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

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

DEFENDANTS' MEMORANDUM IN SUPPORT OF THEIR MOTION TO AMEND THE COURT'S JUDGMENT AND ORDER

INTRODUCTION

For almost fifteen years Pfizer has enjoyed a patent monopoly on amlodipine. Just days from now, Pfizer's last remaining patent will expire. Despite the imminent expiration of Pfizer's Norvasc® monopoly, the Court without any legal basis extended the patent for an *additional* six-months *after* its expiration when it ordered that Mylan is "permanently enjoined 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*." Order at 1 (emphasis added).

The Court's decision to extend the injunction beyond the patent term is legally wrong. This is a patent infringement case, and, as this Court has recognized in an earlier

phase of this case, its authority to grant relief is limited to the term of the patent. Contrary to the assumption embedded in the Order, the FDA's authority to grant pediatric exclusivity to Pfizer (vis-à-vis *other* generics) is not the same as "extend[ing]" the "patent term." Pfizer's patent term expires on March 25. Period. The FDA's grant of pediatric exclusivity did not change the patent term, and whatever the FDA decides to do with regard to the final approval it has already granted to Mylan will have no effect on the patent term.

Perhaps recognizing the legal error underlying the Order, Pfizer asks the Court to change the injunction. In requesting a change "in order to make the judgment comport with the remedies portion of the patent statute," Pfizer implicitly concedes that the current order does not comport with the remedies portion of the patent statute. However, Pfizer's proposed fix will only serve to make matters worse.[1] The Court can only bring the Order into compliance with the governing provisions of the Patent Act, as amended by the Hatch-Waxman Act, by limiting injunctive relief to the term of the patent.[2]

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[1] Mylan will set forth its reasons for why Pfizer's renewed request for relief under 35 U.S.C. § 271(e)(4)(A) is unsupportable in its opposition to Pfizer's Motion to Alter or Amend, which is due to tomorrow, March 14, 2007.

[2] Pfizer's request to extend the patent is especially egregious in light of Congress' intent in passing the Hatch Waxman Act – "to get generic drugs into the hands of patients at reasonable prices – fast." *See 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); *see also* H.R. Rep. No. 98-857 (Part I), at 14-15 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647 (stating that the purpose of the Hatch-Waxman Act was to "make available more low cost generic drugs by establishing a generic drug approval procedure").

Pfizer asks this Court to rule on its motion before patent expiration on March 25. Mylan joins in that request.

BACKGROUND

Amlodipine besylate is a drug approved by the FDA for treating hypertension and chronic stable and vasospastic angina. Opinion at 4. Pfizer was issued two different patents which it contends cover different aspects of amlodipine besylate tablets: United States Patent Nos. 4,572,909 ("the '909 patent") and 4,879,303 ("the '303 patent"). *Id.* at 1, 4. Since November 1992, Pfizer has commercially marketed amlodipine besylate tablets as Norvasc®. *Id.* The '909 patent expired on July 31, 2006. *Id.* at 5. The '303 patent will expire in just over a week, on March 25, 2007. *Id.* at 3.

Nearly five years ago, on May 22, 2002, Mylan filed with the FDA an Abbreviated New Drug Application ("ANDA") No. 76-418, in which it sought approval to commercially sell generic amlodipine besylate tablets by the time Pfizer's patents expired, if not before. *Id.* at 4. By letter dated July 23, 2002, Mylan certified to the FDA, as required by the Hatch-Waxman Act, that it was seeking approval to market a generic version of Norvasc®. *Id.* On September 22, 2002, Pfizer sued Mylan for patent infringement based on Mylan's filing of its ANDA for amlodipine. *Id.* at 5. Whether intentionally or not, Pfizer failed to take the one step that could have forestalled Mylan's effort to obtain final approval of its generic amlodipine: Pfizer failed to bring suit within 45 days of Mylan's certification. Exhibit A, October 3, 2005 Letter from Gary Buehler to S. Wayne Talton (approving ANDA for amlodipine besylate tablets). Had Pfizer done so, the FDA would have been legally prohibited from approving Mylan's ANDA for 30

months, and, if the litigation was still pending after 30 months, Pfizer could have sought a preliminary injunction keeping Mylan off the market until the Court resolved all issues of infringement and validity. 21 U.S.C. § 355(j)(5)(B)(iii) and (iii)(IV). Pfizer's failure to file suit on time left no legal impediment to the FDA's approval of the ANDA. *Id.*; *see also* Exhibit A. In October 2005, Mylan's ANDA received final approval from the FDA.

The FDA granted Mylan final approval despite the fact that in November, 2001, it had granted Pfizer a six-month period of so-called "pediatric exclusivity" for Norvasc®. *See* 21 U.S.C. § 355a. Pediatric exclusivity—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 period during which an application may not be approved under . . . [§ 355(j)(5)(B)] shall be extended by a period of six months after the date the patent expires . . . ." 21 U.S.C. § 355a (b)(1)(B). Pediatric exclusivity does not grant a drug maker a six month patent extension, but acts to prohibit FDA from granting final approval. Here Mylan has *already* received final approval and is the only ANDA filer with final approval. In effect, then, the pediatric exclusivity period applies to all generic competitors *except* Mylan, thus giving Mylan a six-month head start over generic competitors.

In an opinion issued on February 27, 2007, this Court found that Pfizer's patent was valid and enforceable. Opinion at 67. In its Complaint, Pfizer sought an Order from this Court to enter the effective date of Mylan's ANDA to be no earlier than the expiration of the patent. Pfizer requested this relief prior to the FDA's issuance of final

approval on October 3, 2005; final approval that also established the effective date for Mylan's ANDA. The Court correctly did not interfere with the FDA's authority to grant Mylan final approval, but instead took the unprecedented step of enjoining 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.*" *Id.* (emphasis added).

ARGUMENT

THE COURT CANNOT ENJOIN MYLAN'S COMMERCIAL ACTIVITIES WITH RESPECT TO AMLODIPINE BEYOND PATENT EXPIRATION.

As the Court well knows, this is a patent infringement case. Patent infringement is the only claim Pfizer has asserted, the only basis for this Court's jurisdiction, and the only basis for relief. It goes without saying that the patent can be infringed only during the life of the patent. There can be no claim for patent infringement—and no basis for any relief on patent infringement—beyond 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"). 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).[3] Thus, if an injunction is appropriate at all as a remedy for the technical act of patent infringement this Court has found, the injunction must expire when the patent expires—which is in 10 days, on March 25.

This Court's injunction, however, purports to enjoin Mylan from commercial activity for a period of six months *beyond* the expiration of Mylan's patent term. As is evident from the language the Court used, the basis of the extended injunction is the view that the pediatric exclusivity period somehow "extend[s]" the patent term.

The premise is incorrect. The FDA's grant of pediatric exclusivity under 21 U.S.C. § 355a does not extend the patent term, unlike the patent term extension provisions that reside in the Patent Act (35 U.S.C. § 156). Instead, grant of pediatric

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[3] This Court found that "once a patent has expired, injunctive relief is no longer available," and is therefore subject to the "law of the case" doctrine. The Court cannot freely contradict its prior holding absent extraordinary circumstances. *See Craig Cover v. Hydramatic Packing Co. et. al.*, No. 93-6400, 1997 U.S. Dist. LEXIS 6275, *8 (E.D. Pa. Jan. 15, 1997) (The '"law of the case"' doctrine '"posits that when a court decides upon a rule of law, that decision should continue to govern the same issues in subsequent stages in the same case.'" ... "This rule of practice promotes the finality and efficiency of the judicial process by 'protecting against the agitation of settled issues.'") (citing *inter alia Arizona v. California*, 460 U.S. 605, 618 (1983); *Deisler v. McCormack Aggregates Co.*, 54 F.3d 1074, 1086 (3rd Cir. 1995); *see also, F.B. Leopold Co. v. Roberts Filter Mfg Co.*, No. 92-2427, 1995 U.S. Dist. LEXIS 17639, *9-10 (W.D. Pa June 26, 1995) ('"The law of the case doctrine limits the extent to which an issue will be reconsidered once the court has made a ruling on it.' Under this doctrine, 'a decision on an issue of law made at one stage of a case becomes a binding precedent to be followed in successive stages of the same litigation.'" (citing *inter alia Fagan v. City of Vineland*, 22 F.3d 1283, 1290 (3d Cir. 1994)).

exclusivity extends the period during which the FDA may not approve a pending ANDA. Section 355a explicitly calls the six-month period a "market exclusivity" that becomes available if the Secretary of the FDA requests pediatric studies, and "the holder agrees to the request, the studies are completed within any such timeframe, and the reports thereof are submitted in accordance with [the agreed upon protocol] or accepted [by the Secretary][.]" 21 U.S.C. § 355a(c); *see also* 21 U.S.C. § 355a(b) (applying same standards with respect to new drugs that have not yet received the FDA's approval). If the pediatric studies are submitted and/or accepted, "the period during which an [ANDA] application *may not be approved* . . . shall be extended by a period of six months after the date the patent expires (including any patent extensions)." 21 U.S.C. § 355a(2) (emphasis added). As the FDA has explained:

> Pediatric exclusivity attaching to the end of a patent term is *not a patent term extension* under 35 U.S.C. § 156. Rather it extends the period during which the approval of an abbreviated drug application (ANDA) or 505(b)(2) application may not be approved by FDA.

Exhibit B, *Guidance for Industry: Qualifying for Pediatric Exclusivity Under Section 505A of the Federal Food, Drug, and Cosmetic Act* (Sept. 1999) at 12 (emphasis added). Thus, as is evident from the statute's language, the FDA's grant of pediatric exclusivity has one legal effect only: it prevents the FDA from granting final approval to a pending ANDA during the pediatric exclusivity period.

Moreover, precisely because pediatric exclusivity is not the same as a patent term extension, this Court's injunction is not only temporally extended but substantively overbroad. Pediatric exclusivity prohibits a generic drug company only from one

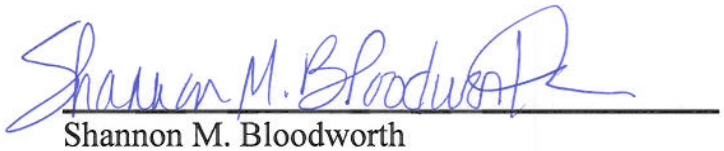
activity—selling the drug in the commercial market. Nothing in the statute so much as suggests that it is impermissible for a generic drug maker to prepare for commercial marketing—in other words, to make the drug, use it, or import it. So to the extent that this Court has prohibited Mylan from "making, using, . . . or importing . . . Amlodipine Tablets" after the patent term expires, it is overly broad even on its own terms.

In sum, as even Pfizer tacitly concedes, there can be little question that this Court's post-expiration injunction will fail on appeal, to the extent that it is premised on the view that the pediatric exclusivity period extends the patent term. This Court should accept Pfizer's request to fix the mistake, but should do so by eliminating any post-expiration injunctive relief.

CONCLUSION

For the reasons set forth above, this Court should amend the Order entered on February 27, 2007, to limit any injunction on Mylan's commercial activities with respect to the patent term, and to exclude activities which are exempted from infringement under the Safe Harbor Provisions of 35 U.S.C. § 271(e)(1). Defendants' [Proposed] Amended Order is submitted herewith.

Respectfully submitted,



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Date: March 13, 2007

CERTIFICATE OF SERVICE

The undersigned hereby certifies that the foregoing **DEFENDANTS' MOTION TO AMEND THE COURT'S JUDGMENT AND ORDER** was electronically filed on March 13, 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.

Shannon M. Bloodworth