

IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

_____	)	
WARNER CHILCOTT COMPANY, LLC	)	
	)	
and	)	
	)	
HOFFMANN-LA ROCHE INC.,	)	
	)	
Plaintiffs,	)	
v.	)	Civil Action No. 1:10-CV-59
	)	
	)	
MYLAN PHARMACEUTICALS INC.,	)	
	)	
Defendant.	)	
_____	)	

**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 relates to an identical patent infringement action pending before the United States District Court for the District of Delaware, *Warner Chilcott Company, LLC and Hoffmann-La Roche Inc. v. Mylan Pharmaceuticals, Inc.* (Civil Action No. 10-285) (the “Delaware Mylan Action”), pertaining to ANDA No. 200477 filed by Mylan for approval to approval to market a generic version of Once-a-Month ACTONEL®. The Delaware Mylan Action was filed on April 8, 2010 and has not yet been assigned.

The present action also relates to three other actions pending in the United States District Court for the District of Delaware: (1) *The Procter & Gamble Co. and Hoffmann-La Roche Inc. v. Teva Pharmaceuticals U.S.A., Inc.* (C.A. No. 08-627-JJF) (the “Delaware 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 “Delaware 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 “Delaware Apotex Action”), also involving the ‘938 Patent. The Delaware Teva Action, the Delaware Sun Action, and the Delaware 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 Defendant Mylan by virtue of the fact that, *inter alia*, Mylan is a West Virginia corporation.

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

**The '938 Patent**

7. 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.

8. 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**

9. 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.

10. 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®.

11. 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.

12. 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**

13. Each of the preceding paragraphs 1 to 12 is incorporated as if fully set forth herein.

14. 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).

15. 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.

16. 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.

Respectfully submitted,

OF COUNSEL:

Attorneys for:  
WARNER CHILCOTT COMPANY, LLC

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 (*pro hac vice* application  
pending)  
Wilmer Cutler Pickering Hale and Dorr LLP  
399 Park Avenue  
New York, New York 10022  
(212) 230-8800

Attorney for:  
HOFFMANN- LA ROCHE INC.

Mark E. Waddell, Esq. (*pro hac vice*  
application pending)  
Loeb & Loeb LLP  
345 Park Avenue  
New York, New York 10154-1895  
Telephone No.: (212) 407-4000  
Facsimile No.: (212) 407-4990

Dated: April 9, 2010

/s/ Frank E. Simmerman, Jr.

Frank E. Simmerman, Jr. (WVSB# 3403)  
Chad L. Taylor (WVSB#10564)  
Simmerman Law Office, PLLC  
254 East Main Street  
Clarksburg, WV 26301-2170  
Telephone: 304-623-4900

Attorneys for:  
WARNER CHILCOTT COMPANY, LLC and  
HOFFMANN-LA ROCHE INC.