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Client Alert

Business Litigation & Antitrust Practice Group

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European Commission Finds "Pay For Delay" Deals On The Decline In Europe But Pharma Sector Antitrust Scrutiny Continues

On July 6, 2011 the European Commission (Commission) published the results of its second monitoring exercise of patent settlements in the pharmaceutical sector (Second Monitoring Report). The Commission notes "with satisfaction" that there is a continued decline in the number of patent settlements it considers to be "potentially problematic" under EU antitrust law. The absolute number of patent settlements increased in relative terms in 2010, showing that the Commission does not prevent companies from settling patent disputes within the boundaries of EU antitrust law. However, ongoing probes at EU and Member State level indicate that the sector will continue to be under the antitrust spotlight.

Background

Companies operating in the EU pharmaceutical sector will be familiar with the Commission's sustained interest in their business which reached a high-water mark with an 18-month sector inquiry and final report in July 2009 (Final Report).

However, the sector inquiry provided only a limited indication of which patent settlements would invite antitrust scrutiny in the EU. In relation to patent settlements, the Final Report stated:

"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 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."[1]

The Commission began its first monitoring exercise of patent settlements in the pharmaceutical sector in January 2010 by issuing a request to companies for copies of patent settlements. On July 5, 2010 the Commission published the findings of its first stage of monitoring patent settlements (First Monitoring Report).

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On January 17, 2011 the Commission launched its second monitoring exercise of patent settlements. The aim of the monitoring exercise was to better understand the use of patent settlements in the EU and to help in identifying those that might need further antitrust scrutiny.

Commission approach to settlements

The Commission, in the course of its monitoring exercises, has identified patent settlements in the pharmaceutical sector that it considers may prove to be problematic from an EU antitrust perspective. Of particular interest are:

- settlements that lead to delay of generic entry in return for payment by the originator company to the generic company;

- settlements that contain restrictions beyond the exclusionary zone of the patent, i.e. beyond its geographic scope, its period of protection or its material scope (e.g. beyond the patent claims). At first glance, these agreements would not appear to be directly related to any IP rights granted by the patents concerned;

- settlement agreements on a patent for which the patent holder knows that it does not meet the patentability criteria. For example, if the patent was granted following the provision of incorrect, misleading or incomplete information.

The Commission is nevertheless at pains to emphasise that settlements are a generally accepted, legitimate way of ending private disagreements and can save court time (as well as for other administrative bodies) and thus have an overall positive impact on the interests of society. However, it considers that settlements which may fall into one of the above categories can be deemed problematic as any societal benefits may be more than outweighed by the negative effects of the agreement on competition between potential competitors. In cases of such problematic settlements, ultimately, it may be the consumer who pays the price for such a delay in market entry. It is thus necessary to make an assessment of each individual case.

Findings in the Second Monitoring Report

Key findings of the Commission in the Second Monitoring Report include:

- Increase in patent settlements: The Second Monitoring Report identified 89 patent settlement agreements between originator and generic companies in 2010. This compares with 207 such agreements during the 8.5 years covered by the sector inquiry which concluded in July 2009. This also compares with 93 agreements during the 18 months covered in the first monitoring exercise.

- Decrease in “problematic” settlements: The number of settlements considered potentially problematic from an EU antitrust perspective – in particular those that limit generic entry against payment from the originator to the generic company - decreased significantly in importance and number. In the period covered by the sector inquiry, such settlements accounted for 22% (i.e. 45 out of 207) of the settlements reviewed. In the first monitoring period, the figure dropped to 10% (9 out of 93) of the settlements. Throughout 2010, and based on

the second monitoring exercise only 3% (3 out of 89) of the settlements fell into the category that might attract EU antitrust scrutiny.

- Patent litigation and alternative dispute resolution: The increase in patent settlements in 2010 is put forward by the Commission as evidence that antitrust scrutiny has not hindered companies from concluding settlements in general. This observation may be set against statements of certain stakeholders that the Commission would be forcing companies to litigate each patent dispute until the end. In the majority of cases, the Commission finds that companies were able to find solutions that are usually considered unproblematic from an EU antitrust perspective.

Ongoing scrutiny of the pharma sector shows no signs of relenting

European level

In a parallel announcement, the Commission has closed an antitrust investigation against Boehringer Ingelheim which had been accused of effectively blocking the launch of rival products to its treatment for lung disease blockbuster *Spiriva*, which has global sales of about €3 billion a year. Boehringer Ingelheim settled with competitor, Almirall, whereby Boehringer agreed to remove the alleged blocking position for Europe and grant a licence for two countries outside Europe. Amirall will now be able to launch its combination medicines (pending market authorisation).

While the Commission has noted that the results of the current monitoring exercise are positive, Commissioner Almunia emphasises that the Commission will "remain vigilant" that companies respect antitrust law and do not delay development of cheaper pharmaceuticals.

The Commission has confirmed that none of the cases identified in the second monitoring exercise will automatically trigger an in-depth antitrust investigation by it, yet the Commission has a number of ongoing cases before it. So far the Commission has opened three formal proceedings with respect to patent settlements involving Laboratoires Servier[2], Lundbeck[3] and Teva and Cephalon[4]. The outcome of these ongoing investigations is awaited.

Member State level

Meanwhile antitrust investigations in the pharmaceutical sector continue at the Member State level. For example, on April 13, 2011, the UK Office of Fair Trading announced that it has issued a decision finding that Reckitt Benckiser has infringed the EU and UK prohibitions on abuse of a dominant position (specifically Article 102 of the Treaty on the functioning of the European Union and the Chapter II prohibition of the UK Competition Act 1998), and imposing a fine of £10.2 million. The infringement relates to Reckitt Benckiser's decision in 2005 to withdraw and de-list its Gaviscon Original product from the NHS prescription channel in 2005, after the expiration of its patent but before the generic name for the product was available.

Also, in Italy, the Italian Competition Authority (ICA) began investigations in October 2010 into Pfizer's alleged attempt to abuse administrative procedures to extend the protection for its active ingredient *latanaprost*. It was alleged that this was an abuse of its dominant position in the Italian market for treatment of visual glaucoma as it was an attempt to block or delay market access for generics. Ratiopharm, a generics producer,

lodged the complaint and accused Pfizer of gaining an extension of the patent protection without the launch of any new product on the market as the extension was based on a divisional patent that had been declared invalid by the European Patent Office in Munich. In May 2011 the ICA published the proposed commitments which Pfizer has offered to close the investigation - some of which include that Pfizer will grant a royalty-free licence and will refrain from seeking further patent protection; it will drop legal action against generic manufacturers; and will publish on its website information regarding medicines containing the same active ingredient. If the ICA makes these commitments binding on Pfizer then it will allow for immediate opening of Ratiopharm's competing generic drug, *Xalatan*, and will also inform consumers and doctors of similar products to the branded treatment.

Final thoughts

The Commission will repeat its patent settlement monitoring exercise in 2012, indicating that EU antitrust scrutiny of the pharmaceutical sector will continue at least during next year. In the absence of a means to seek clarity from the Commission on proposed settlements *ex ante*, a case by case assessment is required of patent settlements.

The Commission's enforcement of antitrust law in the pharmaceutical sector is a good example of the evolving era of EU antitrust enforcement. Currently that enforcement landscape comprises a number of elements including the overall policy approach at EU-wide level; sector and monitoring inquiries as an information gathering and enforcement tool; commitments to resolve individual antitrust cases, and follow-up cases at EU and national level.

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1 Final Report, paragraph 1573.
2 MEMO 09/322
3 IP/10/08
4 IP/11/511