IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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| BOEHRINGER INGELHEIM PHARMACEUTICALS INC., BOEHRINGER INGELHEIM INTERNATIONAL GMBH, and BOEHRINGER INGELHEIM CORPORATION, | ) | |
| Plaintiffs, | ) | C.A. No. _____ |
| v. | ) | |
| 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 Applications ("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. 10,258,637.

## 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, 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 product to Laurus Generics, which will then market and sell the product 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 corporation.

16. Alternatively, to the extent the above facts do not establish personal jurisdiction over Laurus Lab, 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 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 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 incorporated under the laws of the State of Delaware; (2) intends to market, sell, or distribute Laurus' 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. 10,258,637

20. On April 16, 2019, the USPTO duly and legally issued United States Patent No. 10,258,637 ("the '637 patent") entitled "Pharmaceutical Composition, Method 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 '637 patent is attached as Exhibit 1. The '637 patent is assigned to BII. BIC and BIPI are licensees of the '637 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. JARDIANCE® is listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations database ("Orange Book") as having New Chemical Exclusivity until August 1, 2019.

23. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the ’637 patent is listed in the Orange Book with respect to JARDIANCE®.

24. The ’637 patent covers the use of JARDIANCE®.

## ACTS GIVING RISE TO THIS ACTION

### COUNT I —INFRINGEMENT OF THE ’637 PATENT

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

26. 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.

27. Laurus has represented that the Laurus ANDA refers to and relies upon the JARDIANCE® NDA and contains data that, according to Laurus, demonstrate the bioavailability or bioequivalence of the Laurus ANDA Products to JARDIANCE®.

28. Plaintiffs received a letter from Laurus on or about August 15, 2019, stating that Laurus had included certifications in the Laurus ANDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that, *inter alia*, certain claims of the ’637 patent are either invalid or will not be infringed by the commercial manufacture, use, or sale of the Laurus ANDA Products (the “Laurus Paragraph IV Certification”). Laurus intends to engage in the commercial manufacture, use, offer for sale, and/or sale of the Laurus ANDA Products prior to the expiration of the ’637 patent.

29. Laurus has infringed at least one claim of the ’637 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted the Laurus ANDA, by which Laurus seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Laurus ANDA Products prior to the expiration of the ’637 patent.

30. Laurus has declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the Laurus ANDA Products in the event that the FDA approves the Laurus ANDA. Accordingly, an actual and immediate controversy exists regarding Laurus's infringement of the '637 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

31. Laurus's use, offer to sell, or sale of the Laurus ANDA Products in the United States during the term of the '637 patent would further infringe at least one claim of the '637 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

32. On information and belief, Laurus's ANDA Products, 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 '637 patent either literally or under the doctrine of equivalents.

33. On information and belief, the use of Laurus's ANDA Products constitutes a material part of at least one of the claims of the '637 patent; Laurus knows that its ANDA Products are especially made or adapted for use in infringing at least one of the claims of the '637 patent, either literally or under the doctrine of equivalents; and its ANDA Products are not staple articles of commerce or commodities of commerce suitable for substantial noninfringing use.

34. On information and belief, the offering to sell or sale of Laurus's ANDA Products would contributorily infringe at least one of the claims of the '637 patent, either literally or under the doctrine of equivalents.

35. On information and belief, Laurus had knowledge of the '637 patent and, by its promotional activities and package inserts for its ANDA Products, knows or should know that it will aid and abet another's direct infringement of at least one of the claims of the '637 patent, either literally or under the doctrine of equivalents.

36. On information and belief, the offering to sell, or sale of Laurus's ANDA Products by Laurus would actively induce infringement of at least one of the claims of the '637 patent, either literally or under the doctrine of equivalents.

37. Plaintiffs will be substantially and irreparably harmed if Laurus is not enjoined from infringing the '637 patent.

38. 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 Laurus and for the following relief:

a. A Judgment be entered that Laurus has infringed at least one claim of the '637 patent by submitting the Laurus 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 Laurus, 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 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 '637 patent, and (ii) seeking, obtaining or maintaining approval of ANDAs until the expiration of the '637 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 Laurus'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 '637 patent, including any extensions;

e. That Boehringer be awarded monetary relief if Laurus commercially uses, offers to sell, or sells its respective proposed generic versions of JARDIANCE® or any other product that infringes or induces or contributes to the infringement of the '637 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/ Brian P. Egan*

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