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The ECJ's Lundbeck judgment offers little new on patent settlements but gives birth to an interesting principle: sector inquiries give rise to a duty of diligence

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On 25 March 2021, the European Court of Justice ("ECJ") dismissed all the appeals against the European Commission's decision to fine Lundbeck and several other companies for entering into anti-competitive patent settlement agreements.[1]

The judgments largely repeat the position taken by the ECJ in its January 2020 Paroxetine judgment (see our alert). They notably confirm that:

- the concept of a restriction by object of Article 101 should be interpreted narrowly;
- patent settlement agreements cannot automatically be considered a restriction by object, even if they include a value transfer from the originator to the generic;
- however, where the value transfers cannot have any explanation other than as a reflection of the commercial interests of the parties not to compete, the agreement can restrict competition "by object".

Background Facts

The origins of the **Lundbeck** case go back to January 2002, when Lundbeck's molecule patent on citalopram (an anti-depressant) expired. Lundbeck still had a number of process patents that covered possible ways to produce citalopram.

Around the same period, a number of patent disputes arose between Lundbeck and generic producers, which raised arguments on non-infringement or invalidity of the patents in return. While some patent infringement proceedings with some generics went all the way to a final judgment, Lundbeck concluded six agreements (which the EC picked up and objected to) with four groups of generic producers, according to which the latter agreed to postpone their market entry for short periods (which Lundbeck argued were in line with the time needed to obtain a judgment in the other cases) against financial compensation.

The Commission first became aware of these patent settlement agreements in October 2003 through information received from the Danish Competition Authority, and at the time considered

the agreements not worth investigating, calling it a "gray area". But it was only in June 2013 (more than 10 years after the settlement agreements were entered into, and just before the statute of limitations for fines expired), that the Commission adopted its decision which fined Lundbeck €93.7 million and the four generic producers a total of €52.2 million for delaying the market entry of generic versions of Lundbeck's branded citalopram.

The Commission found that Lundbeck and the generic manufacturers were at least potential competitors, and that the agreements restricted competition "by object", in particular since the amounts that Lundbeck paid to the generic companies allegedly broadly corresponded to the profits that the generic companies anticipated making had they entered the market. "By object" infringements of EU competition law are those which are by their very nature harmful to competition, and the Commission does not have to show any anti-competitive effects in order to find a violation, although, to be fair, the Commission did also include an analysis of anti-competitive effects in its decision.

In September 2016, the General Court fully upheld the Commission's decision. Lundbeck subsequently appealed the GC's judgment before the ECJ.

Key points of the judgment

Potential competition – same approach as Paroxetine

Closely following its reasoning in the recent ruling in the Paroxetine case,[2] the ECJ held that the General Court was right to find that at the time the settlement agreements were concluded, Lundbeck and the manufacturers of generic medicines were potential competitors.

The key findings were as follows:

- As a general rule, in order to assess whether an undertaking is a potential competitor the test is whether there are "real and concrete possibilities" of it joining the market and competing with the undertakings present in it. In the context of the present case, and taking into account the specificities of the pharmaceutical sector, a generic manufacturer is a potential competitor if it has "a firm intention and an inherent ability" to enter the market, and "does not meet barriers to entry that are insurmountable".
- It is not necessary to demonstrate with certainty that the manufacturers of generic medicines would have entered the market and that the entry would inevitably have been successful, but only that those manufacturers had real and concrete possibilities in that respect.
- The existence of potential competition must be assessed at the time when the settlement agreement was concluded. The fact that the patent at stake was validated in later litigation is not relevant to assess whether the generic is a potential competitor at the time of the settlement.
- The existence of a patent that protects the manufacturing process of an active ingredient that is in the public domain cannot, as such, be regarded as an insurmountable barrier. Likewise, the fact that a generic has not already obtained a marketing authorisation does not exclude that it is a potential competitor.
- A competition authority does not have to review the strength of the patent or the chance it will be found to be infringed.

Restrictions of competition by object – following the recent line of cases

The ECJ followed the reasoning in its recent ruling in Paroxetine, which itself fits in with recent cases such as **Cartes Bancaires and Maxima Latvija**.[3] It upheld the GC"s ruling.

The key findings were as follows:

- The concept of restriction of competition "by object" must be interpreted strictly and can be applied only to some agreements between undertakings which reveal, in themselves and having regard to the content of their provisions, their objectives, and the economic and legal context of which they form part, a sufficient degree of harm to competition.
- The characterisation as a "restriction by object" is appropriate when it is plain from the examination of the settlement agreements concerned that the transfers of value from the originator to the generic "cannot have any explanation other than the parties" common commercial interest not to engage in competition on the merits".
- The analysis of whether the net gain via the value transfers was sufficiently significant to act as an incentive to the generic manufacturer to refrain from entering the market concerned and not to compete on the merits with the originator should be addressed on a case-by-case basis.

In the case at hand, the Court found that the General Court made no error in characterising the settlement agreements as a restriction by object given that, on the facts of the case, it was clearly the Lundbeck payments (and not the patents) that led the generics to accept the restrictions to their entry, and Lundbeck had identified no pro-competitive effects attached to the agreements liable to question their harm to competition.

Due process, excessive delay and the sector inquiry

Xellia Pharmaceuticals and Alpharma argued that the Commission had infringed their rights of defence by failing to inform them in a timely manner of the existence of an inquiry concerning them, which had the consequence that they did not retain exculpatory evidence. They argued that the Commission's investigation started in 2003 but they were only told about it in 2010 and 2011.

The General Court held that their rights of defence had not been infringed since they had failed to comply with their obligation of diligence, which ought to have caused them to keep any document that might prove useful to their defence.

The ECJ held that the General Court had erred in law by imposing an obligation of diligence derived from case law that is applicable only to the period after the initiation of the administrative procedure by the Commission. In respect of Xellia Pharmaceuticals and Alpharma, the period of diligence could only apply from 2010 and 2011 when the procedure was opened for them.

However, the ECJ did not set aside the General Court's decision. The ECJ found that the companies were, following the opening of the Commission's pharmaceutical sector inquiry in January 2008, bound by a specific duty of care requiring them to ensure appropriate document retention to ensure that they had in their possession the necessary evidence to deal with investigations or judicial proceedings following the sector inquiry. That was 4½ years after the

expiry of the agreements in question, which the ECJ found was not too long to infringe their rights of defence.

The ECJ reasoned that when the Commission initiates sector inquiries, "undertakings belonging to the sector concerned and, in particular, those which have concluded agreements expressly referred to in the decision initiating the inquiry, as was the case with Zoetis and Xellia, must expect that individual procedures may possibly be initiated against them in the future." The opening of the Sector Inquiry was accordingly a "factor which should lead them to take precautions against the loss, due to the passage of time, of evidence that might prove to be useful to them in the context of subsequent administrative procedures or judicial proceedings."

Comment

The Lundbeck judgment closely follows Paroxetine when it comes to patent settlements, both as regards potential competition and by object infringements. So it does not herald a change to the current state of the law. Indeed, it follows the new orthodoxy on by object infringements, by again reminding us that this concept should be interpreted narrowly – while finding that the Commission was entitled to find this to be a by object infringement based on the facts of this case.

The duty of care to ensure document retention based on the opening of a sector inquiry is novel. Sector inquiries are now seemingly a red light to anyone that is or may be under investigation. That marks a difference in how they are perceived. While the ECJ's findings end this due process argument, looked at from a distance, it does seem odd in due process terms that the two companies concerned were first informed of the investigation so late in the day – in one case 8 years after the agreement expired – and 3 years after the Commission started the sector inquiry.

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1 Judgment in Cases C-586/16 P Sun Pharmaceutical Industries and Ranbaxy (UK) v Commission, C-588/16 P Generics (UK) v Commission, C-591/16 P Lundbeck v Commission, C-601/16 P Arrow Group and Arrow Generics v Commission, C-611/16 P Xellia Pharmaceuticals and Alpharma v Commission, and C-614/16 P Merck v Commission.

2 Case C-307/18 Generics (UK) and Others. See our alert of 14 February 2020: https://www.whitecase.com/publications/alert/court-justice-ruling-paroxetine.

3 Case C-67/13 P Groupement des Cartes Bancaires v Commission, EU:C:2014:2204 ('Cartes Bancaires") and Case C-345/14 Maxima Latvija, EU:C:2015;784.

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This entry was posted on Friday, March 26th, 2021 at 11:57 pm and is filed under European Court of Justice, Patent settlements, Pharmaceuticals, Restriction by object
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