UNITED STATES DISTRICT COURT
DISTRICT OF MARYLAND

TEVA PHARMACEUTICAL INDUSTRIES LTD. and TEVA PHARMACEUTICALS USA, INC.,

Plaintiffs,

v.

LUPIN LIMITED. and LUPIN PHARMACEUTICALS, INC.,

Defendants.

Civil Action No. JFM 07 CV 0121

COMPLAINT FOR DECLARATORY JUDGMENT

For their Complaint against Defendants Lupin Limited and Lupin Pharmaceuticals, Inc., 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, Lupin Limited is an Indian corporation having a principal place of business at Laxmi Towers, "B" Wing, 5th Floor, Bandra Kurla Complex, Mumbai – 400 051, India.

4. On information and belief, Lupin Pharmaceuticals, Inc. is a Virginia corporation having a principal place of business at Harborplace Tower, 111 South Calvert Street, 21st Floor, Baltimore, MD 21202.

5. On information and belief, Lupin Pharmaceuticals, Inc. is a wholly-owned subsidiary of Lupin Limited.

6. On information and belief, Lupin Pharmaceuticals, Inc. acts as the agent of Lupin Limited. Lupin Limited and Lupin Pharmaceuticals, Inc. collectively will be referred to hereafter as "Defendants."

NATURE OF THE ACTION

7. 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

8. This court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

9. This Court may declare the rights and other legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because this is a case of actual controversy within the Court's jurisdiction.

10. The Court has personal jurisdiction over Lupin Pharmaceuticals, Inc. because of its presence in Maryland and its continuous and systematic contacts with the state of Maryland.

11. The Court has personal jurisdiction over Lupin Limited because of its presence in Maryland and its continuous and systematic contacts with the state of Maryland, including those made through Lupin Pharmaceuticals, Inc.

12. 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

13. 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."

14. 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.

15. 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.

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

17. 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.

18. 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.

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

Plaintiffs' Generic Exclusivity

20. 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. Teva USA sells generic sertraline hydrochloride tablets in the United States that are manufactured by Teva Ltd.

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

22. Ivax Pharmaceuticals, Inc. ("Ivax"), a separate wholly-owned subsidiary of Teva Ltd., filed ANDA No. 75-719 with the FDA, also seeking permission to market generic sertraline hydrochloride tablets in the United States.

23. Ivax's ANDA was approved on June 30, 2006. Under § 355(j) of the Act, Ivax obtained a limited period of exclusivity from the FDA for its generic sertraline products in the United States.

Pursuant to this exclusivity, the FDA will not approve any other ANDA for generic sertraline hydrochloride tablets for a period of 180 days from the date Ivax first commercially marketed a product under its ANDA. This exclusivity period expires on February 6, 2007, *i.e.*, the FDA may grant final approval to other ANDA holders beginning on February 7, 2007.

24. Ivax has selectively waived its exclusivity period with respect to Teva USA's ANDA No. 76-465. Following this selective waiver, the FDA granted final approval to Teva's ANDA on August 11, 2006.

Defendants' Imminent Infringement of the Patents In Suit

25. On information and belief, Defendants have filed ANDA No. 77-670 with the FDA, seeking permission to market generic sertraline hydrochloride tablets in competition with Plaintiffs.

26. On information and belief, the FDA has tentatively approved Defendants' ANDA, and will issue final approval upon the expiration of Ivax's exclusivity period.

27. On information and belief, Defendants plan and intend to import, manufacture, use, sell and/or offer to sell in the United States their sertraline hydrochloride tablets immediately upon receiving final FDA approval. On information and belief, Defendants plan and intend to engage in these activities prior to the expiration of the patents in suit.

28. On information and belief, the sertraline hydrochloride API contained in Defendants' tablets is or will be made by a process that infringes one or more claims of the patents in suit. Accordingly, Defendants' plans and intentions to import, manufacture, use, sell and/or offer to sell in the United States their sertraline hydrochloride tablets constitute imminent, threatened acts of infringement under 35 U.S.C. § 271(g), which give rise to an actual controversy over which this Court may exercise jurisdiction.

29. On information and belief, the sertraline hydrochloride API contained in Defendants' tablets is or will be 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. 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 will attempt to market products containing that polymorph.

30. 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/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 or will be made by a process that infringes one or more claims of the '987 patent and/or the '073 patent.

31. 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 or will be made by a process that infringes one or more claims of the '721 patent and/or the '340 patent.

32. Plaintiffs have made a reasonable effort to determine the process by which the sertraline hydrochloride API in Defendants' tablets is or will be made. Currently, Plaintiffs are unable to obtain from a public source samples of Defendants' tablets or API, or any information regarding the method used to manufacture the API. On November 30, 2006, Teva Ltd. notified Lupin Pharmaceuticals, Inc. of the existence of the patents in suit and requested a description of the manufacturing process for the API believed to be used in Defendants' tablets, and a sample of the API. In order to protect the confidentiality of Defendants' information, Teva Ltd. offered to enter into a confidentiality agreement.

33. Defendants have not responded to Teva Ltd.'s requests for information relating to the manufacturing process for the API believed to be used in their tablets despite Teva Ltd.'s offer to review any material subject to a confidentiality agreement. Defendants also have not provided a sample of their API.

34. On information and belief, even if Plaintiffs had been able to obtain samples of Defendants' tablets and/or API from a public source or from Defendants, Plaintiffs are not aware of any analytical technique or combination of techniques that could be used to definitively establish that the sertraline hydrochloride in the tablets was made by one or more of the methods claimed in the patents in suit. For this reason, Plaintiffs cannot conclusively determine whether Defendants' tablets and/or API infringe the patents in suit unless and until Defendants disclose to Plaintiffs the method by which the sertraline hydrochloride API contained therein is or will be made. Analysis of any samples, however, likely would have allowed Plaintiffs to determine their polymorphic form, which could have allowed Plaintiffs to narrow the number of asserted patents, or even have led to nonassertion of patents if neither Form II nor Form V were found.

35. 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 will infringe the patents in suit.

36. On information and belief, Defendants' infringement will be willful and deliberate.

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

COUNT I
DECLARATORY JUDGMENT OF PATENT INFRINGEMENT

38. The allegations of paragraphs 1 to 37 are incorporated by reference as if fully set forth herein.

39. The importation, manufacture, use, sale and/or offer to sell by the Defendants of their sertraline hydrochloride tablets pursuant to ANDA No. 77-670 will infringe 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. Declaring that the '073, '987, '721 and '340 patents are valid and enforceable;

b. Declaring that Defendants will infringe one or more claims of the '073, '987, '721 and/or '340 patents;

c. Declaring that Defendants' infringement will be willful and that this is an exceptional case under 35 U.S.C. § 285;

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.

Respectfully submitted,

Dated: January 12, 2007

Edward T. Colbert (Bar # 05447)
KENYON & KENYON LLP
1500 K Street, NW
Washington, DC 20005-1257
(202) 220-4200
(202) 220-4201 (fax)
Attorneys for Plaintiffs Teva Pharmaceutical Industries Ltd. and Teva Pharmaceuticals USA, Inc.

Of Counsel:

KENYON & KENYON LLP
Steven J. Lee
Robert V. Cerwinski
One Broadway
New York, NY 10004-1050
Phone (212) 425-7200
Fax (212) 425-5288