



EU General Court Rules on Pay-for-Delay Agreements in Patent Disputes

In a series of judgments, the European Union General Court (“General Court”) on September 8, 2016, upheld a 2013 Commission decision (including €146 million in fines) against Danish drug maker Lundbeck and four generics producers for entering into an agreement to settle patent disputes concerning the antidepressant Citalopram®. This is the first time a European Union court has ruled on such agreements. In particular, the General Court validated the Commission’s analysis of pay-for-delay agreements as “by object” violations of EU competition law, which means they are automatically illegal and that the European Commission does not have to show any anticompetitive effects of such agreements in order to find a violation of competition law.

Background

Pay-for-delay agreements have been in the spotlight of the European Commission since 2008 when the Commission launched its sector inquiry into the pharmaceutical industry.

In this inquiry, the Commission categorized the settlements according to two variables. First, the possibility to delay entry into the market by generic firms and, second, the transfer of value from an innovator company to the generic. In view of these two variables,

the Commission classified the patent settlements into three categories:

- Type A: there is no restriction on the ability of the generic firm to market its product.
- Type B-I: there is a restriction on the ability to market (e.g. non-challenge or non-infringement clause) but without any reverse payment.
- Type B-II: there is a restriction on the ability to market and a reverse payment from the innovator company to the generic one (direct transfer of money, distribution agreements, side deals or a license).

According to the Commission, the type A and type B-I settlements do not raise any competition issues. However, the Commission took the view that type B-II agreements constitute a “by object” violation of competition law. According to the Commission, pay-for-delay agreements between an innovator and a generic company that restrict the ability of the generic company to enter the market in exchange for a transfer of value raise competition issues. This is because, in the view of the Commission, they induce the sharing of profits to the detriment of patients and public health budgets.

Following the sector inquiry, four investigations were launched, three resulting in fines imposed by the Commission. In June 2013, a fine of €145 million was imposed on Lundbeck and four generic firms. In December 2013, Johnson & Johnson and Novartis were fined €16 million for delaying the entry of the generic product Fentanyl®. In July 2014, Servier and five generic companies were fined €427.7 million for blocking entry of a generic version of Perindopril®. In April 2011, an investigation was launched to assess the compatibility with competition law of the agreements concluded between Cephalon and Teva concerning the generic Modafinil®.

The judgment of the General Court constitutes the first confirmation of the Commission's findings.

It may be worthwhile to compare the Commission's approach with the approach by U.S. courts and U.S. antitrust agencies. Early on, despite several challenges by the U.S. Federal Trade Commission and private plaintiffs, pay-for-delay agreements generally were found to be lawful as long as the terms of the agreement fell within the scope of a presumptively valid patent. However, in 2012, this "scope of patent" test was rejected by the U.S. Court of Appeals for the Third Circuit in favor of a "quick look" rule of reason approach, by which pay-for-delay settlements were deemed *prima facie* unlawful. This led to a clear split among circuits, with some courts adhering to the "scope of patent" analysis and others analyzing agreements under the "quick-look" rule.

The U.S. Supreme Court clarified the position regarding pay-for-delay agreements and held, in the *Actavis* case, that they must be reviewed under the full rule of reason. The rule of reason consists of a case-by-case analysis, which requires weighing the procompetitive and anticompetitive effects of a particular agreement. Although the Court reasoned that "large" and "unjustified" payments may violate the antitrust laws, it left the task of developing the rule of reason analysis more fully to the lower courts. Albeit different, the U.S. approach is more comparable to the restriction-by-effect where the procompetitive and anticompetitive effects of an agreement are analyzed. By contrast, while the by-object restriction approach taken by the European Commission may also allow for the weighing up of the procompetitive and anticompetitive effects of an agreement under article 101(3), this rarely is successful.

The Commission's Decision

In 2013, the Commission fined Lundbeck (€92.3 million) and four generic companies (€52.2 million) for having concluded several anticompetitive agreements aimed at delaying market entry of the generic version of Citalopram®.

At the time of the agreements, Lundbeck's patent on the molecule and the initial processes had already expired. However, Citalopram® was still protected through other process patents covering some but not all processes to produce that particular drug.

Before the patent expiry, some generic firms had started proceedings to launch a generic version of Citalopram®, leading to several patent disputes between Lundbeck and the generic producers. Lundbeck claimed infringement of its patent, and generic producers argued either noninfringement or the invalidity of the patent. However, there was no court decision before the execution of the agreements, and all except one (the agreement concluded with Alpharma concerning the European Economic Area) were concluded before the start of any litigation procedure.

In this specific context, Lundbeck entered into six agreements with four groups of generic companies. Under the terms of the agreements, the generic firms delayed their entry into the market in exchange for a financial payment from Lundbeck.

The Commission concluded that the object of those agreements was to restrict competition. According to the Commission, Lundbeck and the generic firms were potential (in some cases, actual) competitors; the generic companies limited their effort to launch their products, and the agreements were related to a transfer of value from Lundbeck to the generic companies, which considerably reduced their incentive to enter the market.

General Court Judgment

The General Court fully confirmed the Commission's conclusions. First, it affirmed the fact that Lundbeck and the generic companies were at least potential competitors and that the settlements were therefore horizontal agreements

between competitors. Second, it confirmed that the object of the agreements was to restrict competition, so that the Commission did not have to show any actual restrictive effect of the agreements. Third, it agreed that the scope of patent test does not constitute the suitable test for this type of agreement. Finally, it also emphasized that each agreement went beyond the scope of Lundbeck's patent.

First, the General Court confirmed that, at the time of the agreements, the generic companies were at least potential competitors. It outlined several reasons for this: The Lundbeck process patents blocked some but not all possibilities of market entry. Therefore, they did not constitute an "insurmountable barrier for the generic companies." As a matter of fact, generic companies had "real and concrete possibilities" to enter the market. They had made important investments to enter the market and concluded supply and development agreements. In addition, they had obtained (or tried to obtain) a marketing authorization and were able to actually make the generic version.

Furthermore, in some cases, the parties were even actual competitors. For instance, between the expiration of the agreement between Lundbeck and Merck relating to the United Kingdom (July 2003) and the second agreement (August 2003), Merck sold generic products. Merck also entered the market in 2002 in Sweden for five months under the agreement concerning the European Economic Area.

The EU judges emphasized that it would have been surprising that Lundbeck was willing to pay such an amount if it did not perceive the generic entry as a potential threat.

Second, the General Court also confirmed that the object of the agreements was to restrict competition and that a large value transfer implies a restriction by object. Under Article 101 TFEU, an agreement can restrict competition by its object or by its effects. An agreement restricts competition by its object when, by its very nature, it is harmful to the functioning of normal competition. The anticompetitive character is so clear that it does not require an analysis of the potential anticompetitive effects. By contrast, when an agreement does not restrict competition by its object, it is necessary to look at its effects.

According to the General Court, the reverse payment served as "a deal-clincher," as it was used as an incentive for the generic companies to stop trying to enter the market. Therefore, the EU judges concluded that the Commission was right by arguing that "the very existence of reverse payments and the disproportionate nature of those payments were relevant factors in establishing whether the agreements at issue constituted restriction of competition by object." Furthermore, the General Court emphasized that the size of the reverse payment is an indicator of the strength or the weakness of a patent.

The reverse payment corresponded to the profit or turnover that generic companies expected to make during the term of the agreements if they had entered the market. The General Court therefore emphasized that the parties "exchanged the uncertainty for the certainty that the generic companies would not enter the market, by means of significant reverse payment, thus eliminating all competition."

The General Court also found that the agreements at issue were not objectively necessary to achieve a legitimate objective, namely the protection and enforcement of a patent. They could have brought an action before the competent national court to protect their patents.

Third, the General Court clarified that the scope of patent test does not constitute the right approach to pay-for-delay agreements. According to the scope of patent approach, the competition rules do not apply to a patent settlement agreement as long as it remains within the scope of the patent, that is: (i) the agreement concerns only infringing products and (ii) it allows the entry of generic products before the expiry of the patent. The parties maintained that "the contractual restrictions falling within the patent holder's temporal, territorial and material rights do not infringe competition law, because those restrictions are analogous to the restrictions inherent in the underlying patent." Adopting such an approach would mean that (i) Lundbeck's patent is valid and (ii) the generic companies would infringe it.

However, the General Court rejected the scope of patent test, as the U.S. Supreme Court had done in the *Actavis* case. The context in which these agreements were concluded is

characterized by a great uncertainty. In fact, the validity of Lundbeck's patent was not confirmed, and it is not certain that the generic product was actually infringing Lundbeck's patent. Therefore, the scope of patent test was based only on "a subjective assessment, by the applicants, of the scope of their patents and of their validity, whereas a national court or a competent authority may have taken a different view."

The General Court also confirmed the findings of the Commission that the agreements went beyond the scope of Lundbeck's patent. The commitments of each agreement were not limited to infringing Citalopram® and, in some agreements, granted a discretionary power to Lundbeck as to whether or not the generic company was infringing its patent.

Conclusion

The judgment of the General Court confirmed the treatment of certain types of pay-for-delay agreements as "by-object restrictions." It concluded that there was no need to examine the effects of the agreements by analyzing the counterfactual scenario.

While this judgment will reinforce the Commission's efforts to fight against pay-for-delay agreements, it makes it more difficult for companies to conclude settlements without facing the risk of antitrust violations and fines. At the same time, the judgment does not give companies clear guidance on when such a settlement would constitute a violation of the competition laws.

In fact, the conclusion as to the restriction by-object was based on different factors. First, Lundbeck and the generic companies were potential competitors. The latter agreed to refrain from entering the market in exchange of a payment from the former. Moreover, the agreements went beyond the scope of the patent as it concerns not only infringing Citalopram®, and there was no guarantee that after the agreement, Lundbeck would refrain from infringement actions. Finally, the General Court emphasized that the payment corresponded to the expected profits of the generic companies if they would have entered the market.

However, there is no indication of the importance or weighing of all these factors, and therefore it is not possible to know to what extent a pay-for-delay agreement becomes legal in the absence of one or more of these factors. Furthermore, the extent to which a payment is sufficiently large to attract competition scrutiny is blurred.

On the other side of the Atlantic, the position is not particularly clear either. The U.S. Supreme Court held that pharmaceutical patent settlements can potentially be anticompetitive when a brand manufacturer makes a "large" and "unjustified" payment to a potential generic competitor. This raises several questions. First of all, it remains unclear whether or not the notion of reverse payment also includes side deals, licenses, etc. or, on the contrary, is limited to cash payment. Secondly, the extent to which a large payment becomes too large and raises competition issues is confusing as well.

Pay-for-delay agreements will continue to attract the Commission's attention. However, in the absence of guidance, it remains crucial for pharmaceutical companies that would like to enter into agreements with generic manufacturers to carefully assess the developing legal situation.

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