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

NU-PHARM INC. Plaintiff-Appellant, v. FOOD AND DRUG ADMINISTRATION, MICHAEL O. LEAVITT, Secretary of Health and Human Services, and ANDREW C. VON ESCHENBACH, M.D., Commissioner of Food and Drugs, Defendants-Appellees, and ABBOTT LABORATORIES, Intervenor-Defendant-Appellee.	)	No. 08-5017

NU-PHARM'S OPPOSITION TO DEFENDANTS-APPELLEES' MOTION FOR SUMMARY AFFIRMANCE

Nu-Pharm's appeal raises important issues of statutory construction—***issues that have never been fully briefed by the parties and that the district court below refused to address on the merits***. Consequently, granting FDA's and Abbott's motion to summarily affirm the district court's dismissal would deprive Nu-Pharm from ever having its APA case heard on the merits. Appellees' motion must be denied.

Appellees have not met their "heavy burden" for establishing that summary disposition of this appeal is justified. They have not demonstrated that the merits of their case are clear and that full briefing is unnecessary. They also have not presented this Court with any other basis sufficient to justify the dismissal of Nu-Pharm's APA claims. Indeed, given the facts and circumstances of this appeal, Appellees can never make the required showing.

As set forth in its complaint, Nu-Pharm is statutorily entitled to immediate final approval of its divalproex sodium 500 mg ANDA. FDA, however, unlawfully refuses to award that approval despite the fact that Nu-Pharm has satisfied all substantive requirements for final approval; the statutory 30-month stay of approval has expired; and the court hearing Abbott's infringement action against Nu-Pharm has not made any findings of patent infringement. The district court below improperly refused to address the merits of Nu-Pharm's APA challenge to FDA's final agency action, and instead declined to exercise jurisdiction, dismissing Nu-Pharm's complaint and denying Nu-Pharm's motion for preliminary injunctive relief for prudential reasons. The district court's disposition cannot be upheld on grounds of comity, nor can it be upheld on FDA's proposed alternative grounds of *res judicata* or failure to state a claim.

The fact is, FDA's clear disregard for Nu-Pharm's statutory rights requires full and expedited consideration by this Court to prevent Nu-Pharm from

suffering any further irreparable harm from being excluded from the divalproex sodium market. The parties should have the opportunity to brief the significant statutory issues raised by Nu-Pharm's appeal, and this Court should have an opportunity to thoroughly consider the arguments raised by each party. FDA's Motion for Summary Affirmance and Abbott's Joinder thereto, therefore, must be denied.

ARGUMENT

The law is clear: "To summarily affirm an order of the district court, this court must conclude that 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 movant bears the "heavy burden of establishing that the merits of his case are so clear that expedited action is justified," and the Court must view the record and all resulting inferences "in the light most favorable to the [non-movant]." *Id.* (citation omitted). While this appeal certainly deserves expedited consideration, FDA and Abbott have not met (and can never meet) their heavy burden justifying summary affirmance, particularly in light of Nu-Pharm's showing on the merits.

I. Appellees Have Not Demonstrated That Their Position On The Merits Is Clear, Or That This Court Would Not Benefit From Further Briefing.

As discussed in greater detail in Nu-Pharm's Motion to Expedite and Reply thereto, the district court's dismissal of Nu-Pharm's statutory APA claim is subject to substantial challenge on appeal.[1] The district court below erred in dismissing Nu-Pharm's complaint on prudential grounds, and the merits of Nu-Pharm's APA claim—and Nu-Pharm's claim alone—is not only supported by the governing statute, it is compelled by the plain and unambiguous language of that provision. Moreover, because the statutory issues raised by Nu-Pharm have never been fully addressed by the parties, and this Court would benefit from further briefing, summary affirmance is not warranted here.

As Nu-Pharm has explained, the doctrine of comity is to be employed only "in strictly limited circumstances." *Nw. Forest Res. Council v. Dombeck*, 107 F.3d 897, 901 (D.C. Cir. 1997). Dismissal is not warranted where there is no case pending in another jurisdiction, and the separate prior litigation did not involve the same parties, issues, or subject matter. *See id.* Here, neither Nu-Pharm nor FDA were parties to the *Apotex* action; the *Apotex* action was not even pending at the

[1] Nu-Pharm incorporates herein its prior submissions. Specifically, Nu-Pharm incorporates those arguments directed to the merits of its statutory claim and the district court's refusal to exercise jurisdiction for prudential reasons. (*See* Nu-Pharm's Corrected Mot. to Expedite at 9-18; Nu-Pharm's Reply in Support of Mot. To Expedite at 2-7.)

time that Nu-Pharm filed its APA claim challenging FDA's unlawful interpretation and application of the Federal Food, Drug, and Cosmetic Act ("FFDCA"); and the issues of statutory construction raised in Nu-Pharm's action for declaratory and injunctive relief under the APA were not at issue—nor could they have been raised—in either the *Apotex* action or the *Nu-Pharm* patent action. The district court therefore clearly erred by refusing to exercise jurisdiction (that it admittedly had) over Nu-Pharm's APA claim for alleged prudential reasons.

Additionally, the plain language of the statute supports Nu-Pharm's position on the merits of its APA claim against FDA. Under the clear terms of the FFDCA, where an ANDA applicant has submitted a paragraph IV certification and is sued by the patent owner within the statutory 45-day period, FDA "*shall*" award immediate final ANDA approval "upon the expiration of the thirty-month period beginning on the date of the receipt of the [paragraph IV] notice," unless the court hearing the applicant's patent case orders that approval be delayed. *See* 21 U.S.C. § 355(j)(5)(B)(iii) (emphasis added). Here, Nu-Pharm's ANDA contains a paragraph IV certification to Abbott's patents; Abbott sued Nu-Pharm for infringement within the 45-day period; Nu-Pharm's 30-month stay has expired; and no court decision has been rendered by the patent court hearing the action arising from Nu-Pharm's paragraph IV certification. FDA's refusal to grant final approval to Nu-Pharm's divalproex sodium ANDA upon expiration of the 30-

month stay is thus arbitrary, capricious, and contrary to law in violation of the APA. *See* 5 U.S.C. § 706(2)(A).

Significantly, neither FDA nor Abbott has *ever* addressed the statutory arguments Nu-Pharm raises—either in the lower court or before this Court—and the district court itself failed to evaluate the merits of Nu-Pharm's APA claim. Indeed, in their briefs below, their responses to Nu-Pharm's motion to expedite this appeal, and their own affirmative motions to this Court, FDA and Abbott intentionally avoided the merits of Nu-Pharm's claim. Yet, they seek summary affirmance on grounds of comity and other grounds never even addressed by Nu-Pharm or ruled on by the district court.[2] Because neither FDA nor Abbott has explained its position on the merits of Nu-Pharm's statutory APA claim, and the district court itself took no position on the merits of Nu-Pharm's case, Nu-Pharm has not been afforded an opportunity to challenge FDA's final agency action and, of course, Appellees have not presented this Court with a sufficient basis to justify the district court's decision. Moreover, because Nu-Pharm has raised a substantial challenge on the merits of its statutory APA claim, while FDA and Abbott have failed to demonstrate that the merits of their claims are "clear," there should be

[2] As noted by the district court, the January 24, 2008 hearing "focused on essentially one question, . . . whether th[e] court should decline, for prudential reasons, to exercise jurisdiction in this case . . . ." (*See* Nu-Pharm Mot. To Expedite, Siwik Decl. Ex. D, Hearing Tr. at 6.)

little question that additional briefing and argument would benefit the disposition of this appeal.

Accordingly, Appellees' motion for summary affirmance should be denied. *See Johnson v. DEA*, No. 98-5468, 1999 WL 229014, at *1 (D.C. Cir. Mar. 2, 1999) (denying motion for summary affirmance because appellees' affidavit did not give appellant "a realistic opportunity to challenge the agency's exemption claims, and [did] not permit meaningful review of the district court's decision"); *see also Juda v. U.S. Customs Serv.*, No. 99-5333, 98CV00533, 2000 WL 1093326, at *1 (D.C. Cir. June 19, 2000) (denying motion for summary affirmance because appellees' affidavit "does not provide detailed and specific information . . . so as to justify the district court's award of summary judgment").

II. Nu-Pharm's APA Claim Is Not Barred By *Res Judicata*.

FDA's contends that, even if this Court refuses to affirm the district court's decision based on the reasoning provided by the court below (as it should), Nu-Pharm's APA claim is barred by *res judicata*. (*See* FDA Mot. at 22-23.) Not so. Indeed, *Taylor v. Blakey*, the only case cited by FDA, identifies the very reasons why *res judicata* does not apply here. *See* 490 F.3d 965 (D.C. Cir. 2007). Specifically, in *Taylor*, as FDA acknowledges, the plaintiff's complaint was dismissed on grounds of *res judicata* because a party found to be a virtual representative of the plaintiff "had previously sought *the same relief* and lost."

(FDA Mot. at 22) (emphasis added); *see also Taylor*, 490 F.3d at 978 (finding that "Taylor has raised the same claim as had Herrick"). Such is not the case here.

As this Court repeatedly has explained, "under *res judicata*, 'a final judgment on the merits of an action precludes the parties or their privies from relitigating issues *that were or could have been raised* in that action.'" *Drake v. FAA*, 291 F.3d 59, 66 (D.C. Cir. 2002) (emphasis added) (quoting *Allen v. McCurry*, 449 U.S. 90, 94 (1980)); *see also Taylor*, 490 F.3d at 969 (stating that "[r]es judicata bars relitigation both of 'issues that were' [or] 'could have been raised' in the prior action" (citation omitted)); *Page v. United States*, 729 F.2d 818, 820 (D.C. Cir. 1984) (same).

"The doctrine does not bar a litigant from doing in the present what he had no opportunity to do in the past." *Drake*, 291 F.3d at 67. Here, the issues raised in Nu-Pharm's APA complaint were not, and could not have been, raised in either the *Apotex* action or the *Nu-Pharm* action. The *Apotex* action originated as a patent infringement case between Abbott and Apotex, and developed into a contempt proceeding over whether Apotex had violated a prior injunction. The *Nu-Pharm* action is a patent infringement suit, but between Abbott and Nu-Pharm. In contrast, the current litigation is an APA claim between Nu-Pharm and FDA, arising from FDA's unlawful refusal to award immediate final approval to Nu-

Pharm's divalproex sodium 500 mg ANDA upon the expiration of Nu-Pharm's statutory 30-month stay in clear violation of the plain language of the FFDCA.

Further, these cases involve not only different parties, but also different rights, different injuries, and different requests for relief. In the *Apotex* and *Nu-Pharm* actions, Abbott sought to protect certain purported patent rights through separate infringement actions and a contempt proceeding against Apotex. Abbott sought, and obtained, injunctive relief pertaining to its divalproex sodium patents against Apotex, but never against Nu-Pharm in the *Nu-Pharm* action. Nu-Pharm's APA action, on the other hand, involves a claim against unlawful arbitrary and capricious agency action in violation of the plain language of the FFDCA. Nu-Pharm seeks a declaration that FDA has violated the statute and an injunction directing the Agency to comply with its explicit statutory obligation and award Nu-Pharm immediate final approval of its 500 mg ANDA product.

Moreover, Nu-Pharm's APA action involves a different nucleus of facts. This appeal centers around the proper construction of 21 U.S.C. § 355(j)(5)(B)(iii), under which FDA "shall" approve an otherwise approvable ANDA once the applicable 30-month stay expires, unless the district court hearing the action filed within the 45-day period and arising from the paragraph IV certification decides that the patent has been infringed. The relevant date for purposes of determining ANDA approval, and for purposes of Nu-Pharm's appeal,

is the date on which the 30-month stay expires. Nu-Pharm's 30-month stay did not expire until November 13, 2007—over a year after the *Apotex* Court entered its October 6, 2006 contempt order and injunction against the Apotex and Nu-Pharm divalproex sodium ANDAs. FDA's refusal to award Nu-Pharm final approval *after* November 13, 2007 is the final agency action which Nu-Pharm challenges here. Obviously, Nu-Pharm did not, and could not have, asserted its APA claim, based on a statutory violation and administrative decision that did not occur until November 13, 2007, at any time during the *Apotex* contempt proceedings. And, of course, Nu-Pharm could not have presented its APA claim to either the *Nu-Pharm* Court or the *Apotex* Court for the separate independent reason that venue for Nu-Pharm's APA claim against the Agency "would be improper in Chicago," where FDA would not even consent to be sued. (*See* Nu-Pharm Mot. To Expedite, Siwik Decl. Ex. D, Hearing Tr. at 26.)[3]

FDA's entire *res judicata* argument improperly focuses on the issue of "virtual representation" and whether Nu-Pharm could be considered "in privity" with Apotex (a position with which Nu-Pharm strongly disagrees). This Court, however, need not reach this issue in order to find that the *Apotex* Order does not preclude Nu-Pharm's claims. The facts and legal issues presented in this appeal of

[3] References to "Siwik Decl." are to the Declaration of Christine J. Siwik, which was previously filed with the Court concurrently with Nu-Pharm's Motion to Expedite Consideration of This Appeal.

an APA claim against FDA are not remotely related in "time, space, origin, or motivation" to those in either the *Apotex* or *Nu-Pharm* patent infringement actions. *I.A.M. Nat'l Pension Fund, Benefit Plan A v. Indus. Gear Mfg. Co.*, 723 F.2d 944, 949 n.5 (D.C. Cir. 1983). Nu-Pharm's APA action raises different legal theories involving different parties, and involves different rights, statutory provisions, and an intervening administrative decision.

The district court's dismissal of Nu-Pharm's APA claims against FDA therefore cannot properly be affirmed on *res judicata* grounds. *See, e.g., Drake*, 291 F.3d at 66-67 (*res judicata* did not bar claim that FAA's determination unlawfully disregarded terms of federal regulation when such agency determination "plainly arose after the first action began"); *Negley v. FBI*, 169 F. App'x 591, 593-94 (D.C. Cir. 2006) (suit to obtain FBI records in San Francisco not barred by judgment in suit to obtain records in Sacramento because renewed request covered a different location and different time, and therefore raised new factual questions); *Page,* 729 F.2d at 820 (dismissal of plaintiff's first suit was not *res judicata* of second suit "[s]ince Page's 1972 action obviously could not have asserted claims based on facts that were not yet in existence"); *I.A.M. Nat'l Pension Fund*, 723 F.2d at 949 (*res judicata* did not apply because "the two causes of action differ in that each asserts different rights, alleges different injuries, and arises from different facts").

III. The Allegations In Nu-Pharm's APA Complaint Are Sufficient To State A Claim.

Finally, FDA urges this Court to summarily affirm the district court's decision because Nu-Pharm's complaint allegedly fails to state a claim under Federal Rule of Civil Procedure 12(b)(6). (*See* FDA Mot. at 23.) FDA is wrong again. Dismissal of a claim pursuant to Rule 12(b)(6) "is inappropriate unless the 'plaintiff can prove no set of facts in support of his claim which would entitle him to relief.'" *Browning v. Clinton*, 292 F.3d 235, 242 (D.C. Cir. 2002) (quoting *Conley v. Gibson*, 355 U.S. 41, 45-46 (1957)). This Court must "treat the complaint's factual allegations as true [and] must grant plaintiff the benefit of all reasonable inferences from the facts alleged." *Gilvin v. Fire*, 259 F.3d 749, 756 (D.C. Cir. 2001). Under this liberal standard, Nu-Pharm's APA complaint most assuredly has sufficiently stated a claim for relief.

"A plaintiff can state a claim that an agency's action was 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law' in a number of ways. Those include alleging that the agency failed to articulate an adequate explanation for its new policy, and that it failed to consider factors made relevant by Congress." *James v. Hurson Assocs., Inc. v. Glickman*, 229 F.3d 277, 284 (D.C. Cir. 2000) (internal citations omitted). Nu-Pharm's complaint alleges that FDA has blatantly disregarded its statutory obligations under 21 U.S.C. § 355(j)(5)(B)(iii) by refusing to award final approval to Nu-Pharm's 500 mg

ANDA product immediately upon expiration of Nu-Pharm's statutory 30-month stay, and that the Agency's statutory violation is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" under the APA. Nu-Pharm not only has stated a claim that is "plausible on its face" (FDA Mot. at 24), but Nu-Pharm also has demonstrated that the district court's dismissal of its complaint is subject to substantial challenge under these same principles of statutory construction. No more is required to survive dismissal under Rule 12(b)(6).

The truth is that FDA simply is unwilling to take-on the straight-forward statutory arguments raised in Nu-Pharm's complaint, as demonstrated by the Agency's refusal to address these arguments anywhere below or in its motion to this Court. FDA, for example, states that "[t]he heart of Nu-Pharm's argument then is that the court hearing the infringement action filed against Nu-Pharm . . . did not issue a finding of infringement or order delay[ing] approval," but then fails to take any position whatsoever on this clear issue of statutory construction. (FDA Mot. at 26.) Instead, FDA contends that "[t]he gravamen of Nu-Pharm's argument seems to be that the Illinois court has no authority to do what it did" and that this should have been presented to the Illinois court. (FDA Mot. at 27 n.9.) Again, FDA conveniently misses the point. Nu-Pharm does not take issue with the *Apotex* Court Order itself, but rather, as described in detail in Nu-Pharm's complaint and

prior motions, Nu-Pharm challenges solely FDA's refusal to abide by the statute it administers.

Moreover, as explained above, Nu-Pharm could not have raised its current APA claim in either Illinois action. Indeed, the court below acknowledged that "with the FDA . . . and the federal defendants as the original defendants in this case, it may well be that there would not have been either *in personam* jurisdiction over the federal defendants in Chicago, or venue might not have been appropriate with just the FDA and the federal defendants as the defendants in this case." (Nu-Pharm Mot. To Expedite, Siwik Decl. Ex. D, Hearing Tr. at 38.)

In the end, FDA's attempt to side-step the statutory construction issues raised by Nu-Pharm's complaint is the Agency's assertion that it was "bound to give effect to [the *Apotex* Court's] order." (FDA Mot. at 26; *see also id.* at 27-28.) This argument fails on two separate levels. *First*, contrary to what the Agency would have this Court believe, FDA does *not* always follow court orders issued in actions to which the Agency is not a party. For instance, in *American Bioscience, Inc. v. Thompson*, FDA refused to follow the recommendation of the U.S. District Court for the Central District of California that the Agency toll the period in which the NDA-holder could timely list a patent. *See* 269 F.3d 1077, 1082 (D.C. Cir. 2001). FDA refused because, according to the Agency, "FDA was not a party to the California litigation; [the acting director of FDA's Office of

Generic Drugs] was not sure that the FDA had the authority to toll the statutory time limit; [and] tolling would set an undesireable precedent." *Id.* Here, FDA similarly was not a party to the *Apotex* action; FDA does not have the authority to ignore the clear terms of the FFDCA directing FDA to approve Nu-Pharm's 500 mg ANDA immediately upon expiration of the 30-month stay; and FDA's blatant disregard of the plain language of the statute unquestionably sets an "undesireable precedent." *See* 21 U.S.C. § 355(j)(5)(B)(iii). FDA thus was free, and indeed obligated, to award Nu-Pharm immediate final approval as soon as its 30-month stay expired on November 13, 2007. *See id.* The Agency's refusal to do so gives rise to a claim for relief under the FFDCA and the APA.

Second, the Agency's argument is internally inconsistent. FDA expresses grave concerns about complying with the terms of a court order entered in a suit to which the Agency was not even a party, yet it appears to have no difficulty ignoring the clear dictates of the statute it is charged with administering, as well as its own past practices and policies. FDA is not free to ignore "the unambiguously expressed intent of Congress." *See Chevron U.S.A., Inc. v. Natural Res. Def. Council*, 467 U.S. 837, 842-43 (1984). Moreover, FDA cannot ignore its own implementing regulations, or its prior administrative decisions, wherein the Agency has never, to Nu-Pharm's knowledge, delayed one ANDA applicant's approval based on an unfavorable decision in a separate action that did not arise

out of that applicant's paragraph IV certification and was not filed within the statutory 45-day period. *See* 21 C.F.R. § 314.94(a)(12)(viii)(A) (stating that an applicant shall amend its patent certification "if a final judgment *in the action against the applicant* is entered finding the patent to be infringed" (emphasis added)).

The district court's decision therefore cannot be summarily affirmed for failure to state a claim under Rule 12(b)(6).

CONCLUSION

Appellees have not met their "heavy burden" justifying summary affirmance here. They have not demonstrated that the merits of their claim are "clear," nor have they presented this Court with a sufficient basis to justify the dismissal of Nu-Pharm's claims—either on the grounds put forth by the district court, or on the alternative grounds raised in FDA's motion. The parties, therefore, should have the opportunity to fully brief and argue the important statutory issues raised by Nu-Pharm's appeal, and FDA's motion for summary affirmance, and Abbott's joinder thereto, should be denied.

Dated: February 29, 2008.

Respectfully submitted,

NU-PHARM INC.

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 29th day of February 2008, a true and correct copy of the foregoing Nu-Pharm's Opposition to Defendants-Appellees' Motion for Summary Affirmance was served via hand delivery upon the following:

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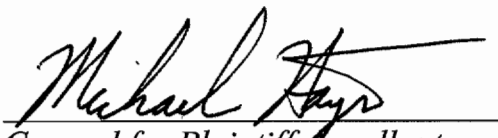

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