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February 13, 2008

VIA HAND
Mr. Mark Langer
Clerk, United States Court of Appeals for the District of Columbia Circuit
333 Constitution Avenue, N.W.
Washington, D.C. 20001

Re: *Nu-Pharm Inc. v. FDA, et al.*, No. 08-5017

Dear Mr. Langer:

Enclosed please find for filing in the above-referenced case an original and five (5) copies each of the following materials:

1. Intervenor-Defendant-Appellee Abbott Laboratories' Response to Nu-Pharm's Motion to Expedite Appeal, with Addendum and Exhibits;

2. Disclosure Statement;

3. Certificate as to Parties, Rulings, and Related Cases; and

4. Amended Entry of Appearance.

Please file-stamp the extra copy of each of these materials and allow the messenger to return those stamped copies to me. Thank you in advance for your assistance. Please feel free to contact me with any questions.

Respectfully,

Gregory A. Castanias

Enclosures

cc: Ms. Nancy Dunn, Deputy Special Counsel to the Clerk, D.C. Circuit (with enclosures; by hand delivery)
William A. Rakoczy, Esq. (with enclosures; by hand delivery)
Michael D. Hays, Esq. (with enclosures; by hand delivery)
Drake Cutini, Esq. (with enclosures; by hand delivery)

No. 2008-5017

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,
ANDREW C. VON ESCHENBACH, M.D., Commissioner of Food and Drugs,
Defendants-Appellees,

and

ABBOTT LABORATORIES,
Intervenor-Defendant-Appellee.

Appeal from the United States District Court for the District of Columbia, In Case No. 08-C-00070, Richard W. Roberts, United States District Judge

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INTERVENOR-DEFENDANT-APPELLEE ABBOTT LABORATORIES' RESPONSE TO NU-PHARM'S MOTION TO EXPEDITE APPEAL

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I. INTRODUCTION

On October 6, 2006, Judge Posner (sitting by designation in the Northern District of Illinois) issued an Injunction Order that prevented Nu-Pharm's ANDA from being finally approved by the FDA before January 29, 2008. Nu-Pharm knew of this order at the time it was entered, but not until January 14, 2008 – *fifteen months later* – did Nu-Pharm claim that this order should not bar approval of its ANDA. As Judge Roberts found in this case, "Nu-Pharm sat on its hands for at least 15 months." (Mot.,[1] Ex. D at 39.)

Even since then, Nu-Pharm has not been acting with the sort of dispatch one might expect from a party claiming to be irreparably harmed and thus requiring immediate relief and expedited treatment from this Court. Nu-Pharm took five days from Judge Roberts' ruling just to notice its appeal. Then it waited a full week to enter its appearances and seek expedition from this Court. Still, even then, Nu-Pharm did not act diligently: Its motion was not delivered to the Court by hand, and it was not designated as an "emergency" motion. Most notably, though, Nu-Pharm has proposed a briefing schedule that can only be characterized as "leisurely" – at least for its own purposes. Under the proposed schedule, which should *not* be adopted by this Court, Nu-Pharm would have over five weeks from Judge Roberts' decision to file its opening brief, and it would retain the full two

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[1] Nu-Pharm's Motion for Expedited Consideration of this appeal is cited as "Mot. at ___."

weeks for the writing of its reply brief. The only parties whose briefing time would be substantially shortened under Nu-Pharm's proposal are the appellees – Abbott and the Government. In this light, Nu-Pharm has no credible claim for expediting this appeal in the manner it seeks.

Rather than propose this leisurely schedule, Nu-Pharm might have self-expedited this appeal by filing its own brief early, thereby allowing appellees the benefit of the full 30 days to which they would ordinarily be entitled for their responsive briefs. Abbott would not have objected to such a schedule. Abbott does, however, oppose Nu-Pharm's request to the extent that Nu-Pharm seeks to constrict the amount of time for Abbott to file its responsive brief.

Even so, as discussed below, Nu-Pharm has offered no justification for such extraordinary relief, choosing instead merely to argue the merits of its appeal. There is no reason why this appeal needs to be resolved on an expedited basis.

II. FACTUAL BACKGROUND

This marks the fourth appeal in this long-running patent infringement action. Abbott owns two patents that cover divalproex sodium, the active ingredient in Depakote®, a prescription drug widely used in the treatment of epilepsy and other conditions. In 1997, Apotex, Inc. (through its former TorPharm division) filed ANDA No. 75-112 with the FDA, seeking approval of a proposed generic divalproex sodium product. Abbott initiated a timely patent-infringement action

under the Hatch-Waxman Act, 35 U.S.C. § 271(e)(2). The district court awarded summary judgment in favor of Abbott in 2001, and the Federal Circuit affirmed as to all issues save one, remanding the case for a limited trial on infringement only. *See Abbott Labs v. TorPharm, Inc.*, 300 F.3d 1367 (N.D. Ill. 2002).

On remand, the infringement trial was held before Circuit Judge Richard A. Posner, sitting by designation. Judge Posner ruled that Apotex's proposed generic drug was infringing and, pursuant to 35 U.S.C. § 271(e)(4), entered an Injunction Order barring Apotex from making or using its infringing divalproex sodium product and mandating that "[t]he effective date for *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 5,212,326." (Emphases added.) In appeal number two, the Federal Court affirmed the district court's judgment and Injunction Order in all respects. *See Abbott Labs v. TorPharm, Inc.*, 122 Fed App'x 511 (Fed. Cir. 2005).

The third appeal arose from Apotex's attempt to sidestep the 2004 Injunction Order. Apotex submitted a new ANDA (No. 77-615) to the FDA in 2005, seeking approval of the very same divalproex sodium product already adjudged to infringe and enjoined by Judge Posner. *See Abbott Labs. v Apotex, Inc.*, 455 F. Supp. 2d 831, 834-35 (N.D. Ill. 2006). Attempting to evade the Injunction Order, Apotex

drafted the ANDA, but arranged to have it filed in the name of Nu-Pharm, Inc., a six-person company that sells Apotex-made products in Canada. (*Id.*)

Because Nu-Pharm's initial notice made no mention of Apotex, Abbott filed a separate suit against Nu-Pharm under 35 U.S.C. § 271(e)(2) before Judge Rebecca Pallmeyer in the U.S. District Court for the Northern District of Illinois. *See id.*; *see also* Case No. 05-C-3714 (N.D. Ill., Pallmeyer, J.). Once discovery in that action revealed that Apotex, not Nu-Pharm, actually developed, tested, and retains all rights in the second ANDA product – and that the Apotex/Nu-Pharm ANDA product is identical to Apotex's previous, infringing product – Abbott filed a motion before Judge Posner seeking to have his previous injunction enforced against the new ANDA.

After reviewing extensive briefing and conducting an evidentiary hearing at which both sides presented expert testimony, Judge Posner ruled that (i) there is no difference between the divalproex-sodium product described in ANDA No. 77-615 and the Apotex/TorPharm ANDA product; and (ii) the new product infringes Abbott's patents-in-suit. *See Abbott*, 455 F. Supp. 2d at 837-39. Accordingly, he entered an amended Injunction Order making clear that, among other things, the effective date of any approval by FDA of ANDA No. 77-615 can be no earlier than January 29, 2008, when Abbott's patents expire. (*See* Exhibit B (2006 Injunction Order).)

On October 11, 2007, the Federal Circuit affirmed Judge Posner's factual findings – including his finding that "Apotex's choice of Nu-Pharm to file the ANDA was a subterfuge intended to give Apotex a crack at another district judge" and his finding that Apotex "file[d] a second ANDA to a drug having no more than a colorable difference from the first." *Abbott Labs. v. TorPharm, Inc.*, 503 F.3d 1372, 1379, 1381 (Fed. Cir. 2007). The Federal Circuit also affirmed Judge Posner's decision to extend his 2004 Injunction Order to cover the Apotex/Nu-Pharm ANDA. *See id.* at 1381.

Apotex and Nu-Pharm, however, refused to admit defeat. While Apotex petitioned the Supreme Court for certiorari (on January 7, 2008), Nu-Pharm filed this lawsuit in the U.S. District Court for the District of Columbia, demanding emergency injunctive relief against the FDA. (*See* Exhibit C (Nu-Pharm Complaint, dated January 14, 2008).) The new lawsuit demanded that the district court order the FDA to immediately approve the Apotex/Nu-Pharm ANDA, thereby placing the FDA in the position of acting in violation of Judge Posner's 2006 Injunction Order. (*See id.*) Astonishingly (in light of the history set forth above), Nu-Pharm told the district court here that Nu-Pharm had "not had its day in court anywhere to date," and that Judge Posner's 2006 Injunction Order did not apply to it. (*See* Mot., Ex. D at 8, 10.)

Abbott (which was not originally a party to the D.C. suit) immediately moved to intervene. Both Abbott and the FDA moved to dismiss Nu-Pharm's spurious lawsuit and, in a hearing held before Judge Roberts on January 24, 2008, these motions were granted. (*Id.* at 40-41.) The district court denied all of Nu-Pharm's requests for emergency injunctive relief, noting that Judge Posner's amended Injunction Order was one that "Nu-Pharm knew about, certainly on October 6, 2006 or shortly thereafter," yet Nu-Pharm unjustifiably delayed seeking relief from that injunction for fifteen months. (*See id.* at 37, 40.) For prudential reasons, the district court declined to exercise jurisdiction over this case, finding that the relief sought by Nu-Pharm was directly contrary to the 2006 Injunction Order, whose validity had been affirmed by the Federal Circuit. (*Id.* at 39-41.) Nu-Pharm then filed this appeal.

III. ARGUMENT

A. Nu-Pharm Is Not Entitled To Expedited Consideration Of This Appeal.

This appeal does not merit expedited consideration.

First, although Nu-Pharm sought a temporary restraining order (or a preliminary injunction) in the district court, the urgency was entirely of Nu-Pharm's own making. As the district court explained, "the injunction entered by Judge Posner on October the 6th, 2006, was one that Nu-Pharm knew about, certainly on October 6th, 2006 or shortly thereafter, as counsel has conceded."

(Mot., Ex. D at 37.) And, even if "Nu-Pharm had no obligation to attempt to . . . file anything before Judge Posner, Nu-Pharm clearly had an opportunity to appear before Judge Posner or attempt to appear before Judge Posner if it was important to make [the arguments now made in the district court]." (*Id.*) Yet, as the district court acknowledged, "[t]here's no evidence that they took advantage of that opportunity." (*Id.*) Instead, Nu-Pharm "waited at least 15 months or so between the issuance of Judge Posner's injunction and . . . filing the action here to attempt to have that argument made or to attempt to achieve relief that varies from that which Judge Posner had granted . . . ." (*Id.*)

Nu-Pharm cannot sleep on its rights for well over a year and then claim that it needs immediate injunctive relief to prevent irreparable harm. Similarly, here, Nu-Pharm need not and ought not receive expedited consideration of its meritless claims when it is Nu-Pharm's dilatory conduct – not any intervening circumstance – that provides the basis for Nu-Pharm's rushed appellate schedule.

Second, there is no record evidence showing that Nu-Pharm is commercially prepared to market, sell, or distribute the Apotex/Nu-Pharm ANDA product *even if* Nu-Pharm were to receive a judgment in its favor. Without a showing that Nu-Pharm's product is scientifically and commercially viable, there is no reason to expedite this appeal, because a judgment in Nu-Pharm's favor still would not enable Nu-Pharm to immediately market its product.

Third, even apart from Judge Posner's Injunction Order, the relief requested by Nu-Pharm is barred by statute until July 29, 2008. At FDA's request, Abbott conducted a series of pediatric tests regarding its divalproex-sodium products. In return for this important testing, FDA granted Abbott a six-month period of pediatric exclusivity, during which time FDA cannot finally approve any ANDA for a divalproex-sodium product. Nu-Pharm has not challenged the FDA's decision to award Abbott this period of regulatory exclusivity. *See* 28 U.S.C. § 355a(c)(B). As such, even if the district court's judgment were reversed by this Court, the FDA – by statute – could not finally approve Nu-Pharm's ANDA until July 29, 2008.

There is no need to expedite this appeal.

B. Nu-Pharm's Arguments To The Contrary Are Misplaced.

Nu-Pharm's arguments in favor of expedited treatment of this appeal are unavailing and should be rejected.

First, Nu-Pharm argues the merits of its case, claiming that (i) the district court wrongly declined to exercise jurisdiction over this case; and (ii) the FDA's "decision" not to grant final approval of the Apotex/Nu-Pharm ANDA is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." (Mot. at 9-12.) Both arguments are specious.

FDA – like Nu-Pharm – was bound by Judge Posner's 2006 Injunction Order. *See Apotex, Inc. v. FDA*, 508 F. Supp. 2d 78, 86 (D.D.C. 2007) (explaining

that the FDA was "not free to disregard" a court order finding that a generic's ANDA product infringed certain patents). The Federal Circuit affirmed Judge Posner's ruling that Apotex's "Nu-Pharm" product (like the previously-enjoined Apotex product) infringed Abbott's patents. And, by affirming Judge Posner's authority to extend his 2004 Injunction Order to cover the Apotex/Nu-Pharm ANDA product, the Federal Circuit *rejected* Nu-Pharm's claim here that Judge Pallmeyer (in the separate *Abbott v. Nu-Pharm* action) was "the only court which may be used to delay approval . . . ." (Mot. at 16.) So, because FDA was bound by the 2006 Injunction Order, the district court properly declined to exercise jurisdiction over a suit that would require the court to review the previous orders of courts with concurrent jurisdiction – and, in fact, encouraged the court to reach the opposite result.

Second, Nu-Pharm argues that it will suffer "irreparable harm" if it is forced to wait until July 29, 2008 to enter the market for divalproex sodium products because there may be other generic applicants eligible for final approval at that time. (Mot. at 18-19.) But, it again bears noting, there is no evidence anywhere in this record (or anywhere else) that Nu-Pharm has the present capacity to enter the market with a generic divalproex sodium product before that date. Moreover, the fact that Nu-Pharm would prefer not to compete with other manufacturers does not mean it will suffer "irreparable harm" absent relief in this case; it simply means

that Nu-Pharm will have to play by the same rules as everyone else.[2] Nu-Pharm's (and Apotex's) preference not to play by those rules does not mean that this appeal should be expedited.

Third, Nu-Pharm urges the Court to expedite this appeal because the public is somehow being harmed by not having access to Nu-Pharm's infringing drug product. (Mot. at 19-20.) Not so. Its assertions of harm to the public are entirely speculative: Even if it could be said that delaying approval until after July 29, 2008 would work some sort of harm to the public interest, such a brief delay would be minimal, and would scarcely outweigh the strong public interests in maintaining a healthy patent system, protecting the rights of patent holders against infringement, and maintaining respect for court orders. Nu-Pharm's (mistaken) invocation of the public interest in no way justifies expedited treatment.

C. Nu-Pharm Could Have Chosen To Expedite This Appeal By Filing Its Own Briefs Early.

Finally, as noted above, Nu-Pharm's motion should have been largely unnecessary because it should have filed any such action over 15 months ago. Even now, aside from its belated filing of this challenge, Nu-Pharm could have

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[2] Nu-Pharm also claims that it is (somehow) relevant that divalproex sodium is the Canadian company's first U.S. product. But the fact that Nu-Pharm is a Canadian company does not mean that U.S. law does not apply to it. The FDA cannot finally approve Nu-Pharm's product prior to the expiration of Abbott's pediatric exclusivity, regardless of whether Nu-Pharm has one or one hundred potential products for sale in the U.S. market.

self-expedited this appeal by filing its opening brief early, and proposing a schedule that cut time from its – and not appellees' – allotted time. By so doing, Nu-Pharm could have cut as many days or weeks from this proceeding as it wished. As discussed above, however, there is no good reason why Abbott's (or the Government's) briefing time should be cut short; Abbott should be afforded the full 30 days it would normally receive to respond to Nu-Pharm's brief.

* * * *

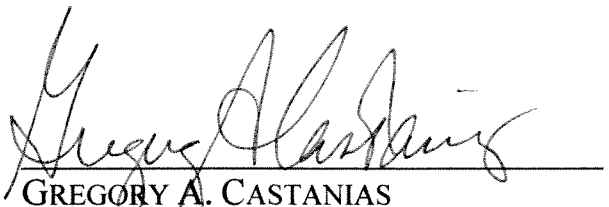
Given (i) the breathtaking relief that Nu-Pharm's complaint seeks (*i.e.*, to force the FDA to violate another court's injunction order), (ii) Nu-Pharm's long and continued history of sleeping on its rights, (iii) the minimal (indeed, speculative) harm that would be caused by requiring Nu-Pharm to wait until after July 29, 2008, before entering the marketplace, and (iv) the absence of any other "strongly compelling" reason to expedite the schedule for this appeal (*Handbook of Practice and Internal Procedures, United States Court of Appeals for the District of Columbia Circuit* at 33), there is no basis in law or reason to grant Nu-Pharm's request to expedite the briefing schedule in this case.

IV. CONCLUSION

Nu-Pharm's motion should be denied.

Dated: February 13, 2008

Respectfully submitted,



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Attorneys for Intervenor-Defendant-Appellee Abbott Laboratories

CERTIFICATE OF SERVICE

I hereby certify that on this 13th day of February, 2008, I served *Intervenor-Defendant-Appellee Abbott Laboratories' Response to Nu-Pharm's Motion to Expedite Appeal* via hand upon:

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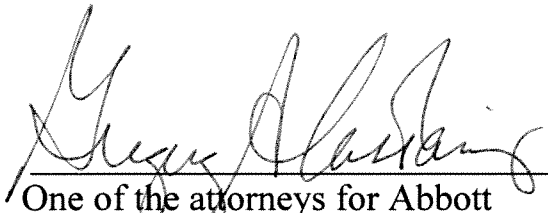
Counsel for Defendants-Appellees



One of the attorneys for Abbott Laboratories

ADDENDUM TO

INTERVENOR-DEFENDANT-APPELLEE ABBOTT LABORATORIES' RESPONSE TO NU-PHARM'S MOTION TO EXPEDITE APPEAL

DISCLOSURE STATEMENT

In accordance with Federal Rule of Appellate Procedure 26.1 and Circuit Rule 26.1, Abbott Laboratories, through counsel, states that:

1. Abbott Laboratories is a public company.

2. Abbott Laboratories has no parent company, and no publicly-held company has an ownership interest of 10 percent or more in Abbott Laboratories.

3. Abbott Laboratories is a company involved in the development, manufacture, and sale of medicines and other health care products.

CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Pursuant to Circuit Rule 28, Abbott Laboratories, through counsel, states that:

1. The parties who appeared before the district court and who are before this Court are:

- Nu-Pharm, Inc. (Plaintiff-Appellant);
- Food and Drug Administration (Defendant-Appellee);
- Michael O. Leavitt, Secretary of Health and Human Services (Defendant-Appellee);
- Andrew C. von Eschenbach, Commissioner of Food and Drugs (Defendant-Appellee); and
- Abbott Laboratories (Intervenor-Defendant-Appellee).

2. This case involves review of a judgment of the United States District Court for the District of Columbia, Judge Richard W. Roberts, denying Nu-Pharm, Inc.'s motion for a temporary restraining order and/or preliminary injunction, and dismissing the complaint. (*See* Exhibit A (1.24.08 Order in Case No. 1:08-CV-00070).) The district court has not indicated whether this decision will be published. A copy of the district court's order is attached to Abbott's Response as Exhibit A, and the transcript explaining the bases for the district court's judgment was attached to Nu-Pharm's Motion to Expedite Consideration of this Appeal as Exhibit D.

3. There are no related cases pending before this Court. There are, however, related cases pending before other courts, all of which involve Apotex's, and, later, Nu-Pharm's, Abbreviated New Drug Applications for divalproex sodium, which is covered by Abbott's patents. First, there is Abbott's suit against Apotex, Inc. and Apotex, Corp., in the Northern District of Illinois, Case No. 97-C-7515. Summary judgment was awarded in that case to Abbott, and against Apotex, on March 30, 2001. *See Abbott Labs. v. TorPharm, Inc.*, 156 F. Supp. 2d 738 (N.D. Ill. 2001). The Federal Circuit found the patents to be valid, enabled, and enforceable, but found that an open fact issue precluded summary judgment. *See Abbott Labs. v. TorPharm, Inc.*, 300 F.3d 1367, 1380-81 (Fed. Cir. 2002). On remand, Judge Richard A. Posner, sitting by designation in the Northern District of Illinois, held a bench trial, determined that Apotex's product infringed Abbott's patents, and entered an injunction prohibiting FDA approval of Apotex's ANDA product before Abbott's patents expired. *See Abbott Labs. v. TorPharm, Inc.*, 309 F. Supp. 2d 1043 (N.D. Ill. 2004). The Federal Circuit affirmed this judgment in its entirety. *See Abbott Labs. v. TorPharm, Inc.*, 122 Fed. App'x 511 (Fed. Cir. 2005).

When Nu-Pharm then submitted an ANDA for divalproex sodium, Abbott sued Nu-Pharm in the Northern District of Illinois in Case No. 05-C-3714 before Judge Rebecca Pallmeyer. Abbott moved to enforce Judge Posner's 2004

Injunction Order against Apotex in 2006, when it learned that Nu-Pharm was merely an alter ego or tool of Apotex. On October 6, 2006, Judge Posner again ruled in Abbott's favor, this time extending his injunction to cover Nu-Pharm's ANDA product. *See Abbott Labs. v. Apotex, Inc.*, 455 F. Supp. 2d 831 (N.D. Ill. 2006). Judge Posner's extension of his previous injunction – and his factual findings regarding infringement and the identity of Nu-Pharm and Apotex – were upheld by the Federal Circuit on October 11, 2007. *See Abbott Labs. v. TorPharm, Inc.*, 503 F.3d 1372 (Fed. Cir. 2007). On January 7, 2008, Apotex petitioned the U.S. Supreme Court for certiorari in that case (No. 07-912).

EXHIBITS TO

INTERVENOR-DEFENDANT-APPELLEE ABBOTT LABORATORIES' RESPONSE TO NU-PHARM'S MOTION TO EXPEDITE APPEAL

Exhibit A

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

NU-PHARM INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	**Civil Action No. 08-70 (RWR)**
	)	
FOOD & DRUG ADMIN., et al.,	)	
	)	
Defendants.	)	
	)	

ORDER

For the reasons stated on the record in open court on January 24, 2008 during a hearing in this case at which counsel for all parties appeared, it is hereby

ORDERED that Nu-Pharm Inc.'s motion for temporary restraining order and/or preliminary injunction, and request for emergency relief pending appeal [3], be, and hereby are, DENIED. It is further

ORDERED that the complaint be, and hereby is, DISMISSED. This is a final, appealable order.

SIGNED this 24th day of January, 2008.

/s/
RICHARD W. ROBERTS
United States District Judge

Exhibit B

UNITED STATES DISTRICT COURT FOR THE
NORTHERN DISTRICT OF ILLINOIS,
EASTERN DIVISION

ABBOTT LABORATORIES, *Plaintiff,* v. APOTEX, INC., and APOTEX CORPORATION, *Defendants.*	No. 97 C 7515 Judge Richard A. Posner sitting by designation.

INJUNCTION ORDER

RICHARD A. POSNER, Circuit Judge:

Apotex, Inc., Apotex Corp., and their respective affiliates, successors in interest, and assigns are enjoined from commercially manufacturing, using, selling, or offering to sell generic divalproex sodium which the Court has found to be infringing, including divalproex sodium products synthesized using the processes employed in connection with ANDA No. 77-615, within the United States, or from importing such products into the United States, until Abbott's U.S. Patent Nos. 4,988,731 and 5,212,326 expire and defendants have received final approval from FDA to market generic divalproex sodium.

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.

IT IS SO ORDERED.

ENTER:

Richard A. Posner

RICHARD A. POSNER, Circuit Judge
United States District Court

DATED: October 06, 2006

Exhibit C

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

NU-PHARM INC.
50 Mural Street, Units 1 and 2
Richmond Hill, Ontario L4B I E4,

Plaintiff,

v.

FOOD AND DRUG ADMINISTRATION
5600 Fishers Lane
Rockville, Maryland 20857,

MICHAEL O. LEAVITT
Secretary of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201, and

ANDREW C. VON ESCHENBACH, M.D.
Commissioner of Food and Drugs
5600 Fishers Lane
Rockville, Maryland 20857,

Defendants.

Case No.

Case: 1:08-cv-00070
Assigned To : Roberts, Richard W.
Assign. Date : 1/14/2008
Description: TRO/PI

COMPLAINT

Plaintiff Nu-Pharm Inc. ("Nu-Pharm"), for its Complaint against the United States Food and Drug Administration; Michael O. Leavitt, in his official capacity as the Secretary of Health and Human Services; and Andrew C. von Eschenbach, M.D., in his official capacity as the Commissioner of the United States Food and Drug Administration (collectively, "FDA"), alleges as follows:

Nature Of The Action

1. Nu-Pharm respectfully brings this action for declaratory and injunctive relief challenging FDA's unlawful refusal to grant Nu-Pharm final approval for its abbreviated new drug application ("ANDA") for divalproex sodium delayed-release 500 mg tablets—a

prescription drug currently marketed solely by Abbott under the brand-name Depakote® for the treatment of epilepsy.

2. Nu-Pharm has satisfied all substantive requirements for final approval for its divalproex sodium delayed-release 500 mg tablet product. Nu-Pharm's 500 mg product is not subject to any stays of approval, nor has any court decision of patent infringement been rendered, or injunction been entered, against Nu-Pharm in any action to which Nu-Pharm is a party. Indeed, the only statutory stay of approval to which Nu-Pharm's 500 mg product was subject expired months ago, on November 13, 2007. Accordingly, FDA has no lawful basis or authority to withhold Nu-Pharm's approval.

3. FDA nonetheless has withheld final approval in clear contravention of the applicable provisions of the Federal Food, Drug, and Cosmetic Act ("FFDCA"). Pursuant to the Administrative Procedure Act ("APA"), FDA's actions are arbitrary, capricious, an abuse of discretion, contrary to law, and in excess of statutory authority.

4. To prevent devastating and irreparable harm to Nu-Pharm, the Court should enter immediate injunctive relief requiring FDA to grant final, effective approval of Nu-Pharm's ANDA for divalproex sodium delayed-release 500 mg tablets, which will permit Nu-Pharm to begin marketing its lower-priced generic drug promptly after the expiration of Abbott's patents.

Parties

5. Plaintiff Nu-Pharm Inc. is a corporation organized and existing under the laws of Canada, with a place of business at 50 Mural Street, Units 1 and 2, Richmond Hill, Ontario Canada L4B 1 E4.

6. Defendant Michael O. Leavitt is the Secretary of Health and Human Services ("HHS"), and the official charged by law with administering the FFDCA. He is sued in his

official capacity. Secretary Leavitt maintains offices at 200 Independence Avenue, S.W., Washington, D.C. 20201.

7. Defendant Andrew C. von Eschenbach, M.D., is the Commissioner and senior official of FDA. He is sued in his official capacity. Commissioner von Eschenbach has been delegated the authority to administer the drug approval provisions of the FFDCA through FDA. He maintains offices at 5600 Fishers Lane, Rockville, Maryland 20857.

8. Defendant FDA is an agency within the Public Health Service and is a part of HHS. FDA maintains offices at 5600 Fishers Lane, Rockville, Maryland 20857.

Jurisdiction and Venue

9. This action arises under the FFDCA, 21 U.S.C. § 301 *et seq.*, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355 and 35 U.S.C. § 271) ("Hatch-Waxman") and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, § 1102(b)(1), Pub. L. No. 108-173, 117 Stat. 2066 (2003) (codified as amended at 21 U.S.C. § 355 and 35 U.S.C. § 271) ("MMA"); the APA, 5 U.S.C. § 551 *et seq.*; and the Declaratory Judgment Act, 28 U.S.C. §§ 2201, 2202. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1361.

10. This Court has personal jurisdiction over the federal Defendants because they are either located and/or conduct substantial business in, or have regular and systematic contact with, this District. Venue is proper in this District under 28 U.S.C. § 1391(e).

11. FDA's agency action and/or inaction constitutes an actual controversy, for which Nu-Pharm is entitled to review and relief under 5 U.S.C. §§ 702, 704-706. Nu-Pharm has

standing to maintain this action, pursuant to the APA, as a legal entity that has been adversely affected by final agency action and/or agency action unlawfully withheld.

12. There exists an actual, substantial, and continuing controversy between the parties regarding FDA's application of the FFDCA and, in particular, the Agency's refusal to award immediate final approval to Nu-Pharm's ANDA for divalproex sodium delayed-release tablets, 500 mg. This Court may declare the rights and legal relations of the parties under 28 U.S.C. §§ 2201, 2202.

Background

I. Statutory Framework For Approval Of New And Generic Drugs.

A. New Drugs—NDAs And Patent Listing Requirements.

13. A company seeking to sell an original, new drug must file a new drug application ("NDA") with FDA, together with information on any patent that "claims the drug for which the applicant submitted the application or which claims a method of using such drug . . . ." 21 U.S.C. § 355(b)(1); *see also id.* § 355(c)(2). After approving the NDA, FDA publishes this patent information in the "Orange Book." *See id.*; 21 C.F.R. § 314.53(e).

B. Generic Drugs—ANDAs And Patent Certifications.

14. A company seeking FDA approval to market a generic version of a previously-approved NDA drug may file an ANDA that includes one of four certifications with respect to each Orange Book-listed patent for the NDA drug: (I) that there is no patent information; (II) that the listed patent has expired; (III) that the ANDA applicant will not market its generic drug until after the expiration of the listed patent; or (IV) that the listed patent is invalid and/or will not be infringed by the proposed generic drug, a so-called "paragraph IV certification." *See* 21 U.S.C. § 355(j)(2)(A)(vii).

15. With certain exceptions not applicable here, an ANDA applicant seeking FDA approval to market its generic drug before expiration of the Orange Book-listed patent must submit a paragraph IV certification and notify the patentee (and the NDA-holder) of the factual and legal bases for that certification. *See* 21 U.S.C. § 355(j)(2)(B).

16. Submitting an ANDA with a paragraph IV certification constitutes a technical act of infringement under 35 U.S.C. § 271(e)(2)(A), thereby vesting the district courts with subject matter jurisdiction to adjudicate whether the proposed generic drug infringes the relevant patent before the drug has actually been marketed.

17. By bringing suit, the patentee triggers an automatic stay of FDA approval. FDA cannot finally approve the ANDA for 30 months, regardless of the merit, or lack thereof, of the patent infringement case. *See* 21 U.S.C. § 355(j)(5)(B)(iii). Before expiration of the 30 months, the stay can be terminated by a decision of the court hearing the patent infringement action finding that the proposed ANDA product does not infringe the patent and/or that the patent is invalid. *See id.* § 355(j)(5)(B)(iii)(I).

18. Upon expiration of the 30-month stay, if there is no court decision by the district court hearing the patent infringement litigation finding the patent valid and infringed, the ANDA applicant is statutorily entitled to, and FDA "shall" grant, final effective approval of the ANDA (assuming the applicant has otherwise satisfied FDA's substantive ANDA approval requirements). 21 U.S.C. § 355(j)(5)(B)(iii).

II. Factual Background.

A. Abbott's NDA No. 18-723 For Depakote® (Divalproex Sodium) Delayed-Release Tablets.

19. Abbott Laboratories ("Abbott") holds approved NDA No. 18-723 for divalproex sodium delayed-release tablets, 500 mg, which are sold under the brand-name Depakote® for, among other things, the treatment of epilepsy.

20. Abbott submitted information to FDA on two patents for listing in the Orange Book in connection with Depakote® (divalproex sodium) delayed-release tablets, 500 mg and NDA No. 18-723: U.S. Patent Nos. 4,988,731 ("the '731 patent") and 5,212,326 ("the '326 patent"), both of which are set to naturally expire on January 29, 2008. By virtue of Abbott's submission, information for the '731 and '326 patents was listed, and to date remains listed, in FDA's Orange Book.

B. Nu-Pharm's ANDA No. 77-615 For Divalproex Sodium Delayed-Release Tablets, 500 mg.

21. On March 7, 2005, Nu-Pharm submitted ANDA No. 77-615 for divalproex sodium delayed-release tablets, 500 mg, together with paragraph IV certifications to both the listed '731 and '326 patents. Nu-Pharm has satisfied all substantive requirements for approval.

22. As required by statute and regulation, Nu-Pharm duly notified Abbott of its ANDA and paragraph IV certifications to the '731 and '326 patents. Abbott received Nu-Pharm's notice of paragraph IV certification to the '731 and '326 patents on May 13, 2005.

23. In response, Abbott sued Nu-Pharm for alleged infringement of the '731 and '326 patents under 35 U.S.C. § 271(e)(2)(A) in the United States District Court for the Northern District of Illinois, Eastern Division (hereinafter, "the *Nu-Pharm* Action" or "*Nu-Pharm* Court"). *See Abbott Labs v. Nu-Pharm Inc.*, Civ. A. No. 05-3714 (N.D. Ill.).

24. The only 30-month stay arising out of the *Nu-Pharm* Action applicable to Nu-Pharm's 500 mg product expired on November 13, 2007—30 months after Abbott received Nu-Pharm's notice of paragraph IV certification. The *Nu-Pharm* Court has not extended the 30-month stay or entered any rulings or orders on the merits of the patent infringement dispute. In fact, to date, the *Nu-Pharm* Court has stayed the *Nu-Pharm* Action in its entirety, without any substantive merits ruling.

C. FDA's Unlawful Refusal To Grant Final Approval Of Nu-Pharm's ANDA No. 77-615 For Divalproex Sodium Tablets, 500 mg.

25. After the 30-month stay arising out of the *Nu-Pharm* Action expired on November 13, 2007, Nu-Pharm duly requested, and reasonably expected to receive, immediate final FDA approval of Nu-Pharm's ANDA No. 77-615 for its divalproex sodium delayed-release 500 mg tablets. On December 11, 2007, FDA informed Nu-Pharm that it would not grant final approval based on an order entered in a contempt proceeding to which Nu-Pharm was not a party. *See Abbott Labs. v. Apotex, Inc.*, Civ. A. No. 97-7515 (N.D. Ill.) (hereinafter, the "*Apotex* Action" or "*Apotex* Court"). The *Apotex* Action, on which FDA based its decision, arose out of the submission of a different ANDA by a different company; namely Apotex's ANDA No. 75-112 for divalproex sodium delayed-release tablets that was found to infringe Abbott's patents. In a subsequent contempt proceeding to which Nu-Pharm was not a party, the *Apotex* Court extended the order and injunction over Apotex's ANDA to cover Nu-Pharm's ANDA. Again, Nu-Pharm was not a party to this proceeding, and the *Nu-Pharm* Court hearing the infringement action based on Nu-Pharm's paragraph IV ANDA has not entered any orders or injunctions concerning Nu-Pharm's ANDA.

26. On December 21, 2007, Nu-Pharm made a written submission to FDA requesting final approval of Nu-Pharm's 500 mg product on the ground that the 30-month stay has expired

and no orders concerning patent infringement or validity have been entered in the *Nu-Pharm* Action. On January 9, 2008, FDA orally denied Nu-Pharm's request based on the *Apotex* Court's order.

27. FDA's decision violates the plain and unambiguous language of the FFDCA, which provides that FDA shall immediately approve an ANDA where, as in this case, the applicable 30-month stay has expired and the court hearing the patent infringement action that is the subject of the paragraph IV ANDA (here, the *Nu-Pharm* Court) has made no finding of infringement or validity. In these circumstances, Congress mandated and directed FDA to approve the ANDA immediately, assuming that all other substantive requirements for approval have been satisfied.

28. FDA therefore has no lawful basis or authority to withhold final approval of Nu-Pharm's 500 mg divalproex sodium tablets under ANDA No. 77-615 based on a court order in a wholly separate contempt proceeding to which Nu-Pharm was not a party. FDA's decision violates not only the plain language of the statute, but also contradicts the underlying purpose of the FFDCA, which is to speed the introduction of affordable, quality generic drugs to the public. FDA's decision also violates the Agency's prior interpretation of the relevant statutory provision. Absent immediate injunctive relief requiring the approval of Nu-Pharm's 500 mg product, Nu-Pharm will be unable to begin marketing its lower-priced generic drug promptly after the expiration of Abbott's patents.

29. FDA's decision constitutes final agency action for purposes of judicial review under the APA.

30. Nu-Pharm has exhausted its administrative remedies. Any additional effort to seek administrative relief from the Agency would be futile and would result in further irreparable prejudice and harm to Nu-Pharm.

Count I
(Violation of the FFDCA and APA)

31. Nu-Pharm repeats and realleges the foregoing paragraphs as though fully alleged herein.

32. FDA's decision refusing to grant final approval of Nu-Pharm's generic divalproex sodium delayed-release 500 mg tablets under ANDA No. 77-615 is arbitrary, capricious, an abuse of discretion, and not in accordance with the law within the meaning of 5 U.S.C. § 706(2)(A), in excess of statutory authority within the meaning of 5 U.S.C. § 706(2)(C), and in violation of the FFDCA.

33. Nu-Pharm has no adequate remedy at law.

Count II
(Relief Pending Review, 5 U.S.C. § 705)

34. Nu-Pharm repeats and realleges the foregoing paragraphs as though fully alleged herein.

35. Under 5 U.S.C. § 705, to prevent devastating and irreparable harm to Nu-Pharm, Nu-Pharm is entitled to immediate final approval of its divalproex sodium delayed-release 500 mg tablets pending resolution of this matter on the merits, including an appeal to the D.C. Circuit.

Request for Relief

WHEREFORE, Nu-Pharm respectfully prays that this Honorable Court enter judgment in its favor and against the federal Defendants, as follows:

(a) Entry of judgment declaring that FDA's refusal to grant final effective approval of Nu-Pharm's ANDA No. 77-615 for divalproex sodium delayed-release 500 mg tablets is arbitrary, capricious, an abuse of discretion, and contrary to law;

(b) Entry of an injunction requiring FDA to immediately award final approval for Nu-Pharm's divalproex sodium delayed-release 500 mg tablets under ANDA No. 77-615;

(c) Entry of an order awarding Nu-Pharm its reasonable attorneys' fees and costs of prosecuting this action; and

(d) Such other and further relief as the Honorable Court deems just and proper.

Dated: January 14, 2008.

Respectfully submitted,

NU-PHARM INC.

By: William A. Rakoczy
One of its attorneys

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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, ANDREW C. VON ESCHENBACH, M.D., Commissioner of Food and Drugs,
Defendants-Appellees,

and

ABBOTT LABORATORIES,
Intervenor-Defendant-Appellee.

No. 08-5017

On appeal from the U.S. District Court for the District of Columbia, in Case No. 08-C-00070

DISCLOSURE STATEMENT

In accordance with Federal Rule of Appellate Procedure 26.1 and Circuit Rule 26.1, Abbott Laboratories, through counsel, states that:

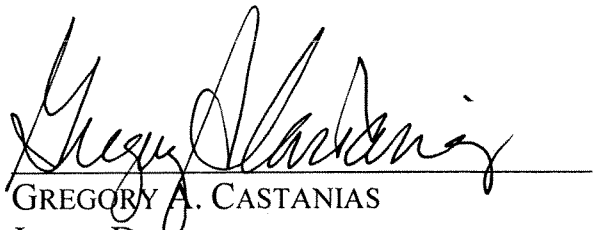
1. Abbott Laboratories is a public company.

2. Abbott Laboratories has no parent company, and no publicly-held company has an ownership interest of 10 percent or more in Abbott Laboratories.

3. Abbott Laboratories is a company involved in the development, manufacture, and sale of medicines and other health care products.

Dated: February 13, 2008

Respectfully submitted,



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Attorneys for Intervenor-Defendant-Appellee Abbott Laboratories

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I hereby certify that on this 13th day of February, 2008, I served *Abbott's Disclosure Statement* via hand upon:

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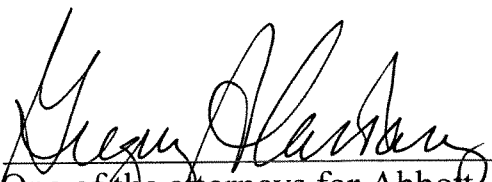

One of the attorneys for Abbott Laboratories

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, ANDREW C. VON ESCHENBACH, M.D., Commissioner of Food and Drugs, Defendants-Appellees, and ABBOTT LABORATORIES, Intervenor-Defendant-Appellee.	No. 08-5017 On appeal from the U.S. District Court for the District of Columbia, in Case No. 08-C-00070

CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Pursuant to Circuit Rule 28, Abbott Laboratories, through counsel, states that:

1. The parties who appeared before the district court and who are before this Court are:

- Nu-Pharm, Inc. (Plaintiff-Appellant);
- Food and Drug Administration (Defendant-Appellee);
- Michael O. Leavitt, Secretary of Health and Human Services (Defendant-Appellee);
- Andrew C. von Eschenbach, Commissioner of Food and Drugs (Defendant-Appellee); and

- Abbott Laboratories (Intervenor-Defendant-Appellee).

2. This case involves review of a judgment of the United States District Court for the District of Columbia, Judge Richard W. Roberts, denying Nu-Pharm, Inc.'s motion for a temporary restraining order and/or preliminary injunction, and dismissing the complaint. (*See* Intervenor-Defendant-Appellee Abbott Laboratories' Response to Nu-Pharm's Motion to Expedite Appeal ("Abbott's Response"), Exhibit A (January 24, 2008 Order in Case No. 1:08-CV-00070).) The district court has not indicated whether this decision will be published. A copy of the district court's order is attached to Abbott's Response as Exhibit A, and the transcript explaining the bases for the district court's judgment was attached to the Motion of Appellant Nu-Pharm Inc. to Expedite Consideration of This Appeal as Exhibit D.

3. There are no related cases pending before this Court. There are, however, related cases pending before other courts, all of which involve Apotex's, and, later, Nu-Pharm's, Abbreviated New Drug Applications for divalproex sodium, which is covered by Abbott's patents. First, there is Abbott's suit against Apotex, Inc. and Apotex, Corp., in the Northern District of Illinois, Case No. 97-C-7515. Summary judgment was awarded in that case to Abbott, and against Apotex, on March 30, 2001. *See Abbott Labs. v. TorPharm, Inc.*, 156 F. Supp. 2d 738 (N.D. Ill. 2001). The Federal Circuit found the patents to be valid, enabled, and

enforceable, but found that an open fact issue precluded summary judgment. *See Abbott Labs. v. TorPharm, Inc.*, 300 F.3d 1367, 1380-81 (Fed. Cir. 2002). On remand, Judge Richard A. Posner, sitting by designation in the Northern District of Illinois, held a bench trial, determined that Apotex's product infringed Abbott's patents, and entered an injunction prohibiting FDA approval of Apotex's ANDA product before Abbott's patents expired. *See Abbott Labs. v. TorPharm, Inc.*, 309 F. Supp. 2d 1043 (N.D. Ill. 2004). The Federal Circuit affirmed this judgment in its entirety. *See Abbott Labs. v. TorPharm, Inc.*, 122 Fed. App'x 511 (Fed. Cir. 2005).

When Nu-Pharm then submitted an ANDA for divalproex sodium, Abbott sued Nu-Pharm in the Northern District of Illinois in Case No. 05-C-3714 before Judge Rebecca Pallmeyer. Abbott moved to enforce Judge Posner's 2004 Injunction Order against Apotex in 2006, when it learned that Nu-Pharm was merely an alter ego or tool of Apotex. On October 6, 2006, Judge Posner again ruled in Abbott's favor, this time extending his injunction to cover Nu-Pharm's ANDA product. *See Abbott Labs. v. Apotex, Inc.*, 455 F. Supp. 2d 831 (N.D. Ill. 2006). Judge Posner's extension of his previous injunction – and his factual findings regarding infringement and the identity of Nu-Pharm and Apotex – were upheld by the Federal Circuit on October 11, 2007. *See Abbott Labs. v. TorPharm,*

Inc., 503 F.3d 1372 (Fed. Cir. 2007). On January 7, 2008, Apotex petitioned the U.S. Supreme Court for certiorari in that case (No. 07-912).

Dated: February 13, 2008

Respectfully submitted,

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Attorneys for Intervenor-Defendant-Appellee Abbott Laboratories

CERTIFICATE OF SERVICE

I hereby certify that on this 13th day of February, 2008, I served *Abbott's Certificate as to Parties, Rulings, and Related Cases* via hand upon:

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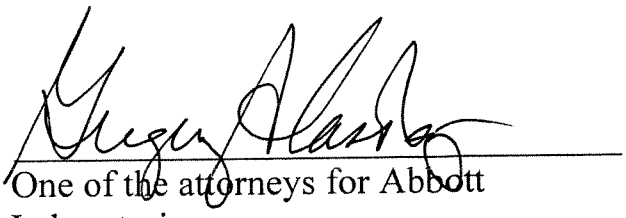

One of the attorneys for Abbott Laboratories

United States Court of Appeals

District of Columbia Circuit
Washington, D.C. 20001-2866

Case Caption: Nu-Pharm Inc.

v.

FDA, et al.

Case No: 08-5017

AMENDED **ENTRY OF APPEARANCE**

Party Information

The Clerk shall enter my appearance as counsel for the following parties:
(List each party represented individually. Use an additional blank sheet as necessary)

Q Appellant(s)/Petitioner(s) Q Appellee(s)/Respondent(s) Q Intervenor(s) Q Amicus Curiae

Abbott Laboratories (Appellee)

Names of Parties

Names of Parties

Counsel Information

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2nd Counsel: Please see attached.

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Firm Address: 51 Louisiana Avenue, N.W., Washington, D.C. 20001

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Notes: This form must be submitted by a member of the Bar of the U.S. Court of Appeals for the D.C. Circuit.
Names of non-member attorneys listed above will not be entered on the court's docket.
Applications for admission are available on the court's web site at http://www.cadc.uscourts.gov/

ADDENDUM TO AMENDED ENTRY OF APPEARANCE FOR ABBOTT LABORATORIES (APPELLEE) IN *NU-PHARM INC. V. FDA, ET AL.*, NO. 08-5017

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*Applications pending for admission to practice before the United States Court of Appeals for the District of Columbia Circuit.

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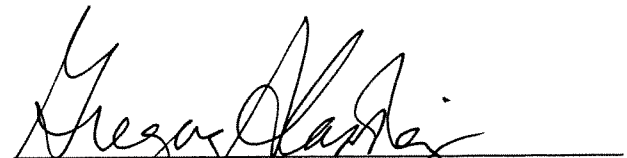

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