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U.S. Supreme Court Adopts "Rule of Reason" Test for Reverse Payment Settlements

The U.S. Supreme Court last week in *FTC v. Actavis, Inc.* adopted a "rule of reason" test for determining the legality of a "reverse payment" settlement of "paragraph IV" infringement litigation between a branded drug manufacturer and its generic competitor. Although the adoption of a "rule of reason" test is usually hailed as good news for businesses, there is reason to be more cautious in this market context.

Typically, the "rule of reason" is invoked in lieu of rule holding a particular type of restraint, such as vertical price fixing, *per se* illegal. *E.g. Leegin Creative Leather Products, Inc. v. PSK, Inc.,* 127 S. Ct. 2705 (2007). However, the *Activis* decision means that in most circuits examining "reverse payment" settlements, a rule of reason analysis will replace a rule of presumptive legality. *Activis* was a victory for the Federal Trade Commission (FTC), and enlarges the opportunity for antitrust class actions. Negotiating a resolution to paragraph IV infringement cases may become more demanding. More significantly, because a rule of reason analysis requires examination of all of the facts and circumstances that may bear on anticompetitive intent and effect, the number of follow-on antitrust cases may increase, and fewer will be subject to early dismissal.

For at least 10 years, private parties and the FTC have challenged the legality, under the antitrust laws, of "reverse payment" settlements of infringement litigation that companies with patents for Food and Drug Administration (FDA)-approved drugs have brought against firms that, as part of their abbreviated new drug applications (ANDA) under the Hatch-Waxman Act, have certified that their generic products either do not infringe the patent covering the branded drug, or that the patent is invalid. Ordinarily, one would expect patent litigation to be resolved by the alleged infringer's paying the patentee. However, these settlements include a term calling for a "reverse" payment, from the patentee to the alleged infringer, as well as the infringer's agreement to delay the market entry to which it is, or may become entitled under the ANDA process. Antitrust challenges to such settlements have resulted in the adoption of two different tests for legality.

Under the "scope of patent" test, courts reviewing antitrust challenges to reverse payment settlements asked whether the particular terms of the "reverse payment" settlement permitted the patentee to achieve market protection beyond the scope of its patent. If so, and absent sham litigation or fraud in the procurement of the patent, the settlement was deemed immune from challenge. *See* the decision reversed in *Activis, FTC v. Watson Pharms, Inc*., 677 F.3d 1298, 2012 WL 1427789, at *11 n.8, *12 (11th Cir. 2012).

The Third Circuit criticized the "scope of patent" test for lacking any antitrust scrutiny at all. *K-Dur Antitrust Litigation,* 686 F.3d 197, 214 (3d Cir. 2012). Because a "reverse payment" settlement is an agreement between competitors for one of them to delay its market entry, thus restraining competition, the Third Circuit subjected such settlements to a "quick look rule of reason" test, holding that "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." Under this test, the defendants could rebut the *prima facie* case by showing that the payment (1) was for a purpose other than delayed entry or (2) offers some pro-competitive benefit. 686 F.3d at 218.

In *Activis,* the United States Supreme Court rejected both tests, and held that reverse payment settlements should be reviewed under a full rule of reason analysis. The Court reversed the dismissal of the FTC's complaint and remanded the case to give the FTC the opportunity to prove its case. Writing for the Court, Justice Breyer discussed the criteria that would inform a rule of reason inquiry in this context, including the size of the payment, 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 for the payment. The Court recognized that the existence and degree of any anticompetitive consequence from such a settlement might also vary from one industry to another.

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