SHEPPARD MULLIN
SHEPPARD MULLIN RICHTER & HAMPTON LLP
Antitrust Law BLOG
Current Antitrust News and Regulatory Developments

Antitrust Law Blog

Posted at 5:22 PM on January 25, 2010 by Sheppard Mullin

FTC Chair Calls for Ban to Pay-For-Delay Settlements

On January 13, 2010, the Federal Trade Commission released a study critical of "pay-for-delay" patent litigation settlements by which brand-name drug companies pay generic competitors to keep generic drugs off the market. The same day, the Chairman of the FTC, Jon Leibowitz, and Representatives Chris Van Hollen (D-Md.), Bobby Rush (D-Ill.) and Mary Jo Kilroy (D-Ohio) held a news conference during which they urged Congress to include a provisional banning such settlements in the final health care reform bill.

The FTC study, "Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions," examined the impact of pay-for-delay settlements over the past six years and found that, on average, such settlements preclude generic entry for 48 months. Agreements containing provisions for payments by the brand-name company to the generic on average precluded generic drug entry for nearly 17 months longer than agreements without payment provisions. According to the study, most of such agreements are still in effect and currently protect at least $20 billion in sales of brand-name drugs from generic competition. In addition, the study projected that pay-for-delay agreements will cost American consumers $35 billion over the next 10 years, or $3.5 billion per year.

Chairman Leibowitz said consumers are forced to pay inflated prices or forgo their medication because of such settlements. "Pay-for-delay deals are a bad prescription for America: when drug companies agree not to compete, consumers lose," Leibowitz stated. "These are collusive, price-fixing deals," said Representative Van Hollen. "It means the consumer pays a lot more for their pharmaceuticals."

Pay-for-delay settlements are an unintended outgrowth of the Hatch-Waxman Act, a 1984 law intended to promote price competition by encouraging generic drug companies to challenge the patents protecting brand-name drugs. Under the Act, the first generic to challenge a brand-name's patent gains the exclusive right to sell its generic version for six months before other generics can enter the market. But it also gives brand-name companies who sue generic infringers an automatic 30-month stay of generic entry.

Such patent infringement litigation often is settled. A number of the settlements have delayed generic market entry and have involved payments by the brand-name company to the generic, either by direct payments or through agreements by which the generic is paid to provide goods or services. In fiscal year 2009, drug companies entered into 19 settlement agreements that involved

both delaying generic entry and compensation from the brand-name to the generic.

The House-passed version of the health care overhaul bill includes a provision authored by Representative Rush that would make pay-for-delay settlements illegal. The Senate version does not address the issue, but Senator Herb Kohn (D-Wis.) has offered an amendment to prohibit such settlements. In addition, nine Democratic senators recently wrote to Senate leaders to urge that the House's provision be included in the final health care legislation. Van Hollen stated that he thinks the House language has a "very decent chance at getting in the final bill."

According to the research firm IMS Health, generics account for only about 22 percent of prescription drug spending, although they represent nearly 75 percent of the prescriptions written. That means that 78 percent of drug expenditures goes to the 25 percent of prescriptions written for brand-name drugs. Considering only federal government spending, the Congressional Budget Office estimates that the House provision could save the government $1.8 billion over the next 10 years.

Authored By:

Robert L. Magielnicki
(202) 218-0002
RMagielnicki@sheppardmullin.com