Reverse payments

The EU seems to be doing slightly better than the US in tackling this controversial type of pharmaceutical patent settlement

*by **Logan Breed** and **Eric Stock****

Patent litigation in the pharmaceutical industry is a fierce business. Typically, a brand name drug manufacturer is seeking to stop a competitor from selling a "generic" version of the incumbent's drug that the incumbent believes infringes its hard-won intellectual property. The strength of the relevant patents in these cases is often in dispute, and especially in light of the high costs of patent litigation, there is significant pressure on both parties to settle. In some cases, the parties reach a settlement that provides for a compromise generic entry date as well as some additional consideration flowing from the brand name manufacturer to the generic manufacturer.

Detractors of such settlements refer to them as "reverse payments" because they result in consideration flowing from the patent holder to the alleged infringer (whereas in other IP litigation the settlement payment typically goes in the other direction). Supporters of these types of deals contend, however, that as long as the brand name manufacturer's patents are valid and infringed by the generic drug, then any settlement agreement restricting the entry date for the generic drug could not have had any harmful impact on lawful competition.

On both sides of the Atlantic, antitrust enforcers have acted over the last few years to thwart litigation settlements between pharmaceutical companies that involve such reverse payments because the enforcers believe that these settlements are anticompetitive and improperly raise consumers' costs by keeping out less expensive generic drugs. However, the European Commission recently seems to have had more success than its US counterpart in curtailing this practice. If this trend continues, it could signal a divergence in the types of pharmaceutical patent litigation settlements that can be implemented in the EU and the US.

Pharmaceutical patents and competition in the EU

The European Commission conducted a sector inquiry in 2009 that provided some indication of which patent settlements would invite antitrust scrutiny in the EU. The final report stated that "[agreements] that are designed to keep competitors out of the market may also run afoul of [EU] competition law. Settlement agreements that limit generic entry and include a value transfer from an originator company [or, in US terms, the 'branded company'] to one or more generic companies are an example of such potentially anticompetitive agreements, in particular where the motive of the agreement is the sharing of profits via payments from originator to generic companies to the detriment of patients and public health budgets."

Monitoring of settlements

The Commission began its first monitoring exercise of patent settlements in the European pharmaceutical sector in January 2010 by issuing a request to companies for copies of such settlements. Recently, the Commission published the findings of its second stage of monitoring patent settlements. The study found a decrease in potentially problematic reverse payment settlements in the EU – the total number dropped to 89 agreements from 93 in the preceding 18 months. Furthermore, the number of settlements that limit entry and involve consideration from the branded producer to the generic company decreased significantly more. Such settlements fell from nine out of 93 in the first monitoring exercise to only three out of 89 of the settlements in the most recent exercise.

Commission vice president in charge of competition policy, Joaquin Almunia, stated: "I note with satisfaction that the number of patent settlements potentially problematic under EU antitrust law continues to decrease without calling into account companies' legitimate right to settle disputes amicably." Almunia added that the Commission "will remain vigilant that companies' behaviour respects antitrust law and [does] not delay entry of cheaper pharmaceuticals". The EU intends to continue the review programme in 2012.

Boehringer Ingelheim investigation

The Commission also simultaneously closed a long-running investigation against Boehringer Ingelheim, which had been accused of delaying the launch of a rival drug to its blockbuster treatment for lung disease, Spiriva, which has global sales of about €3bn year.

Almirall, a Spanish company, had alleged that the German drugmaker had filed for baseless patents in 2003 regarding new treatments for chronic obstructive pulmonary disease. The Commission investigated Boehringer's alleged misuse of the patent system regarding combinations of three broad categories of active substances treating the disease with a new active substance that had been discovered by Almirall. Almirall complained that Boehringer's patent applications would block or unnecessarily delay the entry of its products that would compete with Spiriva.

Last autumn, the Commission asked Boehringer and Almirall to find a "mutually acceptable solution" to their dispute within the limits of EU competition law. Boehringer ultimately agreed to remove the alleged blocking positions in Europe and granted a licence for two countries outside Europe, which lifts the obstacles to the launch of Almirall's products "and the Commission no longer needs to pursue the case" because Almirall will now be able to launch its medicines without delay (pending market authorisation). This case is indicative of the Commission's ability to extract the concessions it desires from the parties in pharmaceutical patent settlements without resorting to the courts.

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Pharmaceutical patents and competition in the US

The story is slightly different in the US. Earlier this summer, the US Federal Trade Commission issued a report finding that the number of pharmaceutical patent settlements involving a reverse payment increased approximately 60% between FTC fiscal years 2009 and 2010.

The FTC has long believed that stopping reverse payment settlements is one of its highest enforcement priorities. For example, last year the FTC chairman, Jon Leibowitz, testified to Congress that reverse payment cases are "one of the Commission's top competition priorities" because agreements "to eliminate potential competition and share the resulting profits are at the core of what the antitrust laws proscribe." Moreover, a recent FTC study concluded that the practice costs US consumers over $3.5bn per year.

The FTC believes patent settlements that include payments to the generic company are presumptive antitrust violations because they amount to what the FTC calls "pay for delay"—ie the payment is, in the FTC's view, in return for acceptance of a later date for generic entry. Under the FTC's reasoning, such settlements are unlawful regardless of who ultimately would have won the patent litigation because, without the payment, the generic company would have insisted that the settlement had an earlier entry date.

Most US courts, however, have rejected this reasoning. They have found that patent settlements cannot harm competition without proof that the settlement impacted on competition outside the scope of a valid patent. This has been the outcome for the following cases: *Schering-Plough Corporation v FTC*, *In re Tamoxifen Citrate Antitrust Litig* and *In re Ciprofloxacin Hydrochloride Antitrust Litig*. The courts have typically required those challenging such settlements to show that the settlement impacts competition from products not covered by the patents, or that the underlying patent infringement case was "objectively baseless" or based on "fraud."

The AndroGel story

The FTC has fought hard, albeit unsuccessfully, to overturn these decisions. Last year, the US District Court for the Northern District of Georgia dismissed an antitrust challenge brought by the FTC and private plaintiffs to a reverse payment patent settlement relating to Solvay's testosterone gel, AndroGel. In September 2006, Solvay settled patent litigation with generic defendants. The terms of the settlement provided for an agreed-upon date for generic entry and that, in return for a payment, one of the generic companies would act as a backup supplier of AndroGel for Solvay.

In February 2010, the court granted a motion by the defendants to dismiss the FTC's complaint. The court's decision was based on the plaintiffs' failure to plead facts indicating that the patent settlement impacted on competition outside the scope of the branded manufacturer's (Solvay's) patents. The case was yet another setback for efforts by the FTC to reverse the trend of judicial decisions analysing reverse payment patent settlements in a manner that the FTC views as improperly lenient. The decision was not unexpected, given that the court issuing the decision sits within the jurisdiction of the Eleventh Circuit Court of Appeals, which has already ruled adversely to the FTC's position on the antitrust treatment of patent settlements in prior cases (for example, in the *Schering-Plough* case). The court's decision dismissing the challenge to the patent settlement has been appealed to the Eleventh Circuit.

The AndroGel story does not end there. Last month, the FTC investigated the merger of Paddock (one of the companies involved in the AndroGel settlement) and Perrigo, another company that has filed with the FDA for a generic version of AndroGel. The FTC concluded that Perrigo's purchase of Paddock's assets would result in harmful concentration in the markets for a number of generic drugs, and therefore it required the parties to agree to a consent order that would protect competition. The consent contains a provision prohibiting the parties from entering into any future reverse payment settlement with any branded producer of a testosterone gel product (ie AndroGel). In short, the FTC used its regulatory power to extract a concession regarding reverse payments that it could not win in the courts.

The legislative option

In addition to the several antitrust lawsuits that it has brought challenging these types of settlements and the filing of amicus briefs in private litigation, the FTC has strongly promoted the idea of legislation that would ban or improve its ability to challenge patent settlements with reverse payments. A bill that would impact on most such settlements advanced to the Senate floor earlier this summer. The proposed legislation would, among other things, and in most cases, put the burden of proof on the parties to demonstrate that a patent settlement with a reverse payment is not anticompetitive. A recent speech by Commissioner Rosch, however, acknowledged that the legislation has an uphill battle to be passed, especially in the US House of Representatives.

Commissioner Rosch also suggested in his speech that if the FTC's efforts in Congress and the courts continue to fail, it is possible that the FTC will seek to exercise its rulemaking authority, for example, by issuing a rule providing that reverse payment patent settlements are "inherently suspect" under the FTC Act, and shifting the burden of proof to the defendants to demonstrate that these deals are not anticompetitive. Such an effort would be sure to face significant legal challenges by industry participants asserting that the FTC has no legal authority to issue such a rule, and it may lead to a legislative battle in Congress.

Conclusion

These recent developments illustrate that the competition enforcers on both sides of the Atlantic place a high priority on reining in pharmaceutical litigation settlements that involve payments from the branded company to the generic company, together with an agreed-upon date for generic entry. At first blush, the European Commission may seem to be enjoying more success in its efforts. However, despite the reversals that it has suffered, the Federal Trade Commission continues to investigate alleged anticompetitive conduct in the pharmaceutical industry and to pursue creative ways to challenge it under the antitrust laws. Pharmaceutical companies considering IP settlements in the US should do so with caution and seek to minimise the chances that the FTC will select their settlement for a future enforcement action.