IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

PFIZER INC., Plaintiff and Counterclaim-Defendant, v. MYLAN LABORATORIES INC. and MYLAN PHARMACEUTICALS INC., Defendants and Counterclaim-Plaintiffs.	Civil Action No. 02-CV-1628 Hon. Terrence F. McVerry

DEFENDANTS' MEMORANDUM IN OPPOSITION TO PLAINTIFF'S MOTION TO AMEND THE COURT'S JUDGMENT AND ORDER

INTRODUCTION

Pfizer asks the Court to enter an amended order pursuant to 35 U.S.C. § 271(e)(4)(A) that the "effective date of . . . Mylan's Abbreviated New Drug Application . . . shall be a date which is not earlier than the date of expiration of the '303 patent (March 25, 2007, with attached six months of pediatric exclusivity ending on September 25, 2007, to which Pfizer is entitled) . . ." [Proposed] Amended Judgment, [Dkt. No. 237] at 2. This is the second time Pfizer has requested the Court to enter a delayed effective date for Mylan's ANDA; Pfizer tried to convince the Court to include the same provision in its trial brief. *See Trial Brief of Pfizer* [Dkt. No. 205] at 33-34. The Court declined to do so then and should decline to do so now.

There are at least three reasons why the Court should not include § 271(e)(4)(A) relief in the final judgment:

First, The Hatch-Waxman Act explicitly limits § 271(e)(4)(A) relief to the FDA's grant of *tentative* approval of a Paragraph IV ANDA, in which case the effective date of that approval

is governed by § 355(j)(5)(B)(iii) of the Act. In this case the FDA already has granted *final* approval to Mylan's amlodipine ANDA "effective [October 3, 2005]." The Hatch-Waxman Act does not permit the Court to "order . . . the effective date . . ." of an ANDA that is *already* approved and effective.

Second, even if Mylan's approval were tentative and the Court had the power to reset the effective date, § 355(j)(5)(B)(iii) of the Act provides that § 271(e)(4)(A) relief may only be entered after the district court's judgment "is affirmed" on appeal, making Pfizer's request for that relief premature.

Third, the Hatch-Waxman Act does not permit a court to delay the effective date of an ANDA beyond patent expiration. Pfizer's proposed § 271(e)(4)(A) order seeks to delay Mylan's effective date until expiration of its pediatric exclusivity, an action that can only be taken by the FDA.

Fourth, the order that Pfizer requests is a form of permanent injunctive relief. Pfizer has failed to make the showings required for such relief as set forth in the Supreme Court's recent decision in *eBay v. MercExchange, LLC*, 126 S. Ct., 1837 (2006).

LEGAL BACKGROUND[1]

Congress amended Title 21 of the Federal Food, Drug and Cosmetic Act and Title 35 of the Patent Act when it enacted the *Drug Price Competition and Patent Term Restoration Act of 1984*, now commonly referred to as the "Hatch-Waxman Act."[2] The purpose of the Hatch-Waxman Act was to "make available more low cost generic drugs by establishing a generic drug

[1] Defendants incorporate herein the Background section of their *Memorandum In Support of Their Motion to Amend the Court's Judgment and Order* [Dkt. No. 244-2], submitted yesterday.

[2] The "Hatch-Waxman Act," as used herein, refers to the *Drug Price Competition and Patent Term Restoration Act of 1984*, Pub. L. No. 98-417, 98 Stat. 1585 (1984), codified at 21 U.S.C. §§ 355, 360cc and 35 U.S.C. §§ 156, 271 and 282.

approval procedure." H.R. REP. NO. 98-857(I), at 14 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2647. In enacting the Hatch-Waxman Act, Congress struck a balance between incentives for innovation and incentives "for quickly getting lower-cost generic drugs to market." *Teva Pharms. Indus. Ltd. v. Crawford*, 410 F.3d 51, 54 (D.C. Cir. 2005); *see also In re Barr Labs., Inc. v. Nat'l Assoc. of Pharmaceutical Manufacturers*, 930 F.2d 72, 76 (D.C. Cir.), *cert. denied*, 502 U.S. 906 (1991) (The purpose of the Hatch-Waxman Act was "to get generic drugs into the hands of patients at reasonable prices – fast."); *see also Andrx Pharms., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 802 (D.C. Cir. 2001) ("Although the Congress was interested in increasing the availability of generic drugs, it also wanted to protect the patent rights of the pioneer applicants."), *cert. denied*, 535 U.S. 931 (2002).

The Hatch-Waxman Act lowered the regulatory barriers facing generic drug companies and sought to encourage generic drug companies to challenge patents blocking generic market entry. *See Andrx Pharms., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1371 (Fed. Cir. 2002). To expedite the approval process of generic drugs, the Hatch-Waxman Act permits the submission of an Abbreviated New Drug Application ("ANDA") to the FDA in order to obtain approval to commercially market the generic product. To receive FDA approval, the ANDA needs to establish that its product is bioequivalent and therapeutically equivalent to the branded product – in this case Norvasc®. *See* 21 U.S.C. § 355(j)(2)(A).

Prior to the Hatch-Waxman Act, generic companies were often prohibited from even developing or seeking approval of a generic drug by an innovator's patent. The Hatch-Waxman Act created the safe harbor provisions of § 271(e)(1), which exempts from infringement the making, using, offering to sell, selling or importing of a patented invention if such use is

reasonably related to the development and submission of information under a federal law that regulates drugs. *See* 35 U.S.C. § 271(e)(1).

In order to quickly resolve patent challenges and infringement claims associated with pending ANDAs, Congress created a "highly technical" cause of action for patent infringement under 35 U.S.C. § 271(e)(2) with a specialized menu of remedies listed at § 271(e)(4). *See Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990) ("Not only is the defined act of infringement artificial, so are the specified consequences, [] set forth in paragraph (e)(4)."). "Congress's objective in creating § 271 was to strike a 'careful balance between the policies of fostering the availability of generic drugs and of providing sufficient incentives for research on breakthrough drugs.'" *Bristol-Myers Squibb Co. v. Royce Labs., Inc.*, 69 F.3d 1130, 1133-34 (Fed. Cir. 1995) (quoting *Abbreviated New Drug Application Regulations*, 59 Fed. Reg. 50,338 (1994) (citations omitted)).

Congress sought to encourage the expeditious resolution of any patent infringement claims, and therefore closely tied the statutory triggers for such infringement claims to the ANDA applicant's filing of a certification under § 355(j) of the Hatch-Waxman Act. Section 355(j) requires an ANDA to include one of four possible certifications for each patent that covers the relevant brand name drug listed in the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly called the "Orange Book." *See* 21 U.S.C. § 355(j)(2)(A)(vii). A "Paragraph IV" certification is required for the applicant to sell the ANDA drug prior to the expiration of an Orange Book patent, and must certify that the listed patent – "in the opinion of the applicant and to the best of his knowledge" – is "invalid or will not be infringed by the manufacture, use, or sale of the new [generic] drug[.]" 21 U.S.C. § 355(j)(2)(A)(vii)(IV). The ANDA filer also must provide the patent holder with a notice letter

that sets forth a detailed statement of the basis for the applicant's belief that the patent is invalid or not infringed. *See* 21 U.S.C. § 355(j)(2)(B).

The notice letter is important because the patent holder has 45 days from the receipt of the letter to bring suit against the ANDA filer in order to gain the benefit of the so-called 30-month stay during which the FDA is prohibited from granting final approval of the ANDA. 21 U.S.C. § 355(j)(5)(B)(iii). Also by bringing suit within 45 days, the patentee may, prior to the expiration of the 30-month stay, seek a preliminary injunction prohibiting the ANDA filer from engaging in the commercial manufacture or sale of the ANDA drug until the court decides the issues of patent validity and infringement. 21 U.S.C. § 355(j)(5)(B)(iii)(IV).[3]

In the absence of a 30-month stay, the Hatch-Waxman Act requires that the ANDA be made effective immediately:

> If the applicant made a [paragraph IV] certification … the approval shall be made effective immediately … [.]

§ 355(j)(5)(B)(iii). The FDA's approval of an ANDA becomes effective on the date the agency issues a letter approving the drug. *See* 21 C.F.R. § 314.105(d). Mylan received final approval from the FDA for its amlodipine ANDA on October 3, 2005. *See* Exhibit A, *Defendants' Memorandum in Support of Their Motion to Amend the Court's Judgment and Order* (March 13, 2007) [Dkt. No. 244-4], Letter from G. Buehler to S. Talton, dated October 3, 2005 at 1 (stating that Mylan's "ANDA is approved.").

[3] In this case, Pfizer, whether by design or inadvertence, filed suit *after* the 45-day period provided by§ 355(j)(5)(B)(iii). *See* Exhibit A, *Defendants' Memorandum in Support of Their Motion to Amend the Court's Judgment and Order* (March 13, 2007) [Dkt. No. 244-4], Letter from G. Buehler to S. Talton, dated October 3, 2005 at 2 ("[Mylan] ha[s] notified the agency that Mylan complied with section 505(j)(5)(B) of the Act, and that no action for infringement of the '909 patent… was brought against Mylan, within the statutory 45-day period… .").

ARGUMENT

I. THE COURT SHOULD DECLINE PFIZER'S INVITATION TO COMMIT LEGAL ERROR

A. THE HATCH-WAXMAN ACT EXPLICITLY LIMITS § 271(e)(4)(A) RELIEF TO ANDAS THAT HAVE NOT RECEIVED FINAL APPROVAL

Pfizer's motion contends that the "relief requested is needed to make the judgment comport with the remedies provision of the patent statute, 35 U.S.C. § 271(e)(4)(A)" (Pl.'s Br.[4] at 1), but Pfizer's proposed amended judgment, if granted, would be against the plain language of the Hatch-Waxman Act and cause the Court to commit, not correct a manifest error of law.

The Hatch-Waxman Act comprises two interrelated statutory frameworks that govern the relief available to the patent holder: 35 U.S.C. § 271(e)(4)(A) and 21 U.S.C. § 355(j)(5)(B)(iii). Section 271(e)(4)(A) on its face is limited to ANDAs that have not received final approval, that is, ANDAs that are not already effective:

> (A) the court shall *order the effective date* of any approval of the drug … *to be* a date which is not earlier than the date of the expiration of the patent which has been infringed[.]

35 U.S.C. § 271(e)(4)(A) (emphasis added). The use of the future tense indicates that this relief is available when approval has not taken place and an effective date has not yet been set. A court cannot "order the effective date… " of an ANDA that has *already* become effective. This interpretation is confirmed by the language of companion §§ 271(e)(4)(B) and (C) which provide for injunctive relief and damages, respectively, and expressly apply to an *approved* ANDA. Thus, § 271(e)(4) which, by its terms, provides all of the available remedies, is symmetrical. Subsection A provides the remedy when the ANDA has not yet received final FDA approval and Subsections B and C provide the remedies when, as here, the ANDA has been finally approved.

[4] "Pl.'s Br." as used herein refers to *Pfizer Inc.'s Memorandum of Law in Support of Its Motion to Amend the Court's Judgment and Order* (March 8, 2007) [Dkt. No. 238].

Section 355(j)(5)(B)(iii) of the Hatch-Waxman Act confirms this reading of § 271(e)(4)(A) by providing that § 271(e)(4)(A) relief is available only under two circumstances, set forth in subsections (II) and (IV), none of which is present here:

> **(II)** if before the expiration of such [30-month] period the district court decides that the patent has been infringed—
>
> *** * ***
>
> (bb) if the judgment of the district court is not appealed or is affirmed, the approval shall be made effective on the date specified by the district court in a court order under section 271(e)(4)(A) of title 35, United States Code[.]
>
> *** * ***
>
> **(IV)** if before the expiration of such period the court grants preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent has been infringed, the approval shall be made effective as provided in subclause (II).

21 U.S.C. § 355(j)(5)(B)(iii) (emphasis added). Here, subsection **(II)** does not apply because there was no 30-month in effect due to Pfizer's failure to bring suit within 45 days of receiving Mylan's notice letter. Similarly, subsection **(IV)** does not apply because the Court did not grant a preliminary injunction "before the expiration of" the 30-month period, of which there was none.

The express statutory language of § 271(e)(4)(A) and § 355(j)(5)(B)(iii) of the Hatch-Waxman Act makes clear that this Court lacks the authority to take any action with respect to the effective date of Mylan's ANDA. In the face of this unambiguous statutory language, Pfizer points to § 271(e)(4)(A)'s use of the word "shall." *See* Pl.'s Br. at 2, ¶ 3. But the word "shall" cannot trump § 355(j)(5)(B)(iii), and repeal the checks and balances carefully implemented in the Hatch-Waxman Act. *See FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 132-33 (2000) ("'[T]he words of a statue must be read in their context and with a view to their place in the overall statutory scheme.' … 'A court must [] interpret the statute as a symmetrical and

coherent regulatory scheme,' and 'fit, if possible, all parts into a harmonious whole.'") (citations omitted). Furthermore, the word "shall" in § 271(e)(4)(A) does not mandate the Court to enter such relief, but is instead permissive. Indeed, Judge Posner, in the only published decision that has evaluated the propriety of relief under § 271(e)(4)(A), found that the word "shall" in § 271(e)(4)(A) meant "may." *SmithKline Beecham Corp. v. Apotex Corp.*, 247 F. Supp. 2d 1011, 1049 (N.D. Ill. 2003), *aff'd on other grounds*, 365 F.3d 1306 (Fed. Cir. 2004). In doing so, Judge Posner explained:

> "[S]hall versus may" arguments are weak in general and in this case. As the Supreme Court noted in *Gutierrez de Martinez v. Lamagno*, 515 U.S. 417, 432 n. 9 [] (1995), "Though 'shall' generally means 'must,' legal writers sometimes use, or misuse, 'shall' to mean 'should,' 'will,' or even 'may.' For example, certain of the Federal Rules use the word 'shall' to authorize, but not to require, judicial action. *See, e.g.*, Fed. Rule Civ. Proc. 16(e) ('The order following a final pretrial conference *shall* be modified only to prevent manifest injustice.') (emphasis added); Fed. Rule Crim. Proc. 11(b) (A *nolo contendere* plea '*shall* be accepted by the court only after due consideration of the views of the parties and the interest of the public in the effective administration of justice.') (emphasis added).

Id. at 1049 (citations omitted). On this basis, Judge Posner denied plaintiff § 271(e)(4)(A) relief. *Id.*

Pfizer also relies on *Mylan Labs., Inc. v. Thompson*, 389 F.3d 1272, 1282 (D.C. Cir. 2004) to support its argument that a § 271(e)(4)(A) order is "mandatory when the court holds that the brand-name manufacturer's patent is valid and infringed." Pl.'s Br. at 2, ¶ 3. But Pfizer's reliance on *Mylan* is misplaced. In *Mylan*, the court was faced with an administrative review of the FDA's interpretation of the pediatric exclusivity act, 21 U.S.C. § 355a.[5] *Mylan*, 389 F.3d at 1274. The dispute between the FDA and Mylan arose from Mylan's disagreement

[5] 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) created section 505A of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 355a). The provisions were reenacted and enhanced in 2002 as the *Best Pharmaceuticals for Children Act*, Pub. Law 107-109, 115 Stat. 1408 (Jan. 4, 2002).

with the FDA's interpretation of the *effect* of a § 271(e)(4)(A) order, which was entered by the district court for the district of Vermont in the underlying patent dispute. *Id.* at 1278. The *Mylan* court addressed the propriety of a § 271(e)(4)(A) order in the first instance only in *dicta* and certainly did *not* hold that a § 271(e)(4)(A) order is mandatory. *Mylan*, 389 F.3d at 1280 ("We therefore accord *Chevron* deference to the FDA's letter decision here, as we have previously done on at least one other occasion."); *Cf. SmithKline*, 247 F. Supp. 2d at 1050-1051 (denying § 271 relief and holding that it is a form of injunctive relief and, as such, equitable and not mandatory). What the *Mylan* court did hold was that the FDA's interpretation reasonably resolved a purported statutory ambiguity involving the pediatric exclusivity provision. *See Mylan*, 389 F.3d at 1284.

In this case, it is Pfizer that disagrees with the FDA's refusal to act on Mylan's final approval. *Mylan* stands for the proposition that Pfizer's remedy is to bring an administrative appeal of the FDA's decision not to revoke Mylan's final approval. This Court is bound by the express terms of § 355(j)(5)(B)(iii) of the Hatch-Waxman Act, which does not authorize § 271(e)(4)(A) relief where, as here, the patent holder did not timely bring suit and the FDA has already determined Mylan's ANDA to be effective and approved. Section 355(j)(5)(B)(iii) denies Pfizer the benefit of a 30-month stay and denies Pfizer the benefit injunctive relief pursuant to § 271(e)(4)(A).

B. SECTION 355(j)(5)(B)(iii) MANDATES THAT § 271(e)(4)(A) RELIEF IS ONLY AVAILABLE UPON THE FEDERAL CIRCUIT'S AFFIRMANCE OF THE DISTRICT COURT'S DECISION

Even if the Hatch-Waxman Act permitted the entry of § 271(e)(4)(A) relief, Pfizer's request is still premature. *See Harsco Corp. v. Zlotnicki*, 779 F.2d 906, 909 (3d Cir. 1985). Section 355(j)(5)(B)(iii), as amended by the *Medicare Prescription Drug, Improvement and*

Modernization Act of 2003 ("MMA"), Pub. L. 108-173, 117 Stat. 2066 (Dec. 8, 2003)[6], makes explicit that § 271(e)(4)(A) relief is not available until the Federal Circuit's affirmance on appeal. Prior to the MMA, § 355(j)(5)(B)(iii)(II) (2002) provided,

> [I]f before the expiration of [the 30-month stay] period the court decides that such patent has been infringed, the approval shall be made effective on such date as the court orders under section 271(e)(4)(A) of title 35[.]

As amended, § 355(j)(5)(B)(iii)(II) now provides,

> (II) if before the expiration of such [30-month] period the district court decides that the patent has been infringed—
>
> > (bb) *if the judgment of the district court… is affirmed*, the approval shall be made effective on the date specified by the district court in a court order under section 271(e)(4)(A) of title 35, United States Code[.]

21 U.S.C. § 355(j)(5)(B)(iii) (2006) (emphasis added). The italicized language was added to the statute in order to clarify *when* § 271(e)(4)(A) relief is available and expresses Congress' clear intent that a patentee's eligibility for such relief is premised on the district court's decision being either affirmed on appeal or not appealed.[7]

Similarly, prior to the MMA, § 355(j)(5)(B)(iii)(IV), formerly § 355(j)(5)(B)(iii)(III) provided,

> (III) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent is invalid or not infringed, the approval shall be made effective <u>on the date of such court decision</u>.

---

[6] The MMA amendments to these provisions of 21 U.S.C. § 355(j)(5)(B)(iii) are applicable to this litigation because the litigation was pending on or after December 8, 2003, the MMA's date of enactment. *See* MMA, Section 1101(c)(1).

[7] Mylan has already appealed the district court's judgment and order. *See Defendants' Notice of Appeal to the United States Court of Appeals for the Federal Circuit* [Dkt. No. 235].

21 U.S.C. § 355(j)(5)(B)(iii)(III) (2002) (emphasis added). However, the MMA amended this section by deleting the underlined language and inserting a reference to § 355(j)(5)(B)(iii)(II). Section 355(j)(5)(B)(iii)(IV), as implemented by MMA, now provides,

> (IV) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent has been infringed, the approval shall be made effective *as provided in subclause (II)* [providing that § 271(e)(4)(A) relief may be entered when the district court's decision "is affirmed."].

21 U.S.C. § 355(j)(5)(B)(iii)(IV) (2006) (emphasis added).

Section 355(j)(5)(B)(iii)(II) and (IV) by their own terms make clear that Pfizer – which did not receive a 30-month stay and has not obtained an affirmation of the Court's decision on appeal – has failed to meet a key prerequisite for § 271(e)(4)(A) relief. The Court cannot ignore the "is affirmed" language added by the MMA because although both § 271(e)(4)(A) and § 355(j)(5)(B)(iii) are part of the same statutory scheme, the later amendments to § 355(j)(5)(B)(iii) speaks with greater specificity to the question at hand and was passed almost three decades after § 271(e)(4)(A). *See Brown & Williamson*, 529 U.S. at 132-33 ("[T]he meaning of one statute may be affected by other Acts, particularly where Congress has spoken subsequently and more specifically to the topic at hand."). It is likewise improper to interpret § 271(e)(4)(A) without regard to § 355(j)(5)(B)(iii) because § 355(j)(5)(B)(iii) and § 271(e)(4)(A) are part of the same statutory scheme and need to be interpreted *in pari materia*. *See Ambassador Div. of Florsheim Shoe v. United States*, 748 F.2d 1560, 1565 (Fed. Cir. 1984) (stating that when different statutory provisions are enacted *in pari materia*… "legislative intent to have them work harmoniously together, and for neither to frustrate the other, or partially repeal it, is very much to be inferred").

Section 355(j)(5)(B)(iii)(II) and (IV) are both applicable and directly control whether § 271(e)(4)(A) relief is appropriate in this case. Pfizer failed to meet the statutory prerequisites for § 271(e)(4)(A) relief because it has not yet obtained an affirmation of the district court's rulings on appeal.

C. SECTION 271(e)(4)(A) DOES NOT ALLOW THE COURT TO DELAY MYLAN'S EFFECTIVE DATE DURING THE 6-MONTH PEDIATRIC EXCLUSIVITY PERIOD

In its *Motion to Amend the Court's Judgment and Order* ("Motion to Amend") [Dkt. No. 237], Pfizer asks this Court to revise its order "to make the judgment comport with the remedies provision of the patent statute, 35 U.S.C. § 271(e)(4)(A)" and to set the "effective date of any approval" of Mylan's ANDA to "be a date which is not earlier than the date of expiration of the '303 patent (March 25, 2007, with attached six months pediatric exclusivity ending on September 25, 2007, to which Pfizer is entitled)[.]" Pl.'s Br. at 1; [Proposed] Amended Judgment at 2, respectively. Even if the Court were to determine that § 271(e)(4)(A) relief were available in this case, however, § 271(e)(4)(A) does not give the Court the power to set Mylan's effective date beyond the expiration of the patent.

A patent can be infringed only during the life of the patent. *See, e.g., Lans v. Digital Equipment Corp.*, 252 F.3d 1320, 1328 (Fed. Cir. 2001) ("[T]he district court cannot enjoin [an infringement defendant] from infringing an expired patent. Thus, the district court correctly ruled that [the patentee] has not stated a claim on which relief can be granted."); *Kearns v. Chrysler Corp.*, 32 F.3d 1541, 1550 (Fed. Cir. 1994) ("[W]hen the rights secured by a patent are no longer protectable by virtue of expiration or unenforceability, entitlement to injunctive relief becomes moot because such relief is no longer available"). That fundamental principle is reflected in § 271(e)(4)(A), which provides that the Court can order "the effective date of any

approval of the drug . . . to be a date which is not earlier than the *date of the expiration of the patent*… ." 35 U.S.C. § 271(e)(4)(A) (emphasis added).

This Court recognized this fundamental limit on its own jurisdiction, and on its remedial authority, when it dismissed the case as to the '909 patent, because "[i]t is not disputed that once a patent has expired, injunctive relief is no longer available." *Pfizer Inc. v. Mylan Laboratories, Inc.*, No. 02-1628, 2006 U.S. Dist. LEXIS 75856, *6 (W.D. Pa. Oct. 18, 2006). The Court's earlier decision is consistent with the language of § 271(e)(4)(A), and Pfizer's attempt to extend § 271(e)(4)(A) beyond patent expiration should be rejected on the same basis.

D. PFIZER HAS FAILED TO MAKE ANY SHOWING THAT THE COURT COMMITTED A MANIFEST ERROR IN DENYING PFIZER'S REQUEST FOR INJUNCTIVE RELIEF UNDER § 271(e)(4)(A)

Pfizer asks the Court to enter an Order to delay the effective date of Mylan's *already* effective ANDA. This is Pfizer's second request for such relief. *See Trial Brief of Pfizer* [Dkt. No. 205] at 33-34 (requesting the relief sought in its Complaint). Before Mylan's ANDA received Final Approval, Pfizer sought the following relief:

> A judgment providing that *the effective date of any FDA approval* for Mylan Laboratories and Mylan Pharmaceuticals to make, use, sell, offer for sale, or import the Mylan Amlodipine Tablets described in ANDA No. 76-418 *be no earlier than the date on which the '909 patent term*, as extended by the Patent Term Restoration and the pediatric exclusivity period, expires and no earlier than the date on which the '303 patent term, as extended by the pediatric exclusivity period, *expires*[.]

Complaint [Dkt. No. 1] at 7 (emphasis added). As is obvious from the language employed in the Complaint, Pfizer's requested relief was rooted in 35 U.S.C. § 271(e)(4)(A). However, the Court denied Pfizer's request. Pfizer's Motion to Amend does not set forth any "manifest error of fact or law" on the Court's part. *See Blackiston v. Johnson*, No. 91-5111, 1995 U.S. Dist. LEXIS 13823, at *4 (E.D. Pa. Sept. 21, 1995) ("[I]n order to prevail on a motion to amend or

alter a judgment" . . . the movant carries a heavy burden and "must show that the motion is necessary to correct manifest errors of law or fact").

Indeed, Pfizer not only fails to establish a "manifest error of law or fact," but it also fails to prove that it is entitled to *any* injunctive relief under § 271(e)(4)(A). As Judge Posner explained in *SmithKline Beecham Corp. v. Apotex Corp.*, a § 271(e)(4)(A) order is an injunction:

> Section 271(e)(4)(A) is an amendment to the patent statute and it provides relief in the nature of an injunction, for an injunction is simply a court order (other than a purely procedural one) to do or not to do something. As a form of patent injunction, the delay order is subject to the principles that govern such injunctions….

247 F. Supp. 2d at 1051. Recently, the Supreme Court instructed both district courts and the Federal Circuit to apply "the traditional four-factor framework that governs the award of injunctive relief" in patent cases. *eBay*, 126 S. Ct. at 1841. Therefore, to obtain an injunction, Pfizer had to demonstrate: "(1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction." *eBay*, 126 S. Ct. at 1839. In the proceedings leading up to the February 27, 2007 order, Pfizer failed to do this. This failure is Pfizer's responsibility alone. It cannot be imputed to the Court, as Pfizer now seeks to do.[8] Pfizer has made no showing that it is entitled to injunctive relief under 271(e)(4)(A), and therefore, under the Supreme Court's decision in *eBay*, is not entitled to such relief.

[8] Pfizer tries now instead to convince the Court that § 271(e)(4)(A) relief is mandatory, not equitable. *See* Pl.'s Br. at 2, ¶ 3. Not only is Pfizer's argument off the mark (*see* Section I.A, above), it is too little too late. *See Porter v. NationsCredit Consumer Disc. Co.*, No. 03-03768, 2007 U.S. Dist. LEXIS 286, at *4-5 (E.D. Pa. Jan. 3, 2007) ('"Motions to alter or amend the judgment should be granted sparingly.'" (citation omitted)).

II. PFIZER'S PROPOSED JUDGMENT DOES NOT ACCOUNT FOR MYLAN'S EXEMPTED ACTIVITIES UNDER THE SAFE HARBOR PROVISIONS OF 35 U.S.C. § 271(e)(1)

Pfizer's proposed amended judgment is also too broad because it would improperly enjoin Mylan's use of the amlodipine besylate compound, in spite of Mylan's statutory right to do so under the safe harbor provisions of 35 U.S.C. § 271(e)(1).

Section 271(e)(1) protects Mylan's activities that may be related to obtaining FDA approval:

> (e)(1) It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention … solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

35 U.S.C. § 271(e)(1); *see also Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 202 (2005) ("[I]t [is] apparent from the statutory text that § 271(e)(1)'s exemption from infringement extends to all uses of patented inventions that are reasonably related to the development and submission of *any* information under the FDCA.") (emphasis in original).

Therefore, Mylan requests that the Court refuse to adopt Pfizer's [Proposed] Amended Judgment to the extent that it applies to any use of amlodipine besylate generally.

CONCLUSION

For the reasons set forth above, this Court should deny in its entirety Pfizer's motion to amend the Court's judgment and order.

Date: March 14, 2007

Respectfully submitted,

/s/ Shannon M. Bloodworth
Shannon Bloodworth
HELLER EHRMAN LLP
1717 Rhode Island Avenue, NW
Washington DC 20036
(202) 912-2000

David J. Harth
HELLER EHRMAN LLP
1 East Main Street
Madison Wisconsin 53703
(608) 663-7470

E. Anthony Figg
Steven Lieberman
Minaksi Bhatt
ROTHWELL, FIGG, ERNST
& MANBECK PC
1425 K Street, NW
Suite 800
Washington, DC 20005
(202) 783-6040

Stuart A. Williams
Pa. I.D. No. 28063
Jill Ondos
Pa. I.D. No. 78434
MYLAN LABORATORIES INC.
1500 Corporate Drive
Suite 400
Canonsburg, Pennsylvania 15317
(724) 514-1840

Attorneys for Defendants and Counterclaim-Plaintiffs Mylan Laboratories Inc. and Mylan Pharmaceuticals Inc.

CERTIFICATE OF SERVICE

The undersigned hereby certifies that the foregoing **DEFENDANTS' MEMORANDUM IN OPPOSITION TO PLAINTIFF'S MOTION TO AMEND THE COURT'S JUDGMENT AND ORDER** was electronically filed on March 14, 2007. Notices of filing will be sent to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's System.

/s/ Shannon M. Bloodworth
Shannon M. Bloodworth