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 MEMORANDUM OF LAW IN SUPPORT OF ITS MOTION TO AMEND THE COURT'S JUDGMENT AND ORDER

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Attorneys for Plaintiff and Counterclaim-Defendant, Pfizer Inc.

Plaintiff Pfizer Inc. ("Pfizer") submits this brief in support of its motion pursuant to Rule 52(b), Fed. R. Civ. P., to amend the Court's Judgment and Order. Rule 52(b) provides that within ten days of its entry, a judgment may be amended pursuant to motion made by a party. This motion is timely made and, as we demonstrate below, 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). Additionally, because the patent-at-issue soon will expire (March 25, 2007), Pfizer requests that this motion promptly be resolved. A copy of Pfizer's proposed Amended Judgment is attached as Exhibit 1 to Pfizer's motion, filed herewith.

1. As the Court is aware, Mylan Pharmaceuticals, Inc. filed an Abbreviated New Drug Application ("ANDA") seeking FDA approval to market generic copies of Norvasc® tablets, 2.5, 5 and 10 mg dosage strengths ("generic Norvasc® tablets"). In its ANDA, Mylan certified pursuant to 21 C.F.R. 314.94(a)(12)(i)(A)(4) ("paragraph IV certification") that it was seeking approval to market its generic Norvasc® tablets prior to expiration of Pfizer's U.S. Patent No. 4,879,303 (the "'303 patent"). Pfizer thereafter filed this action against Mylan Pharmaceuticals, Inc. and Mylan Laboratories, Inc. (collectively, "Mylan") pursuant to 35 U.S.C. § 271(e)(2)(A), for infringement of the '303 patent. On October 3, 2005, during the pendency of the action, the FDA granted final approval to Mylan's ANDA for generic Norvasc® tablets.

2. After a bench trial held from November 28, 2006 through December 6, 2006, the Court entered the February 27th Judgment and Order based on findings of fact and conclusions of law that Pfizer's '303 patent is valid, enforceable and infringed by Mylan. The Judgment generally resolves the action in Pfizer's favor and against Mylan, and the Order enjoins Mylan from "making, using, selling, offering to sell, or importing into the United States the

Mylan Amlodipine Tablets described in ANDA No. 76-418 until after the expiration of Pfizer's '303 patent term, as extended by the pediatric exclusivity period."

3. The patent remedy statute, 35 U.S.C. § 271(e)(4)(A), provides that if infringement of a valid patent is found, "the court shall order the effective date of any approval of the drug . . . involved in the infringement to be a date which is not earlier than the date of expiration of the patent which has been infringed." (Emphasis supplied.) The Court of Appeals for the District of Columbia held that section 271(e)(4)(A) "directs that upon a finding of infringement the district court establish a new effective date for [final] approval which is 'not earlier than the date of the expiration of the patent which has been infringed.'" *Mylan Labs., Inc. v. Thompson,* 389 F.3d 1272, 1282 (D.C. Cir. 2004). In other words, entry of the section 271(e)(4)(A) order is mandatory when the court holds that the brand-name manufacturer's patent is valid and infringed.

4. Here the Court has held that the '303 patent is valid, unenforceable and infringed by Mylan and enjoined Mylan from launching its generic Norvasc® tablets, but did not include a section 271(e)(4)(A) order in the February 27th Judgment and Order. On February 28, 2007, Pfizer submitted to the FDA this Court's findings of fact and conclusions of law, and the February 27th Judgment and Order. In a telephone conversation on March 7, 2007, the FDA advised Pfizer that the FDA will not reset Mylan's effective approval date without a judgment including a section 271(e)(4)(A) order. While we disagree with the FDA's view, we nonetheless are filing this motion for an Amended Judgment to carry out the Court's clear intent and to make that intent clear to the FDA. Accordingly, Pfizer's proposed Amended Judgment adds to the February 27th Judgment and Order the directive that is mandated by the patent statute.

5. In addition, the proposed Amended Judgment has a few minor changes unrelated to the section 271(e)(4)(A) order. The February 27th Judgment and Order does not specifically address Mylan's counterclaims seeking declarations that the '303 patent is invalid, unenforceable or not infringed. Dismissal of those counterclaims directly and necessarily follows from the Court's findings that the '303 patent is valid, enforceable and infringed and removes any question that Mylan's counterclaims remain alive. Accordingly, Pfizer's proposed Amended Judgment includes a provision specifically dismissing all of Mylan's counterclaims. The final paragraph of the proposed Amended Judgment, which grants Pfizer injunctive relief, has been revised slightly for purposes of clarity.

6. For the foregoing reasons Pfizer requests that the Court grant its motion and enter its proposed Amended Judgment. Furthermore, Pfizer respectfully requests that such relief be granted on or before March 20, 2007, so that Pfizer can present the Amended Judgment to the FDA in sufficient time for it to act prior to March 25, 2007 (Sunday), the expiration date of the '303 patent.

Dated: March 8, 2007

Respectfully submitted,

By: /s/ John J. Richardson

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