IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

WARNER CHILCOTT COMPANY, LLC and HOFFMANN-LA ROCHE INC., Plaintiffs, v. MYLAN PHARMACEUTICALS, INC., Defendant.	C. A. No. _____

COMPLAINT

Plaintiffs Warner Chilcott Company, LLC ("WCCLLC") and Hoffmann-La Roche Inc. ("Roche"), by their attorneys, hereby allege as follows:

Nature of the Action

This is an action for patent infringement of U.S. Patent No. 7,192,938 (the "'938 Patent"), arising under the patent laws of the United States, Title 35, United States Code, §§ 271 and 281. This action relates to an Abbreviated New Drug Application ("ANDA"), No. 200477 filed by Mylan Pharmaceuticals Inc. ("Mylan") with the U.S. Food and Drug Administration ("FDA") for approval to market 150 mg risedronate sodium tablets ("Mylan 150 mg Risedronate Sodium Tablets"), which are a generic version of a 150 mg form of WCCLLC's ACTONEL® drug product ("Once-a-Month ACTONEL®").

Related Actions

This action is related to three patent infringement actions currently pending before this Court: (1) *The Procter & Gamble Co. and Hoffmann-La Roche Inc. v. Teva Pharmaceuticals*

U.S.A., Inc. (C.A. No. 08-627-JJF) (the "Teva Action"), involving the '938 Patent (and two other patents); (2) *The Procter & Gamble Co. and Hoffmann-La Roche Inc. v. Sun Pharma Global, Inc.* (C.A. No. 09-61-GMS) (the "Sun Action"), also involving the '938 Patent; and (3) *The Procter & Gamble Co. and Hoffmann-La Roche Inc. v. Apotex, Inc. and Apotex Corp.* (C.A. No. 09-143-JJF) (the "Apotex Action"), also involving the '938 Patent. The Teva Action, the Sun Action, and the Apotex Action also arise under 35 U.S.C. §§ 271 and 281 and relate to ANDAs filed by those entities for approval to market generic versions of Once-a-Month ACTONEL®.

The present action further relates to several actions for infringement of the '938 Patent (and other patents) pending before Judge Stanley Chesler in the United States District Court for the District of New Jersey: *Hoffmann-La Roche Inc. v. Apotex, Inc., et al.*, Civ. No. 2:07-4417 (SRC)(MAS), *Hoffmann-La Roche Inc. v. Apotex, Inc., et al.*, Civ. No. 2:08-3065 (SRC)(MAS), *Hoffmann-La Roche Inc. v. Apotex, Inc., et al.*, Civ. No. 2:08-4053 (SRC)(MAS), *Hoffmann-La Roche Inc. v. Cobalt Pharmaceuticals Inc., et al.*, Civ. No. 2:07-4539 (SRC)(MAS), *Hoffmann-La Roche Inc. v. Cobalt Pharmaceuticals Inc., et al.*, Civ. No. 2:07-4540 (SRC)(MAS), *Hoffmann-La Roche Inc. v. Cobalt Pharmaceuticals Inc., et al.*, Civ. No. 2:08-4054 (SRC)(MAS), *Hoffmann-La Roche Inc. v. Dr. Reddy's Laboratories, Ltd., et al.*, Civ. No. 2:07-4516 (SRC)(MAS), *Hoffmann-La Roche Inc. v. Dr. Reddy's Laboratories, Ltd., et al.*, Civ. No. 2:08-3607 (SRC)(MAS), *Hoffmann-La Roche Inc. v. Dr. Reddy's Laboratories, Ltd., et al.*, Civ. No. 2:08-4055 (SRC)(MAS), *Hoffmann-La Roche Inc. v. Genpharm Inc., et al.*, Civ. No. 2:07-4661 (SRC)(MAS), *Hoffmann-La Roche Inc. v. Genpharm Inc., et al.*, Civ. No. 2:08-4052 (SRC)(MAS), *Hoffmann-La Roche Inc. v. Orchid Chemicals et al.*, Civ. No. 2:07-4582 (SRC)(MAS), and *Hoffmann-La Roche Inc. v. Orchid Chemicals et al.*, Civ. No. 2:08-4051 (SRC)(MAS) (collectively, the "New Jersey Boniva Actions"). Each of the New Jersey Boniva

Actions pertains to ANDAs filed by the defendants in those actions for approval to market generic versions of Boniva® Once-Monthly.

Parties

1. Plaintiff WCCLLC is a corporation organized and existing under the laws of Puerto Rico, having offices at Union St., Road 195, Km 1.1, Fajardo, Puerto Rico.

2. Plaintiff Roche is a corporation 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. Upon information and belief, Defendant Mylan is a corporation organized and existing under the laws of the state of West Virginia, having an office and place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505.

Jurisdiction and Venue

4. This action arises under the patent laws of the United States of America, and this Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 1400(b), 2201, and 2202.

5. This court has personal jurisdiction over Mylan because, *inter alia*, upon information and belief, it has committed, or aided, abetted, contributed to, or participated in the commission of a tortious act of patent infringement in filing ANDA No. 200477, which has led to foreseeable harm to WCCLLC and Roche, both corporations actively engaged in business in Delaware.

6. This court also has personal jurisdiction over Mylan by virtue of, *inter alia*, its systematic and continuous contacts with Delaware as set forth below.

7. Upon information and belief, Mylan manufactures numerous generic pharmaceutical products and sells these products throughout the United States, including in the State of Delaware.

8. Upon information and belief, Mylan regularly does business in the State of Delaware and has engaged in a persistent course of conduct within the State of Delaware by continuously and systematically placing goods into the stream of commerce for distribution throughout the United States, including the State of Delaware, and/or by selling pharmaceutical products in the State of Delaware.

9. Upon information and belief, Mylan admitted that "pharmacists [have] filled prescriptions in the State of Delaware with drug products from Mylan Pharmaceuticals."

10. Upon information and belief, Mylan, under its "Mylan Pharmaceuticals" trade name, is registered, under 24 *Del. C.* § 2540, to distribute its generic pharmaceutical products in the State of Delaware and holds current and valid "Distributor/Manufacturer CSR" and "Pharmacy-Wholesale" licenses from the Delaware Board of Pharmacy.

11. Upon information and belief, Mylan has previously availed itself of this forum for the purpose of litigating its patent disputes. For example, in 2002, Mylan filed a patent infringement lawsuit in *Mylan Pharmaceuticals Inc. v. Kremers Development Company et al.*, C.A. No. 02-1628 (D. Del.). Mylan has also submitted to this Court's jurisdiction by asserting counterclaims in other civil actions in this jurisdiction. Specifically, Mylan admitted jurisdiction (for the purpose of the litigation) and filed counterclaims in *Forest Laboratories, Inc. et al. v. Dr. Reddy's Laboratories, Inc., et al.*, C.A. No. 08-52 (D. Del.); *AstraZeneca Pharmaceuticals LP, et al. v. Mylan Pharmaceuticals, Inc.* C.A. No. 07-805 (D. Del.); *Sciele Pharmaceuticals v. Mylan Pharmaceuticals Inc.*, C.A. No. 07-664 (D. Del.); *Sanofi-Aventis, et al. v. Actavis, et al.*, C.A.

No. 07-572 (D. Del.); *Boehringer Ingelheim International GMBH, et al. v. Mylan Pharmaceuticals Inc., et al.*, C.A. No. 05-854 (D. Del.); *Janssen Pharmaceuticals N.V., et al., v. Mylan Pharmaceuticals Inc., et al.*, C.A. No. 05-371 (D. Del.); and *AstraZeneca LP, et al. v. Mylan Pharmaceuticals Inc.*, C.A. No. 08-453 (D. Del.).

12. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

The '938 Patent

13. Roche is the owner by assignment of the '938 patent, co-exclusively licensed to WCCLLC and entitled "Method of Treatment Using Bisphosphonic Acid," which the United States Patent and Trademark Office duly and legally issued on March 20, 2007. A true and correct copy of the patent is attached hereto as Exhibit A. The claims of the '938 Patent are valid and enforceable. Roche owns all right and title to the '938 Patent, except as licensed to WCCLLC, and has the right to sue for and obtain equitable relief and damages for infringement. Under WCCLLC's license, WCCLLC has the right to sue for and obtain equitable relief and damages for infringement of the '938 Patent.

14. The FDA-approved dosing regimen for Once-a-Month Actonel® is covered by certain claims of the '938 Patent. The 150 mg commercial formulation of risedronate sodium was approved by the FDA on April 22, 2008 and is manufactured and sold by WCCLLC as Once-a-Month Actonel®. The FDA's official publication of approved drugs (the "Orange Book") includes Actonel® in its 150 mg dosage form listed together with the '938 Patent.

Infringement by Mylan

15. By letter dated February 23, 2010 (the "Mylan Notice Letter"), Mylan notified WCCLLC and Roche that Mylan had submitted ANDA No. 200477 to the FDA under Section

505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), seeking approval to engage in the commercial manufacture, use, and sale of the Mylan 150 mg Risedronate Sodium Tablets, a generic version of FDA-approved Once-a-Month ACTONEL®, before the expiration date of the '938 Patent. Upon information and belief, Mylan intends to engage in commercial manufacture, use, and sale of the Mylan 150 mg Risedronate Sodium Tablets promptly upon receiving FDA approval to do so.

16. By filing ANDA No. 200477, Mylan has necessarily represented to the FDA that the components of the Mylan 150 mg Risedronate Sodium Tablets have the same active ingredients as those of the corresponding components of the Once-a-Month ACTONEL®, have the same route of administration, dosage form, and strengths as the corresponding components of Once-a-Month ACTONEL®, are bioequivalent to the corresponding components of the Once-a-Month ACTONEL®, and that Mylan 150 mg Risedronate Sodium Tablets have substantially the same proposed labeling as Once-a-Month ACTONEL®.

17. In the Mylan Notice Letter, Mylan notified WCCLLC and Roche that its ANDA contained a "Paragraph IV certification" asserting that, in Mylan's opinion, the commercial, manufacture, use or sale of Mylan 150 mg Risedronate Sodium Tablets will not infringe any valid and enforceable claim of the '938 Patent.

18. This complaint is being filed before the expiration of forty-five days from the date WCCLLC and Roche received the Mylan Notice Letter.

Count I

19. Each of the preceding paragraphs 1 to 18 is incorporated as if fully set forth herein.

20. Mylan's submission of ANDA No. 200477 to obtain approval to engage in the commercial manufacture, use, offer to sell, sale, or importation of Mylan 150 mg Risedronate Sodium Tablets in the United States prior to the expiration of the '938 Patent constitutes infringement of one or more of the valid claims of the '938 Patent under 35 U.S.C. § 271(e)(2)(A).

21. Upon FDA approval of Mylan's ANDA No. 200477, Mylan will further infringe the '938 Patent by making, using, offering to sell, and selling in the United States, or importing into the United States, Mylan 150 mg Risedronate Sodium Tablets in the United States, and by actively inducing and contributing to infringement by others, in violation of 35 U.S.C. § 271(a)-(c) unless enjoined by this Court.

22. If Mylan's infringement of the '938 Patent is not enjoined, WCCLLC and Roche will suffer substantial and irreparable harm for which there is no adequate remedy at law.

Prayer for Relief

WHEREFORE, WCCLLC and Roche pray that this Court grant the following relief:

a. A declaration that the '938 Patent is valid and enforceable;

b. A judgment that the Mylan 150 mg Risedronate Sodium Tablets infringe one or more claims of the '938 Patent, that Mylan's submission of its ANDA No. 200477 is an act of infringement, and that Mylan's making, using, offering to sell, or selling in the United States, or importing into the United States, Mylan 150 mg Risedronate Sodium Tablets will infringe the '938 Patent;

c. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of Mylan's ANDA No. 200477 shall be a date that is not earlier than the latest expiration date of the '938 Patent;

d. An Order permanently enjoining Mylan, and its affiliates and subsidiaries, and each of their officers, agents, servants and employees, from making, using, offering to sell, or selling in the United States, or importing into the United States, Mylan 150 mg Risedronate Sodium Tablets until after the expiration date of the '938 Patent;

e. Damages or other monetary relief to WCCLLC and Roche if Mylan engages in the commercial manufacture, use, offer to sell, sale, or importation of the Mylan 150 mg Risedronate Sodium Tablets prior to the expiration of the '938 Patent;

f. Reasonable costs of suit incurred by WCCLLC and Roche in this action; and

g. Such further and other relief as this Court deems proper and just.

/s/ Steven J. Fineman

Frederick L. Cottrell III (2555)
Cottrell@rlf.com
Steven J. Fineman (4025)
Fineman@rlf.com
Laura D. Hatcher (#5098)
Hatcher@rlf.com
Richards Layton & Finger, P.A.
P.O. Box 551
One Rodney Square
Wilmington, DE 19899-0551
(302) 651-7700

Attorneys for Warner Chilcott Company, LLC and Hoffmann-La Roche Inc.

OF COUNSEL:

William F. Lee
Vinita Ferrera
Allen C. Nunnally
Wilmer Cutler Pickering Hale and Dorr LLP
60 State Street
Boston, Massachusetts 02109
(617) 526-6000

David B. Bassett
Wilmer Cutler Pickering Hale and Dorr LLP
399 Park Avenue
New York, New York 10022
(212) 230-8800

Attorneys for Warner Chilcott Company, LLC

Mark E. Waddell, Esq.
Loeb & Loeb LLP
345 Park Avenue
New York, New York 10154-1895
(212) 407-4000

Attorneys for Hoffmann-La Roche Inc.

Dated: April 8, 2010