

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. _____

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' submission of an Abbreviated New Drug Application ("ANDA") to the Food and Drug Administration ("FDA") seeking approval to manufacture and sell generic versions of Plaintiffs' TRIJARDY® XR (empagliflozin, linagliptin, and metformin hydrochloride extended release) tablets prior to the expiration of United States Patent Nos. 8,551,957, 9,155,705, 9,415,016, 9,949,998, 10,022,379, 10,258,637, and 10,406,172.

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. 215072 (the “Lupin ANDA”) for Lupin’s 5 mg/2.5 mg/1000 mg; 10 mg/5 mg/1000 mg; 12.5 mg/2.5 mg/1000 mg; 25 mg/5 mg/1000 mg empagliflozin/linagliptin/metformin extended-release tablets (the “Lupin ANDA Product”), 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 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. 215072, 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.); *Boehringer Ingelheim Pharmaceuticals Inc. et al v. Lupin Limited et al*, C.A. No. 19-01866-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.); *Boehringer Ingelheim Pharmaceuticals Inc. et al v. Lupin Limited et al*, C.A. No. 19-01866-CFC (D. Del.).



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