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

MEMORANDUM OF MYLAN LABORATORIES INC. AND MYLAN PHARMACEUTICALS INC. IN SUPPORT OF THEIR EMERGENCY MOTION FOR A PARTIAL STAY OF THE MARCH 16, 2007 ORDER OF THE COURT PENDING APPEAL

Mylan seeks a stay of that part of the March 16 Order of the Court, that provides pursuant to § 271(e)(4)(A) that "the effective date of any approval of Mylan's [amlodipine ANDA] . . . shall be a date which is not earlier than the date of expiration of the '303 patent (March 25, 2007)[.]" Order of Court [Dkt. No. 247] at 2. Mylan has obtained final FDA approval of its ANDA, final approval that would otherwise permit Mylan to enter the market immediately upon market expiration. If not stayed, there is a real danger that the Court's order will prompt the FDA to revoke that approval, keeping Mylan off the market even after the patent has expired, much to Mylan's detriment. Only by staying the § 271(e)(4)(A) order can the Court preserve the *status quo* while Mylan seeks expedited appellate review.

FACTS

In November 2001, FDA granted Pfizer a six-month period of so-called "pediatric exclusivity" for Norvasc®. *See* 21 U.S.C. § 355a; *see also Pfizer's Response to Mylan's Motion*

to Dismiss the Claim of Infringement of the '909 Patent for Lack of Subject Matter Jurisdiction [Dkt. No. 172-1], at 4. This protection—which the FDA, alone, grants and administers—is available when a drug maker submits studies demonstrating potential pediatric applications of a drug and the FDA finds the studies acceptable. *See* 21 U.S.C. § 355a(a), (d). Once the FDA grants pediatric exclusivity, the consequence is that the FDA will put off granting final approval of a generic manufacturer's ANDA until six months after the patent has expired. Thus, the protection does not literally grant a drug maker the exclusive right to market a drug during that six-month period post-expiration; but acts to prohibit the FDA from granting final approval to ANDA applicants until the patent's expiration. Since the expiration date of the '303 patent is March 25, 2007, the six-month pediatric exclusivity period, to the extent applicable to a competitor seeking final approval of an ANDA, will expire on September 25, 2007. *See Findings of Fact and Conclusions of Law* [Dkt. No. 233] at 3. In effect, the pediatric exclusivity period applies to all generic competitors except Mylan, thus giving Mylan a six-month head start over generic competitors.

A decision not to stay the Court's injunction would seriously disadvantage Mylan Pharmaceuticals and the public who would be the beneficiaries of a safe, bioequivalent, and affordable alternative to Norvasc®. If the injunction is not stayed, and Pfizer prevails in persuading the FDA to revoke Mylan's final approval, Mylan will lose its opportunity to obtain a first entrant, leadership position in the market for generic amlodipine besylate, and thereby lose the opportunity to capture a sizable portion of the amlodipine market and associated sales that are forecasted to reach the hundreds of millions of dollars – harms for which there is no legal redress. Being the first to launch into the generic marketplace also permits Mylan to retain a greater market share in the long term by securing distribution channels, favorable positioning in

customer supply programs and access to customers. *See Declaration of Brian S. Roman in Support of Mylan's Emergency Motion for a Partial Stay of the March 16, 2007 Order of the Court Pending Appeal* ("Roman Decl.") at ¶ 6. Thus, the market leading position translates directly into a huge and lasting commercial advantage.

ARGUMENT

I. THIS COURT SHOULD STAY THE ORDER TO THE EXTENT THAT IT PURPORTS TO RESET THE EFFECTIVE DATE OF MYLAN'S FINAL APPROVAL.

This Court should grant Mylan's motion to stay the order because Mylan can satisfy the traditional four-factor test: (1) Mylan can make a strong showing that it is likely to succeed on the merits; (2) Mylan will be irreparably injured without a stay; (3) the issuance of the stay will not substantially injure Pfizer; and (4) the public interest supports a stay. *Standard Havens Prods., Inc. v. Gencor Indus., Inc.*, 897 F.2d 511, 512 (Fed. Cir. 1990), *cert. denied*, 506 U.S. 817 (1992) (citing *Hilton v. Braunskill*, 481 U.S. 770, 776 (1987)); *Boehringer Ingelheim Vetmedia, Inc. v. Schering-Plough Corp.*, 106 F. Supp. 2d 696, 708 (D.N.J. 2000) (citing *Standard Havens*). Each factor need not be given equal weight, and the strength of one factor may diminish the showing necessary for another. *See id.* at 512-13 (surveying cases).

A. MYLAN'S APPEAL OF THE DISTRICT COURT'S ORDER IS LIKELY TO SUCCEED ON THE MERITS.

Because this Court has rejected its arguments concerning the impropriety of § 271(e)(4)(A) in these circumstances, Mylan will not belabor them. It bears emphasis, however, that this Court can, and should, grant a stay even if it disagrees with Mylan's position on the merits. "'[I]t is not necessary that [Mylan's] right to final decision'" be "'absolutely certain . . . it will ordinarily be enough that that the [movant] has raised questions going to the merits so serious, substantial, difficult and doubtful as to make them a fair ground for litigation . . . .'"

Standard Havens Prods., Inc., 897 F.2d at 513 (quoting *Hamilton Watch Co. v. Benrus Watch Co.*, 206 F.2d 738, 740 (2d Cir. 1953)). Thus, a stay should be issued either where (1) Mylan "'establishes that it has a strong likelihood of success on appeal, or where, [2] failing that, it can nonetheless demonstrate a *substantial* case on the merits'" along with other factors militating its favor. *Standard Havens Prods., Inc.*, 897 F.2d at 513 (quoting *Hilton*, 481 U.S. at 778) (emphasis added).

On appeal, Mylan will contend that this Court does not have the power, in this patent infringement case, to review, much less revoke, Mylan's final approval. Even if this Court concludes otherwise, the least that can be said is that Mylan "has raised questions going to the merits so serious, substantial, difficult and doubtful as to make them a fair ground for litigation.'" *Standard Havens Prods.*, 897 F.2d at 513 (citation omitted). So long as Mylan can "'demonstrate a *substantial* case on the merits,'" along with a strong showing on the other factors, a stay should be granted. *Id.* at 513 (quoting *Hilton*, 481 U.S. at 778) (emphasis added); *id.* at 512-13 ("When there 'is substantial equity, and need for judicial protection, whether or not movant has shown a mathematical probability of success' then '[a]n order maintaining the status quo is appropriate.'"). We turn next to those other factors.

B. THE OTHER EQUITABLE FACTORS STRONGLY FAVOR A STAY.

The balance of harms overwhelmingly favors a stay of the § 271(e)(4)(A) order. So, too, does the public interest.

1. Mylan Will Be Irreparably Harmed If A Stay Is Not Granted.

A decision not to stay the Order would inflict devastating harm on Mylan and its customers. The FDA has informed Pfizer that it will not revoke Mylan's final approval unless the Court enters a § 271(e)(4)(A) order. *Pfizer's Memorandum of Law in Support of Its Motion to Amend the Court's Judgment and Order* [Dkt. No. 238] at ¶ 4**.** Now that the Court *has*

entered a § 271(e)(4)(A) order, and if this injunction is not stayed, it is likely that Mylan will lose its currently held leadership position in the market for generic amlodipine, and thereby suffer economic losses for which there is no legal redress. As stated above, that translates into a lost opportunity to capture a sizable portion of the amlodipine market and its associated sales, forecasted to reach the hundreds of millions of dollars. *See* Roman Decl. at ¶ 6. The only thing standing between Mylan and this gain is this Court's § 271(e)(4)(A) order, which contravenes the Hatch-Waxman Act, which gives Mylan an officially sanctioned head start over other generic producers. This head start will permit Mylan to secure distribution channels, favorable positioning in customer supply programs, and access to customers, thereby enabling Mylan to retain a greater market share in the long term. *See id.*

If, as Mylan expects, the Federal Circuit eventually concludes that the § 271(e)(4)(A) order was improper, Mylan will have no recourse to recoup its loss. It will never be able to recover its lost market share, and it will not be able to sue Pfizer, or anyone else, for money damages.

2. A Stay Would Not Substantially Harm Pfizer.

While devastating financial losses await Mylan if the § 271(e)(4)(A) order is not stayed, a stay would cause Pfizer no material harm. It would have no impact on Pfizer's exclusive right to use the patented invention during the patent term—which is due to expire in just over a week. Pfizer's grant of pediatric exclusivity only protects it for a period of six months from competition from all generic manufacturers that have not yet received FDA final approval. Because Mylan has already received final approval, Pfizer's pediatric exclusivity has no impact on Mylan. Therefore, a stay permitting Mylan to continue commercial activity would not harm Pfizer, and not granting a stay would provide Pfizer with a windfall.

3. A Stay Best Advances The Public Interest.

The overwhelming weight of various vital public interests favors a stay of the § 271(e)(4)(A) order. Public health will benefit if Mylan is able to increase the availability of life-saving amlodipine products immediately upon expiration of the patent. The public interest will also be advanced by decreasing the costs of amlodipine drugs, mitigating health care costs paid by consumers and both private and government insurers. Similarly, the public interest is served when the amount of protection that Congress bestowed on patents is honored rather than thwarted by an unlawful extension of the life of the patent.

II. A STAY OF THE 271(e)(4)(A) ORDER IS NECESSARY TO PRESERVE THE *STATUS QUO* DURING MYLAN'S EMERGENCY FEDERAL CIRCUIT APPEAL

Mylan's request for a stay of the Court's § 271(e)(4)(A) order, pending the resolution of its motion on appeal, is necessary to preserve the *status quo*. As explained in *Mylan's Memorandum in Support of Their Motion to Amend the Court's Judgment and Order* [Dkt. No. 244-2], at 3-4, the FDA issued final approval to Mylan's ANDA No. 76-418 on October 3, 2005 – roughly 1.5 years ago. Mylan faces irreparable harm if that final approval is now revoked pursuant to a § 271(e)(4)(A) order that Mylan considers legally unsupportable. Once Mylan has lost its final approval, Mylan's ANDA will have to be re-evaluated by the FDA, before the FDA will again issue Mylan final approval. It is FDA's policy to completely review an entire ANDA application, even those with tentative approval, prior to issuing final approval. *See Barr Labs., Inc. v. Thompson*, 238 F. Supp. 2d 236, 245-50 (D.D.C. 2002) (affirming FDA's decision that tentatively approved ANDAs do not have vested right to immediate approval upon patent expiry); 59 Fed. Reg. 50338, at 50352 (requiring a complete review of the application "to determine whether there have been any changes in the conditions under which the application was tentatively approved.").

If the § 271(e)(4)(A) order is not stayed pending appeal, the harm to Mylan will be complete – whether it wins on appeal or not. In such situations, a stay is necessary in order to preserve the *status quo* during the pendency of Mylan's emergency appeal to determine the propriety of the Court's judgment and order. *See AARP v. EEOC*, 390 F. Supp. 2d 437, 462-63 (E.D. Pa. 2005) (granting stay of permanent injunction "where 'the denial of a stay will utterly destroy the status quo, irreparably harming appellants, but the granting of a stay will cause relatively slight harm to appellee, appellants need not show an absolute probability of success in order to be entitled to a stay.'" (quoting *Providence Journal Co. v. FBI*, 595 F.2d 889, 889 (1st Cir. 1979)).

CONCLUSION

For the reasons set forth above, this Court should stay that portion of the March 16 Order of the Court granting relief under 35 U.S.C. § 271(e)(4)(A).

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Respectfully submitted,

/s/ Shannon M. Bloodworth

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