Pay-for-Delay:

How Drug Company Pay-Offs Cost Consumers Billions

An FTC Staff Study
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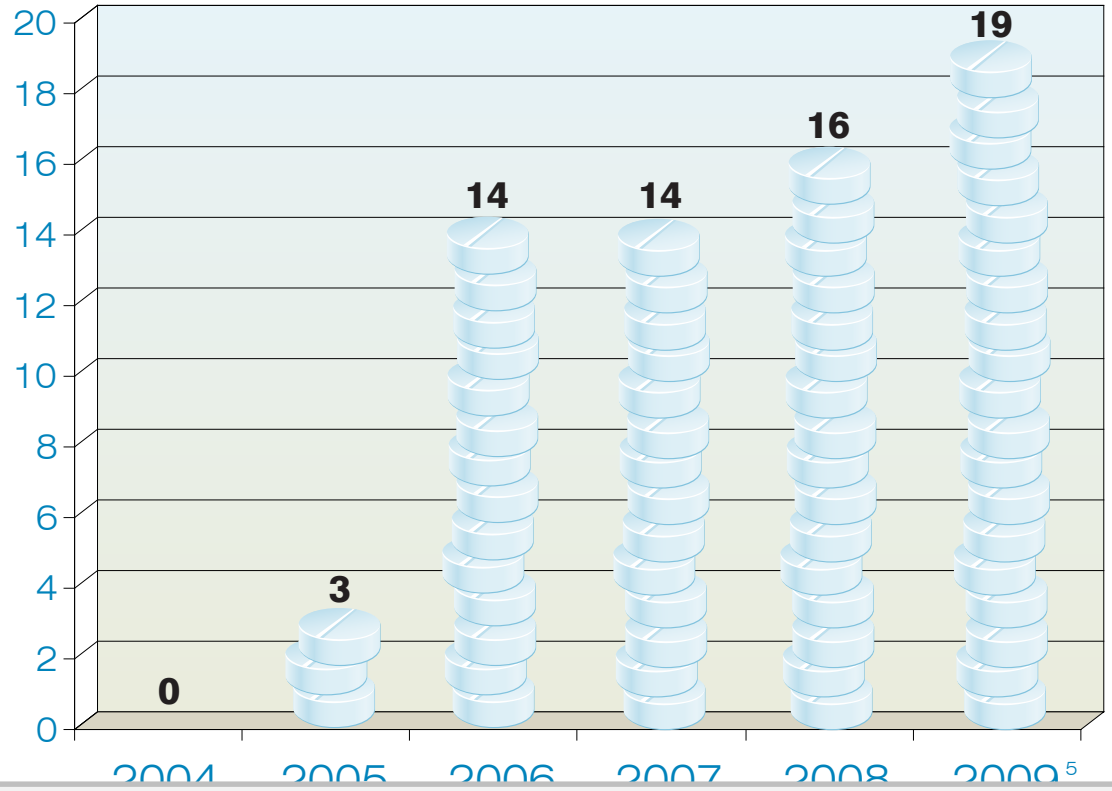
Summary

- Brand-name pharmaceutical companies can delay generic competition that lowers prices by agreeing to pay a generic competitor to hold its competing product off the market for a certain period of time. These so-called "pay-for-delay" agreements have arisen as part of patent litigation settlement agreements between brand-name and generic pharmaceutical companies.
- "Pay-for-delay" agreements are "win-win" for the companies: brand-name pharmaceutical prices stay high, and the brand and generic share the benefits of the brand's monopoly profits. Consumers lose, however: they miss out on generic prices that can be as much as 90 percent less than brand prices. For example, brand-name medication that costs $300 per month might be sold as a generic for as little as $30 per month.
- The Federal Trade Commission's (FTC) investigations and enforcement actions against pay-for-delay agreements deterred their use from April 1999 through 2004.[1] In 2003, an appellate court held that such agreements were automatically (or *per se*) illegal.[2]
- Since 2005, however, a few appellate courts have misapplied the antitrust law to uphold these agreements.[3] Following those court decisions, patent settlements that combine restrictions on generic entry with compensation from the brand to the generic have re-emerged.

Agreements with Delay and Compensation[4]



[5]

- Agreements with compensation from the brand to the generic on average prohibit generic entry for nearly 17 months longer than agreements without payments, where the average is calculated using a weighted average based on sales of the drugs.[6] Most of these agreements are still in effect. They currently protect at least $20 billion in sales of brand-name pharmaceuticals from generic competition.[7]

- Pay-for-delay agreements are estimated to cost American consumers $3.5 billion per year – $35 billion over the next 10 years.[8]

Recommendation

Pay-for-delay agreements have significantly postponed substantial consumer savings from lower generic drug prices. The Commission has recommended that Congress should pass legislation to protect consumers from such anticompetitive agreements.

Background

Pay-for-delay agreements appear in some settlements of patent litigation between brand-name and generic pharmaceutical companies. That patent litigation usually takes place within the framework for generic entry established by the Hatch-Waxman Act.[9] Under that Act, a generic competitor may seek entry prior to expiration of the patents on a brand-name drug. Generic drug entry before patent expiration can save consumers billions of dollars. Generics have an incentive to challenge brand patents because the first generic to file its application can obtain 180 days of marketing exclusivity during which it is the only generic on the market. To seek FDA approval for entry before patent expiration, a generic must declare that its product does not infringe the relevant patents or that the relevant patents are invalid.

Typically, brand-name pharmaceutical companies challenge the generic's declaration, and litigation ensues between the brand-name and generic pharmaceutical manufacturers to determine whether the relevant patents are valid and infringed. For the brand to prevail and block entry, it must successfully defend the validity of its patents and demonstrate that the generic's product would infringe those patents. In 2002, the FTC issued a study showing that generics prevailed in 73% of the patent litigation ultimately resolved by a court decision between 1992 and June 2002.[10]

Given the costs and potential uncertainty of patent litigation, brand-name and generic pharmaceutical companies sometimes settle their patent litigation before a final court decision. For example, the parties may agree that the generic can enter at some time before the patent's expiration date, but not as soon as the generic seeks through its litigation. Absent compensation to the generic for the delay in its entry, such settlement agreements are unlikely to raise antitrust issues.

The FTC's 2002 study determined, however, that some brand-name and generic pharmaceutical companies had settled their patent litigation through agreements that compensated generics for substantial delays in generic entry. The FTC recommended that Congress pass legislation to require pharmaceutical companies to file certain agreements with the FTC. The intent of the legislation was "to put an end to this exploitation of the provision in Hatch-Waxman that grants a short-term protection from competition to the first manufacturer to bring a generic version of a brand name drug to market."[11]

Congress acted on the FTC's recommendation. Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the "MMA"), pharmaceutical companies must file certain agreements with the FTC and the Department of Justice within ten days of their execution.[12]

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