IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

WARNER CHILCOTT COMPANY, LLC and HOFFMANN-LA ROCHE INC., Plaintiffs, v. TEVA PHARMACEUTICALS USA, INC., Defendant.	Civil Action No. 08-627-LPS

FIRST AMENDED COMPLAINT

Plaintiffs Warner Chilcott Company, LLC ("WCCLLC") and Hoffmann-La Roche Inc. ("Roche"), by its attorneys, hereby allege as follows:

Nature of the Action

This is an action for patent infringement of U.S. Patent No. 5,583,122 ("the '122 Patent"), U.S. Patent No. 7,192,938 ("the '938 Patent"), and U.S. Patent No. 6,165,513 ("the '513 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 Teva Pharmaceuticals USA, Inc. (ANDA No. 79-215) 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 previously adjudicated by this Court and affirmed by the Federal Circuit, all involving U.S. Patent No. 5,583,122 (the "'122 Patent"): *The Procter & Gamble Co. v. Teva Pharmaceuticals U.S.A., Inc.* (C.A. No. 04-940-

JJF), *The Procter & Gamble Co. v. Teva Pharmaceuticals U.S.A., Inc.* (C.A. No. 08-66-JJF), and *The Procter & Gamble Co. v. Teva Pharmaceuticals U.S.A., Inc.* (C.A. No. 08-191-JJF) (the "Prior Actonel Actions"). The Prior Actonel Actions also arose under 35 U.S.C. §§ 271 and 281, and related respectively to ANDA No. 77-132 (filed by Teva for approval to market a generic version of Procter & Gamble's ACTONEL® drug product in 5 mg, 30 mg, and 35 mg forms), ANDA No. 79-215 (previously filed by Teva only for approval to market a generic version of Procter & Gamble's ACTONEL® drug product in 75 mg form), and ANDA No. 90-234 (filed by Teva for approval to market a generic version of Procter & Gamble's ACTONEL® drug product in 35 mg form co-packaged with 1,250 mg calcium carbonate tablets USP).

On February 28, 2008, the Court issued an Opinion finding claims 4, 16, and 23 of the '122 patent were not invalid by reason of obviousness or obviousness-type double patenting. On May 23, 2008, the Court entered judgment in favor of Procter & Gamble and against Teva, which had stipulated to infringement, on Procter & Gamble's claims arising out of Teva's submission of ANDA No. 77-132. The Court also entered identical judgments with respect to ANDA No. 79-215 and ANDA No. 90-234 pursuant to the parties' agreement that, if the asserted claims of the '122 patent were not found to be invalid, they would also be infringed by the products proposed in Teva's two later-filed ANDAs. Teva appealed these decisions, and, following consolidation of the appeals, briefing, and oral argument, the Federal Circuit affirmed the decision of this Court on May 13, 2009.

This action is further related to three patent infringement actions currently pending before this Court, (1) *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"), involving the '938 Patent, (2) *The Warner Chilcott Company, LLC and Hoffmann-La Roche Inc. v. Apotex Inc. and Apotex*

Corp. (C.A. No. 09-143-LPS) (the "Apotex Action"), also involving the '938 and '513 Patents, 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 Sun Pharma Global, Apotex, 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 Sun Pharma Global, Apotex, 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, Defendant Teva Pharmacetuicals USA, Inc. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania. Upon information and belief, Teva is a wholly-owned subsidiary of Teva Pharmaceutical Industries Ltd.

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. Teva is subject to personal jurisdiction in this judicial district.

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

Once-a-Month ACTONEL®

7. 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.

8. 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 Patents-in-Suit

9. Following completion of the acquisition of P&G's pharmaceutical business by Warner Chilcott plc, pursuant to the General Patent Assignment Agreement, dated October 30, 2009 and duly recorded with the United States Patent and Trademark Office ("PTO"), WCCLLC is the owner by assignment of the '122 Patent, entitled "Pharmaceutical Compositions Containing Geminal Diphosphonates," which the United States Patent and Trademark Office duly and legally issued on December 10, 1996. A true and correct copy of the '122 Patent is attached hereto as Exhibit A. The claims of the '122 Patent are valid and enforceable. The '122 Patent expires on December 10, 2013. WCCLLC owns all right and title to the '122 Patent and has the right to sue for and obtain equitable relief and damages for infringement. 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 '122 Patent.

10. Following completion of the acquisition of P&G's pharmaceutical business by Warner Chilcott plc, pursuant to the General Patent Assignment Agreement, dated October 30, 2009 and duly recorded with the PTO, WCCLLC is the owner by assignment of the '513 Patent, entitled "Film-Coated Tablet For Improved Upper Gastrointestinal Tract Safety," which the United States Patent and Trademark Office duly and legally issued on December 26, 2000. A true and correct copy of the '513 Patent is attached hereto as Exhibit B. The '513 Patent expires on June 10, 2018. The claims of the '513 Patent are valid and enforceable. WCCLLC owns all right and title to the '513 Patent and has the right to sue for and obtain equitable relief and damages for infringement. 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 '513 Patent.

11. 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.

12. 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.

13. The 150 mg commercial formulation of risedronate sodium known as Once-a-Month ACTONEL® is manufactured, marketed, and sold by WCCLLC and is covered by claims of the '122, '513, and '938 Patents. The FDA's official publication of approved drugs (the "Orange Book") includes ACTONEL® in the above-identified 150 mg dosage listed together with the '122, '513, and '938 Patents.

Infringement by Teva

14. By letter dated August 12, 2008 (the "Teva Notice Letter"), Teva notified Procter & Gamble and Roche that Teva had amended ANDA No. 79-215 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 tablets containing 150 mg of risedronate sodium, a generic version of FDA-approved Once-a-Month ACTONEL®, before the expiration dates of the '122, '513, and '938 Patents. Upon information and belief, Teva intends to engage in commercial manufacture, use, and sale of the Teva 150 mg Risedronate Sodium Tablets promptly upon receiving FDA approval to do so.

15. By filing amended ANDA No. 79-215, Teva has necessarily represented to the FDA that the components of the Teva 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 Teva 150 mg Risedronate Sodium Tablets have substantially the same proposed labeling as Once-a-Month ACTONEL®.

16. A sample of Teva's 150 mg Risedronate Sodium Tablets shows that the form of the tablets is oval-shaped and film-coated. A true and accurate copy of a photograph of a tablet from that sample is attached as Exhibit D.

17. In the Teva Notice Letter, Teva notified Procter & Gamble that its ANDA contained a "paragraph IV certification" asserting that, in Teva's opinion, the commercial manufacture, use or sale of Teva 150 mg Risedronate Sodium Tablets will not infringe any valid and enforceable claim of the '122, '513, and '938 Patents.

18. On September 26, 2008, P&G and Roche filed an original Complaint alleging infringement of the '122, '513, and '938 Patents prior to the expiration of forty-five days from the date Procter & Gamble and Roche received the Teva Notice Letter.

Count I

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

20. Teva's submission of amended ANDA No. 79-215 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of Teva Risedronate Sodium Tablets, 150 mg, prior to the expiration of the '122 Patent constitutes infringement of one or more of the valid claims of the '122 Patent under 35 U.S.C. § 271(e)(2)(A), including but not limited to claims 4, 16, and 23.

21. Upon FDA approval of Teva's amended ANDA No. 79-215, Teva will further infringe the '122 Patent by making, using, offering to sell, and selling Teva 150 mg Risedronate Sodium Tablets in the United States, and by actively inducing and contributing to infringement by others, unless enjoined by this Court.

22. WCCLLC will be substantially and irreparably damaged and harmed if Teva's infringement of the '122 patent is not enjoined. WCCLLC does not have an adequate remedy at law.

Count II

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

24. Teva's submission of amended ANDA No. 79-215 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of Teva 150 mg Risedronate Sodium Tablets prior to the expiration of the '513 Patent constitutes infringement of one or more of the valid claims of the '513 Patent under 35 U.S.C. § 271(e)(2)(A).

25. Upon FDA approval of Teva's amended ANDA No. 79-215, Teva will further infringe the '513 Patent by making, using, offering to sell, and selling Teva 150 mg Risedronate Sodium Tablets in the United States, and by actively inducing and contributing to infringement by others, unless enjoined by this Court.

26. WCCLLC will be substantially and irreparably damaged and harmed if Teva's infringement of the '513 patent is not enjoined. WCCLLC does not have an adequate remedy at law.

Count III

27. Each of the preceding paragraphs 1 to 26 is incorporated as if fully set forth.

28. Teva's submission of amended ANDA No. 79-215 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of Teva 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).

29. Upon FDA approval of Teva's amended ANDA No. 79-215, Teva will further infringe the '938 Patent by making, using, offering to sell, and selling Teva 150 mg Risedronate Sodium Tablets in the United States, and by actively inducing and contributing to infringement by others, unless enjoined by this Court.

30. WCCLLC and Roche will be substantially and irreparably damaged and harmed if Teva's infringement of the '938 patent is not enjoined. WCCLLC and Roche do not have an adequate remedy at law.

Prayer for Relief

WHEREFORE, WCCLLC and Roche pray that this Court grant the following relief:

(a) A declaration that the '122, '513, and '938 Patents are valid and enforceable;

(b) A judgment that one or more claims of each of the '122, '513, and '938 Patents are infringed by Teva 150 mg Risedronate Sodium Tablets, that Teva's submission of its amended ANDA No. 79-215 is an act of infringement, and that Teva's making, using, offering to sell, selling, or importing Teva Risedronate Sodium Tablets, 150 mg, will infringe the '122, '513, and '938 Patents;

(c) An Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of Teva's amended ANDA No. 79-215 shall be a date which is not earlier than the latest expiration date of the '122, '513, and '938 Patents;

(d) An Order permanently enjoining Teva, and its affiliates and subsidiaries, and each of their officers, agents, servants and employees, from making, using, offering to sell, selling, or importing Teva 150 mg Risedronate Sodium Tablets until after the expiration dates of the '122, '513, and '938 Patents;

(e) Damages or other monetary relief to WCCLLC and Roche if Teva engages in the commercial manufacture, use, offer to sell, sale, or importation of the Teva 150 mg Risedronate Sodium Tablets prior to the expiration of the '122, '513, and '938 Patents;

(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.

/s/ Laura D. Hatcher

Frederick L. Cottrell, III (#2555)
cottrell@rlf.com
Steven J. Fineman (#4025)
fineman@rlf.com
Laura D. Hatcher (#5098)
hatcher@rlf.com
Richards Layton & Finger, P.A.
One Rodney Square
P.O. Box 551
Wilmington, DE 19899
(302) 651-7700

Attorneys for Plaintiffs Warner Chilcott Company, LLC and Hoffmann-La Roche Inc.

Of Counsel:

William F. Lee
Vinita Ferrera
Allen C. Nunnally
Wilmer Cutler Pickering Hale and Dorr LLP
60 State Street
Boston, MA 02109
(617) 526-6000

David B. Bassett
Wilmer Cutler Pickering Hale and Dorr LLP
399 Park Avenue
New York, NY 10022
(212) 230-8800

Attorneys for Warner Chilcott Company, LLC

Mark E. Waddell, Esq.
Loeb & Loeb LLP
345 Park Avenue
New York, New York 10154-1895
Telephone No.: (212) 407-4000
Facsimile No.: (212) 407-4990

Attorneys for Hoffmann-La Roche Inc.

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:

Richard K. Herrmann
Mary B. Matterer
Amy A. Quinlan
Morris James LLP
500 Delaware Avenue, Suite 1500
Wilmington, DE 19801

Robert E. Colletti
Frommer Lawrence & Haug LLP
745 Fifth Avenue
New York, New York 10151

Karen L. Pascale, Esquire
Young Conaway Stargatt & Taylor
The Brandywine Building
1000 West Street - 17th Floor
P.O. Box 391
Wilmington, DE 19899-0391

Richard William Riley, Esquire
Duane Morris LLP
1100 North Market Street
Suite 1200
Wilmington, DE 19801

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

James Galbraith, Esquire
Maria Luisa Palmese, Esquire
Antony Pfeffer, Esquire
Kenyon & Kenyon LLP
One Broadway
New York, NY 10004

Steven E. Feldman, Esquire
Husch Blackwell Sanders Welsh & Katz, LLP
120 South Riverside Plaza
22nd Floor
Chicago, IL 60606

/s/ Laura D. Hatcher
Laura D. Hatcher (#5098)
Hatcher@rlf.com