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## DOJ Formally Aligns Itself With FTC In Opposition To Reverse Payment Settlements

The new Department of Justice, with Christine Varney at the helm of its antitrust division, has changed course to finally (and formally) align itself with the Federal Trade Commission in opposition to reverse payment settlements in the pharmaceutical industry. On July 6, 2009, the DOJ filed a brief with the Second Circuit (at the court's invitation) in *In re Ciproflaxin Hydrochloride Antitrust Litigation* which marks the DOJ's first formal opposition to reverse payment settlements, *i.e.*, settlements of patent disputes in which the brand drug-maker makes a "reverse" or "exclusion" payment to the would-be generic competitor to delay its entry into the relevant drug market. This represents a significant departure from the DOJ of the Bush era, which took a stance contrary to the FTC's before the U.S. Supreme Court, even criticizing its sister agency's "high degree of suspicion of any reverse payment settlement."

In its *Cipro* brief, the DOJ initially took note of the unique characteristics of the pharmaceutical industry leading to the prevalence of reverse payment settlements -- settlements which the DOJ further noted are virtually nonexistent in other contexts. That is, the entrance of generics into a particular market has dramatic economic consequences because generics are priced significantly lower than equivalent branded drugs (as much as 80% lower, according to the FTC). Thus, the profit that a generic firm anticipates making by entering the market is much less than the amount of profit the brand patent holder stands to lose from the same sales. Moreover, the regulatory framework of the Hatch Waxman Act essentially precludes the possibility of lost profits damages, leaving few incentives for brand patent holders to try to litigate patent disputes to a final judgment in their favor. In this context, it is therefore likely to be in the interests of both the patent holder and the generic to share in the monopoly profits and agree not to compete. Such settlements, the DOJ argues, must accordingly be scrutinized under the antitrust laws which are intended to preserve maximum competition.

The DOJ went on to argue that because such settlements may also serve legitimate purposes, they are appropriately scrutinized under the rule of reason, which takes into account the efficiency-enhancing justifications of the agreement, as well as its anticompetitive potential. Under the rule of reason standard, the antitrust plaintiff may establish a prima facie case of liability by demonstrating that the brand patent holder made a payment to the generic, and that the payment was accompanied by the generic's agreement to withdraw its patent challenge.

The antitrust defendants may then either negate the prima facie case (by proving that the payment was in fact made for some legitimate concession other than withdrawal of the patent challenge) or rebut the presumption of anticompetitiveness. The DOJ explained that defendants may clearly rebut the presumption if they can show that the payment amount was commensurate with the patent holder's avoided litigation costs.

If the payment amount is greatly in excess of avoided litigation costs, the rule of reason inquiry should focus on the competitive effects of the settlement terms, particularly focusing on the nature and extent of generic competition permitted therein. If the settlement precludes generic competition all the way up to the date the patent is set to expire, then the defendants would be unlikely to prevail because their settlement eliminated any *possibility* of generic entry prior to patent expiration. If, on the other hand, the settlement contemplates generic entry sometime before patent expiration, then defendants may satisfy their burden by showing that, despite the reverse payment, "the agreed upon date and other terms of entry [of the generic into the market] reasonably reflected their contemporaneous evaluations of the likelihood that a judgment in the patent litigation would have resulted in generic competition before patent expiration." In other words, defendants would have to show that the settlement preserved a level of competition reasonably consistent with what had been expected if the infringement litigation went to judgment.

The DOJ also made clear that it is neither necessary nor appropriate to examine the merits of the underlying patent dispute when undergoing the above rule of reason inquiry. To do otherwise would unduly complicate the litigation by requiring a mini-trial of the patent dispute to adjudicate antitrust liability, and, accordingly, reduce parties' incentives to settle. And, both the plaintiff and defendant in the patent dispute would suddenly find themselves on the same side of the antitrust action, thereby diminishing the accuracy of any mini-trial on the patent dispute.

The DOJ's new position undoubtedly will have a significant impact on the heated debate over the legality of reverse payment settlements. Now that the DOJ has aligned itself with the FTC, only time will tell if courts will also change course and begin regarding such settlements as presumptively anticompetitive. In the meantime, pharmaceutical companies should also keep a close watch on proposed regulation currently making their way through the legislative process which would ban such settlements altogether.

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