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How Recent Pro-Preemption Wave May Lift Brand-Name Drugs

Law360, New York (November 16, 2015, 3:51 PM ET) -- Recent and upcoming cases show the pharmaceutical preemption defense to be alive and well. In Wyeth v. Levine, the U.S. Supreme Court held that preemption for branded manufacturers hinged on their ability to show "clear evidence" that the U.S. Food and Drug Administration would have rejected the substance of the labeling change at issue in the lawsuit. 555 U.S. 555, 571 (2009). In the aftermath of Wyeth, many courts routinely denied preemption motions brought by branded manufacturers, even in compelling situations, without deep consideration of Wyeth's "clear evidence" standard.

With companies continuing to face liability for using warnings specifically dictated by the FDA, a growing number of courts are taking a fresh look at the bounds of conflict preemption, and the results are promising. Two recent cases reinforce the viability of the preemption defense, and the defense is featured in two key appeals that are awaiting resolution.

Two Key Preemption Decisions

On Nov. 9, 2015, two key preemption decisions were issued in very different contexts. In the incretin diabetes litigation, the federal and state coordination judges held a joint hearing on Sept. 11, 2015, on whether plaintiffs' claims alleging a failure to warn about pancreatic cancer were preempted. Both courts issued rulings on the same day granting the defendants' preemption motions. In federal court, Judge Anthony J. Battaglia in San Diego ruled that "clear evidence exists that the FDA would have rejected a reference to pancreatic cancer in product labeling." In re Incretin-Based Therapies Products Liab. Litig., No. 13-md-2452, at *2 (S.D. Cal. Nov. 9, 2015). Judge Battaglia noted that the FDA thoroughly reviewed the alleged increased risk of pancreatic cancer, rejected a citizen petition requesting the withdrawal of one of the drugs at issue due to increased pancreatic cancer risk, and expressed on numerous occasions that "a causal association between the drugs and pancreatic cancer was indeterminate." Id. at *17. His state counterpart in Los Angeles, Judge William F. Highberger, who prior to the joint hearing had indicated his tentative decision to deny the motion, also informed the parties on Nov. 9 that he will be granting the preemption motions for the cases pending before him.

On the same day, Judge Matthew F. Kennelly of the Northern District of Illinois issued an opinion granting a motion to dismiss filed by defendant manufacturers of generic testosterone replacement therapy drugs. In re Testosterone Replacement Therapy Products Liability Litigation. Coordinated Pretrial Proceedings, No. 14-cv-1748-MFK (N.D. Ill. Nov. 9, 2015). Failure-to-warn claims against generic manufacturers are generally preempted under PLIVA Inc. v. Mensing, 131 S. Ct. 2567 (2011), based on the Supreme Court's reasoning that generic manufacturers cannot use the "changes being effected" regulation to unilaterally change their warnings. The plaintiffs in the Testosterone Replacement Therapy

cases argued that their case was outside Mensing, because they focused on the reference listed drug (RLD), which is "the standard to which all generic versions must be shown to be bioequivalent." In re Testosterone, No. 14-cv-1748-MFK, at *2 (internal quotations omitted). Usually, the RLD is a branded medicine, but here, because the brand holder relinquished its new drug application, the FDA designated a generic as the RLD. The plaintiffs argued that the special status as an RLD should change the Mensing analysis, but the court found that a generic RLD designee, just like any other generic company, cannot make unilateral label changes through the "changes being effected" process, and thus the plaintiffs' failure-to-warn claims were preempted under Mensing.

The Third Circuit Fosamax Appeal

In addition to these two decisions, two pending appeals present key preemption questions that could shape pharmaceutical litigation going forward. The first case is being briefed in the Third Circuit in the Fosamax litigation.

In 2013, then-Judge Joel A. Pisano issued one of the first decisions giving teeth to Wyeth's "clear evidence" standard, finding in the bisphosphonate litigation that plaintiffs' warning claims were preempted given the "clear evidence" that the FDA would have rejected a warning of the risk of "atypical femur fractures," because the agency rejected a prior approval supplement from the defendant manufacturer which used the term "stress fractures." In re Fosamax (Alendronate Sodium) Products Liability Litigation, 951 F. Supp. 2d 695, 705 (D.N.J. 2013). The court entered judgment in 2014 dismissing hundreds of claims, and briefing is underway in the Third Circuit. In re Fosamax (Alendronate Sodium) Products Liability Litigation, Nos. 14-1900 et al. (3d Cir.).

The Next Supreme Court Battle?

The threshold for meeting the "clear evidence" standard may soon be clarified by the Supreme Court. This would be the first Supreme Court decision addressing this question outside the generic context since Wyeth v. Levine, over six years ago.

Petitioners Johnson & Johnson and McNeil-PPC Inc. have filed a petition for a writ of certiorari in Reckis v. Johnson & Johnson, in which the Supreme Judicial Court of Massachusetts refused to apply preemption and affirmed a massive judgment against a defendant manufacturer of branded ibuprofen for failing to adequately warn of the risk of toxic epidermal necrolysis (TEN). 471 Mass. 272, 290-92 (Mass. 2015). Even though the warning language requested by the plaintiff was exactly the same as language rejected by the FDA in response to a citizen petition, the SJC did not find that the FDA's rejection amounted to "clear evidence" sufficient to preempt plaintiff's failure-to-warn claim. Covington & Burling LLP authored an amicus brief on behalf of the Biotechnology Industry Organization, theConsumer Healthcare Products Association, and the Pharmaceutical Research and Manufacturers of America urging the Supreme Court to take the case, arguing that the regulatory record "demonstrated not only that FDA would have rejected the change [] requested, but that FDA actually did reject that precise change." The court is expected to rule on the petition in the next several months, unless it decides to call for the views of the solicitor general. If the court accepts review, it could prove to be the most important preemption decision for branded pharmaceuticals since Wyeth v. Levine.

Collectively, these cases emphasize both the continued vitality of the preemption defense and the need for careful regulatory interactions.

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DISCLOSURE: Covington & Burling LLP authored an amicus brief on behalf of the Biotechnology Industry Organization, the Consumer Healthcare Products Association, and the Pharmaceutical Research and Manufacturers of America urging the U.S. Supreme Court to review the case of Reckis v. Johnson & Johnson discussed in this article.