David E. De Lorenzi, Esq.
Sheila F. McShane, Esq.
GIBBONS P.C.
One Gateway Center
Newark, New Jersey 07102-5310
Telephone No.: (973) 596-4500
Facsimile No.: (973) 596-0545

OF COUNSEL:

Brian D. Coggio, Esq.
John D. Garretson, Esq.
Irene E. Hudson, Esq.
FISH & RICHARDSON P.C.
601 Lexington Avenue, 52nd Floor
New York, New York 10022
Telephone No.: (212) 765-5070
Facsimile No.: (212) 258-2291

Attorneys for Plaintiff
HOFFMANN-LA ROCHE INC.

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF NEW JERSEY

HOFFMANN-LA ROCHE INC., Plaintiff, v. TEVA PHARMACEUTICALS USA, INC. AND TEVA PHARMACEUTICAL INDUSTRIES LTD., Defendants.	Civil Action No. _____ **COMPLAINT**

Plaintiff Hoffmann-La Roche Inc. ("Roche") for its Complaint against Defendants, Teva Pharmaceuticals USA, Inc. ("Teva USA") and Teva Pharmaceutical Industries Ltd. ("Teva Ltd."), 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 a principal place of business at 340 Kingsland Street, Nutley, New Jersey 07110.

3. On information and belief, Teva USA regularly transacts business in the State of New Jersey, has multiple offices in the State of New Jersey, and is a corporation organized under the laws of Delaware with a principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454.

4. On information and belief, Teva Ltd. is a company organized and existing under the laws of Israel having its principal place of business at 5 Basel St., Petach Tikva 49131, Israel.

5. On information and belief, Teva USA is a wholly owned subsidiary of Teva Ltd.

6. On information and belief, Teva USA is controlled and/or dominated by Teva Ltd.

7. On information and belief, Teva Ltd. conducts its operations through subsidiaries in the United States, including New Jersey, through Teva USA.

JURISDICTION AND VENUE

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

9. On information and belief, Teva USA, directly or through its subsidiaries, 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. Teva USA's United States product portfolio includes over 300 products. On further information and

belief, Teva USA is conducting business within this District, and also has facilities located at 92 Route 46 East, Elmwood Park, New Jersey 07407; 482 Hudson Terrace, 2nd Floor, Englewood Cliffs, New Jersey 07632; 8-10 Gloria Lane, Fairfield, New Jersey 07004; 1801 River Road, Fair Lawn, New Jersey 07410; 209 McLean Boulevard, Paterson, New Jersey 07504; 140 Hopper Avenue, Waldwick, New Jersey 07463; and 400 Chestnut Ridge Road, Woodcliff Lake, NJ 07677. Teva USA, either directly 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.

10. On information and belief, this Court has personal jurisdiction over Teva USA 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 consent to be sued in New Jersey; (4) its systematic and continuous contacts with New Jersey; and (5) its course of conduct that is designed to cause the performance of tortious acts that will result in foreseeable harm in New Jersey.

11. On information and belief, Teva USA has submitted to the jurisdiction of the United States District Court for the District of New Jersey at least in the following cases:

- *Sepracor Inc. v. Teva Pharmaceuticals USA, Inc.*, No. 09-1302 (DMC) (MF);
- *Elan Pharma Int'l Ltd. v. Teva Pharmaceuticals USA, Inc.*, No. 08-1085 (JAG) (MCA);
- *Sanofi-Aventis U.S. LLC v. Teva Pharmaceuticals USA, Inc.*, No. 07-2837 (FLW);
- *Celgene Corp. v. Teva Pharmaceuticals USA, Inc.*, No. 07-4459 (FLW) (TJB);
- *Merck Sharp & Dohme Pharmaceutical SRL v. Teva Pharmaceuticals USA, Inc., et al.*, No. 07-2264 (GEB); and
- *Hoffmann-La Roche Inc. v. Teva Pharmaceuticals USA, Inc., et al.*, No. 07-4284 (SRC) (MAS).

12. On information and belief, Teva USA acts under the direction, control and influence of Teva Ltd. with respect to the acts and conduct alleged in this Complaint.

13. Teva USA's acts are continuous and systematic contacts with the State of New Jersey, as an agent of Teva Ltd., and are also attributable to Teva Ltd. for jurisdictional purposes.

14. Teva USA and Teva Ltd. have jointly filed at least twenty-nine complaints for patent infringement in this judicial district in 2007, and therefore, have submitted themselves to the jurisdiction of this Court.

15. For all of the reasons set forth above, this Court has personal jurisdiction over Teva Ltd.

16. Venue is proper in this Court under Title 28, United States Code §§ 1391(c) and 1400(b), because Teva USA and Teva Ltd., acting in concert, employ individuals in this judicial district and have offices and manufacturing facilities in this judicial district, and thus purposefully avail themselves of the privilege of conducting activities within New Jersey.

THE PATENT IN SUIT

17. 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.

18. 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 method of

use, *inter alia*, is protected by Roche's '949 patent and is approved by the United States Food and Drug Administration ("FDA").

STATEMENT OF FACTS COMMON TO ALL COUNTS

19. This action arises because of Teva USA's 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).

20. 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").

21. 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 for Xeloda®.

22. 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.

23. 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).

24. 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).

25. Teva USA has filed ANDA No. 91-649 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 right for the '949 patent.

26. On or about October 7, 2009, Roche received a letter from Mr. Nicholas Tantillo, as Teva USA's Senior Director, Regulatory Affairs, purporting to be a notice of Teva USA'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)(ii) with respect to Roche's '949 patent that is currently listed in the Orange Book ("Paragraph IV Notice").

27. Teva USA's Paragraph IV Notice to Roche states Teva USA's 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 currently expires at midnight on December 14, 2013. Notwithstanding the United States Patent and Trademark Office's grant of patent protection to Roche, Teva USA asserts in its Paragraph IV Notice that this patent is invalid, unenforceable, or would not be infringed by its generic capecitabine product.

28. Teva USA'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 an act of infringement and, thus, creates a justiciable controversy between Roche and Teva USA with respect to the subject matter of Teva USA's purported ANDA and Roche's '949 patent.

29. Teva USA filed its ANDA for a generic copy of Roche's Xeloda® brand capecitabine drug product because both Teva USA and Teva Ltd. 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.

30. Upon information and belief, Teva Ltd. actively and knowingly aided and abetted Teva USA's filing of its ANDA seeking approval to market generic copies of Roche's brand Xeloda ® capecitabine drug product.

COUNT ONE

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

31. Roche alleges paragraphs 1 through 30 above as if set forth herein.

32. On information and belief, Teva USA 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 or will not be infringed by the manufacture, use, or sale of the generic copy of Xeloda® brand capecitabine drug product covered by Teva USA's ANDA.

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

34. Commercial manufacture, use, offer for sale, sale, and/or importation of Teva USA's 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).

35. Roche is entitled to the relief provided by 35 U.S.C. § 271(e)(4)(A), including, *inter alia*, an order of this Court that the effective date of approval for Teva USA's ANDA be a date that is not earlier than the expiration date of the '949 patent, which is currently December 14, 2013.

36. Roche will be irreparably harmed by Teva USA's 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

37. Roche alleges paragraphs 1 through 30 and 32 through 36 above as if set forth herein.

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

39. Roche is further entitled to a declaration that, if Teva USA, 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 Teva USA's proposed generic version of Xeloda® brand capecitabine drug product into the United States, or induces or contributes to such conduct, Teva USA would further infringe the '949 patent under 35 U.S.C. §§ 271(a), (b) and/or (c).

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

COUNT THREE

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

41. Roche alleges paragraphs 1 through 30, 32 through 36 and 38 through 40 above as if set forth herein.

42. On information and belief, Teva USA and Teva Ltd. 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

43. On information and belief, when Teva Ltd. actively and knowingly aided and abetted Teva USA with the filing of its ANDA seeking approval to market the generic capecitabine drug product, Teva Ltd. was aware of the '949 patent and knew that Teva USA's filing of its ANDA constituted an act of infringement.

44. On information and belief, Teva USA and Teva Ltd. 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 No. 91-649 throughout the United States and in New Jersey.

45. On information and belief, Teva Ltd. actively induced Teva USA to submit ANDA No. 91-649 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, Teva Ltd. will be actively involved with Teva USA's manufacture, offer for sale and sale of generic copies of Roche's Xeloda® capecitabine drug products. By engaging in a cooperative venture with Teva USA to submit ANDA No. 91-649 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, Teva Ltd. has committed and act of indirect infringement of the '949 patent under 35 U.S.C. § 271(b).

46. 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.

47. Plaintiff Roche will be irreparably harmed by Teva USA and Teva Ltd.'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 Teva USA 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 Teva USA's ANDA No. 91-649 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 Teva USA'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 that Teva Ltd. has infringed the '949 patent by inducing Teva USA's infringement of the '949 patent through actively and knowingly aiding and abetting Teva USA's filing of its ANDA;

F). A judgment declaring that if Teva USA and Teva Ltd., 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 Teva USA and Teva Ltd. 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 prior to December 15, 2013, the day after the current expiration of the said patent;

H). An award of attorneys' fees from Teva USA and Teva Ltd. 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: October 16, 2009
Newark, New Jersey

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

One Gateway Center
Newark, New Jersey 07102-5310
Telephone No.: (973) 596-4500
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Brian D. Coggio, Esq.
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Attorneys for Plaintiff
HOFFMANN-LA ROCHE INC.