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UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF NEW JERSEY

HOFFMANN-LA ROCHE INC., Plaintiff, v. ROXANE LABORATORIES, INC., and BOEHRINGER INGELHEIM ROXANE, INC. Defendants.	Civil Action No. _____ ***Document electronically filed.***

COMPLAINT

Plaintiff Hoffmann-La Roche Inc. ("Roche") for its Complaint against Roxane Laboratories, Inc. ("Roxane Labs") and Boehringer Ingelheim Roxane, Inc. ("BI Roxane"), 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, Roxane Labs is a corporation organized under the laws of Nevada, with a principal place of business at 1809 Wilson Road, Columbus, Ohio 43228-9579.

4. On information and belief, BI Roxane is a corporation organized under the laws of Delaware, with a principal place of business at 700 Manor Park Drive, Columbus, Ohio 43228-9397.

JURISDICTION AND VENUE

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

6. On information and belief, Roxane Labs is in the business of formulating, manufacturing, marketing and selling generic pharmaceutical drugs that it distributes in New Jersey and throughout the United States. Roxane Labs, either directly and/or through one or more of its agents or distributors, sells and/or distributes a substantial volume of its pharmaceutical products in New Jersey.

7. On information and belief, BI Roxane is in the business of manufacturing and selling generic pharmaceutical drugs that are distributed by Roxane Labs in New Jersey and throughout the United States.

8. On information and belief, this Court has personal jurisdiction over Roxane Labs and BI Roxane by virtue of one or more of the followings: (1) their registrations to do business in New Jersey including their appointment of registered agents in New Jersey for the receipt of service of process; (2) the sale of generic pharmaceutical drugs in New Jersey; (3) their previous consent to be sued in New Jersey; (4) the systematic and continuous contacts with New Jersey; and (5) the course of conduct that is designed to cause the performance of tortious acts that will result in foreseeable harm in New Jersey.

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

THE PATENT IN SUIT

10. 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 ("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.

11. 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, and the Xeloda® brand capecitabine drug product is a N^4-(substituted-oxycarbonyl)-5'-deoxy-5-fluorocytidine.

STATEMENT OF FACTS COMMON TO ALL COUNTS

12. This action arises because of Roxane Labs' efforts to gain approval from the FDA to market a generic version of Roche's Xeloda® brand capecitabine drug product prior to the expiration of Roche's patent rights covering it. 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).

13. 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").

14. In compliance with that statutory obligation, Roche has 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 same in the Orange Book.

15. 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. 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.

16. As relevant here, the generic drug company may state that it does not seek FDA approval to market its generic drug product prior to patent expiration of the listed patent (a "Paragraph III certification"). 21 U.S.C. § 355(j)(2)(A)(vii)(III). Alternatively, 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 is "invalid or will not be infringed" (commonly called a "Paragraph IV certification"). 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

17. The '949 patent is listed in the Orange Book, maintained by the FDA, 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).

18. On information and belief, Roxane Labs has filed ANDA No. 200483 with the FDA seeking approval to market a 150 mg and 500 mg generic copy of Roche's Xeloda® brand capecitabine drug product prior to expiration of Roche's patent rights for the '949 patent.

19. On or about November 16, 2009, Roche received a letter from Mr. Wilson, as Vice President of Scientific & Regulatory Affairs of Roxane Labs, purporting to be a notice of the filing of an ANDA seeking to market a generic copy of Roche's Xeloda® brand capecitabine drug product and allegedly containing a Paragraph IV certification required by 21 U.S.C. §§ 355(j)(2)(B)(i) and (ii) with respect to Roche's '949 patent by Roxane Labs.

20. Roxane Labs' Paragraph IV Notice to Roche states Roxane Labs' intention to seek approval to market a generic version of Roche's Xeloda® brand capecitabine drug product prior to expiration of Roche's '949 patent, which expires at midnight on December 14, 2013. Notwithstanding the United States Patent and Trademark Office's grant of the '949 patent to Roche, Roxane Labs asserts in its Paragraph IV Notice that this patent is invalid.

21. Roxane Labs' efforts to seek FDA approval to market a generic copy of Roche's Xeloda® brand capecitabine drug product prior to expiration of Roche's '949 patent constitutes on act of infringement and, thus, creates a justiciable controversy between Roche and Roxane Labs with respect to the subject matter of Roxane Labs' purported ANDA and Roche's '949 patent.

22. Roxane Labs filed its ANDA for a generic copy of Roche's Xeloda® brand capecitabine drug product because Roxane Labs seeks 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)

23. Roche alleges paragraphs 1 through 22 above as if set forth herein.

24. On information and belief, Roxane Labs included a Paragraph IV certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with its ANDA alleging that the '949 patent is invalid.

25. Pursuant to 35 U.S.C. § 271(e)(2)(A), Roxane Labs committed an act of infringement by filing an ANDA with a Paragraph IV certification that seeks FDA marketing approval for Roxane Labs' generic copy of Roche's Xeloda® brand capecitabine drug product prior to expiration of Roche's '949 patent.

26. Commercial manufacture, use, offer for sale, sale, and/or importation of Roxane Labs' generic copy of Roche's Xeloda® brand capecitabine drug product prior to expiration of the '949 patent will infringe Roche's '949 patent under 35 U.S.C. § 271(e)(4)(C).

27. 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 Roxane Labs' ANDA be a date that is not earlier than the expiration date of the '949 patent, which is currently December 14, 2013.

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

COUNT TWO

Declaratory Judgment Of Infringement Of The '949 Patent Under 35 U.S.C. § 271

29. Roche alleges paragraphs 1 through 22 and 24 through 28 above as if set forth herein.

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

31. Roche is further entitled to a declaration that, if Roxane Labs and BI Roxane, prior to patent expiry, commercially manufacture, use, offer for sale or sell their proposed

generic versions of Xeloda® brand capecitabine drug product within the United States, import Roxane Labs' proposed generic version of Xeloda® brand capecitabine drug product into the United States, or induce or contribute to such conduct, Roxane Labs and BI Roxane would further infringe the '949 patent under 35 U.S.C. § 271(a), (b) and/or (c).

32. Roche will be irreparably harmed by Roxane Labs' and BI Roxane's 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 Roxane Labs infringed Roche's '949 patent under 35 U.S.C. § 271(e)(2)(A) by submitting the aforesaid ANDA with a Paragraph IV certification seeking to market its generic version of Xeloda® capecitabine drug products prior to the expiration of the '949 patent;

C) An Order pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of Roxane Labs' ANDA No. 200483 be a date that is not earlier than the expiration date of the '949 patent, which is currently December 14, 2013;

D) A judgment that the commercial manufacture, use, offer for sale, sale, and/or importation of Roxane'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;

E) A judgment declaring that if Roxane Labs and BI Roxane, their respective officers, agents, servants, employees, licensees, representatives, and attorneys, 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;

F) A permanent injunction pursuant to 35 U.S.C. § 271(e)(4)(B) restraining and enjoining Roxane Labs and BI Roxane and their respective officers, agents, servants and employees, and those persons 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;

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

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

Respectfully submitted,

GIBBONS P.C.

Dated: December 15, 2009
Newark, New Jersey

s/Sheila F. McShane
By: David E. De Lorenzi, Esq.
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