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 COMBINED OPPOSITION TO MYLAN'S MOTION TO AMEND THE COURT'S JUDGMENT AND ORDER AND REPLY IN SUPPORT OF ITS MOTION TO AMEND THE COURT'S JUDGMENT

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PRELIMINARY STATEMENT

Mylan's opposition seeks to undermine the result of the trial and has no legal basis.

It is undisputed that the FDA awarded Pfizer a period of six months' pediatric exclusivity on the '303 patent after Pfizer conducted the pediatric clinical trials requested by the FDA. (Stip. Facts ¶¶ 9-10; Mylan Moving Br. 4.) The judgment of this Court that the '303 patent was valid, infringed and enforceable establishes that Pfizer has a right to the additional six months of pediatric exclusivity under 21 U.S.C. § 355a.

21 U.S.C. § 271(e)(4)(A) directs that, upon finding patent infringement, the court issue an order resetting final ANDA approval to a date not earlier than the expiration date of the infringed patent. Pfizer's motion to amend the judgment seeks only to include the mandatory language of 35 U.S.C. § 271(e)(4)(A), which the FDA has said that it requires in order to reset the date of Mylan's final ANDA approval, thereby automatically implementing the pediatric exclusivity to which Pfizer is entitled. Pfizer's proposed amendment is, thus, purely formal, incorporating the precise words used in the statute. Mylan's proposed amended judgment, on the other hand, seeks to exclude the mandatory language of section 271(e)(4)(A), and to deny Pfizer its right of pediatric exclusivity without any basis whatsoever.

Mylan is no stranger to last-minute challenges to pediatric exclusivity. The FDA, in another case in which Mylan was a party, granted pediatric exclusivity to a brand-name manufacturer over Mylan's objections under precisely the same circumstances as are present here. In so doing, the FDA interpreted 35 U.S.C. § 271(e)(4)(A) as both mandatory and applicable whether or not an ANDA has received final approval and whether or not a 30-month stay had ever been in effect. The FDA's decision and the statutory interpretation on which it was based were confirmed by both the federal district court and the Court of Appeals for the District

of Columbia. Mylan's half-hearted attempt to distinguish itself from those squarely applicable precedents is unavailing.

In asserting unsupported and illogical constructions of section 271(e)(4)(A), Mylan seeks to undermine the valuable right of pediatric exclusivity which both Congress and the FDA have recognized provides important incentives for developing clinical data in pediatric populations. 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.

ARGUMENT

THE COURT SHOULD INCLUDE THE MANDATORY LANGUAGE OF SECTION 271(e)(4) IN THE JUDGMENT IN ORDER TO GIVE EFFECT TO PFIZER'S PEDIATRIC EXCLUSIVITY RIGHT

A. The Section 271(e)(4)(A) Order Resetting Final ANDA Approval is Mandatory

1. The Statutory Language of Section 271(e)(4)(A) is Clear

35 U.S.C. § 271(e)(4)(A), a provision of the patent statute, directs that a court, in a Hatch-Waxman patent infringement suit, upon deciding that the asserted patent is valid and infringed, order that the effective date of an ANDA approval be no earlier than the date that the infringed patent expires ("section 271(e)(4)(A) order" or "resetting order"). The statutory language makes clear that entry of the section 271(e)(4)(A) order is mandatory: "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." 35 U.S.C. § 271(e)(4)(A) (emphasis added). In explaining the function and purpose of section 271(e)(4)(A) Congress confirmed that the section's relief is mandatory: under section

271(e)(4)(A), the "court *must* order the effective date of any ANDA relating to a drug involved in the infringement to be a date not earlier than the expiration date of the infringed patent." H.R. Rep. No. 98-857, pt. II, at 27 (1984), *as reprinted in* 1984 U.S.C.C.A.N. 2647, 2711 (emphasis added).

2. The FDA and Courts Have Already Rejected Mylan's Arguments Regarding Its Final Approval and the Lack of a 30-Month Stay

Mylan, in its motion, and in its answer to Pfizer's motion, makes two arguments that the pediatric period should not apply and the mandatory statutory language should be ignored. First, Mylan contends that, because the FDA has issued a "final approval" of Mylan's ANDA, this Court is powerless to affect the approval. Second, Mylan contends that the right of pediatric exclusivity does not apply because the statutory 30-month stay, 21 U.S.C. § 355(j)(5)(B)(iii), did not apply in this case.[1] Both of these arguments were made by Mylan to the FDA and in two courts in a series of cases concerning its ANDA for the drug fentanyl (the "fentanyl cases"). Both of Mylan's arguments were repeatedly rejected by the FDA, the D.C. District Court, the D.C. Circuit Court of Appeals and the Federal Circuit.

a. <u>The FDA's Fentanyl Ruling</u>

In the fentanyl cases, beginning with *Alza Corp. v. Mylan Labs., Inc.*, 310 F. Supp. 2d 610 (D. Vt. 2004), ALZA sued Mylan for patent infringement based on Mylan's filing

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[1] Mylan's argument that a 30-month stay is a prerequisite to pediatric exclusivity is illogical, because the 30-month stay, even if it had applied, would have expired in approximately March, 2005 (7 months prior to Mylan's approval), at which time the FDA was free to finally approve the ANDA, even if the stay had originally applied. Pfizer was awarded the six-month period of pediatric exclusivity pursuant to 21 U.S.C. § 355a, and that exclusivity period was listed in the Orange Book with the '303 patent covering Norvasc® in November 2001, well before Mylan filed the ANDA that precipitated this litigation. There is plainly no provision in the statute that makes the pediatric exclusivity right evaporate if the patent litigation is subsequently not concluded in 30 months.

of a paragraph IV ANDA seeking to market fentanyl before the ALZA patents and the pediatric exclusivity period covering it expired. Like this case, ALZA failed to sue within the 45-day period after notice, and no statutory 30-month stay applied to the litigation. Also like this case, the FDA granted final approval to the Mylan ANDA while the litigation was pending. Before the patent expired, the district court in the patent infringement action held that the patent was valid, infringed and enforceable, and issued a judgment containing the language of section 271(e)(4)(A) providing that "the effective date of . . . Mylan's ANDA . . . shall be no earlier than the date of expiration of the [ALZA patent Mylan infringed]," *Alza*, 310 F. Supp. 2d at 637, which Pfizer seeks to add to the judgment in this case.

Based upon the district court judgment, the FDA reset the final approval date of the Mylan ANDA to a date after the expiration of the patent and ruled that the period of pediatric exclusivity applied. The FDA rested its decision granting ALZA pediatric exclusivity on its determination that the section 271(e)(4)(A) order of the district court in the patent infringement action that "the effective date of Mylan's ANDA shall be no earlier than the date of expiration of the [ALZA patent Mylan infringed]," necessarily transformed Mylan's ANDA approval from final to tentative. (Exhibit 1, FDA Letter at p. 11). The FDA rejected Mylan's argument that a final ANDA approval could not be revoked. It held that section 271(e)(4)(A) "mandates a withdrawal of effective approval where, as here, an ANDA applicant has received a final effective approval and subsequently loses its patent lawsuit with a finding that the patent is valid and infringed." (Ex. 1, FDA Letter at p. 12 n.10).[2] The FDA further concluded that, when the

[2] In rejecting Mylan's argument based on final approval, the FDA concluded that "this outcome makes little sense, and would substantially diminish the incentives for innovator firms to undertake the studies requested by FDA to earn pediatric exclusivity which was so tenuous and easily evaded." (Ex. 1, FDA letter, page 13 at fn. 11.).

ALZA patent expires, pediatric exclusivity attaches under 21 U.S.C. § 355a(c)(2)(A)(i). (Ex. 1, FDA Letter at p. 12).

b. The Court Decisions in Fentanyl

Mylan then sued the FDA in the U.S. District Court for the District of Columbia arguing that the agency's revocation of its final approval based on the patent court's section 271(e)(4)(A) order was unlawful. *See Mylan Labs., Inc. v. Thompson*, 332 F. Supp. 2d 106 (D.D.C. 2004). Just as did the FDA, the court rejected Mylan's argument that a section 271(e)(4)(A) order is not available when an ANDA has received final approval. Contrary to Mylan's contention that *Mylan Labs., Inc. v. Thompson* concerned only the effect, and not the propriety, of the district court's 271(e)(4)(A) order, the court expressly ruled that section 271(e)(4)(A) does apply where final approval has been granted by the FDA. Thus, the court held that the "application of the remedies in § 271(e)(4)(A) . . . applies with equal force to both approved ANDAs and pending ANDAs and there can be no contention that the [patent] court erroneously applied § 271(e)(4)(A) to Mylan's finally approved ANDA." *Id.* at 119.

Mylan then took the two arguments it raises here to the Court of Appeals for the District of Columbia Circuit. The D.C. Circuit affirmed, holding that if a patent is held valid and infringed, the application of the provisions of section 271(e)(4)(A) are mandatory:

> Moreover, the patent remedy statute *directs* that upon a finding of infringement the district court establish a new effective date for approval 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), and the FDA was bound under the district court's order to treat the status of Mylan's ANDA under the FDCA "the same as that of other ANDAs blocked from final approval by patent or exclusivity rights."

Mylan Labs., Inc. v. Thompson, 389 F.3d 1272, 1282 (D.C. Cir. 2004) (emphasis added). Thus, the D.C. Circuit also ruled that the patent court's 271(e)(4)(A) order was not only proper, but also required.

Yet additionally, on an appeal from the patent infringement judgment, the Federal Circuit also held that pediatric exclusivity was available to ALZA. In *Alza Corp. v. Mylan Labs., Inc.*, 391 F.3d 1365 (Fed. Cir. 2004), the Federal Circuit affirmed the patent court's judgment. Because the patent had already expired, the Federal Circuit relied on the right of pediatric exclusivity as the basis for its jurisdiction to decide the merits of the appeal. If the 271(e)(4)(A) order had been in error and had pediatric exclusivity been unavailable, because of the absence of a 30-month stay or the FDA's final approval of Mylan's ANDA, the Federal Circuit would have had no basis for its jurisdiction.

c. The Fentanyl Cases Are Dispositive Here

The procedural posture of this case is identical to that in the fentanyl cases. Although the FDA previously has approved Mylan's amlodipine ANDA (as it had approved Mylan's fentanyl ANDA), this Court found that Mylan infringed Pfizer's valid and enforceable '303 patent. Accordingly, section 271(e)(4)(A) mandates that this Court enter the order resetting final ANDA approval. That order, in turn, requires the FDA to convert its final approval of Mylan's ANDA to tentative and for pediatric exclusivity to attach.

Furthermore, in addition to the squarely applicable precedent, the legislative history of section 271(e)(4) specifically refutes Mylan's argument that if final approval has been granted, the court no longer has the power to issue a section 271(e)(4)(A) order. The House of Representatives' report specifically contemplates that a court will issue the resetting order, regardless of whether the FDA has granted final approval to the ANDA: "In the case where an

ANDA *had been approved*, the order would mandate a change in the effective date [of ANDA approval]." H.R. Rep. No. 98-857, pt. I, at 46 (1984) as reprinted in 1984 U.S.C.C.A.N. 2647, 2679 (emphasis added.)

Mylan is in error in relying on the dictum in Judge Posner's decision in *SmithKline Beecham Corp. v. Apotex Corp.* to argue that the 271(e)(4)(A) language is not mandatory. For one thing, Mylan overlooked the fact that the Federal Circuit vacated its panel opinion at 365 F.3d 1306 (Fed. Cir. 2004), cited by Mylan, and issued a new decision *en banc* (not cited by Mylan) at 403 F.3d 1331 (Fed. Cir. 2005). In *SmithKline,* 247 F. Supp. 2d 1011 (N.D. Ill. 2003), *aff'd on other grounds*, 365 F.3d 1306 (Fed. Cir. 2004), *vacated and aff'd en banc on other grounds*, 403 F.3d 1331 (Fed. Cir. 2005), Judge Posner, sitting as a district judge by designation, first ruled that there was no infringement of the patent. 247 F. Supp. 2d at 1052. As an alternative ground, he held that the ANDA filer had an equitable defense to infringement because SmithKline itself had created the conditions that made practice of the non-infringing prior art impossible. *Id.*

The Federal Circuit, in the *en banc* decision that Mylan overlooked, held that the patent was invalid because it was anticipated. 403 F.3d at 1345-46. The Federal Circuit expressly declined to address the new equitable defense that Judge Posner tried to create in his alternative holding because it was moot. *Id.* at 1342. His decision, thus, has no precedential value for interpreting section 271(e)(4)(A).[3]

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[3] Moreover, Judge Posner was addressing whether he was compelled to issue an injunction that he felt was not equitable. Here, the Court has determined that the injunction is proper, and the only issue is whether the judgment should include the mandatory language of the statute that the FDA looks for to reset the approval date and make pediatric exclusivity effective.

B. Mylan's Other Arguments That Section 271(e)(4)(A) Is Inapplicable Are Similarly Meritless

Mylan also argues that the statutory provision governing effective approval dates for ANDAs with paragraph IV certifications precludes the application of pediatric exclusivity until after an appeal has been decided affirming this Court's judgment. The assertion is baseless. Section 355(j)(5)(B)(iii)(II) of 21 U.S.C. addresses the timing of FDA approval based on various outcomes of the patent litigation *during the 30-month stay* (*i.e.*, "before the expiration of such period"). The provision does not address what the court should order upon finding patent infringement.

Section 355(j)(5)(B)(iii) provides generally that the FDA may not approve an ANDA during a 30-month period if a patent infringement suit is brought against the ANDA filer within 45 days of receipt of the ANDA notice letter. It then addresses the consequences on ANDA approval of a judicial decision of infringement during the 30-month stay. First, it allows the FDA to approve the ANDA on the date during the 30-month stay that the district court enters a judgment for the ANDA filer that the patent is invalid or not infringed. Section 355(j)(5)(B)(iii)(I)(aa). On the other hand, if during the 30-month stay the district court rules in favor of the patent holder and the ANDA filer appeals, the FDA cannot thereafter give final approval to the ANDA, even if the 30-month stay expires, unless and until the district court is reversed on appeal. 21 U.S.C. § 355(j)(5)(B)(iii)(II)(aa)(AA). If there is no appeal, or the judgment of infringement is affirmed, then the FDA cannot finally approve until the date set by the section 271(e)(4)(A) order in the court's judgment. 21 U.S.C. § 355(j)(5)(B)(iii)(II)(bb).

The statute is completely inapplicable here, because it addresses only the effect of the 30-month stay on FDA approval when judgment of the district court is entered *during* the 30-month stay. Even assuming *arguendo* that the statute were applicable, Mylan seeks to turn it on

on its head, arguing that, even though it lost the case in the district court, the judgment cannot be effective to reset the ANDA approval date until after an appeal. There is no basis in the statute for that construction -- the statutory provisions Mylan relies on say nothing about what the court should order upon its finding of infringement -- and the outcome of the fentanyl cases flatly refutes Mylan's position.

C. This Court Can Enforce By Injunction Pfizer's Clear Right to Pediatric Exclusivity

The Federal Circuit, in *Alza v. Mylan*,391 F.3d 1365 (Fed. Cir. 2004), held that it had the jurisdiction to adjudicate the appeal of the patent infringement action after the patent had expired because the right of pediatric exclusivity was at issue. 391 F.3d 1365, 1368 (Fed. Cir. 2004). The Federal Circuit, contrary to Mylan's contention, held that the right of pediatric exclusivity was effectively an extension of the patent right that it could enforce, stating:

> The '580 patent issued on May 13, 1986. It was due to expire in July of 2004; however, following the Food and Drug Administration's approval of the pediatric use of Duragesic® , *the patent will now expire* on January 23, 2005.

391 F.3d at 1368. (Emphasis added.)

Furthermore, whether the pediatric exclusivity right is semantically an extension of the patent right or not, Mylan's argument that the Court cannot enforce any right but those included in the patent statue is baseless and without authority. Because Pfizer complied with all the requirements of the pediatric exclusivity statute, and because its patent was valid and enforceable, it has the clear legal right to preclude Mylan from marketing its generic ANDA product until the expiration of the period of pediatric exclusivity, whether that right emanates independently from the patent statute or from the joint operation of patent statute and the related provisions of 21 U.S.C. § 355a. This Court has the power and duty to protect the rights that Pfizer established in the litigation, as the above precedents amply demonstrate.

CONCLUSION

Mylan's arguments contain not a single policy reason or logical reading of the statutory language that would justify denying Pfizer the benefit of the period of pediatric exclusivity it legitimately earned on a patent that is valid and enforceable. Rather, it seeks to turn the important incentive into a pointless game. Pfizer's motion to amend the judgment to add the statutory language mandated by section 271(e)(4)(A) should be granted.

Pfizer submitted a proposed form of amended judgment with its original motion. Because the patent expiration is next week, March 25, 2007, and the amended judgment must be taken to the FDA, time is short and critical.

Dated: March 16, 2007

Respectfully submitted,

By: /s/ John J. Richardson

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