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SECOND CIRCUIT REVIEW

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Products Liability Law Held Not Pre-Empted; Circuits Split

In this month's column, we report on a decision issued earlier this month by the U.S. Court of Appeals for the Second Circuit, holding that federal law does not preempt a Michigan statute that allows product liability claims to proceed against drug manufacturers concerning drugs whose Food and Drug Administration (FDA) approval is fraudulently procured.

In so ruling, the Second Circuit declined to defer to a U.S. Court of Appeals for the Sixth Circuit decision reaching the opposite result, thereby creating a circuit split on the issue, and demonstrating how the transfer of a case as part of multidistrict litigation can be outcome dispositive.

In *Desiano v. Warner-Lambert & Co.*,[1] the Second Circuit addressed two significant issues: (1) what deference, if any, is owed to a sister circuit's decision interpreting the laws of a state within that sister circuit, and (2) whether, pursuant to Supreme Court precedent on implied preemption of "fraud-on-the-FDA" claims, a state statute that creates an exception to drugmaker immunity if FDA approval was gained by withheld or misrepresented information, is preempted by federal law. The Second Circuit, in a unanimous opinion written by Judge Guido Calabresi and joined by Judges Wilfred Feinberg and Barrington D. Parker, concluded that deference is not owed where the question is whether the state law is preempted by federal law; it then determined that the state law claims at issue were not preempted by federal law.

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Legal Framework

The statute at issue in *Desiano*, enacted by Michigan in 1995, immunizes drug manufacturers from liability claims arising out of products approved by the Food and Drug Administration (FDA).[2] The law does not extend immunity, however, to a drugmaker that "intentionally 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concerning the drug that is required to be submitted…and the drug would not have been approved, or the [FDA] would have withdrawn approval for the drug if the information were accurately submitted."[3]

In *Buckman Co. v. Plaintiffs' Legal Committee*, the U.S. Supreme Court held that federal law preempts state "fraud-on-the-FDA" claims—i.e., claims against drug manufacturers grounded in claims of fraud on the FDA.[4] The *Buckman* plaintiffs sought damages under a California fraud-on-the-FDA statute, asserting that the defendant manufacturer fraudulently obtained FDA approval of its medical device. The Supreme Court found the presumption against federal preemption of state law claims inapplicable, as "[p]olicing fraud against federal agencies is hardly a field which the States have traditionally occupied," adding that the California "fraud-on-the-FDA" claims conflicted with, and therefore were impliedly preempted by, the federal Food, Drug and Cosmetic Act (FDCA) and the Medical Device Act (MDA).[5]

Buckman was subsequently applied by the Sixth Circuit in *Garcia v. Wyeth-Ayerst Labs*,[6] where the court held that, under *Buckman*, federal law preempted Michigan's drugmaker immunity statute. The court reasoned that Michigan's law differed from the California statute at issue in *Buckman*: whereas the *Buckman* claims were based directly on defrauding the FDA, under Michigan's law—and the *Garcia* claims—fraud on the FDA is merely an exception to general immunity for drug manufacturers. But the *Garcia* Court found this difference "immaterial in light of *Buckman*" and held that "state tort remedies requiring proof of fraud committed against the FDA are foreclosed since federal law preempts such claims."[7] On that basis, the court ruled that the statute was impliedly preempted, but only where fraud on the FDA would be found by state courts; where the FDA itself has found fraud in the approval process, a plaintiff could rely on the fraud exception in bringing a claim.

Facts and Procedural History

Plaintiffs in *Desiano* were Michigan residents alleging injuries caused as a result of Rezulin, a drug sold by defendants and used for treating Type-2 diabetes. The FDA approved Rezulin in 1997, but it was subsequently found to cause adverse effects on the liver. Defendants agreed to make various FDA-authorized label changes and, ultimately, withdrew the drug from the U.S. market at the FDA's request. Plaintiffs then sued defendants in Michigan and other state courts, alleging a variety of Michigan law claims. Defendants removed the actions to federal court, where they were consolidated and transferred by the Judicial Panel on Multidistrict Litigation to the U.S. District Court for the Southern District of New York.

Defendants moved for judgment on the pleadings, arguing that *Buckman* and *Garcia* foreclosed liability under Michigan law.

The district court agreed and dismissed the claims, holding that it owed "quite substantial deference" to the Sixth Circuit's decision in *Garcia* under *Factors Etc., Inv. v. Pro Arts, Inc.*,[8] a Second Circuit case holding that a federal court should give "conclusive deference" to "a ruling by a court of appeals deciding the law of a state within its circuit."[9] The district court also reasoned that "[i]f plaintiffs covered by the Michigan statute were able to litigate claims of fraud on the FDA in individual personal injury suits, whether in state or federal courts, the potential would exist for the FDA's personnel to be drawn into these controversies on a case-by-case basis over and over again"—a situation that would be "wholly impractical." The court held that the fraud exception in the Michigan statute was preempted, "except where the plaintiff relies on a finding by the FDA, or in an action brought by the FDA, of material fraud in the new drug approval process absent which approval would not have been given."[10] The court granted judgment on the pleadings and dismissed plaintiffs' claims, leading to the instant appeal.

Second Circuit Decision

On appeal, the Second Circuit first addressed the deference owed to a court of appeals' interpretation of state law from within its own circuit. The court explained that under its decision in *Factors*, "conclusive deference is owed, except when the court of appeals' decision is weakened by subsequent development in state law, or was contrary to state precedent." The court observed, however, that *Factors* created no obligation to defer to a sister circuit's interpretation of federal law, even in the context of transferred cases.[11] The court reasoned that it was bound to follow the Sixth Circuit's conclusions in *Garcia* as to questions of Michigan law—specifically, *Garcia's* determination that Michigan's statute does not create a new cause of action for misleading the FDA. But the instant appeal was not governed primarily by state law, the Second Circuit explained. "Rather, the question of whether federal law impliedly preempts part of Michigan's statutory scheme depends on significant issues of federal law including, inter alia, the meaning of Supreme Court precedents, e.g., *Buckman*, and the scope of federal statutes, e.g., FDCA."[12] The Second Circuit held that it was obligated to address these issues independently.

The Second Circuit disagreed with *Garcia's* determination that the differences between the California fraud-on-the-FDA claims preempted in *Buckman* and the Michigan claims at issue here were immaterial. The court found that there were three crucial differences.

First, contrary to *Buckman*, the presumption against federal preemption of state law did apply to the Michigan statute. In *Buckman*, the Supreme Court found that the well-established presumption against preemption did not apply to state fraud-on-the-FDA claims because policing fraud against federal agencies was not a traditional area of state concern. In contrast, Michigan's statute does not attempt to police fraud against the FDA; its objective is merely "to regulate and restrict when victims could continue to recover under preexisting state products liability law."[13] This effort to limit state-based tort liability falls within the state's traditional interest in matters of health and safety, a "sphere in which the presumption against preemption applies, indeed, stands at its strongest."[14]

Second, the *Desiano* plaintiffs did not allege fraud-on-the-FDA-type claims; their claims sounded in traditional state tort law. The court emphasized two characteristics that *Buckman* used to distinguish fraud-on-the-FDA claims from traditional tort claims. One is the source of the duty allegedly breached. Fraud-on-the-FDA claims involve a "newly concocted" duty between a manufacturer and a federal agency; in contrast, traditional tort claims are based on traditional duties between product manufacturers and consumers. The Second Circuit found no reason to believe that Congress intended to gut the traditional state law duties between drugmakers and consumers. Another distinctive fraud-on-the-FDA characteristic is that proof of fraud-on-the-FDA is alone sufficient to impose liability. But plaintiffs' Michigan claims were based on a wide variety of common law duties. "*Buckman* cannot be read as precluding such preexisting common-law liability based on other wrongs," the court explained, "even when such liability survives only because there was also evidence of fraud against the FDA."[15]

Third, the Michigan statute does not make fraud on the FDA an element of a products liability claim, in contrast to the fraud-on-the-FDA claims in *Buckman*; it merely creates a defense drugmakers may assert.[16] The court concluded that "[u]ntil and unless Congress states explicitly that it intends invalidation of state common law claims merely because issues of fraud may arise in the trial of such claims, we decline to read general statutes like the FDCA and the MDA as having that effect."[17]

Finally, the court addressed the concern stated in *Buckman* and echoed in *Garcia* and the district court's decision: that permitting fraud-on-the-FDA suits would give drugmakers an incentive to deluge the FDA with information, in order to insulate themselves against liability. The court found that any time evidence of fraud-on-the-FDA is considered—e.g., in the majority of states where such evidence is permitted but not conclusive—there is an incentive to provide extraneous information to the FDA. The court concluded that "[o]nly where proof of fraud is by itself sufficient to impose liability—and indeed is the sole basis of liability (as it was in *Buckman*)—does the incentive to flood the FDA appreciably escalate."[18] The Court expressed concern that the Sixth Circuit's reading of this policy concern in *Buckman* meant that, unless a state entirely barred evidence of fraud-on-the-FDA in a tort case, the policy could justify invalidating any product liability suit against a drug manufacturer.

Conclusion

Under the Second Circuit's ruling in *Desiano v. Warner-Lambert & Co.*, a federal court's "conclusive deference" to a court of appeals' interpretation of state law from within its own circuit does not extend to the court of appeals' interpretation of federal law as it applies to that state law. The Second Circuit chose not to defer to the Sixth Circuit's interpretation of federal preemption law as it applies to a Michigan statute granting immunity from products liability to drugmakers in certain circumstances. In so ruling, the court created a circuit split, and made clear that, at least as to Michigan state tort claims against drug manufacturers in which fraud-on-the-FDA is an affirmative defense, the door is still wide open to product liability lawsuits, if only in the Second Circuit. The Supreme Court may have the last word; until then, *Desiano* has created a scenario under Michigan law in which drug manufacturers face uncertain liability and plaintiffs have every incentive to seek forums for their actions, outside their home circuit.

1. __F3d__, 2006 WL 2846454 (2d Cir. Oct. 5, 2006).
2. Mich. Comp. Laws §600.2946(5) (hereinafter MCL §2946(5)).
3. MCL §2946(5)(a) (internal citations omitted).
4. 531 US 341, 348 (2001).
5. Id. at 347 (citing 21 USC §301, et seq., and 21 USC §§360e(b)(1)(A)-(B)).
6. 395 F3d 961 (6th Cir. 2004).
7. Id. at 966 (citation omitted).
8. 652 F2d 278 (2d Cir. 1981).
9. Id. at 279.
10. *Desiano* at *3.
11. Id. at *5, citing *Menowitz v. Brown*, 991 F2d 36 (2d Cir. 1993).
12. *Desiano* at *6.
13. Id. at *8.
14. Id.
15. Id. at *9.
16. Id. at *10, citing *Taylor v. Smithkline Beecham Corp.*, 658 NW2d 127, 134 (Mich. 2003).
17. *Desiano* at *10.
18. Id. at *11.