CLIENT UPDATE

SUPREME COURT SAYS 'REVERSE PAYMENT' GENERIC DRUG SETTLEMENTS ARE SUBJECT TO RULE OF REASON ANTITRUST REVIEW

NEW YORK
Daniel M. Abuhoff
dmabuhoff@debevoise.com

Gary W. Kubek
gwkubek@debevoise.com

Michael Schaper
mschaper@debevoise.com

Terrianne M. Patnode
tmpatnod@debevoise.com

On June 17, 2013, the U.S. Supreme Court issued a much anticipated ruling in *Federal Trade Commission v. Actavis, Inc.* regarding the validity of so-called "pay for delay" or "reverse settlement" agreements between brand and generic drug manufacturers. Such agreements may arise when a generic drug manufacturer seeks to bring its drug to market and makes the certification required under the Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Act) to the Food and Drug Administration that its generic drug does not infringe upon the valid patent rights of another manufacturer. This Paragraph IV certification often leads to patent litigation between the generic and brand manufacturers. Such litigation has frequently ended in a settlement whereby the generic manufacturer agreed to delay marketing its product for several years (but usually not as long as the expiration of the allegedly infringed patent) in exchange for a large monetary settlement and sometimes a marketing arrangement with the brand drug manufacturer.

The FTC and private plaintiffs have challenged many of these settlements as anticompetitive. Lower courts have split in their treatment of these lawsuits, with some dismissing the claims so long as the settlement did not expand the scope or timing of the exclusion under the patent, while other decisions have allowed the claims to proceed.

The Supreme Court rejected the defendants' argument, relied on by the 11th Circuit, that a "general legal policy favoring the settlement of disputes" or the difficulty of evaluating the reasonableness of the settlement should immunize these agreements from antitrust challenge. But the Court also rejected the FTC's argument that such settlements should be treated as presumptively illegal and thus subject to invalidation under a "quick look" analysis. The Court said that such treatment is appropriate only where "an observer with even a rudimentary understanding of economics could conclude that the arrangements in question would have an anticompetitive effect on customers and markets."

The Supreme Court held that "because the likelihood of a reverse payment bringing about anticompetitive effects depends upon its size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification . . . , the FTC must prove its case as in other rule-of-reason cases." The Court rejected the notion that "the Commission need litigate the patent's validity" in every case, but it "le[ft] to the lower courts the structuring of the present rule-of-reason antitrust litigation."

This decision was not unexpected in light of the Court's questioning at oral argument. But it creates a widely feared risk of extended, expensive litigation to evaluate the existence of legitimate justifications against the risk of unjustified competitive harm. The Court evinced awareness of that concern and urged trial courts to "structure antitrust litigation so as to avoid, on the one hand, the use of antitrust theories too abbreviated to permit proper analysis, and, on the other, consideration of every possible fact or theory irrespective of the minimal light it may shed on the basic question – that of the presence of significant unjustified anticompetitive consequences." The Court noted that "by examining the size of the payment," a trial court "may well be able to assess its likely anticompetitive effects along with its potential justifications without litigating the validity of the patent and parties may well find ways to settle patent disputes without the use of reverse payments."

* * *

Please do not hesitate to contact us with any questions.

June 18, 2013