

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. Plaintiff Boehringer Ingelheim Pharma GmbH & Co. KG (“BIPKG”) is a limited liability partnership organized and existing under the laws of Germany, having a principal place of business at Binger Strasse 173, 55216 Ingelheim, Germany.

6. BIPI, BII, BIC, and BIPKG are collectively referred to hereinafter as “Boehringer” or “Plaintiffs.”

7. On information and belief, Defendant Aurobindo Pharma Ltd. (“Aurobindo”) is a corporation organized and existing under the laws of India, having a principal place of business at Plot #2, Maitri Vihar, Ameerpet, Hyderabad, Andhra Pradesh, India 500038.

8. On information and belief, Aurobindo 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 West Virginia, through its own actions and through the actions of its agents and subsidiaries, including Aurobindo Pharma USA, Inc., from which Aurobindo derives a substantial portion of its revenue.

9. On information and belief, Aurobindo prepared and submitted ANDA No. 208415 (the “Aurobindo ANDA”) to the FDA for Aurobindo’s 5 mg linagliptin tablets (the “Aurobindo ANDA Product”).

JURISDICTION AND VENUE

10. 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).

11. Venue is proper in this Court because, among other things, Aurobindo 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)(3), 1400(b).

PERSONAL JURISDICTION OVER AUROBINDO

12. Plaintiffs reallege paragraphs 1-11 as if fully set forth herein.

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

14. This Court has personal jurisdiction over Aurobindo because, *inter alia*, Aurobindo, 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; and (2) intends to market, sell, and/or distribute the infringing Aurobindo ANDA Product to residents of this State upon approval of the Aurobindo ANDA, either directly or through at least one of its wholly-owned subsidiaries or agents.

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

BACKGROUND

U.S. PATENT NO. 9,486,526

16. On November 8, 2016, the PTO duly and legally issued United States Patent No. 9,486,526 (the "'526 patent") entitled "Treatment for Diabetes in Patients Inappropriate for Metformin Therapy" to inventors Klaus Dugi, Eva Ulrike Graefe-Mody, Ruth Harper, and Hans-Juergen Woerle. A true and correct copy of the '526 patent is attached as Exhibit 1.

TRADJENTA®

17. BIPI is the holder of New Drug Application ("NDA") No. 201280 (the "TRADJENTA® NDA") for linagliptin, for oral use, in 5 mg dosage, which is sold under the trade name TRADJENTA®.

18. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '526 patent is listed in the "Orange Book" with respect to TRADJENTA®.

19. The '526 patent covers the TRADJENTA® product and/or the use thereof.

ACTS GIVING RISE TO THIS ACTION

COUNT I — INFRINGEMENT OF THE '526 PATENT

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

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

22. Aurobindo has represented that the Aurobindo ANDA refers to and relies upon the TRADJENTA[®] NDA and contains data that, according to Aurobindo, demonstrate the bioavailability or bioequivalence of the Aurobindo ANDA Product to TRADJENTA[®].

23. Plaintiffs received a letter from Aurobindo on or about March 13, 2017 stating that Aurobindo had included a certification in the Aurobindo ANDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that, *inter alia*, certain claims of the '526 patent are either invalid or will not be infringed by the commercial manufacture, use, or sale of the Aurobindo ANDA Product (the "Aurobindo Paragraph IV Certification"). Aurobindo intends to engage in the commercial manufacture, use, offer for sale, and/or sale of the Aurobindo ANDA Product prior to the expiration of the '526 patent.

24. Aurobindo has infringed at least one claim of the '526 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted the Aurobindo ANDA, by which Aurobindo seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Aurobindo ANDA Product prior to the expiration of the '526 patent.

25. Aurobindo has declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the Aurobindo ANDA Product in the event that the FDA approves the Aurobindo ANDA. Accordingly, an actual and immediate controversy exists regarding Aurobindo's infringement of the '526 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

26. Aurobindo's manufacture, use, offer to sell, or sale of the Aurobindo ANDA Product in the United States or importation of the Aurobindo ANDA Product into the United States during the term of the '526 patent would further infringe at least one claim of the '526 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

27. On information and belief, the Aurobindo ANDA Product, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '526 patent either literally or under the doctrine of equivalents.

28. On information and belief, the use of the Aurobindo ANDA Product constitutes a material part of at least one of the claims of the '526 patent; Aurobindo knows that its ANDA Product is especially made or adapted for use in infringing at least one of the claims of the '526 patent, either literally or under the doctrine of equivalents; and its ANDA Product is not staple articles of commerce or commodities of commerce suitable for substantial noninfringing use.

29. On information and belief, the offering to sell, sale, and/or importation of the Aurobindo ANDA Product would contributorily infringe at least one of the claims of the '526 patent, either literally or under the doctrine of equivalents.

30. On information and belief, Aurobindo had knowledge of the '526 patent and, by its promotional activities and package inserts for its ANDA Product, knows or should know that they will aid and abet another's direct infringement of at least one of the claims of the '526 patent, either literally or under the doctrine of equivalents.

31. On information and belief, the offering to sell, sale, and/or importation of the Aurobindo ANDA Product by Aurobindo would actively induce infringement of at least one of the claims of the '526 patent, either literally or under the doctrine of equivalents.

32. Plaintiffs will be substantially and irreparably harmed if Aurobindo is not enjoined from infringing the '526 patent.

33. 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 Aurobindo and for the following relief:

- a. A Judgment be entered that Aurobindo has infringed at least one claim of the '526 patent by submitting the Aurobindo 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 Aurobindo, 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 manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of drugs or methods of administering drugs claimed in the '526 patent, and (ii) seeking, obtaining or maintaining approval of its ANDA until the expiration of the '526 patent or such other later time as the Court may determine;
- d. A Judgment be entered ordering that pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the Aurobindo ANDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall not be earlier than the latest of the expiration dates of the '526 patent, including any extensions;
- e. That Boehringer be awarded monetary relief if Aurobindo commercially uses, offers to sell, or sells its proposed generic version of TRADJENTA[®] or any other product that infringes or induces or contributes to the infringement of the '526 patent within the United States, prior to the expiration of those patents, 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.

Dated: February 5, 2020

OF COUNSEL:

Leora Ben-Ami, P.C.
Thomas F. Fleming
Jeanna M. Wacker
Mira A. Mulvaney
Sam Kwon
Ashley Ross
Christopher J. Citro
KIRKLAND & ELLIS LLP
601 Lexington Avenue
New York, NY 10022
(212) 446-4679
leora.benami@kirkland.com
thomas.fleming@kirkland.com
jeanna.wacker@kirkland.com
mira.mulvaney@kirkland.com
sam.kwon@kirkland.com
ashley.ross@kirkland.com
christopher.citro@kirkland.com

/s/ James F. Companion
James F. Companion (#790)
Sandra K. Law (#6071)
Schrader Companion Duff & Law, PLLC
401 Main Street
Wheeling, WV 26003
(304) 233-3390
jfc@schraderlaw.com
skl@schraderlaw.com