Supreme Court Revives FTC Reverse Payment Challenge; Says Agreements Can Violate Antitrust Laws

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The U.S. Supreme Court has issued one of its more anticipated rulings of this term in a decision that aims squarely at the intersection of antitrust and intellectual property law. In its 5-3 opinion in *Federal Trade Commission v. Actavis, Inc.*, the Court reversed the Eleventh Circuit?s dismissal of a Federal Trade Commission (?FTC?) challenge to a patent litigation settlement between branded drug manufacturer Solvay Pharmaceuticals and generic rivals Actavis, Paddock Laboratories, and Par Pharmaceutical. In addition to reinstating the FTC?s lawsuit against this particular settlement agreement, the Court?s ruling also establishes a ?rule of reason? test under which future similar settlement agreements will be judged ? striking a compromise between the FTC?s and the drug makers? respective wishes.

Background: The FTC?s Longstanding Battle Against Reverse Payment Agreements

A ?reverse payment? settlement agreement typically arises when a patent-holding branded drug manufacturer sues one or more generic drug manufacturers who are attempting to gain regulatory approval to enter the market. The branded drug maker claims that the generic company?s product infringes its patent, while the generic manufacturer counterclaims that the branded manufacturer?s patent is either invalid or not infringed. The parties agree to settle their litigation, with the branded company paying the generic company and the generic company agreeing not to produce or market its generic pharmaceutical until some future date (in some cases sooner than the branded company?s patent is set to expire).

The pharmaceutical industry has defended these types of settlement agreements because they avoid uncertain, expensive and time-consuming patent litigation, and can allow for generic drug entry into the marketplace earlier than would have occurred if the branded company?s patent were upheld. The FTC has opposed what it artfully calls these ?pay-for-delay? agreements since the early 2000s, claiming that they impede competition between branded and generic drug companies and cost consumers billions of dollars.

Neither the FTC nor private parties achieved an enviable success rate in challenging ?pay-for-delay? deals in court, prior to the Supreme Court?s ruling. Although the Sixth Circuit appeared intolerant of such agreements in a 2003 decision, numerous other federal appellate courts ? the Eleventh, Second, and Federal Circuits ? generally protected reverse payment settlements from attack so long as the patent was not obtained by fraud, the patent infringement lawsuit was not baseless, and the restriction on the generic manufacturer did not exceed the scope of the patent. The Eleventh Circuit dismissed the FTC?s current lawsuit under this standard; however, a recent Third Circuit ruling that reverse payment settlements are presumptively illegal created a clear circuit split, thus paving the way for the Supreme Court?s review.

?In Scope? Reverse Payment Settlements To Be Evaluated For Reasonableness

Under the Supreme Court?s ruling, reverse payment settlement agreements are not shielded from antitrust scrutiny, even if the restraint on the generic?s competitive conduct falls within the scope of the branded manufacturer?s patent. Justice Breyer?s majority opinion expressed some skepticism about these forms of settlement, calling them ?unusual? and indicating that particularly large payment amounts may be unjustified and probative of anticompetitive conduct. With this opinion, the Court has somewhat shifted the antitrust/IP pendulum back in favor of antitrust law?s policy of prohibiting unreasonable restraints on competition.

However, while some may be quick to portray this as an FTC victory, it actually reflects a compromise between the positions of the Commission (presumptive illegality) and the pharmaceutical industry (presumptive legality if restraint within patent scope). The Court declined to grant the FTC?s request that it hold reverse payment agreements presumptively unlawful, such that courts could invalidate them after only a ?quick look? with little analysis of market effects. Instead, the Supreme Court stated that ?[a]n antitrust defendant may show in the antitrust proceeding that legitimate justifications are present, thereby explaining the presence of the challenged term and showing the lawfulness of that term under the rule of reason.? The Court declined, however, to further define the contours of a rule of reason analysis for reverse payment settlements, leaving that to the discretion of trial courts.

Looking Ahead

The Supreme Court?s holding means that reverse payment settlement agreements will be evaluated on a fact-specific, case-by-case basis. Such agreements may still be permissible, and parties will want to carefully structure them in order to pass antitrust muster. For companies that still wish to settle uncertain and costly patent infringement suits, permitting the generic manufacturer and alleged infringer to begin marketing its product within the branded company?s patent term will not be enough. The parties must weigh the size of the payment, the strength of the asserted patent, the expected cost of infringement litigation, the value of non-monetary settlement provisions (*e.g.*, marketing, distribution, research and development efforts), and other legitimate justifications for the agreement. What constitutes a ?reasonable? settlement agreement between branded and generic manufacturers will, hopefully, become clearer to the business community as lower courts address future challenges over time.

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