IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BOEHRINGER INGELHEIM PHARMACEUTICALS INC., BOEHRINGER INGELHEIM INTERNATIONAL GMBH, BOEHRINGER INGELHEIM CORPORATION and BOEHRINGER INGELHEIM PHARMA GMBH & CO. KG,	)	C.A. No. _____
Plaintiffs,	)	
v.	)	
HETERO USA INC., HETERO LABS LIMITED UNIT-V and HETERO LABS LIMITED	)	
Defendants.	)	

COMPLAINT

Plaintiffs, Boehringer Ingelheim Pharmaceuticals Inc., Boehringer Ingelheim International GmbH, Boehringer Ingelheim Corporation, and Boehringer Ingelheim Pharma GmbH & Co. KG (collectively, "Boehringer" or "Plaintiffs"), by their undersigned attorneys, for their Complaint against Defendants Hetero USA Inc., Hetero Labs Limited Unit-V, and Hetero Labs Limited (collectively, "Hetero"), 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' TRADJENTA® (linagliptin) tablets prior to the expiration of United States Patent Nos. 9,486,526 and 10,034,877.

THE PARTIES

2. Plaintiff Boehringer Ingelheim Pharmaceuticals Inc. ("BIPI") is a corporation organized and existing under the laws of the state of Delaware, having its 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 its principal place of business at Binger Strasse 173, 55216 Ingelheim am Rhein, 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 its principal place of business at Binger Strasse 173, 55216 Ingelheim am Rhein, Germany.

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

7. On information and belief, Hetero USA Inc. is a corporation organized and existing under the laws of Delaware, having its principal place of business at 1035 Centennial Avenue, Piscataway, New Jersey 08854.

8. On information and belief, Hetero Labs Limited Unit-V is a corporation organized and existing under the laws of India, having its principal place of business at Polepally Village, Jadcherla Mandal, Mahabubnagar 509 301, Andhra Pradesh, India.

9. On information and belief, Hetero Labs Limited is a corporation organized and existing under the laws of India, having its principal place of business at 7-2-A2, Hetero Corporate Industrial Estates, Sanath Nagar, Hyderabad 500 018, Andhra Pradesh, India.

10. On information and belief, Hetero USA Inc. is a wholly-owned subsidiary of Hetero Labs Limited, and is the U.S. regulatory agent for Hetero Labs Limited and Hetero Labs Limited Unit-V.

11. On information and belief, Hetero Labs Limited Unit-V is a division of Hetero Labs Limited.

12. Hetero USA Inc., Hetero Labs Limited Unit-V, and Hetero Labs Limited are collectively referred to hereinafter as "Hetero" or "Defendants."

13. On information and belief, Hetero Labs Limited Unit-V and Hetero Labs Limited are 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 their own actions and through the actions of their agents and subsidiaries, including Hetero USA Inc., from which Hetero Labs Limited Unit-V and Hetero Labs Limited derive a substantial portion of their revenue.

14. On information and belief, Hetero Labs Limited Unit-V and Hetero Labs Limited acted in concert with Hetero USA Inc. to prepare and submit ANDA No. 217749 (the "Hetero ANDA") for Hetero's 5 mg linagliptin tablets (the "Hetero ANDA Product"), which was done at the direction of, under the control of, and for the direct benefit of Hetero Labs Limited Unit-V and Hetero Labs Limited.

15. On information and belief, Hetero intends to commercially manufacture, market, offer for sale, and sell the Hetero ANDA Product throughout the United States, including in the State of Delaware, in the event the FDA approves the Hetero ANDA.

JURISDICTION AND VENUE

16. 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).

17. Venue is proper in this Court because, among other things, Hetero USA Inc. is incorporated in the State of Delaware and therefore "resides" in this judicial district. 28 U.S.C. § 1400(b). Hetero Labs Limited Unit-V and Hetero Labs Limited are Indian corporations not residing in any United States district and may be sued in any judicial district. 28 U.S.C. § 1391(c).

PERSONAL JURISDICTION OVER HETERO USA INC.

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

19. On information and belief, Hetero USA 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 Hetero USA Inc. because, *inter alia*, Hetero USA Inc., on information and belief: (1) is incorporated under the laws of the State of Delaware, (2) intends to market, sell, or distribute Hetero ANDA Product to residents of this State; (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.

PERSONAL JURISDICTION OVER HETERO LABS LIMITED UNIT-V

21. Plaintiffs reallege paragraphs 1–20 as if fully set forth herein.

22. On information and belief, Hetero Labs Limited Unit-V develops, manufactures, and/or distributes generic drugs for sale and use throughout the United States, including in this judicial district.

23. This Court has personal jurisdiction over Hetero Labs Limited Unit-V because, *inter alia*, Hetero Labs Limited Unit-V, 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 the infringing Hetero ANDA Product to residents of this State upon approval of ANDA No. 217749, 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 Hetero USA Inc., which is a Delaware corporation; and (4) wholly owns Hetero USA Inc., which is a Delaware corporation.

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

PERSONAL JURISDICTION OVER HETERO LABS LIMITED

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

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

27. This Court has personal jurisdiction over Hetero Labs Limited because, *inter alia*, Hetero Labs Limited, 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 the infringing Hetero ANDA Product to residents of this State upon approval of ANDA No. 217749, 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 Hetero USA Inc., which is a Delaware corporation; and (4) wholly owns Hetero USA Inc., which is a Delaware corporation.

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

THE PATENTS-IN-SUIT

29. On November 8, 2016, the United States Patent and Trademark Office ("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-Jurgen Woerle. A true and correct copy of the '526 patent is attached at Exhibit 1. Boehringer is the owner of all right, title and interest to the '536 patent, including the right to sue for infringement.

30. On July 31, 2018, the PTO duly and legally issued United States Patent No. 10,034,877 ("the '877 patent") entitled "Treatment for Diabetes in Patients Inappropriate for Metformin Therapy" to inventors Klaus Dugi, Eva Ulrike Graefe-Mody, Ruth Harper, and Hans-Jurgen Woerle. A true and correct copy of the '877 patent is attached at Exhibit 2. Boehringer is the owner of all right, title and interest to the '877 patent, including the right to sue for infringement.

TRADJENTA®

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

32. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '526 and '877 patents are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to TRADJENTA®.

33. The '526 and '877 patents cover the TRADJENTA® product and/or the use thereof.

ACTS GIVING RISE TO THIS ACTION

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

35. The Hetero ANDA refers to and relies upon the TRADJENTA® NDA and contains data that, according to Hetero, demonstrate the bioequivalence of the Hetero ANDA Product and TRADJENTA®.

36. Plaintiffs received a letter from Hetero on or about December 5, 2022, stating that Hetero had included a certification in the Hetero ANDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that, *inter alia*, certain claims of the '526 and '877 patents are either invalid or will not be infringed by the commercial manufacture, use, or sale of the Hetero ANDA Product (the "Hetero Paragraph IV Certification"). Hetero intends to engage in the commercial manufacture, use, offer for sale, and/or sale of the Hetero ANDA Product prior to the expiration of the '526 and '877 patents.

37. The Hetero Paragraph IV Certification offered confidential access to unspecified portions of the Hetero ANDA on terms and conditions set by Hetero. To date, Hetero has not provided access to the Hetero ANDA.

COUNT I — INFRINGEMENT OF THE '526 PATENT

38. Plaintiffs reallege and incorporate by reference the allegations contained in paragraphs 1–37.f

39. Hetero 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 Hetero ANDA, by which Hetero seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation

of the Hetero ANDA Product prior to the expiration of the ’526 patent. In the Hetero Paragraph IV Certification, Hetero did not contest infringement of any claim of the ’526 patent.

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

41. Hetero’s manufacture, use, offer to sell, or sale of the Hetero ANDA Product in the United States or importation of the Hetero 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).

42. On information and belief, the Hetero 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.

43. On information and belief, the use of the Hetero ANDA Product constitutes a material part of at least one of the claims of the ’526 patent; Hetero 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.

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

45. On information and belief, Hetero 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.

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

47. Plaintiffs will be substantially and irreparably harmed if Hetero is not enjoined from infringing the ’526 patent.

COUNT II — INFRINGEMENT OF THE ’877 PATENT

48. Plaintiffs reallege and incorporate by reference the allegations contained in paragraphs 1–47.

49. Hetero has infringed at least one claim of the ’877 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted the Hetero ANDA, by which Hetero seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Hetero ANDA Product prior to the expiration of the ’877 patent. In the Hetero Paragraph IV Certification, Hetero did not contest infringement of any claim of the ’877 patent.

50. Hetero has declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the Hetero ANDA Product in the event that the FDA approves the Hetero ANDA. Accordingly, an actual and immediate controversy exists regarding Hetero’s infringement of the ’877 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

51. Hetero’s manufacture, use, offer to sell, or sale of the Hetero ANDA Product in the United States or importation of the Hetero ANDA Product into the United States during the

term of the ’877 patent would further infringe at least one claim of the ’877 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

52. On information and belief, the Hetero 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 ’877 patent either literally or under the doctrine of equivalents.

53. On information and belief, the use of the Hetero ANDA Product constitutes a material part of at least one of the claims of the ’877 patent; Hetero knows that its ANDA Product is especially made or adapted for use in infringing at least one of the claims of the ’877 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.

54. On information and belief, the offering to sell, sale, and/or importation of the Hetero ANDA Product would contributorily infringe at least one of the claims of the ’877 patent, either literally or under the doctrine of equivalents.

55. On information and belief, Hetero had knowledge of the ’877 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 ’877 patent, either literally or under the doctrine of equivalents.

56. On information and belief, the offering to sell, sale, and/or importation of the Hetero ANDA Product by Hetero would actively induce infringement of at least one of the claims of the ’877 patent, either literally or under the doctrine of equivalents.

57. On information and belief, Hetero does not deny that the Hetero ANDA Product will infringe the claims of the '877 patent and in the Hetero Paragraph IV Certification, Hetero did not deny that the Hetero ANDA Product will infringe the claims of the '877 patent.

58. Plaintiffs will be substantially and irreparably harmed if Hetero is not enjoined from infringing the '877 patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that the Court enter judgment against Hetero and for the following relief:

a. A judgment that Hetero has infringed at least one claim of the 9,486,526 and 10,034,877 patents;

b. A preliminary and permanent injunction pursuant to 35 U.S.C. § 271(e)(4)(B) and/or 35 U.S.C. § 283 enjoining Hetero, its officers, agents, servants, employees, and those persons acting in active concert or participation with all or any of them from: (i) manufacturing, using, offering to sell, or selling the Hetero ANDA Product within the United States, or importing the Hetero ANDA Product into the United States prior to the expiration of the 9,486,526 and 10,034,877 patents, and (ii) seeking, obtaining or maintaining approval of the Hetero ANDA until the expiration of the 9,486,526 and 10,034,877 patents or such other later time as the Court may determine;

c. A judgment ordering that pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA No. 217749 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 9,486,526 and 10,034,877 patents, including any extensions;

d. If Hetero manufactures, uses, offers to sell, or sells the Hetero ANDA Product within the United States, or imports the Hetero ANDA Product into the United States, prior to the expiration of either of the 9,486,526 and 10,034,877 patents, including any extensions, a judgment awarding Plaintiffs monetary relief together with interest;

e. A judgment that this is an exceptional case and that Plaintiffs be awarded their attorneys' fees incurred in this action pursuant to 35 U.S.C. § 285;

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/ Jack B. Blumenfeld

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January 13, 2023