IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

BOEHRINGER INGELHEIM PHARMACEUTICALS INC., BOEHRINGER INGELHEIM INTERNATIONAL GMBH, BOEHRINGER INGELHEIM CORPORATION, and BOEHRINGER INGELHEIM PHARMA GMBH & CO. KG,	)	FILED FEB 5 2020 U.S. DISTRICT COURT-WVND WHEELING, WV 26003
Plaintiffs,	)	
v.	)	C.A. NO. 1:20-cv-19 Keeley
MYLAN PHARMACEUTICALS INC., MYLAN INC., and MYLAN LABORATORIES LIMITED,	)	
Defendants.	)	

COMPLAINT

Plaintiffs, Boehringer Ingelheim Pharmaceuticals Inc.; Boehringer Ingelheim International GmbH; and Boehringer Ingelheim Corporation; and Boehringer Ingelheim Pharma GmbH & Co. KG, by their undersigned attorneys, for their Complaint against Defendants, Defendants Mylan Pharmaceuticals Inc.; Mylan Inc.; and Mylan Laboratories Limited, 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' submissions of Abbreviated New Drug Applications ("ANDA") to the Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic version of

Plaintiffs' TRADJENTA® (linagliptin) tablets prior to the expiration of United States Patent No. 9,486,526.

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 the State 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 Mylan Pharmaceuticals Inc. ("Mylan Pharms") is a corporation organized and existing under the laws of the State of West Virginia, having a principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505.

8. On information and belief, Mylan Pharms is in the business of, among other things, developing, preparing, manufacturing, selling, marketing, and distributing generic pharmaceutical products throughout the United States, including in the State of West Virginia.

9. On information and belief, Defendant Mylan Inc. is a corporation organized and existing under the laws of the State of Pennsylvania, having a principal place of business at Robert J. Coury Global Center, 1000 Mylan Blvd., Canonsburg, Pennsylvania 15317.

10. On information and belief, Defendant Mylan Laboratories Limited ("Mylan Labs") is a corporation organized and existing under the laws of India and has a principal place of business at Plot No. 564/A/22, Road No. 92, Jubilee Hills 500034, Hyderabad, India.

11. On information and belief, Mylan Pharms is a wholly owned subsidiary of Mylan Labs, which, in turn is a wholly owned subsidiary of Mylan Inc.

12. On information and belief, the acts of Mylan Pharms complained of herein were done with the cooperation, participation, and assistance of Mylan Inc. and Mylan Labs.

13. Mylan Pharms, Mylan Labs, and Mylan Inc. are collectively referred to herein as "Mylan."

14. On information and belief, Mylan Inc. 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 Mylan Pharms and Mylan Labs, from which Mylan Inc. derives a substantial portion of its revenue.

15. On information and belief, Mylan Inc. acted in concert with Mylan Pharms and Mylan Labs to prepare and submit ANDA No. 208431 (the "Mylan ANDA") for Mylan Pharms's 5 mg linagliptin tablets (the "Mylan ANDA Product").

16. On information and belief, Mylan Inc. acted in concert with Mylan Pharms and Mylan Labs to prepare and submit the Mylan ANDA for the Mylan ANDA Product, which was done at the direction of, under the control of, and for the direct benefit of Mylan Inc. Following

FDA approval of the Mylan ANDA, Mylan Pharms will manufacture and supply the approved generic product, which will then market and sell the product throughout the United States at the direction, under the control, and for the direct benefit of Mylan Inc.

17. A complaint against Mylan containing the same allegations as set forth herein was filed in the United States District Court for the District of Delaware on September 20, 2019. Boehringer timely files the instant complaint in order to preserve its rights under 21 U.S.C. § 355(c)(3)(C) in the event that Mylan challenges the personal jurisdiction of the United States District Court for the District of Delaware.

JURISDICTION AND VENUE

18. 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).

19. Venue is proper in this Court because, among other things, Mylan 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). Mylan 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). Moreover, Mylan has litigated previous Hatch-Waxman patent infringement disputes in the Northern District of West Virginia.

PERSONAL JURISDICTION OVER MYLAN PHARMS

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

21. On information and belief, Mylan Pharms 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 Mylan Pharms because, *inter alia,* Mylan Pharms, on information and belief: (1) has substantial, continuous, and systematic contacts with

this judicial district; (2) is incorporated in the State of West Virginia and maintains a principal place of business in this judicial district; (3) makes its generic drug products available in this judicial district; (4) intends to market, sell, or distribute Mylan's ANDA Products to residents of this judicial district; (5) maintains a broad distributorship network within this judicial district; and (6) enjoys substantial income from sales of its generic pharmaceutical products in this judicial district.

23. Additionally, on information and belief, Mylan Pharms has previously been sued in this judicial district without objecting on the basis of lack of personal jurisdiction and has availed itself of this judicial district through the assertion of counterclaims and by filing suit in the Northern District of West Virginia.

PERSONAL JURISDICTION OVER MYLAN INC.

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

25. On information and belief, Mylan 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 Mylan Inc. because, *inter alia,* Mylan Inc., on information and belief: (1) intends to market, sell, or distribute Mylan's ANDA Products to residents of this State; (2) controls Defendant Mylan Pharms, which is incorporated in the State of West Virginia and maintains a principal place of business in this judicial district; (3) makes its generic drug products available in this State through Mylan Pharms, which is incorporated in the State of West Virginia and maintains a principal place of business in this judicial district; (4) maintains a broad distributorship network within this State; and (5) enjoys substantial income from sales of its generic pharmaceutical products in this State.

27. Additionally, on information and belief, Mylan Inc. has previously been sued in this judicial district without objecting on the basis of lack of personal jurisdiction and has availed itself of this judicial district through the assertion of counterclaims.

PERSONAL JURISDICTION OVER MYLAN LABS

28. Plaintiffs reallege paragraphs 1–27 as if fully set forth herein.

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

30. This Court has personal jurisdiction over Mylan Labs because, *inter alia,* Mylan Labs, on information and belief: (1) intends to market, sell, or distribute Mylan's ANDA Products to residents of this judicial district; (2) controls Defendant Mylan Pharm., which is incorporated in the State of West Virginia and maintains a principal place of business in this judicial district.

31. Additionally, on information and belief, Mylan Labs has previously been sued in this judicial district without objecting on the basis of lack of personal jurisdiction and has availed itself of this judicial district through the assertion of counterclaims.

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

BACKGROUND

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

33. 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®

34. 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®.

35. TRADJENTA® is listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations database ("Orange Book") as having New Chemical Exclusivity until May 2, 2016.

36. 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®.

37. The '526 patent covers the TRADJENTA® product and the use thereof.

ACTS GIVING RISE TO THIS ACTION

COUNT I — INFRINGEMENT OF THE '526 PATENT

38. Plaintiffs reallege paragraphs 1-37 as if fully set forth herein.

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

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

41. Plaintiffs received a letter from Mylan on or about March 15, 2017 stating that Mylan had included a certification in the Mylan 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 Mylan ANDA Product (the "Mylan Paragraph IV Certification"). Mylan intends to engage in the commercial manufacture, use, offer for sale, and/or sale of the Mylan ANDA Product prior to the expiration of the '526 patent.

42. Mylan 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 Mylan ANDA, by which Mylan seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Mylan ANDA Product prior to the expiration of the '526 patent.

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

44. Mylan's manufacture, use, offer to sell, or sale of the Mylan ANDA Product in the United States or importation of the Mylan 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).

45. On information and belief, the Mylan 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.

46. On information and belief, the use of the Mylan ANDA Product constitutes a material part of at least one of the claims of the '526 patent; Mylan 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.

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

48. On information and belief, Mylan 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.

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

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

51. 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 Mylan and for the following relief:

a. A Judgment be entered that Mylan has infringed at least one claim of the '526 patent by submitting the Mylan 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 Mylan, 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 ordering that pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the Mylan 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 date of the '526 patent, including any extensions;

e. That Boehringer be awarded monetary relief if Mylan 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 that 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.

Dated: February 5, 2020

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