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HOFFMANN-LA ROCHE INC.

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF NEW JERSEY

HOFFMANN-LA ROCHE INC., Plaintiff, v. ACCORD HEALTHCARE INC. and INTAS PHARMACEUTICAL LTD., Defendants.	Civil Action No. _____

COMPLAINT

Plaintiff Hoffmann-La Roche Inc. ("Roche") for its Complaint against Accord Healthcare Inc. ("Accord") and Intas Pharmaceutical Ltd. ("Intas") (collectively "Defendants"), to the best of its knowledge, information and belief, hereby alleges as follows:

NATURE OF THE ACTION

1. This is an action for infringement of United States Patent No. 5,472,949 ("the '949 patent"). Roche brings this action to enforce its patent rights covering Xeloda® capecitabine 150 mg and 500 mg tablets, the first oral chemotherapy drug approved in the United States. Xeloda® has been approved in the United States for the treatment of breast and colorectal cancer and Dukes' C Stage III colon cancer. A copy of the '949 patent is attached to this Complaint as Exhibit A.

PARTIES

2. Roche is a company organized and existing under the laws of the State of New Jersey with its principal place of business at 340 Kingsland Street, Nutley, New Jersey 07110.

3. On information and belief, Accord is a corporation organized under the laws of North Carolina, with its principal place of business at 1009 Wilson Road, Suite 210-B, Durham, North Carolina 27703.

4. On information and belief, Accord is in the business of selling generic pharmaceutical products, which it distributes in the State of New Jersey and throughout the United States.

5. On information and belief, Accord is licensed with the New Jersey Department of Health and Senior Services as a seller of pharmaceuticals in the State of New Jersey.

6. On information and belief, generic drug products developed and manufactured by Accord and approved by the FDA are for sale and are sold in the State of New Jersey, including eleven (11) approved pharmaceuticals listed on the New Jersey Medicare formulary.

7. Accord has previously submitted to the jurisdiction of this Court in *Astrazeneca Pharmaceuticals LP, et al. v. Accord Healthcare, Inc., et al.*, Civil Action No. 3:08-cv-04804-JAP-TJB and *Astrazeneca Pharmaceuticals LP v. Accord Healthcare, Inc., et al.*, Civil Action No. 3:09-cv-00619-JAP-TJB.

8. Accord has availed itself of the legal protections of the State of New Jersey, having asserted counterclaims filed in this jurisdiction.

9. On information and belief, Intas is a corporation organized under the laws of India, with its principal place of business at Chinubhai Centre Off. Nehru Bridge Ashram Road, Ahmedabad 380009, Gujarat, India.

10. On information and belief, Intas is in the business of manufacturing and selling generic pharmaceutical drugs that are marketed and distributed by Accord in New Jersey and throughout the United States.

11. Intas has previously submitted to the jurisdiction of this Court in *Astrazeneca Pharmaceuticals LP, et al. v. Accord Healthcare, Inc., et al.*, Civil Action No. 3:08-cv-04804-JAP-TJB and *Astrazeneca Pharmaceuticals LP v. Accord Healthcare, Inc., et al.*, Civil Action No. 3:09-cv-00619-JAP-TJB.

12. Intas has availed itself of the legal protections of the State of New Jersey, having asserted counterclaims filed in this jurisdiction.

13. On information and belief, Accord is a wholly-owned subsidiary and agent of Intas.

14. On information and belief, the acts of Accord complained of herein were done upon the initiation, direction and control of, and with the authorization of, and/or with the cooperation, participation and assistance of Intas.

JURISDICTION AND VENUE

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

16. On information and belief, Defendants are in the business of formulating, manufacturing, marketing and/or selling generic pharmaceutical drugs that they distribute in New Jersey and throughout the United States. Defendants, either directly and/or through one or more of their agents or distributors, sell and/or distribute a substantial volume of their pharmaceutical products in New Jersey.

17. This Court has personal jurisdiction over Defendants because, *inter alia*, Defendants have previously submitted to jurisdiction in this Court, and have availed themselves of the jurisdiction of this Court by asserting counterclaims in lawsuits filed in the United States District Court for the District of New Jersey and have maintained continuous and systematic contacts with the State of New Jersey.

18. Venue is proper in this District under 28 U.S.C. §§ 1391 and 1400(b).

THE PATENT IN SUIT

19. On December 5, 1995, the '949 patent, titled "N^4-(Substituted-Oxycarbonyl)-5'-Deoxy-5-Fluorocytidine Compounds, Compositions and Methods of Using Same," was duly and legally issued by the United States Patent and Trademark Office ("U.S. PTO"). Roche is the lawful owner by assignment of all rights, title and interest in and to the '949 patent, including all rights to sue and recover for infringement thereof.

20. The '949 patent covers N^4-(substituted-oxycarbonyl)-5'-deoxy-5-fluorocytidine compounds, compositions and methods of using same. Capecitabine is a N^4-(substituted-oxycarbonyl)-5'-deoxy-5-fluorocytidine compound. The Xeloda® drug product contains capecitabine.

STATEMENT OF FACTS COMMON TO ALL COUNTS

21. This action arises from Accord's efforts to gain approval from the FDA to market a generic version of Roche's Xeloda® brand capecitabine drug products prior to the expiration of Roche's '949 patent . The FDA approved Roche's Xeloda® brand capecitabine drug product for marketing in the United States under Roche's New Drug Application ("NDA") No. 20-896, pursuant to section 505(b) of the Federal Food, Drug, and Cosmetics Act ("FFDCA"), 21 U.S.C. § 355(b).

22. With the passage of the Hatch-Waxman Act in 1984, the FFDCA provisions with respect to the generic drug approval process were amended in several important respects. One provision requires innovator drug companies to submit patent information to the FDA "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1). The FDA then publishes the submitted patent information in a publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly referred to as the "Orange Book").

23. In compliance with that statutory obligation, Roche submitted patent information to the FDA in connection with its NDA No. 20-896 for Roche's Xeloda® brand capecitabine drug product, and the FDA has published the same in the Orange Book.

24. The Hatch-Waxman Act further amended the FFDCA to permit drug companies to gain approval of generic copies of innovator drugs (also called the "reference drug") by referencing studies performed by the innovator, without having to expend the same considerable investment in time and resources as does the innovator company. Thus, generic drug companies are permitted to file what is referred to as an Abbreviated New Drug Application ("ANDA") under 21 U.S.C. § 355(j). When filing an ANDA, generic drug companies are required to review the patent information that the FDA listed in the Orange Book for the reference drug and make a statutory certification (commonly called "patent certification") with respect to same.

25. As relevant here, the generic drug company may seek FDA approval to market its generic drug product prior to patent expiration by alleging in its ANDA that the listed patent(s) is/are "invalid or will not be infringed" (commonly called a "Paragraph IV certification"). 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

26. The '949 patent is listed in the Orange Book as a patent "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1).

27. On information and belief, Accord has filed ANDA No. 202593 with the FDA seeking approval to market 150 mg and 500 mg generic copies of Roche's Xeloda® brand capecitabine drug products prior to expiration of Roche's '949 patent.

28. On or about February 17, 2011, Roche received a letter from Dr. Samir Mehta, President of Accord Healthcare Inc., purporting to be a notice of Accord's filing an ANDA seeking to market a generic copy of Roche's Xeloda® brand capecitabine drug products and allegedly containing a Paragraph IV certification as required by 21 U.S.C. §§ 355(j)(2)(B)(i) and (ii) with respect to Roche's '949 patent.

29. Accord's Paragraph IV Notice to Roche states Accord's intention to seek FDA approval to market generic versions of Roche's Xeloda® brand capecitabine drug products prior to expiration of Roche's '949 patent, which expires at midnight on December 14, 2013. Notwithstanding the U.S. PTO's grant of the '949 patent to Roche, Accord asserts in its Paragraph IV Notice that the '949 patent is invalid.

30. Accord's efforts to seek FDA approval to market a generic copy of Roche's Xeloda® brand capecitabine drug products prior to expiration of Roche's '949 patent constitutes an act of infringement and, thus, creates a justiciable controversy between Roche and Defendants with respect to the subject matter of Accord's purported ANDA and the validity and infringement of Roche's '949 patent.

31. Accord filed its ANDA for a generic copy of Roche's Xeloda® brand capecitabine drug products because Defendants seek to enter the capecitabine market that Roche has created by providing advantageous treatment for breast and colorectal cancer and Dukes' C stage III colon cancer.

COUNT ONE

Infringement of the '949 Patent Under 35 U.S.C. § 271(e)(2)

32. Roche alleges paragraphs 1 through 31 above as if set forth herein.

33. On information and belief, Accord included a Paragraph IV certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with ANDA No. 202593 alleging that the '949 patent is invalid.

34. Upon information and belief, Intas initiated, directed and controlled the activities of Accord with regard to ANDA No. 202593 and the capecitabine drug product described therein.

35. Pursuant to 35 U.S.C. § 271(e)(2)(A), Defendants Intas and Accord committed an act of infringement by filing with the FDA ANDA No. 202593 with a Paragraph IV certification that seeks FDA marketing approval for a generic copy of Roche's Xeloda® brand capecitabine drug products prior to expiration of Roche's '949 patent.

36. Any commercial manufacture, use, offer for sale, sale, and/or importation of Defendants' generic capecitabine drug products prior to expiration of the '949 patent will infringe Roche's '949 patent under 35 U.S.C. § 271(e)(4)(C).

37. Roche is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an Order of this Court that the effective date of approval for Defendants' ANDA No. 202593 be a date that is not earlier than the expiration date of the '949 patent, which is currently December 14, 2013.

38. Roche will be irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Roche does not have an adequate remedy at law.

COUNT TWO

Infringement of the '949 Patent Under 35 U.S.C. § 271(b)

39. Roche alleges paragraphs 1 through 38 above as if set forth herein.

40. On information and belief, Intas actively induced Accord to submit ANDA No. 202593 to the FDA to obtain approval under the FFDCA to engage in the commercial manufacture, use, or sale throughout the United States including New Jersey of Accord's generic copy of Roche's Xeloda® brand capecitabine drug products. By actively inducing submission of the ANDA, Intas has committed an act of indirect infringement with respect to the '949 patent under 35 U.S.C. § 271(b).

41. Any commercial manufacture, use, offer for sale, and/or importation of Accord's generic copy of Roche's Xeloda® brand capecitabine drug products prior to patent expiry will infringe the '949 patent under 35 U.S.C. § 271(a) and Intas' conduct will actively induce such infringement under 35 U.S.C. § 271(b).

COUNT THREE

Declaratory Judgment of Infringement of the '949 Patent Under 35 U.S.C. § 271

42. Roche alleges paragraphs 1 through 41 above as if set forth herein.

43. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

44. Roche is entitled to a declaration that, if Defendants, prior to patent expiry, commercially manufacture, use, offer for sale or sell Accord's proposed generic version of Xeloda® brand capecitabine drug product within the United States, import Accord's proposed generic version of Xeloda® brand capecitabine drug product into the United States, or induce or contribute to such conduct, Defendants would infringe the '949 patent under 35 U.S.C. § 271(a), (b) and/or (c).

45. Roche will be irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Roche does not have an adequate remedy at law.

RELIEF SOUGHT

WHEREFORE, Plaintiff requests:

A) A judgment and decree that the '949 patent is valid and enforceable;

B) A judgment that Defendants infringed Roche's '949 patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 202593 with a Paragraph IV certification seeking to market generic versions of Xeloda® capecitabine drug products prior to the expiration of the '949 patent;

C) A judgment that Intas infringed Roche's '949 patent under 35 U.S.C. § 271(b) by actively inducing Accord to infringe Roche's '949 patent under 35 U.S.C. § 271(e)(2)(A);

D) An Order pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of Accord's ANDA No. 202593 be a date that is not earlier than the expiration date of the '949 patent, which is currently December 14, 2013;

E) A judgment that the commercial manufacture, use, offer for sale, sale, and/or importation of Accord's generic version of Xeloda® capecitabine drug products prior to the expiration of the '949 patent will constitute an act of infringement of the said patent under § 271;

F) A judgment declaring that if Defendants, their respective officers, agents, servants, employees, licensees, and representatives, and all other persons acting or attempting to act in active concert or participation with them or acting on their behalf, engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic versions of Xeloda® capecitabine drug products prior to the expiration of the '949 patent, such conduct will constitute an act of infringement of the '949 patent under § 271;

G) A permanent injunction pursuant to 35 U.S.C. § 271(e)(4)(B) restraining and enjoining Defendants and their respective officers, agents, servants and employees, licensees,

and representatives and those persons in acting or attempting to act in active concert or participation with any of them, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States of their generic versions of Xeloda® capecitabine drug products prior to December 15, 2013, the day after the current expiration of the '949 patent;

H) An award of attorneys' fees under 35 U.S.C. § 285; and

I) Such other and further relief as the Court may deem just and proper.

Respectfully submitted,

GIBBONS P.C.

Dated: March 2, 2011
Newark, New Jersey

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