UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

ALCON MANUFACTURING, LTD., ALCON LABORATORIES, INC., and KYOWA HAKKO KOGYO CO. LTD.,	)	
Plaintiffs,	)	CIVIL ACTION NO:
vs.	)	1:06-cv-1[illegible]-SEB-TAB
APOTEX INC. and APOTEX CORP.	)	
Defendants.	)	

COMPLAINT

Alcon Manufacturing, Ltd., Alcon Laboratories, Inc., and Kyowa Hakko Kogyo Co. Ltd. (collectively "Plaintiffs"), by their attorneys, for their Complaint, allege as follows:

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, that arises out of the filing by Defendants Apotex Inc. and Apotex Corp. of an Abbreviated New Drug Application ("ANDA") with the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic version of Patanol® ophthalmic solution, a drug product containing olopatadine hydrochloride, prior to the expiration of U.S. Patent No. 5,641,805 ("the '805 patent").

PARTIES

2. Plaintiff Alcon Manufacturing, Ltd. is a limited partnership organized and existing under the laws of the State of Texas, having its principal place of business at 6201 South Freeway, Fort Worth, Texas 76134.

3. Plaintiff Alcon Laboratories, Inc. is a corporation organized and existing

under the laws of the State of Delaware, having its principal place of business at 6201 South Freeway, Fort Worth, Texas 76134.

4. Plaintiff Kyowa Hakko Kogyo Co. Ltd. ("Kyowa") is a corporation organized and existing under the laws of Japan, having its principal place of business at 1-6-1 Otemachi, Chiyoda-ku, Tokyo 100-8185, Japan.

5. Upon information and belief, Defendant Apotex Inc. is a corporation organized and existing under the laws of Canada, having its principal place of business at 150 Signet Dr., Weston, Ontario M9L 1T9, Canada.

6. Upon information and belief, Defendant Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.

7. Except where otherwise noted, Apotex Inc. and Apotex Corp. are referred to collectively herein as "Apotex."

JURISDICTION AND VENUE

8. Jurisdiction and venue are proper in this district pursuant to 28 U.S.C. §§ 1331, 1338(a), 1391, and 1400(b).

9. Upon information and belief, Apotex Inc. ships Apotex products from Canada to a distribution and operations center located in Indianapolis, Indiana.

10. Upon information and belief, Apotex Corp., a wholly-owned subsidiary of Apotex Inc., operates the operations and distribution center in Indianapolis through which it distributes Apotex products for sale throughout the United States.

COUNT I
(Patent Infringement)
(Defendants Apotex Inc. and Apotex Corp.)

11. Plaintiffs incorporate each of the preceding paragraphs 1-10 as if fully set forth herein.

12. Alcon Laboratories, Inc. holds the approved New Drug Application, No. 20-688, for Patanol® ophthalmic solution. The active ingredient of Patanol® is olopatadine hydrochloride. The New Drug Application was granted on December 18, 1996. Patanol® is approved for the treatment of the signs and symptoms of allergic conjunctivitis.

13. United States Patent No. 5,641,805, entitled "Topical Ophthalmic Formulations for Treating Allergic Eye Diseases", was duly and legally issued on June 24, 1997, to Alcon Laboratories, Inc. and Kyowa Hakko Kogyo Co. Ltd., as assignees of John Michael Yanni, Stella M. Robertson, Eiji Hayakawa, and Masahi Nakakura.

14. Alcon Laboratories, Inc. has assigned the '805 patent to Alcon Manufacturing, Ltd.

15. Alcon Laboratories, Inc. has been granted a license under the '805 patent and sells drug products covered by the '805 patent under the trademark Patanol® pursuant to a New Drug Application held by Alcon Laboratories Inc. and approved by the FDA.

16. By letter dated October 2, 2006 (the "Notice Letter"), Apotex notified Alcon, Inc., Alcon Manufacturing, Ltd., and Kyowa that Apotex had submitted an ANDA, No. 78-350, to the FDA. The purpose of the ANDA was to obtain approval under the Federal Food, Drug, and Cosmetic Act ("FDCA") to engage in the commercial manufacture, use, and sale of a drug product containing olopatadine hydrochloride prior to the expiration of the '805 patent.

17. Upon information and belief, the drug product containing olopatadine

hydrochloride that is the subject of ANDA No. 78-350 is covered by one or more claims of the '805 patent.

18. In the Notice Letter, Apotex also notified Alcon, Inc., Alcon Manufacturing, Ltd., and Kyowa that, as part of its ANDA, Apotex had filed certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

19. Apotex's filing of the ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of a drug product containing olopatadine hydrochloride before the expiration of the '805 patent is an act of infringement of that patent under 35 U.S.C. § 271(e)(2)(A).

20. Upon information and belief, Apotex acted without a reasonable basis for believing that it would not be liable for infringement of the '805 patent.

21. Plaintiffs will be substantially and irreparably damaged by infringement of the '805 patent.

22. Unless Apotex is enjoined from infringing the '805 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT II
(Inducing Infringement)
(Defendant Apotex Inc.)

23. Plaintiffs reallege paragraphs 1 through 22 above as if fully set forth herein.

24. Upon information and belief, Apotex Inc. participated in the selection of the olopatadine hydrochloride product which is the subject of ANDA No. 78-350 and was responsible for and controlled the filing of said ANDA.

25. Upon information and belief, Apotex Inc., is liable as an infringer of the

'805 patent under 35 U.S.C. § 271(b) for knowingly inducing, with the specific intent of encouraging, Apotex Corp. to infringe the '805 patent by filing the ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of drug products containing olopatadine hydrochloride before the expiration of the '805 patent.

26. Plaintiffs will be irreparably harmed if Apotex Inc. is not enjoined from inducing the infringement of the '805 patent.

27. Upon information and belief, Apotex Inc. acted without a reasonable basis for believing that it would not be liable for inducing infringement of the '805 patent.

WHEREFORE, Plaintiffs request the following relief:

(a) A judgment providing that the effective date of any FDA approval for Apotex to commercially make, use, or sell olopatadine hydrochloride or any drug product containing olopatadine hydrochloride be not earlier than the expiration date of United States Patent No. 5,641,805;

(b) A preliminary and permanent injunction against any infringement by Apotex of United States Patent No. 5,641,805 through the commercial manufacture, use, sale, offer for sale, or importation into the United States of olopatadine hydrochloride or any drug product containing olopatadine hydrochloride;

(c) A preliminary and permanent injunction against any inducement of infringement by Apotex Inc. of United States Patent No. 5,641,805;

(d) A declaration that this in an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;

(e) Costs and expenses in this action; and

(f) Such further and other relief as this Court may deem just and proper.

Respectfully submitted,

Dated: November 15, 2006

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