

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.)

DR. REDDY’S LABORATORIES LTD.)
and DR. REDDY’S LABORATORIES,)
INC.,)

Defendants.)

C.A. No. _____

COMPLAINT

Plaintiffs Boehringer Ingelheim Pharmaceuticals Inc., Boehringer Ingelheim International GmbH, and Boehringer Ingelheim Corporation, by their undersigned attorneys, for their Complaint against Defendants, Dr. Reddy’s Laboratories Ltd. and Dr. Reddy’s 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 a generic version of Plaintiffs’ JARDIANCE® (empagliflozin) 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 Dr. Reddy’s Laboratories Ltd. (“DRL Ltd.”) is a corporation organized and existing under the laws of India, having a principal place of business at 8-2-337 Road No. 3, Banjara Hills, Hyderabad, 500034, India.

7. On information and belief, DRL Ltd. controls and directs a wholly owned subsidiary in the United States named Dr. Reddy’s Laboratories, Inc. (“DRL Inc.”). DRL Inc. is a New Jersey corporation having a principal place of business at 107 College Road East, Princeton, New Jersey 08540.

8. DRL Ltd. and DRL Inc. are collectively referred to hereinafter as “DRL.”

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

10. On information and belief, DRL Inc. acted in concert with DRL Ltd. to prepare and submit ANDA No. 212336 (the “DRL ANDA”) for DRL Ltd.’s 10 mg and 25 mg empagliflozin tablets (“DRL ANDA Products”), which was done at the direction of, under the control of, and for the direct benefit of DRL Ltd. Following FDA approval of the DRL ANDA, DRL Ltd. will manufacture and supply the approved generic products to DRL 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 DRL 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, each Defendant is a foreign corporation or the agent of 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, DRL has litigated previous Hatch-Waxman patent infringement disputes in the District of Delaware and has not contested venue in those cases. *See, e.g., Boehringer Ingelheim Pharmaceuticals Inc. et al. v. Dr. Reddy’s Laboratories, Ltd. et al.*, C.A. No. 19-1495, D.I. 9 (D. Del. Sept. 4, 2019); *Boehringer Ingelheim Pharmaceuticals Inc. et al. v. Dr. Reddy’s Laboratories, Ltd. et al.*, C.A. No. 18-779, D.I. 12 (D. Del. Jan. 11, 2019); *Novartis Pharmaceuticals Corporation v. Dr. Reddy’s Laboratories Inc. et al.*, C.A. No. 22-498, D.I. 12 (D. Del. May 10, 2022). Further, DRL did not

contest venue, and filed counterclaims, in this District in the prior case in which Boehringer filed a lawsuit against DRL arising from DRL's submission of the DRL ANDA. *See Boehringer*, C.A. No. 19-1495, D.I. 9; *Boehringer*, C.A. No. 18-1779, D.I. 12.

PERSONAL JURISDICTION OVER DRL LTD.

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

14. On information and belief, DRL 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 DRL Ltd. because, *inter alia*, DRL 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 DRL's infringing ANDA Products to residents of this State upon approval of ANDA No. 212336, either directly or through at least one of its wholly-owned subsidiaries or agents; (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 on its own and through DRL Inc.

16. On information and belief, DRL 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 Pharmaceuticals Inc. et al. v. Dr. Reddy's Laboratories, Ltd. et al.*, C.A. No. 19-1495, D.I. 9 (D. Del. Sept. 4, 2019); *Boehringer Ingelheim Pharmaceuticals Inc. et al. v. Dr. Reddy's Laboratories, Ltd. et al.*, C.A. No. 18-1779, D.I. 12 (D. Del. Jan. 11, 2019); *Novartis Pharmaceuticals Corporation v. Dr. Reddy's Laboratories Inc. et al.*, C.A. No. 22-498, D.I. 12 (D. Del. May 10, 2022).

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

PERSONAL JURISDICTION OVER DRL INC.

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

19. On information and belief, DRL Inc. 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 DRL Inc. because, *inter alia*, DRL Inc., on information and belief: (1) intends to market, sell, or distribute DRL's infringing ANDA Products to residents of this State; (2) is controlled by Defendant DRL Ltd. and is acting on behalf of DRL Ltd. with respect to the DRL ANDA; (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.

21. On information and belief, DRL 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., Boehringer Ingelheim Pharmaceuticals Inc. et al. v. Dr. Reddy's Laboratories, Ltd. et al.*, C.A. No. 19-1495, D.I. 9 (D. Del. Sept. 4, 2019); *Boehringer Ingelheim Pharmaceuticals Inc. et al. v. Dr. Reddy's Laboratories, Ltd. et al.*, C.A. No. 18-1779, D.I. 12

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