

US: 'Pay to delay' generic drugs can be illegal (Update)

June 17 2013, by Jesse J. Holland

The Supreme Court ruled Monday that deals between pharmaceutical corporations and their generic drug competitors, which government officials say keep cheaper forms of medicine off the market, can be sometimes be illegal and therefore challenged in court.

The justices voted 5-3 to allow the government to inspect and challenge what it calls "pay-for-delay" deals or "reverse payment settlements."

"This court's precedents make clear that patent-related settlement agreements can sometimes violate anti-trust law," said Justice Stephen Breyer, who wrote the court's opinion.

Reverse payment settlements arise when generic companies file a challenge at the Food and Drug Administration to the patents that give brand-name drugs a 20-year monopoly. The generic drugmakers aim to prove the patent is flawed or otherwise invalid, so they can launch a generic version well before the patent ends.

Brand-name drugmakers then usually sue the generic companies, which sets up what could be years of expensive litigation. When the two sides aren't certain who will win, they often reach a compromise deal that allows the generic company to sell its cheaper copycat drug in a few years—but years before the drug's patent would expire. Often, that settlement comes with a sizable payment from the brand-name company to the generic drugmaker.

Drugmakers say the settlements protect their interests but also benefit consumers by bringing inexpensive copycat medicines to market years earlier than they would arrive in any case generic drugmakers took to trial and lost. But federal officials counter that such deals add billions to the drug bills of American patients and taxpayers, compared with what would happen if the generic companies won the lawsuits and could begin marketing right away.

"This decision makes clear that drug companies can be sued to stop anticompetitive pay-for-delay agreements,' said New York Attorney General Eric T. Schneiderman. " It will be an important weapon in the fight for affordable drug prices and quality healthcare for every citizen."

But Steve Reed, a lawyer at Morgan, Lewis & Bockius LLP, said the decision could delay the entry of generics into the market.

Chief Justice John Roberts, who wrote the dissent for himself and Justices Antonin Scalia and Clarence Thomas, said ordinarily the high court would say that any deal that would end costly and time-consuming litigation would be thought of as a good thing.

"The majority's rule will discourage settlement of patent litigation," Roberts said. "Simply put, there would be no incentive to settle if, immediately after setting, the parties would have to litigate the same issue—the question of patent validity—as part of a defense against an antitrust suit."

The Justice Department asked the court to rule that all reverse payment settlements were illegal, but Breyer said that was going too far. The deals' "complexities lead us to conclude that the FTC must prove its case," he said.

Justice Samuel Alito did not take part in the case.

The case is Federal Trade Commission vs. Actavis, Inc., 12-416.

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Citation: US: 'Pay to delay' generic drugs can be illegal (Update) (2013, June 17) retrieved 23 April 2024 from <https://medicalxpress.com/news/2013-06-court-drugs-illegal.html>

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