IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

WARNER CHILCOTT COMPANY, LLC and HOFFMAN-LA ROCHE INC., Plaintiffs, v. TEVA PHARMACEUTICALS USA, INC., Defendant.	C.A. No. 08-627-LPS

DEFENDANT TEVA PHARMACEUTICALS USA, INC.'S
ANSWER TO FIRST AMENDED COMPLAINT

Teva Pharmaceuticals USA, Inc. ("Teva USA"), through its undersigned counsel, hereby answers the First Amended Complaint of plaintiffs Warner Chilcott Company, LLC ("WC") and Hoffman-La Roche Inc. ("Roche") (collectively "Plaintiffs") as follows. This Answer is based on Teva USA's knowledge as to its own activities, and upon information and belief as to the activities of others. The numbered paragraphs below correspond to the numbered paragraphs in Plaintiffs' First Amended Complaint (D.I. 129). To the extent not specifically admitted herein, the allegations of the First Amended Complaint are denied.

Nature of the Action

Teva USA admits that this action arises under the Patent Laws of the United States, and that it "relates to" amended Abbreviated New Drug Application ("ANDA") No. 79-215 for risedronate drug products in a 150 mg dosage form. Teva USA is without information with respect to the remaining allegations of this paragraph and therefore denies them.

Related Actions

Teva USA admits that this action is "related to" three patent infringement actions adjudicated before a court in this district ("the court") and subsequently appealed to the Federal Circuit, all involving U.S. Patent 5,583,122 ("the '122 patent"), and that those three actions were *The Procter & Gamble Co. v. Teva Pharmaceuticals USA, Inc.*, (No. 04 CV 940), *The Procter & Gamble Co. v. Teva Pharmaceuticals USA, Inc.*, (No. 08 CV 066), and *The Procter & Gamble Co. v. Teva Pharmaceuticals USA, Inc.*, (No. 08 CV 191), (collectively, "the Prior Actions"). Teva USA further admits that the actions on appeal "relate to" Teva USA's ANDA No. 77-132 covering 5 mg, 30 mg, and 35 mg doses of risedronate, Teva USA's ANDA No. 75-215 previously filed covering a 75 mg dose of risedronate, and ANDA No. 90-234 covering a 35 mg dose of risedronate co-packaged with 1,250 mg calcium carbonate tablets USP, respectively.

Teva USA admits that on February 28, 2008, the court issued an Opinion in case no. 04-CV-940 finding that claims 4, 16, and 23 of the '122 patent were not invalid for obviousness or obviousness-type double patenting, and that the Teva USA had previously stipulated that the manufacture, use, importation, sale or offer for sale of the product covered by ANDA No. 77-132 would infringe the claims at issue, if they were valid. Teva USA further admits that the Federal Circuit affirmed the decision of the court on May 13, 2009.

Teva USA admits that this action is "related to" three actions currently pending before the court, (1) *The Procter & Gamble Co. and Hoffman-La Roche Inc. v. Sun Pharma Global, Inc.* (No. 09-CV-61 (LPS)) (the "Sun Pharma Global Action"), (2) *Warner Chilcott Co., LLC and Hoffman-La Roche Inc. v. Apotex Inc. and Apotex Corp.* (No. 09-CV-143 (LPS)) (the "Apotex Action"), and *Warner Chilcott Co., LLC and Hoffman-La Roche Inc. v. Mylan Pharm.* (No. 10-CV-285 (LPS)) (the "Mylan Action"). Teva USA further admits that this action was previously consolidated with the Sun Pharma Global, Apotex, and Mylan Actions for all pretrial purposes.

Parties

1. Teva USA is without information sufficient to form a belief as to the allegations of this paragraph, and therefore denies them.

2. Teva USA is without information sufficient to form a belief as to the allegations of this paragraph, and therefore denies them.

3. Teva USA admits that it is Delaware corporation with a principal place of business at 1090 Horsham Road, North Wales, Pennsylvania. Teva USA further admits that it is a wholly-owned indirect subsidiary of Teva Pharmaceutical Industries Ltd. Otherwise denied.

Jurisdiction and Venue

4. Upon information and belief, Teva USA admits that Plaintiffs purport to state claims that arise under the patent laws of the United States, and that the court has subject matter jurisdiction over patent infringement actions pursuant to 28 U.S.C. § 1338(a). Otherwise denied.

5. Admitted.

6. Admitted for personal jurisdictional purposes only.

Once-a-Month ACTONEL

7. Teva USA is without information sufficient to form a belief as to the allegations of this paragraph, and therefore denies them.

8. Teva USA is without information sufficient to form a belief as to the allegations of this paragraph, and therefore denies them.

The Patents in Suit

9. Upon information and belief, Teva USA admits that the United States Patent and Trademark Office issued U.S. Patent No. 5,583,122 ("the '122 patent"), entitled "Pharmaceutical Compositions Containing Geminal Diphosphonates" on December 10, 1996. Teva USA admits that the '122 patent is currently scheduled to expire on December 10, 2013.

Teva USA lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in this paragraph and therefore denies them.

10. Upon information and belief, Teva USA admits that the United States Patent and Trademark Office issued U.S. Patent No. 6,165,513 ("the '513 patent"), entitled "Film-Coated Tablet For Improved Upper Gastrointestinal Tract Safety" on December 26, 2000. Teva USA denies that the '513 patent was "duly and legally" issued and further denies that "the claims of the '513 patent are valid and enforceable." Teva USA admits that the '513 patent is currently scheduled to expire on June 10, 2018. Teva USA lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in this paragraph and therefore denies them.

11. Upon information and belief, Teva USA admits that the United States Patent and Trademark Office issued U.S. Patent No. 7,192,938 ("the '938 patent"), entitled "Method of Treatment Using Bisphosphonic Acid" on March 20, 2007, and that the patent on its face states that it was assigned to "Hoffman-La Roche Inc." Teva USA denies that the '938 patent was "duly and legally" issued and further denies that "the claims of the '938 patent are valid and enforceable." Teva USA admits that the '938 patent is currently scheduled to expire on May 6, 2023. Teva USA lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in this paragraph and therefore denies them.

12. Upon information and belief, Teva USA admits that '938 patent states on its face that it was assigned to "Hoffman-la Roche Inc." Teva USA lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in this paragraph and therefore denies them.

13. Upon information and belief, Teva USA admits that the Orange Book lists the '122 patent in connection with 5 mg, 30 mg, 35 mg, 75 mg, and 150 mg Actonel tablets. Teva

USA further admits that the Orange Book also lists the '513 and '938 patents in connection with 150 mg Actonel Tablets. Teva USA lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in this paragraph and therefore denies them.

Allegations of Infringement

14. Teva USA admits that it has filed amended ANDA No. 79-215 for approval to market 150 mg risedronate sodium tablets before the expiration date of the '122, '513, and '938 patents, and that it provided notice of that filing to P&G by letter of August 12, 2008. Otherwise denied.

15. Teva USA admits that amended ANDA No. 79-215 meets all the statutory and regulatory requirements for an ANDA. Otherwise denied.

16. Denied.

17. Admitted.

18. Admitted.

Count I

19. *See* responses to paragraphs 1–18.

20. Teva USA admits that the submission of an ANDA for a drug claimed in a patent or the use of which is claimed in a patent can be a technical act of infringement under 35 U.S.C. § 271(e)(2). Otherwise denied.

21. Denied.

22. Denied.

Count II

23. *See* responses to paragraphs 1-22.

24. Teva USA admits that the submission of an ANDA for a drug claimed in a patent or the use of which is claimed in a patent can be a technical act of infringement under 35 U.S.C. § 271(e)(2). Otherwise denied.

25. Denied.

26. Denied.

Count III

27. *See* responses to paragraphs 1–26.

28. Teva USA admits that the submission of an ANDA for a drug claimed in a patent or the use of which is claimed in a patent can be a technical act of infringement under 35 U.S.C. § 271(e)(2). Otherwise denied.

29. Denied.

30. Denied.

Response to Prayer for Relief

Teva USA denies that Plaintiffs are entitled to any of the relief sought in the "Prayer for Relief" section of the First Amended Complaint.

DEFENSES

Teva USA, without prejudice to the denials set forth in its Answer, alleges the following defenses to Plaintiffs' First Amended Complaint. Teva USA reserves its right to assert additional defenses as it learns more information through discovery.

FIRST DEFENSE

2. Teva USA's manufacture, sale, use, offer for sale or sale and/or importation of drug product pursuant to amended ANDA No. 79-215 has not infringed, does not infringe and will not infringe one or more of the claims of the '513 patent.

SECOND DEFENSE

3. The claims of the '513 patent are invalid for failure to comply with one or more requirements of 35 U.S.C. § 100 *et. seq.*, including, but not limited to, §§ 101, 102, 103, and/or 112.

THIRD DEFENSE

4. Teva USA's manufacture, sale, use, offer for sale or sale and/or importation of drug product pursuant to amended ANDA No. 79-215 has not infringed, does not infringe and will not infringe one or more of the claims of the '938 patent.

FOURTH DEFENSE

5. The claims of the '938 patent are invalid for failure to comply with one or more requirements of 35 U.S.C. § 100 *et. seq.*, including, but not limited to, §§ 101, 102, 103, and/or 112.

PRAYER FOR RELIEF

WHEREFORE, Teva USA respectfully requests that the Court enter judgment against Plaintiffs to include:

A. A judgment dismissing Plaintiffs' First Amended Complaint with prejudice;

B. A judgment denying of each of Plaintiffs' requested forms of relief against Teva USA;

C. A judgment that the '513 patent is invalid and would not be infringed by Teva USA's commercial marketing of its proposed 150 mg risedronate product;

D. A judgment that the '938 patent is invalid and would not be infringed by Teva USA's commercial marketing of its proposed 150 mg risedronate product;

E. An award to Teva USA of its reasonable costs and attorney's fees and expenses in connection with this action; and

F. Such other and further relief as the Court may deem just and proper.

YOUNG CONAWAY STARGATT & TAYLOR LLP

/s/ Karen L. Pascale

February 3, 2011

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CERTIFICATE OF SERVICE

I, Karen L. Pascale, Esquire, hereby certify that on February 3, 2011, I caused to be electronically filed a true and correct copy of the foregoing document with the Clerk of the Court using CM/ECF, which will send notification that such filing is available for viewing and downloading to the following counsel of record:

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I further certify that I caused a copy of the foregoing document to be served the following counsel of record in the manner indicated:

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