IN 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

REPLY IN SUPPORT OF APPELLANT NU-PHARM'S MOTION TO EXPEDITE CONSIDERATION OF THIS APPEAL

Expedited consideration of this appeal is necessary for Nu-Pharm to obtain any meaningful relief from this Court. Nu-Pharm is suffering significant and unrecoverable harm each day its generic product is kept off the market, and Nu-Pharm risks losing all of the competitive advantages to which it is statutorily entitled if this appeal is not decided well in advance of July 29, 2008. Nu-Pharm has also demonstrated a substantial challenge to the district court's decision below, based on the plain language of the Federal Food, Drug, and Cosmetic Act

("FFDCA"), and neither FDA nor Abbott seriously disputes this statutory interpretation on the merits. Finally, 28 U.S.C. § 1657(a) requires this Court to expedite consideration of this case.

I. Judge Roberts' Decision Is Subject To Substantial Challenge.

In this APA action, Nu-Pharm challenges FDA's unlawful interpretation and application of the FFDCA. Because the Agency's interpretation "is subject to substantial challenge" on appeal, expedited consideration is warranted. FDA and Abbott essentially ignore the Agency's statutory interpretation at issue here. But the plain language of the statute admits of only one construction: Nu-Pharm is entitled to immediate final approval and should be permitted to launch *now*—not five or six months from now—and only expedited consideration of this appeal will enable Nu-Pharm to take advantage of a ruling upholding this statutory directive. Moreover, the district court had no lawful basis for refusing to exercise jurisdiction in this case.

A. The Plain Language Of The Statute Supports The Relief Nu-Pharm Seeks.

As Nu-Pharm has explained, under the plain language of the statute, FDA "shall" approve an otherwise approvable ANDA once the applicable 30-month stay expires, unless the district court hearing the action, which is filed within the 45-day period and arises out of the applicant's paragraph IV certification, decides that the patent has been infringed. *See* 21 U.S.C.

§ 355(j)(5)(B)(iii). FDA is entitled to no discretion on this point. Indeed, FDA admits that, "[a]t the end of 30 months (or such shorter or longer period as the court orders), FDA *will* approve the ANDA in spite of the patent and ongoing litigation if the ANDA is otherwise ready for approval, and there are no other barriers to approval." (FDA Resp. at 13) (emphasis added).

FDA also agrees that the relevant court for purposes of delaying ANDA approval is "the court hearing the patent infringement litigation," and that the order that matters is an order that "results" from "patent litigation between an ANDA applicant and NDA holder or patent owner." (*Id.* at 14.) Here, the district court hearing the patent infringement action arising out of Nu-Pharm's paragraph IV certification to Abbott's patents is the *Nu-Pharm* Court, not the *Apotex* Court, but the *Nu-Pharm* Court has not entered any such orders.[1] Thus, because Nu-Pharm has satisfied all substantive requirements for final approval, Nu-Pharm was

[1] Abbott asserts that the Federal Circuit rejected Nu-Pharm's claim that the *Nu-Pharm* Court is "the only court which may be used to delay approval" of its ANDA. (Abbott Resp. at 9.) Not so. The Federal Circuit simply determined that the *Apotex* Court could "try issues relating to the Nu-Pharm ANDA in a contempt proceeding." *Abbott Labs. v. TorPharm, Inc.*, 503 F.3d 1372, 1379 (Fed. Cir. 2007). The court *never* addressed the issue of statutory interpretation at issue in this appeal, *i.e.*, whether, under the plain and unambiguous language of the statute, FDA can lawfully deny ANDA approval upon expiration of an applicant's 30-month stay where the court hearing the infringement action arising out of the paragraph IV certification has entered no findings of patent infringement or validity.

entitled to final approval of its divalproex sodium ANDA effective immediately upon expiration of its 30-month statutory stay.

The district court refused to address Nu-Pharm's statutory interpretation argument in its oral ruling and order, and both FDA and Abbott similarly fail to address the merits of this argument. It is not an answer for FDA merely to point to an order entered in an action to which neither Nu-Pharm nor FDA were parties. FDA cannot avoid a clear statutory mandate, and certainly cannot depart from the plain and unambiguous language of its governing statute. An Agency decision and interpretation that conflicts with the plain language of the FFDCA is arbitrary, capricious, and contrary to law under the APA. For this reason alone, the decision under review is subject to substantial challenge and expedited review is warranted.

B. The District Court Had No Lawful Basis For Declining Jurisdiction.

FDA rightly concedes that "federal courts are under an obligation to exercise the jurisdiction given to them" and that courts may decline such jurisdiction only in "exceptional circumstances."[2] (FDA Resp. at 20, 21.) "Exceptional circumstances," however, are not present here. Unlike the cases

[2] FDA raises additional jurisdictional arguments in the context of a motion for summary affirmance. Nu-Pharm will properly address those arguments in a separate response. Nu-Pharm's reply is limited to FDA's discussion of the general principles of comity originally addressed in Nu-Pharm's motion.

FDA cites, the court below was not justified in declining jurisdiction based either on the need to avoid duplicative litigation, or on grounds of comity.

First, this case does not involve the potential for parallel litigation because Nu-Pharm's APA action against FDA does not involve the same facts, legal issues, or parties as either the *Nu-Pharm* action or the *Apotex* action.[3] The *Apotex* action originated as a patent infringement case between Abbott and Apotex, which developed into a contempt proceeding over whether Apotex had violated a prior injunction. The *Nu-Pharm* action also involved a patent infringement matter, but as between Abbott and Nu-Pharm. In contrast, here, Nu-Pharm seeks judicial review under the APA of final Agency action based on a statutory interpretation that conflicts with the plain language of the FFDCA. Nu-Pharm's current legal claim against FDA under the APA, therefore, raises no concerns over judicial inefficiency or inconvenience.

Second, despite FDA's assertions to the contrary, the issues here could not—by the Agency's own admission—have been presented to the *Apotex* Court.

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[3] In contrast, the cases cited by FDA involved suits where the same factual and legal issues were at stake. *See Handy v. Shaw, Bransford, Veilleux & Roth*, 325 F.3d 346, 353 (D.C. Cir. 2003) (district court dismissal constituted legal error even where case involved same subject matter); *Feller v. Brock*, 802 F.2d 722 (4th Cir. 1986) (plaintiffs in each action challenged the Department of Labor's actions with respect to certifying growers); *Common Cause v. Judicial Ethics Comm.*, 473 F. Supp. 1251 (D.D.C. 1979) (plaintiffs in second action sought disclosure of same financial records at issue in original restraint proceedings); *Hilton Hotels Corp. v. Weaver*, 325 F.2d 1010 (D.C. Cir. 1963) (stating "[t]his case raises issues of fact and law virtually identical to those which were considered by the [Third Circuit]").

(*See* FDA Resp. at 17.) In fact, FDA expressly conceded that venue for Nu-Pharm's APA action "would be improper in Chicago." (Nu-Pharm Mot. Siwik Decl. Ex. D at 26.) The district court agreed, stating that "with the FDA . . . and the federal defendants as the original defendants in this case, it may well be that there would not have been either *in personam* jurisdiction over the federal defendants in Chicago, or venue might not have been appropriate with just the FDA and the federal defendants as the defendants in this case." (*Id.* at 38.) Thus, under the Agency's own authority, the doctrine of comity does not support the district court's refusal to exercise jurisdiction over Nu-Pharm's APA action because the remedy that Nu-Pharm seeks against the Agency is not available in either the *Nu-Pharm* Court or the *Apotex* Court. *See Lapin v. Shulton, Inc.*, 333 F.2d 169, 172 (9th Cir. 1964) (stating that a court may decline jurisdiction for reasons of comity and orderly administration "so long as it is apparent that a remedy is available [from the rendering court]").

And third, exceptional circumstances do not exist here simply because the *Apotex* Court's injunction was entered more than 15 months ago. Contrary to the suggestions by the district court, FDA, and Abbott, Nu-Pharm could not have sought its requested declaratory and injunctive relief under the APA against FDA at the time of the *Apotex* decision. Nu-Pharm's action against the Agency did not become ripe until after Nu-Pharm's 30-month stay had expired and FDA had

officially denied Nu-Pharm's request for final ANDA approval. *See Abbott Labs. v. Gardner*, 387 U.S. 136, 148 (1967) ("courts traditionally have been reluctant to apply [injunctive and declaratory judgment remedies] to administrative determinations unless these arise in the context of a controversy 'ripe' for judicial resolution"). As the Supreme Court explained in a case involving Abbott, the ripeness doctrine was designed "to prevent the courts . . . from entangling themselves in abstract disagreements . . . and also to protect the agencies from judicial interference until an administrative decision has been formalized and its effects felt in a concrete way by the challenging parties." *Id.* at 148-49. Here, FDA's administrative decision was not "formalized" until after Nu-Pharm's 30-month stay expired on November 13, 2007, and FDA eventually denied Nu-Pharm's written request for final approval on January 9, 2008. Nu-Pharm filed this action for declaratory and injunctive relief just five days later, on January 14, 2008. In sum, Nu-Pharm could not have challenged the Agency's administrative decision under the APA any earlier than it did.

II. Nu-Pharm Will Suffer Significant Irreparable Harm Absent Expedited Relief.

There is no question that once Abbott's pediatric exclusivity period expires on July 29, 2008, Nu-Pharm will no longer be able to take advantage of limited generic competition for divalproex sodium tablets. Instead, if the Court does not address Nu-Pharm's appeal until after this time, such delay could cost Nu-

Pharm over $132 million and threaten its relationships with customers, which, in turn, may destroy its ability to grow and develop its U.S. business. (*See* Nu-Pharm Mot. Siwik Decl. Ex. G ¶¶ 7, 9-10.)[4]

Abbott contends that "the fact that Nu-Pharm would prefer not to compete with other manufacturers does not mean it will suffer 'irreparable harm' absent relief in this case," but Nu-Pharm's motion for expedited consideration is grounded on much more than a "preference" not to "play by the same rules as everyone else." (*See* Abbott Resp. at 9-10.) What Abbott and FDA continue to ignore is the fact that Nu-Pharm is not in the same position "as everyone else." Unlike other divalproex sodium paragraph IV ANDA-filers, Nu-Pharm, to its knowledge, was the *only* applicant entitled to final approval prior to the natural expiration of Abbott's patents.[5]

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[4] The fact that Nu-Pharm is a new entrant to the U.S. market does not detract from its showing of irreparable harm, as FDA suggests. (*See* FDA Resp. at 4 n.3.) FDA's argument, taken to its logical and absurd conclusion, would prevent any new market entrant, particularly small businesses, from ever being able to show irreparable harm.

[5] Abbott also argues that expedited consideration is unnecessary "[w]ithout a showing that Nu-Pharm's product is scientifically and commercially viable." (Abbott Resp. at 7.) Yet, FDA has issued Nu-Pharm tentative approval for its products and, therefore, has deemed Nu-Pharm's divalproex sodium tablets safe and effective for use as recommended in the submitted labeling. *See* http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Label_ApprovalHistory#apphist.

Nu-Pharm was entitled to final approval as of November 13, 2007—more than two months before Abbott's patents naturally expired. By that time, Nu-Pharm had satisfied all substantive requirements for final approval, the 30-month stay period had expired, and the district court hearing Abbott's infringement action against Nu-Pharm had not made any substantive decisions. Thus, contrary to what Abbott would have this Court believe, the relief requested by Nu-Pharm was and is *not* "barred by statute until July 29, 2008." (*See* Abbott Resp. at 8.) Rather, as FDA has explained, 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* Nu-Pharm Mot. Siwik Decl. Ex. A at 5 n.4.) Thus, while "everyone else" may have been rightfully denied access to the market during Abbott's pediatric exclusivity period, by virtue of FDA's refusal to approve Nu-Pharm's ANDA after the 30-month stay had expired, Nu-Pharm was unlawfully denied the opportunity to take advantage of limited generic competition during this six-month period.

III. Expedited Consideration Of This Appeal Is In The Public Interest.

Finally, expedited consideration of this appeal will not have any detrimental effect on the patent system nor will it encroach upon "the rights of patent holders against infringement." (*See* Abbott Resp. at 10.) Abbott already has received, and benefitted from, the entire statutory period of protection

contemplated by the patent system. That period expired naturally on January 29, 2008, and Nu-Pharm did not market its product during this time. The only period of exclusivity to which Abbott is still entitled is a period of pediatric exclusivity, which only pertains to ANDA applicants that are not eligible for final approval prior to the natural expiration of its patents. Nu-Pharm does not fit into this category. Therefore, while both Nu-Pharm and the public will be harmed absent expedited consideration of this appeal, neither FDA nor Abbott will be prejudiced in the least.

CONCLUSION

For these reasons, the Court should expedite briefing, argument, and consideration of this appeal pursuant to the proposed schedule set forth in Nu-Pharm's Motion.

Dated: February 19, 2008.

Respectfully submitted,

NU-PHARM INC.

By: _____
One of its attorneys

Michael D. Hays
Daniel D. Prichard
DOW LOHNES PLLC
1200 New Hampshire Ave., N.W.
Suite 800
Washington, D.C. 20036
(202) 776-2000
(202) 776-2222 (facsimile)

William A. Rakoczy
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)

Counsel for Plaintiff-Appellant Nu-Pharm Inc.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 19th day of February 2008, a true and correct copy of the foregoing Reply In Support of Appellant Nu-Pharm's Motion To Expedite Consideration Of This Appeal was served via hand delivery upon the following:

Drake Cutini
U.S. Department of Justice
Office of Consumer Litigation
Room 950 North
1331 Pennsylvania Ave., N.W.
Washington, D.C. 20004
Counsel for the Federal Defendants-Appellees

Gregory A. Castanias
Christopher S. Perry
JONES DAY
51 Louisiana Avenue, N.W.
Washington, D.C. 20001-2113
Counsel for Intervenor-Defendant-Appellee
Abbott Laboratories

Counsel for Plaintiff-Appellant
Nu-Pharm Inc.