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.*	Civil Action No. _____

COMPLAINT FOR DECLARATORY JUDGMENT

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 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. Under the Act, ANDA holders must provide detailed information to the FDA about how the API to be used in their proposed generic products will be made. Suppliers of API typically are reluctant to disclose confidential information about their manufacturing processes to their customers. Such API suppliers typically submit this confidential information directly to the FDA in the form of a Drug Master File ("DMF"), which the FDA keeps on file. Customers of the API supplier who file ANDAs may then reference the DMF in their ANDAs. Upon receiving an ANDA referencing a DMF, the FDA will separately review the DMF as part of the ANDA approval process. Accordingly, the act of filing a DMF indicates that the present intent of the filer is to supply API to at least one ANDA holder.

26. On information and belief, Defendant Torrent Pharmaceutical Ltd. has filed DMF No. 18311 for sertraline hydrochloride API with the FDA through Torrent Pharma Inc.

27. On information and belief, Defendants plan and intend to supply sertraline hydrochloride API to one or more third party ANDA holder(s), with the knowledge and intent that the third party 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. Plaintiffs have made a reasonable effort to determine the identity of the third party ANDA

holder(s) that Defendants intend to supply. Currently, Plaintiffs are unable to obtain from a public source any information regarding the entities that Defendants intend to supply.

28. On information and belief, Defendants plan and intend to supply the third party ANDA holder(s) with the knowledge and intent that the third party ANDA holder(s) will engage in the activities described in paragraph 27 immediately upon receiving final approval of the ANDA(s) by the FDA, and that said approval will occur shortly after Ivax's exclusivity period expires.

29. On information and belief, Defendants plan and intend to supply the third party ANDA holder(s) with the knowledge and intent that the third party ANDA holder(s) will engage in the activities described in paragraph 27 prior to the expiration of the patents in suit.

30. On information and belief, Defendants plan and intend to import sertraline hydrochloride into the United States for sale to third party ANDA holder(s).

31. On information and belief, Defendants' sertraline hydrochloride API is or 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 import and sell sertraline hydrochloride API 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.

32. On information and belief, Defendants' plans and intentions to supply sertraline hydrochloride API to third party ANDA holder(s) outside of the United States for incorporation into products that it knows will be imported and sold in the United States constitutes 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.

33. 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.

34. 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.

35. 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.

36. 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.

37. Defendants have not responded to Teva Ltd.'s requests for information relating to their manufacturing process despite Teva Ltd.'s offer to review any material subject to a supplied confidentiality agreement.

38. Further, Plaintiffs have been unable to obtain from a public source samples of the API Defendants are selling, or intend to sell, to the third party ANDA holder(s) they are supplying or will supply. However, on information and belief, even if Plaintiffs had been able to obtain samples of Defendants' API form a public source, Plaintiffs are not aware of any analytical technique or combination of techniques that could be used to definitively establish that the API was made by one or more of the methods claimed in the patents in suit. For this reason, Plaintiffs cannot conclusively determine whether Defendants' API infringes the patents in suit unless and until Defendants disclose to Plaintiffs the method by which the API is made.

39. 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.

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

41. 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

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

43. The importation, sale and/or offer to sell by the Defendants of their sertraline hydrochloride API pursuant to DMF No. 18311 will infringe one or more claims of the '073, '987, '721 and/or '340 patents under 35 U.S.C. § 271.

COUNT II
DECLARATORY JUDGMENT OF INDUCEMENT OF PATENT INFRINGEMENT

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

45. The supply of sertraline hydrochloride API pursuant to DMF No. 18311 by the Defendants to companies who will engage in the importation, sale and/or offer to sell 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 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 will induce infringement of one or more claims of the '073, '987, '721 and/or '340 patents;

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

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.

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