

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

_____ )		
WARNER CHILCOTT COMPANY, LLC and )	)	
HOFFMANN-LA ROCHE INC., )	)	
	)	
Plaintiffs, )	)	Civil Action No. _____
	)	
v. )	)	
	)	
SUN PHARMA GLOBAL, INC. )	)	
	)	
Defendant. )	)	
_____ )	)	

**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 Sun Pharma Global, Inc. (“Sun”) (ANDA No. 90-886) with the U.S. Food and Drug Administration (“FDA”) for approval to market 150 mg risedronate sodium tablets (“Sun 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 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 Action”); and (4) *Warner Chilcott Company, LLC and Hoffmann-La Roche Inc. v. Mylan Pharmaceuticals, Inc.* (C.A. No. 10-285-LPS) (the “Mylan Action”). The Teva Action, the Sun ‘938 Action, the Apotex Action, and the Mylan 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 Sun ‘938 Action relates to Sun’s ANDA 90-886, which is the same ANDA implicated in this action. The Teva Action, the Sun ‘938 Action, the Apotex Action, and the Mylan 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, Sun Pharma Global, Inc. is a corporation organized and existing under the laws of the British Virgin Islands, having a place of business in Town Tortola, British Virgin Islands, and is a wholly owned subsidiary of Sun Pharmaceutical Industries, Ltd. (a corporation organized and existing under the laws of India, having a principle place of business in Mumbai, India).

**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 Sun by virtue of, *inter alia*, its systematic and continuous contacts with Delaware, including through its parent corporation, Sun Pharmaceutical Industries, Ltd.

6. This Court also has personal jurisdiction over Sun because it has committed an act of patent infringement in filing ANDA No. 90-886 that has led to foreseeable harm and injury to two corporations actively engaged in business in Delaware, Warner Chilcott and Roche.

7. In addition, Sun has previously admitted that this Court has personal jurisdiction over it in *Sanofi-Aventis, et al. v. Sun Pharmaceutical Industries, Ltd. et al.* (C.A. No. 08-350-GMS).

8. Sun has submitted to this Court's jurisdiction without objection in the related Sun '938 Action.

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

**Once-a-Month ACTONEL®**

10. 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**

11. 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.

12. 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.

13. 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 Sun**

14. By letter dated December 12, 2008 ("First Sun Notice Letter"), Sun notified The Procter & Gamble Co. ("P&G")<sup>1</sup> and Roche that Sun had submitted ANDA No. 90-886 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 Sun 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, the parent to the '634 Patent.

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<sup>1</sup> Once-a-Month ACTONEL® was originally developed, manufactured, marketed, and sold by P&G, the original NDA holder, prior to the sale of P&G's pharmaceutical business in 2009 to Warner Chilcott.

15. By letter dated October 27, 2010 (“Second Sun Notice Letter”), Sun notified Warner Chilcott and Roche that its ANDA No. 90-886 contained a “Paragraph IV certification” asserting that, in Sun’s opinion, the commercial manufacture, use or sale of Sun 150 mg Risedronate Sodium Tablets will not infringe any valid and enforceable claim of the ‘634 Patent.

16. By filing ANDA No. 90-886, Sun has necessarily represented to the FDA that the components of the Sun 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 Sun 150 mg Risedronate Sodium Tablets have substantially the same proposed labeling as Once-a-Month ACTONEL®. Upon information and belief, Sun intends to engage in commercial manufacture, use, and sale of the Sun 150 mg Risedronate Sodium Tablets promptly upon receiving FDA approval to do so.

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

### **Count I**

18. Each of the preceding paragraphs 1 to 15 is incorporated as if fully set forth.

19. Sun’s submission of ANDA No. 90-886 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of Sun 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).

20. Upon FDA approval of Sun’s ANDA No. 90-886, Sun will further infringe, directly or indirectly, the ‘634 Patent by making, using, offering to sell, and selling Sun 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.

21. If Sun'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 Sun infringed the '634 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 90-886 with a Paragraph IV Certification seeking to market the Sun 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 Sun's ANDA No. 90-886 shall be a date that is not earlier than the expiration date of the '634 Patent;
- (d) A judgment that Sun would infringe, either directly or indirectly, the '634 Patent upon marketing of the Sun 150 mg Risedronate Sodium Tablets after grant of FDA approval and during the unexpired term of the '634 Patent;
- (e) An Order permanently enjoining Sun, 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 Sun 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 Sun engages in the commercial manufacture, use, offer to sell, sale, or importation of the Sun 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

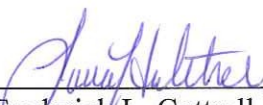
(h) Such further and other relief as this Court deems proper and just.

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Dated: December 10, 2010