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UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

ABBOTT LABORATORIES, an Illinois Corporation, Plaintiff, v. WOCKHARDT LIMITED, an Indian corporation, and WOCKHARDT USA INC., a Delaware corporation, Defendants.	Civil Action No. *Document Filed Electronically*

COMPLAINT

Plaintiff Abbott Laboratories ("Abbott"), for its complaint against defendants Wockhardt Limited and Wockhardt USA Inc. (together, "Defendants"), alleges as follows:

THE PARTIES

1. Abbott Laboratories ("Abbott") is a corporation organized under the laws of the State of Illinois, having its headquarters and principal place of business at Abbott Park, Illinois 60064.

2. Wockhardt Limited ("Wockhardt") is a corporation organized under the laws of India, and having its principal place of business at Wockhardt Towers Bandra-Kurla Complex,

Bandra (East), Mumbai - 400 051, Maharashtra, India. Wockhardt maintains an office in the United States at 135 Route 202/206, Bedminster, New Jersey, 07921.

3. Wockhardt USA, Inc. ("Wockhardt USA") is a corporation organized under the laws of the State of Delaware. Wockhardt USA maintains an office at 135 Route 202/206, Bedminster, New Jersey, 07921. Wockhardt USA is a wholly-owned subsidiary of Wockhardt. Wockhardt USA operates as the authorized U.S. agent of Wockhardt with regard to drug products that Wockhardt seeks approval from the United States Food and Drug Administration ("FDA") to market in the United States, including the product described in Abbreviated New Drug Application No. 78-705 ("the ANDA").

JURISDICTION AND VENUE

4. This Court has subject matter jurisdiction over this suit pursuant to 28 U.S.C. § 1331 and § 1338(a), as it arises under an Act of Congress relating to patents, Title 35, United States Code, §§ 1, et seq.

5. This Court has personal jurisdiction over Defendants by virtue of, among other things, Defendants' systematic and continuous contacts with this judicial district, where both Defendants maintain offices.

6. Wockhardt is the named applicant for ANDA No. 78-705, which it submitted to the FDA by and through its agent, Wockhardt USA. Wockhardt is, therefore, subject to personal jurisdiction in this judicial district for purposes of this action, which arises directly from the filing of the ANDA.

7. Venue properly exists in this judicial district pursuant to 28 U.S.C. § 1391 and § 1400(b).

FACTUAL BACKGROUND

The '086 Patent

8. Abbott sells a prescription drug product under the trademark DEPAKOTE®, which product is indicated for the treatment of epileptic seizures or convulsions, bipolar disease, and migraine headaches. The active ingredient in DEPAKOTE® is divalproex sodium.

9. On August 4, 2000, the FDA approved Abbott's New Drug Application No. 21-168 to market DEPAKOTE® ER (extended-release) tablets in a 500 mg dosage strength. As a result, DEPAKOTE® ER is included in the FDA's list of "Approved Drug Products With Therapeutic Equivalence Evaluations," also known as the "Orange Book." Approved drugs listed in the Orange Book may be used as the basis of a later applicant's Abbreviated New Drug Application to obtain approval of the applicant's generic drug product under the provisions of 21 U.S.C. §355(j).

10. Abbott is the owner of and has the right to enforce United States Patent No. 6,713,086 ("the '086 patent"), entitled Controlled Release Formulation of Divalproex Sodium. (A copy of the '086 patent is attached as Exhibit A, and is incorporated by reference.) The '086 patent issued on March 30, 2004, and expires December 18, 2018.

11. The '086 patent, and other patents, are listed in the FDA's Orange Book in association with DEPAKOTE® ER.

Wockhardt Notifies Abbott Regarding the Filing of ANDA 78-705

12. Abbott received a letter from Wockhardt, dated March 28, 2007, which stated, *inter alia*, that (i) Wockhardt had submitted ANDA No. 78-705 to the FDA, requesting approval to market a generic version of DEPAKOTE® ER -- called "Divalproex Sodium Extended-Release Tablets" -- in a 500 mg dosage strength; (ii) the ANDA included a Paragraph IV Certification (21 U.S.C. § 355(j)(2)(A)(vii)(IV)) directed to the '086 patent, and (iii) Wockhardt

seeks FDA approval to market the proposed generic product before that patent expires. This letter was on Wockhardt stationery and listed Wockhardt's address as 135 Route 202/206, Bedminster, New Jersey, 07921.

13. The applicant for ANDA No. 78-705 is Wockhardt, with Wockhardt USA acting as authorized U.S. agent for all matters relating to the ANDA, including submitting the ANDA to FDA, coordinating communications with FDA relating to the ANDA, and other responsibilities.

14. A representative of Wockhardt USA actually signed the official application form submitted to FDA, certifying under penalty of perjury that all information in the ANDA is true and accurate and that all applicable laws and regulations governing approved applications -- including regulations governing drug manufacture, labeling, and marketing -- would be followed.

15. On information and belief, if the ANDA is approved by FDA, the proposed generic product will be manufactured by Wockhardt and marketed, distributed, and/or sold in the United States by Wockhardt USA. In addition, if the ANDA is approved by FDA, Wockhardt USA will continue to have responsibility for communicating with FDA post-approval regarding the generic drug product, including the submission of periodic reports relating to adverse events, distribution information, and other relevant matters.

16. The active ingredient in Defendants' proposed generic drug product is divalproex sodium, and the ANDA purports to describe a formulation for achieving a controlled-release of divalproex sodium in patients.

COUNT I: INFRINGEMENT OF THE '086 PATENT

17. Abbott repeats and incorporates by reference each and every allegation of paragraphs 1-16 as if fully set forth herein.

18. Under 35 U.S.C. § 271(e)(2), the submission of an ANDA under 21 U.S.C. § 355(j) for a drug product or formulation claimed in a patent or for a drug use claimed in a

patent is an act of infringement if the applicant seeks FDA marketing approval effective prior to the expiration of the patent. Defendants' submission of ANDA No. 78-705 for approval to sell Divalproex Sodium Extended-Release Tablets in 500 mg dosage strength before the expiration of the '086 patent constitutes an act of infringement of that patent pursuant to 35 U.S.C. § 271(e)(2).

19. Wockhardt USA has actively, knowingly, intentionally, and deliberately induced, aided, and abetted Wockhardt to infringe the '086 patent through the submission of ANDA No. 78-705, and will continue to aid and abet Wockhardt's infringing activities post-approval by directly or indirectly conducting, commissioning, directing, and/or supporting the manufacture, use, importation, testing, packaging, marketing, and/or sale of the infringing product described in ANDA No. 78-705, as well as any ongoing matters of regulatory compliance with the FDA.

20. Defendants' proposed generic version of DEPAKOTE® ER, as described in ANDA No. 78-705, utilizes a controlled-release formulation that infringes the '086 patent.

21. Defendants are liable for infringement of the '086 patent, directly, by contribution, and/or by inducement.

22. Abbott has no adequate remedy at law to redress Defendants' infringement.

PRAYER FOR RELIEF

WHEREFORE, Abbott prays for the following relief:

(a) a judgment that the '086 patent remains valid and enforceable and is infringed under 35 U.S.C. § 271(e)(2) by the filing of ANDA No. 78-705;

(b) an order declaring that ANDA No. 78-705 cannot be approved earlier than the expiration date of Abbott's '086 patent;

(c) an injunction prohibiting Wockhardt USA, Wockhardt, any of their respective affiliates, or those working in concert with them, from commercially manufacturing, selling, offering to sell, importing, or using a formulation covered by the '086 patent, or otherwise infringing one or more claims of the '086 patent during the life of the patent;

(d) an award of Abbott's costs and attorneys' fees pursuant to 35 U.S.C. § 271(e)(4) and § 285; and

(e) such other and further relief as this Court may deem just and proper.

Dated: May 11, 2007

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