IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

PFIZER INC, PFIZER IRELAND PHARMACEUTICALS, WARNER-LAMBERT COMPANY, WARNER-LAMBERT COMPANY, LLC and WARNER-LAMBERT EXPORT LTD., Plaintiffs, v. COBALT PHARMACEUTICALS, INC. Defendant.	)	Civil Action No. 07-___

COMPLAINT

Pfizer Inc, Pfizer Ireland Pharmaceuticals, Warner-Lambert Company, Warner-Lambert Company, LLC and Warner-Lambert Export Ltd., (collectively referred to as "Pfizer"), by their attorneys, for their complaint against Cobalt Pharmaceuticals, Inc. ("Cobalt") allege as follows:

1. This is an action by Pfizer against Cobalt 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. Specifically, infringement of the '995 patent by Cobalt is alleged pursuant to 35 U.S.C. § 271(e)(2)(A) which provides, *inter alia*., that it shall be an act of infringement to file an application under section 505(b)(2) of the Federal Food, Drug and Cosmetic Act for a drug claimed in a patent or the use of which is claimed in a patent if the application seeks approval from FDA to engage in the commercial manufacture, use, and sale of the drug product prior to the expiration of the patent.

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. Upon information and belief, Cobalt is a corporation organized and existing under the laws of Canada, having a place of business at 6500 Kitimat Road, Mississauga, Ontario, Canada L5N 2138.

13. This action arises under Federal Law, specifically 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. Cobalt is subject to personal jurisdiction in this District.

15. Upon information and belief, Cobalt manufactures generic prescription drug products which it markets, distributes and/or sells, directly or indirectly, throughout the United States.

16. Upon information and belief, Cobalt's generic prescription drug products are available for purchase throughout the United States, including Massachusetts.

17. Upon information and belief, Cobalt Laboratories, Inc. ("Cobalt Labs") is a corporation organized and existing under the laws of Delaware with a place of business located 24840 S. Tamiami Trail, Bonita Springs, Florida 34134.

18. Upon information and belief, Cobalt Labs and Cobalt are related corporations, both being indirect subsidiaries of Robin Hood Holdings Ltd., a private corporation organized and existing under the laws of Malta.

19. Upon information and belief, Cobalt Labs acts as the agent and distributor of Cobalt for its generic prescription drug products in the United States and in particular in Massachusetts.

20. Upon information and belief, this Court has personal jurisdiction over Cobalt by virtue of, *inter alia*., its systematic and continuous contacts with Massachusetts, including those contacts through its agent Cobalt Labs; its admission that this Court had personal jurisdiction

over it in the action *Aventis Pharma Deutschland GMBH & King Pharmaceuticals, Inc. v. Cobalt Pharmaceuticals, Inc.*, Civil Action 2003-10492; and its designation of Strategic Bioscience Corporation of Stow Massachusetts as its agent for service of process in Massachusetts.

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

22. 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. Reissue has been sought to address the decision of the Federal Circuit relating to claim 6 on which said Orders are based.

FIRST CLAIM FOR RELIEF;
INFRINGEMENT OF THE '995 PATENT

23. Pfizer realleges paragraphs 1 through 22 above as if fully set forth herein.

24. Pfizer has received a letter dated October 24, 2007 from Cobalt (the "October 24, 2007 letter") which notified Pfizer that Cobalt had filed a New Drug Application (NDA No. 22-245), seeking approval from FDA to engage in the commercial manufacture, use, and sale of a product prior to the expiration of the '995 patent which, according to the October 24, 2007 letter, will contain atorvastatin sodium as the active ingredient. A copy of the October 24, 2007 letter is attached hereto as Exhibit C.

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

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

27. Cobalt has infringed the '995 patent under 35 U.S.C. 271 (e)(2) by filing Cobalt's NDA seeking approval from the FDA to engage in the commercial manufacture, use, or sale of a product prior to the expiration of the '995 patent which, according to the October 24, 2007 letter, will contain atorvastatin sodium as the active ingredient.

28. Pfizer will be irreparably harmed if Cobalt 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 Cobalt's NDA No. 22-245 shall 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 Cobalt, 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 sodium product described in Cobalt's ANDA 22-245 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/ Martin J. O'Donnell

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