

PATENT SETTLEMENTS

The timing of a generic drug's market entry may be determined by "pay for delay" patent settlements between drug companies.

The generic drug sector in the US helps hold down pharmaceutical costs, with prices of widely used drugs typically dropping to commodity levels once multiple-generic competition begins. In some cases, the innovator (brand-name) company can settle patent litigation with a single generic drug firm by negotiating a payment to the challenger in exchange for agreement on a set, future date for generic entry—and, in the process, blocking all other generic launches of the same drug. That, in turn, delays the start of the erosion in the brand-name price—even in cases where the underlying patents are eventually deemed invalid. These so-called pay-for-delay agreements have been challenged by antitrust regulators with some success. However, federal courts have not agreed with antitrust authorities that there should be a bright-line rule defining those agreements as anticompetitive, prompting proposals for legislation to address the issue directly.

Background

The 1984 Drug Price Competition and Patent Term Restoration Act (known as the [Hatch-Waxman Act](#)) instituted a process for identifying and litigating innovator companies' patent claims to determine when a generic firm can launch a competitor.

One byproduct of the Hatch-Waxman Act is the emergence of settlements to resolve patent lawsuits whereby a brand company and a single generic firm agree on a generic launch date months or years in the future and, in the process, block any other generics from coming to market. The settlements often involve a payment from the innovator company to the generic firm, called a "reverse payment." These settlements are referred to as pay-for-delay agreements because they postpone the start of generic competition later than the date the generic company asserted in litigation that it should be able to launch if the patents in question are overturned.

Settling companies argue that the agreements are appropriate and pro-consumer: Typically, the generic can come to market before the expiration date of at least one patent at issue, and the certainty of the timing benefits purchasers. Litigation settlements, by their nature, involve compromise, and settling companies reject the description that the agreement is pay-for-delay. Consumer

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advocates, however, argue that the settlements are anticompetitive and keep drug prices higher than they would otherwise be. The Federal Trade Commission (FTC) [agrees](#), having brought multiple cases challenging the settlements over the past two decades.

However, the FTC has not persuaded federal courts to draw a bright line defining agreements involving reverse payments as presumptively anticompetitive. While the number of settlements that the FTC views as suspect has declined in recent years, such cases continue to occur—and the potential impact on drug pricing can be significant, particularly for high-price and/or high-volume drugs. Proposed solutions require an understanding of the unintended effects of the Hatch-Waxman Act that shape the settlements.

■ Patent Adjudication And “First Generic” Incentives

The Hatch-Waxman Act establishes a special process for adjudicating patent rights asserted by innovator pharmaceutical companies over their brands. Inno-

“The law includes an incentive for generic companies to challenge patents.”

vator companies must publicly identify patents that they believe preclude generic competition. Companies filing a generic drug application (an Abbreviated New Drug Application, or ANDA) must certify whether they intend to challenge any of those patents or wait until they expire before launching their product. If an ANDA applicant challenges a patent, it states its intent to do so in its application—known as a Paragraph IV certification, after the subsection of the law establishing the process. Assuming that the innovator files suit to protect its patent from the challenger, the Food and Drug Administration (FDA) is prohibited from approving the generic application for thirty months unless a court rules in favor of the generic earlier than that.

The law also includes an incentive for generic com-

panies to challenge patents: six months of market exclusivity granted to “first generics”—meaning that no other generic application for the same drug can be approved for that period of time. Without the incentive, generic companies may be less likely to take on the expense of litigation to challenge a patent, since a victory in court could open up the market to multiple competitors simultaneously.

Over time, first-generic exclusivity became a critical component of the profitability of the generic sector. A first generic is often priced at a relatively modest discount to the brand; once multiple generics enter the market, [pricing erodes](#) rapidly to as much as 90 percent less than the brand, according to an FTC working paper. As a result, even very large generic companies depend on short-periods of high profit margins from a handful of first generics with market exclusivity.

The Hatch-Waxman Act also defined the filing of a generic drug application as an act of patent infringement. This allows the innovator to initiate litigation to protect its patent even before a generic firm has FDA approval to sell a competing product. Normally, patent litigation can be brought only when a competitor is actually selling a potentially infringing product. For the first decade after the Hatch-Waxman Act, the FDA interpreted the generic incentive as applying to the first company to “successfully defend” a patent infringement case. Thus, if more than one generic firm challenged the patents for a given brand, the FDA would wait until one applicant won its case, and that applicant would be awarded the six-month first-generic exclusivity upon approval.

That changed in 1997, when a federal court ruled in *Mova v. Shalala* that the FDA policy contradicted the plain reading of the statute, which says that the six-month exclusivity is awarded to the first applicant to file an ANDA challenging an innovator’s patents. That ruling was upheld [on appeal](#) in 1998, and questions about pay-for-delay settlements began (Exhibit 1).

■ FTC Brings Cases Asserting Anti-Competitive Behavior

The *Mova* ruling changed the dynamics of generic patent settlements dramatically. By law, the FDA cannot approve any subsequent applicants until the first-

to-file applicant's six-month exclusivity expires. So if the first applicant agrees to settle litigation with a negotiated future launch date, that settlement blocks all generic applicants until six months after that date.

Those circumstances raised questions about the terms of many brand/generic settlements. The FTC began to investigate settlements where it believed the innovator and first-to-file challenger might, in effect, be colluding to delay the onset of generic competition. Instead of using the litigation to clear out invalid or inapplicable patents, the FTC believed that the settling parties might agree to preserve most of the claimed patent life—and share the increased profits that the brand-name product collects in the meantime.

The FTC routinely challenges business agreements between competing firms that it believes are anti-competitive. However, courts generally encourage settlements that “split the difference” in patent cases—a legitimate (not anti-competitive) reason for brand and generic firms to compromise on the launch date for the challenger. In building antitrust cases, the FTC explicitly flagged “reverse payments” as a marker of anti-competitive intent. Such payments could be overt cash transfers or side agreements for product licensing or other less direct compensation. The FTC

argued that the flow of money was backwards; in most patent cases, the innovator collects damages or compensation from the alleged infringer—not the other way around.

The FTC brought several antitrust cases starting in 2000 challenging settlements that involved reverse payments and had some success in opening up competition for specific products. The agency also persuaded Congress to include a provision in the Medicare Modernization Act of 2003 requiring that all brand/generic patent settlements be submitted to the FTC for review, giving the agency an opportunity to challenge settlements that it deemed anti-competitive.

However, the agency ultimately failed to persuade federal courts to accept the notion that reverse payments should always be treated as evidence of anti-competitive intent, and several of FTC's early victories were overturned on appeal. In 2013 the issue went to the Supreme Court (*FTC v. Actavis*), which declined to define reverse payments as per se anti-competitive. However, the Court also rejected arguments from the pharmaceutical industry that settlements allowing generic entry before expiration of the patent(s) at issue should be assumed to be pro-competitive. Instead, the Court determined that settlements

EXHIBIT 1

“Pay For Delay”—A Timeline

1984	Hatch-Waxman generic drug law enacted.
1997	<i>Mova v. Shalala</i> decision determines that the first generic applicant to challenge an innovator patent has rights to six months of market exclusivity—and the FDA is prohibited from approving other generic applicants even if they win patent challenges that would allow them to come to market sooner.
1999	FTC investigation of potential pay-for-delay agreements becomes public.
2000	The FTC settles first antitrust case on pay-for-delay grounds, involving Abbott and Geneva Hytrin patent dispute.
2003	Medicare Modernization Act requires disclosure of pharmaceutical patent settlements to the FTC for antitrust review.
2005	Appellate courts overrule the FTC in three cases, declare that reverse payments are not inherently anti-competitive; per FTC testimony, the FTC sees reverse payment settlements resume after five-year hiatus.
2013	Supreme Court rules in <i>FTC v. Actavis</i> that reverse payment cases may be challenged using a “rule of reason” analysis but does not define payments as per se evidence of antitrust violation.
2015	The FTC reaches \$1.2 billion settlement with Cephalon resolving pay-for-delay investigation.
2017	The FTC announces new pay-for-delay cases involving settlements for two different brand-name drugs.

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should be subject to a “rule of reason” test that allows antitrust challenges to continue. Since then, the FTC has concluded a number of additional settlements involving pay-for-delay cases—including a \$1.2 billion recovery from brand company Cephalon in 2015.

■ The Future Of Pay-For-Delay Policy And Drug Pricing

A number of important issues will play into the future impact of patent settlements and pay for delay on drug prices.

STAKEHOLDER ALIGNMENT

On most issues involving interpretation of the Hatch-Waxman Act, the brand and generic industry segments are on opposite sides. However, they are united in their view that patent settlements should be seen as pro-consumer, or at least not inherently anti-competitive.

A PRECEDENT FOR ACTION

According to the FTC, a “bright line” for antitrust enforcement worked in the past. The agency [has noted](#) that settlements involving reverse payments virtually disappeared for five years after the first cases were

brought in 2000—as the industry was put on notice that the FTC viewed such payments as inherently anti-competitive. Reverse payments resumed and accelerated after appellate courts overruled the FTC on that point in 2005.

PAY-FOR-DELAY IN DECLINE

According to the FTC’s most recent (2016) staff [report](#) on the issue, suspect agreements have fallen in absolute terms and as a percentage of all patent settlements reviewed by the agency since the 2013 Supreme Court decision in *FTC v. Actavis*. However, the FTC continues to identify settlements that it believes are anti-competitive, with new cases [announced](#) in 2017.

POTENTIAL SAVINGS

Legislation to support the FTC’s approach would result in modest but meaningful savings for drug purchasers. Legislation setting a standard that reverse payments are presumed anti-competitive would save more than \$2.4 billion in federal spending over ten years, according to the [Congressional Budget Office score](#) of a bill proposed by Sen. Amy Klobuchar (D-MN) in 2015. There would also be savings for consumers and private insurers.

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