UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

ABBOTT LABORATORIES, an Illinois corporation, Plaintiff, v. IMPAX LABORATORIES, INC., a Delaware corporation, Defendant.	Civil Action No.

COMPLAINT

Plaintiff Abbott Laboratories ("Abbott"), for its complaint against defendant IMPAX Laboratories, Inc. ("Impax"), alleges as follows:

THE PARTIES

1. 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. Impax is a corporation organized under the laws of the State of Delaware, having its principal place of business at 30831 Huntwood Avenue, Hayward, California 94544.

JURISDICTION AND VENUE

3. 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.* Specifically, this action arises under the Hatch-Waxman Act, 35 U.S.C. § 271(e)(2).

4. This Court has personal jurisdiction over Impax because, among other things, Impax is a Delaware corporation.

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

FACTUAL BACKGROUND

The '086 and '090 Patents

6. 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.

7. On August 4, 2000, the United States Food and Drug Administration ("FDA") approved Abbott's New Drug Application No. 21-168 to market DEPAKOTE® ER (extended-release) tablets in a 500 mg dosage strength. DEPAKOTE® ER was subsequently approved in a 250 mg dosage strength on May 31, 2002. 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).

8. United States Patent No. 6,713,086 ("the '086 patent"), titled "Controlled Release Formulation of Divalproex Sodium," issued on March 30, 2004. (A copy of the '086 patent is attached as Exhibit A.) The '086 patent expires December 18, 2018.

9. United States Patent No. 6,528,090 B2 ("the '090 patent"), titled "Controlled Release Formulation of Divalproex Sodium," issued on March 4, 2003. (A copy of the '090 patent is attached as Exhibit B.) The '090 patent expires December 18, 2018.

10. Abbott is the owner of and has the right to enforce both the '086 patent and the '090 patent.

11. The '086 patent and the '090 patent are listed in the FDA's Orange Book in association with both the 500 mg and 250 mg dosage strengths of DEPAKOTE® ER.

Impax Notifies Abbott Regarding the Filing of ANDA No. 78-791

12. Abbott received a letter from Impax, dated May 3, 2007, which stated that (i) Impax had submitted Abbreviated New Drug Application No. 78-791 (the "ANDA") to the FDA, requesting approval to market a generic version of DEPAKOTE® ER – called "Divalproex Sodium Extended Release Tablets" – in 500 mg and 250 mg dosage strengths; (ii) the ANDA included a Paragraph IV Certification (21 U.S.C. § 355(j)(2)(A)(vii)(IV)) directed to the '086 patent and the '090 patent; and (iii) Impax seeks FDA approval to market its proposed generic product before the '086 patent and '090 patent expire.

13. Impax attached to its May 3, 2007 letter a purportedly "Detailed Statement of the Factual and Legal Bases" for the Paragraph IV Certification with regards to the '086 patent and the '090 patent. *See* 21 U.S.C. § 355(j)(2)(B)(iv); *see also* 21 C.F.R. § 314.95(c)(6)(i) - (ii). Impax stated its position in that document regarding whether its proposed product would infringe the '086 patent and the '090 patent, but did not argue that either patent is invalid or unenforceable.

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

COUNT I: INFRINGEMENT OF THE '086 PATENT

15. Abbott repeats and incorporates by reference each and every allegation of paragraphs 1-14 as if fully set forth herein.

16. Under 35 U.S.C. § 271(e)(2), the submission of an ANDA under 21 U.S.C. § 355(j) for a drug 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. Impax's submission of ANDA No. 78-791 for approval to sell Divalproex Sodium Extended Release Tablets in 500 mg and 250 mg dosage strengths before the expiration of the '086 patent constitutes an act of infringement of that patent pursuant to 35 U.S.C. § 271(e)(2).

17. Impax's proposed generic version of DEPAKOTE® ER utilizes a controlled-release formulation that infringes the '086 patent.

18. Abbott has no adequate remedy at law to redress Impax's infringement.

COUNT II: INFRINGEMENT OF THE '090 PATENT

19. Abbott repeats and incorporates by reference each and every allegation of paragraphs 1-14 as if fully set forth herein.

20. Under 35 U.S.C. § 271(e)(2), the submission of an ANDA under 21 U.S.C. § 355(j) for a drug 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. Impax's submission of ANDA No. 78-791 for approval to sell Divalproex Sodium Extended Release Tablets in 500 mg and 250 mg dosage strengths before the expiration of the '090 patent constitutes an act of infringement of that patent pursuant to 35 U.S.C. § 271(e)(2).

21. Impax's proposed generic version of DEPAKOTE® ER utilizes a controlled-release formulation that infringes the '090 patent.

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

PRAYER FOR RELIEF

WHEREFORE, Abbott prays for the following relief:

a. a judgment that the '086 patent is infringed under 35 U.S.C. § 271(e)(2) by the filing of ANDA No. 78-791;

b. a judgment that the '090 patent is infringed under 35 U.S.C. § 271(e)(2) by the filing of ANDA No. 78-791;

c. an order declaring that ANDA No. 78-791 cannot be approved earlier than the expiration date of Abbott's '086 patent;

d. an order declaring that ANDA No. 78-791 cannot be approved earlier than the expiration date of Abbott's '090 patent;

e. an injunction preventing Impax, or any of its affiliates, from commercially manufacturing, selling, offering to sell, importing, or using the product described in ANDA No. 78-791, or otherwise infringing one or more claims of the '086 patent during the life of the patent;

f. an injunction preventing Impax, or any of its affiliates, from commercially manufacturing, selling, offering to sell, importing, or using the product described in ANDA No. 78-791, or otherwise infringing one or more claims of the '090 patent during the life of the patent;

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

h. such other and further relief as this Court may deem just and proper.

Dated: June 18, 2007

Respectfully submitted,

CONNOLLY BOVE LODGE & HUTZ LLP

By: _____
Paul E. Crawford
DE State Bar 0493
E-mail: pcrawford@cblh.com
CONNOLLY BOVE LODGE & HUTZ LLP
1007 N. Orange St.
P.O. Box 2207
Wilmington, DE 19899
(T) 302.658.9141
(F) 302.658.5614

Attorneys for Abbott Laboratories

Of Counsel
Daniel E. Reidy; Bar No. 2306948
E-mail: dereidy@jonesday.com
James R. Daly; Bar No. 6181714
Email: jrdaly@jonesday.com
Jason G. Winchester; Bar No. 6238377
Email: jgwinchester@jonesday.com
Jeremy P. Cole; Bar No. 6269551
Email: jpcole@jonesday.com
Melissa B. Hirst; Bar No. 6282498
Email: mbhirst@jonesday.com
JONES DAY
77 West Wacker Drive, Suite 3500
Chicago, Illinois 60601-1692
(T): 312.782.3939
(F): 312.782.8585

Perry C. Siatis
ABBOTT LABORATORIES
100 Abbott Park Road
Abbott Park, Illinois 60064-6034