

To: Our Clients and Friends

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DOJ's Antitrust Division Proposes Tough Standards for "Reverse Payments" Made By Drug Manufacturers to Generic Manufacturers In Settlement of Patent Claims Brought Under the Hatch-Waxman Act

On July 6, 2009, the U.S. Justice Department's Antitrust Division filed a brief which formulated a tough position against "reverse payments" made by branded drug manufacturers in settlement of generic manufacturers' suits brought under the Hatch-Waxman Act to challenge the validity of patents covering branded drugs. In a shift of policy, the Antitrust Division declared that "reverse payments" should be "presumptively unlawful." "Reverse payments" by branded manufacturers cause antitrust concerns because the payments may be utilized as a pretext to buy off potential competition from generic manufacturers who challenge weak patents covering the branded product that could be found invalid in a patent suit.

The Antitrust Division's brief (available at www.usdoj.gov/atr/cases/f247700/247708.htm) was filed in a case before the U.S. Court of Appeals for the Second Circuit, in response to the Court's invitation for the Government's views.¹ According to the Antitrust Division's brief:

- Settlements involving "reverse payments" to generic manufacturers should be judged under the "rule of reason" analysis, and should not be viewed as illegal per se.
- However, any "reverse payments" by the branded manufacturer to the generic manufacturer should be viewed as "presumptively unlawful."
- A branded manufacturer/defendant may rebut that presumption by showing that the amount of the "reverse payment" corresponds to the litigation costs that the defendant could avoid by settling, as well as an allowance reflecting the "costs of business disruption."

¹ Arkansas Carpenters Health and Welfare Fund v. Bayer, AG, Nos. 05-2852-cv, 05-2963-cv (2d Cir.).

- If the amount of a “reverse payment” is greatly in excess of avoided litigation costs, a defendant should not be able to rebut the presumption of unlawfulness unless the period of patent exclusivity against generic competition is also shortened in the settlement.
- If the “reverse payment” is well in excess of avoided litigation costs, and the settlement does shorten the period of patent exclusivity, the defendant can rebut the presumption of unlawfulness by showing that the settlement preserved a “degree of competition reasonably consistent with what had been expected if the [patent] infringement litigation went to judgment.” More specifically, the defendant should have the burden of showing that, despite the reverse payment, the agreed upon entry date of generic competition reflected the parties’ “contemporaneous evaluations of the likelihood that a judgment in the patent litigation would have resulted in generic competition before patent expiration.” This vague standard may be unworkable in practice, and certainly will not provide any bright-line guidance to manufacturers.
- Settlements that do not involve “reverse payments,” but which shorten the period of patent exclusivity of the branded drug, should be evaluated differently. They should be treated as lawful under the antitrust laws when the duration of the shortened period reflects the parties’ realistic expectations as to the likelihood of the patent being invalidated in the court challenge.

The Second Circuit’s request for the Antitrust Division’s views may signal that it is prepared to reconsider the relatively lenient view it took of “reverse payments” in the *Tamoxifen* case decided in 2006. The Court ruled there that a reverse payment does not violate the antitrust laws unless (1) the settlement “extends the monopoly beyond the patent’s scope,” (2) the patent was procured by fraud, or (3) the settled infringement suit was “objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits.”²

If the Second Circuit should adopt the Antitrust Division’s views, there will likely be more inconsistency among the several federal courts of appeals respecting “reverse payments,” not less. That would likely add momentum to legislative efforts to limit or ban reverse payments, such as the proposed Protecting Consumer Access to Generic Drugs Act of 2009, approved recently by a House subcommittee. The Antitrust Division’s new policy brings it closer to the Federal Trade Commission’s view that “reverse payments” are anti-competitive and unlawful.

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² *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 213 (2d Cir. 2006), cert. denied, 127 S. Ct. 3001 (2007).