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.	)	
LUPIN LTD. and LUPIN 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, Lupin Ltd. and Lupin 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 and/or GLYXAMBI® (empagliflozin/linagliptin) 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 Lupin Ltd. is a corporation organized and existing under the laws of India, having a principal place of business at Laxmi Towers, Bandra Kurla Complex, Bandra (East), Mumbai, India 400051.

7. On information and belief, Lupin Ltd. controls and directs a wholly owned subsidiary in the United States named Lupin Pharmaceuticals, Inc. ("Lupin Pharma"). Lupin Pharma is a Delaware corporation having a principal place of business at 111 South Calvert Street, Baltimore, Maryland 21202.

8. Lupin Ltd. and Lupin Pharma are collectively referred to hereinafter as "Lupin."

9. On information and belief, Lupin 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 Lupin Pharma, from which Lupin Ltd. derives a substantial portion of its revenue.

10. On information and belief, Lupin Ltd. acted in concert with Lupin Pharma to prepare and submit ANDA No. 212331 (the "Lupin empagliflozin ANDA") for Lupin Ltd.'s 10 mg and 25 mg empagliflozin tablets and ANDA No. 212335 (the "Lupin empagliflozin/linagliptin ANDA") for Lupin Ltd.'s 10 mg/5 mg and 25 mg/5 mg empagliflozin/linagliptin tablets (the "Lupin ANDA Products"), which was done at the direction of, under the control of, and for the direct benefit of Lupin Ltd. Following FDA approval of the Lupin empagliflozin ANDA and the Lupin empagliflozin/linagliptin ANDA, Lupin Ltd. will manufacture and supply the approved generic product to Lupin Pharma, which will then market and sell the product throughout the United States at the direction, under the control, and for the direct benefit of Lupin Ltd.

JURISDICTION AND VENUE

11. 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).

12. Venue is proper in this Court because, among other things, Lupin Pharma 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). Lupin 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,

Lupin has litigated previous Hatch-Waxman patent infringement disputes in the District of Delaware.

PERSONAL JURISDICTION OVER LUPIN LTD.

13. Plaintiffs reallege paragraphs 1-12 as if fully set forth herein.

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

15. This Court has personal jurisdiction over Lupin Ltd. because, *inter alia*, Lupin 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 Lupin Ltd. infringing ANDA Products to residents of this State upon approval of ANDA No. 212331 or ANDA No. 212335, 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 Lupin Pharma, which is a Delaware corporation; and (4) wholly owns Lupin Pharma, which is a Delaware corporation and is registered as a pharmacy wholesaler and controlled substances distributor/manufacturer with the Delaware Division of Professional Regulation.

16. On information and belief, Lupin 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.*, *Boehringer Ingelheim Pharm. Inc. v. Lupin Ltd.*, C.A. No. 18-1690-CFC (D. Del.); *Bial-Portela v. Lupin Ltd.*, C.A. No. 18-312-CFC (D. Del.).

17. Alternatively, to the extent the above facts do not establish personal jurisdiction over Lupin Ltd., this Court may exercise jurisdiction over Lupin Ltd. pursuant to Fed. R. Civ. P. 4(k)(2) because: (a) Plaintiffs' claims arise under federal law; (b) Lupin Ltd. would be a foreign

defendant not subject to personal jurisdiction in the courts of any State; and (c) Lupin 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 Lupin Ltd. satisfies due process.

PERSONAL JURISDICTION OVER LUPIN PHARMA

18. Plaintiffs reallege paragraphs 1-17 as if fully set forth herein.

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

20. This Court has personal jurisdiction over Lupin Pharma because, *inter alia*, Lupin Pharma, on information and belief: (1) is incorporated under the laws of the State of Delaware; (2) is registered as a pharmacy wholesaler and controlled substances distributor/manufacturer with the Delaware Division of Professional Regulation; (3) intends to market, sell, or distribute Lupin's ANDA Products to residents of this State; (4) makes its generic drug products available in this State; and (5) enjoys substantial income from sales of its generic pharmaceutical products in this State.

21. On information and belief, Lupin Pharma 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.*, *Boehringer Ingelheim Pharm. Inc. v. Lupin Ltd.*, C.A. No. 18-1690-CFC (D. Del.); *Alcon Research, Ltd. v. Lupin Ltd.*, C.A. No. 16-195-GMS-SRF (D. Del.).

BACKGROUND

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

22. 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®

23. 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®.

24. 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.

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

26. The '637 patent covers the use of JARDIANCE®.

GLYXAMBI®

27. 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®.

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

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

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

ACTS GIVING RISE TO THIS ACTION

CLAIM FOR RELIEF — INFRINGEMENT OF THE '637 PATENT

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

32. On information and belief, Lupin submitted the Lupin empagliflozin ANDA and the Lupin empagliflozin/linagliptin ANDA (collectively, the "Lupin ANDAs") to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to market the Lupin ANDA Products.

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

34. Plaintiffs received letters from Lupin on or about May 23, 2019 stating that Lupin had included certifications in the Lupin 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 Lupin ANDA Products (the "Lupin Paragraph IV Certifications"). Lupin intends to engage in the commercial manufacture, use, offer for sale, and/or sale of the Lupin ANDA Products prior to the expiration of the '637 patent.

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

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

37. Lupin's use, offer to sell, or sale of the Lupin 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).

38. On information and belief, the Lupin ANDA Products, when offered for sale, sold, and/or 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.

39. On information and belief, the use of the Lupin ANDA Products constitutes a material part of at least one of the claims of the '637 patent; Lupin 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.

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

41. On information and belief, Lupin 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.

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

43. On information and belief, Lupin does not deny that the Lupin ANDA Products subject to ANDA No. 212331 will infringe the claims of the '637 patent and in the Lupin Paragraph IV Certification, Lupin did not deny that the Lupin ANDA Products subject to ANDA No. 212331 will infringe the claims of the '637 patent.

44. On information and belief, Lupin does not deny that the Lupin ANDA Products subject to ANDA No. 212335 will infringe the claims of the '637 patent and in the Lupin Paragraph IV Certification, Lupin did not deny that the Lupin ANDA Products subject to ANDA No. 212335 will infringe the claims of the '637 patent.

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

46. 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 Lupin and for the following relief:

a. A Judgment be entered that Lupin has infringed at least one claim of the '637 patent by submitting the Lupin 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 Lupin, 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 use, offer to sell, or sale within 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 Lupin'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 date of the '637 patent, including any extensions;

e. That Boehringer be awarded monetary relief if Lupin 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 '637 patent, 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;

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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