IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

MYLAN LABORATORIES INC. and MYLAN PHARMACEUTICALS INC., Plaintiffs, and MUTUAL PHARMACEUTICAL CO., INC., Intervenor-Plaintiff, v. MICHAEL O. LEAVITT, in his official capacity as SECRETARY OF HEALTH AND HUMAN SERVICES, ANDREW C. VON ESCHENBACH, M.D., in his official capacity as COMMISSIONER OF FOOD AND DRUGS, and UNITED STATES FOOD AND DRUG ADMINISTRATION, Defendants, and TEVA PHARMACEUTICALS USA, INC., and APOTEX INC., Intervenor-Defendants.	)	Civil Action No. 07-cv-579 (RMU)

MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF
PLAINTIFFS' APPLICATION FOR A PRELIMINARY INJUNCTION

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INTRODUCTION

Mylan seeks to enjoin the FDA from implementing that part of its April 18, 2007 decision holding that Apotex's ANDA is eligible for approval if the *Pfizer v. Apotex*[1] mandate issues before September 25, 2007. Should the mandate issue, Apotex's ANDA would still be blocked either by pediatric exclusivity or by Mylan's 180-day generic exclusivity. Under the FDA's rules and long-standing practice, Apotex's paragraph IV ANDA automatically converted to a paragraph II ANDA when the last Orange Book patent expired. Section 355a(c)(2)(B) of the Best Pharmaceuticals for Children Act prohibits the approval of *any* paragraph II ANDA during pediatric exclusivity, and the FDA's attempt to reward the second-filer under these circumstances directly contravenes that statute. *See Mova Pharmaceutical Corp. v. Shalala*, 140 F.3d 1060 (D.C. Cir. 1998). Moreover, even if Apotex somehow maintained its paragraph IV certification after patent expiration, § 355(j)(5)(b)(iv) of the Hatch-Waxman Act expressly provides that a paragraph IV ANDA *cannot be approved* until Mylan's 180-day exclusivity period has run.

The FDA has refused to agree to provide this Court with *any* notice prior to approving Apotex's ANDA once the *Pfizer v. Apotex* mandate issues. Because the Federal Circuit could issue its mandate at any time, Mylan faces irreparable harm if the FDA approves Apotex's ANDA and Apotex enters the market, destroying Mylan's right to be free from other generic competition during the statutory period. In order to preserve the *status quo* as well as this Court's jurisdiction to review the FDA's decision to reward the second-filer Apotex at Mylan's expense, the Court should enjoin FDA from approving Apotex's ANDA following issuance of the *Pfizer v. Apotex* mandate until Mylan's claims can be adjudicated on the merits.

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[1] *Pfizer, Inc. v. Apotex, Inc.*, No 2006-1261, 2007 U.S. App. LEXIS 6623 (Fed. Cir. March 22, 2007).

STATEMENT OF FACTS

On May 22, 2002, Mylan became the first ANDA applicant to submit a substantially complete application containing a paragraph IV certification to the patents listed in the Orange Book for the reference listed drug, Norvasc® (amlodipine besylate tablets). Mylan challenged Pfizer's improper patent monopoly on Norvasc a year before the next ANDA filer, Apotex, did so. The FDA granted final approval of Mylan's ANDA on October 3, 2005.

In a letter notifying Mylan that its ANDA had received final approval, the FDA confirmed that because Mylan was the first applicant to file an ANDA with a paragraph IV certification, "Mylan is eligible for 180 days of market exclusivity." *Declaration of Shannon M. Bloodworth in Support of Plaintiffs' Application for a Preliminary Injunction* ("Bloodworth Decl."), Exh. A, October 3, 2005 letter from Gary J. Buehler to Mylan at 2. The letter went on to state, consistent with the plain language of the Hatch-Waxman Act and the FDA's own regulations, that Mylan's 180-day generic marketing exclusivity "will begin to run from the earlier of commercial marketing or court decision dates identified in [21 U.S.C.] section 355(j)(5)(B)(iv)." *Id.* The FDA approved Mylan's amlodipine ANDA despite the fact that in November 2001, the FDA had granted Pfizer so-called pediatric exclusivity pursuant to 21 U.S.C. § 355a. *See* Bloodworth Decl., Exh. B, FDA's Letter Decision dated April 18, 2007 ("FDA Ltr.") at 4.

On September 20, 2002, Pfizer brought suit against Mylan for patent infringement in the United States District Court for the Western District of Pennsylvania (the "Pennsylvania action"). In May 2003, Apotex filed an ANDA with the FDA seeking approval to sell amlodipine besylate tablets prior to the expiration of Pfizer's '303 patent and submitted a paragraph IV certification that its amlodipine besylate products would not violate the '303 patent. On July 30, 2003, Pfizer sued Apotex for patent infringement in the United States

District Court for the Northern District of Illinois (the "Illinois action"). The FDA has not approved Apotex's amlodipine besylate ANDA.

Following a bench trial in the Illinois action, on January 29, 2006, the district court entered judgment dismissing Apotex's invalidity and unenforceability defenses and declaring that Apotex's amlodipine besylate tablets infringed the '303 patent. The district court ordered that the effective date of Apotex's ANDA be no earlier than September 25, 2007 (reflecting the patent term plus six months of pediatric exclusivity) and enjoined Apotex from engaging in commercial activities with respect to amlodipine besylate. Bloodworth Decl., at Exh. C. Apotex appealed the district court judgment to the Federal Circuit.

On February 27, 2007, following a bench trial in the Pennsylvania action, the district court entered judgment dismissing Mylan's invalidity and unenforceability defenses and declaring that Mylan's amlodipine besylate tablets infringed the '303 patent. *See* Bloodworth Decl., at Exh. D. The district court ordered that the effective date of Mylan's ANDA be no earlier than March 25, 2007. *See id.* at Exh. E. Mylan appealed the district court judgment to the Federal Circuit.

On March 22, 2007, the Federal Circuit issued its decision in the *Apotex* case, holding the '303 patent invalid for obviousness under 35 U.S.C. § 103. *See Pfizer, Inc. v. Apotex, Inc.*, No. 06-1261, 2007 U.S. App. LEXIS 6623 (Fed. Cir. Mar. 22, 2007). The following day, the Federal Circuit issued a stay of the district court's order in the Pennsylvania action. *See* Bloodworth Decl., at Exh. F. Later that same day, Mylan began commercial marketing of amlodipine besylate tablets, thereby triggering its 180 days of exclusivity afforded by § 355(j)(5)(B)(iv) of the Hatch-Waxman Act and the FDA's approval letter. *See id.* at Exh. G.

On March 26, 2007, Mylan filed this action and moved for a preliminary injunction prohibiting the FDA from approving any other ANDAs during Mylan's 180-day period of generic exclusivity and the six-month period of pediatric exclusivity. The FDA responded by seeking comments on the applicability and effect of generic and pediatric exclusivity in this case. Bloodworth Decl., at Exh. H. On April 18, 2007, the FDA issued a decision letter ruling that, with one exception, all unapproved ANDAs were blocked by pediatric exclusivity until September 25, 2007. Bloodworth Decl., Exh. B., FDA Ltr. at 9. With respect to Apotex, the FDA ruled that its ANDA *could* be approved if the Federal Circuit were to issue its mandate before September 25, 2007. *Id.*

ARGUMENT

I. LEGAL STANDARDS

Mylan is entitled to a preliminary injunction if it can show "1) a substantial likelihood of success on the merits, 2) that it would suffer irreparable injury if the injunction is not granted, 3) that an injunction would not substantially injure other interested parties, and 4) that the public interest would be furthered by the injunction." *Mova*, 140 F.3d at 1066 (quoting *CityFed Financial Corp. v. Office of Thrift Supervision*, 58 F.3d 738, 746 (D.C. Cir. 1995)). These factors interrelate on a sliding scale and must be balanced against each other. "If the arguments for one factor are particularly strong, an injunction may issue even if the arguments in the other areas are rather weak." *CityFed Fin. Corp.*, 58 F.3d at 746.

II. MYLAN HAS A SUBSTANTIAL LIKELIHOOD OF SUCCEEDING ON THE MERITS OF ITS CLAIM AGAINST THE FDA

Mylan challenges that part of the April 18, 2007 FDA decision holding that Apotex's ANDA is eligible for approval if the *Pfizer v. Apotex* mandate issues before September 25, 2007. The FDA's decision to create an "exception" for Apotex is arbitrary and capricious because even

if the mandate issues before September 25, Apotex's ANDA will still be blocked either by Pfizer's pediatric exclusivity or by Mylan's 180-day generic exclusivity.

A. THE FDA'S DECISION TO MAINTAIN APOTEX'S PARAGRAPH IV CERTIFICATION FOR THE PURPOSE OF ENABLING APOTEX TO AVOID PEDIATRIC EXCLUSIVITY VIOLATES THE PLAIN STATUTORY LANGUAGE, THE FDA'S OWN PRECEDENTS, AND IS ARBITRARY, CAPRICIOUS, AND CONTRARY TO LAW.

In its April 18 decision, the FDA correctly ruled that Pfizer maintains pediatric exclusivity[2] despite the panel decision in *Pfizer v. Apotex* because (1) the mandate has not issued, and (2) the panel decision invalidated only claims 1-3 of the '303 patent, leaving the remaining claims unaffected and the '303 patent "validly listed in the Orange Book." FDA Ltr. at 5-7, 9-10. Inexplicably, however, the FDA ruled that while all other ANDAs are blocked until the mandate issues, "if and when the mandate finalizing the panel's decision issues in the *Apotex* case, Apotex's ANDA will not be blocked by Pfizer's pediatric exclusivity." *Id*. at 9.

When the '303 patent expired on March 25 of this year, Apotex held an unapproved paragraph IV certification. Under longstanding FDA policy and practice, "upon patent expiry, all ANDA applicants are presumed to have paragraph II certifications, [and] the paragraph II provision of the pediatric exclusivity statute, 21 U.S.C. § 355a(c)(2)(A)(i) [] control[s]." FDA Ltr. at 8. That section provides:

[2] The six-month period of pediatric exclusivity was established by the passage of the *Food and Drug Administration Modernization Act of 1997*, Pub. Law 105-115, 111 Stat. 2296 (Nov. 21, 1997). It was reenacted and enhanced in 2002 as the *Best Pharmaceuticals for Children Act*, Pub. Law 107-109, 115 Stat. 1408 (Jan. 4, 2002). Pediatric exclusivity affords a six-month period of marketing exclusivity following expiration of the listed patent during which the FDA may not grant final approval to any ANDA. *See* 21 U.S.C. § 355a (2002). Its purpose is to encourage pharmaceutical companies to study the effects of their drugs in the pediatric population.

> if the drug is the subject of—
>
> > (i) a listed patent for which a [paragraph II] certification has been submitted . . . and for which pediatric studies were submitted prior to the expiration of the patent (including any patent extensions) . . .
> >
> > * * *
> >
> > the period during which an application may not be approved under section 505(c)(3) or section 505(j)(5)(B)(ii) *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)(2)(A)(i) (emphasis added). The language chosen by Congress is clear and unambiguous – upon the patent's expiration, the period during which the FDA may not approve paragraph II ANDAs "*shall*" be extended by six months. There is nothing in the language of subsection (c)(2)(A) that permits an inquiry into whether the patent was held valid or infringed, or whether there was a "favorable decision" that the patent is invalid or not infringed. This analysis applies only to those ANDAs that contain a paragraph IV certification and are accordingly governed by subsection (c)(2)(B). The FDA cannot read the requirements of (c)(2)(B) into (c)(2)(A). *See Western Union Tel. Co. v. FCC*, 729 F.2d 811, 817 (D.C. Cir. 1984) (stating that the agency "cannot simply ignore Congress' words and attempt to write a new statute out of whole cloth"); *cf. Teva Pharms., Indus., Ltd. v. FDA*, 355 F. Supp. 2d 111, 115 (D.D.C. 2004) (rejecting Teva's argument that the FDA acted contrary to the purpose of the FDCA because the plain language of the statute was clear). If the FDA or others (such as Apotex) disagrees with this plain language, then their grievance lies not with the FDA or this Court, "but with the response of the Congress." *Williams Natural Gas Co. v. FERC*, 943 F.2d 1320, 1329 (D.C. Cir. 1991).

The FDA's decision to maintain Apotex's paragraph IV certification is contrary to the FDA's long-standing, well-established rules and policies. For years, the FDA has consistently held that all tentatively approved ANDAs containing a paragraph IV certification *automatically*

become paragraph II certifications upon the relevant patent's expiration. *See Mylan v. Thompson,* 332 F. Supp. 2d 106, 114 (D.D.C. 2004), *aff'd,* 389 F.3d 1272 (D.C. Cir. 2004). The FDA has based this position on 21 U.S.C. § 355(j)(4)(K), which precludes the FDA from approving any ANDA that "contains an untrue statement of material fact." *See also* 21 C.F.R. § 314.94(a)(12)(viii)(C)(1) (mandating a certification change "if, at any time before the effective date of the approval of the application, the applicant learns that the submitted certification is no longer accurate"). Even if the applicant fails or refuses to change its certification to a paragraph II upon the patent's expiration, the FDA's long-standing policy is that the certification is "deemed" changed as a matter of law.

The D.C. Circuit has upheld this policy of automatically changing an unapproved ANDA's paragraph IV certification to a paragraph II certification once it becomes (due to expiration of the relevant patent) "at variance with the legal reality." *Mylan v. Thompson*, 389 F.3d 1272, 1281-1282 (D.C. Cir. 2004).[3] The change occurs at "the 'magic moment' of midnight," and pediatric exclusivity immediately attaches. *Ranbaxy Labs. Ltd. v. FDA,* 307 F. Supp. 2d 15, 19 (D.D.C. 2004), *aff'd,* 2004 U.S. App. LEXIS 8311 (D.C. Cir., Apr. 26, 2004); *see also Dr. Reddy's Laboratories, Inc. v. Thompson*, 302 F. Supp. 2d 340, 351 (D.N.J. 2003) ("*DRL*") (upholding the FDA's rationale that, upon patent expiration, a paragraph IV

[3] In *Mylan v. Thompson*, which involved an ANDA for a fentanyl transdermal patch, Mylan had received final approval, which was subsequently converted to tentative approval pursuant to an order by the Vermont district court. The FDA held that because Mylan was a tentatively approved applicant, its paragraph IV certification converted to a paragraph II certification at the time that the challenged patent expired. The D.C. Circuit, affirming the district court, found "the FDA's application of the statutory provisions both reasonable and supported by *Ranbaxy*." 389 F.3d at 1281-83, *aff'g* 332 F. Supp. 2d 106. This is exactly the situation faced by Apotex, which likewise had a paragraph IV certification with tentative approval at the time the '303 patent expired.

certification in a tentatively approved ANDA is no longer accurate and it converts *de facto* or *de jure* to a paragraph II certification at the moment the patent expires).

Throughout its April 18 decision letter, the FDA repeatedly affirmed its commitment to its "long-standing" rule that, upon expiration of the relevant patent, it would "deem" any outstanding paragraph IV certification in an unapproved ANDA to have become a paragraph II certification. *See* FDA Ltr. at 8 ("It has been FDA's long-standing view, that, when a patent expires before pending patent litigation is resolved, ANDA applicants who have not received final effective approval [such as Apotex] are required under Hatch-Waxman, to change their . . . paragraph IV certifications to paragraph II certifications."); *id.* ("[U]pon patent expiry, all ANDA applicants are presumed to have paragraph II certifications[.]"); *id.* at 9 ("When the '303 patent expired on March 25, 2007, all of the unapproved ANDAs were required to change (or deemed to have changed) to paragraph II certifications and became subject to Pfizer's pediatric exclusivity at that time."); *id.* at 10 ("If one or more of the remaining claims qualified the patent for listing as of the time the patent expired, all of the remaining ANDAs who had . . . paragraph IV certifications at the time of patent expiry are required to maintain their paragraph II certifications."); *id.* ("[W]hen a listed patent expires, a paragraph IV certification is no longer accurate. In these circumstances, the statute and FDA's regulations require ANDA applicants to change form a paragraph IV certification… to a paragraph II certification… . In cases where an applicant neglects to amend its certification to a paragraph II certification after a patent expires, FDA will treat it as having done so."); *id.* at 13 ("[A]ll of the remaining unapproved applications change to a paragraph II certification when the patent expires, as they are required to do, they will no longer be applications containing paragraph IV certifications.").

Based on the FDA's court-approved rules and long-standing agency practice, Apotex's ANDA thus should have been converted to a paragraph II application at midnight on March 25. And at that precise point, § 355a(c)(2)(A) of the BPCA unambiguously provides that "the period during which an application may not be approved . . . *shall* be extended by a period of six months after the date the patent expires" (emphasis added). Yet the FDA, relying on an unarticulated "clear Congressional intent," concluded that "where the ANDA applicant has prevailed in the paragraph IV patent litigation," there should be "an exception to the Hatch-Waxman certification provisions." FDA Ltr. at 9. This "exception," according to the FDA, permits it to continue to treat Apotex's ANDA as a paragraph IV certification even though the '303 patent has expired, unlike any other ANDA.

The Administrative Procedure Act ("APA") requires that the "court shall . . . hold unlawful and set aside agency action, findings, and conclusions found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). The FDA's decision to reward Apotex with a statutorily unauthorized exception to pediatric exclusivity violates the plain statutory language and the FDA's own long-standing, court-approved regulations and practices. *See, e.g.*, *National Treasury Employees Union v. Federal Labor Relations Authority*, 404 F.3d 454, 457-58 (D.C. Cir. 2005) ("The Authority's failure to follow its own well-established precedent without explanation is the very essence of arbitrariness."); *id.* at 457 ("It is well established that . . . any agency's 'unexplained departure from prior agency determinations' is inherently arbitrary and capricious in violation of APA § 706(A)(2)."") (quoting *American Federation of Government Employees, Local 2761 v. Federal Labor Relations Authority*, 866 F.2d 1443, 1446 (D.C. Cir. 1989)); *Verizon Telephone Companies v. FCC*, 453 F.3d 487, 497 (D.C. Cir. 2006) ("[A]n agency acting consistently with

its prior actions is generally what makes an agency action not arbitrary[.]"); *The Greyhound Corp. v. Interstate Commerce Comm'n*, 551 F.2d 414, 416 (D.C. Cir. 1977) ("This court emphatically requires that administrative agencies adhere to their own precedents or explain any deviations from them.").

The FDA's newly fashioned nonstatutory "*Apotex* exception" to pediatric exclusivity also is contrary to *Mova Pharm.*, 140 F.3d at 1060, a case in which the D.C. Circuit held that it is the first *filer*, not the first court victor, that receives exclusivity. In *Mova*, the D.C. Circuit, relying on *Chevron*[4] "step one" struck down the FDA's importation into the statute that to receive 180-day exclusivity, the ANDA filer must "successfully defend" the patent litigation. *See id.* at 1069 ("We conclude that the FDA's successful-defense requirement is inconsistent with the unambiguously expressed intent of Congress."). This case is *Mova* all over again. Here again, the FDA is attempting to read into the plain statutory language a benefit for the first ANDA filer to obtain a "favorable decision," even though the statutory language contains no hint of such a reward. *See* FDA Ltr. at 8.[5]

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[4] *Chevron, U.S.A., Inc. v. NRDC, Inc.*, 467 U.S. 837, 842-43 (1984) ("If a court, employing traditional tools of statutory construction, ascertains that Congress had an intention on the precise question at issue, that intention is the law and must be given effect.").

[5] The FDA's unlawful action cannot be justified on the theory that Apotex should receive a benefit for challenging the '303 patent. Any such argument is contrary to Congress's clear intent, because Mylan is entitled by statute to a period of exclusivity. In any event, Apotex did not take any risk in challenging the '303 patent. It was Mylan's defenses that paved the way for all the subsequent challenges to the '303 patent. Those subsequent-filers had the benefit of the extensive discovery conducted in Mylan's case. This was particularly so for Apotex, which adopted wholesale the invalidity and unenforceability defenses that Mylan had already developed, took extensive (and unacknowledged) advantage of Mylan's research and written work product, and even compelled the production of Mylan's expert reports in its litigation. *See* Bloodworth Decl., Exh. I (attaching Apotex's Motion to Compel the production of Mylan's expert reports). The retirement of the district court judge in Mylan's case and an accompanying delay resulted in Apotex's later-filed case going to trial first, and its appeal being decided before Mylan's appeal. But it was Mylan that first developed the legal and expert foundations for the

The FDA cannot avoid the unambiguous language of the BPCA by hiding behind vague and unexplained notions of Congressional intent. The FDA litigated *Ranbaxy* and *DRL* for the express purpose of receiving judicial approval of its policy of automatically converting paragraph IV certifications to paragraph II certifications upon patent expiration. *See Ranbaxy*, 307 F. Supp. 2d at 19; *DRL*, 302 F. Supp. 2d at 351. It is arbitrary and capricious for the FDA to now abandon that policy in order to carry out a statutorily unauthorized goal of rewarding Apotex at Mylan's expense.

B. EVEN IF THE FDA COULD CONTINUE TO TREAT APOTEX'S ANDA AS A PARAGRAPH IV CERTIFICATION, APOTEX WOULD BE BLOCKED BY MYLAN'S 180-DAY GENERIC EXCLUSIVITY.

If the FDA is correct that Apotex's ANDA can maintain its paragraph IV certification despite the expiration of the '303 patent, then the plain language of the 180-day exclusivity provision of the Hatch-Waxman Act precludes the FDA from granting Apotex final approval. The controlling provision reads[6]:

> If the application contains a certification described in subclause (IV) of paragraph (2)(A)(vii) and is for a drug for which a previous application has been submitted under this subsection continuing [sic] such a certification, the application shall be made effective not earlier than one hundred and eighty days after [generic exclusivity has been triggered].

21 U.S.C. § 355(j)(5)(B)(iv) (2002). As the D.C. Circuit has emphasized, the meaning of the "literal language" of this provision is clear: "Section 355(j)(5)(B)(iv) says that, if an applicant has already filed a paragraph IV ANDA, later applications shall be approved 'not earlier than one

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arguments that led to the Federal Circuit's decision that claims 1-3 of the '303 patent are invalid. It was mere happenstance – a toss of the coin – that led Apotex to reach the Federal Circuit first.

[6] Because Mylan submitted its ANDA with a paragraph IV certification to the '303 patent prior to the enactment of the *Medicare Prescription Drug, Improvement and Modernization Act* ("MMA"), Pub. L. No. 108-173 (Dec. 8, 2003), the pre-MMA statute applies. *See* MMA, § 1102(b)(1).

hundred and eighty days after' the commercial-marketing trigger or the court-decision trigger is satisfied." *Mova*, 140 F.3d at 1069; *see also Lamie v. United States Tr.*, 540 U.S. 526, 534 (2004) ("[W]hen the statute's language is plain, the sole function of the courts—at least where the disposition required by the text is not absurd—is to enforce it according to its terms." (internal quotations and citations omitted)). Mylan activated the "commercial-marketing trigger" on March 23, 2007, so it is entitled to 180 days of generic exclusivity against all other paragraph IV ANDAs. Accordingly, even if Apotex could maintain its paragraph IV certification despite years of FDA practice to the contrary, Mylan's 180-day exclusivity still bars Apotex's approval.

Despite the FDA's decision to the contrary, nothing in the text or legislative history of the Hatch-Waxman Act indicates that generic exclusivity is forfeited upon patent expiration. In fact, Congress adopted the generic exclusivity, *inter alia*, to encourage generics to file paragraph IV challenges to the validity of pharmaceutical patents[7] and to reward such challengers for their risk

[7] *See, e.g.*, 152 Cong. Rec. S7922, at S7928 (daily ed. July 19, 2006) (statement of Sen. Leahy) ("[T]he original intent of the Hatch-Waxman law . . . was to provide incentives for generic companies to challenge the validity of patents on medicines and provide incentives for generic companies to manufacture low-cost medicines" and "that [a] generic company would have the exclusive right for 180 days to make the generic version of the patented medicine); 149 Cong. Rec. S15670-03, at S15746 (daily ed. Nov. 24, 2003) (statement of Sen. Schumer) ("Fourth, the generic provisions revamp the 180-day exclusivity incentive provided in the Hatch-Waxman Act. Under the act, the first generic drug company to challenge a patent on a brand drug has the exclusive right to market its drug for 6 months before any other generic can compete. This feature encourages generic applicants to challenge weak patents and brings consumers much quicker access to affordable generic drugs."); 149 Cong. Rec. S8686-03, at S8691 (daily ed. June 26, 2003) (statement by Sen. Hatch) ("The Waxman-Hatch law provides an incentive for generic firms to challenge patents. To encourage generic competitors to pursue patent challenges in a vigorous fashion, the 1984 law provided 180 days of marketing exclusivity in situations where a generic drug firm could show the pioneer's patents were invalidated or not infringed."); Proposed Rule, 180-Day Generic Drug Exclusivity for Abbreviated New Drug Applications, 64 Fed. Reg. 42873, 42874 (Aug. 6, 1999), *withdrawn on other grounds by* 67 Fed. Reg. 212, 66593 (Nov. 1, 2002) ("Given this risk of patent infringement litigation, section 505(j)(5)(B)(iv) of the act provides an incentive for generic drug applicants to file paragraph IV certifications challenging patents that may be invalid, unenforceable, or not infringed by the product that is the subject of the ANDA."); 54 Fed. Reg. 28872, 28895 (July 10, 1989) ("The

and expense. *See, e.g.*, *Mylan Pharms. Inc. v. Henney*, 94 F. Supp. 2d 36, 40 (D.D.C. 2000) ("As an incentive to the first generic maker to expose himself to the risk of costly patent litigation, the Hatch-Waxman regime provides that the first to file a paragraph IV certified ANDA ("the first filer") is eligible for 180-day period of marketing protection, commonly known as the 180-day exclusivity period ("the Exclusivity Incentive"). By its terms, the Exclusivity Incentive affords the first filer protection from competition from subsequent generic makers for 180 days beginning from the earlier of a commercial marketing or court decision.") (internal citations omitted)); 54 Fed. Reg. 28872, 28895 (July 10, 1989) ("The purpose of [the 180-day exclusivity provision] of the act is to reward the *first* applicant to test the scope or validity of a patent… .") (emphasis added)).[8] This purpose can only be accomplished if the first filer challenging the invalid patent is assured of generic exclusivity, regardless of how long the litigation takes. If potential challengers must consider factors such as the speed of various courts' dockets, the possibility that various presiding judges may retire, and other uncontrollable events in deciding whether to challenge invalid patents, then Congress's clear intent will be precluded.

Mylan was the first to file under paragraph IV, and it was the first to be sued by Pfizer for patent infringement. Mylan's case was delayed due to circumstances outside of its control, including a lengthy delay cause by a change of trial judges. That resulted in the unique posture of these cases: Apotex was able to use Mylan's arguments and expert reports in their litigation and go to trial first. Mylan took the risk that was recognized by Congress as critical, and it is

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purpose of [the 180-day exclusivity provision] of the act is to reward the first applicant to test the scope or validity of a patent. . . .").

[8] The 180-day exclusivity incentive for the first paragraph IV filer has proved powerful and productive. According to an FTC report issued in 2002, generic patent challenges have succeeded in 73% of cases. *See* Federal Trade Commission, "Generic Drug Entry Prior to Patent Expiration," July 2002, at 16, available at http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf.

entitled to the reward of generic exclusivity regardless of how long its case took to resolve. The FDA's ruling that the 180-day period of generic exclusivity does not survive patent expiration cannot justify a "departure from the plain meaning of statutory language," and its reliance on vague notions of Congressional intent cannot satisfy this "considerable burden." *Mylan Pharms. Inc.*, 94 F. Supp. 2d at 55-56; *id.* (noting that to depart from the plain language of a statute, there must be a "clear indication of congressional intent at odds with the text of the statute").

III. MYLAN WILL SUFFER IRREPARABLE HARM ABSENT IMMEDIATE INJUNCTIVE RELIEF FROM THIS COURT.

The FDA has refused to agree to give this Court *any* notice prior to approving Apotex's ANDA. As a result, Mylan faces the real danger that the Federal Circuit's mandate will issue and Apotex's ANDA will be approved before this Court can consider the merits of Mylan's objections. Under this scenario, the Court would be presented with a *fait accompli* and Mylan would be denied the opportunity to be heard before the *status quo* is altered – a result that would cause Mylan irreparable harm and render the FDA's action effectively unreviewable. The D.C. Circuit has emphasized that preliminary injunctive relief is particularly appropriate as a means of insulating parties from imminent harm when another party threatens to suddenly alter the *status quo* in a manner that would deprive another of its rights. *See Barrow v. Graham*, 124 F. Supp. 2d 714, 716 (D.D.C. 2000) ("In the absence of facts that would enable a court fully to assess the merits of the parties' respective positions, a TRO may issue to preserve the *status quo* and to prevent imminent harm until a hearing on the request for a preliminary injunction may be held."). In this case, FDA's approval of Apotex's ANDA upon issuance of the mandate would drastically and irrevocably change the *status quo* before Mylan would have an opportunity to respond.

Moreover, courts have repeatedly recognized that a generic drug manufacturer is

irreparably harmed when it is wrongfully deprived of its 180-day period of marketing exclusivity *vis-à-vis* other generic manufacturers. *See Mova Pharm. Corp. v. Shalala,* 955 F. Supp. 128, 131 (D.D.C. 1997) (finding irreparable harm where the FDA deprived a party of its "180-day statutory grant of exclusivity"); *aff'd by* 140 F.3d at 1067, n. 6 (confirming that Mova's loss of its "'officially sanctioned head start' … suffices to show a severe economic impact to Mova," for purposes of satisfying the irreparable harm standard); *Bracco Diagnostics, Inc. v. Shalala,* 963 F. Supp. 20, 29 (D.D.C. 1997) (granting preliminary injunction and acknowledging that "there is a significant economic advantage to receiving first approval and being the first company to enter the market, *an advantage that can never be fully recouped through money damages or by 'playing catch-up'*") (emphasis added); *Boehringer Ingelheim Corp. v. Shalala,* 993 F. Supp. 1, 2 (D.D.C. 1997) (denying injunctive relief, while recognizing that losing "the advantage of being the first to market" amounts to significant harm for purposes of balancing hardships).

Mylan will suffer tremendous and irreparable harm if it is deprived of its opportunity to be heard, and thus its opportunity to protect its 180-day exclusivity rights. Mylan is currently the only generic drug producer approved to sell amlodipine besylate. If Mylan is deprived – before having any opportunity to be heard – of its status as exclusive generic producer, it would lose all of the benefits that it has worked for five years to obtain. Loss of such exclusivity would impair its access to customers and diminish its ability to establish and retain market share. *See Declaration of Brian Roman.*, ¶ 6; *see also, TorPharm Inc. v. Shalala*, No. 97-1925, 1997 U.S. Dist. LEXIS 21983, at *13-14 (Sept. 15, 1997) ("early market entry is critical to success in the … market because competitors will vie for a small number of long-term contracts").

In addition, since Congress has not allowed the FDA to be sued for the type of decision at issue here, Mylan will not be able to recoup any monetary damages from the FDA. *See United*

States v. Mitchell, 445 U.S. 535, 538 (1980); *see also Komongnan v. United States Marshals Serv.*, 471 F. Supp. 2d 1, 4 (D.D.C. 2006) ("In the absence of an express waiver, sovereign immunity precludes suits against the United States and its agencies."). The "discretionary-function exception" of the Federal Tort Claims Act bars any and all claims against the FDA that are "based upon the exercise or performance or the failure to exercise or perform a discretionary function or duty on the part of a federal agency or an employee of the Government, whether or not the discretion involved be abused." 28 U.S.C. § 2680(a). That Mylan's economic damages are unrecoverable more than justifies the limited injunctive relief that it seeks. *See, e.g., Express One Int'l, Inc. v. United States Postal Serv.*, 814 F. Supp. 87, 91 (D.D.C. 1992) (finding irreparable harm supported where the "non-recoverable monetary losses [movant] faces are therefore real and present" and damages exist "for which there is no recourse"); *Hoffman-Larouche, Inc. v. Califano*, 453 F. Supp. 900, 903 (D.D.C. 1978) (noting that "[i]f the order goes into effect, plaintiff will suffer loss of sales and good will for which it would have *no right of recourse*, and thus its injury will be irreparable" (emphasis added)).

IV. THE BALANCE OF THE RELATIVE HARMS FAVORS ENTRY OF AN INJUNCTION.

The injunctive relief that Mylan requests is limited in nature. Mylan is asking only that it be granted the right to be heard *before* the FDA effectuates any approval of Apotex's ANDA. Such limited injunctive relief would harm no other interested party in this case. In fact, such injunctive relief would provide broad-based benefits to both Mylan and the FDA, since such relief would guarantee that both parties will have the opportunity to prospectively address the legality of any change to Apotex's approval status. Both parties will benefit from the court's views on these issues, and both parties will benefit from having these issues resolved *before* any change to the *status quo* is effectuated.

The same principles apply to Apotex and other generic manufacturers, which are legally precluded from entering the market. As such, these parties will suffer no harm if the FDA is preliminarily enjoined from approving Apotex's ANDA. This is particularly true in light of the high likelihood that this Court would find any intervening FDA approval of Apotex's ANDA to have been unlawful, thereby necessitating the *post-hoc* rescission of any such approval. No party's interests would be served by the uncertainty and confusion that would result from such an *ultra vires* FDA action. Apotex – like the FDA and Mylan – all share an interest in preserving the *status quo* pending judicial consideration of the issues raised by this motion.

V. THE PUBLIC INTEREST WILL BENEFIT FROM AN INJUNCTION

On March 26, 2007, this Court ordered that the FDA could not "grant[] any ANDAs at issue in this matter" for two days after it had notified the Court of its intended course of action. The point of this delay was "[t]o ensure that all interested parties have the opportunity to advance their positions to the court on this matter prior to the FDA taking final action on the pending drug approvals." The court entered a similar order on April 10. Now, some two weeks later, the relevant circumstances have not changed. The public interest again will be served by a temporary injunction that requires the FDA to provide notice before it approves Apotex's ANDA, rendering Mylan's suit effectively unreviewable and destroying the *status quo*.

The injunction will allow Mylan to submit a motion that demonstrates why the FDA has no lawful basis for approving the ANDA. If this Court concludes that Mylan is correct—a result that is likely for the reasons explained above—it can then prohibit the FDA from issuing the approval. By enabling the Court to forestall the FDA's unlawful action, the injunction will promote the well-recognized public interest in ensuring that federal agencies faithfully comply with their statutory mandates as prescribed by Congress. *See, e.g., Mylan Pharms. Inc. v.*

Shalala, 81 F. Supp. 2d 30, 45 (D.D.C. 2000) ("It is in the public interest for courts to carry out the will of Congress and for an agency to implement properly the statute it administers."); *see also Jacksonville Port Authority v. Adams*, 556 F.2d 52, 59 (D.C. Cir. 1977) ("[T]here is an overriding public interest . . . in the general importance of an agency's faithful adherence to its statutory mandate."); *Fund for Animals v. Clark*, 27 F. Supp. 2d 8, 15 (D.D.C. 1998) ("[T]he public has a general interest in 'the meticulous compliance with the law by public officials.'"), quoting *Fund for Animals, Inc. v. Espy*, 814 F. Supp. 142, 152 (D.D.C. 1993). The injunction likewise will enable this Court to avoid the wasted resources and the potential for public confusion that would result if the FDA permitted Apotex to begin selling amlodipine besylate products, only to rescind its approval (and force Apotex to pull its products off the shelves) a few days later based on the Court's grant of relief in favor of Mylan.

Finally, the public has a significant interest in "receiving generic competition to brand-name drugs as soon as is possible." *Boehringer*, 993 F. Supp. at 3. The Hatch-Waxman Act promotes this interest by giving generic drug makers a vital incentive to "incur the potentially substantial litigation costs associated with challenging pioneer drug makers' patents." *Mylan Pharms. Inc.*, 81 F. Supp. 2d at 33. That incentive is the 180-day exclusivity period—the very period that the FDA is attempting to take away in this case. An order requiring the FDA to provide notice at least forty-eight hours before it acts will protect Congress's careful and unmistakable incentive structure by briefly delaying the FDA approval so that Mylan, which has incurred significant costs in defending its ANDA and which would be irreparably harmed by the FDA's unlawful action, receives an opportunity to respond.

CONCLUSION

For these reasons, Mylan seeks a preliminary injunction to prevent the FDA from rendering Mylan's suit effectively unreviewable and to preserve the *status quo*. Mylan respectfully requests the Court to enjoin the FDA from approving Apotex's ANDA following issuance of the *Pfizer v. Apotex* mandate until Mylan's claims can be adjudicated on the merits.

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