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US Supreme Court Allows Antitrust Suits Against "Reverse Payment" Settlements of Patent Litigation

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The US Supreme Court ruled last week, in a 5–3 decision, that "reverse payment" patent settlements between a pioneer drug maker and would-be generic competitors are subject to rule of reason antitrust analysis.

These patent litigation settlements in the pharmaceutical industry have been the subject of Federal Trade Commission enforcement actions and litigation for over a decade. The Court's ruling, in *FTC v. Actavis,* resolves a split among the circuit courts on whether or not such settlements are presumptively legal or presumptively unlawful under a truncated analysis. The Court chose neither course, tasking the lower courts with determining how to apply the rule of reason analysis to such settlements, and in doing so created a new set of uncertainties for pharmaceutical companies.

Background

In 2009, the FTC sued Solvay and three generic pharmaceutical companies, including Actavis, Inc. (known at the time as Watson Pharmaceuticals), which had each sought Food and Drug Administration (FDA) approval to market generic versions of Solvay's AndroGel under the Abbreviated New Drug Application (ANDA) process as provided for under the Hatch-Waxman Act.

The FTC alleged that Solvay agreed to pay the generic companies—through payments that were purportedly compensation for other services which had little value—to abandon their patent challenges and delay bringing their generic versions to the market until 2015. The FTC's contention has been that patent litigation settlements that include payments from the patent holder to the generic drug maker protect the pioneer or brand-name company against the risk of a court ruling that would permit the generic to enter the market and result in lower prices.

The Eleventh Circuit affirmed the dismissal of the FTC's case, reasoning that while the antitrust laws generally prohibit agreements where one firm pays another to stay out of the market, under the patent laws patent holders have the right to exclude others. The Eleventh Circuit further held that even the potential for a subsequent invalidity finding does not render the patent irrelevant to the appropriate antitrust analysis. Short of sham litigation or fraud in obtaining a patent, the court held that a reverse payment settlement should be immune to antitrust attack as long as its terms fall within the scope of the "exclusionary potential" of the patent. The Eleventh Circuit emphasized the public policy of favoring settlement of disputes and the difficulty of assessing the likelihood that the patentee would have succeeded in the lawsuit absent settlement.

The Supreme Court agreed to hear the FTC's appeal last year, after the Third Circuit, in *In re K-Dur Antitrust Litig.,* rejected the scope-of-the-patent test, and held that reverse payment settlement agreements should be presumptively unlawful, adopting a so-called "quick look" standard.

The Supreme Court decision

The Supreme Court rejected both the scope-of-the-patent test and the quick-look approach and adopted a rule of reason analysis. It held that "reverse payment settlements such as the agreement alleged in the complaint before us can sometimes violate the antitrust laws."

Courts must go beyond just patent law policy and measure the effects of a settlement against pro-competitive antitrust policies, according to the Supreme Court. "[T]o refer … simply to what the holder of a valid patent could do does not by itself answer the antitrust question." Justice Breyer, writing for the majority, warned that "there is reason for concern that such settlements taking this form tend to have significant adverse effects on competition." According to the Court, case law does not simply ask whether the patent holder acted within the scope of the patent, but rather "seek[s] to accommodate patent and antitrust policies, finding challenged terms and conditions unlawful unless patent law policy offsets the antitrust law policy strongly favoring competition."

The Supreme Court rejected the FTC's "quick look" approach—under which reverse payment settlements would be "presumptively unlawful"—as inappropriate, because favoring "presumptive rules (or a 'quick-look' approach) is only appropriate where 'an observer with even a rudimentary understanding of economics could conclude that the arrangements in question would have an anticompetitive effect on customers and markets.'" But, the Court reasoned, "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 present payment, and the lack of any other convincing justification."

The Supreme Court left it to the lower courts to determine "the structuring of the present rule-of-reason antitrust litigation," noting, however, that "an unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent's survival. And that fact, in turn, suggests that the payments' objective is to maintain supracompetitive prices to be shared among the patentee and the challenger rather than face what might have been a competitive market." In those instances, a court would not be forced to conduct a detailed exploration of the patent's validity. The Court did note that where a reverse payment reflects traditional settlement consideration, such as "avoided litigation costs" or "fair value for services," there would not be antitrust concern. Thus settlements with "side deals" for fair value should be lawful.

Interestingly, just two days after the *Actavis* decision, the European Commission fined nine drug makers $195 million (€94.8 million) for a deal that it said delayed the market entry of generic versions of Lundbeck's blockbuster anti-depressant drug Celexa® (citalopram). European Commission Vice President Joaquin Almunia argued, "[i]t is unacceptable that a company pays off its competitors to stay out of its market and delay the entry of cheaper medicines. Agreements of this type directly harm patients and national health systems, which are already under tight budgetary constraints. The Commission will not tolerate such anticompetitive practices." The Lundbeck case is the first to impose fines for these types of agreements. Together with the Supreme Court decision in *Actavis,* it may curtail the flexibility that pioneer pharmaceutical companies have in reaching settlements with would-be generic providers.

Implications

While the Supreme Court's decision resolves the split in the Circuits, it creates new uncertainties. The Court gave only limited guidance to the lower courts on applying the rule of reason, prompting Chief Justice Roberts to comment in dissent: "Good luck to the district courts that must, when faced with a patent settlement, weigh the 'likely anticompetitive effects, redeeming virtues, market power, and potentially offsetting legal considerations present in the circumstances.'" Courts will have to grasp at what guidance *is* provided by the majority, and are likely to focus on factors cited by Justice Breyer, including the payment's size relative to the size of the market and avoided litigation costs, whether it reflects fair value for services provided by the generic companies, and any other convincing justification.

The lower courts will have multiple opportunities to apply the new standard soon. In addition to the *Actavis* case itself, on Monday, the Court vacated the ruling in *K-Dur* and ordered the Third Circuit to reevaluate Merck's "reverse-payment" settlement agreements

with two generic drug manufacturers for further consideration in light of *Actavis*.

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