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CJEU "Generics and Others"(C-307/18): competition law concerns of settlement agreements in pharmaceutical matters between the patent holder and the generics manufacturer

On 30 January 2020, the CJEU ruled in a case regarding the competition law concerns of settlement agreements in the area of pharmaceutical patents.

The case arose from a preliminary ruling request made by the UK Competition Appeal Tribunal, which asked for the Court's advice on a settlement agreement concerning patent disputes between the holder of a pharma patent, GlaxoSmithKline (GSK), and several generics manufacturers.

As it is often the case, the litigation pending between the parties involved cross claims, *i.e.* invalidity claims brought by the genericists and infringement claims by the originator, who sued after the former put on the market a generic version of a drug whose principal patent - held by GSK - had just expired. The disputes were settled through agreements including the genericists' undertaking not to enter the relevant market for a given period, in exchange of a monetary payment from GSK.

The UK Competition and Markets Authority imposed financial penalties on the parties to the agreements, taking the view that the latter restricted competition and showed an abuse of GSK's dominant position in the relevant market (GSK was the holder of a process patent for the production of an active ingredient that is in the public domain).

The Court of Justice's ruling confirms the **Opinion** of **Advocate General** Juliane Kokott, who had advised that **an agreement settling a patent dispute can indeed constitute a restriction of competition** by object, or by effect, and that entering into that kind of agreement **may amount to an abuse of a dominant position**.

The interest of the decision at hand lies in the concrete assessment of the application of competition law principles to patent settlement agreements.

Concerning art. 101(1) TFEU, the CJEU stated that it is applicable to this type of agreement if the latter has an appreciable effect within the internal market. In practice, the undertakings concerned must be at least in a relationship of potential competition. This notion must be assessed by evaluating if the genericist has "***a firm intention and an inherent ability to enter the market, and that market entry does not meet barriers to entry that are insurmountable****, which it is for the referring court to assess.*".

Secondly, the agreement can be considered as a restriction of competition "***by object***", pursuant to art. 101(1) TFEU, if the information available proves that the net gain from the sum paid by the originator to the genericist within the settlement agreement "*can have no other explanation than the commercial interest of* the parties to the agreement **not to engage in competition**".

However, basic competition law notions apply in the case at hand too. Thus, restriction of competition may be excluded, if the agreement also bears "*proven pro-competitive effects capable of giving rise to a reasonable doubt that it causes a sufficient degree of harm to competition.*"

Then, the Court interprets art. 101(1) as regards the less serious breach of competition law represented by the notion of "*restriction **by effect***". In this regard, the CJEU notes that in that view, one does not need to

value if the parties would have been successful in the settled trial. Of course, the assessment to be made must concern the functioning of the relevant market, lacking the concerted practice.

Lastly, the CJEU replied to the referring Court's questions about the patent holder's **abuse of a dominant position** (Art. 102 TFEU). In that regard, a **weighing of effects** must be made, as to understand if the strategy consisting in **reaching out of court agreements with potential competitors can restrict competition beyond the specific anticompetitive effects of each of the settlement agreements**.