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FTC Reports Declining Use of Pay-for-Delay Deals in Rx Patent Settlements in FY 2013

Brand-name drug firms decreased their use of so-called pay-for-delay settlements in fiscal year 2013, according to a report released Dec. 22 by the Federal Trade Commission.

The report found that the number of potentially anticompetitive patent dispute settlements between branded and generic drug companies decreased from the 40 reported in FY 2012 to 29 in FY 2013.

Pay-for-delay or reverse payment settlements generally involve payments from branded drug companies to generic drug companies in exchange for keeping the generic off the market.

According to the FTC's latest report, in FY 2013, drug companies filed 145 final patent dispute settlements, of which 29 were deemed potentially anticompetitive.

The 29 settlements potentially involved pay-for-delay settlements because the brand manufacturer compensated the generic manufacturer and the generic manufacturer was restricted from marketing its product in competition with the branded product for some period of time, the report said.

The FTC said the 29 settlements involve 21 different branded pharmaceutical products, with combined annual U.S. sales of approximately $4.3 billion.

Of the 29 potential pay-for-delay settlements, the FTC said that 13 involved generics that were so-called ''first filers,'' meaning the companies were the first to seek FDA approval to market a generic version of the branded drug and, at the time of the settlement, were eligible to market the generic product for 180 days without competition from other generic drugmakers. Under the FDA's regulations, when first filers delay entering the market, other generic manufacturers are blocked from entering.

Although the number of potential pay-for-delay settlements is down from FY 2012, it is similar to FY 2010 and 2011, the FTC said.

The report is based on patent dispute settlements filed by pharmaceutical companies with the FTC and the Department of Justice during FY 2013 pursuant to the Medicare Modernization Act of 2003.

According to the report, the vast majority of these patent disputes were resolved without compensation to the generic manufacturer or without restrictions on generic competition.

Attorney Says FY 2014 Data May Reveal More. Antitrust expert James M. Burns of Dickinson Wright PLLC in Washington told Bloomberg BNA Dec. 23 that the reduction in the number of potential pay-for-delay settlements for FY 2013 likely can be explained, at least in part, by the significant uncertainty during this period regarding how the U.S. Supreme Court would rule in the *Actavis* case, which wasn't decided until June 2013 (22 HLR 921, 6/20/13).

''Where possible,'' Burns said, ''branded and generic pharmaceutical manufacturers undoubtedly sought to resolve patent disputes with settlements containing terms that were less likely to be swept into the scope of the Supreme Court's ruling in *Actavis*.''

In the *Actavis* case, the FTC challenged as anticompetitive a patent litigation settlement in which a branded drugmaker paid two generic drugmakers to delay introduction of their generic version of the testosterone replacement therapy AndroGel. The U.S. Supreme Court said the traditional ''rule of reason'' analysis applied to determine whether settlements of drug patent litigation between branded and generic drug companies are anticompetitive.

Burns said the FTC's FY 2014 data on reverse payment deals will likely be far more interesting, as it will reflect a full year of data tracking pharma's reaction to the *Actavis* case, and will indicate whether branded and generic manufacturers feel confident enough with the guidelines set forth in *Actavis* to structure settlements that they believe will withstand antitrust challenges.

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