THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

NU-PHARM INC.

Plaintiff-Appellant,

v.

FOOD AND DRUG ADMINISTRATION, MICHAEL O. LEAVITT, Secretary of Health and Human Services, and ANDREW C. VON ESCHENBACH, M.D., Commissioner of Food and Drugs,

Defendants-Appellees,

and

ABBOTT LABORATORIES,

Intervenor-Defendant-Appellee.

No. 08-5017

CORRECTED MOTION OF APPELLANT NU-PHARM INC. TO EXPEDITE CONSIDERATION OF THIS APPEAL

Appellant Nu-Pharm Inc. respectfully moves, pursuant to Circuit Rule 47.2 and 28 U.S.C. § 1657, for expedited consideration of this appeal, with appellant's brief due February 29, 2008; appellees' briefs due March 21, 2008; and appellant's reply due April 4, 2008. Nu-Pharm has contacted counsel for Appellees regarding this motion. Abbott indicated that it opposes the motion to the extent that it proposes a shortened time for the filing of Abbott's response brief, while counsel for Federal appellees did not respond.

INTRODUCTION

This appeal involves important considerations of statutory interpretation ignored by FDA and the court below. Under the clear language of the Federal Food, Drug, and Cosmetic Act ("FFDCA"), Nu-Pharm is entitled to immediate final approval of its generic divalproex sodium delayed-release 500 mg tablets. Abbott currently markets its branded divalproex product under the name Depakote®. The FFDCA expressly mandates that FDA "shall" make Nu-Pharm's approval effective immediately upon expiration of the 30-month statutory 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. 21 U.S.C. § 355(j)(5)(B)(iii). Nu-Pharm has satisfied all substantive requirements for final approval; the 30-month stay period has expired; and the district court hearing Abbott's infringement action against Nu-Pharm has not made any substantive decisions. Nevertheless, FDA has refused to grant final approval to Nu-Pharm's ANDA based on an order entered in contempt proceedings in a wholly separate infringement action (one not involving Nu-Pharm) regarding a wholly separate ANDA (one not filed by Nu-Pharm).

Nu-Pharm challenged the Agency's administrative decision below as arbitrary, capricious, and contrary to law under the APA. Nu-Pharm sought both declaratory and emergency injunctive relief that would permit Nu-Pharm to obtain

approval and begin marketing its competing generic product promptly after Abbott's patents expired on January 29, 2008. Absent such relief, Nu-Pharm risked being delayed for another six months by Abbott's pediatric exclusivity that expires on July 29, 2008—an exclusivity that would not apply had FDA granted Nu-Pharm the final approval to which it lawfully is entitled before expiration of Abbott's patents. Rather than address the merits of Nu-Pharm's APA claim against the Agency, over which the district court conceded it had jurisdiction, the court dismissed the complaint, declining to exercise jurisdiction for "prudential reasons" purportedly on the ground that the injunctive relief Nu-Pharm sought would "conflict irreconcilably" with the order entered in the contempt proceedings.

Expedited consideration of this appeal is necessary because the decision under review is subject to substantial challenge, delay will cause further irreparable injury to Nu-Pharm, and the public has an unusual interest in the earlier introduction of lower-priced generic versions of this important medicine. Moreover, absent expedited consideration of this appeal well before July 29, 2008, there is little chance Nu-Pharm could receive *any* meaningful relief whatsoever.

STATUTORY BACKGROUND

This Court is well familiar with the statutory requirements for FDA-approval of generic drugs under the FFDCA. Here, the only relevant statutory provision is that governing the timing of approval for an abbreviated new drug

application ("ANDA") that contains a paragraph IV certification under 21 U.S.C. § 355(j)(2)(A)(vii). The statute provides:

> 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 . . . 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 a paragraph IV ANDA and "an action is brought for infringement of the patent" within 45 days of receiving notice of the paragraph IV certification, "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—unless the district court hearing the action arising out of the paragraph IV certification decides the patent is infringed, approval "*shall* be made effective" upon expiration of the 30-month stay. *Id.* (emphasis added).[1]

[1] Approval can also be delayed if the ANDA filer fails to cooperate in the action or if a preliminary injunction is entered (*id.* § 355(j)(5)(B)(iii)). Neither applies here.

FACTUAL BACKGROUND

A. Nu-Pharm's Divalproex Sodium ANDA.

Nu-Pharm has filed an ANDA (No. 77-615) for divalproex sodium 500 mg tablets, which is approved for the treatment of epilepsy. Abbott listed two patents 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"), both of which naturally expired on January 29, 2008. FDA, however, awarded Abbott pediatric exclusivity in connection with its Depakote® products, which, to the extent applicable, expires July 29, 2008.[2] Nu-Pharm's ANDA contains a paragraph IV certification to both the '731 and '326 patents. Abbott received Nu-Pharm's paragraph IV notice letter on May 13, 2005 and then sued Nu-Pharm in the U.S. District Court for the Northern District of Illinois ("the *Nu-Pharm* action" or "the *Nu-Pharm* Court"). This action triggered a 30-month stay of FDA approval of Nu-Pharm's ANDA, which expired on November 13, 2007.

The *Nu-Pharm* Court has entered no substantive rulings on the merits of the patent infringement dispute, and has made no determination of patent

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[2] Generally, pediatric exclusivity delays approval only of ANDAs that do not have final effective approval before the natural expiration of the listed patents. (*See* Siwik Decl. Ex. A, Apr. 18, 2007 FDA Letter to Amlodipine Besylate ANDA Applicants, at 5 n.4, filed concurrently herewith). Here, FDA should have approved Nu-Pharm's ANDA *before* expiration of Abbott's patents, thus allowing Nu-Pharm to launch its product without delay from Abbott's pediatric exclusivity.

infringement or validity. In August 2006, Nu-Pharm filed a motion for summary judgment of non-infringement before the *Nu-Pharm* Court. Rather than respond, Abbott moved to stay the *Nu-Pharm* action and initiated contempt proceedings in a separate action against an entirely different ANDA applicant—Apotex, Nu-Pharm's supplier of finished divalproex sodium drug products ("the *Apotex* action" or "the *Apotex* Court"). In the contempt proceedings, Abbott asked the *Apotex* Court to "extend" its earlier injunction over Apotex's ANDA to cover and "embrace" Nu-Pharm's wholly separate ANDA.[3]

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 No. 77-615. *Abbott Labs. v. Apotex, Inc.*, 455 F. Supp. 2d 831, 840 (N.D. Ill. 2006). 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

[3] The *Apotex* Court previously found that Apotex's proposed divalproex sodium products, under Apotex's ANDA, would infringe Abbott's patents and, in March 2004, entered an order enjoining their commercial manufacture, sale, and use, and delaying FDA approval until expiration of Abbott's patents. *See Abbott Labs. v. TorPharm, Inc.*, 309 F. Supp. 2d 1043, 1054 (N.D. Ill. 2004), *aff'd* 122 Fed. Appx. 511, 2005 WL 406563 (Fed. Cir. Feb. 14, 2005), *reh'g denied* (Mar. 9, 2005).

> divalproex sodium products synthesized using the processes employed in connection with ANDA No. 77-615, within the United States, or 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.

(Siwik Decl. Ex. B, Injunction Order.)[4] The *Nu-Pharm* Court granted Abbott's motion to stay, which remains in effect. (*See* Siwik Decl. Ex. C, Stay Orders.)

B. FDA's Administrative Ruling.

Nu-Pharm has satisfied all substantive requirements for approval. Thus, 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. Yet, despite the expiration of Nu-Pharm's 30-month stay and the lack of a finding of infringement by the *Nu-Pharm* Court, on January 9, 2008 FDA issued a final administrative decision refusing to award Nu-Pharm final approval of its ANDA solely on the basis of the *Apotex* Court's order.

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[4] On October 11, 2007, the Federal Circuit reversed the *Apotex* Court's finding of contempt against Apotex, but affirmed the extension of the injunction to cover Nu-Pharm's ANDA. *See Abbott Labs. v. TorPharm, Inc.*, 503 F.3d 1372, 1381-83 (Fed. Cir. 2007). Apotex's petition for rehearing *en banc* was denied and its petition for a writ of *certiorari* to the U.S. Supreme Court remains pending.

C. The District Court Denies Nu-Pharm Injunctive Relief And Refuses To Exercise Jurisdiction Over Nu-Pharm's Complaint.

On January 14, 2008, Nu-Pharm sued FDA challenging its administrative decision under the APA. In particular, Nu-Pharm sought both a judicial declaration that FDA's decision was arbitrary, capricious, and contrary to law under the APA and the FFDCA, and preliminary and permanent injunctive relief requiring the Agency to award Nu-Pharm immediate final approval. The court granted Abbott leave to intervene.

On January 24, 2008, the district court held a brief hearing, not to address the merits of Nu-Pharm's APA claim, but rather to address a wholly separate issue raised *sua sponte* by the district court; namely, "whether [the] Court should decline, for prudential reasons, to exercise jurisdiction in this case given the potential for irreconcilable conflicting decisions stemming from Nu-Pharm's request for relief . . . and the relief that was already issued by [the *Apotex* Court]."[5] (Siwik Decl. Ex. D, Hearing Tr. at 6.) After argument, the court, *inter alia*, dismissed the case entirely and declined to exercise jurisdiction—that the court admittedly had—for "prudential reasons" on the grounds that the requested relief "would conflict irreconcilably" with the *Apotex* Court order. (*Id.* at 40). The court also denied Nu-Pharm's motion for temporary restraining order and/or preliminary

[5] FDA's opposition brief never addressed Nu-Pharm's statutory arguments, instead stating that "Nu-Pharm's lengthy statutory arguments are irrelevant." (Siwik Decl. Ex. E, FDA Mem. at 15.)

injunction without ever reaching the merits of Nu-Pharm's APA claim. (*Id.*) Nu-Pharm appealed.

ARGUMENT

The law requires this Court to expedite consideration of this appeal. *See* 28 U.S.C. § 1657(a); Cir. Rule 47.2(a); D.C. Circuit, *Handbook of Practice and Internal Procedures* at 33 (2007). Additionally, Nu-Pharm satisfies the Court's separate criteria for expedited consideration: "the decision under review is subject to substantial challenge," "delay will cause irreparable injury" to Nu-Pharm, and the public has "an unusual interest in prompt disposition" of this appeal. D.C. Circuit, *Handbook of Practice and Internal Procedures* at 33 (2007).

I. The District Court's Decision Is Subject To Substantial Challenge.

The district court's dismissal and denial of Nu-Pharm's motion for injunctive relief hinge entirely on questions of law, which this Court reviews *de novo*. *See Loughlin v. United States*, 393 F.3d 155, 162 (D.C. Cir. 2004) ("federal jurisdiction determinations are purely legal"); *Butler v. West*, 164 F.3d 634, 639 (D.C. Cir. 1999) ("We review statutory interpretation by a district court *de novo*."). Under this standard, the district court's decision is subject to substantial challenge.

A. The District Court Improperly Declined To Exercise Jurisdiction Over Nu-Pharm's Complaint And APA Claim.

As an initial matter, the district court improperly refused to exercise jurisdiction over Nu-Pharm's complaint. Indeed, the court correctly conceded that

it had subject matter jurisdiction over Nu-Pharm's complaint, yet declined to exercise such jurisdiction solely for "prudential reasons." (*See* Siwik Decl. Ex. D, Hearing Tr. at 38, 40.) The court's decision conflicts with the well-accepted principle that "the federal courts 'have a virtually unflagging obligation . . . to exercise the jurisdiction given them.'" *Moses H. Cone Mem'l Hosp. v. Mercury Constr. Corp.*, 460 U.S. 1, 15 (1983) (citation omitted); *see also England v. La. State Bd. of Med. Advisors*, 375 U.S. 411, 415 (1964) ("When a Federal court is properly appealed to in a case over which it has by law jurisdiction, it is its duty to take such jurisdiction." (citation omitted)). Indeed, as this Court has held, the doctrine of comity is to be employed only "in strictly limited circumstances." *Nw. Forest Res. Council v. Dombeck*, 107 F.3d 897, 901 (D.C. Cir. 1997). Dismissal may be warranted only where "there is a *case pending* in another jurisdiction involving the same parties, issues, and subject matter." *Id.* But that is not the case here. The district court therefore clearly erred by declining to exercise the jurisdiction that admittedly it had over Nu-Pharm's APA claim.

First, neither Nu-Pharm nor FDA were parties to the *Apotex* action, nor is that case still currently pending. This alone entitles Nu-Pharm to have its case heard:

> Created to assure judicial efficiency and to reflect abiding respect for other courts, the *doctrine [of comity] surely does not contemplate that fundamental rights of citizens will be adjudicated in forums from which they are absent.*

Id. (emphasis added) (citation omitted). *Second*, the issues and subject matter are not the same in both actions. The *Apotex* action was a contempt proceeding between Abbott and Apotex, involving whether Apotex had violated a prior injunction. In contrast, this action seeks judicial review of final Agency action under the APA. No court has addressed, much less resolved, the issues of statutory construction raised by Nu-Pharm in this APA action. *And third*, the relief sought by Nu-Pharm would not "conflict irreconcilably" with the order of the *Apotex* Court. To begin, Nu-Pharm seeks both declaratory *and* injunctive relief, including a judicial declaration that FDA's decision and interpretation of the FFDCA is arbitrary, capricious, and contrary to law. Such a declaration would not conflict with the *Apotex* Court's order, which only speaks to a delayed effective approval date. At the very least, Nu-Pharm is entitled to have its claim for declaratory relief under the APA heard and decided. Similarly, Nu-Pharm's claim for injunctive relief merely seeks a remedy for FDA's violation of the FFDCA. FDA could provide that remedy without violating any order by recognizing its statutory command and obligation under the FFDCA, reversing its earlier and unlawful statutory interpretation, and making clear what types of orders affect or delay generic approvals under the plain language of the statute.

B. FDA's Administrative Decision Violates The Statute's Unambiguous Text And Purpose.

FDA's decision must be set aside under the APA because it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). The statute requires FDA to approve a pending ANDA once the 30-month stay expires, unless the court hearing that applicant's patent case orders that approval be delayed. *See* 21 U.S.C. § 355(j)(5)(B)(iii). Here, Nu-Pharm's 30-month stay has expired and no such court decision has been rendered. Thus, because "Congress has directly spoken to the precise question at issue" and "the intent of Congress is clear . . . the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." *Chevron U.S.A. v. Natural Res. Def. Council*, 467 U.S. 837, 842-43 (1984).

1. Under The Plain Language Of The FFDCA, Nu-Pharm's 500 mg ANDA Is Entitled To Immediate Final Approval.

FDA states that "Nu-Pharm is correct that FDA must ordinarily approve an otherwise approvable ANDA upon expiration of a 30-month stay." (Siwik Decl. Ex. E, FDA Mem. at 15.) But the statute goes further, dictating that FDA "*shall*" award immediate final approval once the 30-month stay has expired, so long as the court hearing the infringement action has entered no orders of infringement or validity:

> 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). Thus, where, as here, an applicant submits an ANDA with a paragraph IV certification, and an action is brought within the 45-day period and the court hearing the infringement suit has made no finding of infringement, "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.*

As the Supreme Court has instructed, "[t]he word 'shall' is ordinarily the language of command." *Ala. v. Bozeman*, 533 U.S. 146, 153 (2001) (internal quotations and citation omitted). This Court 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). Thus, unless a specific exception applies (none do here), the statute imposes a mandatory duty and obligation upon FDA to approve the ANDA when the 30-month stay expires.

The only potentially relevant statutory exception does not apply here. Under the statute, approval may be delayed 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) (emphasis added). As this Court acknowledges, "[i]t 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) (quotations and citation omitted); *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, "the definite article ['the'] suggest[s] that some specific haulage equipment is referred to [in the regulation], rather than merely haulage equipment in general"). Thus, 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 by the patent owner within the 45-day period against the ANDA applicant whose paragraph IV certification gave rise to the suit. Again, here, that district court is the *Nu-Pharm* Court, and the *Nu-Pharm* Court has made no substantive rulings of any kind.

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). For example, in describing the framework of the statutory provision at issue here, courts have stated:

> ***If the court hearing the infringement action*** declares the patent invalid or not infringed, this automatic [30-month] delay in FDA approval terminates, . . . 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.

Valley Drug Co. v. Geneva Pharms., 344 F.3d 1294, 1297 (11th Cir. 2003) (emphasis added) (citations omitted); *see also Mylan Pharms. v. Thompson*, 268 F.3d 1323, 1327 (Fed. Cir. 2001) ("***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.'" (emphasis added)); *Purepac Pharmaceutical Co. v. Thompson*, 238 F. Supp. 2d 191 (D.D.C. 2002) (noting that the 30-month stay "can be lengthened or shortened ***by the court hearing the case*** if either party fails to 'reasonably cooperate in expediting the action'" (emphasis added)); *Astrazeneca AB v. Mutual Pharm. Co.*, 221 F. Supp. 2d 528, 530 (E.D. Pa. 2002) (stating that ***"[t]he Court in which the suit is pending*** *has the authority to order a shorter or longer stay on the approval time*, if 'either party to the action fail[s] to reasonably cooperate in expediting the action.'" (citation omitted)). Similarly, in *Mylan Laboratories, Inc. v. Thompson*, 332 F. Supp. 2d 106 (D.D.C. 2004), the court explained:

> If the patent holder or NDA is successful in its lawsuit, that is, ***the court hearing the patent infringement litigation concludes that the***

> ***patent is valid and infringed***, the Patent Code provides that 'the court shall order the effective date of any approval of the drug . . . involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed.' 35 U.S.C. § 271(e)(4)(A).

332 F. Supp. 2d at 112 (emphasis added). Courts thus uniformly agree that the only court which may be used to delay approval is the one that is hearing the action brought against the ANDA applicant within the 45-day period for infringement of the patent that is the subject of the certification—here, the *Nu-Pharm* Court hearing the *Nu-Pharm* action.

2. FDA's Interpretation Conflicts With Its Past Policies And Practices And Leads To Absurd Results.

FDA's administrative ruling also must be rejected because it conflicts directly with the Agency's prior practice and policies and leads to absurd results. For instance, in a 2004 draft Guidance for Industry, the Agency expressly opined on "[w]hat court decisions and other judicial actions are relevant for lifting 30-month stays of approval on ANDAs." (Siwik Decl. Ex. F, Draft Guidance at 3.) FDA correctly interpreted § 355(j)(5)(B)(iii) as follows:

> ***If the district court hearing a patent infringement suit resulting from a paragraph IV certification*** decides that the patent at issue is infringed, and this decision is not appealed or is affirmed on appeal, the ANDA . . . may be approved based on the district court's ruling in accordance with the patent's expiration and any extension or exclusivity that remains.

(*Id.* at 5) (emphasis added). FDA thus confirmed that only a decision of infringement by the district court hearing the suit that resulted from the ANDA-filer's paragraph IV certification may delay final approval of that applicant's ANDA. This interpretation comports with the Agency's own implementing regulations, which provide that an applicant shall amend its patent certification "if a final judgment ***in the action against the applicant*** is entered finding the patent to be infringed." 21 C.F.R. § 314.94(a)(12)(viii)(A) (emphasis added).

Furthermore, FDA's administrative ruling runs counter to the Agency's prior administrative decisions. To Nu-Pharm's knowledge, FDA has never delayed one ANDA applicant's approval based on an unfavorable decision in another, unrelated action that did not arise out of that applicant's paragraph IV certification. Moreover, there is no question that, had the *Apotex* Court rendered a decision in favor of Apotex and found that Apotex's or Nu-Pharm's divalproex sodium products did not infringe Abbott's patents, FDA would not have terminated Nu-Pharm's stay solely on that basis. Indeed, to interpret the statute in such a manner would be absurd and, hence, unlawful. *See Teva Pharms., USA v. FDA*, 182 F.3d 1003, 1011 (D.C. Cir. 1999) ("FDA must interpret the statute to avoid absurd results and further congressional intent").

3. FDA's Interpretation Permits, And Indeed Encourages, Improper Gaming And Manipulation Of The Statute.

Finally, FDA's interpretation must be rejected as it allows, and indeed encourages, blatant manipulation and gaming of the system. FDA effectively has allowed Abbott to forestall generic competition upon expiration of its patents through a contempt proceeding against an unrelated applicant, without ever obtaining an order against Nu-Pharm in the patent litigation that Congress intended for resolution of Hatch-Waxman patent disputes. FDA's interpretation impermissibly rewards an NDA-holder for attempting to escape a finding of non-infringement in the patent infringement action *it filed* against a particular ANDA applicant by running to an entirely different district court to extend an injunction order over an entirely different ANDA product. FDA's ruling turns the entire Hatch-Waxman system on its head and can not stand.

II. Nu-Pharm Will Suffer Substantial Irreparable Harm Absent Expedited Consideration.

Nu-Pharm can obtain meaningful relief from this Court only via expedited consideration of this appeal well before July 29, 2008. Divalproex sodium is Nu-Pharm's first foray into the ultra-competitive generic market in the United States. (Siwik Decl. Ex. G, Benyak Decl. ¶ 3.) If Nu-Pharm is forced to wait until Abbott's pediatric exclusivity period expires and all other ANDA applicants obtain final approval, Nu-Pharm estimates that it would lose over

$132.5 million in sales during Nu-Pharm's first full year on the market. (*Id.* ¶ 9.) Such losses are completely unrecoverable from FDA, and in fact will effectively destroy Nu-Pharm's U.S. business. (*Id.*) Additionally, Nu-Pharm will suffer unquantifiable losses and harm to its business and reputation. (*Id.* ¶ 10.) Nu-Pharm will lose access to major customers and contracts, as well as a loss of goodwill that will adversely affect Nu-Pharm's ability to compete in the United States. (*Id.*) Given Nu-Pharm's position as a new-comer to the market, these losses will cause extreme hardship to Nu-Pharm's business and could threaten its very existence, constituting imminent, significant and irreparable harm.

III. The Balance Of Harms And The Public Interest Favor Expedited Consideration.

The balance of harms tips decidedly in favor of expediting Nu-Pharm's appeal. Without such review, Nu-Pharm stands to lose the opportunity for any meaningful relief in this Court as well as its entire U.S. business. FDA and Abbott, on the other hand, will suffer no harm whatsoever from an expedited briefing and disposition schedule. Further, expedited consideration and resolution of this appeal is in the public interest. First, the public's interest is served by requiring FDA to apply the governing statute in a manner that is consistent with the plain language of the statute and prior agency rulings. Second, expedited consideration comports with the purpose of the statute, which seeks to "get generic

drugs into the hands of patients at reasonable prices—fast." *In re Barr Labs.*, 930 F.2d 72, 76 (D.C. Cir. 1991).

CONCLUSION

For all these reasons, the Court should expedite briefing, argument, and consideration of this appeal.

Dated: February 11, 2008.

Respectfully submitted,

NU-PHARM INC.

By: _____
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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 11th day of February 2008, a true and correct copy of the foregoing Corrected Motion of Appellant Nu-Pharm Inc. To Expedite Consideration Of This Appeal was served via hand delivery upon the following:

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