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COUNSEL COMMENTARY

IP: Are "pay for delay" payments anti-competitive or just another settlement agreement?

THE SUPREME COURT SETS OUT CRITERIA FOR DETERMINING WHETHER REVERSE SETTLEMENTS VIOLATE ANTITRUST LAW

In a 5-3 decision in *FTC v. Actavis,* the Supreme Court addressed the question of whether reverse settlement, or "pay for delay," payments from an innovator drug company to a generic drugmaker to delay entry into the market constitute an antitrust violation. The court held that reverse payments are neither presumptively legal nor presumptively unlawful, and set out criteria for analyzing whether the payments were anticompetitive.

How does the generic get on the market?

For a generic drug maker to enter the market, the company must file an Abbreviated New Drug Application (ANDA) with the Food and Drug Administration (FDA). The generic can assert that either there is no patent covering the drug product or certify under Paragraph IV of the FDA's Hatch-Waxman Act that there is a patent covering the product, but the patent is invalid and/or the generic product does not infringe the patented product. The filing of a Paragraph IV certification is itself an act of infringement and the innovator drug maker has 45 days in which to bring suit for infringement. If the drug innovator files a patent infringement complaint, the FDA stays the decision of generic approval for 30 months pending the outcome of litigation. If there is no decision in litigation at the end of 30 months, the FDA continues the approval process and the generic may be approved regardless of the possible patent infringement.

Solvay's road to the Supreme Court

Solvay Pharmaceuticals obtained a patent, expiring in 2020, to a topical form of testosterone marketed under the brand name AndroGel. Prior to the expiration of the patent, two generic drug makers, Watson Pharmaceuticals (now Actavis Inc.) and Paddock Pharmaceuticals each filed an ANDA under Paragraph IV, certifying that Solvay's patent was invalid and/or the generic did not infringe the patent. Solvay filed suit against Actavis and Paddock in 2003. The suit was not decided within the 30-month stay period, and Actavis received approval for a generic form of AndroGel. In 2006, Solvay and Actavis and Paddock settled the litigation, with Solvay paying Actavis, Paddock and a third generic to delay entering the market until five years prior to expiration of the patent, and also paying the generics to help market and distribute AndroGel to doctors.

In 2009, the Federal Trade Commission (FTC) filed suit in the Northern District of Georgia against all parties in the settlement, alleging that the settlement violated antitrust rules under the Sherman Act and arguing that reverse payments should be prohibited. The district court dismissed the FTC complaint, holding that the payment from Solvay

to the generics to delay entry into the market did not extend beyond the exclusionary right that Solvay's patent provided and did not violate antitrust laws. The 11th Circuit affirmed the district court, holding that a reverse payment is "immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent."

The FTC petitioned for *certiorari*, arguing that the court should have at least allowed the FTC to present its argument. In view of the inconsistent application of antitrust laws by different district courts to innovator/generic patent settlements, the Supreme Court granted *certiorari*.

Criteria for review of reverse payments

In reaching its decision, the court outlined that instances have arisen in which reverse payments were an antitrust violation, e.g., *U.S. v Singer Mfg Co.*, in which the sewing machine company cross-licensed patents with other manufacturers to prevent competition from Japanese companies. The court also noted that, even in the pharmaceutical industry, reverse payments have been viewed as lawful under antitrust laws, citing *Schering-Plough Corp. v FTC* and *In re Tamoxifen Citrate Antitrust Litig.*

The court disagreed with the FTC's position that reverse payments are presumptively unlawful and set out rationales to analyze the anti-competitive nature of a reverse payment settlement. The criteria include:

1. Does the restraint at issue have the potential for adverse effects on competition?

2. Are there justifications for reverse payments that are not anti-competitive?

3. Does the size of the payment indicate power to bring harm to the market?

In the decision, the court also considered that it is not necessary to determine patent validity prior to carrying out the antitrust analysis and a large, unjustified reverse payment does not prevent parties from settling in the future.

The court's analysis for each criterion focused on the amount of the payment and the justifications of such payment, noting that the pharmaceutical industry seems to be the only industry in which the patentee pays the potential infringer to settle the lawsuit. The court stated if the payments exceed what would be reasonable profits to the generic or loss to the innovator, there is reason for scrutiny, as these may not be traditional settlement considerations.

The court also suggested that a large payment by the innovator could signal a weak patent that the innovator does not want challenged. However, large reverse settlement payments may be justified if, for example, the payment approximates the cost of a prolonged, expensive litigation, or the innovator senses that even a small risk of an invalidity ruling of its valuable patent is worth settling a potentially protracted lawsuit. Because of the multiple possible justifications for the payments, the court held the FTC should have been allowed to continue its suit, and remanded the case back to the lower courts for application of the criteria above in conjunction with the "rule of reason" typically used to decide antitrust cases.

The dissent (written by Chief Justice John Roberts and Justices Antonin Scalia and Clarence Thomas) opined that the correct analysis should be whether the settlement gives the patentee a monopoly power beyond that already granted by the patent, and predicted that the decision will discourage future settlement in patent litigation.

The U.S.'s viewpoint is trending

Prior to the court's decision, the FTC and Department of Justice had publicly stated their position that reverse settlements are presumptively unlawful. Word of the FTC's positions relating to reverse payments is spreading and taking hold outside our borders. In Europe, reverse settlements were previously viewed as any other settlement agreement and did not violate

EU competition law, regardless of the intent behind the settlement. However, recent EU decisions suggest that Europe is beginning to adopt certain of the FTC's line of thinking that these payments should be scrutinized for their ultimate purpose. Danish drugmaker Lundbeck A/S was fined almost €94M for paying generics to delay market entry while the generics were also fined for accepting such payments. Additionally, the European Commission has fined other drug makers, such as Merck KGaA, Generics UK and Ranbaxy, for anticompetitive practices relating to reverse payments.

Views on the recent U.S. and EU decisions have been mixed. Those in favor say that the extra examination of reverse payments will make the consumer the ultimate winner, leading to more competition in the marketplace and lower drug prices. Others feel that increased scrutiny of reverse settlement payments will only reduce the incentive for drugmakers to settle litigation or reduce the generic's incentive to file Paragraph IV certifications, leading to unpredictability in the marketplace, and ultimately harming the consumer.

The long-term impact of the court's decision remains to be seen. Gone is the presumption that companies have a right to settle as they see fit, as long as it is within their patent rights. Further, large payments or alternative settlement provisions, such as distribution agreements, cross-licensing, etc., could also be subject to extra scrutiny. However, reverse payments are still an allowable means to settle litigation, with legality assessed on a case-by-case basis. The decision suggests that those negotiating the settlements need to make sure the terms and payment amounts are justified and "reasonable" using the criteria set out by the Supreme Court.

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