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FTC Staff Report Summarizes Recent Pay-for-Delay Settlements

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On October 25, 2011, the **Federal Trade Commission (FTC)** Bureau of Competition staff released a report providing an overview of recent settlements filed with the FTC concerning patent disputes between brand and generic pharmaceutical companies (http://www.ftc.gov/opa/2011/10/mma.shtm). Such settlements must be filed with the FTC under the **Medicare Prescription Drug, Improvement, and Modernization Act of 2003**.

According to the FTC staff report, 28 of the 156 final settlements filed with the FTC in fiscal year 2011 were potential reverse payment, or "pay-for-delay," agreements in which the branded pharmaceutical company both provided some type of compensation to the generic and "restricted the generic's ability to market its product." The FTC has long been opposed to pay-for-delay settlements because they can delay the entry of lower-cost generics to market, thereby potentially increasing prescription drug costs for consumers.

The 28 potential pay-for-delay settlements identified by the FTC staff in FY 2011 "involved 25 different branded pharmaceutical products with combined annual U.S. sales of more than $9 billion." Of those 28 settlements, 18 involved generics eligible for 180-day "first-filer" exclusivity, meaning these generics were the first to challenge the patent of the branded drug and were eligible for 180 days of market exclusivity for their generic equivalent. This first-filer exclusivity is provided by the Hatch-Waxman Act, passed by Congress to promote the entry of generic equivalent drugs to the market by granting market exclusivity to those companies first to challenge the patent of a branded drug. The FTC finds pay-for-delay settlements involving potential first-filers particularly troublesome because if a first-filer is delayed entry to the market, other generic manufacturers may also be blocked until the first-filer enters the market.

Notably, compensation provided to a generic as part of a settlement might not take the form of a cash payment. Of the 18 settlements in which a generic was eligible for first-filer exclusivity, 10 included either an agreement by the branded drug company not to compete with an authorized generic equivalent drug or an exclusive license for the generic company to market the authorized generic equivalent drug. An authorized generic—the branded drug manufacturer's generic version of its own drug—can be sold during the generic first-filer's 180-day exclusivity period because the branded drug manufacturer has already received FDA approval for its product. In such circumstances, not only does a pay-for-delay settlement delay the entry of the generic to the market, thus shielding the

branded drug from competition with a lower-cost generic for the duration of the delay, but once the generic enters the market, it does not face competition from other authorized generics during the 180-day exclusivity window.

Overall, the report found that pay-for-delay settlements have been increasing in recent years, with the FTC receiving almost as many potential pay-for-delay settlements in the past two fiscal years as the total number of such agreements filed between FY 2004 and FY 2009.

Practice Note: The FTC's distaste for pay-for-delay settlements is unlikely to abate. Indeed, the FTC has challenged certain pay-for-delay settlements in court, winning only one challenge when the branded drug company's patents had terminated. The FTC has lobbied Congress to restrict pay-for-delay agreements through legislation that presently is pending. Clients need to be alert that entering into pay-for-delay agreements will likely draw the attention of the FTC as there appears to be a strong policy of the FTC to challenge these settlements. Also, see the report on the California *Cipro* cases in this edition of IP Update.

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