UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF NORTH CAROLINA
Civil Action No. 1:15-cv-664

BOEHRINGER INGELHEIM PHARMACEUTICALS INC., BOEHRINGER INGELHEIM INTERNATIONAL GMBH, BOEHRINGER INGELHEIM CORPORATION, and BOEHRINGER INGELHEIM PHARMA GMBH & CO. KG, Plaintiffs, v. INTAS PHARMACEUTICALS, LTD. and ACCORD HEALTHCARE, INC., 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 Intas Pharmaceuticals, Ltd. and Accord Healthcare, 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' submissions of an Abbreviated New Drug Application ("ANDA") to the Food and Drug Administration ("FDA") seeking approval to manufacture and sell generic versions of

Plaintiffs' JENTADUETO® (linagliptin and metformin hydrochloride) tablets prior to the expiration of United States Patent Nos. 8,673,927, and 8,846,695.

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 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.

5. Plaintiff Boehringer Ingelheim Corporation ("BIC") is a corporation organized and existing under the laws of Delaware, having a principal place of business at 900 Ridgebury Road, Ridgefield, CT, 06877.

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

7. On information and belief, Defendant Accord Healthcare, Inc. ("AHI") is a corporation organized and existing under the laws of the State of North Carolina, having a principal place of business at 1009 Slater Road, Suite 210-B, Durham, North Carolina 27703.

8. On information and belief, AHI 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 New Jersey.

9. On information and belief, Defendant Intas Pharmaceuticals, Ltd. ("Intas") is a corporation organized and existing under the laws of India, having a principal place of business at Chinubhai Centre, Off. Nehru Bridge, Ashram Road, Ahmedabad 380009, Gujarat, India.

10. On information and belief, AHI is a wholly-owned subsidiary of Intas.

11. On information and belief, the acts of AHI complained of herein were done with the cooperation, participation, and assistance of Intas.

12. Defendants AHI and Intas are collectively referred to herein as "Accord."

13. A complaint against Accord, among other defendants, containing the same allegations as set forth herein was filed in the United States District Court for the District of New Jersey on August 4, 2015. 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 Accord challenges the jurisdiction of the United States District Court for the District of New Jersey.

JURISDICTION AND VENUE

14. 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).

15. Venue is proper in this Court under 28 U.S.C. §§ 1391 and/or 1400(b).

PERSONAL JURISDICTION OVER AHI

16. Plaintiffs reallege the preceding paragraphs as if fully set forth herein.

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

18. This Court has personal jurisdiction over AHI because, *inter alia*, AHI, on information and belief: (1) intentionally markets and provides pharmaceutical drug products to residents of this State; (2) is incorporated and maintains a principal place of business in this judicial district; (3) maintains a broad distributorship network within this State; and (3) enjoys substantial income from sales of its generic pharmaceutical products in this State.

19. Additionally, on information and belief, AHI has previously consented to this Court's jurisdiction and avails itself of the protections afforded by the Court by asserting counterclaims against plaintiffs in this judicial district. *See, e.g.*, Answer, Defenses, and Counterclaims in *The Medicines Co. v. Accord Healthcare, Inc. and Intas Pharmaceuticals Ltd.*, No. 14-cv-626 (M.D.N.C. Sept. 26, 2014); *Eli Lilly and Co. v. Accord Healthcare, Inc.*, No. 1:11-cv-261 (M.D.N.C. Dec. 12, 2011); *Hospira, Inc. et al., Intas Pharmaceuticals Ltd.*, No. 14-cv-336 (Apr. 28, 2014).

PERSONAL JURISDICTION OVER INTAS

20. Plaintiffs reallege the preceding paragraphs as if fully set forth herein.

21. On information and belief, Intas 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 Intas because, *inter alia*, Intas, on information and belief: (1) intends to market, sell, or distribute Accord's ANDA products to residents of this State; (2) controls Defendant AHI.; (3) operates through its wholly owned subsidiary AHI, which is incorporated and has a principal place of business in this state; (4) makes its generic drug products available in this State; (5) maintains a broad distributorship network within this State; and (6) enjoys substantial income from sales of its generic pharmaceutical products in this State.

23. Additionally, on information and belief, Intas has previously consented to this Court's jurisdiction and avails itself of the protections afforded by the Court by asserting counterclaims against plaintiffs in this judicial district. *See, e.g.*, Answer, Defenses, and Counterclaims in *The Medicines Co. v. Accord Healthcare, Inc. and Intas Pharmaceuticals Ltd.*, No. 14-cv-626 (M.D.N.C. Sept. 26, 2014); *Hospira, Inc. et al., Intas Pharmaceuticals Ltd.*, No. 14-cv-336 (Apr. 28, 2014).

24. Alternatively, this Court may exercise jurisdiction over Intas pursuant to Fed. R. Civ. P. 4(k)(2) because: (a) Plaintiffs' claims arise under federal law; (b) Intas would be a foreign defendant not subject to personal jurisdiction in the courts of any State; and (c) Intas 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, such that this Court's exercise of jurisdiction over Intas satisfies due process.

BACKGROUND

U.S. Patent No. 8,673,927

25. On March 18, 2014, the PTO duly and legally issued United States Patent No. 8,673,927 ("the '927 patent") entitled "Uses of DPP-IV Inhibitors" to inventors Klaus Dugi, Frank Himmelsbach, and Michael Mark. A true and correct copy of the '927 patent is attached as **Exhibit 1.**

U.S. Patent No. 8,846,695

26. On September 30, 2014, the PTO duly and legally issued United States Patent No. 8,846,695 ("the '695 patent") entitled "Treatment For Diabetes In Patients With Inadequate Glycemic Control Despite Metformin Therapy Comprising A DPP-IV Inhibitor" to inventor Klaus Dugi. A true and correct copy of the '695 patent is attached as **Exhibit 2**.

JENTADUETO®

27. 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®.

28. JENTADUETO® 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.

29. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '927, and '695 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.

30. The '927, and '695 patents cover the JENTADUETO® product.

ACTS GIVING RISE TO THIS ACTION

COUNT I -- INFRINGEMENT OF THE '695 PATENT

31. Plaintiffs reallege the preceding paragraphs as if fully set forth herein.

32. On information and belief, Accord submitted ANDA No. 208421 (the "Accord ANDA") to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to market linagliptin and metformin tablets, for oral use, in 2.5 mg/500 mg, 2.5 mg/850 mg, and 2.5 mg/1000 mg dosages. The product subject to Accord's ANDA is herein referred to as the "Accord ANDA Product."

33. Accord's ANDA No. 208421 refers to and relies upon the JENTADUETO® NDA and contains data that, according to Accord, demonstrate the bioequivalence of the Accord ANDA Product and JENTADUETO®.

34. Plaintiffs received a letter from Accord on or about June 30, 2015, stating that Accord had included a certification in the Accord ANDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that, *inter alia*, certain claims of the '695 and '927 patents are either invalid or will not be infringed by the commercial manufacture, use, or sale of the Accord ANDA Product (the "Accord Paragraph IV Certification").

35. Accord has infringed at least one claim of the '695 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted the Accord ANDA, by which Accord seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Accord ANDA Product prior to the expiration of the '695 patent.

36. Accord declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the Accord ANDA Product in the event that the FDA

approves the Accord ANDA. Accordingly, an actual and immediate controversy exists regarding Accord's infringement of the '695 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

37. Accord's manufacture, use, offer to sell, or sale of the Accord ANDA Products in the United States or importation of the Accord ANDA Product into the United States during the term of the '695 patent would further infringe at least one claim of the '695 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

38. On information and belief, Accord's 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 '695 patent either literally or under the doctrine of equivalents.

39. On information and belief, the use of Accord's ANDA Product constitutes a material part of at least one of the claims of the '695 patent; Accord knows that its ANDA Product is especially made or adapted for use in infringing at least one of the claims of the '695 patent, either literally or under the doctrine of equivalents; and its ANDA Product is not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

40. On information and belief, the offering to sell, sale, and/or importation of the Accord ANDA Product would contributorily infringe at least one of the claims of the '695 patent, either literally or under the doctrine of equivalents.

41. On information and belief, Accord had knowledge of the '695 patent and, by its promotional activities and package inserts for its ANDA Product, knows or should know that it will aid and abet another's direct infringement of at least one of the claims of the '695 patent, either literally or under the doctrine of equivalents.

42. On information and belief, the offering to sell, sale, and/or importation of the Accord ANDA Product would actively induce infringement of at least one of the claims of the '695 patent, either literally or under the doctrine of equivalents.

43. Plaintiffs will be substantially and irreparably harmed if Accord is not enjoined from infringing the '695 patent.

44. 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 '927 PATENT

45. Plaintiffs reallege the preceding paragraphs as if fully set forth herein.

46. Accord has infringed at least one claim of the '927 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted the Accord ANDA, by which Accord seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Accord ANDA Product prior to the expiration of the '927 patent.

47. Accord has declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the Accord ANDA Product in the event that the FDA approves the Accord ANDA. Accordingly, an actual and immediate controversy exists regarding Accord's infringement of the '927 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

48. Accord's manufacture, use, offer to sell, or sale of the Accord ANDA Products in the United States or importation of the Accord ANDA Product into the United States during the term of the '927 patent would further infringe at least one claim of the '927 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

49. On information and belief, Accord's 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 '927 patent either literally or under the doctrine of equivalents.

50. On information and belief, the use of Accord's ANDA Product constitutes a material part of at least one of the claims of the '927 patent; Accord knows that its ANDA Product is especially made or adapted for use in infringing at least one of the claims of the '927 patent, either literally or under the doctrine of equivalents; and its ANDA Product is not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

51. On information and belief, the offering to sell, sale, and/or importation of the Accord ANDA Product would contributorily infringe at least one of the claims of the '927 patent, either literally or under the doctrine of equivalents.

52. On information and belief, Accord had knowledge of the '927 patent and, by its promotional activities and package inserts for its ANDA Product, knows or should know that it will aid and abet another's direct infringement of at least one of the claims of the '927 patent, either literally or under the doctrine of equivalents.

53. On information and belief, the offering to sell, sale, and/or importation of the Accord ANDA Product would actively induce infringement of at least one of the claims of the '927 patent, either literally or under the doctrine of equivalents.

54. Plaintiffs will be substantially and irreparably harmed if Accord is not enjoined from infringing the '927 patent.

55. 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 award them relief as follows:

a. That a Judgment be entered that Accord has infringed at least one claim of the '927 and '695 patents by submitting ANDA No. 208421;

b. That 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 Defendants, their officers, agents, servants, employees, and those persons acting in active concert or participation with all or any of them from 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 '927, and '695 patents, and (ii) seeking, obtaining or maintaining approval of ANDAs until the expiration of the '927, and '695 patents or such other later time as the Court may determine;

d. That a Judgment be entered ordering that pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Defendants' 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 '927 and '695 patents, including any extensions;

e. That Boehringer be awarded monetary relief if Defendants commercially use, offer to sell, or sell their proposed generic version of JENTADUETO® or any other product

that infringes or induces or contributes to the infringement of the '927 and '695 patents, 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. That Plaintiffs be awarded their costs and expenses in this action; and

g. For such other and further relief as the Court deems just and appropriate.

This the 11th day of August, 2015.

/s/ Alan M. Ruley
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