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Supreme Court Opens Reverse Payment Patent Settlement Agreements to Antitrust Challenge

Jeffrey May (Wolters Kluwer) · Friday, June 21st, 2013

A “reverse payment” settlement agreement is not entitled to “near-automatic antitrust immunity” simply because its anticompetitive effects fall within the scope of the exclusionary potential of the patent, the U.S. Supreme Court ruled earlier this week in a five-to-three decision. Although such agreements, also known as “pay-for-delay” settlements, are not presumptively unlawful, the FTC should be permitted to challenge reverse-payment agreements between Solvay Pharmaceuticals and would-be generic competitors Watson Pharmaceuticals (now Actavis, Inc.) and Paddock Pharmaceuticals under a rule of reason analysis. The case is *FTC v. Actavis, Inc.*, Dkt. No. 12-416.

Reverse payment agreements generally involve a brand-name drug manufacturer paying a potential rival to abandon patent challenges and delay launching low-cost generic products in competition with the brand name drug. In 2009, the FTC challenged patent settlement agreements related to patents for AndroGel—a testosterone replacement drug often used by men whose bodies do not produce normal levels of testosterone—as unlawful pay-for-delay agreements. The FTC alleged that Solvay and the generic drug makers violated the FTC Act by unlawfully agreeing “to share in Solvay’s monopoly profits, abandon their patent challenges, and refrain from launching their low-cost generic products to compete with AndroGel for nine years.”

In 2010, the federal district court in Atlanta dismissed the complaint (687 F. Supp. 2d 1371, 2010-1 Trade Cases ¶76,914) on the ground that the FTC failed to allege that the settlements, which included exclusion payments to the generic drug companies, exceeded the scope of the manufacturer’s patent on the drug. The U.S. Court of Appeals in Atlanta affirmed (677 F.3d 1298, 2012-1 Trade Cases ¶77,865). The Eleventh Circuit held that “absent sham litigation or fraud in obtaining the patent, a reverse payment settlement is immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent.”

These agreements are subject to antitrust challenge because “there is reason for concern that settlements taking this form tend to have significant adverse effects on competition,” the Court explained. In order to determine whether such agreements violate the antitrust laws, courts need to look beyond patent law policy and measure the alleged anticompetitive effects against procompetitive antitrust policies as well, it was noted.

The Supreme Court recognized the Eleventh Circuit’s concern for the value of settlements and its fear that antitrust scrutiny of a reverse payment agreement would be time-consuming, complex, and expensive. However, five considerations outweighed the Eleventh Circuit’s focus on the

desirability of settlements. Those five considerations include:

(1) the specific restraint at issue has the "potential for genuine adverse effects on competition";

(2) these anticompetitive consequences will at least sometimes prove unjustified;

(3) where a reverse payment threatens to work unjustified anticompetitive harm, the patentee likely possesses the power to bring that harm about in practice;

(4) an antitrust action is likely feasible administratively, as the size of the reverse payment could provide a workable surrogate for a patent's weakness; and

(5) the risk of antitrust liability from a large, unjustified reverse payment does not prevent litigating parties from settling their lawsuit.

Rule of Reason Analysis vs. Quick Look Approach

As was widely expected, the Court rejected the FTC's call for a presumption of illegality for reverse payment agreements. Thus, the FTC would be required to "prove its case as in other rule-of-reason cases."

The Court came to this conclusion "because 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." Although the Court noted that "most if not all reverse payment settlement agreements arise in the context of pharmaceutical drug regulation," another one of the "complexities" that it suggested weighed against a quick-look approach was that anticompetitive consequences might vary among industries.

Dissent

A dissent, written by Chief Justice John Roberts and joined by Justices Antonin Scalia and Clarence Thomas, questioned the majority's "novel approach," saying that it would "discourage the settlement of patent litigation." According to the dissent, almost all of the majority's "five sets of considerations" that overcome concerns about the desirability of settlements "are unresponsive to the basic problem that settling a patent claim cannot possibly impose unlawful anticompetitive harm if the patent holder is acting within the scope of a valid patent and therefore permitted to do precisely what the antitrust suit claims is unlawful."

Wishing "good luck" to district courts faced with antitrust challenges to patent settlements, the dissent said that "although the question posed by this case is fundamentally a question of patent law—i.e., whether Solvay's patent was valid and therefore permitted Solvay to pay competitors to honor the scope of its patent—the majority declares that such questions should henceforth be scrutinized by antitrust law's unruly rule of reason."

Justice Samuel Alito took no part in the consideration or decision of the case.

FTC Chairwoman Edith Ramirez Statement

In response to the Supreme Court's decision, FTC Chairwoman Edith Ramirez said that the FTC intends to move forward with its case. She also noted in a statement that the agency is "assessing

how best to protect consumers' interests in other pay for delay cases."

"The Court has made it clear that pay-for-delay agreements between brand and generic drug companies are subject to antitrust scrutiny, and it has rejected the attempt by branded and generic companies to effectively immunize these agreements from the antitrust laws," Ramirez said. "With this finding, the Court has taken a big step toward addressing a problem that has cost Americans $3.5 billion a year in higher drug prices."

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