Publications

25 JUL 2012

Third Circuit rekindles uncertainty in patent settlements under Hatch-Waxman Act

ANTITRUST ALERT

Paolo Morante
Jarod M. Bona

In a dramatic departure from the prevailing standard for analyzing the antitrust implications of reverse-payment settlements in Hatch-Waxman Act patent disputes, the Third Circuit has squarely rejected the "scope-of-the-patent test" and adopted, instead, a rebuttable presumption that any such settlement involving a payment from the branded pioneer to a generic manufacturer violates federal antitrust law. In *In re K-Dur Antitrust Litigation*, the Third Circuit crafts a new rule, under which parties to a reverse-payment settlement may rebut the presumption of illegality only by showing that either (a) the payment from the pioneer to the generic was for a purpose other than delaying the generic's entry; or (b) the payment offers a pro-competitive benefit that sufficiently offsets the anti-competitive effect of delayed generic entry. As a practical matter, the rule creates a formidable obstacle to reverse-payment settlements in the Hatch-Waxman context and represents a significant policy victory for federal agencies (primarily the Federal Trade Commission) that have opposed such settlements for years without success.

The Third Circuit's decision comes on the heels of the Eleventh Circuit's April 2012 decision in *Federal Trade Commission v. Watson Pharmaceuticals, Inc.*, which rejected an antitrust challenge to a reverse-payment settlement by applying a form of the "scope-of-the-patent" test. The Third Circuit decision effects a clear split among the federal circuits (three of which have adopted the scope-of-the-patent test) and, unless it is vacated by an *en banc* panel, creates a significant opportunity for the Supreme Court to address these issues. As the Eleventh Circuit refused to rehear *Watson en banc* on July 18, either or both of these decisions could become the vehicle for Supreme Court review.

The Hatch-Waxman Act

In many ways, reverse-payment settlements are a product of the Hatch-Waxman Act. Enacted in 1984, the Act was designed to increase competition in the supply of small-molecule drugs by promoting the availability of generic competitors while, at the same time, protecting legitimate patent monopolies by accelerating the resolution of disputes over branded manufacturers' patents. The Act encourages generic competition by enabling generic manufacturers to streamline the FDA approval process through the filing of abbreviated new drug applications (ANDAs), which allow generic companies to rely on the safety and efficacy data submitted by the original drug pioneer.

The Act requires the filing generic to certify that one of the following conditions is satisfied with respect to the branded drug: (1) no patent for the drug was filed with the FDA; (2) the patent has expired; (3) the ANDA drug will not be marketed until the patent expires; or (4) the patent is invalid or would not be infringed by the generic drug. When a generic filer makes the latter certification—known as a "Paragraph IV" certification—the ANDA is deemed an act of infringement and the branded manufacturer can trigger a 30-month stay of the ANDA approval process by suing the generic filer for patent infringement. To encourage generics to file ANDAs, the Act allows the generic "first filer" a 180-day exclusivity period during which no other generic will be approved. This exclusivity period begins to run on the earlier of the day on which the first-filer generic begins marketing a drug under the ANDA and the day on which a trial court hearing the patent infringement dispute between the first filer and the pioneer holds the underlying patent invalid or not infringed.

The above process presents little risk for the generic company—some litigation costs, but limited exposure to damages because, unless the generic chooses to market its drug "at risk," it has not yet caused significant monetary injury to the branded manufacturer. By contrast, the branded company faces substantial risk because it could lose its patent monopoly before the expiration of the patent. For these reasons, the Hatch-Waxman Act often makes it financially rational for the branded manufacturer to

settle a patent infringement claim by paying the generic first-filer to stay off the market and, by virtue of the 180-day exclusivity period, stave off all generic entry until some future date.

The Antitrust Landscape

Until the Third Circuit's *K-Dur* decision, the prevailing approach among federal courts has been to uphold a reverse-payment settlement under the antitrust laws unless (1) the agreement restrains trade beyond the exclusionary scope of the relevant patent; (2) the underlying infringement action is a sham; or (3) the patent was obtained by fraud on the patent office. An important principle of the US patent system underlying the scope-of-the-patent approach is that a patent is presumed valid until proven otherwise. Courts have often cited that principle when declining an invitation from plaintiffs or government enforcers to evaluate the strength of the patent when determining whether a reverse-payment settlement agreement violates the antitrust laws. Thus, the strength of the underlying patent has been generally irrelevant to US courts' analysis of reverse-payment settlements.

Opponents of reverse-payment agreements met with some early success in the antitrust arena. In 2003, the Sixth Circuit condemned one such agreement as *per se* unlawful under the antitrust laws and, in 2001, the DC Circuit had suggested it would take a similar approach. Both of those cases, however, involved an agreement that restrained trade beyond the exclusionary scope of the relevant patent and that did not resolve the underlying patent dispute. For these reasons, the decisions of the Sixth and DC Circuits arguably could be reconciled with the scope-of-the-patent approach subsequently adopted by the Second, Eleventh and Federal Circuits, and did not create the same direct circuit conflict that now exists as a result of *K-Dur*.

The Third Circuit's *K-Dur* Decision

This case arose out of the settlement of two patent cases involving the branded drug K-Dur 20, manufactured by Schering-Plough Corporation. The drug is a sustained-release potassium chloride supplement used to treat potassium deficiencies. The patent, however, was not for the chemical itself — which is commonly known — but was instead a formulation patent on the controlled release coating that was applied to the potassium chloride crystals.

In August 1995, Upsher filed the first ANDA seeking FDA approval to produce a generic version of K-Dur 20. That led to patent litigation between the generic and the name-brand company, which the parties ultimately settled. Upsher agreed to refrain from marketing its generic product until September 1, 2001 (which preceded patent expiration), at which point it would receive a non-royalty-bearing, non-exclusive license to make and sell a generic form of the drug. In addition, Upsher granted the brand company licenses to make and sell several of Upsher's products in exchange for US$60 million, plus smaller sums that depended upon sales.

In December 1995, ESI Lederle filed the second ANDA seeking FDA approval to sell a generic version of K-Dur 20. Litigation once again ensued, but less than a year later a court-supervised mediation led to a settlement agreement. The brand company granted a royalty-free license to ESI beginning on January 1, 2004 (before the patent expired). In addition, the brand company agreed to pay ESI US$5 million up front, then varying additional sums depending upon when the ANDA was approved by the FDA.

The marketing restrictions on the generic companies in both of these agreements were within the exclusionary scope of the relevant patent for K-Dur 20.

The FTC challenged these agreements as anticompetitive under the FTC Act, but the Eleventh Circuit, in *Schering-Plough Corp. v. FTC*, ultimately rejected that challenge because the agreements did not create restraints beyond the exclusionary scope of the patent.

The private class action challenging the same agreements at issue in *Schering-Plough* ended up in the Third Circuit in *K-Dur*. The Third Circuit, however, applied a very different legal standard. After surveying the relevant jurisprudence, the court expressly stated that it "cannot agree with those courts that apply the scope of the patent test." Significantly, the court took "issue with the scope of the patent test's almost unrebuttable presumption of patent validity." The court explained that, although "persons challenging the validity of a patent in litigation bear the burden of defeating a presumption of validity, this presumption is intended merely as a procedural device and is not a substantive right of the patent holder." Indeed, a "patent, in the last analysis, simply represents a legal conclusion reached by the Patent Office."

Recognizing the regulatory context within which the case arose, the court emphasized that its decision should be narrowly interpreted to apply only to reverse payments between patent holders and would-be generic competitors in the pharmaceutical industry. Indeed, under the Third Circuit's rule, "the only settlements subject to antitrust scrutiny are those involving a reverse payment from the name brand manufacturer to the generic challenger."

The Third Circuit's Test

In place of the scope-of-the-patent test, the Third Circuit directed the trial court to apply a "quick look rule of reason analysis based on the economic realities of the reverse payment settlement rather than the labels applied by the settling parties." More specifically, the finder of fact "must treat *any payment* from a

patent holder to a generic patent challenger who agrees to delay entry into the market as *prima facie* evidence of an unreasonable restraint of trade, which could be rebutted by showing that the payment (1) was for a purpose other than delayed entry or (2) offers some pro-competitive benefit."

Notably, the court also agreed with the view, expressed by other circuits and the FTC, that the antitrust analysis of a reverse-payment settlement does not require consideration of the merits of the underlying patent suit. Like the FTC, the Third Circuit took the position that "absent proof of other offsetting consideration, is it logical to conclude that the *quid pro quo* for the payment was an agreement by the generic to defer entry *beyond the date that represents an otherwise reasonable litigation compromise*." Although the opinion does not elaborate on the implications of this point, the Third Circuit's reasoning suggests that trial courts should also disregard the merits of the underlying patent suit in deciding whether a reverse-payment settlement has any pro-competitive justification. Instead, the "pro-competitive" defense "attempts to account for the—probably rare—situations where a reverse payment increases competition." For example, "a modest cash payment that enables a cash-starved generic manufacturer to avoid bankruptcy and begin marketing a generic drug might have an overall effect of increasing the amount of competition in the market."

Conclusion

For many years, the Supreme Court has repeatedly declined invitations by agencies and private parties to review the antitrust implications of reverse-payment patent settlements under the Hatch-Waxman Act. The Third Circuit's *K-Dur* decision (absent *en banc vacatur*) conflicts directly with the Eleventh Circuit's most recent decision applying the prevailing scope-of-the-patent test, which has also been adopted by the Second and Federal Circuits. Moreover, the facts underlying *K-Dur* are the same as those reviewed by the Eleventh Circuit in its earlier application of the scope-of-the-patent test in *Schering-Plough*. The circuit split is thus crystal clear, which may improve the likelihood of Supreme Court review.

For more information about the implications of this ruling for your business, please contact:

Paolo Morante

Jarod Bona