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. _____
v.	)	
ANNORA PHARMA PRIVATE LTD., and HETERO USA INC.,	)	
Defendants.	)	

COMPLAINT

Plaintiffs, Boehringer Ingelheim Pharmaceuticals Inc.; Boehringer Ingelheim International GmbH; and Boehringer Ingelheim Corporation, by their undersigned attorneys, for their Complaint against Defendants, Annora Pharma Private Limited and Hetero USA Inc., hereby allege 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' submissions of Abbreviated New Drug Applications ("ANDAs") to the Food and Drug Administration ("FDA") seeking approval to manufacture and sell generic versions of Plaintiffs' JARDIANCE® (empagliflozin) tablets and/or GLYXAMBI® (empagliflozin/linagliptin) tablets a prior to the expiration of United States Patent Nos. 8,551,957 (the "'957 patent"); 9,949,997 (the "'997 patent"); and/or 9,949,998 (the "'998 patent").

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.

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.

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.

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

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.

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.

8. On information and belief, Annora prepared and submitted ANDA No. 212365 (the "Annora Empagliflozin ANDA") for Annora's 10 mg and 25 mg empagliflozin tablets (the "Annora Empagliflozin Products").

9. On information and belief, Annora prepared and submitted ANDA No. 212364 (the "Annora Empagliflozin/Linagliptin ANDA") for Annora's 10 mg/5 mg and 25 mg/5 mg empagliflozin/linagliptin tablets ("Annora Empagliflozin/Linagliptin Products").

10. The Annora Empagliflozin Products and Annora Empagliflozin/Linagliptin Products, are collectively referred to hereinafter as the "Annora ANDA Products."

11. The Annora Empagliflozin ANDA, and the Annora Empagliflozin/Linagliptin ANDA are collectively referred to hereinafter as the "Annora ANDAs."

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

13. Annora has represented that the Annora Empagliflozin ANDA and the Annora Empagliflozin/Linagliptin ANDA refer to and rely upon the JARDIANCE® NDA and GLYXAMBI® NDA, respectively, and contain data that, according to Annora, demonstrate the bioavailability or bioequivalence of the Annora Empagliflozin Products and/or the Annora Empagliflozin/Linagliptin Products to JARDIANCE® and/or GLYXAMBI®.

14. Plaintiffs received a letter from Annora on or about October 3, 2018 stating that Annora had included a certification in the Annora Empagliflozin ANDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that, *inter alia*, certain claims of the '957, '997, and '998 patents are either invalid or will not be infringed by the commercial manufacture, use, or sale of the Annora ANDA Empagliflozin Products (the "Annora Empagliflozin Paragraph IV Certification"). Annora intends to engage in the commercial manufacture, use, offer for sale, and/or sale of the Annora Empagliflozin Products prior to the expiration of the '957, '997, and '998 patents.

15. Plaintiffs received a letter from Annora on or about October 8, 2018 stating that Annora had included a certification in the Annora Empagliflozin/Linagliptin ANDA, pursuant to

21 U.S.C. § 355(j)(2)(A)(vii)(IV), that, *inter alia*, certain claims of the '957 and '998 patents are either invalid or will not be infringed by the commercial manufacture, use, or sale of the Annora ANDA Empagliflozin/Linagliptin Products (the "Annora Empagliflozin/Linagliptin Paragraph IV Certification"). Annora intends to engage in the commercial manufacture, use, offer for sale, and/or sale of the Annora Empagliflozin/Linagliptin Products prior to the expiration of the '957 and '998 patents.

16. The Annora Empagliflozin Paragraph IV Certification and the Annora Empagliflozin/Linagliptin Paragraph IV Certification are collectively referred to as the "Annora Paragraph IV Certifications."

17. The Annora Paragraph IV Certifications were signed by Somarju Indukuri, U.S. Agent for Annora Pharma Private Limited.

18. 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.

19. On information and belief, Hetero acts as Annora's U.S. Agent for ANDA Nos. 212365 and 212364.

20. 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.

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

22. On information and belief, excerpts of Annora's ANDAs pursuant to the Annora Paragraph IV Certifications were provided to Boehringer by Hetero.

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

JURISDICTION AND VENUE

24. 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).

25. 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).

PERSONAL JURISDICTION OVER ANNORA

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

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

28. 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. 212365, and/or 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.

29. 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.

PERSONAL JURISDICTION OVER HETERO

30. Plaintiffs reallege paragraphs 1-29 as if fully set forth herein.

31. 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.

32. 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.

33. On information and belief, Hetetro has not contested jurisdiction in one or more prior cases arising out of the filing of its ANDAs. *H. Lundbeck A/S et al v. Hetero USA Inc. et al*, 1:18-cv-00176 (D. Del.).

BACKGROUND

U.S. PATENT NO. 8,551,957

34. On October 8, 2013, the USPTO duly and legally issued United States Patent No. 8,551,957 entitled "Pharmaceutical Composition Comprising a Glucopyranosyl-Substituted Benzene Derivate" to inventors Klaus Dugi, Michael Mark, Leo Thomas and Frank Himmelsbach. A true and correct copy of the '957 patent is attached as Exhibit 1. The '957 patent is assigned to BII. BIC and BIPI are licensees of the '957 patent.

U.S. PATENT NO. 9,949,997

35. On April 24, 2018, the USPTO duly and legally issued United States Patent No. 9,949,997 entitled "Pharmaceutical Composition, Methods for Treating and Uses Thereof" to inventors Uli Christian Broedl, Odd-Erik Johansen, Gabriel Woojai Kim, Eric Williams Mayoux, Afshin Salsali, Nima Soleymanlou, Maximilian von Eynatten, Hans-Juergen Woerle, David Z.I. Cherney, Bruce A. Perkins, Andreas Daiber and Thomas Muenzel. A true and correct copy of the '997 patent is attached as Exhibit 2. The '997 patent is assigned to BII. BIC and BIPI are licensees of the '997 patent.

U.S. PATENT NO. 9,949,998

36. On April 24, 2018, the USPTO duly and legally issued United States Patent No. 9,949,998 entitled "Pharmaceutical Composition, Methods 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 '998 patent is attached as Exhibit 3. The '998 patent is assigned to BII. BIC and BIPI are licensees of the '998 patent.

JARDIANCE®

37. BIPI is the holder of New Drug Application ("NDA") No. 204629 for empagliflozin tablets, for oral use, in 10 mg and 25 mg dosages, which is sold under the trade name JARDIANCE®.

38. JARDIANCE® is listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations database ("Orange Book") as having New Chemical Exclusivity until August 1, 2019.

39. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '997, '998 and '957 patents are among the patents listed in the Orange Book with respect to JARDIANCE®.

40. The '997, '998 and '957 patents cover the JARDIANCE® product and its use.

GLYXAMBI®

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

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

43. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '998 and '957 patents are among the patents listed in the Orange Book with respect to GLYXAMBI®.

44. The '998 and '957 patents cover the GLYXAMBI® product and its use.

ACTS GIVING RISE TO THIS ACTION

COUNT I—INFRINGEMENT OF THE '957 PATENT

45. Plaintiffs reallege paragraphs 1-44 as if fully set forth herein.

46. On information and belief, Annora through its own actions and through the actions of its agents and subsidiaries, has submitted the Annora Empagliflozin ANDA and the Annora Empagliflozin/Linagliptin ANDA to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to market the Annora Empagliflozin Products and the Annora Empagliflozin/Linagliptin 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 Empagliflozin ANDA and the Annora Empagliflozin/Linagliptin ANDA.

47. Annora has infringed at least one claim of the ’957 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted the Annora Empagliflozin ANDA and the Annora Empagliflozin/Linagliptin ANDA, by which Annora seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Annora Empagliflozin Products and the Annora Empagliflozin/Linagliptin Products respectively prior to the expiration of the ’957 patent.

48. 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 Empagliflozin Products and/or the Annora Empagliflozin/Linagliptin Products in the event that the FDA approves the Annora Empagliflozin ANDA and/or the Annora Empagliflozin/Linagliptin ANDA. Accordingly, an actual and immediate controversy exists regarding Annora’s infringement of the ’957 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

49. Annora’s manufacture, use, offer to sell, or sale of the Annora Empagliflozin Products and/or the Annora Empagliflozin/Linagliptin Products in the United States or importation of the Annora Empagliflozin Products and/or the Annora Empagliflozin/Linagliptin

Products into the United States during the term of the ’957 patent would further infringe at least one claim of the ’957 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

50. On information and belief, the Annora Empagliflozin Products and/or the Annora Empagliflozin/Linagliptin Products, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the ’957 patent either literally or under the doctrine of equivalents.

51. On information and belief, the use of the Annora Empagliflozin Products and/or the Annora Empagliflozin/Linagliptin Products constitutes a material part of at least one of the claims of the ’957 patent; Annora knows that the Annora Empagliflozin Products and/or the Annora Empagliflozin/Linagliptin Products are especially made or adapted for use in infringing at least one of the claims of the ’957 patent, either literally or under the doctrine of equivalents; and the Annora Empagliflozin Products and/or the Annora Empagliflozin/Linagliptin Products are not staple articles of commerce or commodities of commerce suitable for substantial noninfringing use.

52. On information and belief, the offering to sell, sale, and/or importation of the Annora Empagliflozin Products and/or the Annora Empagliflozin/Linagliptin Products would contributorily infringe at least one of the claims of the ’957 patent, either literally or under the doctrine of equivalents.

53. On information and belief, Annora had knowledge of the ’957 patent and, by its promotional activities and package inserts for its Empagliflozin Products and Empagliflozin/Linagliptin Products, knows or should know that they will aid and abet another’s direct infringement of at least one of the claims of the ’957 patent, either literally or under the doctrine of equivalents.

54. On information and belief, the offering to sell, sale, and/or importation of the Annora Empagliflozin Products and/or the Annora Empagliflozin/Linagliptin Products by Annora would actively induce infringement of at least one of the claims of the ’957 patent, either literally or under the doctrine of equivalents.

55. Plaintiffs will be substantially and irreparably harmed if Annora is not enjoined from infringing the ’957 patent.

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

COUNT II—INFRINGEMENT OF THE ’997 PATENT

57. Plaintiffs reallege paragraphs 1-56 as if fully set forth herein.

58. Annora has infringed at least one claim of the ’997 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted the Annora Empagliflozin ANDA, by which Annora seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Annora Empagliflozin Products prior to the expiration of the ’997 patent.

59. 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 Empagliflozin Products in the event that the FDA approves the Annora Empagliflozin ANDA. Accordingly, an actual and immediate controversy exists regarding Annora’s infringement of the ’997 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

60. Annora’s manufacture, use, offer to sell, or sale of the Annora Empagliflozin Products in the United States or importation of the Annora Empagliflozin Products into the United States during the term of the ’997 patent would further infringe at least one claim of the ’997 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

61. On information and belief, the Annora Empagliflozin Products, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the ’997 patent either literally or under the doctrine of equivalents.

62. On information and belief, the use of the Annora Empagliflozin Products constitutes a material part of at least one of the claims of the ’997 patent; Annora knows that the Annora Empagliflozin Products are especially made or adapted for use in infringing at least one of the claims of the ’997 patent, either literally or under the doctrine of equivalents; and the Annora Empagliflozin Products are not staple articles of commerce or commodities of commerce suitable for substantial noninfringing use.

63. On information and belief, the offering to sell, sale, and/or importation of the Annora Empagliflozin Products would contributorily infringe at least one of the claims of the ’997 patent, either literally or under the doctrine of equivalents.

64. On information and belief, Annora had knowledge of the ’997 patent and, by its promotional activities and package inserts for its Empagliflozin Products, knows or should know that they will aid and abet another’s direct infringement of at least one of the claims of the ’997 patent, either literally or under the doctrine of equivalents.

65. On information and belief, the offering to sell, sale, and/or importation of the Annora Empagliflozin Products by Annora would actively induce infringement of at least one of the claims of the ’997 patent, either literally or under the doctrine of equivalents.

66. Plaintiffs will be substantially and irreparably harmed if Annora is not enjoined from infringing the ’997 patent.

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

COUNT III—INFRINGEMENT OF THE '998 PATENT

68. Plaintiffs reallege paragraphs 1-67 as if fully set forth herein.

69. Annora has infringed at least one claim of the '998 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted the Annora Empagliflozin ANDA and/or the Annora Empagliflozin/Linagliptin ANDA, by which Annora seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Annora Empagliflozin Products and/or the Annora Empagliflozin/Linagliptin Products prior to the expiration of the '998 patent.

70. 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 Empagliflozin Products and/or the Annora Empagliflozin/Linagliptin Products in the event that the FDA approves the Annora Empagliflozin ANDA and/or the Annora Empagliflozin/Linagliptin ANDA. Accordingly, an actual and immediate controversy exists regarding Annora's infringement of the '998 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

71. Annora's manufacture, use, offer to sell, or sale of the Annora Empagliflozin Products and/or the Annora Empagliflozin/Linagliptin Products in the United States or importation of the Annora Empagliflozin Products and/or the Annora Empagliflozin/Linagliptin Products into the United States during the term of the '998 patent would further infringe at least one claim of the '998 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

72. On information and belief, the Annora Empagliflozin Products and/or the Annora Empagliflozin/Linagliptin Products, when offered for sale, sold, and/or imported, and when used

as directed, would be used in a manner that would directly infringe at least one of the claims of the ’998 patent either literally or under the doctrine of equivalents.

73. On information and belief, the use of the Annora Empagliflozin Products and/or the Annora Empagliflozin/Linagliptin Products constitutes a material part of at least one of the claims of the ’998 patent; Annora knows that its Empagliflozin Products and/or its Empagliflozin/Linagliptin Products are especially made or adapted for use in infringing at least one of the claims of the ’998 patent, either literally or under the doctrine of equivalents; and its Empagliflozin Products and/or Empagliflozin/Linagliptin Products are not staple articles of commerce or commodities of commerce suitable for substantial noninfringing use.

74. On information and belief, the offering to sell, sale, and/or importation of the Annora Empagliflozin Products and/or the Annora Empagliflozin/Linagliptin products would contributorily infringe at least one of the claims of the ’998 patent, either literally or under the doctrine of equivalents.

75. On information and belief, Annora had knowledge of the ’998 patent and, by its promotional activities and package inserts for its Empagliflozin Products and/or Empagliflozin/Linagliptin Products, knows or should know that they will aid and abet another’s direct infringement of at least one of the claims of the ’998 patent, either literally or under the doctrine of equivalents.

76. On information and belief, the offering to sell, sale, and/or importation of the Annora Empagliflozin Products and/or the Annora Empagliflozin/Linagliptin Products by Annora would actively induce infringement of at least one of the claims of the ’998 patent, either literally or under the doctrine of equivalents.

77. On information and belief, Annora does not deny that the Annora Empagliflozin Products or the Annora Empagliflozin/Linagliptin Products will infringe the claims of the '998 patent, and in the Annora Paragraph IV Certifications, Annora did not deny that the Annora Empagliflozin Products or the Annora Empagliflozin/Linaglipin Products will infringe the claims of the '998 patent.

78. Plaintiffs will be substantially and irreparably harmed if Annora is not enjoined from infringing the '998 patent.

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

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that the Court enter judgment against Annora and for the following relief:

a. A Judgment be entered that Annora has infringed at least one claim of the '938 and/or '998 patents by submitting the Annora ANDAs;

b. A Judgment be entered that this case is exceptional, and that Plaintiffs are entitled to their reasonable attorneys' fees pursuant to 35 U.S.C. § 285;

c. That Annora, its officers, agents, servants, employees, and those persons acting in active concert or participation with all or any of them be preliminarily and permanently enjoined from: (i) engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of drugs or methods of administering drugs claimed in the '957, '997 and/or '998 patents, and (ii) seeking, obtaining or maintaining approval of

ANDAs until the expiration of the ’957, ’997 and/or ’998 patents or such other later time as the Court may determine;

d. A judgment ordering that pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the Annora ANDAs under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall not be earlier than the latest of the expiration dates of the ’938, ’997 and/or ’998 patents, including any extensions;

e. That Boehringer be awarded monetary relief if Annora commercially uses, offers to sell, or sells its respective proposed generic versions of JARDIANCE®, GLYXAMBI®, or any other product that infringes or induces or contributes to the infringement of the ’957, ’997 and/or ’998 patents, within the United States, prior to the expiration of those patents, including any extensions, and that any such monetary relief be awarded to Boehringer with prejudgment interest;

f. Costs and expenses in this action; and

g. Such other and further relief as the Court deems just and appropriate.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Brian P. Egan

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