UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MICHIGAN

THE PROCTER & GAMBLE COMPANY and HOFFMANN-LA ROCHE INC., Plaintiffs, v. SUN PHARMA GLOBAL, INC., Defendant.	Civil Action No. _____

COMPLAINT

Plaintiffs The Procter & Gamble Company ("Procter & Gamble") 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 B2 (the "'938 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 Pharma Global") (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 Procter & Gamble's ACTONEL® drug product ("Once-a-Month ACTONEL®").

RELATED ACTIONS

The present action is related to an identical patent infringement action pending before the United States District Court for the District of Delaware, *The Procter & Gamble Co. and Hoffmann-La Roche Inc. v. Teva Pharmaceuticals U.S.A., Inc.* (No. 1:09-cv-00061-UNA) (the "Delaware Sun Action"), pertaining to ANDA No. 90-886 filed by Sun Global Pharma for approval to market a generic version of Once-a-Month ACTONEL®. The Delaware Sun Action was filed on January 26, 2009 and has not yet been assigned. The present action relates also to another action for infringement of the '938 Patent (and two other patents) pending before Judge Joseph Farnan in the United States District Court for the District of Delaware, *The Procter & Gamble Co. and Hoffmann-La Roche Inc. v. Teva Pharmaceuticals U.S.A., Inc.* (C.A. No. 1:08-00627-JJF) (the "Delaware Teva Action"), pertaining to amended ANDA No. 79-215 filed by Teva for approval to market a generic version 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. Teva Pharmaceuticals U.S.A., Inc.* (C.A. No. 2:07-cv-04284-SRC-MAS), *Hoffmann-La Roche Inc. v. Gate Pharmaceuticals* (C.A. No. 2:07-cv-04285-SRC-MAS), *Hoffmann-La Roche Inc. v. Orchid Chemicals & Pharmaceuticals, Ltd.* (C.A. No. 2:07-cv-04582-SRC-MAS), and *Hoffmann-La Roche Inc. v. Genpharm, Inc.* (C.A. No. 2:07-cv-04661-SRC-MAS) (collectively, the "New Jersey Boniva Actions"). Each of the New Jersey Boniva Actions pertains to ANDA's filed by the defendants in those actions for approval to market generic versions of Boniva® Once-Monthly.

PARTIES

1. Procter & Gamble is a corporation organized and existing under the laws of the State of Ohio, with its principal place of business at 1 Procter & Gamble Plaza, Cincinnati, Ohio 45202.

2. 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, Sun Pharma Global 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. Upon information and belief, Caraco Pharmaceutical Laboratories, Ltd. ("Caraco") is a corporation organized and existing under the laws of State of Michigan, having a place of business at 1150 Elijah McCoy Drive, Detroit, MI 48202. Upon information and belief, Sun Pharma Global's parent company, Sun Pharmaceutical Industries Ltd., owns a majority share of Caraco, and Sun Pharma Global owns a significant minority stake in Caraco.

6. Upon information and belief, Sun Pharma Global has numerous contracts with Caraco for the supply, manufacturing, distribution, and marketing of generic drugs throughout the United States. Upon information and belief, Sun Pharma Global has supplied to Caraco

though a technology transfer agreement at least 25 pharmaceutical products that are currently marketed or awaiting FDA approval for marketing in the United States.

7. This Court has personal jurisdiction over Sun Pharma Global by virtue of, *inter alia*, its systematic and continuous contacts with Michigan, including through its extensive contacts with, and ownership of, Caraco. This Court also has personal jurisdiction over Sun Pharma Global 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 Michigan, Procter & Gamble and Roche.

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

THE '938 PATENT

9. Roche is the owner by assignment of the '938 Patent, co-exclusively licensed to Procter & Gamble 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 '938 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 Procter & Gamble, and has the right to sue for and obtain equitable relief and damages for infringement. Under Procter & Gamble's license, Procter & Gamble has the right to sue for and obtain equitable relief and damages for infringement of the '938 Patent. The '938 Patent expires on May 6, 2023.

10. The commercial formulation of risedronate sodium developed, manufactured, and sold by Procter & Gamble is known as "ACTONEL®." The formulation and dosing regimen of Once-a-Month ACTONEL® is covered by certain claims of the '938 Patent. ACTONEL® was approved by the FDA for 150 mg on April 22, 2008. The FDA's official publication of approved

drugs (the "Orange Book") includes ACTONEL® in the above-identified dosage form listed together with the '938 Patent.

INFRINGEMENT BY SUN PHARMA GLOBAL

11. By letter dated December 12, 2008 (the "Sun Notice Letter"), Sun Pharma Global notified Procter & Gamble and Roche that Sun Pharma Global 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 the '938 Patent. Upon information and belief, Sun Pharma Global 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.

12. By filing ANDA No. 90-886, Sun Pharma Global 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®.

13. In the Sun Notice Letter, Sun Pharma Global notified Procter & Gamble and Roche that its ANDA contained a "Paragraph IV certification" asserting that, in Sun Pharma Global'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 '938 Patent.

14. This complaint is being filed before the expiration of forty-five days from the date Procter & Gamble and Roche received the Sun Notice Letter.

COUNT I

15. Each of the preceding paragraphs 1 to 14 is incorporated as if fully set forth.

16. Sun Pharma Global'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 '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).

17. Upon FDA approval of Sun Pharma Global's ANDA No. 90-886, Sun Pharma Global will further infringe the '938 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.

18. If Sun Pharma Global's infringement of the '938 patent is not enjoined, Procter & Gamble and Roche will suffer substantial and irreparable harm for which there is no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Procter & Gamble 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 one or more claims of the '938 Patent is infringed by the Sun 150 mg Risedronate Sodium Tablets, that Sun Pharma Global's submission of its ANDA No. 90-886 is an act of infringement, and that Sun Pharma Global's making, using, offering to sell, selling, or importing Sun 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 Sun Pharma Global's ANDA No. 90-886 shall be a date which is not earlier than the latest expiration date of the '938 Patent;

(d) An Order permanently enjoining Sun Pharma Global, and its affiliates and subsidiaries, and each of their officers, agents, servants and employees, from making, using, offering to sell, selling, or importing Sun 150 mg Risedronate Sodium Tablets until after the expiration date of the '938 Patent;

(e) Damages or other monetary relief to Procter & Gamble and Roche if Sun Pharma Global 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 '938 Patent;

(f) Reasonable costs of suit incurred by Procter & Gamble and Roche in this action; and

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

Respectfully submitted,

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