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.	)	
ALEMBIC PHARMACEUTICALS LTD. and ALEMBIC PHARMACEUTICALS, 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, Alembic Pharmaceuticals Ltd. and Alembic Pharmaceuticals, 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, GLYXAMBI® (empagliflozin/linagliptin) tablets and/or SYNJARDY® (empagliflozin/metformin) tablets prior to the expiration of United States Patent No. 10,258,637.

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 Alembic Pharmaceuticals Ltd. ("Alembic Ltd.") is a corporation organized and existing under the laws of India, having a principal place of business at Alembic Road, Vadodara 390003 Gujarat, India 390003.

7. On information and belief, Alembic Ltd. controls and directs a wholly owned subsidiary in the United States named Alembic Pharmaceuticals, Inc. ("Alembic Inc."). Alembic Inc. is a Delaware corporation having a principal place of business at 750 Route 202, Bridgewater, New Jersey 08807.

8. On information and belief, Alembic Inc. acts at the direction, and for the benefit, of Alembic Ltd., and is controlled and/or dominated by Alembic Ltd.

9. Alembic Ltd. and Alembic Inc. are collectively referred to hereinafter as "Alembic."

10. On information and belief, Alembic Ltd. 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, including Alembic Inc., from which Alembic Ltd. derives a substantial portion of its revenue.

11. On information and belief, Alembic Ltd. acted in concert with Alembic Inc. to prepare and submit ANDA No. 212355 (the "Alembic Empagliflozin ANDA") for Alembic Ltd.'s 10 mg and 25 mg empagliflozin tablets ("Alembic Empagliflozin Products").

12. On information and belief, Alembic Ltd. acted in concert with Alembic Inc. to prepare and submit ANDA No. 212354 (the "Alembic Empagliflozin/Linagliptin ANDA") for Alembic Ltd.'s 10 mg/5 mg and 25 mg/5 mg empagliflozin/linagliptin tablets ("Alembic Empagliflozin/Linagliptin Products").

13. On information and belief, Alembic Ltd. acted in concert with Alembic Inc. to prepare and submit ANDA No. 212394 (the "Alembic Empagliflozin/Metformin ANDA") for Alembic Ltd.'s 5 mg/500 mg, 5 mg/1 g, 12.5 mg/500 mg, and 12.5 mg/1 g empagliflozin and metformin hydrochloride tablets ("Alembic Empagliflozin/Metformin Products").

14. The Alembic Empagliflozin Products, Alembic Empagliflozin/Linagliptin Products, and Alembic Empagliflozin/Metformin Products are collectively referred to hereinafter as the "Alembic ANDA Products."

15. The Alembic Empagliflozin ANDA, the Alembic Empagliflozin/Linagliptin ANDA, and the Alembic Empagliflozin/Metformin ANDA are collectively referred to hereinafter as the "Alembic ANDAs."

16. On information and belief, Alembic Ltd. acted in concert with Alembic Inc. to prepare and submit the Alembic ANDAs for the Alembic ANDA Products, which was done at the direction of, under the control of, and for the direct benefit of Alembic Ltd. Following FDA approval of the Alembic Empagliflozin ANDA, the Alembic Empagliflozin/Linagliptin ANDA, and/or the Alembic Empagliflozin/Metformin ANDA, Alembic Ltd. will manufacture and supply the approved generic products to Alembic Inc., which will then market and sell the products throughout the United States at the direction, under the control, and for the direct benefit of Alembic Ltd.

JURISDICTION AND VENUE

17. 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).

18. Venue is proper in this Court because, among other things, Alembic Inc. 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). Alembic Ltd. 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, Alembic has litigated previous Hatch-Waxman patent infringement disputes in the District of Delaware. *See, e.g.*, *H. Lundbeck A/S v. Alembic Pharms. Ltd.*, C.A. No. 18-113-LPS (D. Del.).

PERSONAL JURISDICTION OVER ALEMBIC LTD.

19. Plaintiffs reallege paragraphs 1-18 as if fully set forth herein.

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

21. This Court has personal jurisdiction over Alembic Ltd. because, *inter alia*, Alembic Ltd., 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 Alembic Ltd. infringing ANDA Products to residents of this State upon approval of ANDA No. 212355, ANDA No. 212354 or ANDA No. 212394, 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 Alembic Inc., which is a Delaware corporation; and (4) wholly owns Alembic Inc., which is a Delaware corporation.

22. On information and belief, Alembic Ltd. has not contested jurisdiction in Delaware in one or more prior cases arising out of the filing of its ANDAs, and it has filed counterclaims in such cases. *See, e.g.*, *H. Lundbeck A/S v. Alembic Pharms. Ltd.*, C.A. No. 18-113-LPS (D. Del.).

23. Alternatively, to the extent the above facts do not establish personal jurisdiction over Alembic Ltd., this Court may exercise jurisdiction over Alembic Ltd. pursuant to Fed. R. Civ. P. 4(k)(2) because: (a) Plaintiffs' claims arise under federal law; (b) Alembic Ltd. would be a foreign defendant not subject to personal jurisdiction in the courts of any State; and (c) Alembic Ltd. has sufficient contacts with the United States as a whole, including, but not limited to, filing ANDAs 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 Alembic Ltd. satisfies due process.

PERSONAL JURISDICTION OVER ALEMBIC INC.

24. Plaintiffs reallege paragraphs 1-23 as if fully set forth herein.

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

26. This Court has personal jurisdiction over Alembic Inc. because, *inter alia*, Alembic Inc., on information and belief: (1) is incorporated under the laws of the State of Delaware; (2) intends to market, sell, or distribute Alembic's ANDA Products to residents of this State; (3) makes its generic drug products available in this State; and (4) enjoys substantial income from sales of its generic pharmaceutical products in this State.

27. On information and belief, Alembic Inc. has not contested jurisdiction in Delaware in one or more prior cases arising out of the filing of its ANDAs, and it has filed counterclaims in such cases. *See, e.g.*, *H. Lundbeck A/S v. Alembic Pharms. Ltd.*, C.A. No. 18-113-LPS (D. Del.).

BACKGROUND

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

28. 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.

JARDIANCE®

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

30. 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.

31. 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 JARDIANCE®.

32. The '637 patent covers the JARDIANCE® product and its use.

GLYXAMBI®

33. 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®.

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

35. 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®.

36. The '637 patent covers the GLYXAMBI® product and its use.

SYNJARDY®

37. BIPI is the holder of New Drug Application ("NDA") No. 206111 for empagliflozin and metformin hydrochloride, for oral use, in 5 mg/500 mg, 5 mg/1 g, 12.5 mg/500 mg, and 12.5 mg/1 g dosages, which is sold under the trade name SYNJARDY®.

38. SYNJARDY® is listed in 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 '637 patent is among the patents listed in the Orange Book with respect to SYNJARDY®.

40. The '637 patent covers the SYNJARDY® product and its use.

ACTS GIVING RISE TO THIS ACTION

COUNT I—INFRINGEMENT OF THE '637 PATENT

41. Plaintiffs reallege paragraphs 1-40 as if fully set forth herein.

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

43. Alembic has represented that the Alembic ANDAs refer to and rely upon the JARDIANCE® NDA, GLYXAMBI® NDA, and/or SYNJARDY® NDA, and contain data that, according to Alembic, demonstrate the bioavailability or bioequivalence of the Alembic ANDA Products.

44. Plaintiffs received a letter from Alembic on or about September 26, 2019 stating that Alembic had included certifications in the Alembic Empagliflozin 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 Alembic Empagliflozin Products (the "Alembic Empagliflozin Paragraph IV Certification"). Alembic intends to engage in the commercial manufacture, use, offer for sale, and/or sale of the Alembic Empagliflozin Products prior to the expiration of the '637 patent.

45. Plaintiffs received a letter from Alembic on or about September 26, 2019 stating that Alembic had included certifications in the Alembic Empagliflozin/Linagliptin 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 Alembic Empagliflozin/Linagliptin Products (the "Alembic Empagliflozin/Linagliptin Paragraph IV Certification"). Alembic intends to engage in the commercial manufacture, use, offer for sale, and/or sale of the Alembic Empagliflozin/Linagliptin Products prior to the expiration of the '637 patent.

46. Plaintiffs received a letter from Alembic on or about September 26, 2019 stating that Alembic had included certifications in the Alembic ANDAs, 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 Alembic Empagliflozin/Metformin Products (the "Alembic Empagliflozin/Metformin Paragraph IV Certification"). Alembic intends to engage in the commercial manufacture, use, offer for sale, and/or sale of the Alembic Empagliflozin/Metformin Products prior to the expiration of the '637 patent.

47. The Alembic Empagliflozin Paragraph IV Certification, Alembic Empagliflozin/Metformin Paragraph IV Certification, Alembic Empagliflozin/Linagliptin Certification, and Alembic XR Paragraph IV Certification are collectively referred herein as the "Alembic Paragraph IV Certifications."

48. Alembic 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 Alembic empagliflozin ANDA, the Alembic empagliflozin/linagliptin ANDA, and the Alembic Empagliflozin/Metformin ANDA, by which Alembic seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Alembic Empagliflozin Products, the Alembic

Empagliflozin/Linagliptin Products, and/or the Alembic Empagliflozin/Metformin Products prior to the expiration of the '637 patent.

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

50. Alembic's manufacture, use, offer to sell, or sale of the Alembic Empagliflozin Products, the Alembic Empagliflozin/Linagliptin Products, and/or the Alembic Empagliflozin/Metformin Products in the United States or importation of the Alembic Empagliflozin Products, the Alembic Empagliflozin/Linagliptin Products, and/or the Alembic Empagliflozin/Metformin Products into 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).

51. On information and belief, the Alembic Empagliflozin Products, the Alembic Empagliflozin/Linagliptin Products, and/or the Alembic Empagliflozin/Metformin 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.

52. On information and belief, the use of the Alembic Empagliflozin Products, the Alembic Empagliflozin/Linagliptin Products, and/or the Alembic Empagliflozin/Metformin

Products constitute a material part of at least one of the claims of the ’637 patent; Alembic knows that its Alembic Empagliflozin Products, the Alembic Empagliflozin/Linagliptin Products, and/or the Alembic Empagliflozin/Metformin 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 Alembic Empagliflozin Products, the Alembic Empagliflozin/Linagliptin Products, and/or the Alembic Empagliflozin/Metformin Products are not staple articles of commerce or commodities of commerce suitable for substantial noninfringing use.

53. On information and belief, the offering to sell, sale, and/or importation of the Alembic Empagliflozin Products, the Alembic Empagliflozin/Linagliptin Products, and/or the Alembic Empagliflozin/Metformin Products would contributorily infringe at least one of the claims of the ’637 patent, either literally or under the doctrine of equivalents.

54. On information and belief, Alembic had knowledge of the ’637 patent and, by its promotional activities and package inserts for its Empagliflozin Products, Empagliflozin/Linagliptin Products, and/or Empagliflozin/Metformin Products, knows or should know that they 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.

55. On information and belief, the offering to sell, sale, and/or importation of the Alembic Empagliflozin Products, the Alembic Empagliflozin/Linagliptin Products, and/or the Alembic Empagliflozin/Metformin Products by Alembic would actively induce infringement of at least one of the claims of the ’637 patent, either literally or under the doctrine of equivalents.

56. On information and belief, Alembic does not deny that the Alembic Empagliflozin Products subject to ANDA No. 212355, the Alembic Empagliflozin/Linagliptin

Products subject to ANDA No. 212354, or the Alembic Empagliflozin/Metformin Products subject to ANDA No. 212394 will infringe claims of the '637 patent, and in the Alembic Empagliflozin Paragraph IV Certification, the Alembic Empagliflozin/Linagliptin Paragraph IV Certification, and the Alembic Empagliflozin/Metformin Paragraph IV Certification Alembic did not deny that the Alembic Empagliflozin Products, the Alembic Empagliflozin/Linaglipin Products, or the Alembic Empagliflozin/Metformin Products will infringe the claims of the '637 patent.

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

58. 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 Alembic and for the following relief:

a. A Judgment be entered that Alembic has infringed at least one claim of the '637 patent by submitting the Alembic 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 Alembic, 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 637 patent, and (ii) seeking, obtaining

or maintaining approval of ANDAs until the expiration of the '637 patent 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 Alembic's 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 '637 patent, including any extensions;

e. That Boehringer be awarded monetary relief if Alembic commercially uses, offers to sell, or sells its respective proposed generic versions of JARDIANCE®, GLYXAMBI®, SYNJARDY® or any other product that infringes or induces or contributes to the infringement of the '637 patent, 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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