CLIFFORD CHANCE

The General Court's first ruling on reverse patent settlements

On 8 September, the General Court (GC) confirmed that the reverse patent settlements between Lundbeck and a number of generic companies formed anticompetitive agreements. In a series of judgments, the GC clarified how potential competition should be defined in the context of patent litigation, and for the first time ruled that reverse patent settlements can form an infringement "by object". The judgments are an important clarification on the interaction between intellectual property law and the application of competition law. The parties have two months to decide whether to file an appeal.

Reverse patent settlements as "by object" infringements: the GC's Lundbeck rulings in a nutshell

On 8 September 2016 the GC for the first time ruled on the legality of reverse patent settlements. The GC held that reverse patent settlements can constitute "by object" infringements of Article 101 TFEU in certain circumstances. It thus confirmed the decision and the fines imposed by the European Commission (EC). The affected parties now have two months to decide whether to file an appeal.

On 19 June 2013, the EC fined Lundbeck and four groups of generic companies for a total of € 146 million for entering into a series of patent settlements in 2002. These settlements included restrictions on the ability of the generic companies to enter with a generic version of citalopram, an antidepressant. Instead, the generic companies entered the market as distributors of Lundbeck. In addition, Lundbeck paid the generic companies an amount equivalent to the expected profit under independent entry (the so-called "reverse payments"). The EC decided that these agreements offered Lundbeck the certainty that the generic companies would stay out of the market as long as the agreements lasted.

The GC supported the findings of fact of the EC. The EC presented a negative picture of Lundbeck's conduct and uncertainty over the strength of its IP protection. Of broader relevance is the approach of the GC to the EC's theory of harm: it found that replacing the uncertainty of litigation around the validity and infringement of the patent with the certainty that the generic companies would not enter the market constitutes a "by object" infringement, when certain factors, including a reverse payment are present.

Key issues

- The GC reviewed the decision of the EC on the patent settlements of Lundbeck in relation to citalopram, an antidepressant.
- The appeal of Lundbeck and others was dismissed by the GC.
- It was the first time the GC ruled on the legality of reverse patent settlements and it confirmed that some patent settlements can constitute infringements "by object".
- It also contains key guidance on how to interpret "potential competition" in the context of patents.

To reach this conclusion, the GC relied on various factors, including an analysis of whether the generic companies could be considered potential competitors and under what circumstances a reverse payment is compatible with competition law.

The concept of a potential competitor

Real concrete possibilities

In order for an anticompetitive agreement to arise, the undertakings involved must be at least potential competitors. This raises the question whether generic companies are potential competitors, when confronted with a patent which is presumed to be valid.

In line with existing case law, the GC confirmed that to prove potential competition, the EC needs to show real concrete possibilities for the undertaking to enter the market. In the context of generic entry, the GC clarified that these real concrete possibilities can arise even when there is a (presumptively) valid patent, if there is a possibility of entry (whether at risk or not).

The GC held that the EC has to carry out an analysis of the objective elements in the case, which can include evidence of the parties' perception of the patent strength at the time, investments already carried out by the generic, whether the generic obtained a market authorisation and other relevant factors. Interestingly, the GC placed special emphasis on the fact that in this case, it was unlikely that Lundbeck would have obtained injunctions against the generic companies involved. This left open the question of whether the generic companies could properly be regarded as potential competitors once they are subject to an injunction.

Timing of potential entry

The GC also confirmed the EC does not need to show that generic entry would have taken place during the period covered by the agreement. For potential competition to arise, it is sufficient for the EC to show that entry could have occurred within a time period which is sufficiently short to exert effective competitive pressure.

The GC thus seems to have adopted a broad definition of "real concrete possibilities" in the context of generic entry, both in terms of substance and in a temporal sense. To add to this, at numerous places in the judgments, it emphasised that the existence of the patent settlement agreements in themselves formed evidence that Lundbeck regarded the generic companies as a threat exerting competitive pressure. This circular reasoning has clear implications for companies looking for practical solutions when their IP rights are challenged.

The legality of reverse patent settlements

The EC's approach

Ruling for the first time on this issue, the GC also addressed the question of whether all reverse patent settlements are anticompetitive, and confirmed that it is not always so. The EC's decision had already indicated that a reverse patent settlement is not always problematic, in particular when:

- the payment is linked to the perceived strength of the patent;
- the payment is necessary to find an acceptable and legitimate solution by the parties; and
- it does not include restrictions intended to delay market entry.

The GC's clarification

The GC confirmed that these factors are relevant. In order to assess the perceived strength of the patent the size of the reverse payment may be taken into account, as well as the basis for calculation: if it is linked to the profits the generic would have made had it entered independently, this is likely to be problematic. In short, if the payment can be interpreted as a "deal clincher" to convince the generic to accept entry restrictions, the agreement will potentially be seen as anticompetitive.

Similarly, when the settlement does not resolve the underlying patent dispute, the agreement warrants scrutiny. This is counter-intuitive in light of the fact that the agreements in question contained express statements by the generic companies as to the status of the rights under dispute.

Finally, the GC confirmed that if a reverse patent settlement provides for quicker market entry, there is no issue. This does not include entry as a licensor, but must be fully independent generic entry. If there are restrictions which delay such entry (even within the scope of the patent), a different view is taken. In this respect, the GC made it clear that these restrictions do not necessarily need to eliminate any possibility to enter the market, as long as they reduce the incentive of the generic to do so.

Risk asymmetry

The GC also specifically dealt with the argument that asymmetry of risk explains why reverse payments are sometimes made: originators normally have a lot more to lose when the generic companies enter the market. They may thus be willing to grant significant reverse payments to avoid even a small risk of generic entry. However, the GC emphasised that although this may be the most cost-effective or least risky course of action, generic entry is a normal commercial risk for originators, and such agreements cannot replace the competitive process.

The GC held that the above does not lead to an unworkable legal test which will dissuade companies from entering into settlement agreements that provide for rapid market entry. However, in practice, it is hard to see how an originator is not heavily incentivised to continue to litigate as a result, as the alternative settlement options which were stated as acceptable to the GC are all in favour of the generic companies. It is also of little comfort in jurisdictions that do not readily injunct potentially infringing entrants, with the possibility of lasting adverse effects on patent holders even if they later prevail in litigation. It is therefore no surprise that the judgment attracted immediate criticism from EFPIA.

The "by object" character of the infringement

Replacing uncertainty with certainty

The GC found that the agreements in question replaced a state of uncertainty surrounding the validity and the infringement of the patent with the certainty that the generic companies would not enter the market for the duration of the agreements, in return for significant reverse payments. The GC likened this to market exclusion agreements, emphasising that the goal is to protect potential competition, even if one foreseeable potential outcome of the challenge was that the generic companies were found to be infringing a valid IP right.

As a result, the GC did not require the EC to examine the counterfactual that exclusion was a valid exercise of the IP right (as this is only required for infringement by effect), as long as it could show:

- a sufficient degree of harm to competition, in view of the contents of the provisions of the settlement agreement, the intended objectives and their economic and legal context; and
- real concrete possibilities of entry (which is required to show potential competition).

There is clearly some tension between this finding (that the counterfactual does not need to be examined) and the position of the GC mentioned above that reverse patent settlements that provide for quicker market entry are not viewed as anticompetitive. In this context, quicker is not definitively defined as immediate, leading to potentially contradictory outcomes.

Ancillary restrictions and the scope-of-the-patent test

The GC also ruled that the restrictions in place could not be justified as being objectively necessary to protect Lundbeck's IP rights.

In this context, it explicitly rejected the so-called "scope-of-the-patent" test (previously rejected by the US Supreme Court). Here again, the GC indirectly emphasised the importance of litigation and binding court decisions imposing restrictions on entry or judgments as to validity and infringement. For the GC, as IP rights do not afford protection against challenges to their validity, the presumption of validity is insufficient to justify restrictions being imposed, even within the scope of the patent. Regardless, the GC assessed whether each of the agreements fell within the scope of the patents. For the agreement with GUK in relation to the UK, the GC found that this was in fact the case, contrary to the findings of the EC. However, this in itself was not sufficient to annul the decision, as the settlement was still an agreement not to enter the market in return for a significant payment from Lundbeck.

Other arguments

The parties raised various arguments in defence of the reverse patent settlements, including arguments that they lead to efficiency gains. The GC rejected this argument, as it held that the efficiency gains were not proven by the parties to the required standard of proof.

In relation to the imposition and level of the fine, the GC held that it was not unforeseeable by the parties that the agreements were anticompetitive at the time of conclusion, and so the imposition of a fine was warranted. The fact that the EC in 2005 had expressed doubts as to whether the agreements were in fact anticompetitive did not make a difference in this respect, as this was merely a preliminary assessment, and significant emphasis was placed on the size of the reverse payment as a relevant factor in that assessment.

Wider implications

The EC's investigation and decision came in part as a result of its inquiry into the pharmaceutical sector. After the EC's decision in Lundbeck, it also imposed fines on Servier and five groups of generic companies for a reverse patent settlement, a decision which is currently under appeal. There are also similar cases pending at the national level, in the UK.

The parties in these cases will be carefully considering the current judgments of the GC and their impact on the pending proceedings. Much will likely also depend on whether the parties in the Lundbeck case decide to appeal the judgments to the European Court of Justice. Such an appeal can only deal with points of law.

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