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 COMMISSION 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)

PLAINTIFFS' OPPOSITION TO
APOTEX'S MOTION FOR PRELIMINARY INJUNCTION

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INTRODUCTION

Apotex, the second paragraph IV filer, challenges the FDA's ruling that it is blocked from entering the market for amlodipine besylate tablets by pediatric exclusivity until the Federal Circuit issues its mandate in *Pfizer v. Apotex*.[1] In the first prong of its application for preliminary injunctive relief, Apotex maintains that the FDA's refusal to give final effect to *Pfizer v. Apotex* until the mandate issues is "not consistent with the statutory language" of the Best Pharmaceuticals for Children Act ("BPCA")[2], and is therefore arbitrary and capricious. Mem.[3] at 5. As we show in Part I, however, the relevant statutory provisions are ambiguous. It is not at all clear when "the court determines that a patent is valid and would be infringed" under the relevant BPCA pediatric exclusivity provision. 21 U.S.C. § 355a(c)(2)(B). Nor is it apparent when that determination is superseded by appellate action. The FDA's decision in this case to await a mandate before terminating pediatric exclusivity is, at the very least, a reasonable construction of the statutory language and is supported by substantial legal and policy considerations.

In the second prong of its application, Apotex asks the Court to require the FDA "to recognize that Mylan's ANDA for amlodipine has not had final approval since Mylan lost in the district court, and send a letter to that effect." Mem. at 14. Putting aside the issue of this Court's power to force the FDA to "recognize" things and send letters, Apotex relegates to a footnote the Federal Circuit's *stay* of the very district court judgment upon which it relies. As we show in

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

[2] Pub. L. No. 107-109, 115 Stat. 1408 (2002).

[3] *Apotex's Motion for a Preliminary Injunction* [Dkt. No. 47].

Part II, the Federal Circuit's stay of the district court's judgment legally prevented the FDA from doing what Apotex now claims it was required to do "by operation of law."

Apotex has no reasonable likelihood of prevailing on either prong of its motion. And as we show in Part III, the equitable factors for preliminary injunctive relief, particularly the balance of harms, weigh heavily against Apotex's application.

For all of these reasons, Apotex's application for a preliminary injunction should be denied in its entirety.

ARGUMENT

I. APOTEX HAS NO REASONABLE LIKELIHOOD OF SUCCEEDING ON THE MERITS OF ITS CHALLENGE TO THE FDA'S DECISION TO AWAIT A MANDATE BEFORE TERMINATING PEDIATRIC EXCLUSIVITY.

In its April 18 decision letter, the FDA considered the question whether the pediatric exclusivity provisions of the BPCA, 21 U.S.C. § 355a(c)(2)(B), govern *when* the *Pfizer v. Apotex* decision should be given effect for purposes of pediatric exclusivity. Ltr.[4] at 5-7. Section 355a(c)(2)(B) provides:

> If the drug is the subject of a listed patent for which a certification has been submitted under [paragraph IV], and in the patent infringement litigation resulting from the certification the court determines that the patent is valid and would be infringed, 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 (including any patent extensions).

21 U.S.C. § 355a(c)(2)(B). According to Apotex, this "statutory language is unambiguous" and requires the FDA in this case to declare an immediate end to pediatric exclusivity, without waiting for the Federal Circuit's mandate. Mem. at 4. The problem, of course, is that calling the statutory language unambiguous does not make it so, and the quoted language above says

[4] Letter from Gary Buehler to ANDA Applicant/Holder for Amlodipine Besylate Tablets, dated April 18, 2007 [Dkt. No. 40-2].

nothing about when the FDA should give effect to an appellate panel decision *reversing* a "court determin[ation] that the patent is valid and would not be infringed."

A. THE AUTHORITIES RELIED ON BY APOTEX DO NOT RENDER THE FDA'S MANDATE POLICY ARBITRARY AND CAPRICIOUS

The FDA's decision not to terminate pediatric exclusivity until a court of appeals decision is final necessarily makes the issuance of the appeals court mandate the operative date, for until then the decision is not final. "A court of appeals' judgment or order is not final until issuance of the mandate; at that time the parties' obligations become fixed." Fed. R. App. P. 41(c) note; *see Mercer v. Duke Univ.*, 401 F.3d 199, 212 n.7 (4th Cir. 2005) (quoting with approval the advisory committee note); *United States v. Simmons*, 923 F.2d 934, 956 (2d Cir. 1991) ("A Court of Appeals decision does not become effective until its mandate issues."); *United States v. Foumai*, 910 F.2d 617, 620 (9th Cir. 1990) ("F]inality of an appellate order hinges on the mandate, as does a defendant's expectation of finality."); *Mary Ann Pensiero, Inc. v. Lingle*, 847 F.2d 90, 97 (3d Cir. 1988) ("An appellate court'' decision is not final until its mandate issues."); *Stewart Park & Reserve Coalition Inc. v. Slater*, 374 F. Supp. 2d 243, 248 n.5 (N.D.N.Y. 2005) (quoting with approval the advisory committee note); *United States v. Swan*, 327 F. Supp. 2d 1068, 1071 (D. Neb. 2004).

Until mandate, the court of appeals retains jurisdiction to amend or otherwise change its decision. *Charpentier v. Ortco Contrs.*, No. 06-60217, 2007 U.S. App. LEXIS 4583, at *7 (5th Cir. Feb. 28, 2007) ("This court retains control over an appeal until we issue a mandate. Before our mandate issues, we have the power to alter or modify our judgment. Accordingly, our decision is not final until we issue a mandate.") (footnotes omitted); *Mariscal-Sandoval v.*

Ashcroft, 370 F.3d 851, 856 (9th Cir. 2004) ("Until the mandate issues, we retain jurisdiction. . . .").[5]

Federal Rule of Appellate Procedure 36, cited by Apotex, does not provide that an appellate "judgment" is final. Mem. at 5-6. To the contrary, the rule permits a party to seek rehearing before the decision is final (i.e., before a mandate issues). Rule 36 governs when "[a] judgment is entered." The time to petition the court of appeals for rehearing (either by the panel or en banc) is calculated from entry of judgment. *See* Fed. R. App. P. 35, 40.

Federal Rule of Appellate Procedure Rule 41(d) prevents a mandate from issuing while a petition for rehearing is pending. Rules 35, 36, 40, and 41(d) work together to ensure that the decision is not final and the court of appeals retains jurisdiction until all appellate rights are exhausted. For that very reason, the FDA chose to wait for the mandate to issue. The FDA acted well within its authority in adopting a rule that "reduces the possibility that an appellate opinion will be relied on and then overturned (through an adverse opinion after rehearing or rehearing en banc) in very short order." Ltr. at 7.

Apotex argues that the FDA should not have relied on the advisory committee notes to Fed. R. App. R. 41(c) – to the effect that a court of appeals judgment or order is not final until issuance of the mandate – without considering the advisory committee notes to Rule 41(d). But the note to Rule 41(d) provides Apotex with no support either: "The Committee's objective is to treat a request for a rehearing en banc like a petition for panel rehearing so that a request for a rehearing en banc *will suspend the finality of the court of appeals' judgment* and delay the running of the period for filing a petition for writ of certiorari[.]" Fed. R. App. P. 41(d) note

[5] The Federal Circuit is currently considering whether to take further action in *Pfizer v. Apotex*; and during last week's status conference Apotex's counsel represented that the court has ordered Apotex to respond to Pfizer's petition by May 1, 2007.

(emphasis added). The note only confirms that a court of appeals' decision is not final until the mandate issues.

In *Hibbs v. Winn*, 542 U.S. 88, 97-98 (2004), the Supreme Court interpreted 28 U.S.C. § 2101(c), which instructs that a petition for certiorari must be filed "within ninety days after the entry of . . . judgment." Supreme Court Rule 13(3) similarly provides that "[t]he time to file a petition for a writ of certiorari runs from the date of entry of the judgment or order sought to be reviewed, and not from the issuance date of the mandate (or its equivalent under local practice)." These provisions are parallel to Federal Rules of Appellate Procedure 35 and 40, which calculate the time to seek rehearing from entry of judgment, not mandate. Like Rules 35 and 40, Rule 41(d) prevents the mandate from issuing while a petition for certiorari is pending, again ensuring that the court of appeals retains jurisdiction until all appellate rights are exhausted.

Hibbs most assuredly does not stand for the proposition that "[t]he Supreme Court recognizes that the entry of judgment is 'an appellate court's final adjudication.'" Mem. at 6. The language quoted by Apotex reads in full: "An appellate court's final adjudication, Congress indicated, makes the time from which the period allowed for a certiorari petition begins to run."[6] In *Hibbs*, the Supreme Court rejected the argument that the period for bringing a petition for certiorari began to run from the entry of judgment, because the court of appeals ordered briefing on whether the case should be reheard en banc. That order "suspended the judgment's finality under § 2101(c) . . . ." 542 U.S. at 97. "In other words, 'while [a] petition for rehearing is pending' or while the court is considering, on its own initiative, whether rehearing should be ordered, '*there is no judgment to be reviewed*.'" *Id*. at 98 (quoting *Missouri v. Jenkins*, 495 U.S. 33, 46 (1990)) (emphasis added).

[6] *See Hibbs*, 542 U.S. at 99-100, not at 96-97, as cited by Apotex.

So too here. Under the Federal Rules of Appellate Procedure, Pfizer's petition for rehearing suspended the finality of the Federal Circuit's Rule 36 judgment and, until that petition is decided, "there is no judgment to be reviewed."

Finally, Apotex appeals to one of the recognized Congressional purposes of the Hatch-Waxman Act, the desire to get "generic drugs to consumers as soon as possible." Mem. at 9-10. But by passing the BPCA, the law the FDA is charged with interpreting in this case, Congress evinced an intent to encourage pharmaceutical companies to conduct pediatric testing of patented drugs. Surely a rule that prematurely terminates pediatric exclusivity would be contrary to that intent. The bottom line is that vague statements of general Congressional purposes are of little or no use in interpreting § 355a(c)(2)(B).

B. THE PLAIN LANGUAGE OF § 355a(c)(2)(B) DOES NOT REQUIRE THE FDA TO DECLARE AN END TO PEDIATRIC EXCLUSIVITY BEFORE THE MANDATE ISSUES

Pediatric exclusivity under § 355a(c)(2) of the BPCA operates by delaying the approval of unapproved ANDAs for six months after a patent expires.[7] Ltr. at 5. The operative subsection of § 355a(c)(2) varies according to the certification issued by the ANDA applicant. *Id*. at 5-6. When the applicant submits a paragraph IV certification, "if . . . in the patent infringement litigation resulting from the certification *the court determines that the patent is valid and would be infringed*, the period during which an application may not be approved . . . shall be extended by a period of six months . . ." *See* 21 U.S.C. § 355a(c)(2)(B)(emphasis added).[8]

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[7] Pediatric exclusivity does not apply to Mylan's ANDA because it received final approval in October of 2005, and "therefore, under the literal terms of the statute, [Mylan's] ANDA cannot be delayed." Ltr. at 5 n.4.

[8] As explained in Plaintiff's April 23, 2007, Motion for Preliminary Injunction, based on its rules and longstanding practice, the FDA should have converted Apotex's unapproved paragraph IV ANDA to a paragraph II certification upon patent expiration. *Memorandum of Points and Authorities in Support of Plaintiffs' Application for a Preliminary Injunction* [Dkt.

(Footnote continued)

Applying the language of § 355a(c)(2)(B) to this case, **"in the patent litigation resulting from the certification,"** i.e., the Northern District of Illinois action brought by Pfizer against Apotex, **"the court"** i.e., the district court for the Northern District of Illinois, **"determin[ed],"** i.e., entered a final judgment, **"that the ['303] patent is valid and infringed."** Under the plain language of the statute, the FDA is, at a minimum, prohibited from approving Apotex's ANDA during the six-month pediatric period. Indeed, this is precisely the relief that Northern District of Illinois entered against Apotex. *See Pfizer Inc. v. Apotex Inc.*, No. 03-5289, 2006 U.S. Dist LEXIS 95778 (N.D. Ill. Jan. 24, 2006) (ordering that "the effective date of any approval of Apotex's Abbreviated New Drug Application No. 76-719 shall be [delayed] … with attached six months of pediatric exclusivity … ending on September 25, 2007.").

As to what happens after that, the statute is silent. Section 355a(c)(2)(B) says nothing about whether, once awarded, pediatric exclusivity is lost as soon as the panel decision overturning the district court's finding of validity and infringement is announced or if it is lost after the mandate issues, or even if it is never lost. Because the statute is silent, the FDA correctly concluded, "that the operative phrase – 'the court determines' – is ambiguous as to the action it describes," and that it was therefore required to consider authority outside the statutory language. Ltr. at 6.

No. 44-2], at 5 ("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]." (quoting Ltr. at 8)); *see generally id.* at 5-11. In that case § 355(a)(c)(2)**(A)** would block Apotex's application without regard to the "court's determin[ation]." For purposes of this opposition only, Mylan assumes that § 355(a)(c)(2)**(B)** applies.

C. THE FDA'S DECISION TO AWAIT THE MANDATE WAS REASONABLE AND SUPPORTED BY SUBSTANTIAL LEGAL AND POLICY CONSIDERATIONS

All that is required of an agency faced with statutory ambiguity is that it make a considered and reasonable judgment under the circumstances. *See Mova Pharm. Corp. v. Shalala*, 955 F. Supp. 128, 130 (D.D.C. 1997), *aff'd*, 140 F.3d 1060 (1998) (stating that deference is applied if Congress has not "'directly spoken to the precise question at issue' and if the agency interpretation is reasonable'") (quoting *Chevron U.S.A., Inc. v. Natural Resources Defense Council*, 467 U.S. 837, 842-43 (1984)); *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971) (court to review whether the agency's decision was based on, *e.g.*, a clear error of judgment). The Court must accord substantial deference to the agency's decision, and, if reasonable, approve it. *See Purepac Pharm. Co. v. TorPharm, Inc.*, 354 F.3d 877, 883 (D.C. Cir. 2004) ("FDA interpretations of the FDCA receive deference[.]").

Here, the FDA found that the word "determines" in § 355a(c)(2)(B) reasonably can be read to mean "the fixing or settling of rights," thus requiring it to wait until the appellate decision is "final" before acting. Ltr. at 6. But the FDA went well beyond dictionary definitions, and the April 18 decision provides the FDA other substantial reasons why the statute should be read in this manner:

- The Federal Rules of Civil Procedure and the commentary to the rules support the FDA's reading of the statute. Ltr. at 6-7. As discussed in the following section, the FDA was correct that under the rules of appellate procedure, finality does not occur until the mandate issues.

- As a matter of policy, parties to paragraph IV litigation are best served by a rule that "errs on the side of greater finality." Such a rule "reduces the possibility that an appellate court opinion will be relied on and then overturned . . . ." Ltr. at 7.

- When the patent holder prevails in the district court, the FDA "applies [the district court] decision, unless it is stayed, in determining issues related to ANDA approval." Ltr. at 7. Thus, a district court order under 35 U.S.C. § 271(e)(4)(A) directing that an unsuccessful paragraph IV challenger's approval date be set "not earlier than the expiration of the patent," unless it is stayed, will be given effect

> once final judgment is entered in the district court, even if that judgment is appealed. If the generic challenger prevails on appeal, the FDA will not grant the required "immediate approval" until the mandate issues.

Each of these reasons is eminently reasonable. Though there may be counter-arguments, the FDA's decision to establish an even-handed, bright line, mandate-based rule that "errs on the side of finality" is at the very least a permissible reading of the statue. That is all that is required. *See Chevron*, 467 U.S. at 843 and n.11 ("The court need not conclude that the agency construction was the only one it permissibly could have adopted to uphold the construction, or even the reading the court would have reached if the question initially had arisen in a judicial proceeding.").

II. APOTEX HAS NO REASONABLE LIKELIHOOD OF SUCCEEDING ON ITS CLAIM THAT MYLAN DOES NOT HAVE FINAL APPROVAL

Mylan's October 3, 2005 final approval letter from the FDA is unequivocal: "the ANDA is approved." *Declaration of Shannon M. Bloodworth In Support of Plaintiffs' Application for a Preliminary Injunction*, Exhibit A [Dkt. No. 44-4]. The FDA has never revoked that approval or "converted" it to tentative. Nonetheless, Apotex contends that when the district court in the Pennsylvania action entered a final judgment that included a § 271(e)(4)(A) order that "approval of Mylan's [ANDA] . . . shall be a date which is not earlier than the date of expiration of the '303 patent," Mylan's final approval "became tentative by operation of law" and has remained "tentative" since then. Mem. at 14. Because Mylan only has tentative approval, Apotex argues, the FDA should "order Mylan to immediately cease interstate distribution of amlodipine besylate tablets." Mem. at 16. Apotex is wrong for at least two reasons.

A. THE DISTRICT COURT JUDGMENT DID NOT "CONVERT" MYLAN'S FINAL APPROVAL TO TENTATIVE BY "OPERATION OF LAW"

Apotex insists that no FDA action was needed to rescind Mylan's final approval because Mylan's final approval became tentative by "operation of law." Mem. at 15. What "law" Apotex is referring to remains unclear. The only support cited by Apotex for its "operation of law" argument is *Mylan Laboratories, Inc. v. Thompson*, 389 F.3d 1272 (D.C. Cir. 2004). But *Thompson* did not hold that a final effective FDA approval is rescinded as a matter of law by a patent court's entry of a § 271(e)(4)(A) order, and is in fact inapposite. In *Thompson*, the D.C. Circuit upheld the FDA's decision to attach pediatric exclusivity upon the patent's expiration to Mylan's ANDA, which had been converted by the FDA to tentatively approved due to a district court's § 271(e)(4)(A) order. *Id*. at 1284.

Although Apotex asserts that "[t]here are no meaningful distinctions between the current amlodipine matter and [*Mylan v. Thompson*]," *Id*. at 1278, there are many major factual distinctions that *Thompson* inapposite, not the least of which is that the conversion to a tentative approval in *Thompson* did not occur by "operation of law," but rather by FDA action. In fact, in *Thompson*, after the Vermont district court's § 271(e)(4)(A) order:

> The FDA corresponded and met personally with representatives of both companies to discuss the matter. In a letter dated June 22, 2004, the FDA issued its administrative decision concluding that, as a result of the change in the effective approval date of Mylan's ANDA in the Vermont Court's order, the final approval of Mylan's ANDA had been reclassified and Mylan's prior, finally approved ANDA, was now a "tentative approval."

Mylan Labs, Inc. v. Thompson, 332 F. Supp. 2d 106, 114 (D.D.C.), *aff'd*, 389 F.3d 1272 (2004). In the letter to Mylan, the FDA explicitly stated that "in light of [the Vermont district court's] decision, the Agency hereby rescinds the final approval of ANDA 76-258 issued on November 21, 2003, and regards ANDA 76-258 as tentatively approved." *Thompson*, 389 F.3d at 1278; *Declaration of Shannon M. Bloodworth in Support of Plaintiffs' Opposition to Apotex's Motion*

for Preliminary Injunction (hereinafter "Bloodworth Decl."), Exh. A, Letter from FDA to Mylan rescinding final approval and issuing tentative approval. Here, the FDA has taken no such action.[9]

Apotex's reliance on *Thompson* is particularly misplaced given that *Thompson* is dispositive of why Apotex – an ANDA filer that never received final FDA approval – is barred from marketing its amlodipine besylate products by the six-month period of pediatric exclusivity. As in the case *Thompson*, Apotex had a tentatively approved ANDA at the time of the patent's expiration. Under the holding in *Thompson*, "at the time the applicable patent expired" Apotex's tentatively approved ANDA with its "paragraph IV certification was automatically converted to a paragraph II certification (patent expired)." Mem. at 15. As Apotex "then had a tentatively approved paragraph II ANDA on the date of patent expiration, final approval was blocked for an additional six months after patent expiration by 21 U.S.C. § 355a(c)(2)(A)(i)." *Id.* It is Apotex, not Mylan, that is therefore barred by the six-month period of pediatric exclusivity.

B. APOTEX IGNORES THAT THE DISTRICT COURT'S § 271(e)(4)(A) ORDER WAS STAYED BY THE FEDERAL CIRCUIT

Within a week of issuance, the district court's § 271(e)(4)(A) order was stayed by the Federal Circuit. Upon the entry of the stay, the FDA properly refused to act to reset the effective date of Mylan's approval. As the FDA explained in its April 18th letter decision,

[9] *Thompson* aside, Apotex's arguments would render several FDA regulations superfluous. For example, the FDA defines a "listed drug" as "*evidenced* by the drug product's identification as a drug with an effective approval in the current edition of FDA's "Approved Drug Products with Therapeutic Equivalence Evaluations" [also commonly called the "Orange Book"]. . . as a drug with an effective approval." 21 C.F.R. § 314.3(b) (emphasis added). It would be impossible for the effective approvals to be deemed meaningless by operation of law, as some action by the FDA must be taken in order for the product to be delisted from the Orange Book. Here, Mylan's amlodipine besylate products were never delisted from the Orange Book. *See* Bloodworth Decl., Exh. B., excerpts from the Orange Book listing Mylan's products, dated March 21, 2007 (five days after the District Court's amendment judgment).

> [B]efore FDA took such action [to convert Mylan's final approval to tentative approval], the Federal Circuit stayed the district court injunction in that litigation. After that stay, *FDA had no basis* to convert the approval status of Mylan's ANDA from approved to tentatively approved.

Ltr. at 5-6 n.4 (emphasis added); *see also id.* at 7 ("When the district court decides a patent issue, FDA applies that decision, unless it is stayed, in determining issues related to ANDA approval.").

The FDA is charged with the fair and just administration of the nation's food and drug laws. *See Environmental Defense Fund, Inc. v. Costle*, 657 F.2d 275, 283 (D.C. Cir. 1981) ("While we are admonished from "rubber stamping" agency decisions as correct, our task is complete when 'we find that the agency has engaged in reasoned decisionmaking within the scope of its Congressional mandate.'") (quoting *American Radio Relay League, Inc. v. FCC*, 617 F.2d 875, 879 (1980)) (internal citations omitted)). Improvident action by the FDA would have rendered the Federal Circuit's stay meaningless, indeed it would have deprived the Federal Circuit of the ability to review the district court's judgment. Such an outcome would eviscerate the stay, whose very purpose is to protect a party from losing rights that cannot be regained should the party be successful on appeal. *See, e.g.*, *In re Combined Metals Reduction Co.*, 557 F.2d 179, 188 (9th Cir. 1977) ("[A] party who chooses to appeal but who fails to obtain a stay or injunction pending appeal, risks losing its ability to realize the benefits of the successful appeal.") (internal quotation and citation omitted).

Far from being arbitrary and capricious, the FDA's decision to not reset Mylan's approval date in the face of the Federal Circuit stay was reasonable and prudent.[10] Apotex has

[10] The FDA's decision to treat Apotex, an unapproved ANDA holder at the time the patent expired, differently from all the other unapproved ANDA filers, whose paragraph IV certifications were "deemed" to be converted to paragraph II certifications upon the patent's expiration, is particularly arbitrary and capricious. *See Bracco Diagnostics, Inc. v. Shalala*, 963

(Footnote continued)

provided no reason why this Court should not accord deference to the FDA's recognition of the Federal Circuit's stay.

III. THE EQUITABLE FACTORS FAVOR MYLAN.

Because Apotex has failed to show a substantial likelihood of success on the merits, it must make a "very strong" showing of irreparable harm to obtain a preliminary injunction. *Sandoz, Inc. v. Food & Drug Admin.*, 439 F. Supp. 2d 26, 32 (D.D.C. 2006), *aff'd*, 2006 U.S. App. LEXIS 22343 (D.C. Cir. Aug. 30, 2006) (quoting *Apotex, Inc., v. Food & Drug Admin.*, 2006 U.S. Dist. LEXIS 20894, at *16 (D.D.C. April 19, 2006)). Because its allegations of economic losses are overstated, speculative, and remote at best, Apotex has failed to make the requisite showing. Moreover, the balance of harms weighs strongly in Mylan's favor and the public interest favors maintaining the status quo.

A. APOTEX'S CLAIMED HARM IS OVERSTATED AND SPECULATIVE

Apotex argues that, but for the FDA's decision letter denying it final approval, it would be able "to fight for a leadership position in the marketplace as an early entrant" and would enjoy up to a 30 percent share of the amlodipine besylate market. Mem. at 10-11. Those claims are hardly credible, however, given that Apotex currently has *no* share of the amlodipine besylate market, and is currently legally precluded from entering the market under any legal theory. Moreover, even if Apotex *could* enter the amlodipine besylate market in the near future, it would take no more than a tertiary position to the current market leaders (Pfizer and Mylan), thereby rendering its own ultimate market share far from certain. The speculative and theoretical harms

F. Supp. 20, 27-28 (D.D.C. 1997) (FDA "must treat similar cases in a similar manner unless it can provide a legitimate reason for failing to do so. Government is at its most arbitrary when it treats similarly situated people differently." (internal quotations and citations omitted)).

alleged by Apotex are insufficient to constitute irreparable harm. *See Power Mobility Coalition v. Leavitt*, 404 F. Supp. 2d 190, 205 (D.D.C. 2005) (finding no irreparable injury where harm is speculative); *Wisconsin Gas Co. v. Federal Energy Regulatory Com.*, 758 F.2d 669, 674 (D.C. Cir. 1985) (In order to qualify as irreparable injury, "injury must be both certain and great; it must be actual and not theoretical.").

More fundamentally, any asserted harm is purely economic in nature, and – as the D.C. Circuit has repeatedly held – such a harm would not give rise to the level of irreparable harm – especially where the plaintiff has other legal recourse. *See Wisconsin Gas,* 758 F.2d at 674 (D.C. Cir. 1985) (per curiam) ("It is also well settled that economic loss does not, in and of itself, constitute irreparable harm."). Apotex cites no authority from this Circuit to justify its broad-based allegations of harm. Indeed, its primary legal basis is a Third Circuit case stating that "loss of market share constitutes irreparable harm." *Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Consumer Pharms. Co.,* 290 F.3d 578, 595-96 (3d Cir. 2002). Quite apart from the issue of whether Apotex has actually "lost" market share, it is highly unlikely that the articulation of harm in *Novartis* coincides with the prevailing law of this Circuit. *Compare id. with Bristol-Myers Squibb Co. v. Shalala,* 923 F. Supp. 212, 221 (D.D.C. 1996) (concluding that the plaintiff's unsupported claim that it would lose between 50 and 70 percent of its market was insufficient to allege irreparable harm) (citing *Mead Johnson Pharm. Group v. Bowen,* 655 F. Supp. 53 (D.D.C. 1986))).

Finally, Apotex's claim that is has "no legal redress" for its alleged harms rings particularly hollow in light of its recent assertion of a legal claim against Mylan for a bond valued at over $70 million. Apotex cites to no legal authority to support its contention that it lacks any means of legal recourse for its alleged harms. Indeed, it is impossible to reconcile

Apotex's claim that it is helpless and without any possible legal redress, when the company so recently filed claims before this very court for precisely the legal redress that it now claims not to have.

B. THE BALANCE OF HARMS WEIGHS HEAVILY IN FAVOR OF MYLAN

In contrast to the speculative harms that Apotex alleges, Mylan faces real, irreparable harm from the FDA's threatened actions that are imminent, certain and grave. Mylan's harms – unlike Apotex's – are not merely economic in nature; at their core they are legal harms.

Mylan is faced with a sudden deprivation of its statutorily guaranteed legal rights without any advance notice or procedural protections. If Apotex's demand for immediate final approval is granted – either now or after the mandate issues, Mylan would lose its 180-day exclusivity rights without any prior notice or due process of law. This Circuit has acknowledged that preliminary injunctive relief is particularly appropriate as a means of insulating parties from imminent harm when another party (such as Apotex here) 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.").

If Apotex has its way, Mylan would also suffer a complete deprivation of its 180-day exclusivity rights. 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.,* 955 F. Supp. at 131 (finding irreparable harm where the FDA deprived a party of its "180-day statutory grant of exclusivity"),

(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).

As reflected above, on balance, the harm to Mylan from a grant of the relief sought by Apotex greatly outweighs the harm that Apotex would suffer in the absence of such relief. On the other hand, denial of the relief requested by Apotex would – ultimately – benefit all parties. Judicial restraint in this case would avoid a sudden change to the *status quo*, and would ensure that all interested parties (FDA, Apotex, Pfizer, Mylan and others) could be heard by the court before the *status quo* is altered. Issuance of a mandatory injunction requiring the FDA to approve Apotex's ANDA immediately would be disruptive, and, should such an injunction ultimately be reversed upon appeal, it would necessitate the *post-hoc* rescission of any such forced approval. No party's interests would be served by the uncertainty and confusion that would result from such reversals in policy. 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.

C. THE PUBLIC INTEREST IS SERVED BY MAINTAINING THE *STATUS QUO*

The public interest will be served by maintaining the *status quo* and denying Apotex's request for a mandatory injunction that would require the FDA to approve its ANDA immediately. Judicial restraint here would also avoid a situation in which the court intervenes too aggressively and forces the FDA to take actions that are at odds not only with applicable statutory authorities, but also with the FDA's regulations and its longstanding practices (such as the FDA's "deeming policy"). Judicial restraint would thus 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."); *The 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 *The Fund for Animals, Inc. v. Espy*, 814 F. Supp. 142, 152 (D.D.C. 1993)).

Denial of the mandatory injunctive relief requested by Apotex would likewise enable this Court to avoid the wasted resources and the potential for public confusion that would result if the court required the FDA to approve Apotex's ANDA, only to rescind its approval (and force Apotex to pull its products off the shelves) thereafter if the appellate court chose to reverse the mandatory injunction.

CONCLUSION

For all of these reasons, Apotex's motion for a preliminary injunction should be denied in its entirety.

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Respectfully submitted,

/s/ David J. Harth

David J. Harth (#474632)
HELLER EHRMAN LLP
One East Main Street, Suite 201
Madison, Wisconsin 53703
(608) 663-7460

Shannon M. Bloodworth (#474925)
Joseph P. Whitlock (#484247)
HELLER EHRMAN LLP
1717 Rhode Island Avenue, N.W.
Washington, D.C. 20036
(202) 912-2000

E. Anthony Figg (#345124)
Steven Lieberman (#439783)
Minaksi Bhatt (#434448)
ROTHWELL, FIGG, ERNST & MANBECK PC
1425 K Street, N.W.
Suite 800
Washington, D.C. 20005
(202) 783-6040

Stuart A. Williams
Jill Ondos
MYLAN LABORATORIES INC.
1500 Corporate Drive
Suite 400
Canonsburg, Pennsylvania 15317
(724) 514-1840

Attorneys for Plaintiffs
MYLAN LABORATORIES INC. and
MYLAN PHARMACEUTICALS INC.