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HOFFMANN-LA ROCHE INC.

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF NEW JERSEY

HOFFMANN-LA ROCHE INC.,

Plaintiff,

v.

MYLAN INC., and MYLAN PHARMACEUTICALS INC.,

Defendants.

Civil Action No. _____

COMPLAINT

Document electronically filed.

Plaintiff Hoffmann-La Roche Inc. ("Roche") for its Complaint against Mylan Inc. and Mylan Pharmaceuticals Inc., 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 for 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, Mylan Inc., formerly known as Mylan Laboratories Inc. ("Mylan Inc."), is a corporation organized under the laws of the Commonwealth of Pennsylvania, with a principal place of business at 1500 Corporate Drive, Canonsburg, Pennsylvania 15317.

4. On information and belief, Mylan Pharmaceuticals Inc. ("Mylan Pharms") is a corporation organized and existing under the laws of the state of West Virginia having its principal place of business at 781 Chestnut Ridge Rd., Morgantown, West Virginia 26505.

5. Mylan Inc. and Mylan Pharms are collectively referred to hereinafter as "Mylan."

JURISDICTION AND VENUE

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

7. On information and belief, Mylan Inc. and Mylan Pharms have submitted to the jurisdiction of the United States District Court for the District of New Jersey at least in Warner Chilcott Laboratories Ireland Ltd. et al. v. Impax Laboratories, Inc. et al., 08-6304 (WJM) (MF); Novartis Pharmaceuticals Corp. v. Mylan Pharmaceuticals Inc. and Mylan Inc., 08-5042 (PGS) (ES) and; Sankyo Company, Ltd and Daiichi Sankyo, Inc. v. Mylan Laboratories Inc. and Mylan Pharmaceuticals Inc., 06-3462 (WJM) (RJH).

8. On information and belief, Defendant Mylan Inc., directly or through Mylan Pharms, is in the business of formulating, manufacturing, marketing and selling generic prescription pharmaceutical drugs that it distributes in New Jersey and throughout the United States. Mylan Inc.'s United States product portfolio includes approximately 180 products. On further information and belief, Mylan Inc. is conducting business within this District, and also has facilities located at One Woodbridge Center, 9th Floor, Suite 920, Woodbridge, New Jersey 07095. Mylan, Inc., either directly or through Mylan Pharms and/or through one or more of its subsidiaries, agents, or distributors, sells and/or distributes a substantial volume of its pharmaceutical products in New Jersey. Defendant Mylan Inc. is the majority owner of, and has a controlling interest in, Mylan Pharms.

9. On information and belief, this Court has personal jurisdiction over Mylan Inc. by virtue of, among other things: (1) its presence in New Jersey; (2) its registration to do business in New Jersey including its appointment of a registered agent in New Jersey for the receipt of service of process; (3) its sale of prescription drugs in New Jersey; (4) its registration of prescription drug products in the *New Jersey Generic Formulary of the New Jersey Department of Health and Senior Services*; (5) its consent to be sued in New Jersey; (6) its systematic and continuous contacts with New Jersey; and (7) its course of conduct that is designed to cause the performance of tortious acts that will result in foreseeable harm in New Jersey. On information and belief, the acts of Mylan Inc. complained of herein were done at the direction of, with the authorization of, and/or with the cooperation, participation and assistance of, Mylan Pharms, and, at least in part, benefit the latter.

10. On information and belief, Defendant Mylan Pharms, a wholly owned subsidiary of Mylan Inc., is in the business of manufacturing generic prescription pharmaceutical drugs that it distributes in New Jersey and throughout the United States. On information and belief, the acts of Mylan Pharms complained of herein were done at the direction of, with the authorization of, and/or with the cooperation, participation and assistance of, Mylan Inc., and, at least in part, benefit the latter.

11. On information and belief, this Court has personal jurisdiction over Mylan Pharms by virtue of, among other things: (1) its presence in New Jersey (2) its registration to do business in New Jersey including its appointment of a registered agent in New Jersey for the receipt of service of process; (3) its sale of prescription drugs in New Jersey; (4) its registration of prescription drug products in the New Jersey Generic Formulary of the New Jersey Department of Health and Senior Services; (5) its consent to be sued in New Jersey; (6) its systematic and continuous contacts with New Jersey; and (7) its course of conduct that is designed to cause the performance of tortious acts that will result in foreseeable harm in New Jersey.

12. On information and belief, Mylan Inc. and Mylan Pharms operate as an integrated business ultimately controlled by Mylan Inc. For example, Mylan Inc.'s website, located at http://www.mylan.com/our_businesses/north_america.aspx, lists "Mylan Pharmaceuticals Inc." as one of "Our Businesses" in "North America."

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

THE PATENT IN SUIT

14. 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"). Plaintiff 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.

15. 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 composition. As noted above, Xeloda® is the first oral chemotherapy drug approved in the United States for the treatment of breast and colorectal cancer and Dukes' C Stage III colon cancer. This FDA approved method of use, *inter alia*, is protected by Roche's '949 patent.

STATEMENT OF FACTS COMMON TO ALL COUNTS

16. This action arises because of Mylan's efforts to gain approval from the United States Food and Drug Administration ("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 Plaintiff 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).

17. 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").

18. In compliance with that statutory obligation, Plaintiff 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 for Xeloda®.

19. The Hatch-Waxman Act further amended the FFDCA to permit generic 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.

20. The generic drug company may state that it does not seek FDA approval to market its generic drug product prior to patent expiration (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).

21. 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).

22. On information and belief, Mylan has filed ANDA No. 90-943 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.

23. On or about March 11, 2009, Roche received a letter from Mr. Rakoczy of the firm Rakoczy Molino Mazzochi Siwik LLP, who claims to be Mylan's outside litigation counsel, purporting to be a notice of Mylan's 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 that is currently listed in the Orange Book ("Paragraph IV Notice").

24. Mylan's Paragraph IV Notice to Roche states Mylan's intention to seek approval to market a generic version of Roche's Xeloda® brand capecitabine drug product prior to expiration of a Roche patent listed in the Orange Book, namely Roche's '949 patent, which expires at midnight on December 14, 2013. Notwithstanding the United States Patent and Trademark Office's grant of patent protection to Roche, Mylan asserts in its Paragraph IV Notice that this patent is invalid, unenforceable, or would not be infringed by its generic product.

25. Mylan's 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 Mylan with respect to the subject matter of Mylan's purported ANDA and Roche's '949 patent identified in Mylan's Paragraph IV Notice.

COUNT ONE

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

26. Plaintiff Roche alleges paragraphs 1 through 24 above as if set forth again.

27. On information and belief, Defendants Mylan Inc. and Mylan Pharms, acting jointly, included a Paragraph IV certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with their ANDA alleging that the '949 patent is invalid or will not be infringed by the manufacture, use, or sale of the generic copy of Xeloda® brand capecitabine drug product covered by Mylan's ANDA.

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

29. Plaintiff 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 Mylan's ANDA be a date that is not earlier than the December 14, 2013 expiration date of the '949 patent.

30. On information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's generic copy of Roche's Xeloda® brand capecitabine drug product prior to expiration of the '949 patent will infringe Roche's '949 patent.

COUNT TWO

Infringement Of The '949 Patent Under 35 U.S.C. § 271(b)

31. Plaintiff Roche alleges paragraphs 1 through 29 above as if set forth again.

32. On information and belief, Defendants Mylan Inc. and Mylan Pharms have on more than one occasion collaborated to develop, seek FDA approval for, manufacture, import,

distribute and sell pharmaceutical products (including generic drug products manufactured and sold pursuant to approved ANDAs) in the United States and in New Jersey.

33. On information and belief, Defendants Mylan Inc. and Mylan Pharms acted in concert to seek approval from the FDA to market generic copies of Roche's Xeloda® capecitabine drug products that are the subject of ANDA 90-943 throughout the United States and in New Jersey.

34. On information and belief, Mylan Inc. actively induced Mylan Pharms to submit ANDA No. 90-943 to the FDA to obtain approval to engage in the commercial manufacture, use, or sale of the generic copies of Roche's Xeloda® capecitabine drug products throughout the United States, including New Jersey, prior to patent expiry. On further information and belief, Mylan Inc. will be actively involved in the manufacture, offer for sale and sale of the generic copies of Roche's Xeloda® capecitabine drug products. By engaging in a cooperative venture with Mylan Pharms to submit the ANDA 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, Mylan Inc. has committed and act of indirect infringement of the '949 patent, under 35 U.S.C. § 271(b).

35. On information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of the generic copies of Roche's Xeloda® capecitabine drug products prior to patent expiry will infringe the '949 patent.

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

COUNT THREE

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

37. Plaintiff Roche alleges paragraphs 1 through 35 above as if set forth again.

38. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

39. Plaintiff Roche is further entitled to a declaration that, if Mylan, prior to patent expiry, commercially manufactures, uses, offers for sale or sells its proposed generic version of Xeloda® brand capecitabine drug product within the United States, imports Mylan's proposed generic version of Xeloda® brand capecitabine drug product into the United States, or induces or contributes to such conduct, Mylan would further infringe the '949 patent under 35 U.S.C. § 271(a), (b) and/or (c).

40. On information and belief, healthcare providers administering and/or patients using Mylan's proposed generic version of Xeloda® capecitabine drug products within the United States in the manner and for the indications described in Mylan's ANDA will be direct infringers of Roche's '949 patent under 35 U.S.C. § 271(a). In addition, the healthcare providers' and/or patients' infringing use of Mylan's proposed generic version of Xeloda® capecitabine drug products in the methods claimed in Roche's '949 patent will occur at Mylan's behest and with Mylan's intent, knowledge, and encouragement.

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

EXCEPTIONAL CASE

42. The actions of Defendants Mylan Inc. and Mylan Pharms, individually and collectively, render this an exceptional case under 35 U.S.C. § 285, and therefore Roche is entitled to an award of reasonable attorneys fees from Mylan because their failure to adhere to appropriate legal standards in the Paragraph IV Notice letter.

INJUNCTIVE RELIEF

43. Plaintiff Roche will be irreparably harmed by infringing activities of Mylan 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 Mylan 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 Mylan's ANDA No. 90-943 be a date that is not earlier than the December 14, 2013 expiration date of the '949 patent;

D) A judgment that Mylan Inc. has infringed the '949 patent under 35 U.S.C. § 271(b) by inducing Mylan Pharms to submit ANDA No. 90-943 under the FFDCA, and that the commercial manufacture, use, offer for sale, sale, and/or importation of its 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 that Mylan would infringe and induce infringement of Roche's '949 patent upon marketing of its generic version of Xeloda® capecitabine drug products after grant of FDA approval and prior to the expiration of Roche's '949 patent;

F) A judgment declaring that if Mylan, their 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 its generic version of Xeloda® capecitabine drug products prior to the expiration of the '949 patent, it will constitute an act of infringement of the said patent under § 271;

G) A permanent injunction pursuant to 35 U.S.C. § 271(e)(4)(B) restraining and enjoining Mylan and its 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 its generic version of Xeloda® capecitabine drug products identified in this Complaint, and any other

product that infringes or induces or contributes to the infringement of the '949 patent prior to December 15, 2013, the day after the expiration of the said patent;

H) An award of attorneys fees from Mylan 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: April 8, 2009
Newark, New Jersey

s/ David E. De Lorenzi
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