IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BOEHRINGER INGELHEIM PHARMACEUTICALS INC., BOEHRINGER INGELHEIM INTERNATIONAL GMBH, and BOEHRINGER INGELHEIM CORPORATION,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
AJANTA PHARMA LIMITED,	)	
Defendant.	)	

COMPLAINT

Plaintiffs, Boehringer Ingelheim Pharmaceuticals Inc.; Boehringer Ingelheim International GmbH; and Boehringer Ingelheim Corporation, by their undersigned attorneys, for their Complaint against Defendant, Ajanta Pharma Limited, 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 Defendant' 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 and linagliptin) tablets prior to the expiration of United States Patent Nos. 8,551,957, 9,949,998, 10,258,637, 11,090,323.

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 Ajanta Pharma Limited ("Ajanta") is a corporation organized and existing under the laws of India, having a principal place of business at Ajanta House, Charkop, Kandivli West, Mumbai 400 067, India.

7. On information and belief, Ajanta 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, through its own actions and through the actions of its agents and subsidiaries, from which Ajanta derives a substantial portion of its revenue.

8. On information and belief, Ajanta prepared and submitted ANDA No. 217353 (the "Ajanta ANDA") for Ajanta's 10 mg/5 mg and 25 mg/5 mg empagliflozin and linagliptin tablets (the "Ajanta ANDA Products").

JURISDICTION AND VENUE

9. 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).

10. Venue is proper in this Court because, among other things, Ajanta 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). Moreover, Ajanta has litigated Hatch-Waxman patent infringement disputes in the District of Delaware.

PERSONAL JURISDICTION OVER AJANTA

11. Plaintiffs reallege paragraphs 1–10 as if fully set forth herein.

12. On information and belief, Ajanta develops, manufactures, and/or distributes generic drugs for sale and use throughout the United States, including in this judicial district.

13. This Court has personal jurisdiction over Ajanta because, *inter alia*, Ajanta, on information and belief: (1) has substantial, continuous, and systematic contacts with this State either directly or through at least one of its wholly-owned subsidiaries or agents; (2) intends to market, sell, and/or distribute Ajanta infringing ANDA Products to residents of this State upon approval of ANDA No. 217353, either directly or through at least one of its wholly-owned subsidiaries or agents; (3) enjoys substantial income from sales of its generic pharmaceutical products in this State on its own and through at least one of its wholly-owned subsidiaries or agents.

14. On information and belief, Ajanta has not contested jurisdiction in this district in one or more prior cases arising out of the filing of Ajanta's ANDAs, and it has filed counterclaims in some of such cases. *See, e.g.*, *Merck Sharp & Dohme Corp. v. Ajanta Pharma Ltd.*, C.A. No. 1:20-cv-01496-RGA (D. Del.); *Otsuka Pharma Co. Ltd. vs. Ajanta Pharma Ltd.*, C.A. No. 1:19-cv-01939-LPS (D. Del.) (Ajanta filed counterclaims); *Pfizer Inc. v. Ajanta Pharma Ltd.*, C.A. No.

1:19-cv-517-LPS (D. Del.) (Ajanta filed counterclaims); *Allergan Sales, LLC v. Ajanta Pharma Ltd.*, C.A. No. 1:19- cv-01249-LPS (D. Del.).

15. Alternatively, to the extent the above facts do not establish personal jurisdiction over Ajanta, this Court may exercise jurisdiction over Ajanta pursuant to Fed. R. Civ. P. 4(k)(2) because: (a) Plaintiffs' claims arise under federal law; (b) Ajanta would be a foreign defendant not subject to personal jurisdiction in the courts of any State; and (c) Ajanta has sufficient contacts with the United States as a whole, including, but not limited to, filing an ANDA with the FDA and manufacturing and selling generic pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Ajanta satisfies due process.

BACKGROUND

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

16. On October 8, 2013, the USPTO duly and legally issued United States Patent No. 8,551,957 (the "'957 patent") 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 A. The '957 patent is assigned to BII. BIC and BIPI are licensees of the '957 patent.

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

17. On April 24, 2018, the USPTO duly and legally issued United States Patent No. 9,949,998 (the "'998 patent") 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 B. The '998 patent is assigned to BII. BIC and BIPI are licensees of the '998 patent.

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

18. 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 C. The '637 patent is assigned to BII. BIC and BIPI are licensees of the '637 patent.

U.S. PATENT NO. 11,090,323

19. On August 17, 2021, the USPTO duly and legally issued United States Patent No. 11,090,323 (the "'323 patent") 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 '323 patent is attached as Exhibit D. The '323 patent is assigned to BII. BIC and BIPI are licensees of the '323 patent.

GLYXAMBI®

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

21. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '957, '998, '637, and '323 patents are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations database ("Orange Book") with respect to GLYXAMBI®.

22. The '957, '998, '637, and '323 patents cover the pharmaceutical composition and use of GLYXAMBI®.

ACTS GIVING RISE TO THIS ACTION

COUNT I —INFRINGEMENT OF THE '957 PATENT

23. Plaintiffs reallege paragraphs 1–22 as if fully set forth herein.

24. On information and belief, Ajanta submitted the Ajanta ANDA to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to market the Ajanta ANDA Products.

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

26. Plaintiffs received letters from Ajanta on or about May 18, 2022 stating that Ajanta had included certification in the Ajanta ANDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that, *inter alia*, certain claims of the '957 patent are either invalid or will not be infringed by the commercial manufacture, use, importation, offer for sale, and/or sale of the Ajanta ANDA Products (the "Ajanta Paragraph IV Certification"). Ajanta intends to engage in the commercial manufacture, use, importation, offer for sale, and/or sale of the Ajanta ANDA Products prior to the expiration of the '957 patent.

27. Ajanta 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 Ajanta ANDA, by which Ajanta seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Ajanta ANDA Products prior to the expiration of the '957 patent.

28. Ajanta has declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the Ajanta ANDA Products in the event that the FDA approves the Ajanta ANDA. Accordingly, an actual and immediate controversy exists regarding Ajanta's infringement of the '957 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

29. On information and belief, Ajanta's use, offer to sell, or sale of the Ajanta ANDA Products in 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).

30. On information and belief, the Ajanta ANDA 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.

31. On information and belief, the use of the Ajanta ANDA Products constitutes a material part of at least one of the claims of the '957 patent; Ajanta knows that its ANDA 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 its ANDA Products are not staple articles of commerce or commodity of commerce suitable for substantial noninfringing use.

32. On information and belief, the offering to sell or sale of the Ajanta ANDA Products would contributorily infringe at least one of the claims of the '957 patent, either literally or under the doctrine of equivalents.

33. On information and belief, Ajanta had knowledge of the '957 patent and, by at least its 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 '957 patent, either literally or under the doctrine of equivalents.

34. On information and belief, the offering to sell or sale of the Ajanta ANDA Products by Ajanta would actively induce infringement of at least one of the claims of the '957 patent, either literally or under the doctrine of equivalents.

35. Plaintiffs will be substantially and irreparably harmed if Ajanta is not enjoined from infringing the '957 patent.

36. 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 '998 PATENT

37. Plaintiffs reallege paragraphs 1–36 as if fully set forth herein.

38. On information and belief, Ajanta submitted the Ajanta ANDA to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to market the Ajanta ANDA Products.

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

40. Plaintiffs received letters from Ajanta on or about May 18, 2022 stating that Ajanta had included certification in the Ajanta ANDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that, *inter alia*, certain claims of the '998 patent are either invalid or will not be infringed by the commercial manufacture, use, importation, offer for sale, and/or sale of the Ajanta ANDA Products (the "Ajanta Paragraph IV Certification"). Ajanta intends to engage in the commercial manufacture, use, importation, offer for sale, and/or sale of the Ajanta ANDA Products prior to the expiration of the '998 patent.

41. Ajanta 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 Ajanta ANDA, by which Ajanta seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Ajanta ANDA Products prior to the expiration of the '998 patent.

42. Ajanta has declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the Ajanta ANDA Products in the event that the FDA approves the Ajanta ANDA. Accordingly, an actual and immediate controversy exists regarding Ajanta's infringement of the '998 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

43. On information and belief, Ajanta's use, offer to sell, or sale of the Ajanta ANDA Products in 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).

44. On information and belief, the Ajanta ANDA 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.

45. On information and belief, the use of the Ajanta ANDA Products constitutes a material part of at least one of the claims of the '998 patent; Ajanta knows that its ANDA 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 ANDA Products are not staple articles of commerce or commodity of commerce suitable for substantial noninfringing use.

46. On information and belief, the offering to sell or sale of the Ajanta ANDA Products would contributorily infringe at least one of the claims of the '998 patent, either literally or under the doctrine of equivalents.

47. On information and belief, Ajanta had knowledge of the '998 patent and, by at least its 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 '998 patent, either literally or under the doctrine of equivalents.

48. On information and belief, the offering to sell or sale of the Ajanta ANDA Products by Ajanta would actively induce infringement of at least one of the claims of the '998 patent, either literally or under the doctrine of equivalents.

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

50. 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 '637 PATENT

51. Plaintiffs reallege paragraphs 1–50 as if fully set forth herein.

52. On information and belief, Ajanta submitted the Ajanta ANDA to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to market the Ajanta ANDA Products.

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

54. Plaintiffs received letters from Ajanta on or about May 18, 2022 stating that Ajanta had included certification in the Ajanta 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, importation, offer for sale, and/or sale of the Ajanta ANDA Productss. Ajanta intends to engage in the commercial manufacture, use, importation, offer for sale, and/or sale of the Ajanta ANDA Products prior to the expiration of the '637 patent.

55. Ajanta 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 Ajanta ANDA, by which Ajanta seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Ajanta ANDA Products prior to the expiration of the '637 patent.

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

57. On information and belief, Ajanta's use, offer to sell, or sale of the Ajanta 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).

58. On information and belief, the Ajanta ANDA 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 '637 patent either literally or under the doctrine of equivalents.

59. On information and belief, the use of the Ajanta ANDA Products constitutes a material part of at least one of the claims of the '637 patent; Ajanta 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 commodity of commerce suitable for substantial noninfringing use.

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

61. On information and belief, Ajanta 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.

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

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

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

COUNT IV—INFRINGEMENT OF THE '323 PATENT

65. Plaintiffs reallege paragraphs 1–64 as if fully set forth herein.

66. On information and belief, Ajanta submitted the Ajanta ANDA to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to market the Ajanta ANDA Products.

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

68. Plaintiffs received letters from Ajanta on or about May 18, 2022 stating that Ajanta had included a certification in the Ajanta ANDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that, *inter alia*, certain claims of the '323 patent are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, importation, offer for sale, and/or sale of the Ajanta ANDA Products. Ajanta intends to engage in the commercial manufacture, use, importation, offer for sale, and/or sale of the Ajanta ANDA Products prior to the expiration of the '323 patent.

69. Ajanta has infringed at least one claim of the '323 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted the Ajanta ANDA, by which Ajanta seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Ajanta ANDA Products prior to the expiration of the '323 patent.

70. Ajanta has declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the Ajanta ANDA Products in the event that the FDA approves the Ajanta ANDA. Accordingly, an actual and immediate controversy exists regarding Ajanta's infringement of the '323 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

71. On information and belief, Ajanta's use, offer to sell, or sale of the Ajanta ANDA Products in the United States during the term of the '323 patent would further infringe at least one claim of the '323 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

72. On information and belief, the Ajanta ANDA 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 '323 patent either literally or under the doctrine of equivalents.

73. On information and belief, the use of the Ajanta ANDA Products constitutes a material part of at least one of the claims of the '323 patent; Ajanta knows that its ANDA Products are especially made or adapted for use in infringing at least one of the claims of the '323 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.

74. On information and belief, the offering to sell or sale of the Ajanta ANDA Products would contributorily infringe at least one of the claims of the '323 patent, either literally or under the doctrine of equivalents.

75. On information and belief, Ajanta had knowledge of the '323 patent and, by at least its package inserts for its ANDA Products, knows or should know that they will aid and abet another's direct infringement of at least one of the claims of the '323 patent, either literally or under the doctrine of equivalents.

76. On information and belief, the offering to sell or sale, of the Ajanta ANDA Products by Ajanta would actively induce infringement of at least one of the claims of the '323 patent, either literally or under the doctrine of equivalents.

77. On information and belief, Ajanta does not deny that the Ajanta ANDA Products will infringe the claims of the '323 patent. In the Ajanta Paragraph IV Certification, Ajanta did not deny that the Ajanta ANDA Products will infringe the claims of the '323 patent.

78. Plaintiffs will be substantially and irreparably harmed if Ajanta is not enjoined from infringing the '323 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 Ajanta and for the following relief:

a. A Judgment be entered that Ajanta has infringed at least one claim of the '957, '998, '637, and/or '323 patents by submitting the Ajanta ANDA;

b. That Ajanta, 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, '998, '637, and/or '323 patents, and (ii) seeking, obtaining or maintaining approval of the Ajanta ANDA until the expiration of the '957, '998, '637, and/or '323 patents or such other later time as the Court may determine;

c. A judgment ordering that pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Ajanta ANDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall not be earlier than the expiration date of the '957, '998, '637, and/or '323 patents, including any extensions;

d. That Boehringer be awarded monetary relief if Ajanta commercially uses, offers to sell, or sells its respective proposed generic versions of GLYXAMBI® or any other product that infringes or induces or contributes to the infringement of the '957, '998, '637, and/or '323 patents, within the United States, prior to the expiration of this patent, including any extensions, and that any such monetary relief be awarded to Boehringer with prejudgment interest;

e. 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;

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/ Megan E. Dellinger

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