

Pay-for-Delay: An Unsettled Future Lies Ahead

<https://marketpublishers.com/r/P8A4D280248EN.html>

Date: July 2010

Pages: 36

Price: US\$ 395.00 (Single User License)

ID: P8A4D280248EN

Abstracts

Anti-competitive or just good business?

That's the question facing the pharmaceutical industry and regulators alike, as companies dealing with drugs going off-patent increasingly rely on pay-for-delay agreements that involve delayed generics market entry in exchange for a value transfer. Avoiding costly, lengthy and complex patent litigation, pay-for-delay deals are undeniably emerging as a trend, but are estimated to cost the payer an annual \$3.5 billion.

Direct payment to the generics company is becoming rarer, with unrelated side-deals the form of compensation of choice in both the US and EU. Considered a win-win scenario by both generics and branded industries, the deals are being spurred on by two main factors: the benefit of avoiding expensive and risky litigation for both parties, and the potential gains of extending market exclusivity for the branded company.

How are regulators reacting? No doubt alarmed at the increase in pay-for-delay settlements—none in 2004 and 19 in 2009—the US Federal Trade Commission has begun closely scrutinizing the competitiveness of the arrangements, while the European Commission recently highlighted the deals in its year-long pharma inquiry. While a US ban has yet to be implemented, there is no doubt the issue will come to the forefront in the very near future. Indeed, the House of Representatives recently passed a bill that would allow the Federal Trade Commission to fine companies engaging in anticompetitive deals.

So what is the future of reverse-payment deals?

In *Pay-for-Delay: An Unsettled Future Lies Ahead*, FirstWord examines the current pay-for-delay environment by delving into the deals, the major players and the factors

driving the trend. The report offers insights into the present regulatory environment, company strategy and how the US and European markets differ. Backed by solid statistical and analytical reporting, the dossier also gives readers a full breakdown of patent litigation and settlements across two continents, and identifies which companies are likely to win--and which to lose.

The report offers insights into

Why pay-for-delay agreements are evolving as they are

Why a ban failed to make it into US healthcare reform legislation, and what the future of regulation may hold

The report

Examines the current state of pay-for-delay agreements in the US and Europe

Reviews which companies are engaging most actively in the deals, and which are litigating

Includes statistics, charts and insight into how pay-for-delay deals are taking shape

Reviews strategies used by generics and branded companies

Provides an overview of potential regulatory changes

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