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March 26, 2007

VIA HAND DELIVERY

Honorable Sharon Prost  
United States Circuit Judge  
c/o Jan Horbaly, Clerk  
United States Court of Appeals  
for the Federal Circuit  
717 Madison Place, N.W.  
Washington, DC 20439

Re: Pfizer Inc. v. Mylan Laboratories, Inc. et al. (2007-1194)

Dear Judge Prost:

On behalf of Pfizer Inc. we are filing herewith the Response that is requested in paragraph 1 of the Court's Order issued on March 23, 2007. For the reasons stated in the Response, as the result of Mylan's commercial launch of its generic Norvasc® product last Friday, Pfizer has suffered, and will continue to suffer injury that is both extremely severe and irreparable. Pfizer urgently needs relief from the Court. Specifically, it requests that the temporary stay in paragraph 3 of the Court's March 23, 2007 Order be lifted forthwith.

We very much appreciate the Court's attention to this matter.

Respectfully submitted,



David O. Bickart

cc: David J. Harth, Esq.  
E. Anthony Figg, Esq.

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US COURT OF APPEALS  
FEDERAL CIRCUIT

No. 2007-1194

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*United States Court of Appeals*  
*for the*  
*Federal Circuit*

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PFIZER INC.,

*Plaintiff-Appellee,*

v.

MYLAN LABORATORIES, INC.  
and MYLAN PHARMACEUTICALS, INC.,

*Defendants-Appellants.*

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*Appeal from the United States District Court for the Western District of  
Pennsylvania in case no. 2:02-CV-1628, Judge Terrence F. McVerry*

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**RESPONSE OF PLAINTIFF-APPELLEE PFIZER INC.  
PURSUANT TO THE COURT'S MARCH 23, 2007 ORDER**

FILED  
U.S. COURT OF APPEALS FOR  
THE FEDERAL CIRCUIT

MAR 26 2007

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**MARCH 26, 2007**

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## CERTIFICATE OF INTEREST

Counsel for the appellee, Pfizer Inc., certifies the following:

1. The full name of every party or amicus represented by me is:

Pfizer Inc.

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

N/A

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:

None

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this Court are:

Kaye Scholer LLP; Milton Sherman, Richard G. Greco, Betty A. Ryberg, Joseph V. Saphia, Daniel A. Boglioli, Sapna Walter Palla, Regina O. Kent, Donald Cameron, and David Bickart.

Thorp, Reed & Armstrong, LLP; C. James Zeszutek, and John J. Richardson.

March 26, 2007



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## TABLE OF CONTENTS

	<u>Page</u>
PRELIMINARY STATEMENT.....	1
STATEMENT OF FACTS.....	2
Events Preceding This Court’s March 23, 2007 Order.....	2
This Court’s March 23, 2007 Order.....	4
Events Subsequent To This Court’s March 23, 2007 Order.....	4
ARGUMENT .....	5
I.    How The FDA Applies Pediatric Exclusivity.....	5
II.   The <i>Apotex</i> Decision Did Not Immunize Any ANDA From Pediatric Exclusivity.....	7
III.  If This Court’s Temporary Stay Is Lifted, The FDA Should Implement Pfizer’s Six-Month Period Of Pediatric Exclusivity As to Mylan .....	9
IV.   Pfizer Has Compelling Grounds For Rehearing.....	10
V.    To Prevent Further Irreparable Injury To Pfizer, This Court Should Lift Its Stay Forthwith And Permit Pediatric Exclusivity To Become Effective .....	12
CONCLUSION .....	14

**TABLE OF AUTHORITIES**

Page(s)

**CASES**

*Alza Corp. v. Mylan Labs., Inc.*,  
391 F.3d 1365 (Fed. Cir. 2004)..... 9

*In re Ackermann*,  
444 F.2d 1172 (C.C.P.A. 1971) ..... 10

*In re Chupp*,  
816 F.2d 643 (Fed. Cir. 1987)..... 10

*In Re Neave*,  
370 F.2d 961 (C.C.P.A. 1967) ..... 10

*In re Papesch*,  
315 F.2d 381 (CCPA 1963) ..... 10

*Mylan Labs., Inc. v. Thompson*,  
389 F.3d 1272 (D.C. Cir. 2004) ..... 10

*Optivus Tech., Inc. v. Ion Beam Applications S.A.*,  
469 F.3d 978 (Fed. Cir. 2006)..... 12

*Pfizer Inc. v. Apotex, Inc.*,  
Docket No. 2006-1261 ..... 1

**STATUTES**

21 C.F.R. § 314.107(b)(3)(ii) ..... 8

21 C.F.R. § 314.107(e) ..... 8

21 U.S.C. 355(j)(5)..... 4

21 U.S.C. § 355a..... 5

21 U.S.C. § 355a(c)(1) ..... 5

21 U.S.C. § 355a(c)(2) ..... 5, 6

	<u>Page(s)</u>
35 U.S.C. § 103 .....	3, 11
35 U.S.C. § 271(e)(2) .....	2, 5
35 U.S.C. § 271(e)(4)(A).....	<i>passim</i>
35 U.S.C. § 271(e)(4)(A).....	2
Fed. R. App. P. 40(a).....	7
Fed. R. App. P. 41(b).....	7
Fed. R. App. P. 41(d)(1).....	7
Fed. R. Civ. Pro. 52 .....	11

**MISCELLANEOUS**

S. Rep. No. 107-79 .....	12
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## PRELIMINARY STATEMENT

On March 23, 2007, this Court directed the parties to submit briefs regarding the effect of the Court's ruling in *Pfizer Inc. v. Apotex, Inc.*, Docket No. 2006-1261 (the "*Apotex Decision*") on ANDA approvals and pediatric exclusivity. As explained herein, the Court's Order held Mylan's motion for a stay in abeyance pending the further consideration of these briefs, and also temporarily stayed the district court's order in an attempt to preserve the *status quo* while it considered the parties' submissions.

However, Mylan took advantage of this Court's order on Friday to irrevocably alter the *status quo*. Approximately one hour after Pfizer received this Court's Order, and while Pfizer was seeking clarification of it, Mylan announced that it had commercially launched its generic Norvasc<sup>®</sup> tablets. Mylan's launch permanently altered the market place and caused Pfizer to suffer severe and irreparable injury. Pfizer irrevocably will lose at least part of the benefit of the pediatric exclusivity period, which has a limited duration of six months. Moreover, it will lose very substantial sales on its blockbuster drug Norvasc<sup>®</sup> for which it has no clear and adequate legal remedy. Pfizer estimates the value of its pediatric exclusivity rights to be approximately \$1 billion.

Pfizer shortly will file a petition for panel and *en banc* rehearing of this Court's March 22, 2007 decision in *Apotex*. Pfizer respectfully requests that

the Court lift its temporary stay in this matter while it considers Pfizer's petition for rehearing. Because Pfizer's injury is both severe and irreparable, Pfizer further requests that the Court lift the temporary stay forthwith. Once the temporary stay is lifted, the district court's amended judgment will have full force and effect. Based on the FDA's prior rulings, Pfizer expects that, based on the § 271(e)(4)(A) order in the amended judgment, the FDA will implement Pfizer's pediatric exclusivity pending this Court's resolution of its petition for rehearing.

### **STATEMENT OF FACTS**

#### **Events Preceding This Court's March 23, 2007 Order**

On March 16, 2007, the U.S. District Court for the Western District of Pennsylvania entered judgment in Pfizer's favor in its Hatch-Waxman action against Mylan (the "Amended Judgment"). The action was brought pursuant to 35 U.S.C. § 271(e)(2)(A) and alleged that Mylan, by filing an Abbreviated New Drug Application ("ANDA") for generic Norvasc<sup>®</sup> tablets, infringed Pfizer's U.S. Patent No. 4,879,303 (the "'303 patent). Pursuant to 35 U.S.C. § 271(e)(4)(A), the Amended Judgment prohibits final approval of Mylan's ANDA until a date not earlier than the expiration date of the '303 patent. The Amended Judgment, pursuant to 35 U.S.C. § 271(e)(4)(B), also enjoins Mylan from commercially

marketing its generic Norvasc<sup>®</sup> tablets until the '303 patent expires at midnight on March 25, 2007.<sup>1</sup>

On March 16, 2007, Mylan moved in the district court to stay the § 271(e)(4)(A) order in the Amended Judgment pending its appeal to this Court. On March 19, 2007 the district court denied Mylan's motion. Thereafter, on March 20, 2007, Mylan moved for a stay of the § 271(e)(4)(A) order in this Court.

On March 22, 2007, this Court issued the *Apotex* Decision, holding that claims 1 through 3 of the '303 patent, the only claims Pfizer asserted in its Hatch-Waxman patent infringement action against Apotex, are invalid as obvious pursuant to 35 U.S.C. § 103. Mylan supplemented its motion for a stay pending appeal based on the *Apotex* Decision on March 22, 2007, and again requested the district court to stay its order. Mylan's request was denied.

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<sup>1</sup> The district court's original judgment enjoined marketing through September 25, 2007, when Pfizer's period of pediatric exclusivity expires, but did not contain an order under 35 U.S.C. § 271(e)(4)(A). After FDA informed Pfizer that it would not effectuate pediatric exclusivity by rescinding its approval of Mylan's ANDA in the absence of an order under 35 U.S.C. § 271(e)(4)(A), the district court amended the judgment to include such an order, and revised the marketing injunction so that it ends on March 25, 2007, the date that the '303 patent expired. The district court thus clearly intended pediatric exclusivity to be applied against Mylan's ANDA. The FDA, however, delayed rescinding Mylan's approval because of Mylan's stay motion before this Court.

circumstances will determine how this works, the nine amlodipine besylate ANDAs of which Pfizer is aware can be divided into two groups, as described below. If not for the stay this Court issued on March 23, Pfizer believes that all of these ANDAs would be subject to pediatric exclusivity at this time.

- a. One group of ANDAs includes those that did not challenge the '303 patent. These ANDAs are subject to pediatric exclusivity pursuant to 21 U.S.C. § 355a(c)(2)(A). The FDA cannot approve these ANDAs unless and until their sponsors challenge the '303 patent and obtain court orders holding the '303 patent invalid or not infringed.
- b. The other group of ANDAs consists of those that challenged the '303 patent; were held to infringe the '303 patent and were thus subject to an order under 35 U.S.C. § 271(e)(4)(A) requiring that their approval not be made effective before expiration of the '303 patent. This group included Mylan's ANDA, until this Court issued the temporary stay on March 23, 2007, and also includes the Apotex ANDA. The FDA cannot approve these ANDAs so long as they are subject to orders under 35 U.S.C. § 271(e)(4)(A). As demonstrated below, the *Apotex* Decision that issued last Thursday did not, in and of itself, modify or reverse any orders under 35 U.S.C. § 271(e)(4)(A). Thus, Pfizer's position is that the FDA cannot

approve any of these ANDAs. The Mylan ANDA holds full FDA approval, notwithstanding the district court order under 35 U.S.C. § 271(e)(4)(A) that required FDA to rescind its approval, only because of the temporary stay that this Court issued on March 23, 2007.

## **II. The *Apotex* Decision Did Not Immunize Any ANDA From Pediatric Exclusivity**

The *Apotex* Decision is not final and has no legal effect unless and until this Court issues a mandate implementing the decision. No mandate may issue until the later of seven days following expiration of the time for filing a petition for rehearing, or seven days following disposition of such petition. Fed. R. App. P. 41(b).<sup>2</sup>

Unless and until a mandate issues, Pfizer's position is that the FDA should not give effect to the *Apotex* Decision by altering the approval status of any ANDA, including Apotex's. The FDA's own regulations and guidances support Pfizer's position. FDA guidance on ANDA approvals clearly states that, when a district court's decision of patent infringement in Paragraph IV ANDA

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<sup>2</sup> Pfizer has 14 days following this Court's filing of the decision to file a petition for rehearing. Fed. R. App. P. 40(a). Pfizer will file a petition for rehearing within the 14-day period, and it is making every effort to do so as soon as possible. Issuance of a mandate in the *Apotex* case will be automatically stayed when Pfizer files its petition for rehearing. Fed. R. App. P. 41(d)(1).

### **This Court's March 23, 2007 Order**

On March 23, 2007, this Court issued an Order directing the parties to supply additional information relating to Mylan's stay motion: specifically how the *Apotex* Decision affects Pfizer's pediatric exclusivity and the FDA's approval of Mylan's ANDA. The Court clearly intended to preserve the *status quo* pending its decision on the stay. Thus, the Court held in abeyance Mylan's stay motion and it *temporarily* stayed the district court's order pending the Court's consideration of the parties' further submissions.

### **Events Subsequent To This Court's March 23, 2007 Order**

Pfizer received the Court's March 23, 2007 Order at 12:02 PM. About an hour later, Mylan irrevocably altered the *status quo*. Relying on the temporary stay issued by this Court, Mylan announced that it had launched its generic version of Norvasc<sup>®</sup>, and thereby triggered its 180-day exclusivity under the Hatch-Waxman statute. 21 U.S.C. 355(j)(5)(B)(iv). Thus, Mylan used the temporary stay provision, which clearly was intended to preserve the *status quo* pending further consideration of these supplemental briefs, to irrevocably alter the *status quo* by launching its product onto the commercial market.

Pfizer has been irreparably injured by Mylan's launch. Regardless of what action this Court, or any other court takes in the future, Pfizer will lose substantial sales of Norvasc<sup>®</sup> to Mylan's generic product, and Pfizer has no legal

remedy to recover its losses. Additionally, Pfizer will lose at least some of the six-month pediatric exclusivity period. At approximately 5:00 pm on March 23, 2007, Pfizer announced that in response to Mylan's launch, Pfizer had launched its own generic version of Norvasc<sup>®</sup>. Pfizer was forced to launch by Mylan's premature action in an attempt to mitigate its sales losses as Mylan sought to flood the supply channels.

## **ARGUMENT**

### **I. How The FDA Applies Pediatric Exclusivity**

Pediatric exclusivity operates as an extension of the data, market, and patent exclusivities that apply to innovative products under provisions of the Hatch-Waxman law. *See generally* 21 U.S.C. § 355a(c)(1) & (2); 35 U.S.C. § 271(e)(2)(A). Pediatric exclusivity attaches at the end of a patent term, and adds six months to the statutory restrictions against FDA approval of ANDAs. *See generally* 21 U.S.C. § 355a. Thus, with respect to Pfizer's '303 patent, which expired on March 25, 2007, the term of pediatric exclusivity runs until September 25, 2007.

Because the statutory restrictions of FDA approval for ANDAs operate individually against each ANDA, pediatric exclusivity also operates individually against each ANDA. Thus, the effect of this Court's *Apotex* Decision must be considered individually against each ANDA. Although individual

litigation is reversed on appeal, the agency cannot approve the pending ANDA until “the date the district court issues a judgment that the patent is invalid, unenforceable, or not infringed *pursuant to a mandate issued by a court of appeals.*” See FDA Guidance For Industry, Court Decisions, ANDA Approvals, and 180-Day Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act, ¶ IV(A) (Mar. 2000) (emphasis added); available at <http://www.fda.gov/cder/guidance/3659fnl.pdf>. FDA regulations regarding ANDA approvals also recognize the importance of avoiding premature agency actions based on judgments that are not final. The regulations require an ANDA applicant to notify the FDA of a “final judgment” in patent litigation, 21 C.F.R. § 314.107(e), and they establish an ANDA’s approval date based on “the date the court enters judgment,” 21 C.F.R. § 314.107(b)(3)(ii).

Even assuming *arguendo* that the FDA were inclined to act on the *Apotex* Decision, the decision has no direct effect on Mylan’s approval status. Only an order in the *Mylan* action can affect Mylan’s approval status. Indeed, until this Court entered its temporary stay, the FDA had expressed its intention to withdraw its final approval of Mylan’s ANDA, even though Mylan had brought the *Apotex* Decision to the FDA’s attention.

**III. If This Court's Temporary Stay Is Lifted, The FDA Should Implement Pfizer's Six-Month Period Of Pediatric Exclusivity As to Mylan**

The '303 patent expired at midnight on Sunday, March 25, 2007.

Neither that event, nor this Court's issuance of the temporary stay on March 23, 2007 moots this case. Both this Court and the FDA may enter orders that implement Pfizer's pediatric exclusivity. If this Court lifts its temporary stay, the § 271(e)(4)(A) order in the Amended Judgment will have full force and effect, even though the stay will have been lifted after the '303 patent expired.

As we described in Pfizer's Response to Mylan's stay motion (Pfizer Response at p. 12), ALZA's patent in the fentanyl case expired while Mylan's appeal from the patent judgment was pending in this Court. By exercising jurisdiction over the appeal, this Court concluded that the § 271(e)(4)(A) order from which Mylan appealed had potential effect after patent expiration. *Alza Corp. v. Mylan Labs., Inc.*, 391 F.3d 1365, 1368 (Fed. Cir. 2004). Had the Court read the § 271(e)(4)(A) order as having no effect after the patent expired, then it would have been required to dismiss Mylan's appeal as moot.

Here, the § 271(e)(4)(A) order was entered on March 16, 2007, before the '303 patent expired. The temporary stay that this Court entered does not render the § 271(e)(4)(A) order moot, even though the temporary stay was in effect when the '303 patent expired. Once the temporary stay is lifted, the § 271(e)(4)(A) order in this case requires that the FDA set an effective approval

