IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

THE PROCTER & GAMBLE COMPANY and HOFFMANN-LA ROCHE INC., Plaintiffs, v. APOTEX INC. and APOTEX CORP. Defendants.	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 (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 Apotex Inc. (ANDA No. 90-877) with the U.S. Food and Drug Administration ("FDA") for approval to market 150 mg risedronate sodium tablets ("Apotex 150 mg Risedronate Sodium Tablets"), which is a generic version of a 150 mg form of Procter & Gamble's ACTONEL® drug product ("Once-a-Month ACTONEL®").

Related Actions

This action is related to two 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); and (2) *The Procter & Gamble Co. and Hoffmann-La Roche Inc. v. Sun Pharma Global, Inc.* (C.A. No. 09-61-JJF) (the "Sun Action"), also involving the '938 Patent. The Teva Action and the Sun 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 parties in the Teva Action have submitted an agreed-upon scheduling order that has been entered by the Court.

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, Apotex Inc. is a corporation organized and existing under the laws of Ontario, Canada, having a place of business at 150 Signet Drive, Toronto, Ontario, Canada.

4. Upon information and belief, Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida.

5. Apotex Inc. and Apotex Corp. are hereinafter referred to collectively as "Apotex."

Jurisdiction and Venue

6. 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.

7. This Court has personal jurisdiction over each of Apotex Inc. and Apotex Corp. because, *inter alia*, upon information and belief, they each have committed, or aided, abetted, contributed to, or participated in the commission of a tortious act of patent infringement in filing ANDA No. 90-877, that has led to foreseeable harm and injury to Procter & Gamble and Roche, both corporations actively engaged in business in Delaware.

8. This Court also has personal jurisdiction over each of the Defendants by virtue of, *inter alia*, their systematic and continuous contacts with Delaware as set forth below.

9. Upon information and belief, Apotex Inc., itself and through its agent Apotex Corp., manufactures and/or distributes numerous generic drugs, including alendronate, amlodipine, omeprazole, and risperidone, for sale and use throughout the United States, including in the State of Delaware.

10. Upon information and belief, Apotex Corp. is the United States marketing, sales, and distribution agent for Apotex Inc., wherein following FDA approval of an Abbreviated New Drug Application ("ANDA"), Apotex Inc. manufactures and supplies the approved generic drug product to Apotex Corp., which then markets and sells the product throughout the United States, including in the State of Delaware. Apotex Corp. maintains a website at the URL www.apotexcorp.com, at which it represents that: "Apotex Corp. is the US Company that markets the product of Apotex, Inc., the largest Canadian-owned manufacturer of prescription drugs." Upon information and belief, and consistent with its practice with respect to other

generic products, following any FDA approval of ANDA No. 90-877, Apotex Corp. will sell its generic version of Once-A-Month ACTONEL® through Apotex Corp. throughout the United States, including in this judicial district.

11. Apotex Corp. has been a Delaware corporation since 1992, and its registered agent for service of process is The Corporation Trust Company, Corporation Trust Center 1209 Orange Street, Wilmington, Delaware 19801. In addition, Apotex Corp. is registered with the Delaware Board of Pharmacy as a "Distributor/Manufacturer CSR" and "Pharmacy - Wholesale" pursuant to 24 *Del. C.* § 2540.

12. Apotex Inc. and Apotex Corp. have previously admitted that they are subject to personal jurisdiction in this District. *See, e.g., Allergan, Inc. v. Apotex Inc. and Apotex Corp.*, Civil Action No. 1:07-278-GMS (D. Del.).

13. In addition, both Apotex Inc. and Apotex Corp. have availed themsleves of the legal protections of the State of Delaware by filing claims or counterclaims affirmatively seeking relief in other prior actions in this Court, including, *inter alia*, *Torpharm, Inc., Apotex Corp. and Apotex Inc. v. Pfizer Inc. and Warner-Lambert Company*, Civil Action No. 1:03-cv-00990-SLR (D. Del.), *Apotex Inc. v. AstraZeneca Pharmaceuticals LP*, Civil Action No. 1:08-cv-00358-JJF-LPS (D. Del.), and *Aventis-Pharma S.A. and Sanofi-Aventis U.S., LLC v. Apotex Inc. and Apotex Corp.*, Civil Action No. 1:08-cv-496-GMS (D. Del.).

14. This Court has personal jurisdiction over Apotex Inc. by virtue of, *inter alia*, its systematic and continuous contacts with Delaware.

15. This Court has personal jurisdiction over Apotex Corp. by virtue of, *inter alia*, its systematic and continuous contacts with Delaware.

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

The '938 Patent

17. 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.

18. 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. The 150 mg form of ACTONEL® was approved by the FDA 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 Apotex

19. By letter dated January 19, 2009 (the "Apotex Letter"), Apotex notified Procter & Gamble and Roche that Apotex had submitted ANDA No. 90-877 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 Apotex 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, Apotex intends to engage in commercial

manufacture, use, and sale of the Apotex 150 mg Risedronate Sodium Tablets promptly upon receiving FDA approval to do so.

20. By filing ANDA No. 90-877, Apotex has necessarily represented to the FDA that the components of the Apotex 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 Apotex 150 mg Risedronate Sodium Tablets have substantially the same proposed labeling as Once-a-Month ACTONEL®.

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

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

Count I

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

24. Apotex's submission of ANDA No. 90-877 to obtain approval to engage in the commercial manufacture, use, offer to sell, sale, or importation of Apotex 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).

25. Upon FDA approval of Apotex's ANDA No. 90-877, Apotex will further infringe the '938 Patent by making, using, offering to sell, and selling in the United States, or importing into the United States, Apotex 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.

26. If Apotex'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 Apotex 150 mg Risedronate Sodium Tablets, that Apotex's submission of its ANDA No. 90-877 is an act of infringement, and that Apotex's making, using, offering to sell, or selling in the United States, or importing into the United States, Apotex 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 Apotex's ANDA No. 90-877 shall be a date which is not earlier than the latest expiration date of the '938 Patent;

(d) An Order permanently enjoining Apotex, 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 Apotex 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 Apotex engages in the commercial manufacture, use, offer to sell, sale, or importation of the Apotex 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.

OF COUNSEL:

Attorneys for:
THE PROCTER & GAMBLE COMPANY

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

Attorney for:
HOFFMANN LA-ROCHE INC.

Mark E. Waddell, Esq.
Loeb & Loeb LLP
345 Park Avenue
New York, New York 10154-1895
Telephone No.: (212) 407-4000

Dated: March 4, 2009

Frederick L. Cottrell, III (#2555)
cottrell@rlf.com
Steven J. Fineman (#4025)
fineman@rlf.com
Michelle E. Whalen (#5246)
whalen@rlf.com
Richards Layton & Finger, P.A.
920 N. King Street
Rodney Square
Wilmington, DE 19801-0551
(302) 651-7700

Attorneys for
THE PROCTER & GAMBLE COMPANY and HOFFMANN-LA ROCHE INC.