

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

Plaintiffs,

v.

TORRENT PHARMACEUTICALS LTD. and
TORRENT PHARMA INC.,

Defendants.

C. A. No. _____

COMPLAINT

For their Complaint against Defendants Torrent Pharmaceuticals Ltd. and Torrent Pharma 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, Torrent Pharmaceuticals Ltd. is an Indian corporation having a principal place of business at Off. Ashram Road, Ahmedabad – 380 009, Gujarat, India.

4. On information and belief, Torrent Pharma Inc. is a Delaware corporation having a principal place of business at 2585 Bellflower Dr., Portage, MI 49024.

5. On information and belief, Torrent Pharma Inc. is a wholly-owned subsidiary of Torrent Pharmaceuticals Ltd.

6. On information and belief, Torrent Pharma Inc. acts as the agent of Torrent Pharmaceuticals Ltd. Torrent Pharmaceuticals Ltd. and Torrent Pharma 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 Torrent Pharma Inc. because it is incorporated in the state of Delaware under number 650439.

11. The Court has personal jurisdiction over Torrent Pharmaceuticals Ltd. because of its presence in Delaware and its continuous and systematic contacts with the state of Delaware, including those made through Torrent Pharma 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 Sertraline Product

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.

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 generic sertraline hydrochloride tablets in the United States. The FDA granted final approval to Teva USA's ANDA on August 11, 2006.

22. 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' Imminent Infringement of the Patents In Suit

23. On information and belief, Defendant Torrent Pharma Inc. filed ANDA No. 77-765 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 this ANDA.

24. On information and belief, Defendant Torrent Pharmaceutical Ltd., through Defendant Torrent Pharma Inc., filed Drug Master File ("DMF") No. 18311 for sertraline

hydrochloride API with the FDA. On information and belief, the act of filing a DMF indicates the present intent of the filer to supply API to at least one ANDA holder.

25. On information and belief, Defendants plan and intend to imminently engage in the commercial importation, manufacture, use, sale and/or offer for sale of sertraline hydrochloride tablets in the United States. On information and belief, these commercial activities will take place before the expiration of the patents in suit.

26. On information and belief, Defendants also plan and intend to imminently engage in the commercial importation, manufacture, use, sale and/or offer for sale of sertraline hydrochloride API in the United States. On information and belief, the sertraline hydrochloride API will be supplied to one or more ANDA holders, including Defendant Torrent Pharma Inc. and third party ANDA holder(s), with the knowledge and intent that such ANDA holder(s) will engage in the commercial importation, manufacture, use, sale and/or offer for sale of generic sertraline hydrochloride tablets in the United States. On information and belief, these commercial activities will take place before the expiration of the patents in suit.

27. On information and belief, Defendants' sertraline hydrochloride API and tablets containing the same will be made by a process that infringes one or more of the claims of the patents in suit. Accordingly, Defendants' plans and intentions to engage in the commercial importation, manufacture, use, sale and/or offer for sale of generic sertraline hydrochloride API and tablets in the United States 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.

28. On information and belief, Defendants' plans and intentions to supply sertraline hydrochloride API to ANDA holder(s) outside of the United States for incorporation into

products that it knows will be imported, manufactured, used, sold and/or offered for sale in the United States constitute imminent, threatened inducement of infringement under 35 U.S.C. §§ 271(b) and (g), which gives rise to an actual controversy over which this Court may exercise jurisdiction.

29. On information and belief, Defendants' sertraline hydrochloride API 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. 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 API containing that polymorph to customers intending to sell products in the United States.

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 Defendants' sertraline hydrochloride API, 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 Defendants' sertraline hydrochloride API, 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 Defendants' sertraline hydrochloride API is or will be made. Currently, Plaintiffs are unable to obtain from a public source information regarding the method used to manufacture Defendants' API. On November 30, 2006, Teva Ltd. notified Torrent Pharmaceuticals Ltd. of the existence

of the patents in suit and requested a description of the manufacturing process used by Defendants to make the API. In order to protect the confidentiality of Defendants' information, Teva Ltd. offered to enter into a confidentiality agreement.

33. Defendants have not disclosed any information relating to their manufacturing process to Plaintiffs despite Teva Ltd.'s offer to review such information under a confidentiality agreement.

34. Further, Plaintiffs have been unable to obtain samples of Defendants' tablets or API from a public source. However, on information and belief, even if Plaintiffs had been able to obtain samples of Defendants' tablets or API, Plaintiffs are not aware of any analytical technique or combination of techniques that could be used to definitively establish that the tablets or API were made by one or more of the methods claimed in the patents in suit. For this reason, Plaintiffs cannot conclusively determine whether Defendants' tablets or API infringe the patents in suit unless and until Defendants disclose to Plaintiffs the method by which they are made.

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. Defendants' importation, manufacture, use, sale and/or offer to sell in the U.S. of their sertraline hydrochloride API pursuant to DMF No. 18311, and their sertraline hydrochloride tablets pursuant to ANDA No. 77-765, will infringe one or more claims of the '073, '987, '721 and/or '340 patents.

40. Defendants' infringement will be willful.

**COUNT II
DECLARATORY JUDGMENT OF INDUCEMENT OF PATENT INFRINGEMENT**

41. The allegations of paragraphs 1 to 40 are incorporated by reference as if fully set forth herein.

42. Defendants' supply of their infringing sertraline hydrochloride API to companies that will engage in the importation, manufacture, use, sale and/or offer to sell in the U.S. of products made with that API will induce the infringement of one or more claims of the '073, '987, '721 and/or '340 patents under 35 U.S.C. § 271.

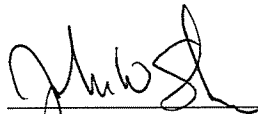
PRAYER FOR RELIEF

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

- a. declaring that Defendants will infringe one or more claims of the '073, '987, '721 and/or '340 patents;
- b. declaring that Defendants will induce infringement of one or more claims of the '073, '987, '721 and/or '340 patents;

- c. declaring that Defendants' infringement and inducement will be willful and that this is an exceptional case under 35 U.S.C. § 285;
- d. declaring that the '073, '987, '721 and '340 patents are valid and enforceable;
- e. permanently enjoining Defendants, their respective officers, agents, servants and employees, and those persons in active concert or participation with any of them, from infringing or inducing the infringement of the '073, '987, '721 and '340 patents;
- f. awarding Plaintiffs damages in accord with 35 U.S.C. § 284;
- g. awarding Plaintiffs their attorneys fees, costs and expenses; and
- h. awarding Plaintiffs such other and further relief as this Court may deem to be just and proper.

Respectfully submitted,



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