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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

TEVA PHARMACEUTICAL INDUSTRIES LTD. and TEVA PHARMACEUTICALS USA, INC., *Plaintiffs,* *v.* COBALT PHARMACEUTICALS, INC. and COBALT LABORATORIES, INC., *Defendants.*	Civil Action No. _____

COMPLAINT AND DEMAND FOR JURY TRIAL

For their Complaint against Defendants Cobalt Pharmaceuticals, Inc. and Cobalt Laboratories, Inc., (collectively, "Defendants"), Plaintiffs Teva Pharmaceutical Industries Ltd.

("Teva Ltd.") and Teva Pharmaceuticals USA, Inc. ("Teva USA") allege as to their own acts, and on information and belief as to the acts of others, as follows:

THE PARTIES

1. Teva Ltd. is a corporation organized under the laws of Israel, and maintains its principal place of business at 5 Basel Street, Petah Tiqva 49131, Israel.

2. Teva USA is a Delaware corporation with its principal place of business located at 1090 Horsham Road, North Wales, Pennsylvania, 19454-1090. Teva USA is a wholly owned subsidiary of Teva Ltd.

3. On information and belief, Cobalt Pharmaceuticals, Inc. is a Canadian corporation having a principal place of business at 6500 Kitimat Road, Mississauga, Ontario, Canada LSN 2B8.

4. On information and belief, Cobalt Laboratories, Inc. is a Delaware corporation having a principal place of business at 24840 S. Tamiami Trail, Bonita Springs, Florida 34134.

5. On information and belief, Cobalt Laboratories, Inc. has designated for service National Registered Agents Inc. of NJ, located at 100 Canal Pointe Boulevard, Suite 108, Princeton, New Jersey 08540.

6. On information and belief, Cobalt Laboratories, Inc. has a New Jersey state I.D. of 100961623.

7. On information and belief, Cobalt Laboratories, Inc. has sold and continues to sell sertraline hydrochloride products in the state of New Jersey.

8. On information and belief, Cobalt Laboratories, Inc. is an affiliate of Cobalt Pharmaceuticals, Inc.

9. On information and belief, Cobalt Laboratories, Inc. acts as the agent of Cobalt Pharmaceuticals, Inc.

NATURE OF THE ACTION

10. This is an action for patent infringement arising under the Patent Laws of the United States, 35 U.S.C. § 1, et seq., and seeking damages and injunctive relief under 35 U.S.C. §§ 281-285.

JURISDICTION AND VENUE

11. This court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

12. The Court has personal jurisdiction over Cobalt Pharmaceuticals, Inc. because of its continuous and systematic contacts with the state of New Jersey, including those made through Cobalt Laboratories, Inc.

13. The Court has personal jurisdiction over Cobalt Laboratories Inc. because of its continuous and systematic contacts with the state of New Jersey, including its designation of a registered agent for service in New Jersey, as well as the previous and continued sales of its sertraline products in New Jersey.

14. Venue is proper in this judicial district based on 28 U.S.C. § 1400 (b) and/or 28 U.S.C. § 1391 (b), (c) and (d).

BACKGROUND

The Patents In Suit

15. Teva Ltd. is the owner of all right, title and interest in United States Patent Nos. 6,600,073 ("the '073 patent"), 6,500,987 ("the '987 patent"), 6,495,721 ("the '721 patent"), and 6,897,340 ("the '340 patent"; collectively, "the patents in suit") relating to, *inter alia*, methods

for manufacturing certain crystalline forms of a chemical compound known as sertraline hydrochloride. Two of these crystalline forms of sertraline hydrochloride are known as "Form II" and "Form V."

16. The '073 patent was duly and legally issued by the United States Patent and Trademark Office ("PTO") on July 29, 2003, for an invention entitled, "Methods for Preparation of Sertraline Hydrochloride Polymorphs." A copy of the '073 patent is attached as Exhibit A.

17. The '987 patent was duly and legally issued by the PTO on December 31, 2002, for an invention entitled, "Sertraline Hydrochloride Polymorphs." A copy of the '987 patent is attached as Exhibit B.

18. The '073 patent and the '987 patent claim, *inter alia*, processes for preparation of sertraline hydrochloride Form V.

19. The '721 patent was duly and legally issued by the PTO on December 17, 2002, for an invention entitled, "Sertraline Hydrochloride Form II and Methods for the Preparation Thereof." A copy of the '721 patent is attached as Exhibit C.

20. The '340 patent was duly and legally issued by the PTO on May 24, 2005, for an invention entitled, "Processes for Preparation of Polymorphic Form II of Sertraline Hydrochloride." A copy of the '340 patent is attached as Exhibit D.

21. The '721 and '340 patents claim, *inter alia*, processes for the preparation of sertraline hydrochloride Form II.

Plaintiffs' Generic Sertraline Product

22. Sertraline hydrochloride is a pharmaceutical compound useful in the treatment of depression. It is the active pharmaceutical ingredient ("API") in the product sold by Pfizer Inc. under the trade name ZOLOFT.

23. Pursuant to the Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq.* (1994), Teva USA filed Abbreviated New Drug Application ("ANDA") No. 76-465 with the United States Food & Drug Administration ("FDA") for permission to market generic sertraline hydrochloride tablets in the United States. The FDA granted final approval to Teva USA's ANDA on August 11, 2006.

24. Since approval of its ANDA, Teva USA has sold generic sertraline hydrochloride tablets in the United States. The tablets sold by Teva USA are manufactured by Teva Ltd.

Defendants' Infringement of the Patents In Suit

25. On information and belief, Cobalt Pharmaceuticals, Inc. filed ANDA No. 77-663 with the FDA, seeking permission to market generic sertraline hydrochloride tablets in competition with Plaintiffs' tablets. On February 6, 2007, the FDA granted final approval of Defendants' ANDA.

26. On information and belief, on or shortly after this approval, Defendants began to import, manufacture, use, sell and/or offer to sell in the United States their sertraline hydrochloride tablets. On information and belief, Defendants have engaged in and intend to continue to engage in these activities prior to the expiration of the patents in suit.

27. On information and belief, the sertraline hydrochloride API contained in Defendants' tablets is made by a process that infringes one or more claims of the patents in suit.

Accordingly, the importation, manufacture, use, sale and/or offer for sale of these tablets in the United States constitute acts of infringement under 35 U.S.C. § 271(g).

28. On information and belief, the sertraline hydrochloride API contained in Defendants' tablets is Form II or Form V. On information and belief, sertraline hydrochloride Forms I, II and V are the crystalline forms that are most likely to be used in a pharmaceutical tablet or capsule. On information and belief, Form I is claimed by an unexpired United States patent assigned to Pfizer Inc., and thus it is unlikely that Defendants are attempting to market products containing that polymorph.

29. On information and belief, Plaintiffs are not aware of any commercially viable process to manufacture Form V sertraline hydrochloride that is not covered by one or more claims of the '987 patent and and/or the '073 patent. Thus, on information and belief, there is a substantial likelihood that the sertraline hydrochloride API in Defendants' tablets, if Form V, is made by a process that infringes one or more claims of the '987 patent and/or the '073 patent.

30. On information and belief, given the scope of Teva Ltd.'s patent rights to methods of making Form II, there is a substantial likelihood that the sertraline hydrochloride API in Defendants' tablets, if Form II, is made by a process that infringes one or more claims of the '721 patent and/or the '340 patent.

31. Plaintiffs have made a reasonable effort to determine the process by which the sertraline hydrochloride API in Defendants' tablets is made. Currently, Plaintiffs cannot discover this process from a public source. On April 3, 2007, Teva Ltd. notified Defendants of the existence of the patents in suit and requested (a) a description of the process; (b) a sample of Defendants' API; and (c) the identification of the name(s) of the manufacturer(s) from which

Defendants have obtained or will obtain the API. In order to protect the confidentiality of Defendants' information, Teva Ltd. offered to enter into a confidentiality agreement.

32. To date, Defendants have not provided Teva Ltd. with (a) any information relating to the manufacturing process for the API believed to be used in their tablets, (b) samples of their API, or (c) the name(s) of the manufacturer(s) from which they have obtained or will obtain their API.

33. In the absence of a sufficient response from Defendants, Plaintiffs have no choice but to resort to judicial process and the aid of discovery to obtain, under appropriate judicial safeguards, the information required to confirm their beliefs as to infringement and to present to the Court evidence that Defendants are infringing the patents in suit.

34. On information and belief, Defendants' infringement is willful and deliberate.

35. As a direct and proximate consequence of the infringement by Defendants, Plaintiffs have been and will continue to be injured in their business and property rights unless the infringement is enjoined by the Court, and have suffered and will continue to suffer injury and damages for which they are entitled to relief.

COUNT I
PATENT INFRINGEMENT

36. The allegations of paragraphs 1 to 35 are incorporated by reference as if fully set forth herein.

37. The importation, manufacture, use, sale and/or offer to sell by the Defendants of their sertraline hydrochloride tablets pursuant to ANDA No. 77-663 infringes one or more claims of the '073, '987, '721 and/or '340 patents under 35 U.S.C. § 271.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for the entry of a judgment from this Court:

a. that Defendants are infringing one or more claims of the '073, '987, '721 and/or '340 patents;

b. that Defendants' infringement has been willful and that this is an exceptional case under 35 U.S.C. § 285;

c. that the '073, '987, '721 and '340 patents are valid and enforceable;

d. permanently enjoining Defendants, their respective officers, agents, servants and employees, and those persons in active concert or participation with any of them, from infringing the '073, '987, '721 and '340 patents;

e. awarding Plaintiffs damages in accord with 35 U.S.C. § 284;

f. awarding Plaintiffs their attorneys fees, costs and expenses; and

g. awarding Plaintiffs such other and further relief as this Court may deem to be just and proper.

JURY DEMAND

Plaintiffs respectfully demand a jury trial pursuant to Rule 38(b) of the Federal Rules of Civil Procedure on all issues so triable.

LITE DEPALMA GREENBERG & RIVAS, LLC

Dated: April 10, 2007

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