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. 09-143-LPS

FIRST AMENDED 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, 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 WCCLLC's ACTONEL® drug product ("Once-a-Month ACTONEL®").

Related Actions

This action is related to three patent infringement actions currently pending before this Court, (1) *Warner Chilcott Company, LLC and Hoffmann-La Roche Inc. v. Teva Pharmaceuticals U.S.A., Inc.* (C.A. No. 08-627-LPS) (the "Teva Action"), involving the '938 Patent (and two other patents), (2) *The Procter & Gamble Company and Hoffmann-La Roche*

Inc. v. Sun Pharma Global, Inc. (C.A. No. 09-61-LPS) (the "Sun Pharma Global Action"), also involving the '938 Patent, and *Warner Chilcott Company, LLC and Hoffmann-La Roche Inc. v. Mylan Pharmaceuticals* (C.A. No. 10-285-LPS) (the "Mylan Action"), also involving the '938 Patent. The Teva, Sun Pharma Global, and Mylan Actions also arise under 35 U.S.C. §§ 271 and 281 and relate to ANDA's filed by those entities for approval to market generic versions of Once-a-Month ACTONEL®. This action was previously consolidated with the Teva, Sun Pharma Global, and Mylan Actions for all pretrial purposes.

Parties

1. Plaintiff Warner Chilcott Company, LLC ("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 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 Ontario, 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. 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.

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. 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.

8. 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.

9. Upon information and belief, Apotex has 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.

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

11. On information and belief, this Court has personal jurisdiction over Apotex by virtue of, *inter alia*, the facts alleged in paragraphs 7-10.

12. This Court also has personal jurisdiction over Apotex 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, WCCLLC and Roche.

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®" was originally developed, manufactured, marketed, and sold by The Procter & Gamble Company ("P&G"). Once-a-Month ACTONEL® (150 mg) was approved by the FDA on April 22, 2008.

15. On August 24, 2009, Warner Chilcott plc, which is the parent company of Plaintiff WCCLLC, and P&G entered into a Purchase Agreement by which Warner Chilcott plc acquired the worldwide prescription pharmaceuticals business of P&G and its affiliates, including the Once-a-Month ACTONEL® business. The acquisition of P&G's pharmaceutical business by Warner Chilcott plc was officially completed on October 30, 2009.

The '938 Patent

16. Roche is the owner by assignment of the '938 Patent 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. The '938 Patent expires on May 6, 2023. The FDA's official publication of approved drugs (the "Orange Book") includes Once-a-Month ACTONEL® in the above-identified 150 mg dosage form listed together with the '938 Patent.

17. Prior to Warner Chilcott plc's acquisition of P&G's pharmaceutical business, the '938 patent was co-exclusively licensed to P&G. When the acquisition was officially completed, P&G's license of the '938 patent was assigned to WCCLLC. 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.

Infringement by Apotex

18. 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.

19. 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®.

20. 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.

21. On March 4, 2009, P&G and Roche filed an original Complaint alleging infringement of the '938 prior to the expiration of forty-five days from the date Procter & Gamble and Roche received the 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 '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).

24. 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 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 '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 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, selling, or importing 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, selling, or importing Apotex 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 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 WCCLLC and Roche in this action; and

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

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Dated: January 10, 2011

CERTIFICATE OF SERVICE

I hereby certify that on January 10, 2011, I electronically filed the foregoing document with the Clerk of Court using CM/ECF which will send notification of such filing(s) and have sent by Electronic Mail to the following:

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I hereby certify that on January 10, 2011, I have sent by Electronic Mail, the foregoing document to the following non-registered participants:

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