Defendants lack sufficient information to form a belief as to the truth of the allegations in Paragraph 9, and therefore deny them.

10. Annora has represented that the Annora ANDA refers to and relies upon the GLYXAMBI® NDA and contains data that, according to Annora, demonstrate the bioavailability or bioequivalence of the Annora ANDA Products to GLYXAMBI®.

ANSWER: Annora admits the allegations in Paragraph 10. Hetero USA lacks sufficient information to form a belief as to the truth of the allegations in Paragraph 10, and therefore denies them.

11. Plaintiffs received a letter from Annora on or about January 9, 2020 stating that Annora had included a certification in the Annora ANDA, pursuant to 21 U.S.C. §

355(j)(2)(A)(vii)(IV), that, inter alia, certain claims of the '637 patent are either invalid or will not be infringed by the commercial manufacture, use, or sale of the Annora ANDA Products (the "Annora Paragraph IV Certification"). Annora intends to engage in the commercial manufacture, use, offer for sale, and/or sale of the Annora ANDA Products prior to the expiration of the '637 patent.

ANSWER: Annora admits that it sent a letter to Plaintiffs dated January 9, 2020 pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alerting Plaintiffs of its certification that it submitted the Annora ANDA to the FDA seeking approval to market and sell Annora's ANDA Products before the expiration of the '637 patent. Annora denies any remaining allegations in Paragraph 11. Hetero USA lacks sufficient information to form a belief as to the truth of the allegations in Paragraph 11, and therefore denies them.

12. The Annora Paragraph IV Certification was signed by Somarju Indukuri, U.S. Agent for Annora Pharma Private Limited.

ANSWER: Annora admits the allegations in Paragraph 12. Hetero USA lacks sufficient information to form a belief as to the truth of the allegations in Paragraph 12, and therefore denies them.

13. On information and belief, Defendant Hetero USA, Inc. ("Hetero") is a corporation existing under the laws of the state of Delaware, having a principal place of business at 1035 Centennial Avenue, Piscataway, New Jersey, 08854.

ANSWER: Hetero admits the allegations in Paragraph 13. Annora lacks sufficient information to form a belief as to the truth of the allegations in Paragraph 13, and therefore denies them.

14. On information and belief, Hetero acts as Annora's U.S. Agent for ANDA No. 212364.

ANSWER: Denied.

15. On information and belief, Somaraju Indukuri acts at the direction of, under the control of, and/or for the benefit of Annora and is controlled by Annora.

ANSWER: Defendants admit that Somaraju Indukuri is a U.S. agent for Grace Consulting Services, Inc. and Grace Consulting Services, Inc. acted as an agent for Annora in connection with the submission of ANDA No. 212364 to the FDA. Defendants deny the remaining allegations of this paragraph.

16. On information and belief, Somaraju Indukuri is the vice president, regulatory affairs of Hetero.

ANSWER: Defendants admit that Somaraju Indukuri is vice president, regulatory affairs of Hetero USA. Defendants deny that Somaraju Indukuri acted on behalf of Hetero USA with regard to ANDA No. 212364.

17. On information and belief, excerpts of Annora's ANDA pursuant to the Annora Paragraph IV Certification was provided to Boehringer by Hetero.

ANSWER: Denied.

18. Defendants Annora and Hetero are collectively referred to herein as "Defendants."

ANSWER: Paragraph 18 contains statements that do not require a response. To the extent a response is required, admitted.

JURISDICTION AND VENUE

19. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100 *et seq.*, generally, and 35 U.S.C. § 271(e)(2), specifically, and this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

ANSWER: Defendants admit that Plaintiffs' Complaint purports to set forth an action for patent infringement arising under 35 U.S.C. §§ 100 *et seq.*, generally, and 35 U.S.C. § 271(e)(2), specifically. The remainder of Paragraph 19 contains legal conclusions to which no response is required. To the extent a response is required, Defendants do not dispute subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

20. Venue is proper in this Court because, among other things, Hetero is incorporated in the State of Delaware and therefore "resides" in this judicial district and/or has committed acts of infringement in this district and has a regular and established place of business in this district.

28 U.S.C. § 1400(b). Annora is a foreign corporation not residing in any United States district and may be sued in any judicial district. 28 U.S.C. § 1391(c).

ANSWER: Hetero USA admits that it is incorporated in the State of Delaware. Annora admits that it is a foreign corporation. Defendants deny the remaining allegations in Paragraph 20. Defendants do not contest venue for the purposes of this action only.

PERSONAL JURISDICTION OVER ANNORA

21. Plaintiffs reallege paragraphs 1-20 as if fully set forth herein.

ANSWER: Insofar as Plaintiffs reallege paragraphs 1-20 of the Complaint, Defendants repeat and reallege their responses thereto, as if fully set forth herein.

22. On information and belief, Annora markets, sells, and distributes generic drugs for sale and use throughout the United States, including in this judicial district.

ANSWER: Annora denies the allegations in Paragraph 22. Annora does not contest personal jurisdiction for the purposes of this action only. Hetero USA lacks sufficient information to form a belief as to the truth of the allegations in Paragraph 22, and therefore denies them.

23. This Court has personal jurisdiction over Annora because, inter alia, Annora, on information and belief: (1) has engaged in substantial, systemic, and continuous contacts with Delaware through its manufacture, importation, sale, or offer for sale of pharmaceutical products in the state of Delaware; (2) intends to market, sell, and/or distribute Annora infringing ANDA Products to residents of this State upon approval of ANDA No. 212364, (3) enjoys substantial income from sales of its generic pharmaceutical products in this State on its own and through collaboration with Hetero USA Inc., which is a Delaware corporation.

ANSWER: Paragraph 23 contains legal conclusions to which no response is required. To the extent a response is required, Annora denies the allegations in Paragraph 23. Annora does not contest personal jurisdiction for the purposes of this action only. Hetero USA lacks sufficient information to form a belief as to the truth of the allegations in Paragraph 23, and therefore denies them.

24. Alternatively, to the extent the above facts do not establish personal jurisdiction over Annora, this Court may exercise jurisdiction over Annora pursuant to Fed. R. Civ. P. 4(k)(2),

as (a) Boehringer's claims arise under federal law; (b) Annora is a foreign defendant not subject to the general personal jurisdiction in the courts of any State; (c) Annora has sufficient contacts with the United States as a whole, including preparation and submission of ANDAs to the 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 24 contains legal conclusions to which no response is required. To the extent a response is required, Annora denies the allegations in Paragraph 24. Annora does not contest personal jurisdiction for the purposes of this action only. Hetero USA lacks sufficient information to form a belief as to the truth of the allegations in Paragraph 24, and therefore denies them.

25. On information and belief, Annora has not contested jurisdiction in one or more prior cases arising out of the filing of its ANDAs, including ANDA No. 212364. *See, e.g., Boehringer Ingelheim Pharm. Inc. v. Annora Labs Ltd., Civ. A. No. 19-1594 (D. Del.); Boehringer Ingelheim Pharm. Inc. v. Annora Pharma Private Ltd., Civ. A. No. 18-1786 (D. Del.).*

ANSWER: Admitted that Annora has not contested personal jurisdiction in one or more cases arising out of the filing of its ANDAs. Hetero USA lacks sufficient information to form a belief as to the truth of the allegations in Paragraph 25, and therefore denies them.

PERSONAL JURISDICTION OVER HETERO

26. Plaintiffs reallege paragraphs 1-25 as if fully set forth herein.

ANSWER: Insofar as Plaintiffs reallege paragraphs 1-25 of the Complaint, Defendants repeat and reallege their responses thereto, as if fully set forth herein.

27. On information and belief, Hetero develops, manufactures, markets and/or distributes active pharmaceutical ingredients, over-the-counter products, and finished dosages for sale and use throughout the United States, including in this judicial district.

ANSWER: Hetero USA denies the allegations in Paragraph 27. Hetero USA does not contest personal jurisdiction for the purposes of this action only. Annora lacks sufficient information to form a belief as to the truth of the allegations in Paragraph 27, and therefore denies them.

28. This Court has personal jurisdiction over Hetero because, inter alia, Hetero, on information and belief: (1) is incorporated under the laws of the State of Delaware; (2) makes its pharmaceutical products available in this State; and (3) enjoys substantial income from sales of its pharmaceutical products in this State.

ANSWER: Paragraph 28 contains legal conclusions to which no response is required. To the extent a response is required, Hetero USA denies the allegations in Paragraph 28. Hetero USA does not contest personal jurisdiction for the purposes of this action only. Annora lacks sufficient information to form a belief as to the truth of the allegations in Paragraph 28, and therefore denies them.

29. On information and belief, Hetero has not contested jurisdiction in one or more prior cases arising out of the filing of its ANDAs, including ANDA No. 212364. *See, e.g., Boehringer Ingelheim Pharm. Inc. v. Annora Labs Ltd.*, Civ. A. No. 19-1594 (D. Del.); *Boehringer Ingelheim Pharm. Inc. v. Annora Pharma Private Ltd.*, Civ. A. No. 18-1786 (D. Del.); *H. Lundbeck A/S et al v. Hetero USA Inc. et al*, 1:18-cv-00176 (D. Del.).

ANSWER: Admitted that Hetero USA has not contested personal jurisdiction in one or more cases arising out of the filing of its ANDAs. Annora lacks sufficient information to form a belief as to the truth of the allegations in Paragraph 29, and therefore denies them.

BACKGROUND

U.S. PATENT NO. 10,258,637

30. On April 16, 2019, the USPTO duly and legally issued United States Patent No. 10,258,637 (“the ’637 patent”) entitled “Pharmaceutical Composition, Method for Treating and Uses Thereof” to inventors Uli Christian Broedl, Sreeraj Macha, Maximilian von Eynatten, and Hans-Juergen Woerle. A true and correct copy of the ’637 patent is attached as Exhibit 1. The ’637 patent is assigned to BII. BIC and BIPI are licensees of the ’637 patent.

ANSWER: Defendants admit that the '637 patent is entitled "Pharmaceutical Composition, Methods for Treating and Uses Thereof" and that it issued on April 16, 2019 to inventors Uli Christian Broedl, Sreeraj Macha, Maximilian von Eynatten, and Hans-Juerger Woerle. Defendants admit that Exhibit 1 attached to the Complaint appears to be a copy of the '637 patent. Defendants admit that BII is listed as the assignee on the face of the '637 patent. Defendants deny that the '637 patent was duly and legally issued. Defendants lack sufficient information to form a belief as to the truth of the remaining allegations in Paragraph 30, and therefore deny them.

GLYXAMBI®

31. BIPI is the holder of New Drug Application ("NDA") No. 206073 for empagliflozin/linagliptin, for oral use, in 10 mg/5 mg and 25 mg/5 mg dosages, which is sold under the trade name GLYXAMBI®.

ANSWER: Denied.

32. GLYXAMBI® is listed in Orange Book as having New Chemical Exclusivity until August 1, 2019.

ANSWER: Admitted.

33. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '637 patent is among the patents listed in the Orange Book with respect to GLYXAMBI®.

ANSWER: Defendants admit that the '637 patent is among the patents listed in the Orange Book with respect to GLYXAMBI®. Defendants deny the remaining allegations in Paragraph 33.

34. The '637 patent covers the use of GLYXAMBI®.

ANSWER: Denied.

ACTS GIVING RISE TO THIS ACTION

COUNT I—INFRINGEMENT OF THE '637 PATENT

35. Plaintiffs reallege paragraphs 1-34 as if fully set forth herein.

ANSWER: Insofar as Plaintiffs reallege paragraphs 1-34 of the Complaint, Defendants repeat and reallege their responses thereto, as if fully set forth herein.

36. On information and belief, Annora through its own actions and through the actions of its agents and subsidiaries, has submitted the Annora ANDA to the FDA, pursuant to 21 U.S.C.

§ 355(j), seeking approval to market the Annora ANDA Products. On information and belief, Annora and Hetero are acting in concert with one another with respect to the preparation, submission and further prosecution of the Annora ANDA.

ANSWER: Annora admits that it submitted the Annora ANDA to the FDA under 21 U.S.C. § 355(j) seeking approval to market the Annora ANDA Products in the United States. Defendants deny any remaining allegations of Paragraph 36.

37. Annora has infringed at least one claim of the '637 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted the Annora ANDA, by which Annora seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Annora ANDA Products prior to the expiration of the '637 patent.

ANSWER: Denied.

38. Annora has declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the Annora ANDA Products in the event that the FDA approves the Annora ANDA. Accordingly, an actual and immediate controversy exists regarding Annora's infringement of the '637 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

ANSWER: Denied.

39. Annora's use, offer to sell, or sale of the Annora ANDA Products in the United States during the term of the '637 patent would further infringe at least one claim of the '637 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

ANSWER: Denied.

40. On information and belief, the Annora ANDA Products, when offered for sale, sold, and/or and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '637 patent either literally or under the doctrine of equivalents.

ANSWER: Denied.

41. On information and belief, the use of Annora's ANDA Products constitutes a material part of at least one of the claims of the '637 patent; Annora knows that its ANDA Products are especially made or adapted for use in infringing at least one of the claims of the '637 patent, either literally or under the doctrine of equivalents; and its ANDA Products are not staple articles of commerce or commodities of commerce suitable for substantial noninfringing use.

ANSWER: Denied.

42. On information and belief, the offering to sell or sale of Annora's ANDA Products would contributorily infringe at least one of the claims of the '637 patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

43. On information and belief, Annora had knowledge of the '637 patent and, by its promotional activities and package inserts for its ANDA Products, knows or should know that it will aid and abet another's direct infringement of at least one of the claims of the '637 patent, either literally or under the doctrine of equivalents.

ANSWER: Annora admits that it had knowledge of the '637 patent. Annora denies any remaining allegations in Paragraph 43. Hetero USA lacks sufficient information to form a belief as to the truth of the allegations in Paragraph 43, and therefore denies them.

44. On information and belief, the offering to sell, or sale of Annora's ANDA Products by Annora would actively induce infringement of at least one of the claims of the '637 patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

45. On information and belief, Annora does not deny that the Annora ANDA products subject to ANDA No. 212364 will infringe the claims of the '637 patent and in the Annora

Paragraph IV Certification Annora did not deny that the Annora ANDA Products will infringe the claims of the '637 patent.

ANSWER: Paragraph 45 contains legal conclusions to which no response is required. To the extent a response is required, Annora admits that the Annora Paragraph IV Certification does not allege non-infringement of the '637 patent, but also does not waive, and expressly reserves, the right to raise additional defenses and arguments, including concerning non-infringement of the '637 patent. Hetero USA lacks sufficient information to form a belief as to the truth of the allegations in Paragraph 45, and therefore denies them.

46. Plaintiffs will be substantially and irreparably harmed if Annora is not enjoined from infringing the '637 patent.

ANSWER: Denied.

47. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Boehringer's reasonable attorney fees.

ANSWER: Denied.

PRAYER FOR RELIEF

Defendants deny that Plaintiffs are entitled to any of the relief requests in Paragraphs (a) through (g) in the Prayer for Relief section of the Complaint.

GENERAL DENIAL

To the extent not specifically admitted above, including but not limited to every instance where Defendants are without knowledge or information sufficient to form a belief about the truth of the allegations, Defendants deny all allegations of the Complaint, including all headings to the extent the headings may be deemed allegations. Further, in each instance where Plaintiffs refer to referenced documents for a description of their content, Defendants deny the allegations to the extent they are inconsistent with those documents

DEFENSES AND AFFIRMATIVE DEFENSES

Without any admissions as to the burdens of proof, or as to any of the allegations in the Complaint, Defendants state the following:

First Affirmative Defense **Non-Infringement of the '637 Patent**

The submission of the Annora ANDA to the FDA and the importation, manufacture, use, offer for sale, or sale of the Annora ANDA Products will not directly, indirectly, contributorily and/or by inducement infringe, either literally or under the doctrine of equivalents, any valid claim of the '637 patent under any section of 35 U.S.C. § 271.

Second Affirmative Defense **Invalidity of the '637 Patent**

The claims of the '637 patent are invalid for failure to satisfy one or more of the conditions for patentability of 35 U.S.C. § 101 *et seq.*, at least for the reasons set forth in the Annora Paragraph IV Certification dated January 9, 2020.

Reservation of Rights

Defendants reserve the right to amend this Answer, including the affirmative defenses, and to raise additional affirmative defenses and prior art, as are supported by information developed through further investigation, discovery or by evidence at trial in this matter.

COUNTERCLAIMS

For its counterclaims against Boehringer Ingelheim Pharmaceuticals Inc., Boehringer Ingelheim International GMBH, and Boehringer Ingelheim Corporation (collectively, "Counterclaim Defendants"), Annora Pharma Private Ltd. ("Annora") states as follows:

The Parties

1. Annora Pharma Private Limited is a company organized and existing under the laws of India, having a principal place of business at Sy. No. 261, Annaram Village, Gummadidal Mandal, Sangareddy District, Telangana State, 502313, India.

2. On information and belief, based on Counterclaim Defendants' allegations, Boehringer Ingelheim Pharmaceuticals Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 900 Ridgebury Rd., Ridgefield, CT 06877.

3. On information and belief, based on Counterclaim Defendants' allegations, Boehringer Ingelheim International GmbH is a private limited liability company organized and existing under the laws of Germany, having a principal place of business at Binger Strasse 173, 55216 Ingelheim, Germany.

4. On information and belief, based on Counterclaim Defendants' allegations, Boehringer Ingelheim Corporation is a corporation organized and existing under the laws of Nevada, having a principal place of business at 900 Ridgebury Road, Ridgefield, CT, 06877.

Nature of the Action

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

6. Annora seeks a declaration that it has not infringed, is not infringing, and will not infringe, or contribute to or induce infringement of any valid and enforceable claim of United States Patent No. 10,258,637 (the "'637 patent"), literally or under the doctrine of equivalents.

7. Annora also seeks a declaration that the claims of the '637 patent are invalid under one or more sections of 35 U.S.C. § 101 *et seq.*

8. As a consequence of Counterclaim Defendants' Complaint against Annora, and based on Annora's denials in its Answer, there exists an actual, continuing, and substantial case or controversy between Counterclaim Defendants and Annora having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding the alleged infringement of the '637 patent.

Jurisdiction and Venue

9. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

10. Counterclaim Defendants have submitted to this Court's personal jurisdiction by suing Annora in this District. On information and belief, Counterclaim Defendants sell products in this District, including the Glyxambi® product at issue in this case, and conduct substantial business in, and have regular and systemic contacts with, this District.

11. This Court is the proper venue under 28 U.S.C. §§ 1391 and 1400(b).

Background

12. On information and belief, based on Counterclaim Defendants' allegations and based on the electronic version of the FDA's publication Approved Drug Products with Therapeutic Equivalence Evaluation (commonly known as the "Orange Book"), Boehringer Ingelheim Pharmaceuticals Inc. is the holder of New Drug Application ("NDA") No. 206073 for empagliflozin;linagliptin tablets of 10 mg; 5 mg and 25 mg; 5 mg, sold in the United States under the name Glyxambi®.

13. The '637 patent is listed in the Orange Book for Glyxambi®.

14. The face of the '637 patent, titled "Pharmaceutical composition, methods for treating and uses thereof," states that it issued on April 16, 2019.

15. On the face of the '637 patent, and on information and belief based on Counterclaim Defendants' allegations, Boehringer Ingelheim International GmbH is the assignee of the '637 patent.

16. Annora submitted an Abbreviated New Drug Application ("ANDA") to the FDA seeking approval to market, sell, manufacture, and/or offer for sale 10 mg/5 mg and 25 mg/5 mg empagliflozin and linagliptin tablets (the "Annora ANDA Products") before the expiration of the '637 patent ("Annora's ANDA").

17. By letter dated January 9, 2020 ("Annora's Notice Letter"), Annora notified Counterclaim Defendants that it had filed certifications provided for in 21 U.S.C. § 355(j)(2)(A)(vii)(IV) for Annora's ANDA that the '637 patent is invalid, unenforceable, and/or will not be infringed by Annora's ANDA Products.

18. In accordance with 21 U.S.C. § 355(j)(2)(B)(iv)(II), Annora's Notice Letter included a detailed statement of the factual and legal basis for the certifications that the '637 patent is invalid, unenforceable, and/or will not be infringed by Annora's ANDA Products.

19. Annora's Notice Letter also included an Offer of Confidential Access ("OCA") pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III).

First Counterclaim
Declaratory Judgment of Non-Infringement of the '637 Patent

20. Annora realleges Paragraphs 1-19 as if fully set forth herein.

21. There is an actual, substantial, and continuing justiciable case or controversy between Annora and Counterclaim Defendants regarding non-infringement of the '637 patent.

22. Counterclaim Defendants have accused Annora of infringing the '637 patent in connection with Annora's ANDA and Annora's ANDA Products.

23. Annora's manufacture, use, offer for sale, sale, and/or importation into the United States of the Annora ANDA Products has not and will not infringe, directly or indirectly, any valid and enforceable claim of the '637 patent, either literally or under the doctrine of equivalents.

24. Because Annora has not and will not infringe any valid and enforceable claim of the '637 patent, Counterclaim Defendants are not entitled to any damages or any other relief from or against Annora.

25. Further, Annora is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation the Annora ANDA Products has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '637 patent, either directly or indirectly.

Second Counterclaim
Declaratory Judgment of Invalidity of the '637 Patent

26. Annora realleges Paragraphs 1-25 as if fully set forth herein.

27. There is an actual, substantial, and continuing justiciable case or controversy between Annora and Counterclaim Defendants regarding invalidity of the '637 patent.

28. The claims of the '637 patent are invalid for failing to satisfy one or more of the conditions for patentability set forth in 35 U.S.C. §§ 101, *et seq.*, including without limitation, 35 U.S.C. §§ 101, 102, 103, 112, and/or 116.

29. Annora is entitled to a judicial declaration that the '637 patent is invalid.

Prayer for Relief

WHEREFORE, Annora respectfully requests that the Court enter the following relief:

A. Declare that by filing the Annora ANDA, Annora has not infringed, is not infringing, and will not infringe, or contribute to or induce infringement of any valid and enforceable claim of the '637 patent, literally or under the doctrine of equivalents, and that Annora

has a lawful right to obtain FDA approval of the Annora ANDA for 10 mg/5 mg and 25 mg/5 mg empagliflozin and linagliptin tablets;

B. Declare that Annora will not infringe, or contribute to or induce infringement of any valid and enforceable claim of the '637 patent, literally or under the doctrine of equivalents, by the importation, manufacture, use, offer for sale of the 10 mg/5 mg and 25 mg/5 mg empagliflozin and linagliptin tablets, that are the subject of the Annora ANDA;

C. Declare that the '637 patent is invalid;

D. Enjoin Counterclaim Defendants, their officers, employees, agents, representatives, attorneys, and others acting on their behalf, from threatening or initiating infringement litigation against Annora or its customers, dealers or suppliers, or any prospective or present sellers, dealers, distributors, or customers of Annora, or charging them either verbally or in writing with infringement of the '637 patent with respect to the 10 mg/5 mg and 25 mg/5 mg empagliflozin and linagliptin tablets, that are the subject of the Annora ANDA;

E. Declare that this is an exceptional case, and that Annora be awarded its attorney fees and costs pursuant to 35 U.S.C. § 285;

F. Declare that Counterclaim Defendants are entitled to no damages, interest, costs, or other relief (including injunctive relief) from or against Annora for infringement of the '637 patent;

G. Award costs and expenses to Annora; and

H. Award Annora such further relief as this Court may deem necessary, just, and proper.

Respectfully submitted,

**BENESCH, FRIEDLANDER, COPLAN
& ARONOFF LLP**

/s/ Kate Harmon

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Kate Harmon (DE #5343)

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CERTIFICATE OF SERVICE

I hereby certify that on April 27, 2020 a copy of the foregoing DEFENDANTS ANNORA PHARMA PRIVATE LTD. AND HETERO USA, INC.'S ANSWER TO PLAINTIFFS' COMPLAINT was filed electronically. Notice of this filing will be sent by operation of the Court's electronic filing system to all parties indicated on the electronic filing receipt. Parties may access this filing through the Court's system.

/s/ Kate Harmon
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Private Ltd and Hetero USA Inc.*