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Supreme Court rules, 5-3, in favor of FTC's ongoing litigation over 'pay-for-delay' patent settlements

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Split decision in FTC vs Activis does not invalidate all such agreements, but also doesn't give pharma companies a free hand to make them

So-called "Paragraph IV" litigation between innovator and generic drug companies have been a bone of contention almost since the Hatch-Waxman Act was passed in 1984. Under that clause, a generic company could sue for market approval of its product, prior to the expiration of the relevant patent, by claiming that the patent would be invalidated during patent-law litigation. FDA could proceed to approve the drug 30 months after the initial filing, pending resolution of the patent dispute. Innovator companies have, along the way, entered into settlements with the generic companies, offering a "reverse" payment (i.e., from the patent holder to the plaintiff) to delay introduction of the generic product until a certain date. The Federal Trade Commission, along with numerous payers along the way, has called these reverse payments an anticompetitive action in violation of the Sherman Antitrust Act.

Now, in a 5-3 ruling, the Supreme Court has given both sides some maneuvering room. The decision does not presumptively agree that the agreements are anticompetitive—but they could be. A legal test that comes out of prior antitrust litigation, the "rule of reason," should apply, said the majority opinion. This will allow FTC, or others, to investigate the full scope and consequences of an agreement, and if the weight of evidence strongly favors an anticompetitive interpretation, the burden shifts to the defendant to prove procompetitive consequences. Conversely, the Court didn't give FTC the latitude to assume a so-called "quick look" evaluation, which starts from the point that such agreements are anticompetitive in and of themselves. "Both branded and generics companies will go forward with these agreements, but in a more careful manner," says Jeffery Cross, a partner at Freeborn & Peters (Chicago) involved in antitrust litigation. And the likelihood is that there could be even more litigation in future cases.

"We are pleased that the Court clearly recognized that settlements require a case-by-case assessment. In establishing the 'rule of reason,' and leaving the decision to lower courts, the ruling continues to provide a lawful pathway for companies to resolve disputes through settlements," said Ralph Neas, president of GPhA. "This preserves all options for generic manufacturers to bring lower-cost generic medicines to patients as soon as possible."

The case originated when Watson Pharma (now Activis) and other generic manufacturers entered into agreements with Solvay Pharmaceuticals (now AbbVie) in 2009 over AndroGel (testosterone). The majority opinion was written by Stephen Breyer, with Justices Roberts, Scalia and Thomas dissenting; Justice Alito abstained.