

Clients & Friends Alert

FTC Continues Aggressive Posture on Reverse Payment Settlement Agreements with Reference to Disgorgement

April 3, 2014

In two recent statements, the FTC reaffirmed its intention to pursue aggressively reverse-payment patent settlement agreements in the pharmaceutical industry.

First, Commission officials stated that they are currently combing through previous pharmaceutical settlement agreements to determine quickly which cases to pursue following the Supreme Court's 2013 ruling in *FTC v Actavis* that reverse payment settlements – also known as “pay-for-delay” settlements – are not immune from antitrust scrutiny. Second, the head of the FTC's Bureau of Competition stated that the Commission will consider “a range of remedies” and will seek “whatever relief is necessary” in any particular case, including “disgorgement,” i.e., requiring companies to give up profits obtained illegally. The Director indicated that the FTC hopes to obtain a billion dollar settlement in at least one pay-for-delay case this year.

Takeaways

The FTC's recent statements highlight important features of the antitrust landscape that parties settling Hatch-Waxman litigation must consider:

- Pursuing pay-for-delay settlements is an FTC priority. The FTC views *FTC v. Actavis* as a green light for an aggressive campaign against pay-for-delay settlements.
- Disgorgement is a real threat. Despite the paucity of disgorgement settlements, there is some law to support the pursuit of disgorgement and the FTC appears to be inclined to use every tool available to accomplish its goals.
- Parties cannot assume that subsequent generic entry will moot ongoing pay-for-delay cases. While generic entry may undermine some FTC claims for injunctive relief, such entry may put additional pressure on regulators to seek disgorgement to the extent injunctive relief is not available.

Additional background on disgorgement remedies in pay-for-delay cases is provided below.

Background

In June of 2013, the U.S. Supreme Court ruled in *FTC v. Actavis* that reverse payment settlements were not immune from antitrust scrutiny and that courts should review the agreements under the rule of reason. Although many questions remain regarding the impact of the *Actavis* decision, it seems that the FTC views the decision as a green light for its enforcement agenda. Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, drug manufacturers are required to file certain settlement agreements with the FTC, and in light of the recent statements from Commission officials regarding *Actavis*, the FTC appears to view the settlements as a fertile field to plow for new cases.

Although the FTC has sought disgorgement in antitrust cases previously, the Commission has focused primarily on injunctive relief. Between 2003 and 2012, operating under a written policy statement outlining the factors used to determine whether monetary remedies were appropriate, the FTC pursued disgorgement in only a couple cases, succeeding in one and losing in the other. During the summer of 2012, the Agency withdrew its policy statement, writing that the Commission “will rely instead upon existing law, which provides sufficient guidance on the use of monetary equitable remedies.”

Late last year, for the first time since withdrawing the policy statement, the FTC argued for monetary damages in an antitrust case. In *FTC v. Cephalon*, the FTC claimed that Cephalon, Inc. paid an excess of \$200 million dollars to generic drug companies in an effort to induce them to abandon their patent challenges against Provigil, a prescription medicine used to improve wakefulness in adults, and to dissuade the generic companies from selling generic version of Provigil. Although the FTC initially sought injunctive relief, it claimed that its pay-for-delay case was not mooted by the 2012 launch of generic versions of Provigil in part because the FTC’s complaint sought “other equitable relief,” which the FTC argued included the equitable relief of disgorgement of the amount by which Cephalon was unjustly enriched while the anticompetitive settlements were in place. This disgorgement claim could amount to hundreds of millions, if not billions, of dollars.

The FTC’s statements in Washington last week, including the statement about seeking a \$1 billion pay-for-delay settlement, suggest that *Cephalon* might not be an outlier. According to Commission officials, disgorgement remedies in pay-for-delay litigation may take a prominent role, especially “where an injunction is going to happen too late to give consumers the benefit.”

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Please feel free to contact the following attorneys, if you have any questions about this alert.

Rick Rule	+1 202 862 2420	rick.rule@cwt.com
Andrew Forman	+1 202 862 2243	andrew.forman@cwt.com
Dan Howley	+1 202 862 2326	daniel.howley@cwt.com
Jessica Michaels	+1 202 862 2299	jessica.michaels@cwt.com