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Practice Group:

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Third Circuit Says *Actavis* Not Limited to Cash

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In the first decision by a federal appeals court interpreting the U.S. Supreme Court's landmark ruling in *FTC v. Actavis*, the Third Circuit recently held in *King Drug Co. of Florence v. SmithKline Beecham Corp.* that so-called pay-for-delay settlement agreements of Hatch-Waxman Act-related patent litigation may be subject to antitrust scrutiny even if they do not involve cash payments from a brand-name drug-maker to a generic. The Third Circuit reversed the dismissal of the plaintiffs' putative class action against the defendant branded and generic drug-makers, but it did not judge the merits of the antitrust claims on the facts.

Cash vs. "No Authorized Generic"

In the prototypical situation, a "reverse payment" settlement in the Hatch-Waxman context involves the branded patentee paying cash to the generic alleged infringer to abandon its claims of patent invalidity and/or non-infringement and refrain from immediate entry into the market. In *Actavis*, the Supreme Court addressed such a settlement, rejecting the "scope of the patent test" (a bright-line rule that "reverse-payment" settlements were immune under the antitrust laws if the asserted anticompetitive effects fell within the scope of the patent) and holding that "reverse payment" settlements are subject to antitrust scrutiny under a full rule of reason analysis. The *Actavis* court reasoned that a large reverse payment often suggests that the branded patentee has serious doubts about the patent's survival, permitting the inference that the branded manufacturer's objective in making the payment is to maintain supracompetitive prices to be shared by the branded and generic drug-makers rather than face a competitive market.

In the Third Circuit case, unlike *Actavis*, the complaint alleged violations of the Sherman Act based on a patent settlement where no cash changed hands. The patent litigation settlement included a commitment by the branded manufacturer to forego selling its own generic version of the patented drug at issue during the 180-day period following the generic's entry into the market (the "no AG agreement"). Under the Hatch-Waxman Act, only the branded manufacturer (potentially selling its own "authorized generic") and the first generic manufacturer to file an Abbreviated New Drug Application have the right to sell a generic version of the drug during that 180-day period. According to a Federal Trade Commission report, a no AG agreement is potentially worth hundreds of millions of dollars to the generic manufacturer, which would face no competition in the generic market during the 180-day period and could charge supracompetitive prices.

The Third Circuit's Decision

Under these facts, the Third Circuit confronted the question of whether Actavis is limited to "reverse payments" of cash only or extends to the no AG agreement. The court of appeals found *Actavis'* rule of reason analysis applicable to the no AG agreement, describing it as "an unusual, unexplained reverse transfer of considerable value from the patentee [the branded manufacturer] to the alleged infringer [the challenging generic]," which could give

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rise to "the inference that it is a payment to eliminate the risk of competition." The court reasoned that a no AG agreement may have anticompetitive consequences if the branded manufacturer uses it to induce the generic drug-maker to abandon its patent fight and delay generic entry, preserving the brand's monopoly. Moreover, the no AG agreement may result in higher prices even after the challenging generic introduces its product. "The no-AG agreement transfers the profits the patentee would have made from its authorized generic to the settling generic—plus potentially more, in the form of higher prices, because there will now be a generic monopoly instead of a generic duopoly."

Notably, the Third Circuit also rejected the defendants' argument that no AG agreements are distinguishable from "reverse payments" and immune from antitrust scrutiny because they constitute exclusive licenses permitted under patent law. The court reasoned that a patentee's power to issue a license does not permit it to use that power to cause anticompetitive harm by eliminating the risk of competition in the marketplace. The court was careful to confine its opinion to the specific facts of "reverse payments" of valuable consideration in connection with patent settlements in the Hatch-Waxman context, stating "[w]e make no statement about patent licensing more generally."

The Third Circuit reversed the dismissal of the complaint, reviving the plaintiffs' putative class action, and remanded the case for discovery and litigation under the rule of reason.

Key Takeaways

The Third Circuit's decision is notable principally because it makes clear that, at least in the Third Circuit, the Supreme Court's ruling in *Actavis* cannot be limited to pay-for-delay deals involving cash consideration. Furthermore, while the court of appeals focused on no AG agreements, the court's reasoning emphasizing the potential anticompetitive effects of the reverse transfer of valuable consideration from a patentee to the alleged infringer is sufficiently broad that it need not be limited to such agreements. Thus, even if a proposed patent settlement in the Hatch-Waxman context does not involve a reverse cash payment or a no AG agreement, branded and generic manufacturers should more generally consider whether the terms of their proposed settlement arguably postpone market entry and harm consumers through lessened competition and higher prices. Attempts to disguise such an arrangement as an exclusive license may be met with skepticism.

Because of the apparent breadth of the Third Circuit's reasoning, this may mean that defendants in that circuit — where many of the nation's largest pharmaceutical companies are based or are otherwise subject to jurisdiction — now face even greater challenges to obtain an early dismissal of pay-for-delay antitrust claims, leaving the parties to litigate the deal at issue under the rule of reason. Forum-shopping plaintiffs may now flock to file in the Third Circuit.

At present, it is not clear whether other federal appellate courts will follow the Third Circuit's lead (the district court's decision in *In re Loestrin 24 FE Antitrust Litig.*, MDL No. 13-2472-S-

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PAZ, 2014 WL 4368924, at *10 (D.R.I. Sept. 4, 2014), holding that *Actavis* applies only to monetary payments, is currently before the First Circuit). However, one thing is certain: the Third Circuit has set down a marker that other courts addressing non-cash pay-for-delay deals must now confront.

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