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FTC v. Actavis: Supreme Court Adopts Rule of Reason for "Reverse Payment" Settlements

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On June 17, 2013, the Supreme Court decided Federal Trade Commission v. Actavis, Inc., No. 12-416, by a 5-3 vote (Justice Alito recused), resolving a circuit split over the appropriate antitrust standard to apply when evaluating "reverse payment" Hatch-Waxman patent litigation settlements between branded and generic pharmaceutical companies. The Court did not adopt either standard previously employed by the courts of appeal and urged by the parties and *amici*, but instead held that the rule of reason governed. The Court expressly left to the lower courts the details of how to apply the rule of reason, and remanded for further proceedings.

Background

Actavis resolves a split between the Second, Eleventh and Federal Circuits, on the one hand, and the Third Circuit on the other, regarding the antitrust test under which to assess Hatch-Waxman settlements where payment flows from the branded company to the generic. The Eleventh Circuit (the court of appeal in *Actavis*) as well as the Second and Federal Circuits had held that such a settlement was lawful so long as the settlement's restrictions were within the "scope of the patent"-that is, so long as the generic supplier did not agree to stay off the market beyond patent expiration or to refrain from

marketing products not within the patent's claims. The Third Circuit, on the other hand, had held (in a case decided shortly after the Eleventh Circuit's ruling in *Actavis*, and which the Supreme Court placed on hold in response to a petition for certiorari) that under the "quick look" standard such a settlement was presumptively unlawful unless the branded company could show that the payment was "for something other than a delay in market entry" or was otherwise pro-competitive. *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 218 (3rd Cir. 2012).

Actavis involved settlements between Solvay, the NDA holder for AndroGel (a prescription testosterone cream) and Actavis and Paddock, generic companies that filed ANDAs to market generic versions of the drug. Under the settlements' terms, Actavis and Paddock agreed not to market generic versions of AndroGel until a date several years before patent expiration. Solvay also contemporaneously agreed to make payments to each of the generic companies (as well as to Par, another generic company that had partnered with Paddock) purportedly for product promotion and manufacturing services the generics agreed to perform. The FTC alleged that those services had little independent value and that the payments were intended to secure the generics' agreement to stay out of the market and were therefore unlawful. The district court dismissed the complaint. On appeal, the FTC urged the Eleventh Circuit to hold that reverse payments were presumptively unlawful-a quick look test under which the burden would shift to the defendant to justify the agreement terms as pro-competitive. The Eleventh Circuit, however, affirmed the district court's decision under the scope of the patent test.

Decision

Writing for the majority, Justice Breyer rejected both the scope of the

patent and the quick look tests, and adopted the rule of reason test even though no court previously had done so in this context and no party urged the Court to do so. The Court first reasoned that "what the holder of a valid patent could do does not by itself answer the antitrust question," and observed that it would be "incongruous" to measure the anticompetitive effects of reverse payment settlements "solely against patent law policy, rather than by measuring them against procompetitive antitrust policies as well." *Actavis* at 8. The Court then reviewed several of its precedents and concluded that they "make clear that patent-related settlement agreements can sometimes violate the antitrust laws" and that courts should analyze such agreements "by considering traditional antitrust factors such as likely anticompetitive effects, redeeming virtues, market power, and potentially offsetting legal considerations present in the circumstances…." *Id.* at 9-10.

The Court recognized that there was some support for the policy favoring settlement reflected in the scope of the patent test, but declined to make that policy determinative based on "five sets of considerations." *Id.* at 14. *First*, the Court observed that reverse payment settlements have potential for genuine anticompetitive effects, namely higher prices to consumers. While the Court acknowledged that in most contexts it would be difficult if not impossible to buy off all competitors, the Court relied in part on what it termed "special incentives for collusion" created by Hatch-Waxman's first filer provisions (which give a potentially very lucrative 180-day generic exclusivity period to the first generic applicant to challenge a patent listed as claiming the relevant branded drug). *Id.* at 17. *Second*, the Court opined that these anticompetitive consequences at least sometimes will prove unjustified, such as where reverse payments go beyond traditional settlement considerations like avoided litigation costs or fair value for services secured as part of the settlement. *Third*, the Court reasoned that a large reverse payment is an indicator that the patentee likely has market

power because a firm without the power to charge prices higher than a competitive level is unlikely "to pay 'large sums' to induce 'others to stay out of its market.'" *Id.* at 18. *Fourth*, the Court rejected the argument that assessing the settlement's impact on competition necessitated an impractical reexamination of validity and infringement issues from the underlying case. The Court suggested that, in many cases, it may not be necessary to re-litigate the merits of a settled patent claim because, for example, an "unexplained large reverse payment would normally suggest that the patentee has serious doubts about the patent's survival" and could "provide a workable surrogate for a patent's weakness, all without forcing a court to conduct a detailed exploration of the validity of the patent itself." *Id.* at 18-19. *Fifth*, the Court dismissed the argument that a rule subjecting settlements to routine scrutiny would chill settlements, opining that the parties could settle in ways not involving a "large, unjustified reverse payment." *Id.* at 19.

The Court also held that the FTC's quick-look approach was inappropriate because the question whether reverse payment settlements cause anticompetitive consequences was too complex to warrant a presumption of illegality.

The Court therefore concluded that the rule of reason applied, and that the "likelihood of a reverse payment bringing about anticompetitive effects depends upon its size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification." *Id.* at 20. The Court declined to specify further how the rule of reason should be applied in this context, and expressly left the particulars of implementation to the lower courts. *Id.* at 21.

Chief Justice Roberts, joined by Justices Scalia and Thomas, dissented,

arguing that the Court should have affirmed under the scope of the patent test.

The Court has not yet addressed K-Dur, although it likely will grant certiorari, vacate and remand for proceedings consistent with the Actavis opinion.

Implications

The *Actavis* decision significantly increases the likelihood that Hatch-Waxman settlements involving "delayed" entry and some form of payment from the branded company to the generic (even if in connection with business transactions arranged in connection with the settlement) will be challenged by the government and private plaintiffs. It also increases the risk-except in the Third Circuit, which had adopted the stricter "quick look" approach-that such challenges will result in unsuccessful outcomes for pharmaceutical companies given the relatively amorphous rule of reason standard, the difficulties in obtaining dismissal or summary judgment under that standard, the discretion conferred on the lower courts to articulate its application on a case-by-case basis, and the general uncertainties associated with trial-especially jury trial. Risk can be minimized by settling on terms that do not arguably suggest payment from the branded company to the generic (such as an agreement as to entry-date only), or by litigating the patent case to its conclusion.

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