IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

THE PROCTER & GAMBLE COMPANY,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No.:
	)	
TEVA PHARMACEUTICALS USA, INC.,	)	
	)	
Defendant.	)	

COMPLAINT

Plaintiff The Procter & Gamble Company ("Procter & Gamble"), by its attorneys, hereby alleges as follows:

Nature of the Action

This is an action for patent infringement 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 Abbreviated New Drug Application ("ANDA") filed by Teva Pharmaceuticals USA, Inc. ("Teva") (ANDA No. 90-234) with the U.S. Food and Drug Administration ("FDA") for approval to market a generic version of a 35 mg form of Procter & Gamble's ACTONEL® drug product co-packaged with 1,250 mg calcium carbonate tablets USP, equivalent to 500 mg elemental calcium.

Related Actions

This action is related to two patent infringement actions currently pending before this Court, *The Procter & Gamble Co. v. Teva Pharmaceuticals U.S.A., Inc.* (C.A. No. 04-940-JJF) and *The Procter & Gamble Co. v. Teva Pharmaceuticals U.S.A., Inc.* (C.A. No. 08-66-JJF) (the "Pending Actions"), both involving U.S. Patent No. 5,583,122 (the "'122 Patent"). The Pending Actions also arise under 35 U.S.C. §§ 271 and 281, and relate 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 and ANDA No. 79-215 filed by Teva for approval to market a generic version of Procter & Gamble's ACTONEL® drug product in 75 mg form. On February 28, 2008, the Court issued an Opinion in C.A. No. 04-940-JJF finding claims 4, 16, and 23 of the '122 patent valid and enforceable and stating that the Court will enter judgment in favor or Procter & Gamble and against Teva on Procter & Gamble's claims of infringement arising out of Teva's submission of ANDA No. 77-132.

Parties

1. Procter & Gamble is a corporation organized and existing under the laws of the State of Ohio, with its principal place of business at 1 Procter & Gamble Plaza, Cincinnati, Ohio.

2. Upon information and belief, Teva 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

3. 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.

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

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

Procter & Gamble's ACTONEL® Patents

6. Procter & Gamble 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. Procter & Gamble 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 '122 Patent expires on December 10, 2013.

7. The commercial formulation of risedronate sodium developed, manufactured, and sold by Procter & Gamble is known as "ACTONEL®," and is covered by claims of the '122 Patent. ACTONEL® was approved by the FDA for 30 mg tablets on March 27, 1998; for 5 mg tablets on April 14, 2000; for 35 mg tablets on May 25, 2002; and for 75 mg tablets on April 16, 2007. In addition, on August 12, 2005, the FDA approved 35 mg tablets of ACTONEL® co-packaged with 1,250 mg calcium carbonate tablets (equivalent to 500 mg elemental calcium) for a course of treatment whereby one ACTONEL® tablet is taken on day 1 and one calcium carbonate tablet is taken on each of days 2 through 7 of a weekly course ("ACTONEL® with Calcium"). The FDA's official publication of approved drugs (the "Orange Book") includes ACTONEL® in the above-identified dosages and ACTONEL® with Calcium listed together with the '122 Patent.

Infringement by Teva

8. By letter dated February 19, 2008 (the "Teva Notice Letter"), Teva notified Procter & Gamble that Teva had submitted ANDA No. 90-234 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 35 mg of risedronate sodium co-packaged with 1,250 mg calcium carbonate tablets, equivalent to 500 mg elemental calcium (the "Teva Risedronate with Calcium"), a generic version of FDA-approved ACTONEL® with

Calcium, before the expiration date of the '122 Patent. Upon information and belief, Teva intends to engage in commercial manufacture, use, and sale of the Teva Risedronate with Calcium promptly upon receiving FDA approval to do so.

9. By filing ANDA No. 90-234, Teva has necessarily represented to the FDA that the components of the Teva Risedronate with Calcium co-packaged product have the same active ingredients as those of the corresponding components of the ACTONEL® with Calcium co-packaged product, have the same route of administration, dosage form, and strengths as the corresponding components of ACTONEL® with Calcium, are bioequivalent to the corresponding components of ACTONEL® with Calcium, and that Teva Risedronate with Calcium has substantially the same proposed labeling as ACTONEL® with Calcium.

10. 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 Risedronate with Calcium will not infringe any valid and enforceable claim of the '122 Patent.

11. This complaint is being filed before the expiration of forty-five days from the date Procter & Gamble received the Teva Notice Letter.

Count I

12. Each of the preceding paragraphs 1 to 11 is incorporated as if fully set forth.

13. Teva's submission of ANDA No. 90-234 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of Teva Risedronate with Calcium 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.

14. Upon FDA approval of Teva's ANDA No. 90-234, Teva will further infringe the '122 Patent by making, using, offering to sell, and selling Teva Risedronate with Calcium in the

United States, and by actively inducing and contributing to infringement by others, unless enjoined by this Court.

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

Prayer for Relief

WHEREFORE, Procter & Gamble prays that this Court grant the following relief:

a. A declaration that the '122 Patent is valid and enforceable;

b. A judgment that a claim or claims of the '122 Patent are infringed by Teva Risedronate with Calcium, that Teva's submission of its ANDA No. 90-234 is an act of infringement, and that Teva's making, using, offering to sell, selling, or importing Teva Risedronate with Calcium will infringe the '122 Patent;

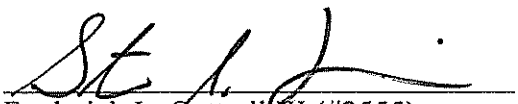
c. An Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of Teva's ANDA No. 90-234 shall be a date which is not earlier than the expiration date of the '122 Patent;

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 Risedronate with Calcium until after the expiration date of the '122 Patent;

e. Damages or other monetary relief to Procter & Gamble if Teva engages in the commercial manufacture, use, offer to sell, sale, or importation of the Teva Risedronate with Calcium prior to the expiration of the '122 Patent;

f. Reasonable costs of suit incurred by Procter & Gamble in this action; and

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



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