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Intellectual Property

Use of Pay-for-Delay Deals Jumps In Drug Patent Settlements, FTC Reports

Brand-name drug firms significantly increased the use of pay-for-delay settlements in fiscal year 2012, according to a report issued on Jan. 17 by the Federal Trade Commission.

The report found that the number of potentially anticompetitive patent dispute settlements between branded and generic drug companies jumped from 28 in FY 2011 to 40 in FY 2012. The figure is the highest of any year since the FTC began collecting data in 2003, the report noted.

The 40 pay-for-delay deals involved different branded pharmaceutical products with combined annual U.S. sales of more than $8.3 billion, the FTC observed.

Reverse payment settlements generally involve payments from branded drug companies to generic drug companies in exchange for the generic staying off the market.

The report said that, in nearly half of the settlements, branded firms may have used the promise that they would not develop or market an authorized generic (AG) as a payment to stall generic drug firms from marketing a competing product. An authorized generic drug is a branded prescription drug produced by the brand-name manufacturer and repackaged as a generic.

''Sadly, this year's report makes it clear that the problem of pay-for-delay is getting worse, not better,'' FTC Chairman Jon Leibowitz declared in a statement. ''More and more brand and generic drug companies are engaging in these sweetheart deals, and consumers continue to pay the price.''

David A. Balto, a Washington, D.C., antitrust practitioner, who formerly served as assistant director for policy and evaluation in FTC's Bureau of Competition, quipped: ''One cannot say the drug companies lack chutzpah.'' In a Jan. 17 email to BNA, Balto noted: ''It is amazing and disappointing that they would increase these payoffs at a time where controlling health care costs is a critical national priority.''

Generic Drug Lobby Slams Report. But the Generic Pharmaceutical Association (GPhA), the lobby for the generic drug industry, slammed the FTC's latest report in a Jan. 17 statement.

''The FTC is wrong on the facts, wrong on the public policy, and wrong on the law,'' Ralph G. Neas, GPhA's president and chief executive officer, said in the statement. ''If successful, the FTC position would dramatically undermine the law of the land and cost patients and consumers billions of dollars every year.''

Neas asserted: ''The FTC is continuing to perpetuate the myth that pro-competitive, pro-consumer patent settlements are harmful to consumers—an unsubstantiated position that has repeatedly failed to receive support in both Congress and the courts.'' He added: ''Patent settlements have never prevented competition beyond the patent expiry, and generally have resulted in making lower-cost generics available months and even years before patents have expired.''

Supreme Court Poised to Act. The U.S. Supreme Court is poised to act on the reverse payments issue this year. In December, the Court granted a writ of certiorari to review a decision involving so-called reverse payment deals and the testosterone drug AndroGel (103 ATRR 731).

The case will give the Supreme Court the opportunity to decide the legality of agreements between branded and generic drugmakers that call for payments and delayed generic drug entry as part of a patent litigation settlement. The Court's ruling should resolve a longstanding circuit split on whether such deals are anticompetitive.

With the FTC's brief to the Supreme Court in the AndroGel case due the week of Jan. 24, James M. Burns, of Dickinson Wright PLLC in Washington, D.C., told BNA Jan. 17: ''One can expect that the statistics in the new report will be highlighted by the FTC as it seeks to persuade the Court of both the continuing importance of the issue and potential harm to consumers from the practice.''

Burns added: ''The timing of the issuance of the report seems, at the very least, fortuitous for the FTC.''

Balto said: ''It is time for the Supreme Court to step up to the plate and declare these deals illegal.''

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The FTC report is available at http://op.bna.com/hl.nsf/r?Open=deln-942qwj — on the FTC's website.

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