U.S. Supreme Court Finds Patent Settlements Subject to Antitrust Scrutiny

In one of the most closely watched cases to reach the U.S. Supreme Court in recent years, the Court, on June 17, handed down a decision reversing a federal appellate court and concluding that a patent settlement agreement involving the drug AndroGel® between brand drug company Solvay Pharmaceuticals and generic drug companies Actavis, Inc. (formerly Watson Pharmaceuticals) and Paddock Laboratories could be challenged as anticompetitive by the Federal Trade Commission (FTC). While declining to hold such agreements resolving brand vs. generic drug patent disputes presumptively unlawful, a majority of the Supreme Court Justices, in a 5-3 opinion, found that the FTC should have been permitted an opportunity in the trial court to prove its antitrust claims, and concluded that the a patent's inherent exclusionary characteristics do not immunize the litigants' settlement agreement from judicial scrutiny.

Federal Appellate Courts Were Sharply Divided on the Issue

In so ruling, the Supreme Court put to rest, for the time being, a vigorous point-counterpoint debate that had been roiling among federal appellate courts for several years. The disagreement centered on the extent to which courts could review these agreements under the antitrust laws. Indeed, a few Circuit Courts of Appeal doubted that they could be effectively challenged at all in most circumstances, and other Circuit Courts found to the contrary: The Third Circuit in the K-Dur® antitrust litigation saying "yes," and the Eleventh (AndroGel®, K-Dur®, Hytrim®), Second (Tamoxifen®) and Federal (Cipro®) Circuits effectively saying "no." Other federal appellate courts, such as the Sixth and District of Columbia Circuits, as the Third Circuit, also had struck down patent settlement agreements (involving Cardizem®) as constituting illegal restraints of trade.

In this context, then, the time was more than ripe for America's top court to weigh in on these issues and determine whether the Eleventh Circuit's "scope of the patent" test, or the Third Circuit's "quick look" rule of antitrust impact was the most appropriate standard to apply in evaluating the marketplace effect of brand-generic drug patent settlement agreements.

The Supreme Court's "Rule of Reason" Approach to Patent Settlement Agreements

Faced with competing policies favoring the settlement of litigation, promoting generic drug competition under Hatch-Waxman, and upholding the exclusivity of brand patent protections, the Supreme Court was faced with the daunting task of melding all of these notable and salutary objectives into a decision giving force to each.

First, the Court concluded that while the anticompetitive effects of the settlement agreement at issue, which provided for payments to the generics to defer their market entry, might "fall within the scope of the exclusionary potential of Solvay's patent," the agreement is not thereby immunized from an antitrust challenge. "[T]here is reason for concern," the Court noted, "that such settlement agreements tend to have significant adverse effects on competition."

Second, the Court found that the public policy strongly favoring the settlement of expensive, protracted litigation, typical of Paragraph IV challenges of brand drug patents, must be weighed against the concern that "[p]ayment for staying out of the market keeps prices at patentee-set levels and divides the benefit between the patentee and the challenger, while the consumer loses." There are other ways to settle patent lawsuits, the Court said, that may not raise antitrust concerns.

Third, in refusing to hold reverse payment settlement agreements prima facie unlawful, the Court directed trial and appellate courts reviewing such agreements to apply a “rule of reason” analysis rather than the Third Circuit’s “quick look” approach. In this manner, the Court concluded, there may be “offsetting or redeeming virtues” to such settlements establishing the lawfulness of the arrangement.

What is the Impact of the Court’s Decision?

The Generic Pharmaceutical Association, in a press release issued following the Supreme Court’s decision, applauded the rejection of the FTC’s view that all such agreements are presumptively illegal. The GPhA also noted, however, that the Court’s ruling would make it more expensive for generics to litigate patent challenges under Hatch-Waxman. Other critics have suggested that the ruling would preclude or delay the availability of lower cost generic drug options to consumers and frustrate the objectives of generic drug legislation. Parties to currently pending patent litigation, and those involved in challenges to prior patent settlement agreements, will now have to determine on a case-by-case basis whether patent settlements, past, present and future, can satisfy the new standards articulated by the Supreme Court.

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