



Recent FTC “Pay-for-Delay” Development

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On Monday, September 8, 2014, the Federal Trade Commission (“FTC”) filed a “pay-for-delay” antitrust lawsuit against, *inter alia*, AbbVie contending that the companies filed baseless patent infringement lawsuits against potential generic competitors for their testosterone replacement drug, AndroGel®. While these suits were pending, AbbVie entered into a “pay-for-delay” settlement agreement with a generic manufacturer which permitted the generic manufacturer rights to sell a unrelated, less lucrative cholesterol treatment, Tricor, in exchange for the generic manufacturer abandoning its countersuit against AbbVie, which alleged that the AndroGel® patent was invalid. The FTC contends that this deal made no business sense for AbbVie other than as anticompetitive compensation to delay AndroGel®.

As we have noted *previously*¹, the FTC has increasingly scrutinized deals between the manufacturers of brand-name and generic prescription drugs to delay the release of generic drugs. While the FTC has regarded these “pay-for-delay” deals with skepticism for more than a decade, the Supreme Court’s 2013 decision in *Federal Trade Commission v. Actavis* provided regulators with additional ammunition in evaluating these deals. The *Actavis* decision held that courts should apply the “rule of reason” in evaluating “pay-for-delay” deals and implied that cash considerations for generic companies not entering the market were illegal. The FTC estimated that these deals cost consumers \$3.5 billion in increased prices per year. The release of generic drugs exert major downward market pressure on the sale of brand name drugs, as the first generic retails for an average of 20 percent below that of the brand name, and an 85 percent discount is common in markets with multiple generics. Monday’s action was the first new lawsuit by the FTC instituted over an alleged “pay-for-delay” deal since the Supreme Court decided *Actavis*, which involved the same AndroGel® patents at issue in Monday’s lawsuit.

In a “pay-for-delay” deal, a brand-name manufacturer provides incentives, including financial and marketing, to generic drug manufacturers in exchange for generic manufacturers delaying the release of a generic version of a patented drug by preemptively settling challenges to the patent of the brand-name drug. The FTC has viewed these agreements as anticompetitive and contend that such deals are *per se* illegal. In *Actavis*, the Supreme Court declined to go so far as to declare all “pay-for-delay” presumptively illegal, but held that agreements are governed by the “rule of reason” and that courts should examine a number of factors before determining whether the restraint was reasonable.

AGG has significant experience in these types of matters. If you have any questions, please contact [Jeffrey Jacobovitz](#)² (former FTC attorney) or [Alan Minsk](#)³ (Chair of AGG’s Food and Drug Practice).

1 <http://www.agg.com/Life-Science-Hot-Topics-in-Antitrust-02-10-2014/>

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