Increased Scrutiny of Reverse Payment Settlements:
Recent Cases in E.D. of PA and 2nd Circuit Suggest Change May Be Ahead for Pharma Clients

By Francis P. Newell and Jonathan M. Grossman
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Two recent opinions suggest a greater willingness on the part of the federal judiciary to scrutinize more closely so-called "reverse payment settlements" that have once again become prevalent in the pharmaceutical industry.

Reverse payment settlements are entered into by a brand-name drug manufacturer and one or more generic drug manufacturers to resolve patent litigation triggered by the generic manufacturers' prospective entry into the market. These settlements have been widely criticized as unlawful restraints of trade by, among others, the Federal Trade Commission, which refers to them as "pay-for-delay settlements."

Until recently, however, the courts have generally held such agreements lawful. U.S. District Court Judge Mitchell S. Goldberg's recent decision in *King v. Cephalon* and a 2nd U.S. Circuit Court of Appeals panel's unusual invitation for en banc review of its decision in the *Cipro* litigation, however, may suggest increased skepticism by courts to these settlements.

Ironically, reverse payment settlements, which many critics now suggest anticompetitively raise prices for pharmaceuticals, could be viewed as a natural result of a law commonly known as the Hatch-Waxman Act, the intent of which, inter alia, was to lower pharmaceutical prices by bringing generic pharmaceuticals to market more quickly.

Enacted in 1984, Hatch-Waxman significantly shortened the FDA approval process for generic versions of brand-name drugs, allowing generic manufacturers to file an Abbreviated New Drug Application (ANDA) with the FDA. It also provided a process whereby the first ANDA filer is granted a 180-day exclusivity period, during which the FDA may not approve the ANDA of any other generic manufacturer.

Importantly, this exclusivity period does not begin until the drug is first commercially marketed, so if the generic manufacturer delays entry for any reason, other potential generic manufacturers are blocked from entering as well. Additionally, if the brand-name manufacturer initiates patent litigation against the generic while the ANDA is pending, the FDA is prohibited from approving it for 30 months or until a final decision by a district court that the patent is invalid or not infringed.

One result of this regulatory scheme is that many brand-name and generic manufacturers have chosen to settle patent litigation between them through reverse payment settlements. A typical settlement involves the brand-name manufacturer paying the generic manufacturer cash in exchange for an agreement by the generic manufacturer to: delay entering the market until an agreed-upon point in time; and retain the right to the 180-day exclusivity period, thereby preventing other generic manufacturers from

entering the market for that period as well.

Critics of such settlements describe them as nothing more than payoffs by brandname manufactures to maintain their monopolies and maximize profits at the expense of consumers. Supporters, on the other hand, argue that such agreements are an efficient way for both parties to reduce uncertainty and avoid the costs of protracted litigation.

The FTC has been among the leading critics of reverse payment settlements, and beginning in 1999, it began to challenge them in court as per se violations of the antitrust laws. Initially, the FTC's aggressive enforcement brought reverse payment settlements to a halt — none were entered into between 1999 and 2004 — but these settlements have again become en vogue as decisions in three federal circuits have upheld their legality.

Interestingly, the first appeals court to weigh in on a reverse payment arrangement struck down the agreement as a per se unlawful restraint on trade. *In re Cardizem* involved an agreement between a brandname manufacturer (Hoescht Marion Roussel or HMR) and a generic manufacturer (Andrx) that had already obtained conditional ANDA approval to take effect upon expiration of the statutory 30-month stay. Because the 30-month stay would have expired prior to the conclusion of the patent litigation between the parties, Andrx could have begun selling a generic version of Cardizem in competition with HMR.

Before doing so, however, HMR and Andrx entered into an agreement under which HMR agreed to pay Andrx $10 million per quarter and Andrx agreed to not market generic Cardizem until there was a final, unappealable decision in Andrx's favor in the patent litigation. Andrx also agreed to retain its 180-day exclusivity period, but notably did not withdraw from the patent litigation.

In 2003, the 6th Circuit held that the settlement agreement was a "classic example of a per se illegal restraint of trade" under the Sherman Act. Because the parties did not settle the underlying patent litigation, however, *Cardizem* has largely been distinguished from the later holdings of three other circuits.

The 11th Circuit was the first circuit to uphold the legality of reverse payment settlements, first in *In re Valley Drug* (2003) and then in *In re Schering-Plough* (2005). The *Schering-Plough* decision was particularly noteworthy because it overturned an FTC decision following a lengthy administrative trial.

The 11th Circuit specifically rejected the FTC's contention that reverse payment settlements are per se illegal, instead emphasizing that patents, which explicitly grant exclusionary rights to the patent holder, are by definition anticompetitive (i.e., a legal monopoly) and are therefore not normally subject to the antitrust laws. It therefore held that antitrust scrutiny of reverse payment settlements should be limited to an examination of: the scope of the exclusionary potential of the brand-name patent; the scope of the settlement agreement; and the resulting anticompetitive effects.

Notably absent from this analysis is an objective

assessment of the validity of the patent claims, other than to confirm that the litigation is not a sham, and whether the settlement reasonably reflects the expected outcome of the patent litigation. Therefore, the essence of the 11th Circuit holding is that as long as the scope of a reverse payment settlement does not exceed the scope of the brand-name patent, it is not subject to challenge under the antitrust laws. In *Schering-Plough*, the FTC filed a petition for certiorari, which was opposed by the Bush-era Department of Justice, but the Supreme Court declined to review the case.

In 2006, the 2nd Circuit, in a 2-1 decision, upheld the legality of a reverse payment settlement under facts significantly unfavorable to the defendants. In *In re Tamoxifen*, the generic manufacturer (Barr Laboratories) had already obtained a district court order declaring AstraZeneca's brand-name patent invalid. While AstraZeneca's patent appeal was pending, the parties entered into an agreement under which AstraZeneca paid Barr $61 million and Barr agreed to: delay its entry into the market until after the expiration of AstraZeneca's patent; and take procedural steps to ensure that the offending patent order would be vacated.

The majority in *Tamoxifen* outlined a test under which a reverse payment settlement would violate the antitrust laws only if the scope of the settlement exceeded the scope of the patent or if the patent claims of the brand-name manufacturer were "objectively baseless" or a "sham." The majority further concluded that the district court's order declaring AstraZeneca's patent invalid was insufficient evidence that the claim was baseless or a sham and therefore upheld the lower court's granting of the defendants' motion to dismiss. Because *Tamoxifen* was dismissed on the pleadings notwithstanding the questionable validity of the brand-name manufacturer's patent, some commentators have suggested the law of the 2nd Circuit is that reverse payment settlements within the scope of the claimed patent are per se legal.

In 2008, the Federal Circuit endorsed the reasoning of the 11th and 2nd Circuit decisions in upholding the district court's grant of summary judgment against indirect purchasers in the *Cipro* litigation. It started and ended its analysis with the conclusion that the settlement at issue was within the "exclusionary zone" of the brandname manufacturer's patent.

In doing so, the Federal Circuit rejected the FTC's argument that the district court should have assessed the validity of the patent, holding that such an inquiry was unnecessary unless there was evidence that the patent was obtained fraudulently or that the patent litigation was a sham. It also cited the long-standing policy in the law in favor of settlements and concluded that this policy applies even where it may have some adverse effects on competition.

Faced with a largely hostile judiciary, and in the wake of the 2008 elections, opponents of reverse payment settlements began to focus on achieving their objectives through legislation. For much of the past 18 months, the prospects of such legislation being enacted seemed excellent. After all, as a senator, President Obama had co-sponsored bipartisan legislation to

prohibit reverse payment settlements.

As the president and Congress negotiated a health care reform bill, the inclusion of a ban on reverse payment settlements, which was proffered as a cost-savings tactic to both consumers and the government, seemed a natural fit. Indeed, such a ban was in the health care reform bill passed by the House and may have very well been included in the final legislation if not for the complicated rules related to the budget reconciliation process that the Democrats used to avoid a Republican filibuster. Stand-alone bills to ban reverse payment settlements have significant support in both the House and the Senate, but with a crowded legislative agenda, and strong opposition by the pharmaceutical industry, passage in the near future seems unlikely.

Particularly in light of this legislative defeat, the recent decisions in the Eastern District of Pennsylvania and the 2nd Circuit have been welcome news to reverse payment opponents. On March 29, in the first reverse payment settlement case within the 3rd Circuit, Goldberg denied the defendants' motions to dismiss in *King* and three related suits, including one brought by the FTC.

On its face, the court's discussion of the relevant case law and conclusion that the appropriate test is whether the settlement exceeded the exclusionary patent rights held by the brand-name manufacturer would suggest that it was adopting the pro-defendant standards of the 2nd, 11th and Federal circuits. In applying this test to the defendants' motion to dismiss, however, the court carefully reviewed the plaintiff's allegations regarding the invalidity of the underlying patent and concluded the allegations were sufficient to raise factual questions that could only be resolved through discovery.

This decision may indicate a willingness by the court to evaluate the merits of the patent claim, which stands in marked contrast to the holdings of the 11th and Federal Circuits and, in particular, to the 2d Circuit's *Tamoxifen* decision, where a motion to dismiss was upheld even though the underlying patent had previously been held invalid.

One month later, a 2nd Circuit panel issued a decision in the *Cipro* direct purchaser appeal. Acknowledging that *Tamoxifen* was controlling law, the panel affirmed a grant of summary judgment to the defendants. After doing so, however, the unanimous panel noted the "exceptional importance of the antitrust implications of reverse exclusionary payment settlements" and therefore "invite[d]" the plaintiffs to petition for rehearing en banc.

The panel then went on to outline a number of reasons that *Tamoxifen* might be re-examined including: the Department of Justice in its amicus brief urged repudiation of *Tamoxifen,* which was a reversal of the Bush-era DOJ position on reverse payment settlements; reverse payment settlements increased in the wake of *Tamoxifen*; reverse payment settlements are contrary to the policy objectives of the Hatch-Waxman Act and that both sponsors of the legislation, Sen. Orrin Hatch, R-Utah, and Rep. Henry A. Waxman, D-Calif., have criticized them; and *Tamoxifen* "relied on an unambiguous mischaracterization" regarding the particulars of the Hatch-Waxman Act.

So where does this leave us? As articulated in its amicus brief in *Cipro*, the DOJ now advocates an analysis that would treat reverse payment settlements as "presumptively unlawful," but afford defendants an opportunity to rebut that presumption. Clearly, at least three 2nd Circuit judges seem ready to overturn or significantly modify *Tamoxifin*. If their colleagues agree, a new more plaintiff-friendly standard in the 2nd Circuit could impact the holding of the 3rd Circuit in the likely event that *King* is ultimately appealed.

And of course, a significant change in 2nd Circuit law would create a circuit split that did not exist when the Supreme Court declined to grant cert in *Schering-Plough* and could justify Supreme Court review.

So in other words, stay tuned.