**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF COLUMBIA**

NU-PHARM INC.
50 Mural Street, Units 1 and 2
Richmond Hill, Ontario L4B I E4,

Plaintiff,

v.

FOOD AND DRUG ADMINISTRATION
5600 Fishers Lane
Rockville, Maryland 20857,

MICHAEL O. LEAVITT
Secretary of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201, and

ANDREW C. VON ESCHENBACH, M.D.
Commissioner of Food and Drugs
5600 Fishers Lane
Rockville, Maryland 20857,

Defendants.

Case No.

Case: 1:08-cv-00070
Assigned To : Roberts, Richard W.
Assign. Date : 1/14/2008
Description: TRO/PI

## COMPLAINT

Plaintiff Nu-Pharm Inc. ("Nu-Pharm"), for its Complaint against the United States Food and Drug Administration; Michael O. Leavitt, in his official capacity as the Secretary of Health and Human Services; and Andrew C. von Eschenbach, M.D., in his official capacity as the Commissioner of the United States Food and Drug Administration (collectively, "FDA"), alleges as follows:

## Nature Of The Action

1. Nu-Pharm respectfully brings this action for declaratory and injunctive relief challenging FDA's unlawful refusal to grant Nu-Pharm final approval for its abbreviated new drug application ("ANDA") for divalproex sodium delayed-release 500 mg tablets—a

prescription drug currently marketed solely by Abbott under the brand-name Depakote® for the treatment of epilepsy.

2. Nu-Pharm has satisfied all substantive requirements for final approval for its divalproex sodium delayed-release 500 mg tablet product. Nu-Pharm's 500 mg product is not subject to any stays of approval, nor has any court decision of patent infringement been rendered, or injunction been entered, against Nu-Pharm in any action to which Nu-Pharm is a party. Indeed, the only statutory stay of approval to which Nu-Pharm's 500 mg product was subject expired months ago, on November 13, 2007. Accordingly, FDA has no lawful basis or authority to withhold Nu-Pharm's approval.

3. FDA nonetheless has withheld final approval in clear contravention of the applicable provisions of the Federal Food, Drug, and Cosmetic Act ("FFDCA"). Pursuant to the Administrative Procedure Act ("APA"), FDA's actions are arbitrary, capricious, an abuse of discretion, contrary to law, and in excess of statutory authority.

4. To prevent devastating and irreparable harm to Nu-Pharm, the Court should enter immediate injunctive relief requiring FDA to grant final, effective approval of Nu-Pharm's ANDA for divalproex sodium delayed-release 500 mg tablets, which will permit Nu-Pharm to begin marketing its lower-priced generic drug promptly after the expiration of Abbott's patents.

## Parties

5. Plaintiff Nu-Pharm Inc. is a corporation organized and existing under the laws of Canada, with a place of business at 50 Mural Street, Units 1 and 2, Richmond Hill, Ontario Canada L4B 1 E4.

6. Defendant Michael O. Leavitt is the Secretary of Health and Human Services ("HHS"), and the official charged by law with administering the FFDCA. He is sued in his

official capacity. Secretary Leavitt maintains offices at 200 Independence Avenue, S.W., Washington, D.C. 20201.

7. Defendant Andrew C. von Eschenbach, M.D., is the Commissioner and senior official of FDA. He is sued in his official capacity. Commissioner von Eschenbach has been delegated the authority to administer the drug approval provisions of the FFDCA through FDA. He maintains offices at 5600 Fishers Lane, Rockville, Maryland 20857.

8. Defendant FDA is an agency within the Public Health Service and is a part of HHS. FDA maintains offices at 5600 Fishers Lane, Rockville, Maryland 20857.

**Jurisdiction and Venue**

9. This action arises under the FFDCA, 21 U.S.C. § 301 *et seq.*, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355 and 35 U.S.C. § 271) ("Hatch-Waxman") and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, § 1102(b)(1), Pub. L. No. 108-173, 117 Stat. 2066 (2003) (codified as amended at 21 U.S.C. § 355 and 35 U.S.C. § 271) ("MMA"); the APA, 5 U.S.C. § 551 *et seq.*; and the Declaratory Judgment Act, 28 U.S.C. §§ 2201, 2202. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1361.

10. This Court has personal jurisdiction over the federal Defendants because they are either located and/or conduct substantial business in, or have regular and systematic contact with, this District. Venue is proper in this District under 28 U.S.C. § 1391(e).

11. FDA's agency action and/or inaction constitutes an actual controversy, for which Nu-Pharm is entitled to review and relief under 5 U.S.C. §§ 702, 704-706. Nu-Pharm has

standing to maintain this action, pursuant to the APA, as a legal entity that has been adversely affected by final agency action and/or agency action unlawfully withheld.

12. There exists an actual, substantial, and continuing controversy between the parties regarding FDA's application of the FFDCA and, in particular, the Agency's refusal to award immediate final approval to Nu-Pharm's ANDA for divalproex sodium delayed-release tablets, 500 mg. This Court may declare the rights and legal relations of the parties under 28 U.S.C. §§ 2201, 2202.

## Background

### I. Statutory Framework For Approval Of New And Generic Drugs.

#### A. New Drugs—NDAs And Patent Listing Requirements.

13. A company seeking to sell an original, new drug must file a new drug application ("NDA") with FDA, together with information on any patent that "claims the drug for which the applicant submitted the application or which claims a method of using such drug . . . ." 21 U.S.C. § 355(b)(1); *see also id.* § 355(c)(2). After approving the NDA, FDA publishes this patent information in the "Orange Book." *See id.*; 21 C.F.R. § 314.53(e).

#### B. Generic Drugs—ANDAs And Patent Certifications.

14. A company seeking FDA approval to market a generic version of a previously-approved NDA drug may file an ANDA that includes one of four certifications with respect to each Orange Book-listed patent for the NDA drug: (I) that there is no patent information; (II) that the listed patent has expired; (III) that the ANDA applicant will not market its generic drug until after the expiration of the listed patent; or (IV) that the listed patent is invalid and/or will not be infringed by the proposed generic drug, a so-called "paragraph IV certification." *See* 21 U.S.C. § 355(j)(2)(A)(vii).

15. With certain exceptions not applicable here, an ANDA applicant seeking FDA approval to market its generic drug before expiration of the Orange Book-listed patent must submit a paragraph IV certification and notify the patentee (and the NDA-holder) of the factual and legal bases for that certification. *See* 21 U.S.C. § 355(j)(2)(B).

16. Submitting an ANDA with a paragraph IV certification constitutes a technical act of infringement under 35 U.S.C. § 271(e)(2)(A), thereby vesting the district courts with subject matter jurisdiction to adjudicate whether the proposed generic drug infringes the relevant patent before the drug has actually been marketed.

17. By bringing suit, the patentee triggers an automatic stay of FDA approval. FDA cannot finally approve the ANDA for 30 months, regardless of the merit, or lack thereof, of the patent infringement case. *See* 21 U.S.C. § 355(j)(5)(B)(iii). Before expiration of the 30 months, the stay can be terminated by a decision of the court hearing the patent infringement action finding that the proposed ANDA product does not infringe the patent and/or that the patent is invalid. *See id.* § 355(j)(5)(B)(iii)(I).

18. Upon expiration of the 30-month stay, if there is no court decision by the district court hearing the patent infringement litigation finding the patent valid and infringed, the ANDA applicant is statutorily entitled to, and FDA "shall" grant, final effective approval of the ANDA (assuming the applicant has otherwise satisfied FDA's substantive ANDA approval requirements). 21 U.S.C. § 355(j)(5)(B)(iii).

## II. Factual Background.

### A. Abbott's NDA No. 18-723 For Depakote® (Divalproex Sodium) Delayed-Release Tablets.

19. Abbott Laboratories ("Abbott") holds approved NDA No. 18-723 for divalproex sodium delayed-release tablets, 500 mg, which are sold under the brand-name Depakote® for, among other things, the treatment of epilepsy.

20. Abbott submitted information to FDA on two patents for listing in the Orange Book in connection with Depakote® (divalproex sodium) delayed-release tablets, 500 mg and NDA No. 18-723: U.S. Patent Nos. 4,988,731 ("the '731 patent") and 5,212,326 ("the '326 patent"), both of which are set to naturally expire on January 29, 2008. By virtue of Abbott's submission, information for the '731 and '326 patents was listed, and to date remains listed, in FDA's Orange Book.

### B. Nu-Pharm's ANDA No. 77-615 For Divalproex Sodium Delayed-Release Tablets, 500 mg.

21. On March 7, 2005, Nu-Pharm submitted ANDA No. 77-615 for divalproex sodium delayed-release tablets, 500 mg, together with paragraph IV certifications to both the listed '731 and '326 patents. Nu-Pharm has satisfied all substantive requirements for approval.

22. As required by statute and regulation, Nu-Pharm duly notified Abbott of its ANDA and paragraph IV certifications to the '731 and '326 patents. Abbott received Nu-Pharm's notice of paragraph IV certification to the '731 and '326 patents on May 13, 2005.

23. In response, Abbott sued Nu-Pharm for alleged infringement of the '731 and '326 patents under 35 U.S.C. § 271(e)(2)(A) in the United States District Court for the Northern District of Illinois, Eastern Division (hereinafter, "the *Nu-Pharm* Action" or "*Nu-Pharm* Court"). *See Abbott Labs v. Nu-Pharm Inc.*, Civ. A. No. 05-3714 (N.D. Ill.).

24. The only 30-month stay arising out of the *Nu-Pharm* Action applicable to Nu-Pharm's 500 mg product expired on November 13, 2007—30 months after Abbott received Nu-Pharm's notice of paragraph IV certification. The *Nu-Pharm* Court has not extended the 30-month stay or entered any rulings or orders on the merits of the patent infringement dispute. In fact, to date, the *Nu-Pharm* Court has stayed the *Nu-Pharm* Action in its entirety, without any substantive merits ruling.

### C. FDA's Unlawful Refusal To Grant Final Approval Of Nu-Pharm's ANDA No. 77-615 For Divalproex Sodium Tablets, 500 mg.

25. After the 30-month stay arising out of the *Nu-Pharm* Action expired on November 13, 2007, Nu-Pharm duly requested, and reasonably expected to receive, immediate final FDA approval of Nu-Pharm's ANDA No. 77-615 for its divalproex sodium delayed-release 500 mg tablets. On December 11, 2007, FDA informed Nu-Pharm that it would not grant final approval based on an order entered in a contempt proceeding to which Nu-Pharm was not a party. *See Abbott Labs. v. Apotex, Inc.*, Civ. A. No. 97-7515 (N.D. Ill.) (hereinafter, the "*Apotex* Action" or "*Apotex* Court"). The *Apotex* Action, on which FDA based its decision, arose out of the submission of a different ANDA by a different company; namely Apotex's ANDA No. 75-112 for divalproex sodium delayed-release tablets that was found to infringe Abbott's patents. In a subsequent contempt proceeding to which Nu-Pharm was not a party, the *Apotex* Court extended the order and injunction over Apotex's ANDA to cover Nu-Pharm's ANDA. Again, Nu-Pharm was not a party to this proceeding, and the *Nu-Pharm* Court hearing the infringement action based on Nu-Pharm's paragraph IV ANDA has not entered any orders or injunctions concerning Nu-Pharm's ANDA.

26. On December 21, 2007, Nu-Pharm made a written submission to FDA requesting final approval of Nu-Pharm's 500 mg product on the ground that the 30-month stay has expired

and no orders concerning patent infringement or validity have been entered in the *Nu-Pharm* Action. On January 9, 2008, FDA orally denied Nu-Pharm's request based on the *Apotex* Court's order.

27. FDA's decision violates the plain and unambiguous language of the FFDCA, which provides that FDA shall immediately approve an ANDA where, as in this case, the applicable 30-month stay has expired and the court hearing the patent infringement action that is the subject of the paragraph IV ANDA (here, the *Nu-Pharm* Court) has made no finding of infringement or validity. In these circumstances, Congress mandated and directed FDA to approve the ANDA immediately, assuming that all other substantive requirements for approval have been satisfied.

28. FDA therefore has no lawful basis or authority to withhold final approval of Nu-Pharm's 500 mg divalproex sodium tablets under ANDA No. 77-615 based on a court order in a wholly separate contempt proceeding to which Nu-Pharm was not a party. FDA's decision violates not only the plain language of the statute, but also contradicts the underlying purpose of the FFDCA, which is to speed the introduction of affordable, quality generic drugs to the public. FDA's decision also violates the Agency's prior interpretation of the relevant statutory provision. Absent immediate injunctive relief requiring the approval of Nu-Pharm's 500 mg product, Nu-Pharm will be unable to begin marketing its lower-priced generic drug promptly after the expiration of Abbott's patents.

29. FDA's decision constitutes final agency action for purposes of judicial review under the APA.

30. Nu-Pharm has exhausted its administrative remedies. Any additional effort to seek administrative relief from the Agency would be futile and would result in further irreparable prejudice and harm to Nu-Pharm.

**Count I**
**(Violation of the FFDCA and APA)**

31. Nu-Pharm repeats and realleges the foregoing paragraphs as though fully alleged herein.

32. FDA's decision refusing to grant final approval of Nu-Pharm's generic divalproex sodium delayed-release 500 mg tablets under ANDA No. 77-615 is arbitrary, capricious, an abuse of discretion, and not in accordance with the law within the meaning of 5 U.S.C. § 706(2)(A), in excess of statutory authority within the meaning of 5 U.S.C. § 706(2)(C), and in violation of the FFDCA.

33. Nu-Pharm has no adequate remedy at law.

**Count II**
**(Relief Pending Review, 5 U.S.C. § 705)**

34. Nu-Pharm repeats and realleges the foregoing paragraphs as though fully alleged herein.

35. Under 5 U.S.C. § 705, to prevent devastating and irreparable harm to Nu-Pharm, Nu-Pharm is entitled to immediate final approval of its divalproex sodium delayed-release 500 mg tablets pending resolution of this matter on the merits, including an appeal to the D.C. Circuit.

**Request for Relief**

WHEREFORE, Nu-Pharm respectfully prays that this Honorable Court enter judgment in its favor and against the federal Defendants, as follows:

(a) Entry of judgment declaring that FDA's refusal to grant final effective approval of Nu-Pharm's ANDA No. 77-615 for divalproex sodium delayed-release 500 mg tablets is arbitrary, capricious, an abuse of discretion, and contrary to law;

(b) Entry of an injunction requiring FDA to immediately award final approval for Nu-Pharm's divalproex sodium delayed-release 500 mg tablets under ANDA No. 77-615;

(c) Entry of an order awarding Nu-Pharm its reasonable attorneys' fees and costs of prosecuting this action; and

(d) Such other and further relief as the Honorable Court deems just and proper.

Dated: January 14, 2008.

Respectfully submitted,

NU-PHARM INC.

By: William A. Rakoczy
One of its attorneys

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