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' REPLY IN SUPPORT OF MOTION FOR SUMMARY AFFIRMANCE

INTRODUCTION

In their motion for summary affirmance, federal defendants-appellees provided various grounds upon which the district court can – and should – be summarily affirmed ("U.S. Motion"). Nu-Pharm's basic argument in response to all of these grounds is that the merits of its claim have never been addressed by a court, and if summary affirmance is granted the merits will never be heard by a court because its claim could not have been considered by the court in Illinois. Nu-Pharm Opp. at 1, 4, 5, 6, 8, 10, 11, 14.

This argument is based on a contrived and convoluted view of exactly what constitutes Nu-Pharm's "claim." Nu-Pharm attempts to define its claim narrowly so that it would pertain only to APA allegations against FDA, and then argue that that particular claim was not addressed by the Illinois court because FDA was not a party there. See Nu-Pharm Opp. at 5, 8, 10, 11, 14. This is too clever by half.

As explained in defendants' motion for summary affirmance, the United States District Court in Illinois (Judge Posner) held that Nu-Pharm's ANDA infringed Abbott's patent, and enjoined FDA approval of that ANDA until expiration of Abbott's patents. Abbott Labs. v. Apotex, Inc., 455 F.Supp.2d 831 (N.D. Ill. 2006). These findings were explicitly upheld by the Federal Circuit. Abbott Labs. v. Torpharm, Inc., 503 F.3d 1372 (Fed. Cir. 2007). In their motion for summary affirmance, defendants pointed out: 1) this injunction is binding on

Nu-Pharm; and 2) the relief Nu-Pharm seeks here is inconsistent with that injunction. U.S. Motion at 3, 20.

In its response to defendants' motion, Nu-Pharm does not respond or appear to dispute these two points. Nonetheless, Nu-Pharm is attempting to litigate here the issue resolved by Judge Posner, i.e., the timing of FDA approval of its ANDA. As explained further below, this attempt should be rejected and the district court should be summarily affirmed.[1]

ARGUMENT

I. The District Court Properly Declined Jurisdiction

The district court properly declined jurisdiction because the relief sought by Nu-Pharm would conflict with the injunction entered by Judge Posner. U.S. Motion at 17-22. Courts have rejected attempts by plaintiffs to subject defendants to inconsistent orders or to relitigate matters, and have provided various reasons for doing so; e.g., "judicial economy," "prudence," "comity," "consistency," "orderly administration of justice," or "wise judicial administration." Id.

Nu-Pharm's only direct attempt to rebut this point is to argue that the instant case does "not involve the same parties, issues, or subject matter" as the case

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[1] Although Nu-Pharm is attempting to have this appeal expedited, it waited over two weeks to respond to defendants' motion for summary affirmance.

before Judge Posner, and that the case in Illinois is no longer pending. Nu-Pharm Opp. at 4-5. These arguments are incorrect. As discussed above, Nu-Pharm is bound by Judge Posner's injunction, and what it seeks here is inconsistent with Judge Posner's injunction. Thus, for purposes of reviewing Judge Roberts' decision to decline jurisdiction, the "issues" and "subject matter" of the cases are the same. Also, because Nu-Pharm is bound by that injunction and the injunction explicitly pertained to the timing of FDA approval of Nu-Pharm's ANDA, the fact that FDA was not a party is irrelevant.

The essence of Nu-Pharm's complaint is that FDA was required – under its governing statute – to approve Nu-Pharm's ANDA when the statutory 30-month stay expired in November 2007 because infringement had not been found in the patent case pending against Nu-Pharm (before Judge Pallmeyer), and thus FDA was free to ignore the injunction entered by Judge Posner. See U.S. Motion at 26; Complaint ¶¶ 25-35; Nu-Pharm Opp. at 5.[2] Hence, in Nu-Pharm's view, only a finding of infringement or an injunction entered by Judge Pallmeyer should have

[2] This argument is inconsistent with the position by Nu-Pharm's cohort, Apotex, in its certiorari petition, in which Apotex conceded that Judge Posner's injunction precluded FDA approval of Nu-Pharm's ANDA. U.S. Motion at 8.

made any difference.[3] However, Judge Posner entered an injunction that specifically addressed the timing of FDA approval of Nu-Pharm's ANDA. If Nu-Pharm actually believed that Judge Posner was without authority to enter the injunction or that the injunction had no effect on the timing of FDA's approval, Nu-Pharm could have sought to intervene and presented this argument to Judge Posner without FDA's participation. Nu-Pharm's approach, which was to ignore the injunction for 15 months and then urge FDA and the district court to ignore it, is not reasonable, and provides an additional reason to affirm the district court.

Also, this injunction was entered in private patent litigation to which FDA was not a party, as explicitly contemplated by the Hatch-Waxman Amendments. See 35 U.S.C. § 271(e)(4)(A); U.S. Motion at 14-15. This Circuit has recognized that FDA is bound by such orders even when FDA is not a party. Mylan Labs. Inc. v. Thompson, 389 F.3d 1272, 1282 (D.C. Cir. 2004) ("Mylan (duragesic)"); see also Apotex Inc. v. FDA, 508 F.Supp.2d 78, 89 (D.D.C. 2007) ("Apotex (omeprazole)"). In both of these cases, FDA had approved ANDAs but had to reset the effective date of the approvals following court orders entered in private patent litigation. See U.S. Motion at 25-26 for a further discussion of these cases.

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[3] As noted in FDA's motion, Judge Pallmeyer disagreed that Nu-Pharm was free to disregard Judge Posner's injunction. U.S. Motion at 8.

If orders entered in private patent litigation under the Hatch-Waxman Amendments could be re-litigated just because FDA was not a party, the entire purpose of this statutory provision would be undermined.

In addition, because the Illinois injunction has continuing effect, (Nu-Pharm is subject to Abbott's pediatric exclusivity until July 29, 2008), that case is not moot, as suggested by Nu-Pharm. Thus, the Illinois court is where Nu-Pharm must attempt to seek relief from the Illinois injunction. See U.S. Mem. at 17-18.

Nu-Pharm also argues that the defendants have not addressed its claim. Nu-Pharm Opp. at 4, 6. While this is not correct, see Section III infra, it is irrelevant to the comity/wise judicial administration basis for declining jurisdiction because the purpose of declining jurisdiction is to prevent cases from being heard a second time when there is a more appropriate forum. Thus, it is a waste of resources for this Court (or the parties) to address issues that Judge Posner has heard and ruled upon, and there is no need to do so. Nu-Pharm could have and should have raised issues pertaining to the timing of the approval of its ANDA with Judge Posner, even if they are not styled as APA claims against FDA.

II. Res Judicata Bars Nu-Pharm's Complaint

As discussed in FDA's motion, under this Court's recent decision in Taylor v. Blakey, 490 F.3d 965 (D.C. Cir. 2007), Nu-Pharm's claim is barred by res

judicata because Nu-Pharm is attempting to relitigate issues that were litigated before Judge Posner by Nu-Pharm's "virtual representative," Apotex. U.S. Motion at 22-23. Nu-Pharm argues that it is not barred by res judicata because it is not seeking the same relief as Apotex, nor could it seek the relief it seeks here in the Illinois court. Nu-Pharm Opp. at 7-11.

These contentions are meritless. The result of the contempt proceeding before Judge Posner, 455 F.Supp.2d 831, was the explicit addition of Nu-Pharm's ANDA to the previous injunction against Apotex's ANDA, which pertained to the timing of FDA approval, and which resulted in an injunction inconsistent with the relief Nu-Pharm seeks here. Apotex appealed to the Federal Circuit (and is seeking certiorari) arguing that the inclusion of Nu-Pharm's ANDA in the injunction was appropriate. This is the same relief sought by Nu-Pharm in the instant case: It seeks to evade the injunction by arguing that the only court that could have entered such an injunction is the one hearing its own patent litigation (Judge Pallmeyer). Thus Nu-Pharm and its virtual representative, Apotex, are seeking the same relief in two courts.

Nu-Pharm's other argument, that it could not have presented its claim to Judge Posner because it was not ripe until November 2007 when the statutory 30-month stay expired, Nu-Pharm Opp. at 9-10, is similarly meritless. Whether Judge

Posner's injunction should have been ignored by FDA is an issue that could and should have been presented to Judge Posner before November, and, in any event, there is nothing that prevented Nu-Pharm from presenting it to Judge Posner in November (or now). The fact that Nu-Pharm failed to take such an obvious course of action makes it even more apparent that Nu-Pharm has engaged in "tactical maneuvering" in an attempt to avoid preclusion in the case before Judge Posner, which is one of the factors to be considered in the res judicata analysis that this Court discussed in the Taylor case.

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

As defendants discussed in their initial memorandum, the district court can also be affirmed because Nu-Pharm has failed to state a claim under the APA. U.S. Motion at 23-28. Nu-Pharm argues that it has stated a claim because "FDA has blatantly disregarded its statutory obligations. . . ." Nu-Pharm Opp. at 12. As noted above, Nu-Pharm argues that FDA was obligated to approve its ANDA upon the expiration of the statutory 30-month stay in November 2007. However, Nu-Pharm recognizes that this obligation is altered if the court hearing its patent case had made a finding of infringement or invalidity. Complaint ¶ 27; Nu-Pharm Opp. at 5; Nu-Pharm Motion to Expedite Appeal at 12. In this case, Nu-Pharm is contending that such a finding had to have been made by Judge Pallmeyer.

Nu-Pharm asserts that defendants have not addressed the merits of its claim. Nu-Pharm Opp. at 4, 6, 13, 14. Defendants have, however, addressed this claim at length. A finding of infringement against Nu-Pharm was made by Judge Posner, who also found, among other things, that Nu-Pharm was engaged in a subterfuge with Apotex. See U.S. Motion at 1-2, 5-7. The "merits" issue that Nu-Pharm urges is that FDA should have approved its ANDA – pursuant to the statute – despite the existence of Judge Posner's injunction. In both the district court and this Court, defendants have pointed out that Nu-Pharm has failed to state a claim because it cannot be a violation of the APA for FDA to comply with this injunction. Thus, defendants have addressed the merits.

In response, Nu-Pharm argues that FDA was not bound by Judge Posner's order because FDA "does not always follow court orders." Nu-Pharm Opp. at 14. This is not correct for several reasons. First, FDA does not routinely violate court orders, as suggested by Nu-Pharm. The only instance cited by Nu-Pharm is when FDA did not accede to a "recommendation" of a district court to toll the time period in which an NDA holder could list a patent. Id. Nu-Pharm does not cite a single instance in which FDA ignored a court order entered pursuant to 35 U.S.C. § 271(e)(4)(A) (or any actual court order for that matter). In fact, as discussed above, this Circuit has recognized that FDA is "bound" to follow such orders.

Mylan (duragesic). In any event, even if Nu-Pharm had produced an example of FDA not following a court order, that would not demonstrate that FDA's decision here (to follow Judge Posner's order) was a violation of the APA.

Finally, Nu-Pharm argues that FDA has "never, to Nu-Pharm's knowledge, delayed one ANDA applicant's approval based on an unfavorable decision in a separate action. . . ." Nu-Pharm Opp. at 15. The reason is obvious: FDA has never been presented with a situation in which an order directly applicable to an ANDA has been entered "in a separate action," let alone an order entered with findings attributing egregious misconduct to the ANDA applicant such as found to exist here.

CONCLUSION

For the foregoing reasons and the reasons stated in defendants-appellees' motion for summary affirmance, the district court should be summarily affirmed.

Respectfully submitted,

Of Counsel:

JAMES C. STANSEL
Acting General Counsel

GERALD F. MASOUDI
Chief Counsel, Food and
Drug Division

ERIC M. BLUMBERG
Deputy Chief Counsel, Litigation

WENDY S. VICENTE
Associate Chief Counsel

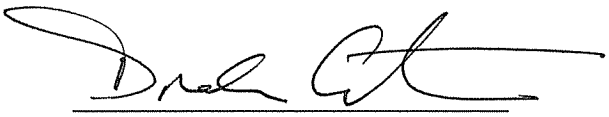
U.S. Dept. of Health &
Human Services
Office of the General Counsel
5600 Fishers Lane
Rockville, MD 20857
301-827-7138

Date: March 7, 2008

JEFFREY S. BUCHOLTZ
Acting Assistant Attorney General

C. FREDERICK BECKNER, III
Deputy Assistant Attorney General

EUGENE M. THIROLF
Director
Office of Consumer Litigation



DRAKE CUTINI
Attorney
Office of Consumer Litigation
U.S. Department of Justice
P.O. Box 386
Washington, D.C. 20044
Tel: 202-307-0044
Fax: 202-514-8742
drake.cutini@usdoj.gov

CERTIFICATE OF SERVICE

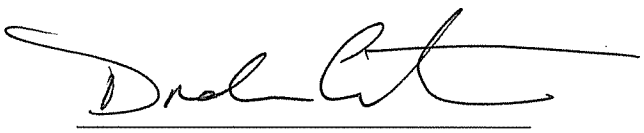
I hereby certify that on this 7TH day of March , 2008, I served copies of the foregoing Federal Defendants-Appellees' Reply in Support of Motion for Summary Affirmance by first class mail upon:

Michael D. Hays
Daniel D. Prichard
Dow Lohnes PLLC
1200 New Hampshire Ave., N.W.
Suite 800
Washington, D.C. 20036

Attorneys for Plaintiff-Appellant Nu-Pharm Inc.

Gregory A. Castanias
Christopher S. Perry
Jones Day
51 Louisiana Ave., N.W.
Washington, D.C. 20001-2113

Attorneys for Intervenor-Defendant-Appellee Abbott Laboratories



Drake Cutini