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. _____
LAURUS LABS LTD. and LAURUS GENERICS 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 Laurus Labs Ltd. and Laurus Generics 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 Laurus Labs Ltd. ("Laurus Labs") is a corporation organized and existing under the laws of India, having a principal place of business at Serene Chambers, Road No. 7, Banjara Hills, Hyderabad-500 034, Telangana, India.

7. On information and belief, Laurus Labs controls and directs a wholly owned subsidiary in the United States named Laurus Generics Inc. ("Laurus Generics"). Laurus Generics is a Delaware corporation having a principal place of business at 400 Connell Dr., Berkeley Heights, New Jersey 07922.

8. Laurus Labs and Laurus Generics are collectively referred to hereinafter as "Laurus."

9. On information and belief, Laurus Labs 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 Laurus Generics, from which Laurus Labs derives a substantial portion of its revenue.

10. On information and belief, Laurus Labs acted in concert with Laurus Generics to prepare and submit ANDA No. 212421 (the "Laurus ANDA") for Laurus Labs' 10 mg and 25 mg empagliflozin tablets (the "Laurus ANDA Products"), which was done at the direction of, under the control of, and for the direct benefit of Laurus Labs. Following FDA approval of the Laurus ANDA, Laurus Labs will manufacture and supply the approved generic products to Laurus Generics, which will then market and sell the products throughout the United States at the direction, under the control, and for the direct benefit of Laurus Labs.

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, Laurus Generics 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). Laurus Labs 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).

PERSONAL JURISDICTION OVER LAURUS LABS

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

14. On information and belief, Laurus Labs 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 Laurus Labs because, *inter alia*, Laurus Labs, 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 Laurus Labs' infringing ANDA Products to residents of this State upon approval of ANDA No. 212421, 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 Laurus Generics, which is a Delaware corporation; and (4) wholly owns Laurus Generics, which is a Delaware company.

16. Alternatively, to the extent the above facts do not establish personal jurisdiction over Laurus Labs, this Court may exercise jurisdiction over Laurus Labs pursuant to Fed. R. Civ. P. 4(k)(2) because: (a) Plaintiffs' claims arise under federal law; (b) Laurus Labs would be a foreign defendant not subject to personal jurisdiction in the courts of any State; and (c) Laurus Labs has sufficient contacts with the United States as a whole, including, but not limited to, filing an ANDA 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 Laurus Labs satisfies due process.

PERSONAL JURISDICTION OVER LAURUS GENERICS

17. Plaintiffs reallege paragraphs 1-16 as if fully set forth herein.

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

19. This Court has personal jurisdiction over Laurus Generics because, *inter alia*, Laurus Generics, on information and belief: (1) is organized under the laws of the State of Delaware; (2) intends to market, sell, or distribute Laurus's ANDA Products to residents of this

State; (3) is controlled by Defendant Laurus Labs; (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.

BACKGROUND

U.S. PATENT NO. 11,090,323

20. On August 17, 2021, the USPTO duly and legally issued United States Patent No. 11,090,323 ("the '323 patent") entitled "Pharmaceutical composition, methods 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 '323 patent is attached as Exhibit A. The '323 patent is assigned to BII. BIC and BIPI are licensees of the '323 patent.

JARDIANCE®

21. 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®.

22. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '323 patent is listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations database ("Orange Book") with respect to JARDIANCE®.

23. The '323 patent covers the use of JARDIANCE®.

ACTS GIVING RISE TO THIS ACTION

COUNT I—INFRINGEMENT OF THE '323 PATENT AS TO THE LAURUS ANDA

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

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

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