

**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 1E4,)	
)	
Plaintiff,)	Case No. 08-cv-00070 (RWR)
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.)	
_____)	

**MEMORANDUM IN SUPPORT OF NU-PHARM'S MOTION FOR TEMPORARY
RESTRAINING ORDER AND/OR PRELIMINARY INJUNCTION**

William A. Rakoczy, D.C. Bar No. 489082
Christine J. Siwik
Lara E. FitzSimmons
RAKOCZY MOLINO MAZZOCHI SIWIK LLP
6 West Hubbard Street, Suite 500
Chicago, Illinois 60610
(312) 222-6301
(312) 222-6321 (facsimile)
wrakoczy@rmmslegal.com

Dated: January 15, 2008

Counsel for Nu-Pharm Inc.

TABLE OF CONTENTS

TABLE OF AUTHORITIES iii

INTRODUCTION 1

BACKGROUND 2

I. Statutory Background. 2

 A. Brand Drugs – NDAs And Patent Listing Requirements. 3

 B. Generic Drugs – ANDAs And Patent Certifications. 3

II. Factual Background. 5

 A. Abbott’s Depakote® (Divalproex Sodium) And Orange Book Patents. 5

 B. Nu-Pharm’s ANDA No. 77-615 For Divalproex Sodium Delayed-Release Tablets, 500 mg..... 6

 C. Contempt Proceedings Against Apotex In *Abbott v. Apotex*, No. 97-7515 (N.D. Ill.), *To Which Nu-Pharm Was Not And Is Not A Party*. 7

 D. FDA Unlawfully Refuses To Award Nu-Pharm Final Approval For Its Divalproex Sodium Delayed-Release 500 mg Tablets. 10

ARGUMENT..... 11

I. Nu-Pharm Has A Substantial Likelihood Of Succeeding On The Merits Of Its Claims. 12

 A. Under The Plain Language Of The FFDCA, FDA Has No Lawful Basis For Withholding Final Approval Of Nu-Pharm’s ANDA No. 77-615 For Divalproex Sodium 500 mg Tablets. 13

 1. Under the plain language of the FFDCA, FDA may delay approval if, and only if, the *Nu-Pharm* Court enters a finding and order of infringement in the *Nu-Pharm* action. 14

 2. Courts have consistently interpreted the statute in accordance with its plain language. 18

 B. FDA’s Decision And Interpretation Cannot Be Squared With The Agency’s Past Practice And Policies. 20

 C. FDA’s Interpretation Leads To Absurd And Inconsistent Results. 22

D.	FDA’s Interpretation Permits, And Indeed Encourages, Improper Gaming And Manipulation Of The Statute.....	24
II.	Nu-Pharm Will Suffer Substantial And Irreparable Harm If An Injunction Is Not Entered.....	25
III.	The Balance Of Harms Weighs In Favor Of Nu-Pharm.....	27
IV.	An Injunction Would Further The Public Interest.....	28
	CONCLUSION.....	28

TABLE OF AUTHORITIES

Federal Cases

Abbott Labs. v. Apotex, Inc.,
455 F. Supp. 2d 831 (N.D. Ill. 2006)..... 7, 9

Abbott Labs. v. TorPharm, Inc.,
122 Fed. Appx. 511, 2005 WL 406563 (Fed. Cir. Feb. 14, 2005)..... 8

Abbott Labs. v. TorPharm, Inc.,
309 F. Supp. 2d 1043 (N.D. Ill. 2004)..... 8

Abbott Labs. v. TorPharm, Inc.,
503 F.3d 1372 (Fed. Cir. 2007) 10

Alabama v. Boseman,
533 U.S. 146 (2001)..... 15

Am. Bioscience, Inc. v. Thompson,
269 F.3d 1077 (D.C. Cir. 2001)..... 25

Am. Bus Ass’n v. Slater,
231 F.3d 1 (D.C. Cir. 2000)..... 16

Ass’n of Am. R.R.s v. Costle,
562 F.2d 1310 (D.C. Cir. 1977)..... 15

Ass’n of Civilian Technicians, Mont. Air Chapter No. 29 v. FLRA,
22 F.3d 1150 (D.C. Cir. 1994)..... 15

* *Astrazeneca AB v. Mutual Pharm. Co.*,
221 F. Supp. 2d 528 (E.D. Pa. 2002)..... 19

Bd. of Governors of Fed. Reserve Sys. v. Dimension Fin. Corp.,
474 U.S. 361 (1986)..... 13

BedRoc Ltd., v. United States,
541 U.S. 176 (2004)..... 14

Blackman v. Dist. of Columbia,
277 F. Supp. 2d 71 (D.D.C. 2003)..... 11

Bush-Quayle ‘92 Primary Comm., Inc. v. Fed. Election Comm’n,
104 F.3d 448 (D.C. Cir. 1997)..... 22

Chevron U.S.A. Inc. v. Natural Res. Def. Council, Inc.,
467 U.S. 837 (1984)..... 13

*Aut horities marked with an asterisk indicate those on which counsel chiefly rely.

Columbia Broad. Sys., Inc. v. FCC,
454 F.2d 1018 (D.C. Cir. 1971)..... 22

Gates & Fox Co. v. Occupational Safety & Health Review Comm'n,
790 F.2d 154 (D.C. Cir. 1986)..... 16

Hughes Aircraft Co. v. Jacobson,
525 U.S. 432 (1999)..... 14

* *Inwood Labs., Inc. v. Young*,
723 F. Supp. 1523 (D.D.C. 1989)..... 13, 24

* *Mova Pharm. Corp. v. Shalala*,
140 F.3d 1060 (D.C. Cir. 1998)..... 11, 13, 22, 23

Mylan Labs., Inc. v. Leavitt,
484 F. Supp. 2d 109 (D.D.C. 2007)..... 6

* *Mylan Labs., Inc. v. Thompson*,
332 F. Supp. 2d 106 (D.D.C. 2004)..... 19

* *Mylan Pharms., Inc. v. Thompson*,
268 F.3d 1323 (Fed. Cir. 2001) 18

Omar v. Harvey,
416 F. Supp. 2d 19 (D.D.C. 2006)..... 11

Phillips v. Saratoga Harness Racing, Inc.,
240 F.3d 174 (2d Cir. 2001) 22

* *Purepac Pharm. Co. v. Thompson*,
238 F. Supp. 2d 191 (D.D.C. 2002)..... 18

Ranbaxy Labs. v. Leavitt,
469 F.3d 120 (D.C. Cir. 2006)..... 24

Ranbaxy Labs., Ltd. v. Leavitt,
459 F. Supp. 2d 1 (D.D.C. 2006)..... 14

Raymen v. United Senior Ass'n,
No. 05-486(RBW), 2005 WL 607916 (D.D.C. Mar. 16, 2005) 11

Sandoz, Inc. v. FDA,
439 F. Supp. 2d 26 (D.D.C. 2006)..... 27

SEC v. Nat'l Sec., Inc.,
393 U.S. 453 (1969)..... 16

* *Teva Pharms. USA, Inc. v. FDA*,
 182 F.3d 1003 (D.C. Cir. 1999)..... passim

TorPharm, Inc. v. Shalala,
 No. Civ.A. 97-1925(JR), 1997 WL 33472411 (D.D.C. Sept. 15, 1997) 25, 27

* *Valley Drug Co. v. Geneva Pharms., Inc.*,
 344 F.3d 1294 (11th Cir. 2003) 18

Federal Statutes

5 U.S.C. § 706(2)(A)..... 2, 12

21 U.S.C. § 355(b)(1) 3

21 U.S.C. § 355(c)(2)..... 3

21 U.S.C. § 355(j)(2)(A)..... 3

21 U.S.C. § 355(j)(2)(A)(vii)..... 3

21 U.S.C. § 355(j)(2)(B)..... 4

* 21 U.S.C. § 355(j)(5)(B)(iii)..... passim

35 U.S.C. § 271(e)(2)(A) 4

Federal Regulations

21 C.F.R. § 314.53(e)..... 3

21 C.F.R. § 314.94(a)(12)(viii)(A) 5, 21

Nu-Pharm Inc. (“Nu-Pharm”) respectfully submits this brief in support of its motion for a temporary restraining order and/or preliminary injunction requiring FDA to immediately award final approval for Nu-Pharm’s Abbreviated New Drug Application (“ANDA”) No. 77-615 for divalproex sodium delayed-release 500 mg tablets.¹

INTRODUCTION

Nu-Pharm is entitled to immediate final approval for its ANDA for divalproex sodium delayed-release 500 mg tablets—a prescription drug currently marketed solely by Abbott under the brand-name Depakote.[®] Nu-Pharm has satisfied all substantive requirements for final approval under the generic drug approval provisions of the Federal Food, Drug, and Cosmetic Act (“FFDCA”). The FFDCA expressly mandates that FDA “shall” make Nu-Pharm’s approval effective immediately upon expiration of the 30-month stay unless the “district court” hearing the “action” that “is brought [within the 45-day period] for infringement of the patent that is the subject of the certification” decides that the patent has been infringed. *See* 21 U.S.C. § 355(j)(5)(B)(iii). Here, Nu-Pharm’s 30-month stay of approval has expired, and the district court hearing the only patent infringement action filed against Nu-Pharm for its proposed divalproex sodium product has not issued any substantive rulings of patent validity or infringement. FDA therefore has no lawful basis or authority to deny Nu-Pharm approval.

FDA nonetheless refuses to grant final approval to Nu-Pharm’s ANDA, purportedly based on an order entered in a contempt proceeding in a wholly separate patent infringement action involving an entirely different ANDA and an entirely different applicant—

¹ In the event the Court denies such relief, Nu-Pharm respectfully moves for emergency relief pending appellate review. Specifically, in the event the Court denies Nu-Pharm’s request for emergency injunctive relief, Nu-Pharm respectfully requests that any adverse FDA decision be stayed and that Nu-Pharm’s 500 mg product be finally approved pending review by, and appeal of this matter to, the United States Court of Appeals for the D.C. Circuit, in order to prevent devastating and irreparable harm to Nu-Pharm.

an action and proceeding to which Nu-Pharm was not a party and did not participate. FDA's decision is arbitrary, capricious, and contrary to law, in clear violation of the Administrative Procedure Act ("APA"), 5 U.S.C. § 706(2)(A). Under the only proper construction of the FDCA, Nu-Pharm's divalproex sodium 500 mg ANDA is entitled to immediate final approval. Indeed, the plain language compels this result. Consequently, Nu-Pharm has a strong likelihood of succeeding on the merits of its claim. Furthermore, Nu-Pharm will suffer severe and irreparable harm absent the requested relief; the balance of harm weighs in favor of granting this relief; and such relief is in the public interest. Accordingly, this Court should enter a temporary restraining order and/or preliminary injunction requiring FDA to award immediate final approval to Nu-Pharm's ANDA for divalproex sodium 500 mg tablets, which will permit Nu-Pharm to begin marketing its lower-priced generic product promptly after the expiration of Abbott's patents on January 29, 2008.²

BACKGROUND

I. Statutory Background.

This action arises under the FDCA, 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").

² Nu-Pharm does not seek to, and will not, market its product until *after* expiration of Abbott's patents on January 29, 2008. (*See* Rakoczy Decl. Ex. D, Benyak Decl. ¶ 6 n.1.)

A. Brand Drugs – NDAs And Patent Listing Requirements.

A company that seeks to sell a new drug must file with FDA a New Drug Application (“NDA”). The applicant must include in its NDA, *inter alia*, technical data on the composition of the drug, the means for manufacturing it, clinical trial results establishing its safety and effectiveness, and labeling describing the use for which approval is requested. *See* 21 U.S.C. § 355(b)(1). The applicant also must submit information to FDA with respect to any patent that “claims the drug for which the application was submitted or which claims a method of using such drug” *Id.*; *see also* 21 U.S.C. § 355(c)(2). FDA publishes all such patent information in the “Orange Book.” *See* 21 C.F.R. § 314.53(e).

B. Generic Drugs – ANDAs And Patent Certifications.

Before 1984, a company seeking to market a generic version of an FDA-approved NDA drug had to complete expensive and time-consuming safety and efficacy studies on the drug, even though the NDA-holder already had established the drug’s safety and efficacy. In 1984, Congress simplified the procedure for obtaining approval of generic drugs with the Hatch-Waxman Amendments to the FDCA. Under Hatch-Waxman, “an abbreviated new drug application process allows applicants . . . to proceed more quickly to the marketplace.” *Teva Pharms. USA, Inc. v. FDA*, 182 F.3d 1003, 1004 (D.C. Cir. 1999).

An ANDA applicant must establish that its generic drug product is bioequivalent to the NDA drug. *See* 21 U.S.C. § 355(j)(2)(A). The ANDA also must include a “certification” to any properly-listed Orange Book patent. *See* 21 U.S.C. § 355(j)(2)(A)(vii). The statute provides four certification options, only one of which is relevant here: that the listed patent is invalid and/or will not be infringed by the proposed drug, a so-called “paragraph IV certification.” *Id.* With certain exceptions not applicable here, an ANDA applicant seeking FDA approval to market its generic drug prior to the expiration of the Orange Book-listed patent

must submit a paragraph IV certification and notify the patentee and NDA-holder of the factual and legal bases for that certification. *See* 21 U.S.C. § 355(j)(2)(B). The submission of an ANDA with a paragraph IV certification constitutes a technical act of infringement under 35 U.S.C. § 271(e)(2)(A), which permits the patent owner to file, and a district court to adjudicate, a suit to determine whether the proposed generic drug infringes the subject patent before the drug has actually been marketed.

The timing of ANDA approval depends, in part, on whether such a suit is filed by the patent owner within 45 days of receiving notice of the ANDA and paragraph IV certification.

The statute reads in relevant part:

If the applicant made a [paragraph IV certification], *the approval shall be made effective immediately unless*, before the expiration of 45 days after the date on which the notice described in paragraph (2)(B) is received, *an action is brought for infringement of the patent that is the subject of the certification* and for which information was submitted to the Secretary under subsection (b)(1) or (c)(2) of this section before the date on which the application (excluding an amendment or supplement to the application), which the Secretary later determines to be substantially complete, was submitted. If such an action is brought before the expiration of such days, *the approval shall be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under paragraph (2)(B)(i) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that –*

(II) if before the expiration of such period the district court decides that the patent has been infringed

21 U.S.C. § 355(j)(5)(B)(iii) (emphasis added).

Thus, where the applicant submits an ANDA with a paragraph IV certification, FDA “shall” make the approval effective immediately, unless “an action is brought for infringement of the patent that is the subject of the certification.” *Id.* If such “action” is brought within the 45-day period after the patent owner and NDA-holder receive notice of the paragraph IV ANDA, “the approval shall be made effective upon the expiration of the thirty-month period

beginning on the date of the receipt of the notice.” *Id.* This instruction is mandatory—FDA has no discretion because the approval “*shall* be made effective” upon expiration of the 30-month stay. *Id.* (emphasis added). The only relevant exception is where “the district court” hearing the “action” that “is brought [within the 45-day period] for infringement of the patent that is the subject of the certification” decides that the patent is infringed before the expiration of the 30-month stay.³ Only in these circumstances may FDA further delay or withhold approval. *See id.*; *see also* Rakoczy Decl. Ex. A, 2004 FDA Draft Guidance at 5)⁴ (acknowledging that approval may be delayed based on an order by “the district court hearing a patent infringement suit resulting from a paragraph IV certification”); 21 C.F.R. § 314.94(a)(12)(viii)(A) (requiring ANDA applicant to amend its patent certification “if a final judgment in the action against the applicant is entered finding the patent to be infringed.”).

II. Factual Background.

A. Abbott’s Depakote[®] (Divalproex Sodium) And Orange Book Patents.

At issue here is the prescription drug divalproex sodium, which Abbott currently markets under the brand-name Depakote[®]. FDA first approved Depakote[®] on March 10, 1983, for the treatment of epilepsy. Abbott submitted information to FDA on two patents for listing in the Orange Book in connection with Depakote[®]: U.S. Patent Nos. 4,988,731 (“the ‘731 patent”) and 5,212,326 (“the ‘326 patent”). (*See* Rakoczy Decl. Ex. B, Depakote[®] Orange Book Listing.) Both the ‘731 and ‘326 patents naturally expire on January 29, 2008. Abbott also has been

³ The court may also delay approval based on the parties’ failure to cooperate in expediting the action, or if a preliminary injunction is entered, 21 U.S.C. § 355(j)(5)(B)(iii), but neither is applicable here.

⁴ All references to “Rakoczy Decl.” herein refer to the Declaration of William A. Rakoczy, submitted concurrently herewith.

awarded a period of pediatric exclusivity in connection with its Depakote[®] products that, to the extent applicable, expires July 29, 2008.⁵ (*See id.*)

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

On March 7, 2005, Nu-Pharm submitted ANDA No. 77-615 for divalproex sodium delayed-release tablets in the 500 mg strength.⁶ (Rakoczy Decl. Ex. D, Benyak Decl. ¶ 3.) Nu-Pharm has satisfied all substantive requirements for approval. (*Id.*) Nu-Pharm's ANDA contains a paragraph IV certification to both the '731 and '326 patents. (*Id.* ¶ 4.) Nu-Pharm's ANDA also designates and identifies Apotex Inc. of Ontario, Canada, as the contract manufacturer for the finished drug product. (*Id.* ¶ 3.) As required by statute and regulation, Nu-Pharm duly notified Abbott of its paragraph IV certifications, along with the legal and factual bases for its certifications, in a notice letter received by Abbott on May 13, 2005. (*Id.* ¶ 4.) In response, on June 24, 2005, 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 "the *Nu-Pharm* Court"). *See Abbott Labs. v. Nu-Pharm Inc.*, No. 05-3714 (N.D. Ill.) (Pallmeyer, J.) This action triggered a 30-month stay of FDA approval of Nu-Pharm's 500 mg tablet ANDA, which expired

⁵ This period of pediatric exclusivity can apply only to ANDAs that do not have final effective approval before the natural expiration of the '731 and '326 patents on January 29, 2008. (*See* Rakoczy Decl. Ex. C, Apr. 18, 2007 FDA Letter to Amlodipine Besylate ANDA Applicants, at 5 n.4 (citing 21 U.S.C. § 355a) (concluding that ANDAs with final approval upon patent expiration are "not blocked by [a brand manufacturer's] pediatric exclusivity . . . under the literal terms of the [pediatric exclusivity] statute")); *see also Mylan Labs., Inc. v. Leavitt*, 484 F. Supp. 2d 109, 120-21 (D.D.C. 2007).

⁶ Nu-Pharm subsequently amended its divalproex sodium ANDA to also include the 125 mg and 250 mg strengths. Those products, however, are not at issue here and, therefore, are not further addressed.

on November 13, 2007—30 months after Abbott received Nu-Pharm’s notice of paragraph IV certification.

The *Nu-Pharm* action is the one and only patent infringement action that Abbott filed in response to the submission of Nu-Pharm’s paragraph IV ANDA. The *Nu-Pharm* Court has not entered any substantive rulings or orders on the merits of the patent infringement dispute, and certainly has not made any determination of patent infringement or validity. In fact, as discussed below, on October 16, 2006, the *Nu-Pharm* Court stayed the *Nu-Pharm* action in its entirety pending resolution of contempt proceedings against an unrelated third-party (Apotex) in another matter involving the same patents but a different ANDA, also discussed below. (*See Rakoczy Decl. Ex. E, Oct. 16, 2006 Docket Entry.*) To date, the *Nu-Pharm* action remains stayed. (*See id. Ex. F, Oct. 31, 2007, Jan. 4, 2008, and Jan. 14, 2008 Docket Entries.*)

C. Contempt Proceedings Against Apotex In *Abbott v. Apotex*, No. 97-7515 (N.D. Ill.), To Which *Nu-Pharm* Was Not And Is Not A Party.

In a contempt proceeding in a wholly separate action against a different generic company (Apotex), to which *Nu-Pharm* is not and was *not a party*, a different district court “extended” an injunction order involving an entirely different ANDA filed by Apotex (ANDA No. 75-112) to cover Nu-Pharm’s ANDA No. 77-615. *See Abbott Labs. v. Apotex, Inc.*, 455 F. Supp. 2d 831, 840 (N.D. Ill. 2006); *see also Rakoczy Decl. Ex. G, Oct. 6, 2006 Docket Entry and Injunction Order, entered in Abbott Labs. v. Apotex, Inc.*, No. 97-7515 (N.D. Ill.) (Posner, J.) (hereinafter “the *Apotex* Court” or “the *Apotex* action”). The *Apotex* Court also ordered that the effective date of approval of the Nu-Pharm ANDA No. 77-615 shall not be earlier than expiration of the ‘731 and ‘326 patents on January 29, 2008. (*See Rakoczy Decl. Ex. G, Oct. 6, 2006 Injunction Order.*) Significantly, however, Nu-Pharm was not and is not a party to the *Apotex* action in any manner. Nor did the *Apotex* action arise from the filing of Nu-Pharm’s

paragraph IV ANDA. Rather, the *Apotex* action involved, and jurisdiction was based on, a completely different paragraph IV ANDA filed by Apotex, *not Nu-Pharm*.

By way of background, the *Apotex* action arises out of the April 1997 submission of Apotex's ANDA No. 75-112 for divalproex sodium delayed-release tablets. Apotex's ANDA No. 75-112 also included paragraph IV certifications to the '731 and '326 patents. In response, Abbott sued Apotex for alleged infringement in Illinois. After a trial and two appeals, the Apotex ANDA was eventually held to infringe the '731 and '326 patents. *See Abbott Labs. v. TorPharm, Inc.*, 309 F. Supp. 2d 1043, 1054 (N.D. Ill. 2004).⁷ As a result, the *Apotex* Court entered an order enjoining the commercial manufacture, sale, and use of the products described in Apotex's ANDA No. 75-112, and also delayed the effective date of approval, until expiration of Abbott's '731 and '326 patents on January 29, 2008. The original order states:

TorPharm, Inc., Apotex, Inc., and Apotex Corp., and their respective affiliates, successors in interest, and assigns are enjoined from commercially manufacturing, using, selling, or offering to sell generic divalproex sodium which the Court has found to be infringing within the United States, or from importing such product into the United States, until Abbott's U.S. Patent Nos. 4,988,731 and 5,212,326 expire and defendants have received final approval from FDA to market generic divalproex sodium.

The effective date of any approval by FDA of ANDA No. 75-112, or any other application concerning defendants' generic divalproex sodium which the Court has found to be infringing, shall be no earlier than January 29, 2008, the date of expiration of Abbott's U.S. Patent Nos. 4,988,731 and 5,212,316.

(Rakoczy Decl. Ex. H, March 31, 2004 Injunction Order). But once again, Nu-Pharm was never a party to—and never participated in—the *Apotex* action, which was completed before Nu-Pharm ever submitted its own ANDA.

⁷ The Federal Circuit subsequently affirmed this judgment without opinion on February 14, 2005. *See Abbott Labs. v. TorPharm, Inc.*, 122 Fed. Appx. 511, 2005 WL 406563 at *1 (Fed. Cir. Feb. 14, 2005), *reh'g denied*, Mar. 9, 2005.

After the completion of fact discovery in the current and unrelated *Nu-Pharm* action, NuPharm filed a motion for summary judgment of non-infringement before the *Nu-Pharm* Court. That same day, however, rather than respond to Nu-Pharm's summary judgment motion, Abbott initiated contempt proceedings in the old *Apotex* action against Apotex.⁸ In particular, Abbott filed a motion to enforce the prior injunction order against Apotex in the *Apotex* action, and requested that the *Apotex* Court "extend" its injunction over Apotex's old ANDA No. 75-112 to cover and "embrace" Nu-Pharm's wholly separate ANDA No. 77-615. Abbott also filed a motion to stay the *Nu-Pharm* action, which the *Nu-Pharm* Court subsequently granted, and the *Nu-Pharm* action has been stayed ever since. (See Rakoczy Decl. Ex. I, Aug. 17, 2006 Docket Entry; see also *id.* Exs. E and F.)

Meanwhile, the *Apotex* Court conducted a one-day summary contempt proceeding in the *Apotex* action, and refused to allow Apotex any time to conduct additional testing and to submit additional evidence. Again, Nu-Pharm was not a party to the *Apotex* action and did not participate in the contempt proceedings to any extent.

On October 6, 2006, despite the fact that Nu-Pharm was not a party to the *Apotex* action or the contempt proceedings, the *Apotex* Court nonetheless granted Abbott's motion, entered a contempt order, and "extend[ed] the injunction" over Apotex's ANDA to cover and "embrace" Nu-Pharm's ANDA as well. *Abbott Labs.*, 455 F. Supp. 2d at 840; Rakoczy Decl. Ex. G, Oct. 6, 2006 Docket Entry. The *Apotex* Court's "extended injunction" states:

Apotex, Inc., Apotex Corp., and their respective affiliates, successors in interest, and assigns are enjoined from commercially manufacturing, using, selling, or offering to sell generic divalproex sodium which the Court has found to be infringing, including divalproex sodium products synthesized using the processes employed in connection with ANDA No. 77-615, within the United States, or

⁸ Abbott clearly did so because Nu-Pharm's summary judgment motion contained unequivocal evidence of non-infringement.

from importing such products into the United States, until Abbott's U.S. Patent Nos. 4,988,731 and 5,212,326 expire and defendants have received final approval from FDA to market generic divalproex sodium.

The effective date of any approval by FDA of ANDA Nos. 75-112 and 77-615, or any other application concerning defendants' generic divalproex sodium which the Court has found to be infringing, shall be no earlier than January 29, 2008, the date of expiration of Abbott's U.S. Patent Nos. 4,988,731 and 5,212,326.

(Rakoczy Decl. Ex. G, Oct. 6, 2006 Injunction Order.) While this new order does not mention Nu-Pharm by name, it does identify Nu-Pharm's ANDA No. 77-615.

Apotex timely appealed the contempt order and new injunction to the Federal Circuit. On October 11, 2007, the Federal Circuit rightly reversed the *Apotex* Court's finding of contempt against Apotex because the injunction did not preclude or otherwise forbid the filing of another ANDA by Nu-Pharm or Apotex. *See Abbott Labs. v. TorPharm, Inc.*, 503 F.3d 1372, 1382-83 (Fed. Cir. 2007). The Federal Circuit, however, affirmed the extension of the injunction to cover Nu-Pharm's ANDA. *Id.* at 1381. The Federal Circuit recently denied Apotex's petition for rehearing *en banc*. Apotex has filed a petition for a writ of *certiorari* to the United States Supreme Court. That petition remains pending.

D. FDA Unlawfully Refuses To Award Nu-Pharm Final Approval For Its Divalproex Sodium Delayed-Release 500 mg Tablets.

After the 30-month stay for Nu-Pharm's 500 mg product expired on November 13, 2007, Nu-Pharm requested, and expected to receive, final FDA approval. (*See* Rakoczy Decl. Ex. D, Benyak Decl. ¶ 6.) But on December 11, 2007, the Agency informed Nu-Pharm that it would not grant a final approval based on the order in the *Apotex* action. (*Id.* ¶ 6.) On December 21, 2007, Nu-Pharm made a detailed written submission requesting immediate final approval on the ground that FDA has no lawful basis or authority to withhold final approval where, as here, the 30-month stay has expired and the *Nu-Pharm* Court has not made any finding of infringement or validity. (*See* Rakoczy Decl. Ex. J, Dec. 21, 2007 Ltr. to Buehler). On

January 9, 2008, FDA informed Nu-Pharm that it would not issue such an approval solely based on the *Apotex* Court's order. (*See id.* Ex. D, Benyak Decl. ¶ 6.) Nu-Pharm now challenges this Agency decision.

ARGUMENT

Courts must weigh four factors in deciding whether to grant a preliminary injunction or temporary restraining order: (1) the likelihood that the moving party will prevail on the merits; (2) the prospect of irreparable injury to the moving party if relief is withheld; (3) the possibility of substantial harm to other parties if relief is granted; and (4) the public interest. *See Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1066 (D.C. Cir. 1998); *Raymen v. United Senior Ass'n*, No. 05-486(RBW), 2005 WL 607916, at *2 (D.D.C. Mar. 16, 2005) (granting temporary restraining order). The movant "need not prevail on each factor in order to receive injunctive relief." *Raymen*, 2005 WL 607916, at *2. "Rather . . . the factors must be viewed as a continuum, with more of one factor compensating for less of another. If the arguments for one factor are particularly strong, an injunction may issue even if the arguments in other areas are rather weak." *Blackman v. Dist. of Columbia*, 277 F. Supp. 2d 71, 77-78 (D.D.C. 2003) (internal quotations and citation omitted) (granting preliminary injunction).

"[I]ssuing an injunction may be justified 'where there is a particularly strong likelihood of success on the merits even if there is a relatively slight showing of irreparable injury.'" *Raymen*, 2005 WL 607916, at *2 (quoting *Blackman*, 277 F. Supp. 2d at 78). Moreover, "[i]n cases that raise questions 'going to the merits so serious, substantial, difficult and doubtful, as to make them fair ground . . . for more deliberative investigation,' . . . courts should eschew an 'exaggeratedly refined analysis of the merits at an early stage in the litigation.'" *Omar v. Harvey*, 416 F. Supp. 2d 19, 22 (D.D.C. 2006) (quoting *Wash. Metro. Area*

Transit Comm'n v. Holiday Tours, Inc., 559 F.2d 841, 844 (D.C. Cir. 1977)). Nu-Pharm satisfies this standard here.

I. Nu-Pharm Has A Substantial Likelihood Of Succeeding On The Merits Of Its Claims.

Under the APA, the Court must set aside FDA's decision because it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). As FDA must concede, Nu-Pharm has satisfied all substantive requirements for final approval of its 500 mg product, and the only 30-month stay of FDA approval has expired. Moreover, the only relevant court—namely, the *Nu-Pharm* Court hearing the *Nu-Pharm* action arising out of Nu-Pharm's paragraph IV ANDA—has not entered any substantive orders, much less any finding of infringement. In these circumstances, the statute admits of no discretion, and mandates that FDA "shall" make Nu-Pharm's approval effective immediately. But FDA has withheld Nu-Pharm's final approval solely on the basis of a court order and injunction entered in the *Apotex* action to which Nu-Pharm was not and is not a party, and which arises from a paragraph IV ANDA filed by Apotex, not Nu-Pharm. Under the plain language of the statute and FDA's own precedent, the order entered against Apotex in the *Apotex* action cannot be used to delay Nu-Pharm's approval. FDA's decision therefore is arbitrary, capricious, and contrary to law.

First, FDA's decision runs afoul of the plain language of the FFDCA because the statute—properly interpreted in view of its plain language and its underlying purpose—requires FDA to award final approval to a pending ANDA as soon as the 30-month stay has expired, so long as the court hearing that ANDA applicant's patent case has entered no order delaying such approval. *Second*, FDA's decision departs from its own precedent, under which it has construed the statute to delay final ANDA approval based solely on an order from the court hearing the

patent infringement action arising from that applicant's paragraph IV ANDA. Indeed, to Nu-Pharm's knowledge, FDA has *never* found a court decision of either infringement or non-infringement in one ANDA-filer's litigation to open or close the market to other generic ANDA-filers for the same product. *Third*, FDA's decision and interpretation leads to fundamentally absurd and inconsistent results. And *fourth*, FDA's interpretation permits, and indeed encourages, improper gaming and manipulation of the statute. Nu-Pharm, therefore, has a strong likelihood of succeeding on the merits of its case.

A. Under The Plain Language Of The FDCA, FDA Has No Lawful Basis For Withholding Final Approval Of Nu-Pharm's ANDA No. 77-615 For Divalproex Sodium 500 mg Tablets.

To determine whether FDA's decision comports with the statute, this Court must determine first "whether Congress has directly spoken to the precise question at issue." *Chevron U.S.A. Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 842 (1984). "If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." *Id.* at 842-43. "When the statute is clear on its face, resort to the legislative history, much less to the agency's interpretation, is not necessary." *Inwood Labs., Inc. v. Young*, 723 F. Supp. 1523, 1525 (D.D.C. 1989); *see also Bd. of Governors of Fed. Reserve Sys. v. Dimension Fin. Corp.*, 474 U.S. 361, 368 (1986) ("The traditional deference courts pay to agency interpretation is not to be applied to alter the clearly expressed intent of Congress."). Where the statute is clear and unambiguous, the Court "do[es] not defer to the agency's interpretation of the statute." *Mova*, 140 F.3d at 1068.

In this case, the intent of Congress could not be clearer: the statute expressly provides that, with certain exceptions not applicable here, if, "before the expiration of [the 45-day period], *an action is brought for infringement of the patent that is the subject of the certification . . . the approval shall be made effective upon the expiration of the thirty-month*

[stay].” 21 U.S.C. § 355(j)(5)(B)(iii) (emphasis added). The only 30-month stay of Nu-Pharm’s approval admittedly has expired, and no exception applies. Nu-Pharm therefore is entitled to immediate final approval under the plain and unambiguous language of the statute.

1. **Under the plain language of the FDCA, FDA may delay approval if, and only if, the *Nu-Pharm* Court enters a finding and order of infringement in the *Nu-Pharm* action.**

“The preeminent canon of statutory interpretation requires [the courts] to presume that the legislature says in a statute what it means and means in a statute what it says there.” *BedRoc Ltd., v. United States*, 541 U.S. 176, 183 (2004) (quotations and citation omitted). “When the words of a statute are unambiguous then, this first canon is also the last: judicial inquiry is complete.” *Ranbaxy Labs., Ltd. v. Leavitt*, 459 F. Supp. 2d 1, 8 (D.D.C. 2006) (quoting *Conn. Nat’l Bank v. Germain*, 503 U.S. 249, 254 (1992)). Here, Congress has spoken to the issue at hand. As such, this Court’s analysis must begin and end with the plain language of the statute. See *Hughes Aircraft Co. v. Jacobson*, 525 U.S. 432, 438 (1999). The relevant provision states:

If the applicant made a [paragraph IV certification], the approval shall be made effective immediately unless, before the expiration of 45 days after the date on which the notice described in paragraph (2)(B) is received, *an action is brought for infringement of the patent that is the subject of the certification* If such an action is brought before the expiration of such days, *the approval shall be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under paragraph (2)(B)(i)* or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that –

(II) if before the expiration of such period the district court decides that the patent has been infringed

21 U.S.C. § 355(j)(5)(B)(iii) (emphasis added).

Under the plain language of the statute, where, as here, an applicant submits an ANDA with a paragraph IV certification, FDA “shall” make the approval effective immediately,

unless “an action is brought for infringement of the patent that is the subject of the certification.” *Id.* If such an action is brought within the 45-day period after the patent owner and NDA-holder receive notice of the paragraph IV ANDA, “the approval shall be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice.” *Id.* This instruction is mandatory—the approval “shall be made effective” upon expiration of the 30-month stay. *Id.* (emphasis added).

As the Supreme Court has instructed, “[t]he word ‘shall’ is ordinarily the language of command.” *Alabama v. Boseman*, 533 U.S. 146, 153 (2001) (internal quotations and citation omitted). The D.C. Circuit similarly has held, “[t]he word ‘shall’ generally indicates a command that admits of no discretion on the part of the person instructed to carry out the directive.” *Ass’n of Civilian Technicians, Mont. Air Chapter No. 29 v. FLRA*, 22 F.3d 1150, 1153 (D.C. Cir. 1994); *see also Ass’n of Am. R.R.s v. Costle*, 562 F.2d 1310, 1312 (D.C. Cir. 1977) (“The word ‘shall’ is the language of command in a statute”). So, too, here. Unless a specific exception applies (and none do here), the statute imposes a mandatory duty and obligation upon FDA to approve the ANDA upon expiration of the 30-month stay.

The only relevant statutory exception, apparently invoked by FDA here, is where the “district court” hearing the “action [that] is brought [within the 45-day period] for infringement of the patent that is the subject of the certification . . . decides that the patent has been infringed.” 21 U.S.C. § 355(j)(5)(B)(iii). But this exception does not, and indeed cannot, apply to the facts of this case. Congress went to great lengths to identify the particular “action” and “court” that matter for purposes of delaying approval. The only “action” referred to is the one that “is brought for infringement of the patent that is the subject of the certification,” and even more specifically, the “action” brought “before the expiration of 45 days after the date on

which the [paragraph IV notice] is received.” *Id.* In other words, for purposes of ANDA approval, the only action that matters is the one brought against the particular ANDA applicant within the 45-day period for infringement of the patent that is the subject of the applicant’s paragraph IV certification.

Congress likewise employed specific language and context to identify the exact “court” that matters. It is not just *any* district court or “*a* district court,” but rather “*the* district court” hearing the “action” that “is brought for infringement of the patent that is the subject of the certification,” and also which is brought “before the expiration of 45 days after the date on which the [paragraph IV notice] is received.” 21 U.S.C. § 355(j)(5)(B)(iii). *See SEC v. Nat’l Sec., Inc.*, 393 U.S. 453, 466 (1969) (“The meaning of particular phrases must be determined in context.”). “It is a rule of law well established that the definite article ‘the’ particularizes the subject which it precedes. It is a word of limitation as opposed to the indefinite or generalizing force of ‘a’ or ‘an.’” *Am. Bus Ass’n v. Slater*, 231 F.3d 1, 4-5 (D.C. Cir. 2000) (quotation and citation omitted) (finding that agency lacked authority to authorize money damages under unambiguous terms of statute that set forth “the remedies” available to persons subject to discrimination); *see also Gates & Fox Co. v. Occupational Safety & Health Review Comm’n*, 790 F.2d 154, 156 (D.C. Cir. 1986) (Scalia, J.) (stating that, where regulation required self-rescuers on “*the* haulage equipment,”--the definite article [‘the’] suggest[s] that some specific haulage equipment is referred to, rather than merely haulage equipment in general”). In other words, the only relevant “district court” for purposes of delaying the date of effective ANDA approval under the statute is “*the* district court” hearing the patent infringement action filed under 35 U.S.C. § 271(e)(2)(A) by the patent owner and NDA-holder within the 45-day period against the ANDA applicant whose paragraph IV certification and notice gave rise to the suit.

The application of this statutory provision to Nu-Pharm's ANDA is straightforward and simple. Nu-Pharm filed an ANDA containing a paragraph IV certification and provided the requisite notice to Abbott, the NDA-holder and patent owner. Within 45 days of receiving that notice, Abbott filed the *Nu-Pharm* action for infringement of the patents that are the subject of Nu-Pharm's paragraph IV certification. The filing of the *Nu-Pharm* action stayed the approval of Nu-Pharm's ANDA for 30-months from the receipt of Abbott's notice of Nu-Pharm's paragraph IV certification. That 30-month period expired on November 13, 2007. Thus, Nu-Pharm's "approval *shall* be made effective" immediately unless "*the* district court" hearing the "action" that "is brought [within the 45-day period] for infringement of the patent that is the subject of the certification," decides that the patent has been infringed. 21 U.S.C. § 355(j)(5)(B)(iii) (emphasis added). In this case, of course, "the district court" and "action" refer solely to the *Nu-Pharm* Court and the *Nu-Pharm* action, respectively. The *Nu-Pharm* Court is the only court hearing the *Nu-Pharm* action that was brought by Abbott within the 45-day period for infringement of the patents that are the subject of Nu-Pharm's paragraph IV certifications. But the *Nu-Pharm* Court has not decided that the patents are infringed, and in fact has made no substantive rulings of any kind in the *Nu-Pharm* action.

The plain language of the statute, therefore, requires FDA to make Nu-Pharm's approval effective immediately. FDA has no lawful basis or authority to continue delaying Nu-Pharm's approval, and certainly not based on any order entered by the *Apotex* Court in the *Apotex* action. The *Apotex* Court admittedly is not the court hearing the action brought within the 45-day period based on Nu-Pharm's paragraph IV certification. The Agency's refusal to approve Nu-Pharm's ANDA therefore violates the plain and unambiguous language of the FDCA and must thus be set aside.

2. Courts have consistently interpreted the statute in accordance with its plain language.

FDA's refusal to approve Nu-Pharm's 500 mg divalproex sodium tablets also conflicts with the manner in which courts have consistently interpreted the relevant terms of § 355(j)(5)(B)(iii). Indeed, courts always have construed the term "court" to mean the court that is hearing the infringement action that arises out of and is the subject of that particular ANDA applicant's paragraph IV certification. For example, in describing the framework of the statutory provision at issue here, the Eleventh Circuit stated:

If the court hearing the infringement action declares the patent invalid or not infringed, this automatic [30-month] delay in FDA approval terminates, 21 U.S.C. § 355(j)(5)(B)(iii)(I), or, if *the court* finds the patent valid and infringed, the approval date will be set for a date on or after the patent's expiration, 21 U.S.C. § 355(j)(5)(B)(iii)(II); 35 U.S.C. § 271(e)(4)(A).

Valley Drug Co. v. Geneva Pharms., Inc., 344 F.3d 1294, 1297 (11th Cir. 2003) (emphasis added). The Federal Circuit has interpreted the statute in similar fashion:

If the patentee files suit within [the 45-day] period, the FDA may not approve the ANDA until the expiration of the patent, judicial resolution of the infringement suit, a judicial determination that the patent is invalid or unenforceable, or thirty months from the patentee's receipt of notice, whichever is earliest. *The court in which the suit is pending* may order a shorter or longer stay on the approval time, if 'either party to the action fails to reasonably cooperate in expediting the action.' 21 U.S.C. § 355(j)(5)(B)(iii).

Mylan Pharms., Inc. v. Thompson, 268 F.3d 1323, 1327 (Fed. Cir. 2001) (emphasis added) (internal citation omitted).

The district courts agree. In *Purepac Pharmaceutical Co. v. Thompson*, 238 F. Supp. 2d 191 (D.D.C. 2002), where the proper interpretation of the statutory provisions governing paragraph IV certifications and their legal consequences were directly at issue, the court stated:

If a suit is initiated, the FDA's approval of the ANDA is automatically stayed for 30 months, a period that can be lengthened or shortened *by the court hearing the*

