UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF PENNSYLVANIA

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

PFIZER INC.'S OPPOSITION TO MYLAN'S MOTION FOR A STAY OF THE COURT'S AMENDED JUDGMENT

PRELIMINARY STATEMENT

Mylan has no basis to seek the extraordinary remedy of a stay of the Amended Judgment in the face of multiple decisions by the FDA and the courts rejecting its legal position as to the applicability of 35 U.S.C. § 271(e)(4)(A). Mylan wants the Court to act as if it had won the patent infringement suit; but it lost and is subject to the specific remedies of the statute.

Granting Mylan a stay would change the status quo by eliminating the procedural route by which the pediatric exclusivity has been implemented by the FDA, and would effectively reverse this Court's March 16, 2007 decision granting in part Pfizer's motion to amend the Judgment. A stay would irreparably injure Pfizer by shortening or perhaps entirely depriving it of the period of pediatric exclusivity, at least until it could be restored in an independent lawsuit, by which time the market for Norvasc® will have been irretrievably damaged.

The pendency of Mylan's motion might induce the FDA to delay re-setting Mylan's ANDA approval to "tentative" until after the patent expires. If that maneuver were to succeed, Mylan would deprive Pfizer of the benefit of the § 271(e)(4)(A) order. Accordingly the motion should be denied forthwith.

ARGUMENT

A STAY OF THIS COURT'S AMENDED JUDGMENT HAS NO LEGAL BASIS, WOULD IRREPARABLY HARM PFIZER AND WOULD UNFAIRLY DEPRIVE PFIZER OF THE SUBSTANCE OF THE RESULT OF THE TRIAL

A. Pfizer's Right to Pediatric Exclusivity After the Determination That its Patent Is Valid and Enforceable Is Clear

Mylan has not – and cannot – demonstrate any likelihood of success on appeal concerning its interpretation of § 271(e)(4)(A). There is no doubt that Pfizer is entitled to the period of pediatric exclusivity it earned on the '303 patent after the patent was held valid and enforceable for the third time.

As explained in the fentanyl cases discussed in Pfizer's March 16, 2007 reply brief in support of its motion to amend the judgment, the FDA, the D.C. District Court, the Court of Appeals for the District of Columbia Circuit, and the Federal Circuit all have concluded that the § 271(e)(4)(A) order resetting the final ANDA approval must be issued following a determination in an ANDA case that the patent is valid and enforceable. That order, the FDA has ruled, requires that it reset any final approval that it previously gave to an ANDA to a tentative approval. The resetting to tentative approval is the procedural means by which the judgment upholding the patent automatically triggers the period of pediatric exclusivity to which the patent

owner is entitled.[1] Both the D.C. district court and the Court of Appeals for the D.C. Circuit confirmed the FDA's interpretation of the statutory mechanism for implementing pediatric exclusivity. *Mylan Labs., Inc. v. Thompson,* 332 F. Supp. 2d 106 (D.D.C. 2004), aff'd, 389 F.3d 1272 (D.C. Cir. 2004).

The Federal Circuit also affirmed the § 271(e)(4)(A) judgment of the patent court in the fentanyl ANDA cases, relying on its § 271(e)(4)(A) order establishing the right of pediatric exclusivity as the basis for its jurisdiction to hear the appeal after patent expiration. *Alza Corp. v. Mylan Labs., Inc.*, 391 F.3d 1365 (Fed. Cir. 2004).

Mylan itself was a party to all of those decisions and the same arguments it makes here were rejected on every occasion. Against the foregoing array of legal authority, Mylan asserts as its sole basis for a reasonable likelihood of success on the merits its own unsupported statutory interpretation that has been repeatedly rejected by the FDA and the courts in the fentanyl cases.

The result upheld in the fentanyl cases is also the only one that is fair and makes sense. Pfizer has a valid and enforceable patent and it earned a period of pediatric exclusivity. Pfizer is entitled to its full patent term and the full six-month pediatric exclusivity period thereafter.

B. A "Stay" of the Amended Judgment During the Appeal Is the Procedural Equivalent of Reversing the Court's Decision to Amend The Judgment

Delaying FDA implementation of the § 271(e)(4)(A) order until after patent

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[1] When the patent expires and approval is tentative, the ANDA certification is automatically converted to one under paragraph II (an application pending when the patent expires) and an award of pediatric exclusivity attaches as a matter of law. *Mylan Labs., Inc. v. Thompson*, 389 F.3d 1272, 1282 (D.C. Cir. 2004).

expiration could mean that the established mechanism for implementing the pediatric exclusivity right will be lost, based on the FDA's stated position. Accordingly, the stay Mylan seeks is the equivalent of granting Mylan all the benefits it would have received had it won the infringement trial. Moreover, in the absence of the procedural route approved by the FDA, the D.C. Circuit and the Federal Circuit[2], Pfizer would be forced to bring an independent action against the FDA to vindicate its right to pediatric exclusivity. In the meantime, contrary to the policy underlying pediatric exclusivity, Mylan might launch its generic product, irreparably damaging the market even if Pfizer's exclusivity were later restored for a portion of the pediatric period.

C. All The Equities And the Public Interest Favor Denying A Stay

Under the ruling of this Court on the merits of the patent infringement trial, Pfizer is entitled to both its full patent period and the period of pediatric exclusivity. Because Pfizer's patent is valid, enforceable and infringed, Mylan has no right to market a generic copy earlier than another generic drug company. Mylan's assertion that it is entitled to "an officially sanctioned head start over other generic producers" (Mylan Br. at 5) under the Hatch-Waxman Act, beginning when the '303 patent expires, is incorrect. The Hatch-Waxman statute provides that the first ANDA applicant who challenges a patent may be eligible for 180 days of market exclusivity over other generics. This exclusivity is lost, however, when the patent expires or if the exclusivity-holder loses its patent litigation. Thus, Mylan has no entitlement to a "head start"

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[2] Pfizer believes that the FDA is required to reset Mylan's final approval to tentative, regardless of the form of the judgment. Because the FDA has indicated it would not act without an express 271(e)(4)(A) Order, an attempt to vindicate that right through independent remedies before the six-month pediatric exclusivity period expires would be very difficult as a practical matter. Mylan could destroy the value of the market while Pfizer sought to enforce its exclusivity rights.

over other generic companies after expiration of the '303 patent. Rather, Mylan is seeking to gain an unlawful head start by manipulating the mechanisms of pediatric exclusivity. 21 U.S.C. § 355(j)(5)(B)(iv). The fact that it was the first to file an unmeritorious challenge to the valid and enforceable '303 patent covering Norvasc® earns Mylan nothing under the Hatch-Waxman Act.

If the stay is denied and the pediatric period is triggered, Mylan can still proceed with an appeal of the Amended Judgment. Should the Federal Circuit reverse and find that patent was invalid or unenforceable, the exclusivity period would end immediately and Mylan would have the opportunity to enter the market.

On the other hand, if this Court were to grant the stay, Pfizer will be remitted to file an independent action that may not be concluded in time to be effective. Thus, Pfizer could be deprived of its very substantial and valuable rights even though it has been found to be legally entitled to them by this Court, as well as the other two courts which have tried this case. Mylan would gain a windfall of early entry into the market, notwithstanding that its challenge to Pfizer's patents was found to be baseless.

The public interest is best served by enforcing the award of pediatric exclusivity as an inducement for the expense and risk of pediatric studies. The FDA has emphasized the public importance of pediatric exclusivity,[3] and has defended it against Mylan's identical prior efforts to undermine it, stating: "[Mylan's statutory interpretation] makes little sense, and would substantially diminish the incentives for innovator firms to undertake the studies requested by

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[3] In 2001, the FDA advised Congress that the "pediatric exclusivity provision has done more to generate clinical studies and useful prescribing information for the pediatric population than any other regulatory or legislative process to date." *See* S. Rep. No. 107-79, Best Pharmaceuticals for Children Act, at 5.

FDA to earn pediatric exclusivity which was so tenuous and easily evaded." (Ex. 1 to Pfizer's March 16, 2007 Brief, FDA letter, page 13 at fn. 11).

Neither the terms of the statute, nor the application of common sense, reward Mylan for bringing a baseless challenge to a patent (particularly in the face of two prior decisions upholding the patent). Because Pfizer has valid and enforceable patent rights and was awarded a period of pediatric exclusivity, the public interest as expressed in the entire statutory scheme, is that all generic companies simultaneously enter the market only upon the expiration of the pediatric exclusivity period.

CONCLUSION

Pfizer respectfully requests that the Court deny Mylan's motion for a stay forthwith.

Dated: March 19, 2007

Respectfully submitted,

By: /s/ John J. Richardson

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