DechertOnPoint

March 2008 / Issue 40

A legal update from Dechert's Mass Torts and Product Liability Group

Warner-Lambert Co. v. Kent: The Supreme Court Splits 4-4 and Leaves the "Fraud-on-the-FDA" Landscape Unclear

A ruling in *Warner-Lambert v. Kent* was eagerly awaited as the case was expected to resolve a federal circuit split on whether fraud-on-the-FDA-based exceptions in state tort reform statutes survived federal preemption. But on March 3, 2008, the U.S. Supreme Court, in a *per curiam* order, affirmed the Second Circuit's decision in a 4-4 split. With no accompanying opinions, the ruling leaves the previous state of the law unchanged and unclarified.

Background

Manufacturers of pharmaceuticals have long defended themselves against state law tort claims by reference to regulatory decisions by the Food & Drug Administration. In response, plaintiffs have alleged that the regulated manufacturer obtained favorable action only by "defrauding" the FDA—by providing inaccurate or incomplete data to the agency. In 2001, the Supreme Court held that federal law impliedly preempted these "fraud-on-the-FDA" claims because they "inevitably conflict with the FDA's responsibility to police fraud consistently with the Agency's judgment and objectives." *Buckman Co. v. Plfs.' Legal Comm.*, 531 U.S. 341, 350 (2001).

A Michigan statute, enacted prior to *Buckman*, provides that prescription drug manufacturers are not subject to liability for an allegedly defective or unreasonably dangerous drug, provided that "the drug was approved for safety and efficacy by the [FDA], and the drug and its labeling were in compliance with the [FDA]'s approval at the time the drug left the control of the manufacturer or seller." Mich. Comp. Laws § 600.2946(5). This statutory immunity does not apply, however, when the manufacturer "[i]ntentionally withholds from or misrepresents to the [FDA] information concerning the drug that is required to be submitted . . . and the drug would not have been approved, or the [FDA] would have withdrawn approval for the drug if the information were accurately submitted." *Id.* Thus, the Michigan statutory scheme does not provide a cause of action based on a "fraud-on-the-FDA" theory, but rather immunizes the drug manufacturer from liability *unless* the plaintiff can prove that the manufacturer's alleged fraud on the FDA resulted in the product being approved.

In *Garcia v. Wyeth-Ayerst Laboratories,* 385 F.3d 961 (6th Cir. 2004), the U.S. Court of Appeals for the Sixth Circuit applied *Buckman* to the Michigan statutory scheme. *Garcia* held that the Michigan statute was impliedly preempted under *Buckman* to the extent that it made proof of successful fraud on the FDA a prerequisite to state tort liability. *Id.* at 966-67. Although recognizing that Michigan law did not establish a specific cause of action for fraud on the FDA, the court found this difference immaterial: "*Buckman* teaches that state tort remedies requiring proof of fraud committed against the FDA are foreclosed since federal law preempts such claims." *Id.* at 966 (citation and quotation marks omitted).

Various state and federal trial courts followed *Garcia* and held that state statutory exceptions requiring proof of fraud on the FDA were

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pre empted under *Buckman*.[1] In 2006, however, the U.S. Court of Appeals for the Second Circuit issued an opinion disagreeing with *Garcia* and its progeny. *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85 (2d Cir. 2006). In *Desiano*, the court held that the Michigan statute's fraud-based exception to state tort law immunity did not raise the same concerns that underlie the Supreme Court's decision in *Buckman* and, thus, the statutory exception is not preempted by federal law. *Id.* at 98. In reaching this conclusion, the court held that, unlike in *Buckman*:

- the Michigan statute could not be viewed as a state's attempt to police fraud against the FDA;
- the plaintiffs were asserting claims rooted in traditional state tort law; and
- the Michigan statute did not require proof of fraud on the FDA as an element of the plaintiff's products liability claim. *Id.* at 93-97.

In 2007, the Supreme Court granted certiorari. *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85 (2d Cir. 2006), *cert. granted sub nom. Warner-Lambert Co. v. Kent*, 128 S.Ct. 31 (2007).

The Decision and Its Implications

On March 3, 2008, the Supreme Court handed down its eagerly anticipated—but anticlimactic—ruling. In a non-precedential *per curiam* order, the Supreme Court affirmed the Second Circuit's decision in a 4-4 split. *Warner-Lambert Co. v. Kent*, No. 06-1498, 552 U.S. ___, 2008 WL 552875 (2008). Chief Justice John Roberts recused himself from the case. There were no accompanying opinions, and the order itself revealed nothing about any individual Justice's position.

The outcome in *Kent* leaves the previous state of the law unchanged. The extant split between the Second and Sixth Circuits impacts defendants in a number of ways. Practically speaking, defendants with cases in New York, Connecticut, or Vermont (the states within the Second Circuit), will be left facing fraud-on-the-FDA state law "exception claims" in federal courts, based on *Desiano*. Those lucky enough to find themselves in Ohio, Michigan, Tennessee, or Kentucky (the states within the Sixth Circuit), however, will find that *Garcia* still governs and that state immunity statutes containing fraud-on-the-FDA exceptions are preempted. Federal courts located in the other 43 states and the District of Columbia are free to apply their own interpretations of *Buckman* to state regulatory schemes that provide exceptions of one sort or another involving proof fraud on the FDA. Five states outside the Second and Sixth Circuits (Texas, Arizona, New Jersey, North Dakota, and Utah) have similar statutory exceptions.

Following *Kent*, both federal and state courts will continue to grapple with the contours of *Buckman* preemption. Manufacturers can expect that the narrow issue presented in *Kent*—whether a state statute's fraud-based exception to a pharmaceutical manufacturer's statutory immunity can survive an implied preemption analysis—will arise in future cases and likely will remain unsettled until another case works its way to the Supreme Court.

Even before the Supreme Court's preemption ruling, the Michigan statute had sparked forum shopping by Michigan plaintiffs. *See Alli v. Eli Lilly & Co.*, 854 N.E.2d 372 (Ind. App. 2006) (rejecting arguments that Michigan law should not apply to a Michigan resident plaintiff). The continuing circuit split on preemption will only increase these efforts. The continuing circuit split also can be expected to influence legal strategy and tactics in multi-district litigation, which is how the *Desiano/Kent* plaintiffs found themselves before the Second Circuit.

Those who hoped for additional clarity from the *Kent* decision are left waiting. The next opportunity will come in *Wyeth v. Levine*, another prescription drug implied preemption case. *Levine* is scheduled to be briefed and argued in the Supreme Court's October 2008 Term.

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[1] *Kobar vs. Novartis Corp.*, 378 F. Supp.2d 1166, 1172-74 (D. Ariz. 2005) (Arizona punitive damages exception predicated on fraud on the FDA preempted); *Henderson v. Merck & Co., Inc.*, 2005 WL 2600220, at *8-11 (E.D. Pa. Oct. 11, 2005) (preempting same Michigan statutory exception at issue in *Garcia*); *Ledbetter v. Merck & Co., Inc.*, 2007 WL 1181991 (Tex. Dist. Ct. April 19, 2007) (Texas fraud on the FDA exception to non-defectiveness presumption preempted).

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