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. _____

COMPLAINT

Plaintiffs Warner Chilcott Company, LLC ("Warner Chilcott") 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. 7,718,634 (the "'634 Patent"), arising under the patent laws of the United States, Title 35, United States Code, §§ 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 ("Teva 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 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 six patent infringement actions currently pending before this Court, (1) *Warner Chilcott Company, LLC and Hoffmann-La Roche Inc. v. Teva Pharmaceuticals USA, Inc.* (C.A. No. 08-627-LPS) (the "Teva '938 Action"), (2) *The Procter & Gamble Company and Hoffmann-La Roche Inc. v. Sun Pharma Global, Inc.* (C.A. No. 09-61-LPS) (the "Sun '938 Action"), (3) *Warner Chilcott Company, LLC and Hoffmann-La Roche Inc.*

v. Sun Pharma Global, Inc. (C.A. No. 10-1085-LPS) (the "Sun '634 Action"), (4) *Warner Chilcott Company, LLC and Hoffmann-La Roche Inc. v. Apotex Inc. and Apotex Corp.* (C.A. No. 09-143-LPS) (the "Apotex '938 Action"), (5) *Warner Chilcott Company, LLC and Hoffmann-La Roche Inc. v. Apotex Inc. and Apotex Corp.* (C.A. No. 10-1111-LPS) (the "Apotex '634 Action"), and (6) *Warner Chilcott Company, LLC and Hoffmann-La Roche Inc. v. Mylan Pharmaceuticals* (C.A. No. 10-285-LPS) (the "Mylan '938 Action"). Each of these actions also arise under 35 U.S.C. §§ 271 and 281 and relate to ANDA's filed by Teva, Sun, Apotex, and Mylan for approval to market generic versions of Once-a-Month ACTONEL®. The Teva '938 Action, Sun '938 Action, Apotex '938 Action, and Mylan '938 Action were previously consolidated for all pretrial 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, Defendant Teva Pharmaceuticals 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®" is manufactured, marketed, and sold by Warner Chilcott. Once-a-Month ACTONEL® (150 mg) was approved by the FDA on April 22, 2008.

The Patents-in-Suit

8. 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.

9. The 150 mg commercial formulation of risedronate sodium known as Once-a-Month ACTONEL® is manufactured, marketed, and sold by Warner Chilcott and is covered by claims of the '634 Patent. The FDA's official publication of approved drugs (the "Orange Book") includes ACTONEL® in the above-identified 150 mg dosage listed together with the '634 Patent.

10. As the assignee of the '634 Patent, Roche has all rights needed to bring this action and to sue for and obtain equitable relief and damages for infringement in Roche's name except

as licensed to Warner Chilcott; under a license from Roche, Warner Chilcott has the right to sue for and obtain equitable relief and damages for infringement of the '634 Patent.

Infringement by Teva

11. By letter dated August 12, 2008 (the "8/08 Teva Notice Letter"), Teva notified Procter & Gamble, former owner of the Once-a-Month ACTONEL® brand, 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®.

12. By letter dated December 10, 2010 ("12/10 Teva Notice Letter"), Teva notified Warner Chilcott and Roche that its ANDA No. 79-215 now contains 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 '634 Patent.

13. 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.

14. 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®.

15. This complaint is being filed before the expiration of forty-five days from the date Warner Chilcott and Roche received the 12/10 Teva Notice Letter.

Count I

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

17. 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 '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).

18. Upon FDA approval of Teva's amended ANDA No. 79-215, Teva will further infringe the '634 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, in violation of 35 U.S.C. § 271(a)-(c), unless enjoined by this Court.

19. Warner Chilcott and Roche will be substantially and irreparably damaged and harmed if Teva's infringement of the '634 patent is not enjoined. Waner Chilcott and Roche do not have an 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 one or more claims of the '634 Patent is infringed by the 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 150 mg Risedronate Sodium Tablets will infringe the '634 Patent;

(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 '634 Patent;

(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 '634 Patent;

(e) Damages or other monetary relief to Warner Chilcott 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 '634 Patent;

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

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

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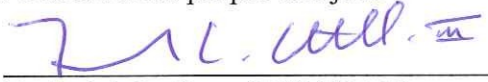

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