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CJEU, Opinion of the Advocate General in C-591/16P (Lundbeck): patent settlements agreements may amount to a restriction of competition "by object"

According to the Advocate General ("AG") Juliane Kokott, the "pay-for-delay" agreements that were concluded between Lundbeck and four manufacturers of generic medical products amounted to restrictions of competition by object, under art. 101 TFEU. Therefore, in her Opinion of 4 June 2020, the AG also concluded that the EU Commission was right in imposing the fine - close to € 94 million - then confirmed by the EU General Court.

Background to the case

On 19 June 2013, the European Commission ("EC") issued a decision in proceedings under Art. 101 TFEU and Art. 53 of the EEA Agreement involving on the one hand the Danish pharmaceutical company Lundbeck and, on the other, manufacturers of generic medicinal products.

The originator undertaking Lundbeck developed the active ingredient called *Citalopram* (contained in an anti-depressant) and was the holder of some patents in the EEA protecting it. In 2002, those patents were about to expire, but Lundbeck still owned secondary patents protecting manufacturing processes of citalopram in several EEA countries. In the same year, Lundbeck entered into six agreements with four English undertakings – namely, Generics UK2, Alpharma, Arrow and Ranbaxy; in a nutshell, Lundbeck made payments to such generic manufacturers in exchange for which the latter agreed to refrain from entering the market.

Although, in principle, **settlement agreements of this kind are not unlawful *per se***, under certain circumstances they may breach competition law rules. In the present case, the EC held that, as the agreements aimed to exclude the generic manufacturers from the market (the so-called "pay-for-delay" agreements), they amounted to restrictions of competition by object. Indeed, Lundbeck's ultimate goal has been defined by the EC as that to delay the market entry of potential competitors, rather than that to amicably solve a patent dispute. Against this scenario, the EC imposed a fine of almost € 94 million on Lundbeck due to its anticompetitive conduct.

Lundbeck acted against the EC's decision before the General Court ("GC"), which dismissed the claim on 8 September 2016. Lundbeck appealed the GC's decision before the Court of Justice ("CJEU").

The Advocate General's Opinion

Pursuant to art. 101 TFEU, agreements having as "*their object or effect the prevention, restriction or distortion of competition within the internal market*" are prohibited. In Juliane Kokott's view, a restriction of competition did exist in this case. Hence, the CJEU should dismiss the appeal and uphold both the GC's judgment and the EC's decisions, which were right in concluding that the 'pay-for-delay' agreements made between Lundbeck and the generic manufacturers amounted to restriction of competition by object.

Preliminarily, the AG assessed whether a competitive relationship between Lundbeck and the generic manufacturers existed. When the settlement agreements at issue, taking the form of patent dispute settlements, were signed, there was a **potential competitive relationship between Lundbeck and the generic manufacturers,** in spite of the process patents owned by Lundbeck and protecting the manufacturing processes of citalopram. Indeed, a generic drug manufacturer may qualify as a potential competitor of the patent holder, in particular if that manufacturer has a strong intention to enter the market, has an inherent ability to enter the market and demonstrates that he is not worried about infringement proceedings and,

instead, is ready to challenge the patent's validity[1]. This proves even truer taking into account that the validity of patents in the pharmaceutical sector is often questionable, and legal proceedings to challenge their validity are rather common.

When assessing the competitive relationships between the operators that are involved in a dispute to apply competition law rules, the EC is not called upon assessing the strength of the patents and the risk of infringement and, ultimately, foresee the outcome of the patent dispute. Instead, the EC's assessment should be limited to establishing whether, "*notwithstanding the existence of that patent, the manufacturer of generic medicinal products has real and concrete possibilities of entering the market at the relevant time*".

The AG thus concluded that "*the General Court did not err in finding that the patents in dispute did not constitute insurmountable barriers to the entry of the generic manufacturers to the citalopram market and that, in order to demonstrate the existence of a potential competitive relationship between Lundbeck and those manufacturers, the Commission was not required to show that the latter were able to enter the market without infringing any of Lundbeck's patent rights*".

Moreover, the absence of a marketing authorization given to generic manufacturers does not exclude the existence of potential competition between the patent holder and the generic manufacturer. A different conclusion would prevent competition law from being applied during the preparatory stages to market entry of generic medicinal products, which also include the steps taken to obtain the marketing authorisation.

The AG held that **the agreements at issue should be classified as restrictions of competition by object.**

While Lundbeck had the right to oppose to infringing acts, it did not have the right to try to delay the entrance of its competitors. **If the patent holder pays a sum of money to the competitor and there is no plausible explanation or evidence justifying such payments other than the will to prevent the competitor from entering the market and challenging the patent validity** – as in the present case – it can be inferred that the patent dispute settlement agreement is a restriction of competition by object: "a *patent dispute settlement agreement is akin to a restriction of competition by object if the value transfer from the patent holder to the generic manufacturer has no explanation other than the common commercial interest of the parties not to engage in competition on the merits*".

Finally, in the AG's view **the EC was right to impose the fines on Lundbeck**. Art. 101 TFEU provides that agreements between competitors aimed at excluding some of them from the market are unlawful. The burden of proof lying with the EC requires it to adduce evidence showing that a diligent economic operator could reasonably have been expected to be aware of the anticompetitive nature of its conduct. The GC correctly applied this standard of proof, and concluded that Lundbeck could not be unaware that its conduct was anticompetitive.

In light of the above, the AG suggested to dismiss the appeal. It remains to be seen whether the CJEU's ruling will follow the AG's Opinion, which, in any event, is not binding on the Court.

[1] See the CJEU's decision in case C-307/18, Generics (UK) and Others.