December 14, 2012

The U.S. Supreme Court agreed, on Friday, December 7, to hear the Federal Trade Commission's appeal of a case challenging "reverse payment" settlements of patent litigation in the pharmaceutical industry, an issue that has been simmering at the FTC and in the lower courts for more than a decade.

The Supreme Court's decision is likely to impact future settlement options and thus the course of future Hatch-Waxman litigation.

The Supreme Court granted certiorari in *FTC v. Watson Pharmaceuticals, Inc.,* a case brought by the FTC challenging settlement agreements Solvay Pharmaceuticals, Inc. entered with three generic manufacturers of the testosterone replacement drug AndroGel. The FTC alleged Solvay was "not likely to prevail" in its infringement actions and the settlements were merely tools to protect monopoly profits that the companies divvied up by means of payments from the patent holder to the generic manufacturers. The FTC's suit was dismissed by the district court, and the Eleventh Circuit affirmed the dismissal.

Supreme Court review is timely given the Third Circuit's recent decision in *In re K-Dur Antitrust Litigation,* which found such "reverse payment" settlement agreements presumptively anticompetitive and illegal. That case involved a challenge to Schering-Plough settlements with generic manufacturers involving potassium chloride supplements.

The question presented in the FTC's certiorari petition is:

> Whether reverse-payment agreements are per se lawful unless the underlying patent litigation was a sham or the patent was obtained by fraud (as the court below held), or instead are presumptively anticompetitive and unlawful (as the Third Circuit has held).

Petitions for certiorari are pending in the *K-Dur* case. The Supreme Court will likely either hear that case simultaneously or stay it until the *Watson* case is decided.

The Eleventh Circuit decision in *FTC v. Watson*

The FTC sued Solvay and three generic firms in February 2009. The three firms had each sought Food and Drug Administration approval to market a generic version of AndroGel under the Abbreviated New Drug Application (ANDA) process as provided for under the Hatch-Waxman Act.

The ANDA process allows generic competitors of patented drugs to seek FDA approval to market a bioequivalent drug before the expiration of patent protection by challenging listed patents as either invalid or not infringed, through a so-called "Paragraph IV Certification." The first ANDA challenger, if successful, is granted a 180-day period of exclusivity to sell its generic drug, during which no other ANDA may be approved by the FDA.

The generic drug makers certified that their AndroGel-equivalent products did not infringe Solvay's patent and that the patent was invalid. The FTC complaint charged that Solvay agreed to pay the generic companies to abandon their patent challenges and delay bringing their generic versions to the market until 2015, through co-promote and back-up supply agreements.

The FTC contends that patent litigation settlements that include payments from the patent holder to the allegedly infringing generic drug maker, known as "reverse payments," protect the brand-name company against the risk of a court ruling that the patent is

invalid or not infringed by the generic competitor and in doing so, keep prices high at the consumers' expense.

The FTC suit was originally filed in California, but was transferred to Georgia where the underlying patent cases had been litigated. The "lynchpin" of the FTC's complaint, according to the Eleventh Circuit, was the FTC's allegation that Solvay "was not likely to prevail" in the patent litigation.

The Eleventh Circuit recognized that the antitrust laws typically prohibit agreements where one company pays a potential competitor not to enter a market, but said the patent "made all the difference because it meant the patent holder had a ‘lawful right to exclude others' from the market," and even the subsequent invalidity of a patent does not render the patent irrelevant to the appropriate antitrust analysis. The court refused to engage in an "after-the-fact calculation of how ‘likely' a patent holder was to succeed in a settled lawsuit if it had not been settled."

In the Eleventh Circuit, as well as the Second Circuit and Federal Circuit, the consensus is that "absent sham litigation or fraud in obtaining a 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."

The Third Circuit ruling on the K-Dur settlement agreements

In stark contrast is the Third Circuit's decision in the *K-Dur* litigation.

In July, the Third Circuit made "reverse payment" settlement agreements between innovator and generic pharmaceutical companies presumptively anticompetitive and adopted a "quick look" rule of reason standard. That decision could have significant implications for how patent litigation between patent holders and generic competitors are settled, since the Third Circuit and its New Jersey and Delaware district courts are a popular venue for Hatch-Waxman patent infringement litigations and home to a large number of pharmaceutical companies.

The settlement agreements in *K-Dur* involved two generic drug manufacturers, Upsher Smith and ESI, which sought FDA approval to market generic versions of Schering-Plough's branded drug. Schering filed a patent infringement suit, which was settled on the eve of trial with a $60 million payment to Upsher in exchange for a license to other products and an agreement from Upsher not to sell its generic drug until 2001. Separately, Schering paid ESI $15 million, and ESI agreed not to market its generic until 2004.

In 2001, the FTC filed an administrative complaint against Schering challenging the settlements, alleging that they unreasonably restrained trade by keeping low-cost generics off the market and improperly preserved Schering's monopoly. While the FTC found the agreements illegal under Section 5 of the FTC Act, the Eleventh Circuit, on appeal, held that the agreements were not unlawful because they did not exceed the scope of the patent and because the payment to Upsher was only for the licenses obtained by Schering as part of the settlement agreement. Although the Court found that there was a payment-for-delay with respect to the settlement with ESI, the Court asserted it was nevertheless a reasonable settlement term protected by the patent laws.

The K-Dur settlements also triggered private antitrust suits by a group of wholesalers and pharmacies, which claimed that they were forced to pay higher prices because generics were kept off the market. The New Jersey district court upheld the agreements based on the scope of patent test. The plaintiffs appealed to the Third Circuit.

After a review of the conflicting decisions of the circuit courts, the Third Circuit stated that "we cannot agree with those courts that apply the scope of the patent test. In our view, that test improperly restricts application of antitrust law and is contrary to the policies underlying Hatch-Waxman Act and a long line of Supreme Court precedent on patent litigation and competition."

According to the Third Circuit, "reverse payments permit the sharing of monopoly rents between would-be competitors without any assurance that the underlying patent is valid." The Congressional intent of the Hatch Waxman Act, it asserted, was to balance

patent protection with promoting incentives for competition in the pharmaceutical industry. The goal was to increase the availability of low cost generics by encouraging litigated challenges to weak or narrow patents. The scope of the patent test, according to the Third Circuit, allows the patent holder to pay a potential competitor not to compete.

The Third Circuit adopted the approach suggested by the D.C. Circuit in *Andrx Pharms., Inc. v. Biovail Corp. Int'l* in 2001, stating that "[s]pecifically, the finder of fact must treat any payment from a patent holder to a generic patent challenger who agrees to delay entry into the market as *prima facie* evidence of an unreasonable restraint of trade, which could be rebutted by showing that the payment (1) was for a purpose other than delayed entry or (2) offers some pro-competitive benefit." Whether the defendant was likely to prevail in the patent litigation did not even enter into the Third Circuit's decision. The Court noted that its holding applies only to reverse payment settlements in the pharmaceutical industry and that nothing in the test limits the ability of parties to otherwise reach a settlement based on a negotiated entry date.

The Supreme Court will now decide what standard should apply. The Court is expected to issue a decision by June 2013.

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