

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

SHIRE LLC,

Plaintiff,

v.

APOTEX INC., APOTEX CORP., and
APOTEX PHARMACEUTICAL
HOLDINGS INC.,

Defendants.

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Civil Action No. 2:08-cv-265

COMPLAINT

Plaintiff Shire LLC (“Shire”), by its undersigned attorneys, for its Complaint against defendants herein, alleges as follows:

THE PARTIES

1. Plaintiff 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. Upon information and belief, defendant Apotex Pharmaceutical Holdings Inc. is a corporation organized and existing under the laws of Canada, having a place of business at 150 Signet Drive, North York, Ontario, Canada M9L 1T9.

3. Upon information and belief, defendant Apotex Inc. is a corporation organized and existing under the laws of Canada, having a place of business at 150 Signet Drive, Weston, Ontario, Canada M9L 1T9. Upon information and belief, Apotex Inc. is a wholly owned subsidiary of Apotex Pharmaceutical Holdings Inc. Upon information and belief,

defendant Apotex Inc. develops, manufactures, markets, and/or distributes generic drugs for sale and use throughout the United States, including this judicial district.

4. Upon information and belief, defendant Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326. Upon information and belief, Apotex Corp. is a wholly owned subsidiary of Apotex Pharmaceutical Holdings Inc. Upon information and belief, defendant Apotex Corp. develops, manufactures, markets, and/or distributes generic drugs for sale and use through the United States, including this judicial district.

5. Unless otherwise stated, Apotex Pharmaceuticals Holdings Inc., Apotex Inc., and Apotex Corp. will be collectively referred to as “Apotex” or “defendants.”

NATURE OF THE ACTION

6. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, involving United States Letters 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 jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

8. This Court has personal jurisdiction over each of the defendants by virtue of the fact that, *inter alia*, each defendant has committed, or actively induced, encouraged, aided, or abetted patent infringement with knowledge that it is in contravention of Shire’s rights. The Court has personal jurisdiction over each of the defendants.

9. This Court has personal jurisdiction over defendants because defendants

have sufficient minimum contacts with the forum as a result of business conducted within the state of Texas. Each defendant—directly or through subsidiaries, intermediaries, or collaborators—ships, distributes, offers for sale, sells, imports, advertises, and/or makes generic drug products throughout the United States, the state of Texas, and the Eastern District of Texas.

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

FACTS COMMON TO ALL COUNTS

11. 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.

12. Apotex Inc. submitted Abbreviated New Drug Application (“ANDA”) No. 78-986 (“Apotex’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, importation, sale and/or offer for sale of Carbamazepine Extended Release Capsules 100 mg, 200 mg and 300 mg (“ANDA products”).

13. Apotex Inc. sent Shire a “Notification of Certification for U.S. Patent Nos. 5,326,570 and 5,912,013 Pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act,” dated May 19, 2008, regarding its ANDA products (“Notice Letter”).

14. Following receipt of the Notice Letter, Shire requested materials from ANDA No. 78-986 and capsules from each lot of the ANDA products. To date, Shire has not received any such materials and capsules.

FIRST COUNT

(Infringement of the '570 Patent)

15. Shire repeats and realleges paragraphs 1 through 14 above as if fully set forth herein.

16. 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 Shire Laboratories' merger with and 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.

17. 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.

18. Upon information and belief, Apotex Inc. filed a paragraph IV certification for the '570 patent in its ANDA to obtain approval to engage in the commercial manufacture, use, importation, sale and/or offer for sale of its ANDA products before the expiration of the '570 patent.

19. 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.” 21 C.F.R. §§ 314.95(c)(6)(i)-(ii).

20. Upon information and belief, as of the date of the Notice Letter (May 19, 2008), Apotex was aware of the statutory provisions and regulations referred to in paragraph 19, above.

21. Apotex Inc.’s Notice Letter stated that the ANDA products do not infringe the ’570 patent. Nevertheless, the Notice Letter provided Shire with insufficient information regarding the ANDA products that are the subject of ANDA No. 78-986. Until Shire receives sufficient information from Apotex, Shire cannot evaluate, confirm or test the correctness of Apotex Inc.’s certification that the ’570 patent has not and would not be infringed. Upon information and belief, therefore, Shire alleges that the submission to the FDA of ANDA No. 78-986 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 by Apotex of one or more claims of the ’570 patent under 35 U.S.C. § 271(e)(2)(A).

22. Upon information and belief, Shire alleges that Apotex’s commercial manufacture, use, sale, offer for sale, or importation into the United States of the ANDA that are the subject of ANDA No. 78-986, will infringe one or more claims of the ’570 patent.

23. Apotex Corp. and Apotex Pharmaceutical Holdings Inc. are jointly and severally liable for Apotex Inc.’s infringement of one or more claims of the ’570 patent. Upon

information and belief, Apotex Corp. and Apotex Pharmaceutical Holdings Inc. actively induced, encouraged, aided, or abetted Apotex Inc.'s submission of ANDA No. 78-986 and its paragraph IV certification to the FDA.

24. Apotex Corp.'s and Apotex Pharmaceutical Holdings Inc.'s inducement, encouragement, aiding, or abetting of the submission of ANDA No. 78-986 and Apotex Inc.'s paragraph IV certification to the FDA constitutes infringement of the '570 patent under 35 U.S.C. § 271(e)(2)(A). Further Apotex Corp.'s and Apotex Pharmaceutical Holdings Inc.'s commercial use, offer for sale, or sale of the ANDA products would infringe the '570 patent.

25. Upon information and belief, Apotex 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.

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

SECOND COUNT
(Infringement of the '013 Patent)

27. Shire repeats and realleges paragraphs 1 through 26 above as if fully set forth herein.

28. 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 upon assignment from Edward M. Rudnic, George W. Belendiuk, John McCarty, Sandra Wassink, and Richard A. Couch. Upon Shire Laboratories' merger with and into Shire, Shire became and remains the owner of the '013 patent. The '013 patent claims, *inter alia*, a pharmaceutical formulation containing

carbamazepine.

29. 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.

30. Upon information and belief, Apotex Inc. filed a paragraph IV certification for the '013 patent in its ANDA to obtain approval to engage in the commercial manufacture, use, importation, sale and/or offer for sale of its ANDA products before the expiration of the '013 patent.

31. 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.” 21 C.F.R. §§ 314.95(c)(6)(i)-(ii).

32. Upon information and belief, as of the date of the Notice Letter (May 19, 2008), Apotex was aware of the statutory provisions and regulations referred to in paragraph 31, above.

33. Apotex Inc.’s Notice Letter stated that the ANDA products do not infringe the '013 patent. Nevertheless, the Notice Letter provided Shire with insufficient information

regarding the ANDA products that are the subject of ANDA No. 78-986. Until Shire receives sufficient information from Apotex, Shire cannot evaluate, confirm or test the correctness of Apotex Inc.'s certification that the '013 patent has not and would not be infringed. Upon information and belief, therefore, Shire alleges that the submission to the FDA of ANDA No. 78-986 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 by Apotex of one or more claims of the '013 patent under 35 U.S.C. § 271(e)(2)(A).

34. Upon information and belief, Shire alleges that Apotex's commercial manufacture, use, sale, offer for sale, or importation into the United States of the ANDA that are the subject of ANDA No. 78-986, will infringe one or more claims of the '013 patent.

35. Apotex Corp. and Apotex Pharmaceutical Holdings Inc. are jointly and severally liable for Apotex Inc.'s infringement of one or more claims of the '013 patent. Upon information and belief, Apotex Corp. and Apotex Pharmaceutical Holdings Inc. actively induced, encouraged, aided, or abetted Apotex Inc.'s submission of ANDA No. 78-986 and its paragraph IV certification to the FDA.

36. Apotex Corp.'s and Apotex Pharmaceutical Holdings Inc.'s inducement, encouragement, aiding, or abetting of the submission of ANDA No. 78-986 and Apotex Inc.'s paragraph IV certification to the FDA constitutes infringement of the '013 patent under 35 U.S.C. § 271(e)(2)(A). Further Apotex Corp.'s and Apotex Pharmaceutical Holdings Inc.'s commercial use, offer for sale, or sale of the ANDA products would infringe the '013 patent.

37. Upon information and belief, Apotex 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 defendants are 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), the submission to the FDA of ANDA No. 78-986 with a paragraph IV certification to obtain approval for the commercial manufacture, use, importation, sale and/or offer for sale in the United States of the ANDA products was an act of infringement of the '570 and '013 patents by Apotex;

(b) A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A) and Apotex Corp.'s and Apotex Pharmaceutical Holdings Inc.'s active inducement, encouragement, aiding, or abetting of the submission to the FDA of ANDA No. 78-986 with a paragraph IV certification to obtain approval for the commercial manufacture, use, importation, sale and/or offer for sale in the United States of the ANDA products was an act of infringement of the '570 and '013 patents;

(c) A judgment declaring that defendants' infringement of the '570 and '013 patents was willful;

(d) A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the ANDA products that are the subject of ANDA No. 78-986 shall be no earlier than the date on which the last of the '570 and '013 patents expires;

(e) A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining defendants and their 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 ANDA products that are the subject of ANDA No. 78-986 until the expiration of the last of the '570 and '013 patents;

(f) A judgment awarding Shire damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if defendants commercially manufacture, use, offer for sale, sell or import any product that infringes either the '570 or '013 patents;

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

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

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

Dated: July 2, 2008

Respectfully submitted,

/s/ Richard A. Sayles

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