UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

BOEHRINGER INGELHEIM PHARMACEUTICALS INC., BOEHRINGER INGELHEIM INTERNATIONAL GMBH, BOEHRINGER INGELHEIM CORPORATION, and BOEHRINGER INGELHEIM PHARMA GMBH & CO. KG, Plaintiffs, v. HEC PHARM CO., LTD., HEC PHARM USA Defendants	)	Civil Action No. _____

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 HEC Pharm Co., Ltd. and HEC Pharm USA (collectively, "Defendants" or "HEC") 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.

2. This action is based on HEC's submission of Abbreviated New Drug Applications ("ANDAs") to the Food and Drug Administration ("FDA") seeking approval to manufacture and sell generic versions of Plaintiffs' TRADJENTA® and JENTADUETO® prior to the expiration of United States Patent Nos. 9,415,016, 10,022,379, and/or 10,034,877 (collectively, the "Patents-in-Suit").

THE PARTIES

3. 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.

4. 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.

5. 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.

6. 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.

7. BIPI, BII, BIPKG and BIC are collectively referred to hereinafter as "Boehringer Ingelheim."

8. On information and belief, Defendant HEC Pharm Co., Ltd. ("HEC Ltd.") is a company organized and existing under the laws of China, having a principal place of business at Binjiang Road 62, Yidu, Yichang, 443300, Hubei, China.

9. On information and belief, HEC Ltd. develops, manufactures, and/or distributes generic drug products for marketing, sale, and/or use throughout the United States.

10. On information and belief, HEC Ltd., itself and through its United States agent, Defendant HEC Pharm USA Inc., manufactures and/or distributes generic drugs for sale and use throughout the United States, including in the Commonwealth of Pennsylvania.

11. On information and belief, HEC Pharm USA Inc. ("HEC USA") is a company organized and existing under the laws of New Jersey, having a principal place of business in Pennsylvania, at 13200 Townsend Rd., Philadelphia, PA 19154.

12. On information and belief, HEC USA is the United States agent of HEC Ltd., wherein following FDA approval of an ANDA, HEC Ltd. manufactures and supplies the approved generic product to HEC USA, which then markets and sells the product throughout the United States, including in the Commonwealth, at the direction, under the control, and for the direct benefit of HEC Ltd.

13. On information and belief, HEC USA is a wholly-owned subsidiary of HEC Ltd.

14. On information and belief, the acts of HEC Ltd. complained of herein were done with the cooperation, participation, and assistance of HEC USA.

15. On information and belief, HEC Ltd. acted in concert with HEC USA to prepare and submit ANDA No. 208335 (the "HEC Linagliptin ANDA") and ANDA No. 208336 (the "HEC Linagliptin/Metformin ANDA"), which was done at the direction of, under the control of, and for the direct benefit of, HEC Ltd.

16. The HEC Linagliptin/Metformin ANDA and HEC Linagliptin ANDA are herein collectively referred to as the "HEC ANDAs."

17. On information and belief, following FDA approval of the HEC ANDAs, HEC Ltd. will manufacture and supply the approved generic products to HEC USA, which will then market and sell the product throughout the United States, including in the Commonwealth, at the direction, under the control, and for the direct benefit of HEC Ltd.

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.

19. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

20. Venue is proper in this Court under 28 U.S.C. §§ 1391 and/or 1400(b). HEC USA has committed acts of infringement in this district and has a principal place of business in Philadelphia, Pennsylvania. 28 U.S.C. § 1400(b). For example, HEC ANDAs provide a Pennsylvania address for HEC USA and the tentative approval letters issued by the FDA listed a Pennsylvania address for HEC USA.

21. HEC Ltd. 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 HEC USA

22. Plaintiffs reallege paragraphs 1-21 as if fully set forth herein.

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

24. This Court has personal jurisdiction over HEC USA because, *inter alia*, HEC USA, on information and belief: (1) has substantial, continuous, and systematic contacts with the Commonwealth; (2) intends to market, sell, and/or distribute HEC's infringing ANDA products to residents of the Commonwealth; (3) maintains a principal place of business in the Commonwealth; (4) maintains a broad distributorship network within the Commonwealth; (5) enjoys substantial income from sales of its generic pharmaceutical products in the Commonwealth; and (6) in connection with HEC ANDAs, represented to the FDA that its location is in the Commonwealth.

PERSONAL JURISDICTION OVER HEC LTD.

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

26. On information and belief, HEC Ltd. 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 HEC Ltd. because, *inter alia*, HEC Ltd, on information and belief: (1) intends to manufacture HEC's infringing ANDA products, and thereafter market, sell, or distribute them to residents of the Commonwealth; (2) controls and/or works in conjunction with Defendant HEC USA, which maintains a principal place of business in this judicial district; (3) makes its generic drug products available in the Commonwealth through HEC USA, which has a principal place of business in Pennsylvania; (4) maintains a broad distributorship network within the Commonwealth; and (5) enjoys substantial income from sales of its generic pharmaceutical products in the Commonwealth. Additionally, HEC Ltd. designated HEC USA (which has a principal pace of business in this judicial district) as its US agent in connection with the HEC ANDAs.

28. Alternatively, to the extent the above facts do not establish personal jurisdiction over HEC Ltd., this Court may exercise jurisdiction over HEC Ltd. pursuant to Fed. R. Civ. P. 4(k)(2) because: (a) Plaintiffs' claims arise under federal law; (b) HEC Ltd. would be a foreign defendant not subject to personal jurisdiction in the courts of any State or Commonwealth; and (c) HEC Ltd. has sufficient contacts with the United States as a whole, including, but not limited to, manufacturing and selling generic pharmaceutical products that are distributed throughout the United States, including in the Commonwealth, such that this Court's exercise of jurisdiction over HEC Ltd. satisfies due process.

BACKGROUND

U.S. Patent No. 9,415,016

29. On August 16, 2016, the PTO duly and legally issued United States Patent No. 9,415,016 (the "'016 patent") entitled "DPP-IV inhibitor combined with a further antidiabetic

agent, tablets comprising such formulations, their use and process for their preparation" to inventors Thomas Friedl, Michael Braun, Kenji Egusa, Hikaru Fujita, Megumi Maruyama, and Takaaki Nishioka. A true and correct copy of the '016 patent is attached as Exhibit 1.

U.S. Patent No. 10,022,379

30. On July 17, 2018, the PTO duly and legally issued United States Patent No. 10,022,379 (the "'379 patent") entitled "DPP-IV inhibitor combined with a further antidiabetic agent, tablets comprising such formulations, their use and process for their preparation" to inventors Thomas Friedl, Michael Braun, Kenji Egusa, Hikaru Fujita, Megumi Maruyama, and Takaaki Nishioka. A true and correct copy of the '379 patent is attached as Exhibit 2.

U.S. Patent No. 10,034,877

31. 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-Juergen Woerle. A true and correct copy of the '877 patent is attached as Exhibit 3.

TRADJENTA® AND JENTADUETO®

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

33. BIPI is the holder of NDA No. 201281 for linagliptin and metformin hydrochloride tablets, for oral use, in 2.5 mg/500 mg, 2.5 mg/850 mg, and 2.5 mg/1000 mg dosages, which are sold under the trade name JENTADUETO®.

34. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '877 patent is listed in the "Orange Book" with respect to TRADJENTA®.

35. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '016 and '379 patents are listed in the Orange Book with respect to JENTADUETO® in 2.5 mg/500 mg, 2.5 mg/850 mg, and 2.5 mg/1000 mg dosages.

36. The '877 patent covers the TRADJENTA® product and the use thereof.

37. The '016 and '379 patents cover the JENTADUETO® product and the use thereof.

ACTS GIVING RISE TO THIS ACTION

COUNT I - INFRINGEMENT OF THE '016 PATENT

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

39. On information and belief, HEC submitted ANDA No. 208336 to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to market linagliptin and metformin, for oral use, in 2.5 mg/500 mg, 2.5 mg/850 mg, and 2.5 mg/1000 mg dosages (the "HEC Combination Products").

40. HEC ANDA No. 208336 refers to and relies upon the JENTADUETO® NDA and contains data that, according to HEC, demonstrate the bioequivalence of the HEC Combination Products and JENTADUETO®.

41. Plaintiffs received letters from HEC on or about July 10, 2017 and September 11, 2018, stating that HEC had included a certification in the HEC Linagliptin/Metformin ANDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that, *inter alia*, certain claims of the '016 and '379 patents are either invalid or will not be infringed by the commercial manufacture, use, or sale of the HEC Combination Products (the "HEC Paragraph IV Certifications").

42. HEC has infringed at least one claim of the '016 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted, the HEC Linagliptin/Metformin ANDA, by which HEC seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the HEC Combination Products prior to the expiration of the '016 patent.

43. HEC's manufacture, use, offer to sell, or sale of the HEC Combination Products in the United States or importation of the HEC Combination Products into the United States during the term of the '016 patent would further infringe at least one claim of the '016 patent under 35 U.S.C. §§ 271 (a), (b), (c), and/or (g).

44. On information and belief, HEC's Combination Products, 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 '016 patent either literally or under the doctrine of equivalents.

45. On information and belief, the use of HEC's Combination Products constitutes a material part of at least one of the claims of the '016 patent; HEC knows that its Combination Products are especially made or adapted for use in infringing at least one of the claims of the '016 patent, either literally or under the doctrine of equivalents; and its Combination Products are not staple articles of commerce or commodities of commerce suitable for substantial noninfringing use.

46. On information and belief, the offering to sell, sale, and/or importation of HEC's Combination Products would contributorily infringe at least one of the claims of the '016 patent, either literally or under the doctrine of equivalents.

47. On information and belief, HEC had knowledge of the '016 patent and, by its promotional activities and package inserts for its Combination Products, knows or should know that it will aid and abet another's direct infringement of at least one of the claims of the '016 patent, either literally or under the doctrine of equivalents.

48. On information and belief, the offering to sell, sale, and/or importation of HEC's Combination Products would actively induce infringement of at least one of the claims of the '016 patent, either literally or under the doctrine of equivalents.

49. Plaintiffs will be substantially and irreparably harmed if HEC is not enjoined from infringing, and from actively inducing or contributing to the infringement of, the '016 patent. Plaintiffs do not have an adequate remedy at law and considering the balance of hardships between Plaintiffs and HEC a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

50. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Boehringer's reasonable attorney fees.

COUNT II - INFRINGEMENT OF THE '379 PATENT

51. Plaintiffs reallege paragraphs 1-50 as if fully set forth herein.

52. On information and belief, HEC submitted ANDA No. 208336 to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to market linagliptin and metformin, for oral use, in 2.5 mg/500 mg, 2.5 mg/850 mg, and 2.5 mg/1000 mg dosages (the "HEC Combination Products").

53. HEC ANDA No. 208336 refers to and relies upon the JENTADUETO® NDA and contains data that, according to HEC, demonstrate the bioequivalence of the HEC Combination Products and JENTADUETO®.

54. Plaintiffs received letters from HEC on or about July 10, 2017 and September 11, 2018, stating that HEC had included a certification in the HEC Linagliptin/Metformin ANDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that, *inter alia*, certain claims of the '016 and '379 patents are either invalid or will not be infringed by the commercial manufacture, use, or sale of the HEC Combination Products (the "HEC Paragraph IV Certifications").

55. HEC has infringed at least one claim of the '379 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted, the HEC Linagliptin/Metformin ANDA, by which HEC seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the HEC Combination Products prior to the expiration of the '379 patent.

56. HEC's manufacture, use, offer to sell, or sale of the HEC Combination Products in the United States or importation of the HEC Combination Products into the United States during the term of the '379 patent would further infringe at least one claim of the '379 patent under 35 U.S.C. §§ 271 (a), (b), (c), and/or (g).

57. On information and belief, HEC's Combination Products, 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 '379 patent either literally or under the doctrine of equivalents.

58. On information and belief, the use of HEC's Combination Products constitutes a material part of at least one of the claims of the '379 patent; HEC knows that its Combination Products are especially made or adapted for use in infringing at least one of the claims of the '379 patent, either literally or under the doctrine of equivalents; and its Combination Products are not staple articles of commerce or commodities of commerce suitable for substantial noninfringing use.

59. On information and belief, the offering to sell, sale, and/or importation of HEC's Combination Products would contributorily infringe at least one of the claims of the '379 patent, either literally or under the doctrine of equivalents.

60. On information and belief, HEC had knowledge of the '379 patent and, by its promotional activities and package inserts for its Combination Products, knows or should know

that it will aid and abet another's direct infringement of at least one of the claims of the '379 patent, either literally or under the doctrine of equivalents.

61. On information and belief, the offering to sell, sale, and/or importation of HEC's Combination Products would actively induce infringement of at least one of the claims of the '379 patent, either literally or under the doctrine of equivalents.

62. Plaintiffs will be substantially and irreparably harmed if HEC is not enjoined from infringing, and from actively inducing or contributing to the infringement of, the '379 patent. Plaintiffs do not have an adequate remedy at law and considering the balance of hardships between Plaintiffs and HEC a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

63. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Boehringer's reasonable attorney fees.

COUNT III - INFRINGEMENT OF THE '877 PATENT

64. Plaintiffs reallege paragraphs 1-63 as if fully set forth herein.

65. On information and belief, HEC submitted ANDA No. 208335 to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to market linagliptin, for oral use, in 5 mg dosages (the "HEC Linagliptin Products").

66. The HEC Combination Products and HEC Linagliptin Products are herein collectively referred to as the "HEC ANDA Products."

67. HEC ANDA No. 208335 refers to and relies upon the TRADJENTA® NDA and contains data that, according to HEC, demonstrate the bioequivalence of the HEC Linagliptin Product and TRADJENTA®.

68. HEC 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 HEC Linagliptin ANDA, by which

HEC seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the HEC Linagliptin Products prior to the expiration of the '877 patent.

69. HEC's manufacture, use, offer to sell, or sale of the HEC Linagliptin Products in the United States or importation of the HEC Linagliptin Products 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), (c), and/or (g).

70. On information and belief, HEC's Linagliptin Products, 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.

71. On information and belief, the use of HEC's Linagliptin Products constitutes a material part of at least one of the claims of the '877 patent; HEC knows that its Linagliptin Products are 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 Linagliptin Products are not staple articles of commerce or commodities of commerce suitable for substantial noninfringing use.

72. On information and belief, the offering to sell, sale, and/or importation of HEC's Linagliptin Products would contributorily infringe at least one of the claims of the '877 patent, either literally or under the doctrine of equivalents.

73. On information and belief, HEC had knowledge of the '877 patent and, by its promotional activities and package inserts for its Linagliptin Products, knows or should know that it 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.

74. On information and belief, the offering to sell, sale, and/or importation of HEC's Linagliptin Products would actively induce infringement of at least one of the claims of the '877 patent, either literally or under the doctrine of equivalents.

75. Plaintiffs will be substantially and irreparably harmed if HEC is not enjoined from infringing, and from actively inducing or contributing to the infringement of, the '877 patent. Plaintiffs do not have an adequate remedy at law and considering the balance of hardships between Plaintiffs and HEC a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

76. 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 Defendants and for the following relief:

a. A Judgment be entered that HEC has infringed at least one claim of the '016, '379, and '877 patents under 35 U.S.C. § 271(e)(2)(A) by submitting the HEC ANDAs;

b. Entry of a permanent injunction enjoining HEC, its officers, agents, servants, employees, and those persons acting in active concert or participation with all or any of them, 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 '016, '379, and '877 patents, and (ii) seeking, obtaining or maintaining approval of ANDAs until the expiration of the '016, '379, and '877 patents or such other later time as the Court may determine;

c. Entry of a judgment declaring that pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Defendants' ANDAs 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 '016, '379, and '877 patents, including any extensions;

d. An award of damages or other relief if HEC commercially uses, offers to sell, sells, or imports into the US its proposed generic versions of TRADJENTA® and/or JENTADUETO® or any other product that infringes, induces, or contributes to the infringement of the '016, '379, and/or '877 patents, prior to the expiration of those patents, including any extensions, and that any such monetary relief be awarded to Boehringer with prejudgment interest;

e. A designation of this case as exceptional, entitling Plaintiffs to their reasonable attorneys' fees pursuant to 35 U.S.C. § 285;

f. An award of costs and expenses in this action; and

g. An award of such other and further relief as the Court deems just and appropriate.

Dated: May 29, 2020

WALSH PIZZI O'REILLY FALANGA LLP

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