Lundbeck Loses Appeal Against ‘Pay-For-Delay’ Decision

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Antitrust/Competition

The General Court (the “GC” or the “Court”) delivered its judgment in the *Lundbeck* ‘pay-for-delay’ case last Thursday (Case T-472/13 *Lundbeck v Commission*).[1] In its judgment, the GC confirms the European Commission (the “Commission”)’s decision (the “Decision”), namely that the agreements between Lundbeck and the generic producers (Merck KGaA/Generics UK (“GUK”), Alpharma, Arrow and Ranbaxy) restricted competition ‘by object’ in violation of Art. 101(1) of the Treaty on the Functioning of the European Union (“TFEU”).

In 2002, Lundbeck concluded agreements concerning its citalopram drug with the four companies active in the production or sale of generic medicinal products. Each of these generic companies received substantial payments from Lundbeck.

The Court upheld the fine of €146 million that the Commission imposed on Lundbeck and the generic companies.

1. ‘At least potential competitors’

In its judgment, the GC first considered Lundbeck’s plea that the Commission was wrong to conclude that Lundbeck and the generic companies were ‘at least potential competitors’. The Court agreed with the Commission that, if the agreements had not been concluded, there would have been real concrete possibilities for the generic companies to enter the citalopram market at the time the agreements were concluded, such that they were potential competitors of Lundbeck in that market.

The GC found that the Commission had carried out a thorough examination of the real concrete possibility that each generic company would enter the market, relying on objective evidence such as the investments and efforts that they had already made to prepare for market entry, including the steps taken by the companies to obtain marketing authorisations and the supply contracts concluded *inter alia* with their active pharmaceutical ingredient suppliers.

It went on to find that the possibility of market entry was not merely theoretical, as illustrated by the fact that some companies (*e.g.*, Merck GUK in the UK and its distributor NM Pharma

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[1] The generic companies also lost their respective appeals: *see* cases T-460/13 *Sun Pharmaceutical Industries and Ranbaxy v Commission*, T-467/13 *Arrow Group and Arrow Generics v Commission*, T-469/13 *Generics (UK) v Commission*, T-470/13 *Merck v Commission*, T-471/13 *Xellia Pharmaceuticals and Alpharma v Commission*.

in Sweden) did enter the market before or after the agreements at issue had been 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 Court further found that the fact that Lundbeck had paid significant amounts to the generic companies reinforced the conclusion that the generic companies were indeed potential competitors, and that Lundbeck had perceived them as a competitive threat to its position on the citalopram market.

2. The 'by object' analysis

A. The 'value transfers'

As part of its analysis under Art. 101(1) TFEU, the Court considered Lundbeck's arguments that the Commission had wrongly assessed the role of the value transfers to the generic companies, erring in taking the view that the provision in the agreements for payments by Lundbeck meant that those agreements had an anticompetitive object. The Court 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 Commission 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 may pass competition law scrutiny if the payment is (i) linked to the strength of the patent (as perceived by each of the parties), (ii) necessary to enable the parties to find an 'acceptable and legitimate solution' to their dispute and (iii) not accompanied by restrictions that intend to delay entry of generics on the market. The Court added that companies may conclude settlements which, although they provide for such reverse payments, are not accompanied by any restriction on market entry by generic companies.

Indeed, the Court characterises the Commission's Decision as having only found that it was the 'disproportionate nature of such payments', combined with factors including (i) the fact that the amounts of those payments corresponded to the profit that the generic companies anticipated making had they entered the market, (ii) that there were no provisions in the agreements allowing the generic companies to launch their products on expiry of the agreements without risking infringement actions by Lundbeck, or (iii) the restrictions in the agreements going beyond the scope of Lundbeck's patents, that led to the conclusion that the agreements at issue had as their object the restriction of competition, within the meaning of Art. 101(1) TFEU.

The Court reiterates on several occasions 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 being enjoined or found to infringe the patents, or having to show the invalidity of Lundbeck's patents) with the certainty that they would not enter, at least during the term of the agreements, as a result of the significant reverse payments.

B. The notion of restriction of competition ‘by object’

The GC rejects Lundbeck’s arguments that the Commission erred when 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 Commission* [2014]) supported its view that the Commission 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, concluding that the Commission correctly applied the case-law.

In *Cartes Bancaires,* the ECJ found that the ‘by object’ concept should be interpreted restrictively, such that it should only be applied to agreements between undertakings which revealed a sufficient degree of harm to competition for the examination of their effects to be considered unnecessary. The ECJ held that certain forms of coordination between undertakings are, by their very nature, injurious to the proper functioning of normal competition. To establish whether an agreement is anti-competitive, it is necessary to consider whether its provisions, objectives and economic and legal context reveal sufficient harm to competition.

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

The Court went on to reject the claim that the Commission erred in applying the case-law on ‘other legitimate objectives’, finding that Lundbeck’s arguments were based on the erroneous premise that its ‘legitimate objective’ (*i.e.*, protecting intellectual property rights) could not have been achieved without restricting competition. It found that Lundbeck did not demonstrate that the restrictions were objectively necessary to protect its intellectual property rights, particularly its crystallisation patent. If it were convinced that its patents were infringed, Lundbeck could have protected its rights by bringing actions 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 Art. 101(1) TFEU, the conditions under which those rights are exercised may fall within the article. In the same vein, the Court confirms that, although the Commission is not competent to determine the scope of a patent, it may take that scope into account if this is relevant to determine whether there has been an infringement of Art. 101 (or 102) TFEU. On that basis, the GC dismissed Lundbeck’s claim that the Commission erred in rejecting the ‘scope of the patent’ test as the relevant standard for assessing patent settlement agreements under Art. 101(1) TFEU. The Court found that, even if the agreements at issue contained restrictions potentially falling within the scope of Lundbeck’s patents, they went beyond the specific subject matter of its intellectual property rights, which included the right to oppose patent infringements, but not the right to conclude agreements by which (actual or potential) competitors were paid not to enter the market.

3. Looking ahead

Lundbeck's press release issued on Thursday states that it 'strongly disagrees' with the GC's judgment and that it will study the judgment and decide whether to appeal to the ECJ. Accordingly, it is quite likely that one or more of the judgments will be appealed to the ECJ.

Lundbeck and the generic companies have two months and ten days from the notification of the judgment (*i.e.*, until November 2016) to decide whether or not to appeal.

Beyond *Lundbeck*, *Servier* is still pending before the GC. While there are a number of elements common to the cases, there are differences (and a line of Article 102 reasoning) that may give Servier some hope for an at least partial win. In addition, there are pending national "pay-for-delay" cases, including the *Paroxetine* case, currently before the UK Competition Appeal Tribunal, on which Thursday's judgment will have a bearing.

If you have any questions concerning the material discussed in this client alert, please contact the following members of our Antitrust/Competition practice:

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