IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

Margarita Gaeta, as guardian ad litem for A.G., a minor, et al.,

Plaintiffs,

v.

Perrigo Pharmaceuticals Co., et al.,

Defendants.
_____/

NO. C 05-04115 JW

ORDER DENYING PLAINTIFFS' MOTION FOR RECONSIDERATION

Presently before the Court is Plaintiffs' Motion for Reconsideration in Light of Wyeth v. Levine.[1] (hereafter, "Motion," Docket Item No. 358.) Defendant Perrigo timely filed an Opposition.[2] The Court conducted a hearing on November 4, 2009. Based on the papers submitted to date and oral argument, the Court DENIES Plaintiff's Motion for Reconsideration.

A. Background

A more detailed outline of the facts and procedural history in this case may be found in the Court's June 13, 2008 Order Granting Defendant Perrigo's Motion for Summary Judgment. (hereafter, "Order," Docket Item No. 244.) The Court reviews the relevant facts and procedural history to the extent they implicate the present Motion.

[1] 129 S. Ct. 1187 (2009).

[2] (Defendant Perrigo Pharmaceutical Company's Opposition to Plaintiffs' Motion for Reconsideration in Light of Wyeth v. Levine, hereafter, "Opposition," Docket Item No. 362.)

In its Order, the Court found that Plaintiffs' state law causes of action were pre-empted to the extent that they allowed for liability based on a lack of adequate warning on Defendant Perrigo's over-the-counter generic drug labeling for its 200 mg ibuprofen product. (Order at 9.) The Court's pre-emption finding rested on two separate grounds: (1) a generic drug manufacturer could not comply with heightened state law warning label requirements without running afoul of FDA regulations which require generic drug labels to conform to the approved labeling for the listed drug; and (2) the FDA interpreted the scope of its authority in the area of drug labeling as broad enough to pre-empt any conflicting or contrary state law. (Order at 5-9.)

On December 31, 2008, Plaintiffs filed a Notice of Appeal of the Court's decision on summary judgment and of the resulting judgment in the case. (See Docket Item No. 335.) On April 2, 2009, Plaintiffs filed a Motion for "Crateo" Indication to Hear a Post-Judgment Motion for Reconsideration in Light of Wyeth v. Levine. (hereafter, "Crateo Motion," Docket Item No. 345.) In their Crateo Motion, Plaintiffs asked the Court to entertain a post-judgment motion for reconsideration of its Order in light of the Supreme Court's holding in Levine, which Plaintiffs contended reflected a controlling change in the law subsequent to the Court's Order. (Crateo Motion at 1-2.) On June 3, 2009, the Court granted Plaintiffs' Crateo Motion,[3] and the Ninth Circuit granted a limited remand for the purpose of allowing the Court to hear Plaintiffs' post-judgment motion for reconsideration. (See Docket Item No. 355.)

Presently before the Court is Plaintiffs' Motion for Reconsideration in Light of Wyeth v. Levine.

B. Discussion

At issue is whether the Supreme Court's recent holding in Levine requires reversal of the Court's Order granting summary judgment to Defendants on the ground that FDA regulations completely pre-empted Plaintiffs' state law failure-to-warn claims. Plaintiffs contend that although the specific facts of Levine involved a brand-name drug, the Court's holding was broad enough to

[3] (See Docket Item No. 354.)

also encompass the interaction between FDA regulations and state tort law with regard to generic drugs. (Motion at 5-6.) Since the Levine Court found that a pharmaceutical company could meet a state-law duty to modify its warning labels without running afoul of applicable FDA regulations, Plaintiffs contend, California laws which imposed a duty on Defendants to modify warning labels on their generic ibuprofen product were likewise not pre-empted. (Id.)

1. Pre-emption of State Law Failure-to-Warn Claims Under Levine

In Levine, plaintiff Diana Levine brought suit against a drug manufacturer, Wyeth, when she developed gangrene after receiving an IV-push injection of Phenergan, Wyeth's brand name for an antihistamine used to treat nausea. 129 S. Ct. at 1191. Levine asserted state law tort claims against Wyeth alleging that Phenergan's labeling was defective because although it warned of the danger of gangrene and amputation following inadvertent intra-arterial injection, the label failed to warn against use of the IV-push method of administering the drug, which was a higher risk procedure than the IV-drip method. Id. at 1191-92. The trial court refused to overturn on pre-emption grounds the jury's verdict in favor of Levine. Id. at 1193. After the Vermont Supreme Court affirmed the trial court's judgment, Wyeth asserted its pre-emption defense in the United States Supreme Court, contending that (1) "it would have been impossible for it to comply with the state-law duty to modify Phenergan's labeling without violating federal law," and (2) "recognition of Levine's state tort action creates an unacceptable 'obstacle to the accomplishment and execution of the full purposes and objectives of Congress' because it substitutes a lay jury's decision about drug labeling for the expert judgment of the FDA." Id. at 1193-94. The Court rejected both arguments. Id. at 1204.

As to Wyeth's impossibility pre-emption defense, the Court found that because FDA regulations permit drug manufacturers to make certain changes to their labels without prior FDA approval, Wyeth could have met its state-law obligation to provide additional warnings without violating FDA labeling requirements. Id. at 1196. Specifically, the Court found that Wyeth could have utilized the FDA's changes being effected ("CBE") regulation, which permits drug manufacturers like Wyeth, without FDA prior approval, to change a label to "add or strengthen a

contraindication, warning, precaution, or adverse reaction" or to "add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product." Id. Although Wyeth was correct in contending that under the CBE procedure, it could have changed the Phenergan label only in response to new information that the FDA had not considered, the Court found that Wyeth's interpretation of what could constitute new information was too cramped: "'newly acquired information' is not limited to new data but also encompasses 'new analyses of previously submitted data.'" Id. at 1196-97. Since Wyeth did not provide any evidence that the FDA would not have approved a change to Phenergan's label, the Court could not conclude that it was impossible for Wyeth to comply with its duties under both state and federal law. Id. at 1198.

The Court also found without merit Wyeth's contention that Levine's tort claims were pre-empted because they interfered with "Congress' purpose to entrust an expert agency to make drug labeling decisions that strike a balance between competing objectives." Id. at 1199. Wyeth relied on the preamble to a 2006 FDA regulation governing the content and format of prescription drug labels ("Preamble") which stated that the Federal Food, Drug, and Cosmetic Act (FDCA) established "both a 'floor' and a 'ceiling'" so that "FDA approval of labeling . . . preempts conflicting or contrary State law." Id. at 1200 (quoting 71 Fed. Reg. 3922). The Preamble went on to declare that certain state-law actions, such as those involving failure-to-warn claims, "threaten FDA's statutorily prescribed role as the expert Federal agency responsible for evaluating and regulating drugs." Id. (quoting 71 Fed. Reg. 3935). The Court found that since the FDA lacked congressional authorization to pre-empt state law directly, the agency's mere assertion that state law is pre-empted did not merit deference. Id. at 1201. Contrary to Wyeth's contention, the Court found that "Congress has repeatedly declined to pre-empt state law" and that "the FDA has traditionally regarded state law as a complementary form of drug regulation." Id. at 1202. Thus, the Court concluded, Levine's state law claims did not frustrate the achievement of congressional objectives. Id. at 1204.

2. Application of Levine

Here, as in Levine, Plaintiff is asserting state-law tort claims against a drug manufacturer for injuries resulting from inadequate labeling. Unlike in Levine, however, the drug at issue here is a generic rather than a brand-name product. The issue then becomes whether the Levine Court's finding that FDA regulations do not pre-empt state tort law claims for inadequate labeling of a brand-name drug governs whether FDA regulations pre-empt state tort law claims for inadequate labeling of a generic drug.

The Court's Order granting summary judgment to Defendants rested on two grounds: (1) a generic drug manufacturer could not comply with heightened state law warning label requirements without running afoul of FDA regulations which require generic drug labels to conform to the approved labeling for the listed drug; and (2) the FDA interpreted the scope of its authority in the area of drug labeling as broad enough to pre-empt any conflicting or contrary state law. (Order at 5-9.) The Court will address the impact of Levine on each of these findings in turn.

a. Impossibility Pre-emption

At issue is whether FDA regulations pre-empt Plaintiffs' state tort claims because it is impossible for a generic drug manufacturer to comply with FDA and state requirements concurrently. In determining whether the CBE process was available to Defendants in this case, the Court stated:

> The FDA will allow certain changes to the label in an approved petition under [21 C.F.R.] § 314.93, which provides:
>
> > A person who wants to submit an abbreviated new drug application for a drug product which is not identical to a listed drug in route of administration, dosage form, and strength, or in which one active ingredient is substituted for one of the active ingredients in a listed combination drug, must first obtain permission from FDA to submit such an abbreviated application.
>
> The FDA may withdraw approval for an [abbreviated new drug application ("ANDA")] if the agency finds that "the labeling for the drug product . . . is no longer consistent with that for the listed drug" or that the label "is false or misleading in any particular." 21 C.F.R. § 314.150(b)(3), (b)(10). For a non-generic drug, a [CBE] supplement to a label "is appropriate to amend the labeling for an approved product . . . to add or strengthen a contraindication, warning, precaution, or adverse reaction only if there is sufficient evidence of a causal association with the drug." 73 Fed. Reg. 2848, 2849 n.1 (background to proposed rule). However, "CBE changes are not available for generic drugs approved under an [ANDA] . . . . To the contrary, a generic drug manufacturer is required to conform to the approved labeling for the listed drug." Id.; see 21 C.F.R. § 314.150(b)(10);

> 57 Fed. Reg. 17950, 17953, and 17961. Under these regulations, a generic drug manufacturer cannot change its label to add a warning or contraindication without FDA approval.

(Order at 6-7.)

The Court in Levine did not face the question of whether the CBE regulation allowed generic drug manufacturers to make changes to their labels without prior FDA approval. The Court found only that Wyeth could have used the CBE process to provide additional warnings in its label for Phenergan, a brand-name drug. Defendants here do not claim that the CBE process is not available to them because the requested change is not based on "newly acquired information," as Wyeth did in Levine. Defendants instead contend that the FDA regulations require generic drug labels to conform exactly to the approved labeling for the listed drug, making it impossible for generic drug manufacturers to make unilateral changes to their labels. Levine simply did not address this issue, and thus the Court finds that its Order does not conflict with Levine in holding that FDA regulations pre-empt any state law duty on a generic drug manufacturer to provide warnings beyond those provided in the labeling of the listed drug.

The Court recognizes that there is a split of opinion among those district courts that have addressed the issue of whether manufacturers may utilize the CBE process to modify the labeling of generic drugs prior to FDA approval.[4] However, even those post-Levine district court decisions

[4] Compare Kellogg v. Wyeth, 612 F. Supp. 2d 437 (D. Vt. April 10, 2009) (holding that FDA regulations require name-brand and generic drug manufacturers alike "to revise a label to add or strengthen a warning in light of newly acquired information"), and Stacel v. Teva Pharmaceuticals, 620 F. Supp. 2d 899 (N.D. Ill. March 16, 2009) (same), with Morris v. Wyeth, 582 F. Supp. 2d 861 (W.D. Ky. Oct. 24, 2008) (holding that a generic drug manufacturer may not unilaterally strengthen a drug label without prior FDA approval), and Mensing v. Wyeth, 562 F. Supp. 2d 1056 (D. Minn. July 17, 2008) (same).

The Court notes that although Morris and Mensing were decided prior to Levine, Levine does not disturb either decision since Levine did not address the issue of whether the generic drug manufacturers may utilize the CBE process to unilaterally change their labels.

finding that the CBE process does allow generic drug manufacturers to unilaterally change their labels acknowledge that Levine did not address that narrow question.[5]

Furthermore, the underlying statutory framework governing labeling of name-brand drugs differs substantially from the statutory framework governing labeling of generic drugs. Labeling requirements for generic drugs fall under the purview of the Hatch-Waxman Act, which Congress passed in 1984 with the purpose of: (1) reducing drug prices for consumers, (2) preserving the technologies pioneered by brand-name drug manufacturers, and (3) creating an expedited process for bringing generic drugs to the market through the ANDA. Schering-Plough Corp. v. F.T.C., 402 F.3d 1056, 1059 n.2 (11th Cir. 2005). Under the FDCA's new drug application ("NDA") process, the brand-name drug manufacturer must submit "full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use." 21 U.S.C. § 355(b)(1)(A). Under the ANDA process for generics established under the Hatch-Waxman Act, however, the manufacturer must simply establish that the generic drug is equivalent to the brand-name drug. 21 U.S.C. § 355(j)(2)(A). Since Levine did not construe the Hatch-Waxman Act sections pertaining to labeling requirements for generic drugs, that decision did not discern Congress' intent as to any pre-emptive effect those sections may have on state failure-to-warn claims.

The Court finds that Levine did not address a dispositive issue in this case, namely, whether a generic drug manufacturer may use the CBE process to make warning-label changes without prior FDA approval, and thus Levine does not govern whether the Court may grant summary judgment on Plaintiff's state tort claims based on the defense of impossibility pre-emption. Accordingly, the Court DENIES Plaintiffs' Motion for Reconsideration in Light of Wyeth v. Levine.

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[5] See Kellogg, 612 F. Supp. 2d at 439 ("The generic drug manufacturer defendants point out that because Levine involved a branded drug, not a generic drug, the pre-emption question as applied to generic manufacturers was not before the Supreme Court and was not decided by it. This is of course true."); Stacel, 620 F. Supp. 2d at 904 ("The Court's analysis in Levine is not directly controlling law since Levine dealt with a new drug manufacturer whereas Teva is a generic drug manufacturer.").

b. Pre-emption Due to Scope of FDA's Authority

At issue is whether FDA regulations pre-empt Plaintiffs' state tort claims because the scope of FDA's authority in the area of drug labeling pre-empts any conflicting or contrary state law. In finding Plaintiffs' state-law claims pre-empted, the Court relied in part upon the Preamble that the Supreme Court considered in Levine. (Order at 7-8 (citing 71 Fed. Reg. 3922, 3934-35).) In Levine, the Court explicitly rejected the Preamble as providing a basis for pre-emption, finding that it "does not merit deference" and "is at odds with what evidence we have of Congress' purposes." 129 S. Ct. at 1200-04. Thus, to the extent the Court's Order relied upon the Preamble as a basis for finding Plaintiffs' state tort claims pre-empted, it cannot stand.

However, since the Court's finding of impossibility pre-emption is sufficient to support summary judgment for Defendant, Levine's holding with regard to the Preamble's lack of pre-emptive effect does not require reversal of the Order.

C. Conclusion

The Court holds that the Supreme Court's decision in Wyeth v. Levine did not address the issue of whether a generic drug manufacturer may use the CBE process to unilaterally change a warning label, which is dispositive to this case. Accordingly, the Court DENIES Plaintiffs' Motion for Reconsideration in Light of Wyeth v. Levine.

Since this case was remanded by the Ninth Circuit to this Court for the limited purpose of hearing Plaintiff's post-judgment Motion for Reconsideration of the Court's Order Granting Summary Judgment, the Clerk of Court shall close this file.

Dated: November 24, 2009

JAMES WARE
United States District Judge

THIS IS TO CERTIFY THAT COPIES OF THIS ORDER HAVE BEEN DELIVERED TO:

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Dated: November 24, 2009

Richard W. Wieking, Clerk

By: /s/ JW Chambers
Elizabeth Garcia
Courtroom Deputy