IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

WARNER CHILCOTT COMPANY, LLC and HOFFMANN-LA ROCHE INC., Plaintiffs, v. APOTEX INC. and APOTEX CORP. Defendants.	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 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 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 '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 Action"). This action is also related to another patent infringement action currently pending before this Court in which the '634 Patent is asserted: *Warner Chilcott Company, LLC and Hoffmann-La Roche Inc. v. Sun Pharma Global, Inc.* (C.A. No. 10-1085-UNA) (the "Sun '634 Action"). The Teva Action, the Sun '938 Action, the Apotex '938 Action, the Mylan Action, and the Sun '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 Aotex '938 Action relates to Apotex's ANDA 90-877, which is the same ANDA implicated in this action. The Teva Action, the Sun '938 Action, the Apotex '938 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, Apotex Inc. is a corporation organized and existing under the laws of Canada, having a place of business at 150 Signet Drive, Toronto, Ontario, Canada.

4. Upon information and belief, Apotex Corp. is a subsidiary of Apotex Inc.[1] and 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.

Jurisdiction and Venue

5. 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.

6. Upon information and belief, Apotex Inc. develops and manufactures generic drugs for sale and use in the United States and exports some of its pharmaceutical products for sale in the State of Delaware.

7. Upon information and belief, Apotex Corp. is the United States marketing, sales, and distribution affiliate for Apotex Inc. The web site for Apotex Corp. reports: "Apotex Corp. is the US Company that markets the product of Apotex, Inc., the largest Canadian-owned manufacturer of prescription drugs. Through its sales and marketing headquarters in Weston, Florida and operations center in Indianapolis, Apotex Corp, is committed to providing safe and affordable generic medicines." Apotex Corp. is registered with the Delaware Board of Pharmacy as a "Distributor/Manufacturer CSR" and "Pharmacy - Wholesale" pursuant to Del. Code Ann. tit. 24, §2540.

8. Upon information and belief, Apotex Inc. and Apotex Corp. have maintained continuous and systematic contacts with the State of Delaware, including without limitation through the marketing, sales, and distribution of its pharmaceutical products in Delaware.

9. Upon information and belief, both Apotex Inc. and Apotex Corp. have previously consented to personal jurisdiction in this District as both plaintiffs and defendants.

[1] Apotex Inc. and Apotex Corp. are referenced collectively herein as "Apotex."

10. On information and belief, this Court has personal jurisdiction over Apotex Inc. and Apotex Corp. by virtue of, *inter alia*, the facts alleged in paragraphs 6-9.

11. This Court also has personal jurisdiction over Apotex Inc. because it has committed an act of patent infringement in filing ANDA No. 90-877 that has led to foreseeable harm and injury to two corporations actively engaged in business in Delaware, Warner Chilcott and Roche.

12. Apotex Inc. and Apotex Corp. have submitted to this Court's jurisdiction without objection in the Apotex '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 Apotex

18. By letter dated January 19, 2009 ("First Apotex Notice Letter"), Apotex notified The Procter & Gamble Co. ("P&G")[2] 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 Roche's U.S. Patent No. 7,192,938, the parent to the '634 Patent.

19. By letter dated November 2, 2010 ("Second Apotex Notice Letter"), Apotex notified Warner Chilcott and Roche that its ANDA No. 90-887 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 '634 Patent.

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

[2] 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 plc.

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®. 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.

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

Count I

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

23. Apotex's submission of ANDA No. 90-877 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of Apotex 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 Apotex's ANDA No. 90-877, Apotex will further infringe, directly or indirectly, the '634 Patent by making, using, offering to sell, and selling 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.

25. If Apotex'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 Apotex infringed the '634 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 90-877 with a Paragraph IV Certification seeking to market the Apotex 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 Apotex's ANDA No. 90-877 shall be a date that is not earlier than the expiration date of the '634 Patent;

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

(e) An Order permanently enjoining Apotex, 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 Apotex 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 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 '634 Patent;

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

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

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