

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

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LABORATORY

ALCON MANUFACTURING, LTD.,)
ALCON LABORATORIES, INC., and)
KYOWA HAKKO KOGYO CO. LTD.,)
)
Plaintiffs,)
)
v.)
)
BARR LABORATORIES, INC.,)
)
Defendants.)
_____)

CIVIL ACTION NO:

1: 07-cv-1377-DFH-TAB

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 Defendant Barr Laboratories, Inc. ("Barr") 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 Nos. 5,641,805 and 5,116,863.

PARTIES

2. Plaintiff Alcon Manufacturing, Ltd. 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.

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 Barr is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 400 Chestnut Ridge Road, Woodcliff Lake, NJ 07677.

JURISDICTION AND VENUE

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

7. Upon information and belief, Barr is in the business of marketing pharmaceutical products, which it distributes and sells throughout the United States, including the State of Indiana and the Southern District of Indiana.

COUNT I

(Patent Infringement - 5,641,805)

8. Plaintiffs incorporate each of the preceding paragraphs 1 through 7 as if fully set forth herein.

9. 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.

10. United States Patent No. 5,641,805 (“the ’805 patent”), entitled “Topical Ophthalmic Formulations for Treating Allergic Eye Diseases” (Exhibit A hereto), 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 Masashi Nakakura.

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

12. 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.

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

14. By letter dated September 25, 2007 (the "Notice Letter"), Barr notified Alcon, Inc., Alcon Laboratories, Inc., Alcon Manufacturing, Ltd., and Kyowa that Barr had submitted an ANDA, No. 79-092, 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.

15. Upon information and belief, the drug product containing olopatadine hydrochloride that is the subject of ANDA No. 79-092 is covered by one or more claims of the '805 patent.

16. In the Notice Letter, Barr also notified Alcon, Inc., Alcon Laboratories, Inc., Alcon Manufacturing, Ltd., and Kyowa that, as part of its ANDA, Barr had filed certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

17. Barr'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).

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

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

COUNT II

(Patent Infringement – Patent No. 5,116,863)

20. Plaintiffs incorporate each of the preceding paragraphs 1 through 19 as if fully set forth herein.

21. 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.

22. United States Patent No. 5,116,863 (“the '863 patent”), entitled “Dibenz[b,e]oxepin Derivative and Pharmaceutical Compositions Thereof” (Exhibit B hereto), was duly and legally issued on May 26, 1992, to Kyowa Hakko Kogyo Co. Ltd., as an assignee of Etsuo Oshima, Toshiaki Kumazawa, Shizuo Otaki, Hiroyuki Obase, Kenji Ohmori, Hidee Ishii, Haruhiko Manabe, Tadafumi Tamura, and Katsuichi Shuto.

23. Alcon Laboratories, Inc. has been granted a license under the '863 patent and sells drug products covered by the '863 patent under the trademark Patanol® pursuant to a New Drug Application held by Alcon Laboratories, Inc. and approved by the FDA.

24. Plaintiffs will be substantially and irreparably damaged by infringement of the '863 patent.

25. By letter dated September 25, 2007 (the "Notice Letter"), Barr notified Alcon, Inc., Alcon Laboratories, Inc., Alcon Manufacturing, Ltd., and Kyowa that Barr had submitted an ANDA, No. 79-092, to the FDA. The purpose of the ANDA was to obtain approval under the FDCA to engage in the commercial manufacture, use, and sale of a drug product containing olopatadine hydrochloride prior to the expiration of the '863 patent.

26. Upon information and belief, the drug product containing olopatadine hydrochloride that is the subject of ANDA No. 79-092 is covered by one or more claims of the '863 patent.

27. In the Notice Letter, Barr also notified Alcon, Inc., Alcon Laboratories, Inc., Alcon Manufacturing, Ltd., and Kyowa that, as part of its ANDA, Barr had filed certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

28. Barr'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 '863 patent is an act of infringement of that patent under 35 U.S.C. § 271(e)(2)(A).

29. Upon information and belief, Barr acted without a reasonable basis for believing that it would not be liable for infringement of the '863 patent.

30. Unless Barr is enjoined from infringing the '863 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

WHEREFORE, Plaintiffs request the following relief:

(a) A judgment providing that the effective date of any FDA approval for Barr to commercially make, use, or sell olopatadine hydrochloride or any drug product containing olopatadine hydrochloride be not earlier than the later of the expiration dates of United States Patent Nos. 5,641,805 and 5,116,863;

(b) A preliminary and permanent injunction against any infringement by Barr 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 infringement by Barr of United States Patent No. 5,116,863 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;

(d) A declaration that this is 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: October 23, 2007



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