IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GILEAD SCIENCES, INC., HOFFMANN-La ROCHE INC., F. HOFFMANN-La ROCHE LTD. and GENENTECH, INC.,	)	
Plaintiffs	)	
v.	)	C.A. No. _____
NATCO PHARMA LIMITED and NATCO PHARMA, INC.,	)	
Defendants.	)	

COMPLAINT

Plaintiffs, Gilead Sciences, Inc., Hoffmann-La Roche Inc., F. Hoffmann-La Roche Ltd. and Genentech, Inc. (collectively "Plaintiffs"), for their Complaint against Defendants, Natco Pharma Limited ("Natco Ltd.") and Natco Pharma, Inc. ("Natco Inc.") (collectively "Natco"), to the best of their knowledge, information and belief, hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for infringement of United States Patent No. 5,763,483 ("the '483 Patent"). Plaintiffs institute this action to enforce their patent rights covering Tamiflu® oseltamivir phosphate capsules 75 mg dosage form, that are approved in the United States by the U.S. Food and Drug Agency ('FDA") for the treatment of uncomplicated acute illness due to influenza infection in patients one year or older who have been symptomatic for no more than two days and for the prophylaxis of influenza in patients one year or older.

PARTIES

2. Plaintiff Gilead Sciences, Inc. is a company organized and existing under the laws of the State of Delaware with its principal place of business at 333 Lakeside Drive, Foster City, California 94404.

3. Plaintiff Hoffmann-La Roche Inc. 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.

4. Plaintiff F. Hoffmann-La Roche Ltd. is a company organized and existing under the laws of Switzerland with its principal place of business at CH 4070 Basel, Switzerland.

5. Plaintiff Genentech, Inc. is a company organized and existing under the laws of the State of Delaware with its principal place of business at 1 DNA Way, South San Francisco, California 94080-4990.

6. Upon information and belief, Defendant Natco Ltd. is a corporation organized and existing under the laws of India and has a principal place of business at Natco House, Road No. 2, Banjara Hills, Hyderabad - 500 033, India.

7. On information and belief, Natco Ltd. is developing generic drug products for sale and use throughout the United States, including within this judicial district. On information and belief, Natco Ltd. established Natco Inc. for the purpose of marketing, offering to sell and selling its generic drug products in the United States, including Delaware.

8. On information and belief, Natco Inc. is a Delaware corporation having a principal place of business at 297 Mine Bank Road, Wellsville, PA 17365-9514.

9. On information and belief, Natco Inc. is developing generic drug products for sale and use throughout the United States, including within this judicial district.

10. On information and belief, Natco Inc. is controlled and/or dominated by Natco Ltd.

11. On information and belief, Natco Inc. is a wholly owned subsidiary of Natco Ltd.

JURISDICTION AND VENUE

12. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

13. Natco Ltd. and Natco Inc. maintain a website at the uniform resource locator (URL) http://www.natcopharma.co.in ("the Natco website"), which serves as the website for Natco. According to the website, Natco is in the business of "Research, Developing, Manufacturing and Marketing of Pharmaceutical Substances and Finished Dosage forms."

14. On information and belief, Natco Ltd., independently and with the assistance and/or at the direction of Natco Inc., is developing generic drug products for sale and use throughout the United States, including within this judicial district.

15. On information and belief, Natco Inc., independently and with the assistance and/or at the direction of Natco Ltd., is developing generic drug products for sale and use throughout the United States, including within this judicial district.

16. On information and belief, Natco Ltd. and Natco Inc. operate as an integrated, unitary business. For example, in a January 14, 2011 press release available at the Natco website at http://www.natcopharma.co.in/k_and_c.html, Natco Ltd. states that Natco Inc.

is its "wholly owned subsidiary." Additionally, in a 2011 Bloomberg Law Company Report for Natco Ltd., Natco Inc. is listed as a subsidiary.

17. On information and belief, Natco Ltd. and Natco Inc. acted in concert to develop the Natco generic copy of Plaintiffs' Tamiflu® 75 mg oseltamivir phosphate capsules and to seek approval from the FDA to sell Natco's generic copy of Plaintiffs' Tamiflu® 75 mg oseltamivir phosphate capsules throughout the United States and in this judicial district.

18. On information and belief, Natco Ltd. has filed ANDA No. 202-595 with the FDA. On information and belief, Natco Ltd. and Natco Inc. acted as a single entity in connection with preparing and filing ANDA No. 202-595.

19. On information and belief, and as previously noted, Natco Inc. is a corporation organized and existing under the laws of Delaware. By virtue of its incorporation in Delaware, this Court has personal jurisdiction over Natco Inc.

20. On information and belief, by virtue of, *inter alia*, Natco Ltd.'s relationship with Natco Inc. in connection with the preparation and/or filing of ANDA No. 202-595, and Natco Ltd.'s associated systematic and continuous activities within the state of Delaware, including but not limited to the development of generic drug products for sale to residents of Delaware, this Court has personal jurisdiction over Natco Ltd.

21. On information and belief, separate and apart from its relationship with Natco Inc., Natco Ltd. has purposely availed itself of the state of Delaware by, among other things, making, shipping, using, offering to sell or selling, or causing others to use, offer to sell, or sell pharmaceutical products in the State of Delaware and deriving substantial revenue from such activities.

22. On information and belief, by virtue of, *inter alia*, Natco Ltd.'s purposeful activities directed towards the State of Delaware, including but not limited to the above-described contacts, and the actions taken on its behalf by Natco Inc., a Delaware corporation, in connection with ANDA No. 202-595, this Court has specific personal jurisdiction over Natco Ltd. These activities satisfy due process and confer personal jurisdiction over Natco Ltd. consistent with the Delaware Long Arm Statute.

23. On information and belief, Natco Ltd., directly and/or through its Delaware subsidiary, Natco Inc., caused tortious injury in Delaware to Plaintiff Gilead Sciences Inc. a Delaware corporation, by filing ANDA No. 202-595, further supporting specific and/or general jurisdiction over Natco Ltd. and Natco Inc.

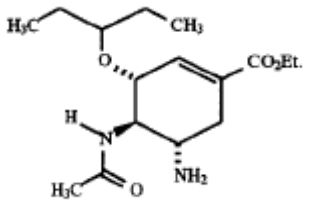
24. Venue is proper in this district under 28 U.S.C. §§ 1391(b), (c) and 1400(b).

BACKGROUND

25. Hoffmann-La Roche Inc. is the holder of New Drug Application ("NDA") No. 21-087 which relates to *inter alia*, capsules containing 75 mg of oseltamivir phosphate formulated as the Tamiflu® brand for the treatment of uncomplicated acute illness due to influenza infection in patients one year or older who have been symptomatic for no more than two days and for the prophylaxis of influenza in patients one year or older. On October 27, 1999, the FDA approved plaintiffs' Tamiflu® oseltamivir phosphate 75 mg drug product for marketing in the United States pursuant to section 505(b) of the Federal Food, Drug, and Cosmetics Act, ("FFDCA"), 21 U.S.C. § 355(b).

26. Gilead Sciences, Inc. is the owner of the ‘483 Patent, (copy attached as Exhibit A), entitled “ Carbocyclic Compounds,” which is duly and legally issued by the United States Patent and Trademark Office on June 9, 1998.

27. The ‘483 Patent claims a compound having the following chemical structure:



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which is the active ingredient in the Tamiflu® product described in NDA No. 21-087, as well as methods for the treatment or prophylaxis of influenza infection using such a compound.

28. The ’483 Patent expires on December 27, 2016, with an extension to June 27, 2017 due to pediatric exclusivity, as reflected in the Orange Book.

29. Hoffmann-La Roche Inc., F. Hoffmann-La Roche Ltd and Genentech, Inc. are the exclusive licensees of the ‘483 Patent.

30. This action arises because of Natco’s efforts to gain approval from the FDA to market generic copies of Plaintiffs’ Tamiflu® oseltamivir phosphate 75 mg drug product prior to the expiration of patent rights covering same.

31. With 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 lists the patent information in a publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly referred to as the "Orange Book").

32. Plaintiffs submitted patent information to the FDA in connection with NDA No. 21-087 Tamiflu® oseltamivir phosphate drug products, and the FDA has published the same for the 75 mg dosage form in the Orange Book.

33. 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 as the innovator. 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 has published in the Orange book for the reference drug and make a statutory certification (commonly called a "patent certification") with respect to each listed patent.

34. The generic drug company may, *inter alia*, state that it does not seek FDA approval to market its generic drug product prior to patent expiration (a "Paragraph III certification"). *See* 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 one or more patents listed in the Orange Book is "invalid or will not be infringed" (commonly called a "Paragraph IV certification"). 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

35. The ’483 Patent, identified in paragraph 1 of this Complaint, 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).

36. On information and belief, Natco filed ANDA No. 202-595 with the FDA seeking approval to market a generic copy of Plaintiffs’ Tamiflu® 75 mg oseltamivir phosphate drug product prior to expiration of the ’483 Patent.

37. On or about February 2, 2011, Dr. A.K.S. Bhujanga Rao, President-Technical of Natco Pharma Ltd., sent to Plantiffs’ a letter purporting to be a notice of Natco’s filing of an ANDA seeking to market a generic copy of Plaintiffs’ Tamiflu® 75 mg oseltamivir phosphate drug product that allegedly contained the Paragraph IV certification required by 21 U.S.C. § 355(j)(2)(B)(ii) with respect to the ’483 Patent listed in the Orange Book for Tamiflu® (“Paragraph IV Notice”).

38. In particular, Natco’s Paragraph IV Notice states that Natco is seeking FDA approval to market a generic copy of the Tamiflu® 75 mg oseltamivir phosphate drug product prior to expiration of the ’483 Patent listed in the Orange Book for Tamiflu®. Notwithstanding the United States Patent and Trademark Office’s grant of patent protection, in its Paragraph IV Notice, Natco asserts that the ’483 Patent is invalid, unenforceable, and/or would not be infringed by its proposed generic products.

39. Natco’s efforts to seek FDA approval to market a generic copy of Plaintiffs’ Tamiflu® 75 mg oseltamivir phosphate drug product prior to expiration of the ’483 Patent constitute acts of infringement pursuant to 21 U.S.C. § 271(e)(2) and, thus, create a

justiciable controversy between the parties with respect to the subject matter of Natco's ANDA and the '483 Patent which has been challenged in Natco's Paragraph IV Notice.

Count 1: Infringement under 35 U.S.C. § 271(e)(2)

40. Plaintiffs incorporate by reference paragraphs 1-39 of this Complaint as if fully set forth herein.

41. On information and belief, Natco Ltd. and Natco Inc. acting jointly, filed ANDA No. 202-595 in order to obtain approval to market Natco's generic copy of Plaintiffs' Tamiflu® oseltamivir phosphate drug product in the United States before the expiration of the '483 Patent. On information and belief, Natco Ltd. and Natco Inc. acting jointly also filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (Section 505(j)(2)(A)(vii)(IV) of the FFDCA), a certification alleging that the claims of the '483 Patent are invalid and/or will not be infringed by their manufacture, use or sale of a generic copy of Plaintiffs' Tamiflu® 75 mg oseltamivir phosphate drug product.

42. Under 35 U.S.C. § 271(e)(2)(A), Natco's submission to the FDA of ANDA No. 202-595 to obtain approval for the commercial manufacture, use, or sale of Natco's generic copy of Plaintiffs' Tamiflu® 75 mg oseltamivir phosphate drug product before the expiration date of the '483 Patent and any additional periods of exclusivity constitutes infringement of one or more claims of the '483 Patent, either literally or under the doctrine of equivalents.

43. Plaintiffs will be irreparably harmed by Natco's infringing activities unless such activities are enjoined by the Court as Plaintiffs do not have an adequate remedy at law. Plaintiffs are entitled to relief provided by 35 U.S.C. § 271(e)(4), including *inter alia*, an

order by this Court that the effective date of any FDA approval of Natco's ANDA shall be no earlier than the expiration date of the '483 Patent and any additional periods of exclusivity.

Count 2: Infringement under 35 U.S.C. §§ 271(a)(b) and/or (c)

44. Plaintiffs incorporate by reference paragraphs 1-43 of this Complaint as if fully set forth herein.

45. On information and belief, Natco Ltd. and Natco Inc. acted in concert to jointly submit ANDA No. 202-595 in order to obtain approval to engage in the commercial manufacture, use or sale of a generic copy of Plaintiffs' Tamiflu® 75 mg oseltamivir phosphate drug product in the United States before the expiration date of the '483 Patent and any additional periods of exclusivity.

46. On information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of a generic copy of Plaintiffs' Tamiflu® 75 mg oseltamivir phosphate drug product will infringe the '483 Patent under 35 U.S.C. §§ 271(a)(b) and/or (c).

47. Upon FDA approval of Natco's ANDA No. 202-595, Natco will directly infringe one or more claims of the '483 Patent, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing Natco's generic copy of Plaintiffs' Tamiflu® 75 mg. oseltamivir phosphate drug product in the United States, and by actively inducing and contributing to infringement by others under 35 U.S.C. §§ 271(b) and (c), unless this Court orders that the effective date of any FDA approval of Natco's ANDA shall be no earlier than the expiration date of the '483 Patent and any additional periods of exclusivity.

48. On information and belief, Natco's oseltamivir phosphate capsules, 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 ’483 Patent, either literally or under the doctrine of equivalents.

49. On information and belief, the use of Natco’s oseltamivir phosphate capsules constitutes a material part of at least one of the claims of the ’483 Patent; Natco knows that its oseltamivir phosphate capsules are especially made or adapted for use in infringing at least one of the claims of the ’483 Patent, either literally or under the doctrine of equivalents; and Natco ’s oseltamivir phosphate capsules are not staple articles of commerce or commodities of commerce suitable for substantial noninfringing use.

50. On information and belief, the offering to sell, sale, and/or importation of Natco’s oseltamivir phosphate capsules would contributorily infringe at least one of the claims of the ’483 Patent, either literally or under the doctrine of equivalents.

51. On information and belief, Natco had knowledge of the ’483 Patent and knows or should know that it will aid and abet another’s direct infringement of at least one of the claims of the ’483 Patent, either literally or under the doctrine of equivalents.

52. On information and belief, the offering to sell, sale, and/or importation of Natco’s oseltamivir phosphate capsules would actively induce infringement of at least one of the claims of the ’483 Patent, either literally or under the doctrine of equivalents.

53. Plaintiffs will be substantially and irreparably harmed by Natco’s infringing activities unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

RELIEF SOUGHT

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in its favor as follows:

A) a judgment that Natco has infringed the ’483 Patent under 21 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 202-595 with a Paragraph IV certification seeking to market its generic copy of Tamiflu® oseltamivir phosphate drug product prior to the expiration date of said patent and any additional periods of exclusivity;

B) a judgment and decree that the ’483 Patent is valid and enforceable;

C) an Order pursuant to 21 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of Natco’s ANDA No. 202-595 be a date that is not earlier than the expiration date of the ’483 Patent and any additional periods of exclusivity;

D) a judgment that Natco would infringe and induce infringement of the ‘483 Patent upon marketing its generic copies of Tamiflu® oseltamivir phosphate drug product prior to the expiration date of said patent and any additional periods of exclusivity;

E) a judgment declaring that if Natco, its 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, and/or importation of Natco’s generic copy of Tamiflu® oseltamivir phosphate drug product prior to the expiration date the ’483 Patent and any additional periods of exclusivity; it will constitute acts of infringement of the ’483 Patent under 35 U.S.C. §§ 271(a)(b) and/or (c);

F) a permanent injunction pursuant to 35 U.S.C. § 271(e)(4)(B) restraining and enjoining Natco 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 copy of Tamiflu® oseltamivir phosphate drug product and any other drug product that infringes

or induces or contributes to the infringement of the '483 Patent prior to the expiration date of the '483 Patent and any additional periods of exclusivity;

G) a judgment that this is an exceptional case and that Plaintiffs are entitled to an award of attorneys fees from Natco under 35 U.S.C. § 285; and

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

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Maryellen Noreika

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