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.	Civil Action No. _____

COMPLAINT

Plaintiffs Warner Chilcott Company, LLC ("Warner Chilcott") 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. 7,718,634 (the "'634 Patent"), arising under the patent laws of the United States, Title 35, United States Code, 35 U.S.C. §§ 271 and 281. This action relates to an amended Abbreviated New Drug Application ("ANDA") filed by Mylan Pharmaceuticals, Inc. ("Mylan") (ANDA No. 200477) 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 Warner Chilcott's ACTONEL® drug product ("Once-a-Month ACTONEL®").

Related Actions

This action is related to four patent infringement actions currently pending before this Court in which U.S. Patent No. 7,192,938 ("the '938 Patent") is asserted: (1) *The Procter & Gamble Co. and Hoffmann-La Roche Inc. v. Teva Pharmaceuticals U.S.A., Inc.* (C.A. No. 08-627-LPS) (the "Teva '938 Action"); (2) *The Procter & Gamble Co. and Hoffmann-La Roche Inc.*

v. Sun Pharma Global, Inc. (C.A. No. 09-61-LPS) (the "Sun '938 Action"); (3) *The Procter & Gamble Co. and Hoffmann-La Roche Inc. v. Apotex, Inc. and Apotex Corp.* (C.A. No. 09-143-LPS) (the "Apotex '938 Action"); and (4) *Warner Chilcott Company, LLC and Hoffmann-La Roche Inc. v. Mylan Pharmaceuticals Inc.* (C.A. No. 10-285-LPS) (the "Mylan '938 Action").

This action is also related to three other patent infringement actions currently pending before this Court in which the '634 Patent is asserted: (1) *Warner Chilcott Company, LLC and Hoffmann-La Roche Inc. v. Sun Pharma Global, Inc.* (C.A. No. 10-1085-LPS) (the "Sun '634 Action"); (2) W*arner Chilcott Company, LLC and Hoffmann-La Roche Inc. v. Apotex, Inc. and Apotex Corp.* (C.A. No. 10-1111-LPS) (the "Apotex '634 Action"); and (3) *Warner Chilcott Company, LLC and Hoffmann-La Roche Inc. v. Teva Pharmaceuticals U.S.A., Inc.* (C.A. No. 11-81-LPS) (the "Teva '634 Action").

The Teva '938 Action, the Sun '938 Action, the Apotex '938 Action, the Mylan '938 Action, the Sun '634 Action, the Apotex '634 Action, and the Teva '634 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 Mylan '938 Action relates to Mylan's ANDA 200477, which is the same ANDA implicated in this action. The Teva '938 Action, the Sun '938 Action, the Apotex '938 Action, and the Mylan '938 Action have been consolidated for all pre-trial purposes.

Parties

1. Plaintiff Warner Chilcott Company, LLC 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 Hoffmann-La Roche Inc. 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 Warner Chilcott 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. Mylan has submitted to this Court's jurisdiction without objection in the Mylan '938 Action.

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

Once-a-Month ACTONEL®

14. The 150 mg commercial formulation of risedronate sodium known as "Once-a-Month ACTONEL®" is manufactured, marketed, and sold by Warner Chilcott. Once-a-Month ACTONEL® (150 mg) was approved by the FDA on April 22, 2008.

The '634 Patent

15. Roche is the owner by assignment of the '634 Patent entitled "Method of Treatment Using Bisphosphonic Acid," which the United States Patent and Trademark Office duly and legally issued on May 18, 2010. A true and correct copy of the '634 Patent is attached hereto as Exhibit A. The claims of the '634 Patent are valid and enforceable. The '634 Patent expires on May 6, 2023.

16. The FDA-approved dosing regimen for Once-a-Month Actonel® is covered by certain claims of the '634 Patent. The FDA's official publication of approved drugs (the "Orange Book") includes Actonel® in its 150 mg dosage form listed together with the '634 Patent.

17. Roche is the assignee of the '634 Patent and has all rights needed to bring this action in Roche's name except as licensed to Warner Chilcott, and has the right to sue for and obtain equitable relief and damages for infringement; under Warner Chilcott's license, Warner Chilcott has the right to sue for and obtain equitable relief and damages for infringement of the '634 Patent.

Infringement by Mylan

18. By letter dated February 23, 2010 ("First Mylan Notice Letter"), Mylan notified Warner Chilcott 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 Roche's U.S. Patent No. 7,192,938, which is related to the '634 Patent.

19. By letter dated February 24, 2011 ("Second Mylan Notice Letter"), Mylan notified Warner Chilcott and Roche that its ANDA No. 200477 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 '634 Patent.

20. 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 Once-a-Month ACTONEL®, and that Mylan 150 mg Risedronate Sodium Tablets have substantially the same proposed labeling as Once-a-Month ACTONEL®. 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.

21. This complaint is being filed before the expiration of forty-five days from the date Warner Chilcott and Roche received the Second Mylan Notice Letter.

Count I

22. Each of the preceding paragraphs 1 to 21 is incorporated as if fully set forth.

23. Mylan's submission of ANDA No. 200477 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of Mylan 150 mg Risedronate Sodium Tablets prior to the expiration of the '634 Patent constitutes infringement of one or more of the valid claims of the '634 Patent under 35 U.S.C. § 271(e)(2)(A).

24. Upon FDA approval of Mylan's ANDA No. 200477, Mylan will further infringe, directly or indirectly, the '634 Patent by making, using, offering to sell, and selling 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.

25. If Mylan's infringement of the '634 patent is not enjoined, Warner Chilcott and Roche will suffer substantial and irreparable harm for which there is no adequate remedy at law.

Prayer for Relief

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

(a) A declaration that the '634 Patent is valid and enforceable;

(b) A judgment that Mylan infringed the '634 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 200477 with a Paragraph IV Certification seeking to market the Mylan 150 mg Risedronate Sodium Tablets prior to the expiration of the '634 patent;

(c) An Order pursuant to 35 U.S.C. § 271(e)(4) providing that the effective date of any FDA approval of Mylan's ANDA No. 200477 shall be a date that is not earlier than the expiration date of the '634 Patent;

(d) A judgment that Mylan would infringe, either directly or indirectly, the '634 Patent upon marketing of the Mylan 150 mg Risedronate Sodium Tablets after grant of FDA approval and during the unexpired term of the '634 Patent;

(e) An Order permanently enjoining Mylan, and its affiliates and subsidiaries, and each of their officers, agents, servants and employees and those persons in active concert or participation with any of them, from making, using, offering to sell, selling within the United States, or importing into the United States Mylan 150 mg Risedronate Sodium Tablets until after the expiration date of the '634 Patent;

(f) Damages or other monetary relief to Warner Chilcott 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 '634 Patent;

(g) Reasonable costs of suit incurred by Warner Chilcott and Roche in this action; and

(h) Such further and other relief as this Court deems proper and just.

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