The European Court of Justice classifies "pay for delay" agreements as restriction of competition "by object"

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The European Court of Justice states in a recent judgment that the so-called "pay for delay" agreements can be classified as having as their object the restriction of competition, and that they may also constitute an abuse of a dominant position. This type of agreement has often been used by manufacturers of originator medicines who have wanted to delay manufacturers of generic products from entering the market following the expiry of a patent.

Background

In the 1990s, GlaxoSmithKline (GSK) marketed a patented anti-depressant medicine named Seroxat. In addition to the main patent for the active ingredient of Seroxat (Paroxetine), GSK also held a number of secondary patents related to various aspects of the manufacturing process.

When, in connection with the expiry of the original patent in 1999, a number of manufacturers of generic medicines, including Generics (UK) Ltd. and Alpharma...
LLC, began to make preparations for manufacturing generic products, GSK brought an action alleging that the generic products were infringing GSK’s secondary patents. However, before a judgment was issued in the infringement proceedings, the parties reached a settlement. Under the terms of the settlement, the manufacturers of generic medicines undertook, among other things – against payment – not to introduce generic products in the market for a certain period.

However, the UK Competition and Markets Authority considered the conduct to be suspicious and therefore opened an investigation. In 2016, the Competition and Markets Authority found that the settlement agreements between GSK and the manufacturers of generic medicines had constituted an infringement of the prohibition against anti-competitive agreements, and that GSK had also abused its dominant position. Consequently, fines corresponding to a total of approx. DKK 400 million were imposed on the parties.

The parties subsequently brought an appeal against that decision before the UK Competition Appeal Tribunal, which in 2018 decided to refer a number of questions to the European Court of Justice for a preliminary ruling. Those questions have now been answered by the European Court of Justice.

Preliminary ruling of the European Court of Justice

By its judgment of 30 January 2020, the European Court of Justice decided on the questions submitted. The Court ruled e.g.:

- that manufacturers of originator medicines and manufacturers of generic medicines must be regarded as potential competitors, no matter that the parties are in dispute over the validity of a patent for which reason it has not been determined whether the manufacturer of generic medicines can lawfully market the generic product. In this context, it is sufficient that the manufacturer of generic medicines has in fact a firm intention and an inherent ability to enter the market. Since the validity of a patent right can be challenged, the existence of such a right does not in itself imply that the manufacturer of generic medicines
is unable to enter the market and thereby exercise competitive pressure;

- that a "pay for delay" agreement must be deemed to restrict competition "by object" if it is obvious that the agreement can have no other reasonable explanation than to prevent competition in the market - considering particularly the value of the payment from the manufacturer of originator medicines to the manufacturer of generic medicines. In this context, however, it is necessary to take into account any pro-competitive effects of the agreement that are capable of giving rise to a reasonable doubt as to whether the agreement causes a sufficient degree of harm to competition;

- that the conclusion of "pay for delay" agreements can constitute an abuse of a dominant position if it is possible to demonstrate a negative effect on competition in the market that exceeds the specific effects of the individual agreements. By way of example, because the agreements all in all have a significant foreclosure effect on the market reserving the market to the manufacturer of the originator medicine to the prejudice of consumers

Be aware of the competition rules when considering "pay for delay" agreements

The tone was already set when the General Court in the Groupe Servier case (T-691/14) in 2018 ruled that "pay for delay" agreements must be deemed to restrict competition "by object". That conclusion seems to have been confirmed now by the European Court of Justice. At the same time, however, it is obvious that if a "pay for delay" agreement cannot be classified as restriction "by object" based on a specific assessment, it is necessary to perform an ordinary assessment of the specific effects of the agreement on the market and on competition.

The fact that the agreements may be deemed to constitute restriction of competition "by object" – and not just "by effect" – implies that the competition authorities are not obliged to carry out an in-depth examination of the anti-competitive effects of the agreement on the market. Instead, the agreements are considered unlawful per se,
and it is then up to each enterprise to document that the agreements bring advantages outweighing the anti-competitive effects they are presumed to have. In practice, it may be extremely difficult to provide sufficient proof thereof.

The judgment of the European Court of Justice implies that manufacturers of medicine must be careful about entering into settlement agreements under which a party must refrain from entering the market. This is also the case if the settlement agreement is reached in the context of a lawsuit about the validity of the patent and the possible infringement thereof by the manufacturer of generic medicines.

Read the judgment of the European Court of Justice
Read our previous newsletter about "pay for delay" agreements (in Danish)