UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

JUDGE CEDARBAUM

SHIRE LLC,

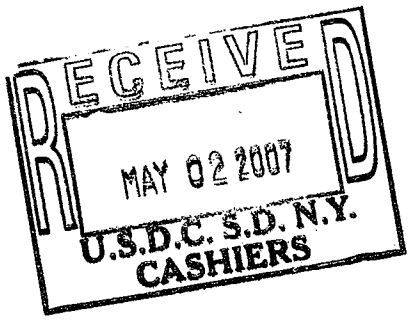
Plaintiff,

v.

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

Defendant.

Civil Action No. 07 CV 3526



COMPLAINT

Plaintiff Shire LLC ("Shire"), for its Complaint against Defendants Teva Pharmaceuticals Industries Ltd. ("Teva Ltd.") and Teva Pharmaceuticals USA, Inc. ("Teva USA"), by its attorneys, hereby alleges as follows:

The Parties

1. Shire is a corporation organized and existing under the laws of the State of Kentucky, having its principal place of business at 9200 Brookfield Court, Florence, Kentucky 41042.

2. Defendant Teva Ltd. is a corporation organized and existing under the laws of Israel, having its principal place of business at 5 Basel Street, Petah Tiqvah, Israel.

3. Defendant Teva USA is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454-1090.

4. Teva USA is a wholly-owned subsidiary of Teva Ltd.

5. Unless otherwise stated, Teva Ltd. and Teva USA will be referred to collectively as "Teva."

Nature of the Action

6. This is an action for patent infringement under the patent laws of the United States, Title 35, United States code, involving United States Patent Nos. 5,326,570 ("the '570 patent;" Exhibit A hereto) and 5,912,013 ("the '013 patent;" Exhibit B hereto).

Jurisdiction and Venue

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

8. Upon information and belief, Teva Ltd. conducts business throughout the United States and specifically within New York.

9. This Court has personal jurisdiction over Teva Ltd. because Teva Ltd. maintains sufficient minimum contacts, both generally and specifically, with this judicial district. The exercise of such jurisdiction is consistent with the requirements of due process and does not offend traditional notions of fair play and substantial justice.

10. Upon information and belief, Teva USA regularly conducts business throughout the United States and specifically derives substantial revenue from goods, food, services, or manufactured products used or consumed in New York, including but not limited to sales and distribution of drugs.

11. This court has personal jurisdiction over Teva USA because Teva USA maintains sufficient minimum contacts, both generally and specifically, with this judicial district. The exercise of such jurisdiction is consistent with the requirements of due process and does not offend traditional notions of fair play and substantial justice.

12. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c), and § 1400(b).

Background

13. Shire is the owner of New Drug Application ("NDA") No. 20-712, which was approved by the Food and Drug Administration ("FDA") for the manufacture and sale of an extended-release capsule containing carbamazepine for the treatment of epilepsy and trigeminal neuralgia. Shire US, Inc. (a related company) markets and sells these compositions in the United States under the trade name Carbatrol®.

14. Upon information and belief, Teva USA submitted Abbreviated New Drug Application ("ANDA") No. 78-592 ("Teva's ANDA") to the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) seeking approval to engage in the commercial manufacture, use, and sale of carbamazepine extended-release capsules at the 100 mg, 200 mg, and 300 mg dosage strengths ("Teva's ANDA Products").

15. Teva USA sent Shire a "Patent Certification Notice – U.S. Patent Nos. 5,326,570 and 5,912,013" pursuant to § 505(j)(2)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)(2)(B)), dated March 20, 2007 ("Teva's Notice Letter" or "Notice Letter").

16. Upon information and belief, Teva Ltd. directed Teva USA to file ANDA No. 78-592, and Teva USA complied. Teva Ltd. also directed Teva USA to submit paragraph IV certifications concerning the '570 and '013 patents, and Teva USA also complied.

17. Upon information and belief, Teva Ltd. and Teva USA were both aware of the '570 and '013 patents when Teva Ltd. directed Teva USA to file ANDA No. 78-592 and submit paragraph IV certifications concerning the '570 and '013 patents.

18. Upon information and belief, Teva Ltd. directed Teva USA to send Shire the Notice Letter and Teva USA complied.

FIRST COUNT
(Infringement of the '570 Patent)

19. Shire repeats and realleges paragraphs 1 through 18 above as if fully set forth herein.

20. The '570 patent, entitled "Advanced Drug Delivery System And Method Of Treating Psychiatric, Neurological And Other Disorders With Carbamazepine," was duly and legally issued on July 5, 1994, to Pharmavene, Inc. ("Pharmavene") upon assignment from Edward M. Rudnic and George W. Belendiuk. Upon Pharmavene's merger with and into Shire Laboratories Inc. ("Shire Laboratories"), Shire Laboratories became the owner of the '570 patent. Upon the merger of Shire Laboratories into Shire, Shire became and remains the owner of the '570 patent. The '570 patent claims, *inter alia,* a drug delivery system for the oral administration of carbamazepine.

21. Pursuant to 21 U.S.C. § 355(b)(1), the '570 patent is listed in "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") as covering Shire's Carbatrol® drug products.

22. Upon information and belief, Teva USA filed a paragraph IV certification for the '570 patent in its ANDA to obtain approval to engage in the commercial manufacture, use or sale of carbamazepine extended-release capsules before the expiration of the '570 patent.

23. 21 U.S.C. § 355(j)(2)(B)(iv)(II) requires that a letter notifying a patent holder of the filing of an ANDA containing a paragraph IV certification "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." Likewise, 21 C.F.R. § 314.95(c)(6) requires a paragraph IV notification to include "[a] detailed statement of the factual and legal basis of applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement is to include "(i) [f]or

each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation." *Id.*

24. On information and belief, as of the date of Teva's Notice Letter (March 20, 2007), Teva was aware of the statutory provisions and regulations referred to in paragraph 23, above.

25. Teva's Notice Letter stated that Teva's ANDA does not infringe the '570 patent. Nevertheless, Teva's Notice Letter provided Shire with insufficient information regarding Teva's ANDA Products that are the subject of ANDA No. 78-592. Until Shire receives sufficient information from Teva, Shire cannot evaluate, confirm or test the correctness of Teva USA's certification that the '570 patent has not and would not be infringed. On information and belief, therefore, Shire alleges that Teva USA's submission to the FDA of ANDA No. 78-592 with a paragraph IV certification for the '570 patent and for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of a drug product before the expiration of the '570 patent is an act of infringement of one or more claims of the '570 patent under 35 U.S.C. § 271(e)(2)(A).

26. On information and belief, Shire alleges that Teva's commercial manufacture, use, sale, offer for sale, or importation into the United States of the proposed drug products that are the subject of ANDA No. 78-592, carbamazepine extended-release capsules at the 100 mg, 200 mg, and 300 mg dosage strengths, will infringe one or more claims of the '570 patent.

27. Upon information and belief, Teva has been aware of the existence of the '570 patent, making the acts of infringement set forth above deliberate and willful, thus rendering this case "exceptional" under 35 U.S.C. § 285.

28. The acts of infringement set forth above will cause Shire irreparable harm for which it has no adequate remedy at law, unless Teva is preliminarily and permanently enjoined by this Court.

SECOND COUNT
(Infringement of the '013 Patent)

29. Shire repeats and realleges paragraphs 1 through 28 above as if fully set forth herein.

30. The '013 patent, entitled "Advanced Drug Delivery System And Method Of Treating Psychiatric, Neurological And Other Disorders With Carbamazepine," was duly and legally issued on June 15, 1999, to Shire Laboratories, a predecessor company to Shire, upon assignment from Edward M. Rudnic, George W. Belendiuk, John McCarty, Sandra Wassink and Richard A. Couch. Upon the merger of Shire Laboratories into Shire, Shire became and remains the owner of the '013 patent. The '013 patent claims, *inter alia*, a pharmaceutical formulation containing carbamazepine.

31. Pursuant to 21 U.S.C. § 355(b)(1), the '013 patent is listed in "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") as covering Shire's Carbatrol® drug products.

32. Upon information and belief, Teva USA filed a paragraph IV certification for the '013 patent in its ANDA to obtain approval to engage in the commercial manufacture, use or sale of carbamazepine extended-release capsules before the expiration of the '013 patent.

33. 21 U.S.C. § 355(j)(2)(B)(iv)(II) requires that a letter notifying a patent holder of the filing of an ANDA containing a paragraph IV certification "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." Likewise, 21 C.F.R. § 314.95(c)(6) requires a paragraph IV notification to include

"[a] detailed statement of the factual and legal basis of applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement is to include "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation." *Id.*

34. On information and belief, as of the date of Teva's Notice Letter (March 20, 2007), Teva was aware of the statutory provisions and regulations referred to in paragraph 33, above.

35. Teva's Notice Letter stated that Teva's ANDA does not infringe the '013 patent. Nevertheless, Teva's Notice Letter provided Shire with insufficient information regarding Teva's ANDA Products that are the subject of ANDA No. 78-592. Until Shire receives sufficient information from Teva, Shire cannot evaluate, confirm or test the correctness of Teva USA's certification that the '013 patent has not and would not be infringed. On information and belief, therefore, Shire alleges that Teva USA's submission to the FDA of ANDA No. 78-592 with a paragraph IV certification for the '013 patent and for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of a drug product before the expiration of the '013 patent is an act of infringement of one or more claims of the '013 patent under 35 U.S.C. § 271(e)(2)(A).

36. On information and belief, Shire alleges that Teva's commercial manufacture, use, sale, offer for sale, or importation into the United States of the proposed drug products that are the subject of ANDA No. 78-592, carbamazepine extended-release capsules at the 100 mg, 200 mg, and 300 mg dosage strengths, will infringe one or more claims of the '013 patent.

37. Upon information and belief, Teva has been aware of the existence of the '013

patent, making the acts of infringement set forth above deliberate and willful, thus rendering this case "exceptional" under 35 U.S.C. § 285.

38. The acts of infringement set forth above will cause Shire irreparable harm for which it has no adequate remedy at law, unless Teva is preliminarily and permanently enjoined by this Court.

PRAYER FOR RELIEF

WHEREFORE, plaintiff respectfully requests the following relief:

(a) A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), Teva USA's submission to the FDA of ANDA No. 78-592 with paragraph IV certifications to obtain approval for the commercial manufacture, use or sale in the United States of its 100 mg, 200 mg, and 300 mg carbamazepine extended-release capsules, was an act of infringement of the '570 and '013 patents;

(b) A judgment declaring that Teva's infringement of the '570 and '013 patents was willful;

(c) A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Teva's carbamazepine extended-release capsules that are the subject of ANDA No. 78-592 shall be no earlier than the expiration date of the last of the '570 and '013 patents;

(d) A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Teva and its officers, agents, servants, employees and attorneys, and those persons in active concert or participation or privity with them or any of them, from engaging in the commercial manufacture, use, offer to sell or sale within the United States or importation into the United States, of the carbamazepine extended-release capsules that are the subject of ANDA No. 78-592 until the expiration of the last of the '570 and '013 patents;

(e) A judgment awarding Shire damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Teva commercially manufactures, uses, offers for sale, sells or imports any product that infringes either the '570 or '013 patents;

(f) A judgment declaring that, pursuant to 35 U.S.C. § 285, this is an exceptional case and awarding Shire its attorneys' fees;

(g) A judgment awarding Shire its costs and expenses in this action; and

(h) A judgment awarding Shire such other and further relief as this Court may deem just and proper.

FROMMER LAWRENCE & HAUG LLP

Dated: May 2, 2006 By: _____

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