

IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF INDIANA  
INDIANAPOLIS DIVISION

FILED  
U.S. DISTRICT COURT  
INDIANAPOLIS DIVISION  
10 FEB 12 AM 10:03  
SOUTHERN DISTRICT  
OF INDIANA  
LAURA A. BRIGGS  
CLERK

ALCON RESEARCH, LTD., )  
ALCON LABORATORIES, INC., and )  
KYOWA HAKKO KIRIN CO., LTD., )

Plaintiffs, )

v. )

WOCKHARDT LIMITED and )  
WOCKHARDT USA, LLC, )

Defendants. )

**1 : 10 -cv- 0 181 RLY -DML**  
Civil Action No. \_\_\_\_\_

**COMPLAINT**

Plaintiffs Alcon Research, Ltd., Alcon Laboratories, Inc., and Kyowa Hakko Kirin 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 Wockhardt 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<sup>®</sup> ophthalmic solution, a drug product containing olopatadine hydrochloride, prior to the expiration of U.S. Patent No. 5,641,805.

**PARTIES**

2. Plaintiff Alcon Research, Ltd. is a corporation organized and existing under the laws of the State of Delaware, having its corporate offices and 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 corporate offices and principal place of business at 6201 South Freeway, Fort Worth, Texas 76134.

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

5. Upon information and belief, defendant Wockhardt Limited is an Indian corporation having a principal place of business at Wockhardt Towers, Bandra-Kurla Complex, Bandra (East), Mumbai, Maharashtra 400 051, India.

6. Upon information and belief, defendant Wockhardt USA, LLC, is a limited liability company organized and existing under the laws of the State of Delaware, having its principal place of business at 20 Waterview Boulevard, Parsippany, NJ 07054. Upon information and belief, Wockhardt USA, LLC is an indirect wholly-owned subsidiary of Wockhardt Limited.

7. Collectively, Wockhardt Limited and Wockhardt USA, LLC are referred to as "Wockhardt."

#### **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. Wockhardt Limited is subject to personal jurisdiction in this Court because, among other things, upon information and belief, Wockhardt Limited itself and through its wholly-owned subsidiary Wockhardt USA, LLC., has purposely availed itself of the benefits and protections of Indiana's laws such that it should reasonably anticipate being haled into court in

this District. Upon information and belief, Wockhardt Limited is a generic pharmaceutical company that, on its own and/or through its wholly-owned subsidiary and agent Wockhardt USA, LLC, manufactures, markets, and/or sells generic drugs throughout the United States, including in the State of Indiana and the Southern District of Indiana and therefore transacts business within the State of Indiana and the Southern District of Indiana related to Plaintiffs' claims, and/or has engaged in systematic and continuous business contacts within the State of Indiana and the Southern District of Indiana. Wockhardt Limited is subject to jurisdiction in the State of Indiana and the Southern District of Indiana on the basis of its inducement of Wockhardt USA, LLC's acts of infringement in the State of Indiana and the Southern District of Indiana. In addition, Wockhardt Limited is subject to personal jurisdiction in the State of Indiana and the Southern District of Indiana because, on information and belief, it controls and dominates Wockhardt USA, LLC, and therefore the activities of Wockhardt USA, LLC in this jurisdiction are attributed to Wockhardt Limited.

10. Wockhardt USA, LLC is subject to personal jurisdiction in this Court because, among other things, upon information and belief, Wockhardt USA, LLC, has purposely availed itself of the benefits and protections of Indiana's laws such that it should reasonably anticipate being haled into court in this District. Upon information and belief, Wockhardt USA, LLC, on behalf of and as the agent of Wockhardt Limited, manufactures, markets, and/or sells generic pharmaceutical products throughout the United States, including in the State of Indiana and the Southern District of Indiana and therefore transacts business within the State of Indiana and the Southern District of Indiana related to Plaintiffs' claims, and/or has engaged in systematic and continuous business contacts within the State of Indiana and the Southern District of Indiana.

11. Upon information and belief, Wockhardt Limited and Wockhardt USA, LLC are part of a vertically integrated and unified organization. Upon information and belief, Wockhardt Limited and Wockhardt USA, LLC will act in concert to distribute and sell the products that are the subject of ANDA No. 200810 throughout the United States, including within the State of Indiana and the Southern District of Indiana. Upon information and belief, Wockhardt Limited and Wockhardt USA, LLC acted in concert to prepare and/or submit ANDA No. 200810. On information and belief, Wockhardt Limited and Wockhardt USA, LLC actively participated in the preparation and/or submission to the FDA of ANDA No. 200810.

12. Wockhardt Limited and Wockhardt USA, LLC both have previously consented to personal jurisdiction in this District. Wockhardt Limited and Wockhardt USA, LLC are both currently defendants and have affirmatively availed themselves of the Courts of this District by asserting counterclaims in previous litigation in the Southern District of Indiana.

### **BACKGROUND**

13. Patanol<sup>®</sup> is an ophthalmic solution for topical administration to the eye. The active ingredient of Patanol<sup>®</sup> is olopatadine hydrochloride.

### **COUNT I – U.S. PATENT NO. 5,641,805**

14. Plaintiffs incorporate each of the preceding paragraphs 1-13 as if fully set forth herein.

15. 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.

16. Alcon Laboratories, Inc.'s interest in the '805 patent has been subsequently assigned to Alcon Research, Ltd.

17. Alcon Laboratories, Inc. sells drug products covered by the '805 patent under the trademark Patanol<sup>®</sup> pursuant to a New Drug Application held by Alcon Laboratories, Inc. and approved by the FDA.

18. Kyowa Hakko Kogyo, Co., Ltd.'s interest in the '805 patent has been subsequently assigned to Kyowa Hakko Kirin Co., Ltd.

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

20. The use of Patanol<sup>®</sup> is covered by one or more claims of the '805 patent, and the '805 patent has been listed in connection with that drug product in the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*.

21. By letter dated February 1, 2010 (the "Notice Letter"), Wockhardt notified Alcon Laboratories, Inc., Alcon Research, Ltd., and Kyowa Hakko Kirin Co., Ltd. that Wockhardt had submitted to the FDA an ANDA, No. 200810, for Wockhardt's ophthalmic solution containing olopatadine hydrochloride, a drug product that is a generic version of Patanol<sup>®</sup> ("Wockhardt's ANDA Product"). 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, offer for sale, sale, and/or importation of Wockhardt's ANDA Product prior to the expiration of the '805 patent.

22. In the Notice Letter, Wockhardt also notified Alcon Laboratories, Inc., Alcon Research, Ltd., and Kyowa Hakko Kirin Co., Ltd. that, as part of its ANDA, Wockhardt 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), with respect to the '805 patent. Upon information and belief, Wockhardt submitted ANDA No. 200810 to the FDA containing a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '805 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, or importation of Wockhardt's ANDA Product.

23. Pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(6), for each claim of the '805 patent that Wockhardt believes would not be infringed by the making, using, offering for sale, sale, or importation of Wockhardt's ANDA Product, Wockhardt was required to provide in its Notice Letter a full and detailed explanation of why each such claim is or would not be infringed.

24. Wockhardt did not assert in its Notice Letter that the making, using, offering for sale, sale, or importation of Wockhardt's ANDA Product would not infringe one or more claims of the '805 patent.

25. The use of Wockhardt's ANDA Product is covered by one or more claims of the '805 patent.

26. Wockhardt has knowledge of the '805 patent.

27. Wockhardt's filing of ANDA No. 200810 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Wockhardt's ANDA Product before the expiration of the '805 patent is an act of infringement of the '805 patent.

28. The use of Wockhardt's ANDA Product would infringe one or more claims of the '805 patent.

29. Upon information and belief, the use of Wockhardt's ANDA Product in

accordance with and as directed by Wockhardt's proposed labeling for that product would infringe one or more claims of the '805 patent.

30. Upon information and belief, Wockhardt will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Wockhardt's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 200810.

31. Upon information and belief, Wockhardt plans and intends to, and will, actively induce infringement of the '805 patent when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

32. Upon information and belief, Wockhardt knows that Wockhardt's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '805 patent, and that Wockhardt's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Wockhardt plans and intends to, and will, contribute to infringement of the '805 patent immediately and imminently upon approval of ANDA No. 200810.

33. The foregoing actions by Wockhardt constitute and/or will constitute infringement of the '805 patent, active inducement of infringement of the '805 patent, and contribution to the infringement by others of the '805 patent.

34. Upon information and belief, Wockhardt acted without a reasonable basis for believing that it would not be liable for infringing the '805 patent, actively inducing infringement of the '805 patent, and contributing to the infringement by others of the '805 patent.

35. Unless Wockhardt is enjoined from infringing the '805 patent, actively

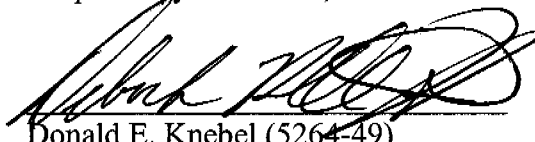
inducing infringement of the '805 patent, and contributing to the infringement by others of the '805 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

WHEREFORE, Plaintiffs request the following relief:

- (a) A judgment that Wockhardt has infringed the '805 patent;
- (b) A judgment ordering that the effective date of any FDA approval for Wockhardt to make, use, offer for sale, sell, market, distribute, or import Wockhardt's ANDA Product, or any product that infringes the '805 patent, be not earlier than the expiration date of the '805 patent, inclusive of any extension(s) and additional period(s) of exclusivity;
- (c) A preliminary and permanent injunction enjoining Wockhardt, and all persons acting in concert with Wockhardt, from making, using, selling, offering for sale, marketing, distributing, or importing Wockhardt's ANDA Product, or any product that infringes the '805 patent, or the inducement of or the contribution to any of the foregoing, prior to the expiration date of the '805 patent, inclusive of any extension(s) and additional period(s) of exclusivity;
- (d) A judgment declaring that making, using, selling, offering for sale, marketing, distributing, or importing Wockhardt's ANDA Product, or any product that infringes the '805 patent, prior to the expiration date of the '805 patent, will infringe, actively induce infringement of, and contribute to the infringement by others of the '805 patent;
- (e) A declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;
- (f) An award of Plaintiffs' costs and expenses in this action; and
- (g) Such further and other relief as this Court may deem just and proper.

Dated: February 12, 2010

Respectfully submitted,



Donald E. Knebel (5264-49)

*dknebel@btlaw.com*

Todd G. Vare (18458-59)

*todd.vare@btlaw.com*

Deborah Pollack-Milgate (22475-49)

*dmilgate@btlaw.com*

Barnes & Thornburg LLP

11 South Meridian Street

Indianapolis, IN 46204

(317) 236-1313

(317) 231-7433 (Facsimile)

*Of Counsel*

Bruce R. Genderson

*bgenderson@wc.com*

Adam L. Perlman

*aperlman@wc.com*

Thomas H.L. Selby

*tselby@wc.com*

Daniel P. Shanahan

*dshanahan@wc.com*

Jessamyn S. Berniker

*jberniker@wc.com*

Shelley J. Webb

*swebb@wc.com*

Williams & Connolly LLP

725 Twelfth Street, N.W.

Washington, DC 20005

(202) 434-5000

(202) 434-5029 (Facsimile)

*Attorneys for Plaintiffs Alcon Research,  
Ltd., Alcon Laboratories, Inc., and  
Kyowa Hakko Kirin Co., Ltd.*