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Supreme Court: reverse payment settlements subject to antitrust scrutiny

What are the risks of future 'pay for delay' settlements between branded and generic manufacturers?

By Martin Pavane and Philip Kouyoumdjian

At the close of its 2013 term, the Supreme Court of the United States handed down one of its more important patent decisions of the session. Because of the potentially serious antitrust implications, all counsel active in the life sciences/Hatch-Waxman space should take note of this decision.

On June 17, 2013, the Supreme Court handed down a decision that addressed a "reverse payment" settlement agreement between Solvay Pharmaceuticals (plaintiff patent holder) and Actavis and Paddock Laboratories (the generic companies who were the alleged infringers). While the Supreme Court acknowledged that the anticompetitive consequences of the agreement fell within the patent holder's lawful right to exclude others from the market, it disagreed with the lower courts that this fact alone immunized the agreement from the antitrust laws.

The Supreme Court held that a settlement agreement in which a patentee pays an accused infringer not to enter the market—even if the agreement allows market entry before the patent term expires—is not presumptively lawful and is still subject to antitrust scrutiny. In remanding the case to the District Court, the Supreme Court articulated the standard for the lower courts to apply when analyzing reverse payment settlements—"the FTC must prove its case as in other rule-of-reason cases."

Underlying facts

In 1999, Solvay Pharmaceuticals filed a New Drug Application (NDA) for AndroGel, and FDA approved Solvay's application in 2000. In 2003, Solvay obtained a patent covering AndroGel (US Patent No. 6,503,894—the "'894 patent"), which was subsequently listed in FDA's Orange Book. Later that year, Actavis, Inc. filed the first Abbreviated New Drug Application (ANDA) for a generic version of AndroGel, and thereafter Paddock Laboratories also filed an ANDA for its generic product. Both Actavis and Paddock certified under Paragraph IV of the Hatch-Waxman Act that they did not infringe the '894 patent, and that the patent was invalid. Thirty months after Solvay sued Actavis and Paddock for infringing the '894 patent, FDA approved Actavis' generic product.

Then, in 2006, all parties to the litigation settled. Actavis agreed that it would not bring its generic product to market until 2015, cutting Solvay patent life by 65 months. Actavis and other generic companies would promote AndroGel until then. In return, Solvay agreed to pay millions of dollars to the generic companies.

FTC action

When the FTC learned of Solvay's reverse payment agreement with the generics, it filed suit against all parties, alleging violation of § 5 of the Federal Trade Commission Act, 15 U.S.C. § 45 by, among other things, agreeing "to share in Solvay's monopoly profits" and refraining from launching generic products to compete with AndroGel for nine years.

Two lower courts dismissed the FTC complaint, but the FTC appealed to the US Supreme Court. Based on a number of factors, the Supreme Court found that it would be "incongruous to determine antitrust legality by measuring the settlement's anticompetitive effects solely against patent law policy, rather than by measuring them against procompetitive antitrust policies as well."

The matter was remanded to the District Court with instructions to analyze the settlement under the "rule-of-reason."

What this means to the pharmaceutical industry

This decision will discourage the settlement of Hatch-Waxman patent litigations—at least in the short run. Because the Supreme Court took a middle-of-the road approach by rejecting the "scope-of-the-patent test" while also holding that pay-for-delay settlements were not presumptively illegal, both branded and generic companies will have to reconsider litigation settlement strategies.

Drug companies will now have to prepare for potential Hatch-Waxman and antitrust litigations. As a result, it may be prudent for pharmaceutical businesses to revise their document retention policies to further emphasize a mindful approach to the generation of potentially privileged documents relating to antitrust issues, as well as IP issues.

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Reprinted from the September/October 2013 issue of Pharmaceutical Commerce

Also, the rule-of-reason doctrine states that only combinations and contracts unreasonably restraining trade violate the antitrust laws; possession of monopoly power is not in itself illegal. Under this doctrine, district courts must consider the circumstances in which a reverse payment agreement was entered. Before parties enter into these types of agreements, they should ask themselves if the benefits of such a business venture is worth the antitrust risk.

Antitrust concerns may be avoided by resorting to a traditional ANDA settlement model. The Court agreed with the FTC that Hatch-Waxman cases may settle by 1) allowing the generic manufacturer to enter the patent holder's market before the asserted patent expires, provided there is no payment from the patentee to the challenger, and 2) permitting the generic to enter the patentee's market by paying the branded company an amount equal to the savings in expenses associated with foregoing the patent litigation. Since reverse payment agreements are now subject to antitrust scrutiny, branded and generic companies will be more likely to enter into these lower-risk ANDA settlement contracts.

Also, the door is open both for other, already-settled reverse-payment agreements to be challenged by the FTC, and for other private parties to bring antitrust actions.

Because reverse payment settlement agreements will be reviewed under the rule-of-reason, presumably some will be held valid and enforceable. However, until the law is settled and the application of the rule-of-reason is established in the context of reverse payments, it will take a brave pair of litigants to enter into a reverse settlement agreement and face the uncertain consequences. PCm

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