

March 7, 2008

## Supreme Court Deadlocks On Whether Michigan “Fraud-On-The-FDA” Exception Is Preempted Under *Buckman*

By Deborah M. Russell, McGuireWoods LLP\*

“The tie goes to the runner” or in this case to the Michigan plaintiffs who are allowed to advance their products liability claims involving the diabetes drug Rezulin. On March 3, 2008, in a 4-4 split decision, the U.S. Supreme Court affirmed the judgment of the Second Circuit, which found no preemption of plaintiffs’ common law claims based on a Michigan statute that requires plaintiffs to prove fraud on the FDA when the drug is FDA-approved or compliant. *Warner-Lambert Co. LLC v. Kent* (formerly *Desiano*), \_\_\_S. Ct. \_\_\_, 2008 WL 552875 (U.S.).

This decision is the second in a trilogy of FDA preemption cases considered by the Court this term. Chief Justice John Roberts’ recusal created the potential for a deadlock.

Although the two-sentence *per curiam* opinion (handed down just one week after oral argument) provides no precedential value, it heightens the anticipation of the Court’s decision in the third FDA preemption case that the Court will hear this fall, *Wyeth v. Levine*, U.S. Supreme Court No. 06-1249. The issue in *Levine* is whether FDA approval of prescription drug labeling provides a preemption defense to state law products liability actions.

The issue presented in *Kent* was whether implied preemption of state law fraud-on-the-FDA claims articulated in *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341 (2001) (*Buckman*) is limited to express claims of fraud-on-the-FDA or whether *Buckman* extends to traditional tort causes of action that require the fact-finder to determine whether the manufacturer withheld material information from or misled the FDA.

Under a Michigan statute, FDA approval provides an absolute defense with an important exception. M.C.L. § 600. 2946(5)(a). If the manufacturer or seller intentionally withholds from or misrepresents to the FDA information that is required to be submitted under the federal Food, Drug and Cosmetics Act (FDCA) and the drug would not have been approved or the FDA would have withdrawn approval if the information were accurately submitted, plaintiff may recover under common law. *Id.*

The district court found that the fraud-on-the-FDA exception to immunity for FDA-approved drugs was preempted under *Buckman*. The Second Circuit reversed, limiting implied preemption under *Buckman* to express “fraud-on-the-FDA” theories of liability. *See Desiano v. Warner-Lambert & Co.*, 467 F.3d 85, 98 (2d Cir. Oct. 5, 2006).

Applying a presumption against preemption, the Second Circuit held that, absent a clear statement from Congress, the common law claims preserved by the immunity exception are not preempted.

The Supreme Court’s split decision in *Kent* leaves intact the Second Circuit’s no preemption ruling.

---

\* Deborah M. Russell is a partner in McGuireWoods LLP's complex products liability department, residing in the Richmond office. She is a co-leader of the firm's life sciences industry team. Her practice primarily involves defending pharmaceutical, medical device and biologics companies in products liability litigation, including individual cases, multi-district litigation coordinated proceedings, cases consolidated for trial and class actions. Her practice also includes counseling clients in FDA regulatory matters and risk management. She is admitted to practice in state and federal courts in Virginia and Maryland. Ms. Russell has received a number of honors, including selection by "The Best Lawyers in America" in the specialties of mass tort litigation and personal injury litigation. She can be reached at (804) 775-1034 or drussell@mcguirewoods.com.

McGuireWoods LLP is a full-service law firm with approximately 750 lawyers in 15 offices in the United States, Europe and Central Asia providing legal counsel to clients around the world.