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

NU-PHARM INC.,	
Plaintiff-Appellant,	
v.	No. 08-5017
FOOD AND DRUG ADMINISTRATION, *et al.*,	
Defendants-Appellees,	
and	
ABBOTT LABORATORIES,	
Intervenor-Defendant-Appellee.	

FEDERAL DEFENDANTS-APPELLEES' COMBINED MOTION FOR SUMMARY AFFIRMANCE AND RESPONSE TO PLAINTIFF-APPELLANT NU-PHARM'S MOTION TO EXPEDITE CONSIDERATION OF THIS APPEAL

INTRODUCTION

In this meritless case, plaintiff Nu-Pharm sought an order from the district 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 that had 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. The district court below, Judge Roberts, had no trouble seeing through this transparent attempt at forum shopping and dismissed the case ten days after it was filed. This Court should summarily affirm.

Although plaintiff argues that the Illinois case is unrelated to Nu-Pharm, that assertion is flatly inconsistent with explicit findings made by the Illinois district court and the Federal Circuit. The Illinois court held in 2004 that the divalproex ANDA of a generic drug manufacturer, Apotex, Inc., infringed intervenor-defendant Abbott Laboratories' patents covering divalproex, and ordered that the effective date of approval of Apotex's ANDA be no earlier than the expiration of Abbott's patents on January 29, 2008. Abbott Labs. v. TorPharm, Inc., 503 F.3d 1372, 1376-77 (Fed. Cir. 2007).

After this order, Nu-Pharm – in its first attempt to do an end run around the judiciary – 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 district court (Judge Richard A. Posner, sitting by designation) determined that Apotex (through Nu-Pharm) had not changed its product in any meaningful way. Abbott Labs. v. Apotex, Inc., 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 infringed the patents, and expanded the injunction it had entered against Apotex to cover Nu-Pharm's ANDA. 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 also affirmed 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 has admitted that it was aware of the Illinois proceeding and that it made no attempt to intervene. See Transcript of Motion Hearing Proceedings before the Honorable Richard W. Roberts, United States District Judge, January 24, 2008 (Attachment D to Nu-Pharm's motion to expedite appeal) at 13-14, 37 (hereinafter "Tr.").[1]

The Illinois injunction explicitly precluded FDA approval of Nu-Pharm's ANDA prior to January 29, 2008.[2] Before Judge Roberts, Nu-Pharm conceded that its requested relief was directly contrary to the injunction entered by Judge Posner. Tr. at 11, 36. Judge Roberts declined jurisdiction for this reason. Id. at 37-38, 40. Nu-Pharm's brazen attempt to undermine the Illinois court and subvert the judicial process should be rejected out of hand by this Court, just as it was by the district court.

The district court can be affirmed on this basis or any of a number of other

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[1] Circuit Rule 27(g)(2) states that a dispositive motion should attach copies of pertinent decisions of the district court; however, the entire transcript of the pertinent proceeding is Attachment D to Nu-Pharm's motion to expedite ("Pl. Motion").

[2] As explained in greater detail infra, on January 29 Nu-Pharm's ANDA became subject to Abbott's six-month pediatric exclusivity, and cannot be approved prior to July 29.

grounds. For example, the complaint alleges that FDA's decision to obey the Illinois injunction was arbitrary, capricious, an abuse of discretion, not in accordance with law, or beyond its statutory authority in violation of the Administrative Procedure Act ("APA"). The government moved to dismiss under Federal Rule of Civil Procedure ("FRCivP") 12(b)(6) because it cannot be in violation of the APA for FDA to obey an explicit injunction entered by a United States District Court. The baseless nature of this case makes it unnecessary for this Court even to reach the question of expedited briefing; Judge Roberts' decision should be affirmed summarily. The weakness of this case also means that the case does not present a "substantial challenge," which is one of this Circuit's requirements for expedited consideration. See Pl. Motion at 9.[3]

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

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[3] Nor does Nu-Pharm meet the "irreparable injury" requirement for expedition. See Pl. Motion at 9. Its assertions of irreparable harm are speculative at best, and its primary allegation, that FDA's decision will "destroy Nu-Pharm's U.S. business," id. at 19, is simply wrong: Nu-Pharm has admitted that it has no U.S. business. Pl. Att. G (Declaration of Richard Benyak) ¶ 3, 7, 10.

ANDA with FDA, seeking approval to market a generic version of divalproex. See 503 F.3d at 1376. As part of its ANDA, Apotex challenged the two Abbott patents that were listed in the Orange Book for that drug.[4] 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. Id. That court also ordered that FDA could approve the ANDA no earlier than the expiration of the patents on January 29, 2008. 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

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

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. 503 F.3d at 1377. 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. Id. Later, Abbott learned that Apotex and Nu-Pharm had coordinated their ANDA efforts. Id.; 455 F.Supp.2d at 835. Abbott filed a motion to enforce the Apotex injunction 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. Id. at 1383. Apotex petitioned the Federal Circuit to rehear the case en banc, which that court denied. See Memorandum in Support of Nu-Pharm's Motion for Temporary Restraining Order and/or Preliminary Injunction, filed in district court ("Pl. TRO"), at 10. Apotex 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 Labs., No. 07-912 (petition for certiorari filed January 7, 2008) ("Cert. Pet.") (portion attached as Exhibit A hereto).[5] 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. See Pl. Att. C. A status hearing was held on January 14, 2008 (the day the instant case was filed), and at that hearing Judge Pallmeyer instructed Nu-Pharm "not to flirt with the idea that the federal judges's [Judge Posner's] order is not binding on it. I think that would not be a wise course." Transcript of Proceedings Before the Honorable Rebecca R. Pallmeyer, January 14, 2008, submitted by Abbott with a Notice of Filing in the proceeding below on January 22, 2008.

On December 17, 2007, Nu-Pharm requested final FDA approval of its ANDA for divalproex. Pl. TRO Exh. J. FDA informed Nu-Pharm's counsel that

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

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.

On January 14, 2008, Nu-Pharm filed this suit against FDA, alleging that FDA's decision to comply with the order entered by Judge Posner was in violation of the APA. Nu-Pharm filed a motion for temporary restraining order and preliminary injunction. Abbott intervened as a defendant. The federal defendants and Abbott moved to dismiss the complaint for failure to state a claim under FRCivP 12(b)(6). Judge Roberts held a hearing on January 24, during which he dismissed the case. The district court stated that "it would be unseemly and inappropriate for this Court to consider entering an order that would be directly in conflict with Judge Posner's order because Nu-Pharm had a full opportunity to seek relief from that order before Judge Posner within the 15 months between his order and today. . . ." Tr. at 37-38. The court held that it was "going to decline, for prudential reasons, to exercise the subject matter jurisdiction that I concede that I do have to entertain the complaint here because I find that the principal relief sought by Nu-Pharm would be relief which would conflict irreconcilably with a properly entered order against the FDA by Judge Posner that was affirmed in its substance by the Federal Circuit." Tr. at 40. On this basis the court dismissed the complaint and denied the motion for preliminary relief. Id. at 40-41. Nu-Pharm

filed a notice of appeal five days later on January 29, and its motion to expedite was filed more than a week after that, on February 7.

In addition, FDA has determined that Abbott successfully completed the requested pediatric studies for Depakote and is therefore eligible for pediatric exclusivity for that drug.[6] Because the patents have expired, this pediatric exclusivity delays for six months the approval of all ANDAs referencing Depakote.

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 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 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

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[6] 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).

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). 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;
> (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 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 the D.C. District Court have

held that FDA is "bound" to follow a court's injunction under 35 U.S.C. § 271(e)(4)(A). Mylan Labs. 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).

ARGUMENT

I. Standard of Review

A district court's decision to decline jurisdiction in favor of another proceeding is reviewed for an abuse of discretion. Wilton v. Seven Falls Co., 515 U.S. 277, 289 (1995); Moses H. Cone Mem'l Hosp. v. Mercury Constr. Corp., 460 U.S. 1, 19 (1983); Handy v. Shaw, Bransford, Veilleux & Roth, 325 F.3d 346, 349 (D.C. Cir. 2003). Any legal issues involved in the exercise of this discretion are reviewed de novo. Handy, 325 F.3d at 349; Serono Labs. v. Shalala, 158 F.3d 1313, 1318 (D.C. Cir. 1998). Summary affirmance is warranted if "the merits of [the] case are so clear that expedited action is justified," and "no benefit will be gained from further briefing and argument of the issues presented." Taxpayers Watchdog, Inc. v. Stanley, 819 F.2d 294, 297-98 (D.C. Cir. 1987). The district court's decision can be affirmed on grounds other than the one it relied upon: "[A]n appellate court can affirm a district court judgment on the basis of 'any grounds which . . . support [it].'" In re Swine Flu Immunization Prods. Liab. Litig., 880 F.2d 1439, 1444 (D.C. Cir. 1989) (quoting in part Dayton Bd. of Educ.

v. Brinkman, 433 U.S. 406, 419 (1977)).

II. The District Court Should be Summarily Affirmed

A. The District Court Properly Declined Jurisdiction

As noted above, the district court declined to exercise jurisdiction because the relief sought by Nu-Pharm would irreconcilably conflict with the injunction entered by Judge Posner. Tr. at 40. This holding was not an abuse of discretion and should be affirmed.

"In the case of parallel litigation in two federal district courts, the 'general principle is to avoid duplicative litigation.'" Handy, 325 F.3d at 349-50, quoting in part Colorado River Water Conservation Dist. v. United States, 424 U.S. 800, 817 (1976). If the parallel cases "involve the same subject matter, the district court should – for judicial economy – resolve both suits in a single forum." Handy, 325 F.3d at 350. Here, it is clearly inefficient to permit Nu-Pharm to litigate issues in the District of Columbia that should be presented to the district court in Illinois, as Judge Roberts held. Tr. at 39 ("These matters would more appropriately be heard by either Judge Posner or Judge Pallmeyer. . . . Nu-Pharm sat on its hands for at least 15 months with not taking advantage of the opportunity to go to that court. . . ."). The issue could have been presented to Judge Posner because "[a] continuing decree of injunction directed to events to come is subject

always to adaptation as events may shape the need." System Fed'n No. 91, Ry. Employees' Dept. v. Wright, 364 U.S. 642, 647 (1961); see also Feller v. Brock, 802 F.2d 722, 728 (4th Cir. 1986).

This principle has been applied when parties have sought to obtain an order from one court that conflicts with an order from another. In Feller, the Fourth Circuit reversed an injunction that had been entered against the Department of Labor because the injunction conflicted with a prior order that had been entered against the agency. The court reached this conclusion even though plaintiffs had not been parties to the initial case, id. at 724, 728, holding: "Prudence requires that whenever possible, coordinate courts should avoid issuing conflicting orders." Id. at 727-28. The court stated that although the comity doctrine might not technically apply because plaintiffs had not been parties to the earlier suit, "[n]evertheless, whatever its label, there is an underlying policy of judicial administration which counsels against the creation of conflicts such as the one at bar." Id. at 728.

Similarly, in Common Cause v. Judicial Ethics Comm., 473 F.Supp. 1251 (D.D.C. 1979), the court dismissed plaintiffs – who were not parties to the prior proceeding – because the relief they were seeking would have subjected the defendants to conflicting orders:

> This Court believes that the interests of comity mandate respect for the holding of a sister court when a de novo review has the potential effect of subjecting one party to conflicting orders from two courts of comparable jurisdiction and authority.
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> To do otherwise, would be tantamount to having this Court sit as an appellate court, reviewing the decision of another trial court.

Id. at 1253-54. See also Martin-Trigona v. United States, 779 F.2d 72, 73 (D.C. Cir. 1985) (relief from an injunction entered by the district court in Connecticut not permitted: "considerations of comity, consistency of treatment, and orderly administration of justice convince us that such an argument should have been directed to the District Court in Connecticut."); Lapin v. Shulton, Inc., 333 F.2d 169, 172 (9th Cir. 1964) (the court affirmed rejection of an attempt to alter an injunction that had been entered by another court: "considerations of comity and orderly administration of justice demand that the nonrendering court should decline jurisdiction of such an action. . . ."); Hilton Hotels Corp. v. Weaver, 325 F.2d 1010 (D.C. Cir. 1963) (this Court dismissed, "in the interests of comity and the orderly administration of justice," a case that had been previously litigated by the same plaintiffs against different defendants in the Third Circuit.).[7]

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[7] This case could also be dismissed on the grounds that Nu-Pharm is actually seeking relief from judgment under FRCivP 60(b) and is doing so in the wrong court. See Bell v. United States, 521 F.Supp.2d 462, 463-64 (D. Md. 2007) ("The

This principle applies with even more force here because Nu-Pharm is bound by the Illinois injunction. As noted above, the injunction explicitly runs to Apotex and affiliates, successors, and assigns. In addition, under FRCivP 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 in active concert with Apotex, and is bound by that injunction. Nu-Pharm is attempting to have Judge Posner's injunction modified or set aside, and this is not the proper court for such an attempt.

Although Nu-Pharm cites the general principle that federal courts are under an obligation to exercise the jurisdiction given to them, Pl. Motion at 9, that principle has been articulated in the context of parallel state court proceedings. See, e.g., Pl. Motion at 10, citing Moses H. Cone Mem'l Hosp. v. Mercury Constr.

Court does not have the power to void the injunction ordered in the District Court for the Middle District of Pennsylvania and affirmed by the Third Circuit. An issuing court has continuing jurisdiction to modify or revoke its injunction. . . . When the Third Circuit affirmed the Pennsylvania order, Bell had a right of appeal. Instead, three years later, after his deadline to appeal has passed, Bell seeks to declare the district court's order void. However, a Rule 60(b)(4) motion is not a substitute for a timely appeal . . . and does not grant this court jurisdiction to review Pennsylvania's Order."). This argument was presented by Abbott in the district court. See Abbott's Omnibus Motion, filed January 18, 2008, at 12-14.

Corp., 460 U.S. 1 (1983); England v. La. State Bd. of Med. Advisors, 375 U.S. 411 (1964). Even in that situation, however, federal jurisdiction is not exercised when exceptional circumstances are present, Colorado River, 424 U.S. at 818; Handy, 325 F.3d at 351. Such circumstances, which can be based on, among other things, "wise judicial administration," were found to exist in Colorado River. See 424 U.S. at 817-21.

Even under this test, if "exceptional circumstances" do not exist in the instant case, it is difficult to imagine a case in which they would exist. Here, the district court in Illinois found that Nu-Pharm had filed the same ANDA as Apotex; that Apotex's use of Nu-Pharm was a "subterfuge" to evade an injunction; that Nu-Pharm was a "tool" and a "stalking horse" for Apotex; that Apotex's use of Nu-Pharm in this manner reflected a "cavalier disregard for judicial findings" and was "the antithesis of good faith." See 455 F.Supp.2d at 835, 839. Perhaps more important, the court held that Nu-Pharm's product infringed Abbott's patent, and this holding was upheld by the Federal Circuit. 503 F.3d at 1380-81. Even after these strong findings, Nu-Pharm, as Judge Roberts noted, "sat on its hands for at least 15 months" without challenging them. These are clearly "exceptional circumstances" that justified Judge Roberts' decision to decline jurisdiction as an

example of "wise judicial administration," and that holding should be affirmed.[8]

B. Res Judicata Bars Nu-Pharm's Complaint

Under this Court's recent decision in Taylor v. Blakey, 490 F.3d 965 (D.C. Cir. 2007), Nu-Pharm's complaint is barred by res judicata. In Taylor, plaintiff's complaint was dismissed because a close associate of plaintiff had previously sought the same relief and lost. The court concluded that plaintiff's associate had been plaintiff's "virtual representative" and, as such, plaintiff's complaint was barred. The factors that the Court considered in making this determination were whether the parties had identity of interests and whether there had been adequate representation, and one of these three factors: 1) a close relationship between the parties; 2) substantial participation by the second party in the first case; or 3) tactical maneuvering by the second party to avoid preclusion. Id. at 971-75.

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[8] Nu-Pharm argues that the relief it seeks would not conflict with the relief ordered by Judge Posner because here it requests declaratory relief. Pl. Motion at 11. The declaration Nu-Pharm seeks would conflict with Judge Posner's order because, hand-in-hand with such a declaration, Nu-Pharm seeks an injunction that would conflict with Judge Posner's order. See Tr. 39-40. See also Wilton v. Seven Falls Co., 515 U.S. at 288 ("If a district court, in the sound exercise of its judgment, determines after a complaint is filed that a declaratory judgment will serve no useful purpose, it cannot be incumbent upon that court to proceed to the merits before staying or dismissing the action."). Judge Roberts did not err in exercising the "substantial" discretion given district courts with respect to declaratory judgments. Id. at 286.

As noted above, Apotex and Nu-Pharm are closely related. The Nu-Pharm ANDA is the same as the Apotex ANDA (in fact, Apotex developed and owns the ANDA, see at 503 F.3d at 1377; 455 F.Supp.2d at 835-37; Abbott Omnibus Motion, filed in district court, at 4-6). As Judge Posner found, Apotex used Nu-Pharm as a subterfuge to evade Judge Posner's injunction. Apotex and Nu-Pharm are represented by the same law firm. Nu-Pharm has admitted that it was aware of the Apotex litigation but chose not to intervene.

Here it is apparent that the factors discussed in Taylor are present: Apotex and Nu-Pharm had identical interests, Apotex was adequately represented (by the same law firm that represents Nu-Pharm), there is a close relationship between the parties, and Nu-Pharm chose not to participate in the Apotex litigation in a transparent attempt to avoid preclusion. This argument was presented to the district court, Tr. 20-21, and Abbott Omnibus Motion at 31-32, and the district court can be affirmed on this basis.

C. Nu-Pharm's Complaint Fails to State a Claim

In the proceeding below, the federal defendants moved to dismiss under FRCivP 12(b)(6) because plaintiff's complaint fails to state a claim.

To prevent dismissal under 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); Major v. Plumbers Local Union No. 5, 370 F.Supp.2d 118, 123 (D.D.C. 2005) ("Conclusory legal and factual allegations . . . need not be considered by the court."); Luck's Music Library, Inc. v. Ashcroft, 321 F.Supp.2d 107, 112 (D.D.C. 2004).

Nu-Pharm does not state a claim "plausible on its face." Twombly, 127 S.Ct. at 1974. Nu-Pharm alleges that FDA's decision to withhold final approval of Nu-Pharm's ANDA was arbitrary, capricious, an abuse of discretion, not in accordance with law, and beyond FDA's authority. Pl. Motion at 11-18;

Complaint ¶¶ 3, 32. Before the United States Supreme Court, however, Apotex's counsel (from the same law firm representing Nu-Pharm here), stated 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.

Because Nu-Pharm's ANDA No. 77-615 is explicitly covered by the injunction entered by Judge Posner, FDA determined that Nu-Pharm's ANDA could not be approved until after January 29, 2008 (at which time it became subject to Abbott's pediatric exclusivity, which runs to July 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. 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. This FDA decision cannot be in violation of the APA.

Courts have recognized that FDA is not free to ignore similar orders entered pursuant to 35 U.S.C. § 271(e)(4)(A). In both Mylan (duragesic) and Apotex (omeprazole), district courts found patent infringement even after FDA had approved ANDAs. Both courts entered injunctions that required FDA to reset the effective dates of the ANDAs. 389 F.3d at 1277; 508 F.Supp.2d at 82. Also, in

both cases the courts held that FDA was bound by the district court injunction and upheld FDA's decision. 389 F.3d at 1282; 508 F.Supp.2d at 85, 86.

FDA was bound to give effect to Judge Posner's order, which expressly pertains to FDA approval of 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, Nu-Pharm argues, "requires FDA to approve a pending ANDA once the 30-month stay expires." Pl. Motion at 12. Nu-Pharm recognizes that this provision does not require approval when "the court hearing the infringement action" has entered a finding of infringement or ordered delay of approval. Id. The heart of Nu-Pharm's argument then is that the court hearing the infringement action filed against Nu-Pharm (before Judge Pallmeyer) did not issue a finding of infringement or order delayed approval; rather, that finding was entered by Judge Posner. Id. at 14-18.

Significantly, Judge Posner found that Apotex and Nu-Pharm had engaged in a subterfuge and that Nu-Pharm was a tool of Apotex. Because of this, the court exercised its equitable powers to extend an order enjoining Apotex's patent infringement to cover Nu-Pharm. None of the cases Nu-Pharm cites contains such an explicit attempt to evade an injunction (or, as Judge Posner held, "contumacy," 455 F.Supp.2d at 836). See Pl. Motion at 14-17. For Nu-Pharm to suggest that a

United States District Court cannot address such conduct or, when it does address such conduct, that FDA should ignore a district court order is astonishing. In addition, Nu-Pharm's repeated assertions that the Illinois case is "separate" and not related to Nu-Pharm, see, e.g., Pl. Motion at 2, 6, 11, 17, 18, is plainly false in light of Judge Posner's findings and, more importantly, an argument that should have been presented to the Illinois court.[9]

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. Motion at 16-17. It is alleged that this could happen 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 product." Id. at 18. The basis for 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. Nu-Pharm blithely ignores the explicit findings of Judge Posner that Apotex and Nu-Pharm are closely related

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[9] The gravamen of Nu-Pharm's argument seems to be that the Illinois court had no authority to do what it did; that is an argument that obviously should have been presented to the Illinois court.

and that Nu-Pharm's ANDA is the result of "subterfuge." It is Nu-Pharm that is attempting to "game the system" by running to this Court to undermine the injunction of the Illinois court.

The order entered by Judge Posner and affirmed by the Federal Circuit applies specifically to Nu-Pharm's ANDA, its infringement of Abbott's patents, and FDA's approval of that ANDA. It was entered in the context of patent litigation just like that discussed above in Mylan (duragesic) and Apotex (omeprazole). FDA's compliance with this injunction cannot be in violation of the APA, and plaintiff's complaint can be dismissed on this basis alone. For these reasons, Nu-Pharm'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. This is reason enough to affirm the district court.

CONCLUSION

For the foregoing reasons, the district court should be summarily affirmed and Nu-Pharm's motion to expedite the appeal should be denied.

Respectfully submitted,

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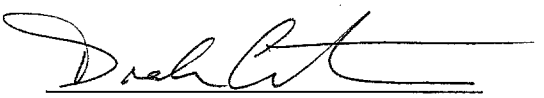

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ATTACHMENT A
TO
FEDERAL DEFENDANTS-APPELLEES'
MOTION FOR SUMMARY AFFIRMANCE
IN
NU-PHARM INC., Plaintiff-Appellant, v. FOOD AND DRUG ADMINISTRATION, *et al.*, Defendants-Appellees, and ABBOTT LABORATORIES, Intervenor-Defendant-Appellee.
Appeal No. 08-5017

No. 07-

IN THE

Supreme Court of the United States

APOTEX, INC. and APOTEX CORPORATION,

Petitioners,

v.

ABBOTT LABORATORIES,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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OPINIONS BELOW

The decision of the United States Court of Appeals for the Federal Circuit (App. A)[1] for which review is sought is available at 503 F.3d 1372 (Fed. Cir. 2007). The decision of the United States District Court for the Northern District of Illinois that was reviewed by the Federal Circuit (App. B) is reported at 455 F. Supp. 2d 831 (N.D. Ill. 2006).

JURISDICTION

The Federal Circuit issued the judgment for which review is sought on October 11, 2007. The Federal Circuit denied Apotex's petition for rehearing en banc on December 5, 2007. (App. C). This Court has jurisdiction to review the judgment of the Federal Circuit under 28 U.S.C. § 1254(1).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

This case involves sections of the Hatch-Waxman Act, which amended the Patent Laws, 35 U.S.C. § 1 *et seq.*, particularly 35 U.S.C. § 271(e) (App. D), and the Food, Drug and Cosmetic laws, 21 U.S.C. § 1 *et seq.*, particularly 21 U.S.C. § 355, governing Abbreviated New Drug Applications ("ANDAs") for pharmaceutical products.

STATEMENT OF THE CASE

The issue before this Court is whether district courts are authorized to use contempt proceedings to issue binding factfindings, injunctions, remedies and

1. References to "App. ___" are to the Appendices attached hereto, as required under Supreme Court Rule 14.1(i).

judgments, absent an arguable act of contempt in the first instance. This issue has considerable significance in patent cases, particularly Hatch-Waxman cases involving drug products, where Congress has strongly incentivized generic drug companies to design around brand name patents to bring cheaper drugs to market before patents expire.

This Hatch-Waxman case involves a decade-long patent dispute between Abbott Laboratories and TorPharm, Inc. (now part of Apotex, Inc.) involving drugs generically called "divalproex sodium." In 2004, Judge Richard A. Posner, sitting by designation in the district court, entered an injunction prohibiting Apotex from commercially manufacturing, using, selling or offering to sell infringing divalproex sodium in the United States, and further prohibiting FDA from approving TorPharm's divalproex sodium ANDA No. 75-112.

The present petition is directed towards post-judgment proceedings that Abbott initiated before Judge Posner in August of 2006. The Federal Circuit acknowledged that the Apotex activities Abbott complained of—serving as a divalproex sodium contract manufacturer for a different ANDA filer, Nu-Pharm—did not violate Judge Posner's 2004 injunction. The Federal Circuit held that Judge Posner abused his discretion in holding Apotex in contempt. The Federal Circuit nevertheless refused to vacate Judge Posner's new infringement factfindings regarding the Nu-Pharm ANDA, and a new injunction prohibiting Apotex from commercially making this second ANDA product, and prohibiting FDA from approving this second ANDA. Apotex thus is subject to contempt punishments despite doing nothing in contempt of a court order.

CERTIFICATE OF SERVICE

I hereby certify that on this 13th day of February, 2008, I served a copy of the foregoing Federal Defendants-Appellees' Combined Motion for Summary Affirmance and Response to Plaintiff-Appellant Nu-Pharm's Motion to Expedite Consideration of this Appeal, plus all attachments and addenda, by first class mail upon:

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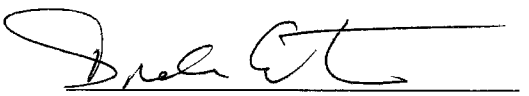

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ADDENDUM
TO
FEDERAL DEFENDANTS-APPELLEES'
MOTION FOR SUMMARY AFFIRMANCE
IN
NU-PHARM INC., Plaintiff-Appellant, v. FOOD AND DRUG ADMINISTRATION, *et al.*, Defendants-Appellees, and ABBOTT LABORATORIES, Intervenor-Defendant-Appellee.
Appeal No. 08-5017

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

NU-PHARM INC.,	)	
Plaintiff-Appellant,	)	
v.	)	**No. 08-5017**
FOOD AND DRUG ADMINISTRATION, *et al.*,	)	
Defendants-Appellees,	)	
and	)	
ABBOTT LABORATORIES,	)	
Intervenor-Defendant-Appellee.	)	

Certificate As To Parties, Rulings, And Related Cases

Pursuant to Circuit Rules 27(a)(4) and 28(a)(1), Michael O. Leavitt, Secretary of Health and Human Services, Andrew C. von Eschenbach, Commissioner of Food and Drugs, and the Food and Drug Administration, defendants-appellees in the above-captioned case, hereby provide the following certificate as to parties, rulings, and related cases:

A. Parties.

All parties, intervenors, and amici appearing before the district court and in this court are listed in the Certificate as to Parties, Rulings, and Related Cases submitted by plaintiff-appellant Nu-Pharm Inc.

B. Rulings Under Review.

References to the ruling at issue appears in the Certificate as to Parties, Rulings, and Related Cases submitted by plaintiff-appellant Nu-Pharm Inc.

C. Related Cases.

The instant case is related to Abbott Laboratories v. Torpharm, Inc., 503 F.3d 1372, 1376-77 (Fed. Cir. 2007), certiorari petition filed January 7, 2008, Apotex, Inc. v. Abbott Laboratories, No. 07-912. This Federal Circuit decision affirmed in part Abbott Laboratories v. Apotex, 455 F.Supp.2d 831, 837 (N.D. Ill. 2006).

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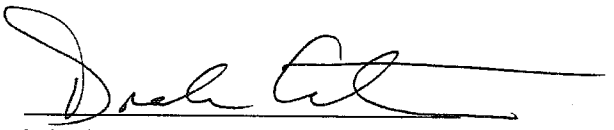

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