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.	)	
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 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/metformin extended-release) tablets prior to the expiration of United States Patent No. 7,579,449 ("the '449 Patent").

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 Michigan corporation having a principal place of business at 270 Prospect Plains Road, Cranbury, New Jersey 08512.

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 Ltd. 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. 214843 (the "Sun 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, and 25 mg/5 mg/1000 mg empagliflozin-linagliptin-metformin hydrochloride extended-release tablets (the "Sun ANDA Product").

12. On information and belief, following FDA approval of the Sun ANDA, Ohm Labs will manufacture and supply the approved generic 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

13. 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).

14. 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, which may be sued in any 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 LTD.

15. Plaintiffs reallege paragraphs 1-14 as if fully set forth herein.

16. 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.

17. This Court has personal jurisdiction over Sun Ltd. because, *inter alia*, Sun, 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 Product to residents of this State upon approval of ANDA No. 214843, 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 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.

18. 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. 20-1153-CFC (D. Del.).

19. Alternatively, to the extent the above facts do not establish personal jurisdiction over Sun Ltd., this Court may exercise jurisdiction over Sun Ltd. pursuant to Fed. R. Civ. P. 4(k)(2) because: (a) Plaintiffs' claims arise under federal law; (b) Sun Ltd. would be a foreign defendant not subject to personal jurisdiction in the courts of any State; and (c) Sun 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 Sun Ltd. satisfies due process.

PERSONAL JURISDICTION OVER OHM LABS

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

21. On information and belief, Ohm Labs 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 Ohm Labs because, *inter alia*, Ohm Labs, on information and belief: (1) is incorporated under the laws of the State of Delaware; (2) intends to make Sun's ANDA Product available in this State; and (3) enjoys substantial income from sales of its generic products in this State.

23. On information and belief, Ohm Labs has not contested jurisdiction in Delaware in one or more prior cases arising out of the filing of its ANDAs. *See, e.g.*, *Boehringer Ingelheim Pharm. Inc. v. Sun Pharm. Indus. Ltd.*, C.A. No. 18-1765-CFC (D. Del.); *Shire LLC et al. v. Ranbaxy Laboratories Ltd. et al.*, C.A. No. 14-827-RGA (D. Del.); *Boehringer Ingelheim Pharm. Inc. v. Sun Pharm. Indus. Ltd.*, C.A. No. 20-1153-CFC (D. Del.).

PERSONAL JURISDICTION OVER SUN INC.

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

25. On information and belief, Sun 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 Sun Inc. because, *inter alia*, Sun Inc., on information and belief: (1) is registered to do business in this State (File Number 4020865); (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 Sun's ANDA Product to residents of this State; (4) makes its generic drug products available in this State; and (5) enjoys substantial income from sale of its generic pharmaceutical products in this State.

27. On information and belief, Sun Inc. has not contested jurisdiction in Delaware in one or more prior cases arising out of the filing of its ANDAs. *See, e.g.*, *Boehringer Ingelheim Pharm. Inc. v. Sun Pharm. Indus. Ltd.*, C.A. No. 18-1765-CFC (D. Del.); *Novartis Pharmaceuticals Corporation v. Sun Pharmaceutical Industries, Ltd. et al.*, C.A. No. 18-1040-LPS (D. Del.); *Boehringer Ingelheim Pharm. Inc. v. Sun Pharm. Indus. Ltd.*, C.A. No. 20-1153-CFC (D. Del.).

BACKGROUND

U.S. PATENT NO. 7,579,449

28. On August 25, 2009, the USPTO duly and legally issued United States Patent No. 7,579,449 ("the '449 Patent") entitled "Glucopyranosyl-Substituted Phenyl Derivatives, Medicaments Containing Such Compounds, Their Use and Process For Their Manufacture" to inventors Matthias Eckhardt, Peter Eickelmann, Frank Himmelsbach, Edward Leon Barsoumian, and Leo Thomas. A true and correct copy of the '449 Patent is attached as Exhibit 1. The '449 Patent is assigned to BII. BIC and BIPI are licensees of the '449 Patent.

TRIJARDY XR®

29. BIPI is the holder of New Drug Application ("NDA") No. 212614 for empagliflozin-linagliptin-metformin hydrochloride extended-release tablets, for oral use, in 5 mg/2.5 mg/1000 mg, 10 mg/5 mg/1000 mg, 12.5 mg/2.5 mg/1000 mg, and 25 mg/5 mg/1000 mg dosages, which is sold under the trade name TRIJARDY XR®.

30. TRIJARDY XR® is listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations database ("Orange Book").

31. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '449 Patent is listed in the Orange Book with respect to TRIJARDY XR®.

32. The '449 Patent covers the pharmaceutical composition and use of TRIJARDY XR®.

ACTS GIVING RISE TO THIS ACTION

COUNT I — INFRINGEMENT OF THE '449 PATENT

33. Plaintiffs reallege paragraphs 1-32 as if fully set forth herein.

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

35. Sun has represented that the Sun ANDA refers to and relies upon the TRIJARDY XR® NDA and contains data that, according to Sun, demonstrate the bioavailability or bioequivalence of the Sun ANDA Product to TRIJARDY XR®.

36. Plaintiffs received a letter from Sun on or about October 14, 2020 stating that Sun had included certifications in the Sun ANDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that, *inter alia*, certain claims of the '449 Patent are either invalid or will not be infringed by the commercial manufacture, use, or sale of the Sun ANDA Product (the "Sun Paragraph IV

Certification"). Sun intends to engage in the commercial manufacture, use, offer for sale, and/or sale of the Sun ANDA Product prior to the expiration of the '449 Patent.

37. Sun has infringed at least one claim of the '449 Patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted, the Sun ANDA, by which Sun seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Sun ANDA Product prior to the expiration of the '449 Patent.

38. Sun has declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the Sun ANDA Product in the event that the FDA approves the Sun ANDA. Accordingly, an actual and immediate controversy exists regarding Sun's infringement of the '449 Patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

39. Sun's use, offer to sell, or sale of the Sun ANDA Product in the United States during the term of the '449 Patent would further infringe at least one claim of the '449 Patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

40. On information and belief, the Sun ANDA Product, 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 '449 Patent either literally or under the doctrine of equivalents.

41. On information and belief, the use of the Sun ANDA Product constitutes a material part of at least one of the claims of the '449 Patent; Sun knows that its ANDA Product is especially made or adapted for use in infringing at least one of the claims of the '449 Patent, either literally or under the doctrine of equivalents; and its ANDA Product is not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

42. On information and belief, the offering to sell or sale of the Sun ANDA Product would contributorily infringe at least one of the claims of the '449 Patent, either literally or under the doctrine of equivalents.

43. On information and belief, Sun had knowledge of the '449 Patent and, by its promotional activities and package inserts for its ANDA Product, knows or should know that it will aid and abet another's direct infringement of at least one of the claims of the '449 Patent, either literally or under the doctrine of equivalents.

44. On information and belief, the offering to sell or sale of the Sun ANDA Product by Sun would actively induce infringement of at least one of the claims of the '449 Patent, either literally or under the doctrine of equivalents.

45. On information and belief, Sun does not deny that the Sun ANDA Product will infringe the claims of the '449 Patent and in the Sun Paragraph IV Certification, Sun did not deny that the Sun ANDA Product subject to ANDA No. 214843 will infringe the claims of the '449 Patent.

46. Plaintiffs will be substantially and irreparably harmed if Sun is not enjoined from infringing the '449 Patent.

47. 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 Sun and for the following relief:

a. A Judgment be entered that Sun has infringed at least one claim of the '449 Patent by submitting the Sun ANDA;

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 Sun, 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, pursuant to 35 U.S.C. § 271(e)(4)(B), 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 '449 Patent, and (ii) seeking, obtaining or maintaining approval of ANDAs until the expiration of the '449 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 Sun's 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 '449 Patent, including any extensions;

e. That Boehringer be awarded monetary relief if Sun commercially uses, offers to sell, or sells its proposed generic version of TRIJARDY XR®, or any other product that infringes or induces or contributes to the infringement of the '449 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/ Megan E. Dellinger

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