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. _____
SUN PHARMACEUTICAL INDUSTRIES LIMITED, SUN PHARMACEUTICAL INDUSTRIES, INC. and OHM LABORATORIES, 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 Sun Pharmaceutical Industries Limited, Sun Pharmaceutical Industries, Inc., and Ohm Laboratories, 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 Defendant's 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), SYNJARDY XR® (empagliflozin/metformin extended release), and/or TRIJARDY XR®

(empagliflozin/linagliptin/metformin extended release) tablets prior to the expiration of United States Patent No. 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 Sun Pharmaceutical Industries Limited ("Sun Ltd.") is a corporation organized and existing under the laws of India, having a principal place of business at Sun House, Plot No. 201 B/1, Western Express Highway, Goregaon (E), Mumbai, Maharashtra, India, 400063.

7. On information and belief, Sun Ltd. controls and directs a wholly owned subsidiary in the United States named Sun Pharmaceutical Industries, Inc. ("Sun Inc."). Sun Inc. is a Delaware corporation having a principal place of business at 2 Independence Way, Princeton, New Jersey 08540.

8. On information and belief, Sun Ltd. controls and directs a wholly owned subsidiary in the United States named Ohm Laboratories, Inc. ("Ohm Labs"). Ohm Labs is a Delaware corporation, having a principal place of business at 14 Terminal Rd, New Brunswick, NJ 08901.

9. Sun Ltd., Sun Inc., and Ohm Labs are collectively referred to as "Sun."

10. On information and belief, Sun 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 Sun Inc. and Ohm Labs from which Sun derives a substantial portion of its revenue.

11. On information and belief, Sun Ltd. acted in concert with Sun Inc. and Ohm Labs to prepare and submit ANDA No. 212343 (the "Sun empagliflozin ANDA") for Sun's 10 mg and 25 mg empagliflozin tablets (the "Sun empagliflozin ANDA Product").

12. On information and belief, Sun Ltd. acted in concert with Sun Inc. and Ohm Labs to prepare and submit ANDA No. 212339 (the "Sun empagliflozin/linagliptin ANDA") for Sun's 10 mg/5 mg and 25 mg/5 mg empagliflozin/linagliptin tablets (the "Sun empagliflozin/linagliptin ANDA Product").

13. On information and belief, Sun Ltd. acted in concert with Sun Inc. and Ohm Labs to prepare and submit ANDA No. 215529 (the "Sun empagliflozin/metformin extended-release ANDA") for Sun's 5 mg/1000 mg, 10 mg/1000 mg, 12.5mg/1000 mg, and 25 mg/1000 mg extended-release tablets (the "Sun empagliflozin/metformin extended-release ANDA Product").

14. On information and belief, Sun Ltd. acted in concert with Sun Inc. and Ohm Labs to prepare and submit ANDA No. 214843 (the "Sun empagliflozin/linagliptin/metformin

extended-release ANDA") for Sun'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 "Sun empagliflozin/linagliptin/metformin extended-release ANDA Product").

15. The Sun empagliflozin ANDA, Sun empagliflozin/linagliptin ANDA, Sun empagliflozin/metformin extended-release ANDA, and Sun empagliflozin/metformin extended-release ANDA are collectively referred to hereinafter as the "Sun ANDAs."

16. The Sun empagliflozin ANDA Product, Sun empagliflozin/linagliptin ANDA Product, Sun empagliflozin/metformin extended-release ANDA Product, and Sun empagliflozin/linagliptin/metformin extended-release ANDA Product are collectively referred to hereinafter as the "Sun ANDA Products."

17. On information and belief, following FDA approval of the Sun ANDAs, Ohm Labs will manufacture and supply the Sun ANDA Products to Sun Inc., which will then market and sell the products throughout the United States, all at the direction, under the control, and for the direct benefit of Sun Ltd.

JURISDICTION AND VENUE

18. 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).

19. Venue is proper in this Court because, among other things, each Defendant 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 and/or is a foreign corporation or the agent of a foreign corporation not residing in any United States judicial district. 28 U.S.C. § 1391(c);

28 U.S.C. § 1400(b). Moreover, Sun has litigated previous Hatch-Waxman patent infringement disputes in the District of Delaware.

PERSONAL JURISDICTION OVER SUN

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

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

22. This Court has personal jurisdiction over Sun Ltd. because, *inter alia*, Sun 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 the infringing Sun ANDA Products to residents of this State upon approval of Sun's ANDAs, either directly or through at least one of its wholly-owned subsidiaries or agents; and (3) enjoys substantial income from sales of its generic pharmaceutical products in this State on its own and through Ohm Labs, which is incorporated in Delaware and through Sun Inc., which is registered as a pharmacy wholesaler and controlled substances distributor/manufacturer with the Delaware Division of Professional Regulation; (4) wholly owns Ohm Labs, which is a Delaware corporation; and (5) wholly owns Sun Inc., which is registered as a pharmacy wholesaler and controlled substances distributor/manufacturer with the Delaware Division of Professional Regulation.

23. On information and belief, Sun 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. Sun Pharm. Indus. Ltd.*, C.A. No. 18-1765-CFC (D. Del.); *Pfizer Inc. et al. v. Sun Pharmaceutical Industries Ltd. et al.*, C.A. No. 17-1597-LPS (D. Del.); *Boehringer Ingelheim Pharm. Inc. v. Sun Pharm. Indus. Ltd.*, C.A. No. 20-

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.