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**UNITED STATES DISTRICT COURT FOR THE
DISTRICT OF NEW JERSEY**

ABBOTT LABORATORIES, an Illinois)
Corporation,)
)
Plaintiff,)
)
v.)
)
SANDOZ, INC., a Colorado corporation,)
)
Defendant.)

Civil Action No.

Document Filed Electronically

COMPLAINT

Plaintiff Abbott Laboratories (“Abbott”), for its complaint against defendant Sandoz, Inc. (“Sandoz”), 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. On information and belief, Sandoz is a corporation organized under the laws of the State of Colorado. Sandoz’s corporate headquarters are located at 506 Carnegie Center, Suite 400, Princeton, New Jersey 08540.

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.

4. This Court has personal jurisdiction over Sandoz by virtue of, among other things, Sandoz's systematic and continuous contacts with this judicial district.

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

FACTUAL BACKGROUND

A. The Abbott 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 ("ANDA") to obtain approval of the applicant's generic drug product under the provisions of 21 U.S.C. § 355(j).

8. Abbott is the owner of and has the right to enforce United States Patent No.6,511,678 (the "678 patent"), entitled Controlled Release Formulation of Divalproex

Sodium. (A copy of the '678 patent is attached as Exhibit A, and is incorporated by reference.) The '678 patent issued on January 28, 2003, and expires December 18, 2018.

9. Abbott is the owner of and has the right to enforce United States Patent No. 6,528,090 (the "'090 patent"), entitled Controlled Release Formulation of Divalproex Sodium. (A copy of the '090 patent is attached as Exhibit B, and is incorporated by reference.) The '090 patent issued on March 4, 2003, and expires December 18, 2018.

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 C, and is incorporated by reference.) The '086 patent issued on March 30, 2004, and expires December 18, 2018.

11. Abbott is the owner of and has the right to enforce United States Patent No. 6,720,004 (the "'004 patent"), entitled Controlled Release Formulation of Divalproex Sodium. (A copy of the '004 patent is attached as Exhibit D, and is incorporated by reference.) The '004 patent issued on April 13, 2004, and expires December 18, 2018.

12. The '678 patent, the '090 patent, the '086 patent, the '004 patent, and other patents, are listed in the FDA's Orange Book in association with both the 500 mg and 250 mg strengths of Depakote[®] ER.

B. Sandoz Notifies Abbott Regarding the Filing of ANDA No. 77-490.

13. Abbott received a letter from Sandoz dated May 17, 2005, stating that (i) Sandoz submitted ANDA No. 77-490 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 the '678 patent, the '090 patent, the '086 patent, and the

'004 patent; and (iii) Sandoz sought FDA approval to market Sandoz's proposed generic product before these and other patents expire.

14. Sandoz attached to its May 17, 2005 letter a purportedly "Detailed Statement of Factual and Legal Bases" for the Paragraph IV Certification with regards to the 678 patent, the '090 patent, the '086 patent, and the '004 patent. *See* 21 U.S.C. § 355(j)(2)(B)(iv); *see also* 21 C.F.R. § 314.95(c)(6)(i) - (ii). Sandoz stated its position in that document regarding whether its proposed product would infringe the 678 patent, the '090 patent, the '086 patent, and the '004 patent, but did not argue that any of these patents are invalid or unenforceable.

15. The active ingredient in Sandoz's 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 '678 PATENT

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

17. 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. Sandoz's submission of ANDA No. 77-490 for approval to sell Divalproex Sodium Extended-Release Tablets in 500 mg and 250 mg dosage strengths before the expiration of the '678 patent constitutes an act of infringement of that patent pursuant to 35 U.S.C. § 271(e)(2).

18. Sandoz's proposed generic version of DEPAKOTE[®] ER, as described in ANDA No. 77-490, utilizes a controlled-release formulation that infringes the '678 patent.

19. Sandoz is liable for infringement of the '678 patent.

20. Abbott has no adequate remedy at law to redress Sandoz's infringement.

COUNT II: INFRINGEMENT OF THE '090 PATENT

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

22. 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. Sandoz's submission of ANDA No. 77-490 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).

23. Sandoz's proposed generic version of DEPAKOTE[®] ER, as described in ANDA No. 77-490, utilizes a controlled-release formulation that infringes the '090 patent.

24. Sandoz is liable for infringement of the '090 patent.

25. Abbott has no adequate remedy at law to redress Sandoz's infringement.

COUNT III: INFRINGEMENT OF THE '086 PATENT

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

27. 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. Sandoz's submission of ANDA No. 77-490 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).

28. Sandoz's proposed generic version of DEPAKOTE[®] ER, as described in ANDA No. 77-490, utilizes a controlled-release formulation that infringes the '086 patent.

29. Sandoz is liable for infringement of the '086 patent.

30. Abbott has no adequate remedy at law to redress Sandoz's infringement.

COUNT IV: INFRINGEMENT OF THE '004 PATENT

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

32. 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. Sandoz's submission of ANDA No. 77-490 for approval to sell Divalproex Sodium Extended-Release Tablets in 500 mg and 250 mg dosage strengths before the expiration of the '004 patent constitutes an act of infringement of that patent pursuant to 35 U.S.C. § 271(e)(2).

33. Sandoz's proposed generic version of DEPAKOTE[®] ER, as described in ANDA No. 77-490, utilizes a controlled-release formulation that infringes the '004 patent.

34. Sandoz is liable for infringement of the '004 patent.

35. Abbott has no adequate remedy at law to redress Sandoz's infringement.

PRAYER FOR RELIEF

WHEREFORE, Abbott prays for the following relief:

(a) a judgment that the '678 patent remains valid and enforceable and is infringed under 35 U.S.C. § 271(e)(2) by the filing of ANDA No. 77-490;

(b) an order declaring that ANDA No. 77-490 cannot be approved earlier than the expiration date of Abbott's '678 patent;

(c) an injunction prohibiting Sandoz and any of its affiliates, or those working in concert with it, from commercially manufacturing, selling, offering to sell, importing, or using a formulation covered by the '678 patent, or otherwise infringing one or more claims of the '678 patent during the life of the patent;

(d) a judgment that the '090 patent remains valid and enforceable and is infringed under 35 U.S.C. § 271(e)(2) by the filing of ANDA No. 77-490;

(e) an order declaring that ANDA No. 77-490 cannot be approved earlier than the expiration date of Abbott's '090 patent;

(f) an injunction prohibiting Sandoz and any of its affiliates, or those working in concert with it, from commercially manufacturing, selling, offering to sell, importing, or using a formulation covered by the '090 patent, or otherwise infringing one or more claims of the '090 patent during the life of the patent;

(g) 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. 77-490;

(h) an order declaring that ANDA No. 77-490 cannot be approved earlier than the expiration date of Abbott's '086 patent;

(i) an injunction prohibiting Sandoz and any of its affiliates, or those working in concert with it, 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;

(j) a judgment that the '004 patent remains valid and enforceable and is infringed

under 35 U.S.C. § 271(e)(2) by the filing of ANDA No. 77-490;

(k) an order declaring that ANDA No. 77-490 cannot be approved earlier than the expiration date of Abbott's '004 patent;

(l) an injunction prohibiting Sandoz and any of its affiliates, or those working in concert with it, from commercially manufacturing, selling, offering to sell, importing, or using a formulation covered by the '004 patent, or otherwise infringing one or more claims of the '004 patent during the life of the patent;

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

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

Dated: December 6, 2007

Respectfully submitted,

RIKER, DANZIG, SCHERER, HYLAND &
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