

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

PFIZER INC,)
PFIZER IRELAND PHARMACEUTICALS,))
WARNER-LAMBERT COMPANY,)
WARNER-LAMBERT COMPANY, LLC)
and)
WARNER-LAMBERT EXPORT LTD.,)

Plaintiffs,)

v.)

Civil Action No. 08-____

TEVA PHARMACEUTICALS USA, INC.,)

Defendant.)

COMPLAINT

Pfizer Inc, Pfizer Ireland Pharmaceuticals, Warner-Lambert Company, Warner-Lambert Company, LLC and Warner-Lambert Export Limited, (collectively referred to as “Pfizer”), by their attorneys, for their complaint against Teva Pharmaceuticals USA, Inc. (“Teva”), allege as follows:

1. This is an action by Pfizer against Teva for infringement of United States Letters Patent No. 5,273,995 (“the ‘995 patent”). A copy of the ‘995 patent is attached hereto as Exhibit A.

2. On December 28, 1993, the United States Patent and Trademark Office issued the ‘995 patent, entitled “[R-(R*R*)]-2-(4-Fluorophenyl)-β, δ-Dihydroxy-5-(1-Methylethyl-3-Phenyl-4-[(Phenylamino) Carbonyl]-1H-Pyrrole-1-Heptanoic Acid, Its Lactone Form And Salts Thereof”, on an application filed by Bruce D. Roth and assigned to Warner-Lambert Company.

PARTIES, JURISDICTION AND VENUE

3. Pfizer Inc is a corporation organized and existing under the laws of the State of Delaware and has a place of business at 235 East 42nd Street, New York, New York 10017.

4. Warner-Lambert Company is a corporation formerly organized under the laws of the State of Delaware with offices for service of process at 235 East 42nd Street, New York, New York 10017. Warner-Lambert Company has been the owner of record of the '995 patent since its issuance.

5. Warner-Lambert Company became a wholly owned subsidiary of Pfizer Inc effective June 19, 2000.

6. Warner-Lambert Company was converted into Warner-Lambert Company, LLC, a Delaware limited liability company by certificate dated December 31, 2002. Warner-Lambert Company, LLC has offices located at 235 East 42nd Street, New York, New York 10017.

7. Pfizer Ireland Pharmaceuticals is a partnership, organized and existing under the laws of Ireland, with registered offices at Pottery Road, Dun Laoghaire, Co. Dublin, Ireland. Pfizer Ireland Pharmaceuticals is a wholly owned, indirect subsidiary of Pfizer Inc.

8. Warner-Lambert Export, Ltd. is a corporation formerly organized under the laws of Ireland with a registered office located at Pottery Road, Dun Laoghaire, Co. Dublin, Ireland.

9. The exclusive licensee of the '995 patent is Pfizer Ireland Pharmaceuticals, formerly Warner-Lambert Export, Ltd.

10. Pfizer holds an approved New Drug Application for an atorvastatin calcium formulation which it sells under the registered name Lipitor[®].

11. The '995 patent is identified pursuant to 21 U.S.C. §355 (b)(1) by the United States Food and Drug Administration ("FDA") as covering Pfizer's Lipitor[®] product.

12. Teva Pharmaceuticals USA, Inc. is a corporation organized and existing under the laws of the State of Delaware, and has a principal place of business located at 1090 Horsham Road, North Wales, Pennsylvania 19454.

13. This action arises under the Patent Laws of the United States, Title 35, United States Code. This Court has subject matter jurisdiction over this action pursuant to the provisions of Title 28, United States Code, Sections 1331 and 1338.

14. Teva is subject to personal jurisdiction in this District.

15. Venue is proper in this District pursuant to the provisions of Title 28, United States Code, Sections 1391 (c), (d) and 1400 (b).

16. An amended final judgment declaring claim 6 of the '995 patent invalid pursuant to the provisions of 35 U.S.C. § 112, ¶ 4 has been entered by the United States District Court for the District of Delaware in Civil Action No. 03-209-JJF, by Orders of the Court dated November 7, 2006 and November 30, 2006 (D.I. 338 and 344). A copy of the final judgment, as amended, is attached as Exhibit B. No relief is sought herein pursuant to claim 6 of the '995 patent.

17. Pfizer received a letter dated April 24, 2007 from Teva (the "April 24, 2007 letter") which notified Pfizer that Teva had filed an Abbreviated New Drug Application (ANDA No. 78-773), seeking approval from FDA to engage in the commercial manufacture, use, and sale of a product containing atorvastatin calcium as the active ingredient prior to the expiration of the '995 patent.

18. The April 24, 2007 letter stated that ANDA No. 78-773 was limited to 80 milligram atorvastatin calcium tablets.

19. On June 7, 2007 Pfizer brought suit against Teva in the United States District Court for the District of Delaware, designated Civil Action No. 07-360 (JJF), alleging infringement of the '995 patent under 35 U.S.C. § 271(e)(2) by filing Teva's ANDA seeking approval from the FDA to engage in the commercial manufacture, use, or sale of a product containing atorvastatin calcium as an active ingredient prior to the expiration of the '995 patent.

20. As of this date, Civil Action No. 07-360 (JJF) remains pending.

FIRST CLAIM FOR RELIEF;
INFRINGEMENT OF THE '995 PATENT

21. Pfizer realleges paragraphs 1 through 20 above as if fully set forth herein.

22. Pfizer has received a letter dated March 12, 2008 from Teva (the "March 12, 2008 letter") which notified Pfizer that Teva had filed an amendment to ANDA No. 78-773 ("Amended ANDA No. 78-773"), seeking further approval from FDA to engage in the commercial manufacture, use, and sale of a product containing atorvastatin calcium as the active ingredient prior to the expiration of the '995 patent. The March 12, 2008 Letter states that the further FDA approval sought by Teva in Amended ANDA No. 78-773 is for 10, 20, and 40 milligram atorvastatin calcium tablets. A copy of the March 12, 2008 letter is attached hereto as Exhibit C.

23. The expiration date for the '995 patent is December 28, 2010.

24. Lipitor® was granted a further period of exclusivity under section 505 of the Food, Drug and Cosmetic Act to June 28, 2011.

25. Teva has infringed the '995 patent under 35 U.S.C. 271 (e)(2) by filing Amended ANDA No. 78-773 seeking approval from the FDA to engage in the commercial manufacture,

use, or sale of a product containing atorvastatin calcium as an active ingredient prior to the expiration of the '995 patent.

26. Pfizer will be irreparably harmed if Ranbaxy is not enjoined from infringing the '995 patent.

WHEREFORE, Pfizer requests the following relief:

- A. A judgment providing that pursuant to 35 U.S.C. §271 (e) (4) (A), the effective date of any FDA approval for Teva's Amended ANDA No. 78-773 be no earlier than June 28, 2011, the date of expiration of the '995 Patent including the period of exclusivity granted to Lipitor under section 505 of the Food, Drug and Cosmetic Act;
- B. A judgment pursuant to 35 U.S.C. §271 (e) (4) (B) permanently enjoining Teva Pharmaceuticals USA, Inc., each of its officers, agents, servants, employees and attorneys, and those persons in active concert or participation with it or any of them, from making, using, selling, offering to sell, or importing the atorvastatin calcium product described in Teva's Amended ANDA 78-773 until June 28, 2011, the expiration date of the '995 patent including the period of exclusivity granted to Lipitor under section 505 of the Food, Drug and Cosmetic Act;
- C. Attorneys' fees in this action under 35 U.S.C. §285;
- D. Costs and expenses in this action; and
- E. Such further and other relief as this Court may deem just and proper.

RESPECTFULLY SUBMITTED,

/s/ Rudolf E. Hutz

Rudolf E. Hutz (#484)

Jeffrey B. Bove (#998)

Mary W. Bourke (#2356)

CONNOLLY BOVE LODGE & HUTZ LLP

1007 North Orange Street

Wilmington, DE 19899

(302) 658-9141

*Attorneys for Plaintiffs Pfizer Inc, Pfizer Ireland
Pharmaceuticals, Warner-Lambert Company,
Warner-Lambert Company, LLC and Warner
Lambert Export, Ltd.*

Dated: April 25, 2008