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U.S. Appeals Court Holds "Reverse Payment" Patent Settlements Unlawful, Setting Up Strong Case for U.S. Supreme Court Review

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On 16 July 2012, a U.S. appeals court issued a decision holding that pharmaceutical patent settlements that restrict generic entry and contain a payment to the generic company are presumptively unlawful under the U.S. antitrust laws. The decision is a major victory for the U.S. Federal Trade Commission's view of pharmaceutical patent settlements with so-called "reverse payments," and dramatically alters the U.S. legal landscape in the U.S. with respect to such settlements. Additionally, by holding that a patent settlement can violate the antitrust laws without proof that it affected competition outside the scope of a valid patent, the decision creates a direct conflict with the holdings of three other U.S. appeals courts, and sets up a strong for U.S. Supreme Court review. Together with recent European Commission activity in this area, this newdecision greatly enhances the antitrust risk of these types of patent settlements.

There has been considerable litigation and enforcement agency interest in settlements of patent infringement lawsuits brought by a brand name pharmaceutical manufacturer against a generic manufacturer where the settlement includes an agreed upon date for generic entry (or some other type of restriction on generic entry) plus a payment from the brand to the generic company. (These payments have sometimes been referred to as "reverse payments.") The U.S. FTC strongly opposes such settlements and believes that they are anticompetitive because, absent the reverse payment, the parties would have supposedly settled their litigation with a later entry date for the generic – and thus, in the FTC's view, the "reverse payment" is almost always a "payment for delay." However, the courts in the U.S. have largely rejected this view, holding that a patent settlement cannot harm competition so long as (1) the exclusion of the generic does not exceed the patent's scope; (2) the patent holder's infringement case was not objectively baseless; and (3) the patent was not procured by fraud on the patent office. These courts have reasoned that patents are presumed valid, and therefore a patent settlement that restricts entry from an infringing product merely prevents entry by a party whose product was not legally entitled to be on the market in the first place.

In *In re K-Dur Antitrust Litig.*, No. 10-2079 (3rd Cir. 2012), the U.S. Court of Appeals for the Third Circuit squarely rejected the "scope of the patent" test, and held that patent settlements with reverse payments are presumptively unlawful under the U.S. antitrust laws, subject to two exceptions. First, if the parties can show that the payment was for a purpose other than to delay entry – e.g., the payment was part of a "side deal" and did not involve consideration paid to the

generic that exceeded the reasonable value of what the generic provided in return — then the settlement might be lawful. Second, the settlement may be lawful if the parties can show a pro-competitive benefit of the settlement that could not be achieved without the payment.

Without the "scope of the patent" test, plaintiffs will find it dramatically easier to challenge reverse-payment patent settlements because it is no longer necessary to prove that the patent infringement case lacked merit. Making such a showing is extremely difficult because it requires a deep analysis of the patent and IP issues and, usually, a showing that the brand manufacturer's case was not only likely to fail, but that it was based on frivolous argments or outright fraud before the patent office.

The Third Circuit reasoned that the "scope of the patent" test improperly presumes that the underlying patent is valid, and thus that the holder is entitled to exclude competition. The court found that this presumption conflicts with the Supreme Court's recognition that "the public interest supports judicial testing and elimination of weak patents." The court also found that having such a permissible legal standard undermines the goal of the Hatch-Waxman Act to increase the availability of low cost generic drugs, and effectively allows "the patent holder to pay its potential generic competitors not to compete". The court was also unconvinced that subsequent challenges by other would-be generic manufacturers would eliminate weak patents preserved through a reverse payment to the initial challenger. The court recognized that the "scope of the patent" test encourages settlement, but found that the laudable preference for settlement cannot supplant "countervailing public policy objectives".

The Third Circuit's decision will not be the final word. As an initial matter, the decision still leaves many questions unanswered, even in the Third Circuit. For example, putting aside liability, wouldn't a private plaintiff still need to show that the generic would have won the patent case in order to obtain damages? It is unclear how a "reverse payment" patent settlement could injure any generic companies or drug purchasers if, had the parties not settled, the brand manufacturer would have won the patent litigation. But more immediately, as noted, the *K-Dur* decision creates a clear split among the U.S. appellate courts and a strong case for U.S. Supreme Court review. The lack of a clear split in the Circuits was likely one of the factors that led the Supreme Court not to hear prior patent settlement cases.

The *K-Dur* decision, especially in combination with the European Commission's recently announced enforcement actions relating to alleged "reverse payment" patent settlements involving the drugs citalopram and perindopril, greatly enhances the antitrust risk of these types of settlements. Additionally, with its hands full litigating "pure" reverse payment cases, the FTC has not brought cases against related practices, such as patent settlements involving a commitment by the brand manufacturer not to launch an authorized generic. In light of these developments, settling pharmaceutical patent infringement litigation with anything other than a simple compromise date for generic entry has now become much higher risk.

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