A landmark judgment

The General Court has affirmed the Lundbeck pay-for-delay decision

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On 8 September, the General Court (the GC) delivered its judgments in the *Lundbeck* pay-for-delay case (Case T-472/13 *Lundbeck v Commission*) and in the related cases filed by Sun Pharmaceutical Industries and Ranbaxy, Arrow Group and Arrow Generics, Generics UK (GUK), Merck, Xellia Pharmaceuticals and Alpharma. These judgments are the GC's first rulings on patent settlements agreements.

In 2002, Lundbeck concluded agreements concerning its antidepressant citalopram with the generic producers. Each generic company received substantial payments from Lundbeck. At the time when the agreements were concluded, the compound patent for citalopram had expired, but certain process patents remained in force.

In its judgment, the GC confirmed the European Commission's (the EC) decision (the Decision) that the agreements between Lundbeck and the generic producers restricted competition by object in violation of article 101(1) of the treaty on the functioning of the European Union (TFEU).

The GC upheld the fine of €146m that the EC imposed on Lundbeck and the generic companies.

At least potential competitors

The GC first considered whether the EC was wrong to conclude that Lundbeck and the generic companies were at least potential competitors. It agreed with the EC that, if the agreements had not been concluded, there would have been a real possibility that at least one of the generic companies would enter the citalopram market at the time that the agreements were concluded, such that they were potential competitors of Lundbeck in that market.

The GC found that the EC had carried out a thorough examination of the potential for entry, relying on objective evidence such as the investments and efforts that the generic companies had already made to prepare for market entry (including the steps taken to obtain marketing authorisations and conclude supply contracts with active pharmaceutical ingredient suppliers). The GC confirmed the EC's view that doubts over the validity of Lundbeck's patent, and the parties' views regarding their probability of success in litigation, showed that the patents "were not capable of blocking any entry of generic undertakings to the market at the time the agreements at issue were concluded". The GC did note, however, that this did not mean that the Commission disregarded the presumption of validity of Lundbeck's process patents.

It went on to find that the possibility of market entry was not merely theoretical, pointing to the fact that some companies (for example, Merck GUK in the UK and its distributor NM Pharma in Sweden) had entered the market before or after the agreements in issue were concluded. In addition, the generic companies could have obtained generic versions of citalopram within a short timeframe based on processes (such as the original, no longer patent protected, cyanation and alkylation processes) which, at the time, had not been held to infringe Lundbeck's patents.

The GC further found that the significant payments from Lundbeck to the generic companies reinforced the conclusion that the generic companies were potential competitors, and that Lundbeck had seen them as competitive threats to its position on the citalopram market.

The "by object" analysis

The value transfers. As part of its article 101(1) TFEU analysis, the GC considered whether the EC had wrongly assessed the role of the value transfers to the generic companies (by taking the view that the provision in the agreements for payments by Lundbeck meant that those agreements had an anticompetitive object). The GC upheld the Decision, stating 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 restrictions of competition 'by object' for the purpose of article 101 TFEU in that, by those payments, the originator undertaking provided an incentive to the generic undertakings not to continue their independent efforts to enter the market".

The GC, however, stressed that the EC did not find that the existence of a reverse payment in a patent settlement is always problematic. Such payments as part of a patent settlement agreement will not be anticompetitive if the payment meets a number of conditions. First, it should be linked to the strength of the patent (as perceived by each of the parties). As the GC put it:

> "where a reverse payment is combined with an exclusion of competitors from the market or a limitation of the incentives to seek market entry, the Commission rightly took the view that it was possible to consider that such a limitation did not arise exclusively from the parties' assessments of the strength of the patents but rather was obtained by means of that payment".

Second, the payment must be necessary to enable the parties to find an "acceptable and legitimate solution" to their dispute. Finally, the payment should not be accompanied by restrictions intended to delay market entry by generics. The GC confirmed that companies may conclude settlements including reverse payments that are not intended to restrict market entry by generic companies.

The GC characterises the EC's Decision as having only found that it was the "disproportionate nature of such payments", combined with the fact that (1) the payments corresponded to the profit that the generic companies anticipated making on market entry, (2) there were no provisions in the agreements allowing the generic companies to launch their products on expiry of the agreements without risking infringement actions

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by Lundbeck, and (3) the restrictions in the agreements went beyond the scope of Lundbeck's patents, that led to the conclusion that the object of the agreements was to restrict competition, within the meaning of article 101(1) TFEU.

The GC reiterated that the agreements and the reverse payments in this case were particularly problematic because they replaced the uncertainty as to whether generic companies would enter the market (without them being enjoined or found to infringe the patents, or having to show the invalidity of the patents) with the certainty that they would not enter, at least during the term of the agreements.

The notion of restriction of competition by object. The GC rejected Lundbeck's argument that the EC erred in treating the agreements as being equivalent to market-sharing agreements, such as those at issue in the BIDS judgment (Case C-209/07 *Beef Industry Development Society and Barry Brothers* [2008]).

In response to Lundbeck's plea that the *Cartes Bancaires* judgment (Case C-67/13 *P Cartes Bancaires v EC* [2014]) supported its view that the EC had erred in classifying the agreements at hand as restricting competition by object, the GC found that the European Court of Justice (the ECJ) did not question the basic principles concerning the concept of a restriction of competition by object established in the case law.

To recap, in *Cartes Bancaires*, the ECJ found that the by object concept should be read narrowly and only applied to agreements between undertakings which revealed a sufficient degree of harm to competition that it was unnecessary to examine their effects. The ECJ held that certain forms of co-ordination between undertakings are, by their very nature, injurious to the proper functioning of normal competition. To establish whether an agreement is anticompetitive, it is necessary to consider whether its provisions, objectives and economic and legal context reveal sufficient harm to competition.

In *Lundbeck*, the GC found that the agreements were comparable to market exclusion agreements (ie serious restrictions of competition since excluding competitors from a market is an extreme form of market sharing and production limitation). As a result, the GC found that the EC was not required to examine also the effects of the agreements. The GC also noted that it is not necessary for a type of agreement to have already been censured by the EC in order for it to restrict competition by object.

The GC went on to find that Lundbeck's argument that the EC erred in applying the case law on "other legitimate objectives" was based on the erroneous premise that its "legitimate objective" (ie protecting intellectual property rights) could not have been achieved without restricting competition. It found that Lundbeck had not demonstrated that the restrictions were objectively necessary to protect its intellectual property rights. If Lundbeck were convinced that its patents would be infringed by the generic companies, it could have protected its rights before the competent national courts.

Finally, the GC noted at several points in its judgment that, although the existence of intellectual property rights is not affected by article 101(1) TFEU, the conditions under which those rights are exercised may fall within article 101(1). In the same vein, the GC confirmed that, although the EC is not competent to determine the scope of a patent, it may take that scope into account where this is relevant to determining whether there has been an infringement of article 101 (or 102) TFEU. The GC found that, even if the restrictions in the agreements potentially fell within the scope of Lundbeck's patents, the agreements went beyond the specific subject matter of its intellectual property rights (which included the right to oppose patent infringement) in paying (actual or potential) competitors not to enter the market.

Potential implications of the GC's ruling

The GC's judgment will require pharmaceutical companies to be particularly careful in crafting settlement agreements that include payments to potential infringers. Although *Lundbeck* is very specific to its facts and context, the GC nevertheless provides some general guidance on when reverse payments are likely to be problematic. The GC makes it very clear that settlement agreements, even those that involve a payment/value transfer to potential entrants, are not necessarily anticompetitive. The analysis must be carried out case-by-case, considering the extent to which the proposed settlement terms restrict the ability of generic companies to enter the market and contain a value transfer that is linked to such entry (an approach that the EC adopted in its 2009 sector inquiry).

An analysis of whether a settlement is by object restrictive of competition should consider a range of different factors, including whether there was a genuine dispute, whether the payments are linked to the estimated profits the generic companies forego by the agreement not to enter (rather than the costs saved by avoiding further litigation and the value of commercial arrangements, for example) and whether the agreement was specifically aimed at delaying generic entry.

If, for example, the purpose of a patent settlement agreement, and any payment to a potential infringer that it entails, is to settle a genuine dispute, if the payments made by the originator company are proportionate and reflect genuine value to the patent holder, and if the agreement reflects the parties' respective views regarding the strength/merits of the patent(s), such an agreement should not raise competition law issues.

It is also important to ensure that such an agreement does genuinely settle a dispute - the fact that Lundbeck remained free to launch an infringement action and the generic companies remained free to challenge the validity of Lundbeck's process patents was held to indicate that there was no genuine underlying dispute being settled.

Similarly, it is important to ensure that a proposed settlement agreement does not go beyond the scope of the patents that are the subject of the dispute. The fact that the settlement covered citalopram made using processes which did not implement the technology that read on the relevant patent, contributed to the conclusion that the agreements between Lundbeck and the generic companies were anticompetitive.

Beyond Lundbeck, the *Servier* decision remains pending before the GC. While there are a number of elements common to the cases, there are some material differences. Subject to the GC's conclusions on the Commission's by object conclusions, it may also address the Commission's by effect and article 102 TFEU reasoning, providing additional guidance for pharmaceutical companies whose settlement agreements do not infringe competition law by object.

The judgment will also likely impact on the pending national pay-for-delay cases, including the paroxetine case currently before the UK Competition Appeal Tribunal.