UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

NU-PHARM INC.,	)	
Plaintiff,	)	
v.	)	Civil Action No. 08-0070 (RWR)
FOOD AND DRUG ADMINISTRATION, *et al.*,	)	
Defendants,	)	
and	)	
ABBOTT LABORATORIES,	)	
Intervenor-Defendant.	)	

MOTION TO DISMISS

Pursuant to Federal Rule of Civil Procedure 12(b)(6), the defendants, the 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, move to dismiss the complaint in this action. The basis for this motion is that the complaint fails to state a claim upon which relief can be granted, as explained further in the memorandum in support of this motion filed herewith.

Respectfully submitted,

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UNITED STATES DISTRICT COURT
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NU-PHARM INC., Plaintiff, v. FOOD AND DRUG ADMINISTRATION, *et al.*, Defendants, and ABBOTT LABORATORIES, Intervenor-Defendant.	)	Civil Action No. 08-0070 (RWR)

FEDERAL DEFENDANTS' MEMORANDUM IN SUPPORT OF MOTION TO DISMISS AND IN OPPOSITION TO PLAINTIFF'S MOTION FOR TEMPORARY RESTRAINING ORDER AND/OR PRELIMINARY INJUNCTION

INTRODUCTION

In this frivolous case, plaintiff Nu-Pharm Inc. ("Nu-Pharm") seeks an order from this Court compelling the Food and Drug Administration ("FDA") to violate an order of the United States District Court for the Northern District of Illinois – an order which has been upheld by the Court of Appeals for the Federal Circuit – and approve Nu-Pharm's abbreviated new drug application ("ANDA") for divalproex sodium delayed-release tablets 500 mg (brand-name Depakote), a drug used to treat epilepsy. Although plaintiff argues that this Illinois case is unrelated to Nu-Pharm, that assertion is flatly inconsistent with explicit findings of the Illinois court.

The Illinois court held in 2004 that the divalproex ANDA of a generic drug

manufacturer, Apotex, Inc. ("Apotex"), infringed intervenor-defendant Abbott Laboratories' ("Abbott's") patents covering divalproex, and ordered that the effective date of approval of Apotex's ANDA be no earlier than the expiration date of Abbott's patents on January 29, 2008. Abbott Laboratories v. Torpharm, Inc., 503 F.3d 1372, 1376-77 (Fed. Cir. 2007). After this order was entered, Nu-Pharm entered into an agreement with Apotex to file essentially the same ANDA in Nu-Pharm's name. In a contempt proceeding resulting from this ruse, the Illinois federal court (Judge Richard A. Posner, sitting by designation) determined that Apotex (through Nu-Pharm) had not changed its product in any meaningful way. Abbott Laboratories v. Apotex, 455 F.Supp.2d 831, 837 (N.D. Ill. 2006) ("Here, there is no difference at all."). The court found that "Apotex's choice of Nu-Pharm to file the ANDA was a subterfuge intended to give Apotex a crack at another district judge, who might, in an infringement suit by Abbott, conclude that it was a different, and noninfringing, product from the one I had enjoined." Id. at 835. Judge Posner held that Apotex's "cavalier disregard for judicial findings," and its "use of Nu-Pharm as a stalking horse, were the antithesis of good faith." Id. at 839. The court held that Nu-Pharm's product also infringed the patents, and expanded the injunction he had entered against Apotex to state: "The effective date of any approval by FDA of [Apotex's and Nu-Pharm's ANDAs] shall be no earlier than January 29, 2008. . . ." 503 F.3d at 1376-77.

The Court of Appeals for the Federal Circuit affirmed this finding: "The district court found that 'Apotex's choice of Nu-Pharm to file the ANDA was a subterfuge intended to give Apotex a crack at another district judge' . . . . We do not disturb that finding. . . ." Id. at 1379. The Federal Circuit went on to affirm the extension of the injunction to cover the Nu-Pharm ANDA: "Because the Nu-Pharm ANDA drug would infringe the claims of the Abbott patents,

the district court did not abuse its discretion in extending the injunction to prohibit the FDA from approving the Nu-Pharm ANDA." Id. at 1381. Nu-Pharm makes no contention that it was in any way prevented from participating in the Illinois case at any stage of the proceedings.

The Illinois injunction explicitly precludes FDA approval of Nu-Pharm's ANDA prior to January 29, 2008. Nevertheless, Nu-Pharm now seeks an order from this Court compelling FDA to violate the Illinois court's order. This brazen attempt to undermine the Illinois court and subvert the judicial process should be rejected out of hand. FDA's decision to obey the Illinois injunction can in no way be characterized as arbitrary, capricious, an abuse of discretion, not in accordance with law, or beyond its statutory authority, as Nu-Pharm argues. Complaint ¶¶ 3, 32; Memorandum in Support of Nu-Pharm's Motion for Temporary Restraining Order and/Or Preliminary Injunction ("Pl. Mem.") at 12. The baseless nature of this case on the merits makes it unnecessary for this Court even to reach the question of emergency relief; this case should be dismissed outright. However, if the Court were to reach the issues raised by Nu-Pharm's motion for emergency relief, Nu-Pharm has made no showing that it is likely to succeed on the merits or that it will suffer irreparable harm in the absence of preliminary injunctive relief. Accordingly, the complaint should be dismissed or, alternatively, Nu-Pharm's motion for a temporary restraining order and/or preliminary injunction should be denied.

PROCEDURAL BACKGROUND

Abbott manufactures divalproex under the brand name Depakote. Brand drugs like Depakote are also known as "pioneer," or "innovator" drugs (in contrast to "generic" drugs), and are generally protected by various patents that cover their chemical composition, formulation, or method of use. In 1997, Apotex filed an ANDA with FDA, seeking approval to market a generic

version of divalproex. Pl. Mem. at 8. As part of its ANDA, Apotex challenged the two Abbott patents that were listed in the Orange Book for that drug.[1] Abbott sued Apotex for infringement of those patents in the Northern District of Illinois ("Illinois court"). As noted above, the Illinois court determined that Apotex's ANDA infringed the patents, and enjoined Apotex, its affiliates, assigns, and successors from manufacturing, using, selling, or offering for sale generic divalproex until expiration of Abbott's patents. 503 F.3d at 1376. That court also ordered that FDA could not approve the ANDA until expiration of the patents:

> 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.

Id. at 1376-77. After this injunction, Apotex entered into an agreement concerning divalproex with Nu-Pharm, which had previously been owned by Apotex's parent company. Id. at 1377 & n.2. Under the agreement, Apotex paid for the costs of preparing another ANDA, which Nu-Pharm filed. Id. at 1377. Judge Posner found that Nu-Pharm's ANDA "had been developed by Apotex, is owned by it, and, as Sherman [Apotex's principal] has testified, we [Apotex] will get our profit out of it, anyway." 455 F.Supp.2d at 835. The court also noted of Mr. Sherman's attempts to evade the initial injunction against Apotex: "This is stubbornness carried to the point of contumacy." Id. at 836.

Nu-Pharm filed the ANDA that is the subject of this lawsuit, No. 77-615, on March 7, 2005. Id. Abbott sued Nu-Pharm for patent infringement in the Northern District of Illinois shortly thereafter, and the case was routinely assigned to a different judge, Judge Pallmeyer. 503

[1] FDA publishes patent information it receives in a publication called "Approved Drug Products With Therapeutic Equivalence Evaluations," also known as the "Orange Book."

F.3d at 1377. Later, Abbott learned that Apotex and Nu-Pharm had coordinated their ANDA efforts. 503 F.3d at 1377; 455 F.Supp.2d at 835. Abbott filed a motion to enforce the injunction in the Apotex action against Nu-Pharm, which, as noted above, Judge Posner granted. Not only did the court find, as discussed above, that Apotex's use of Nu-Pharm amounted to a subterfuge, it stated that Apotex used Nu-Pharm as a "tool" and a "stalking horse." 455 F.Supp.2d at 835. The court concluded that the product that was the subject of Nu-Pharm's ANDA was not any different from Apotex's product. Id. at 837. The court held that it could properly determine infringement in a contempt proceeding in these circumstances, and it again enjoined Apotex, its affiliates, assigns, and successors from manufacturing, using, selling, or offering for sale generic divalproex until expiration of Abbott's patents, and extended the original injunction covering Apotex to expressly include the Nu-Pharm ANDA No. 77-615:

> 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.

503 F.3d at 1376-77.

Apotex appealed, and the Federal Circuit held that the contempt procedure used by the district court was proper, that the Nu-Pharm product was not colorably different from the Apotex product, and that the Nu-Pharm product would infringe Abbott's patents. Id. at 1380-81. Thus, the court affirmed the district court's extension of the injunction to include Nu-Pharm's ANDA, noting that "Judge Posner acted entirely within his discretionary authority to issue an order expanding the original injunction." Id. at 1381. The court reversed the district court's finding that Apotex was in contempt of the original injunction by acting in concert with Nu-Pharm to file

an ANDA on the narrow ground that the injunction did not specifically prohibit the filing of an ANDA. 503 F.3d at 1383. Apotex petitioned the Federal Circuit to rehear the case en banc, which that court denied. Pl. Mem. at 10. Apotex has subsequently filed a petition for certiorari to the United States Supreme Court, arguing that the injunction was improperly expanded to include Nu-Pharm. Apotex, Inc. v. Abbott Laboratories, No. 07-912 (petition for certiorari filed January 7, 2008) ("Cert. Pet.") (portion attached as Exhibit A hereto).[2] In its petition, Apotex recognizes that the new injunction prohibits FDA from approving Nu-Pharm's ANDA: "The Federal Circuit . . . refused to vacate Judge Posner's . . . new injunction prohibiting Apotex from commercially making this second [Nu-Pharm] ANDA product, **and prohibiting FDA from approving this second ANDA.**" Id. at 2 (emphasis added).

Separately, Abbott moved to have the Nu-Pharm case before Judge Pallmeyer stayed in view of the claims relating to Nu-Pharm's ANDA in the Apotex litigation before Judge Posner. That court granted a stay. Pl. Exh. E. A status hearing was held on January 14, 2008 (the day the instant case was filed), and another status hearing has been scheduled for April 17, 2008. Pl. Exh. F.

On December 17, 2007, Nu-Pharm requested final FDA approval of its ANDA for divalproex. Pl. Exh. J. Agency counsel informed Nu-Pharm's counsel that the agency would comply with the Illinois court order, and did not intend to approve the ANDA before expiration of the patents on January 29, 2008. This suit followed.

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[2] Defendants will provide the entire petition should the Court desire to see it.

STATUTORY AND REGULATORY FRAMEWORK

I. New Drug Applications ("NDAs")

FDA approves applications to market drugs under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 355. Pursuant to this provision, pharmaceutical companies seeking to market "pioneer" or "innovator" drugs must first obtain FDA approval by filing an NDA containing extensive scientific data demonstrating the safety and effectiveness of the drug. 21 U.S.C. § 355(a), (b). An NDA applicant must also submit information on any patent that claims the drug or a method of using the drug and for which a claim of patent infringement could reasonably be asserted against an unauthorized party. 21 U.S.C. § 355(b)(1), (c)(2). FDA publishes the patent information it receives in the Orange Book. Id.; see also 21 U.S.C. § 355(j)(7); 21 C.F.R. § 314.53(e).

II. Abbreviated New Drug Applications ("ANDAs")

The Drug Price Competition and Patent Term Restoration Act of 1984 (known as the "Hatch-Waxman Amendments"), codified at 21 U.S.C. §§ 355, 360cc, and 35 U.S.C. §§ 156, 271, 282, permits the submission of ANDAs for approval of generic versions of approved drug products. 21 U.S.C. § 355(j). The ANDA process shortens the time and effort needed for approval by, among other things, allowing the applicant to demonstrate its product's bioequivalence to a drug already approved under an NDA (the "listed" drug) rather than having to reproduce the safety and effectiveness data for that drug. Eli Lilly and Co. v. Medtronic, Inc.,

496 U.S. 661, 676 (1990).[3] If an ANDA applicant establishes that its proposed drug product has the same active ingredient, strength, dosage form, route of administration, labeling, and conditions of use as a listed drug, and that it is bioequivalent to that drug, the applicant can rely on FDA's previous finding that the listed drug is safe and effective. Id. The FDCA sets forth in detail additional information that an ANDA must contain, and lists the numerous deficiencies that may prevent or delay approval of an ANDA. See 21 U.S.C. §§ 355(j)(2), 355(j)(4).

A. Patent Certifications

The timing of approval of ANDAs depends in part on patent protections for the listed drug. An ANDA must contain one of four specified certifications for each patent that "claims the listed drug" or "a use for such listed drug for which the applicant is seeking approval." 21 U.S.C. § 355(j)(2)(A)(vii). The certification must state one of the following:

> (I) that the required patent information relating to such patent has not been filed;
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> (II) that such patent has expired;
>
> (III) that such patent will expire on a particular date; or
>
> (IV) that such patent is invalid or will not be infringed by the drug for which approval is being sought.

Id. If a certification is made under paragraph I or II indicating that patent information pertaining to the drug or its use has not been filed with FDA or the patent has expired, then the patent, by itself, will not delay approval of the ANDA. 21 U.S.C. § 355(j)(5)(B)(I). A certification under paragraph III indicates that the ANDA applicant does not intend to market the drug until after the

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[3] Two drugs are considered bioequivalent if, in general, the rate and extent of absorption of the proposed drug is not significantly different from the rate and extent of absorption of the listed drug. 21 U.S.C. § 355(j)(8)(B).

applicable patent has expired, and FDA will not approve the ANDA until after the patent has expired. 21 U.S.C. § 355(j)(5)(B)(ii).

If an applicant wishes to challenge a patent's validity, or to claim that the patent would not be infringed by the product proposed in the ANDA, the applicant must submit a paragraph IV certification to FDA. The applicant must also provide notice of the paragraph IV certification to the NDA holder and the patent owner and describe the factual and legal basis for the applicant's opinion that the patent is invalid or not infringed. 21 U.S.C. § 355(j)(2)(B). The filing of a paragraph IV certification "for a drug claimed in a patent or the use of which is claimed in a patent" is an act of infringement. 35 U.S.C. § 271(e)(2)(A). This enables the NDA holder and patent owner to sue the ANDA applicant.

If the patent owner or NDA holder brings a patent infringement suit against the ANDA applicant within 45 days after receiving notice of the paragraph IV certification, the suit triggers an automatic stay of FDA approval for 30 months from the date the patent owner or NDA holder received notice of the certification ("30-month stay"). 21 U.S.C. § 355(j)(5)(B)(iii). The 30-month stay can be modified or lifted if the patent court reaches a decision before 30 months expires or otherwise orders a longer or shorter stay period. Id. At 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 approvals of ANDAs are always subject to a court finding of infringement and ordering that the effective date of approval shall be no earlier than the date the patent expires under 35 U.S.C. § 271(e)(4)(A), as described further below.

B. Patent Litigation Stays of Approval

In addition to amending the FDCA, the Hatch-Waxman Amendments amended the patent code to specify the consequences that follow when an NDA holder or patent owner sues the ANDA applicant and wins – that is, the court hearing the patent infringement litigation finds the patent valid and infringed. In these circumstances, 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). In other words, as part of the relief to be entered in the event of a finding of patent infringement, final effective approval of the ANDA that was the subject of the suit must be delayed until "not earlier than" the date the patent has expired.

Accordingly, when patent litigation between an ANDA applicant and NDA holder or patent owner results in a court order stating that the effective date of ANDA approval shall be no earlier than the date the patent expires, FDA may not issue a final effective approval until after the date in the order has passed. As discussed in more detail infra, the D.C. Circuit and this District Court have held that FDA is "bound" to follow a court's injunction under 35 U.S.C. § 271(e)(4)(A). Mylan Laboratories Inc. v. Thompson, 389 F.3d 1272, 1282 (D.C. Cir. 2004) ("Mylan (duragesic)"); Apotex Inc. v. FDA, 508 F.Supp.2d 78, 89 (D.D.C. 2007) ("Apotex (omeprazole)").

C. Pediatric Exclusivity

Congress amended the FDCA in 1997 to provide an economic incentive for drug manufacturers to invest the resources necessary to conduct and submit studies of the effects of

drugs in the pediatric population. The pediatric exclusivity statute, 21 U.S.C. § 355a, provides an additional six months of marketing exclusivity beyond the term of applicable patents and other marketing exclusivities to drug manufacturers that conduct such pediatric studies at FDA's request. S. Rep. No. 105-43, at 52. In general terms, if an ANDA applicant has submitted a paragraph II (the patent has expired) or paragraph III (the patent will expire on a specified date) certification, and pediatric studies have been submitted prior to the expiration of the patent, pediatric exclusivity will delay approval of the ANDA for six months after the date the patent expires. 21 U.S.C. § 355a(c)(1)(B). If the ANDA applicant submitted a paragraph IV certification (patent is invalid or will not be infringed), and the patent court determines that the patent is valid and infringed, "the period during which an [ANDA] may not be approved under . . . [21 U.S.C. §] 355(j)(5)(B) shall be extended by a period of six months after the date the patent expires (including any patent extensions)." 21 U.S.C. § 355a(c)(1)(B)(ii). If the ANDA applicant submitted a paragraph IV certification, is sued by the patent owner or the NDA holder, and the patents expire before FDA approves the ANDA, then FDA will treat the paragraph IV certification as a paragraph II certification, and pediatric exclusivity will attach to delay approval of the ANDA for six months. See 21 U.S.C. § 355a(c)(1)(B)(i); Ranbaxy Labs. Ltd. v. FDA, 307 F.Supp.2d 15, 21 (D.D.C.), aff'd, 96 Fed. Appx. 1 (D.C. Cir. 2004) (upholding FDA's decision to apply pediatric exclusivity to ANDA applicant with previous paragraph IV certification upon patent expiration).

FDA has determined that Abbott successfully completed the requested pediatric studies

for Depakote and is therefore eligible for pediatric exclusivity for that drug.[4] Thus, depending on the type of patent certification filed by an ANDA applicant and the outcome of any related patent litigation, Abbott's pediatric exclusivity may delay for six months the approval of ANDAs referencing Depakote.

ARGUMENT

I. The Complaint Should be Dismissed

A. Standard of Review

To prevent dismissal under Federal Rule of Civil Procedure 12(b)(6), "allegations must be enough to raise a right to relief above the speculative level." Bell Atlantic Corp. v. Twombly, 127 S.Ct. 1955, 1965 (2007). Plaintiffs must allege "facts suggestive of illegal conduct," and present a "claim to relief that is plausible on its face." Id. at 1969, 1974. In reviewing a complaint under this standard, a court may review not only the complaint and documents referenced in the complaint, but matters of judicial notice and matters of public record. EEOC v. St. Francis Xavier Parochial School, 117 F.3d 621, 624 (D.C. Cir. 1997); Marshall County Health Care Auth. v. Shalala, 988 F.2d 1221, 1226 n.6 (D.C. Cir. 1993). The court must accept as true all of plaintiff's well-pled factual allegations; however, courts "accept neither 'inferences drawn by plaintiffs if such inferences are unsupported by the facts set out in the complaint,' nor 'legal conclusions cast in the form of factual allegations.'" Browning v. Clinton, 292 F.3d 235, 242 (D.C. Cir. 2002); Luck's Music Library, Inc. v. Ashcroft, 321 F.Supp.2d 107, 112 (D.D.C. 2004). Dismissal is appropriate when, as here, the plaintiff's complaint is "legally insufficient to

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[4] *See* Electronic Orange Book, available at http://www.accessdata.fda.gov/scripts/cder/ob/docs/patexclnew.cfm?Appl_No=018723&Product_No=002&table1=OB_Rx (showing pediatric exclusivity for two patents covering Depakote).

state claims upon which relief can be granted." See Trudeau v. FTC, 456 F.3d 178, 191 (D.C. Cir. 2006).

B. The Complaint Fails to State a Claim

Even assuming the truth of Nu-Pharm's factual allegations, it is plain that Nu-Pharm does not state a claim that "is plausible on its face." Twombly, 127 S.Ct. at 1974. Nu-Pharm's challenge rests on the premise that "FDA has no lawful basis for withholding final approval of Nu-Pharm's ANDA." Pl. Mem. at 13 (heading); see also id. at 1, 10, 17, 28; Complaint ¶¶ 2, 28. Before the United States Supreme Court, however, Apotex's counsel (from the same law firm representing Nu-Pharm here), states that the Illinois court's order "prohibit[s] FDA from approving this second [Nu-Pharm's] ANDA." Cert. Pet. at 2. The latter representation is correct.

The Illinois court's order states as follows:

> 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.

503 F.3d at 1376-77. Because Nu-Pharm's ANDA No. 77-615 is explicitly covered by that injunction, FDA has determined that it will delay approval of Nu-Pharm's ANDA until after January 29, 2008. In doing so, FDA affords proper respect to the district court's statutory authority under 35 U.S.C. § 271(e)(4)(A) – and the court's inherent equitable powers – to award relief for infringement that includes relief directed at the timing of FDA approvals of ANDAs. Indeed, the district court's authority to issue orders awarding relief under 35 U.S.C. § 271(e)(4)(A) inherently depends upon FDA's compliance with those orders, even when (as

here) FDA does not participate in the private patent litigation.

Courts have recognized that FDA is not free to ignore similar orders entered pursuant to 35 U.S.C. § 271(e)(4)(A). In Mylan (duragesic), after FDA's approval of Mylan's ANDA, a district court in Vermont held that Mylan's ANDA infringed the patent. 389 F.3d at 1277. The Vermont court entered an injunction similar to the one issued by the Illinois court, which required FDA to reset the effective date of Mylan's approval until patent expiration. Id. FDA concluded that, under the district court's ruling, Mylan's final approval would be converted into a tentative approval and, in addition, Mylan would be subject to a six-month pediatric exclusivity period after expiration of the patent. Id. at 1277-78. The D.C. Circuit held that FDA was "bound" by the district court injunction and upheld FDA's decision. Id. at 1282. Similarly, in Apotex (omeprazole), Apotex's ANDA had been approved and Apotex had been marketing the product for about four years when a district court in New York ruled that Apotex's product infringed the applicable patents, and that Apotex was subject to a six-month pediatric exclusivity period. 508 F.Supp.2d at 81. To give effect to the court's order under 35 U.S.C. § 271(e)(4)(A), FDA reset the effective date of Apotex's approval until the six-month exclusivity period had expired. Id. at 82. Apotex sued FDA to compel FDA to violate the district court's order, just as Nu-Pharm does in this case. The court rejected plaintiff's challenge to FDA's action: "The plaintiff has not convincingly argued that the FDA is free to disregard a court order when it imposes a period of exclusivity despite the patent's expiration." Id. at 85. The court also stated that plaintiff "has not persuasively argued that the FDA had discretion to exercise in this circumstance." Id. at 86.

Although Nu-Pharm repeatedly asserts that it is not related to the Illinois case, see, e.g.,

Pl. Mem. at 1, 7, 12, 20, 23, 24, that assertion is refuted by explicit findings made by the Illinois court and affirmed by the Federal Circuit. As noted above, Judge Posner explicitly held that Apotex was using Nu-Pharm as a "subterfuge," and that Nu-Pharm was a "tool" and a "stalking horse" for Apotex. 455 F.Supp.2d at 835-36. Judge Posner further found that Nu-Pharm's ANDA had been developed by Apotex, was owned by Apotex, and was the same as the Apotex ANDA. Id. at 835, 837. Plaintiff's contention that Nu-Pharm is not related to the Illinois case is an argument that should have been presented to the Illinois court.

FDA must give effect to the court's order, which expressly pertains to Nu-Pharm's ANDA. Nu-Pharm attempts to avoid this obvious conclusion by arguing that FDA must follow the plain language of 21 U.S.C. § 355(j)(5)(B)(iii), which addresses FDA approval of ANDAs upon expiration of a 30-month stay. Pl. Mem. at 13-20. While Nu-Pharm is correct that FDA must ordinarily approve an otherwise approvable ANDA upon expiration of a 30-month stay, in this case, FDA is subject to a direct court order requiring FDA to delay the approval of Nu-Pharm's ANDA until after January 29, 2008.

Thus, Nu-Pharm's statutory arguments miss the point entirely because Nu-Pharm fails to recognize (at least before this Court) FDA's obligation to give effect to the Illinois court's order. For this reason, Nu-Pharm's lengthy statutory arguments are irrelevant. This Circuit (in Mylan (duragesic), 389 F.3d at 1281-82), and this court (in Apotex (omeprazole), 508 F.Supp.2d at 84-86), have rejected arguments that FDA's decisions to follow court orders were improper because they were inconsistent with the statute. FDA's determination to follow the court's order in this case can in no way be characterized as arbitrary, capricious, contrary to law, or beyond its

authority. Nu-Pharm's complaint must therefore be dismissed.[5]

In this same vein, Nu-Pharm argues that FDA's decision cannot be squared with the agency's past practice in implementing 21 U.S.C. § 355(j)(5)(B)(iii), because FDA has never interpreted the terms "court" or "action" in that statute "to mean separate, unrelated actions brought against other ANDA-filers." Pl. Mem. at 20; see id. at 16-21. In the normal course, the court hearing a patent case and the court issuing an order granting relief for patent infringement are the same court. Here, however, because of Apotex and Nu-Pharm's attempted subterfuge, the court that heard Apotex's case exercised its equitable powers to extend an order enjoining Apotex's patent infringement to cover Nu-Pharm. None of the cases cited by Nu-Pharm contains such an explicit attempt to evade an injunction (or, as Judge Posner held, "contumacy," 455 F.Supp.2d at 836). For Nu-Pharm to suggest that a United States District Court cannot address such conduct or that FDA should disobey such an order is astonishing. In any event, this argument should have been addressed to the Illinois court.

Nu-Pharm also makes the remarkable argument that FDA's decision to obey an explicit court order "leads to absurd results" and encourages "blatant manipulation and gaming of the system." Pl. Mem. at 23, 24. It is alleged that this could happen because FDA can use a finding of infringement in one case to delay approval of other ANDAs, id. at 23, and because, in the future, NDA holders can avoid patent litigation by "running to an entirely different district court to extend an injunction order over an entirely different ANDA filer." Id. at 24. The basis for

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[5] In Count II, Nu-Pharm cites 5 U.S.C. § 705. Complaint ¶ 35. Nu-Pharm does not assert that FDA has violated this section, only that Nu-Pharm "is entitled to immediate final approval" under this section. That section only authorizes an agency or a court to postpone the effective date of agency action. It has no application to the relief requested by Nu-Pharm, which is a mandatory injunction.

these arguments is the unbelievable suggestion that Judge Posner would have enjoined approval of an ANDA by an entity completely unrelated to Apotex (Mylan Pharmaceuticals, for example). The notion that any United States District Judge could be tricked into entering such an order is not remotely plausible. Plaintiff has again ignored the explicit findings of Judge Posner that Nu-Pharm is a "tool" and a "stalking horse" for Apotex, and that Apotex's attempt to use Nu-Pharm to file the ANDA was a subterfuge. Apotex and Nu-Pharm are clearly "related," as Judge Posner explicitly held. It is Nu-Pharm that is attempting to "game the system" by running to this Court to undermine the injunction of the Illinois court.

For these reasons, plaintiff's attempt to persuade the Court to enjoin FDA to act in direct conflict with the order of another United States District Court – which was upheld on appeal – does not present a claim "that is plausible on its face." Twombly, 127 S.Ct. at 1974. For FDA to follow the law cannot be arbitrary, capricious, an abuse of discretion, or not in accordance with law; nor can it be in excess of statutory authority. This is reason enough to dismiss the complaint.[6]

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[6] Plaintiff's complaint can be dismissed for additional reasons. For instance, plaintiff is obviously attempting to have Judge Posner's injunction modified or set aside, and this is not the proper court for such an attempt. See, e.g., Feller v. Brock, 802 F.2d 722, 727-29 (4th Cir. 1986) (injunction against Department of Labor improper because agency was subject to injunction from another case (in which plaintiffs were not parties)); Common Cause v. Judicial Ethics Comm., 473 F.Supp. 1251 (D.D.C. 1979) (case dismissed since defendants were bound by an order of another court (plaintiffs were not parties to the other case)). This principle applies with even more force in the instant case because it is clear that plaintiff is bound by the Illinois injunction. As noted above, the injunction explicitly runs to Apotex and affiliates, successors, and assigns. Under Rule 65(d), an injunction is binding not only on the party to the case, but on the party's officers, agents, servants, employees, attorneys, and anyone in active concert with any of these entities. Given the findings of Judge Posner discussed above, Nu-Pharm is clearly in active concert with Apotex, and is bound by that injunction.

II. Nu-Pharm's Motion for Emergency Relief Should be Denied

A. Standard of Review

Even if the Court were to review Nu-Pharm's motion for emergency relief, that motion should be denied because plaintiff has not met the high standard necessary to justify such relief. To obtain either a TRO or a preliminary injunction, a party must demonstrate that: (1) it has a substantial likelihood of success on the merits; (2) it will suffer irreparable injury in the absence of preliminary relief; (3) other interested parties will not be substantially injured if the requested relief is granted; and (4) granting such relief would serve the public interest. See Mova Pharm. Corp. v. Shalala, 140 F.3d 1060, 1066 (D.C. Cir. 1998); Mylan Laboratories Inc. v. Leavitt, 484 F.Supp.2d 109, 117 (D.D.C. 2007) ("Mylan (amlodipine)"); Boehringer Ingelheim Corp. v. Shalala, 993 F. Supp. 1, 1 (D.D.C. 1997). Although the four factors are to be balanced on a sliding scale, "[i]t is particularly important for the movant to demonstrate a substantial likelihood of success on the merits." Mylan (amlodipine), 484 F.Supp.2d at 117. Moreover, "if a party makes no showing of irreparable injury, the court may deny the motion for injunctive relief without considering the other factors." Id.

The interim injunctive relief Nu-Pharm seeks is "an extraordinary form of judicial relief" that is not to be entered lightly; such motions are thus granted sparingly. Id.; Bristol-Myers Squibb Co. v. Shalala, 923 F. Supp. 212, 215 (D.D.C. 1996). Moreover, Nu-Pharm's request that this Court order FDA to grant final approval of Nu-Pharm's ANDA is a "mandatory injunction" that must be reviewed "with even greater circumspection." Mylan Pharm., Inc. v. Shalala, 81 F.Supp.2d 30, 36 (D.D.C. 2000); see also Mylan v. Thompson, 139 F.Supp.2d 1, 18

(D.D.C.), rev'd other grounds, 268 F.3d 1323 (Fed. Cir. 2001).

B. Plaintiff is Not Likely to Succeed on the Merits

For all of the reasons stated above, FDA has properly given effect to the Illinois court's order. That court ordered that the approval of Nu-Pharm's ANDA be delayed at least until the patents had expired. As a matter of law, FDA's determination to follow that order is not, as Nu-Pharm alleges, "arbitrary, capricious, and contrary to law" or beyond FDA's authority. Mylan (duragesic), 389 F.3d at 1281-82; Apotex (omeprazole), 508 F.Supp.2d at 86.

Additionally, the relief that Nu-Pharm seeks from this Court would indisputably conflict with the Illinois court's injunction. This Court is not the proper forum for Nu-Pharm to challenge or undermine that determination. Plaintiff has no likelihood of success in this case.

C. Nu-Pharm Will Not Suffer Irreparable Harm Absent Preliminary Injunctive Relief

Not only has Nu-Pharm failed to make the requisite showing of likely success on the merits, it has also failed to demonstrate that it will suffer irreparable harm absent injunctive relief. Courts insist that only *irreparable* harm justifies the issuance of a preliminary injunction. Indeed, "[t]he *sine qua non* of granting any preliminary injunctive relief is a clear and convincing showing of irreparable injury to the plaintiff." Experience Works, Inc. v. Chao, 267 F.Supp.2d 93, 96 (D.D.C. 2003). Because Nu-Pharm's likelihood of success on the merits is exceedingly slim, Nu-Pharm "would have to make a very substantial showing of severe irreparable injury" to prevail on its motion. Nat'l Pharm. Alliance v. Henney, 47 F.Supp.2d 37, 41 (D.D.C. 1999).

Irreparable injury is a "very high standard." See Varicon Int'l v. OPM, 934 F. Supp. 440, 447 (D.D.C. 1996); Bristol-Myers, 923 F.Supp. at 220. The injury alleged must be certain, great,

actual, and imminent, and economic harm alone is not enough. Wisconsin Gas Co. v. FERC, 758 F.2d 669, 674 (D.C. Cir. 1985); Apotex, Inc. v. FDA, No. 06-0627, 2006 WL 1030151 (D.D.C. April 19, 2006) at *16 ("Apotex (pravastatin)") ("In this jurisdiction, harm that is "merely economic" in character is not sufficiently grave under this standard.""); Boivin v. US Airways, Inc., 297 F.Supp.2d 110, 118 (D.D.C. 2003); Bristol-Myers, 923 F. Supp. at 220. The alleged harm must cause "extreme hardship," as described below:

> To satisfy the standard of irreparable injury to justify a preliminary injunction, the movants' loss must be "more than simply irretrievable." Mylan Laboratories Inc. v. Thompson, 139 F.Supp.2d 1, 27 (D.D.C. 2001); see also Wisc. Gas Co. v. FERC, 758 F.2d 669, 674 (D.C. Cir. 1985). Instead, the injury must be such that it "cause[s] extreme hardship to the business, or even threaten[s] destruction of the business." Gulf Oil Corp. v. Dep't of Energy, 514 F. Supp. 1019, 1025 (D.D.C. 1981); see also Sandoz, Inc. v. FDA, 439 F.Supp.2d 26 (D.D.C. 2006) (noting that "[t]o successfully shoehorn potential economic loss into the irreparable harm requirement, a plaintiff must establish that the economic harm is so severe as to 'cause extreme hardship to the business' or threaten its very existence.").

Mylan (amlodipine), 484 F.Supp.2d at 123; see also Experience Works, 267 F.Supp.2d at 96 ($21.1 million reduction in funding is serious financial blow, but one frequently faced by other similar entities, and not an economic loss that threatens survival of the business); Sociedad Anonima Vina Santa Rita v. Dep't of Treasury, 193 F.Supp.2d 6, 14 (D.D.C. 2001) ("financial harm alone cannot constitute irreparable injury unless it threatens the very existence of the movant's business").

In the present case, Nu-Pharm does not come close to establishing that it would suffer irreparable injury in the absence of the preliminary injunctive relief it seeks. Nu-Pharm states that it cannot achieve timely market entry unless it obtains immediate injunctive relief from this Court because, if FDA does not approve its ANDA before January 29, 2008, the ANDA approval

will be subject to Abbott's pediatric exclusivity period and will be delayed for six months. Pl. Mem. at 25. Nu-Pharm alleges that this delay in market entry will "effectively destroy" its U.S. business, but this claim is particularly hollow because it admits that it does not even have any U.S. business. See Decl. of Richard Benyak, Pl. Exh. D ¶¶ 9, 10.

Nu-Pharm also alleges it is a "small" company and that its "U.S. business opportunity" will be destroyed. Id. ¶ 10. Nu-Pharm's status as a "small" company, however, does not increase the nature of its alleged harm, when the Illinois court has determined that Nu-Pharm is merely a "stalking horse" for Apotex, see 455 F.Supp.2d at 835, which is Canada's largest pharmaceutical company. See http://www.apotex.com/CorporateInformation/Default.asp?flash=Yes. Regardless, any alleged lost opportunity was always contingent upon the risk that Nu-Pharm's ANDA would be found to infringe Abbott's patents, and that its approval would therefore be delayed to include a period of pediatric exclusivity – a risk that Nu-Pharm knowingly assumed when it filed its ANDA. And, despite Nu-Pharm's protest that it was not a party to the Illinois action, the Illinois court in fact determined that Nu-Pharm's product was not any different from Apotex's product, and thus properly within the scope of an expanded injunction that precluded FDA approval before Abbott's patents expired. 455 F.Supp.2d at 837; 503 F.3d at 1381. Moreover, given the Illinois court's judgment that Apotex used bad faith in its development and testing of Nu-Pharm's product, and in using Nu-Pharm as a "stalking horse" to get around the original injunction, 455 F.Supp.2d at 839, the risk that Nu-Pharm's product would be found to infringe was substantial, and the "opportunity" that Nu-Pharm would have to market its drug before patent expiration was minimal at best. Thus, Nu-Pharm cannot succeed on its claim that such a lost "opportunity" is

irreparable.

Nu-Pharm asserts that it will suffer a loss of "access to major customers and contracts, as well as suffer a loss of goodwill that will adversely affect Nu-Pharm's ability to compete in the United States." Pl. Mem. at 27. Nu-Pharm's claims are speculative and unsupported, and do not meet the high standards set forth above. This is particularly true here, where Nu-Pharm has admitted that it does not have any U.S. business, and therefore has no established goodwill that it can lose.

D. The Balance of Harms Weighs Against Nu-Pharm's Request for Relief

Nu-Pharm has also failed to show that any harm it would suffer in the absence of injunctive relief outweighs the potential harm to others, or that the entry of such relief would further the public interest. Although FDA has no commercial stake in the outcome of this litigation, FDA is the government agency charged with implementing the statutory scheme governing the approval of generic drugs. As such, FDA's interest coincides with the public interest. Apotex (pravastatin), 2006 WL 1030151 at *18 (FDA interest "is deemed to be aligned with that of the public" when administering a statute placed within its charge); Serono Labs, Inc. v. Shalala, 158 F.3d 1313, 1326 (D.C. Cir. 1998) (determining that the public interest is "inextricably linked" to Congress' purpose in passing the Hatch-Waxman Amendments); Mylan (amlodipine), 484 F.Supp.2d at 123-24 ("With regard to FDA, the risk of harm, as an agency tasked with carrying out its duties to the public, is in equipoise with that of Hatch-Waxman itself.").

FDA agrees that consumers benefit from lower-cost generic competitors in the pharmaceutical marketplace, but it is also important to ensure that the rewards and incentives

contained in the statute are properly allocated in the manner Congress intended – including the incentive for brand name companies to research and develop new drug treatments, and to test those products in pediatric populations. See Mylan (amlodipine), 484 F.Supp.2d at 124. Here, the Illinois court – exercising the authority granted to it by the Hatch-Waxman Amendments, as well as its own inherent equitable power – entered a remedy that expressly required FDA to delay approval of Nu-Pharm's ANDA to ensure that Abbott would obtain relief for both Apotex's and Nu-Pharm's infringement of Abbott's patents. Nu-Pharm's request that this Court issue an order that would directly contravene the Illinois court's order improperly disregards the role that Congress assigned to the Illinois patent court within the Hatch-Waxman scheme, as well as the equitable powers of the court to issue appropriate relief. Perhaps even more important, allowing litigants to evade injunctions by running to another court is clearly not in the public interest.

Moreover, any financial harm Nu-Pharm would suffer in the absence of injunctive relief would be at least equaled by the harm that both Abbott and Nu-Pharm's generic competitors would suffer should the requested relief be granted. In such event, Abbott would lose the full benefit of the pediatric exclusivity it earned by conducting pediatric studies of its product, while other generic manufacturers would lose sales because of Nu-Pharm's premature market entry. Thus, the balance of the harms does not support Nu-Pharm's motion for relief. See Serono, 158 F.3d at 1326 ("[Serono's] injury must be weighed against the next factor – the extent to which an injunction will substantially injure the other party. . . . [a]nd that balance of harms results roughly in a draw."). Accordingly, Nu-Pharm has failed to demonstrate that the balance of harms and the public interest support its request for temporary and/or preliminary injunctive relief.

CONCLUSION

For the foregoing reasons, Nu-Pharm's complaint should be dismissed or, in the alternative, its motion for temporary restraining order and/or preliminary injunction should be denied.

Respectfully submitted,

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