Court of Justice of the European Union
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Press and Information

Advocate General's Opinion in Case C-307/18
Generics (UK) and Others

Advocate General Kokott proposes that the Court should find that an agreement in settlement of a dispute between the holder of a pharmaceutical patent and a manufacturer of generic medicinal products may be contrary to EU competition law

Such an agreement may be regarded as a restriction of competition by object or by effect and as an abuse of a dominant position

The pharmaceutical group GlaxoSmithKline (GSK) held a patent for the active ingredient of the anti-depressant medicinal product paroxetine and secondary patents protecting particular manufacturing processes of that active ingredient. When the main patent expired in 1999, several manufacturers of generic medicinal products[1] planned to enter the UK market with generic paroxetine. In that context, disputes arose between GSK and those generic manufacturers, in which the validity of GSK's secondary patents was contested. GSK and the generic manufacturers subsequently entered into agreements in settlement of those disputes, in which the generic manufacturers, in essence, consented, for an agreed period, not to enter the market with their own generic products in exchange for payments by GSK.

The Competition and Markets Authority (UK) took the view that those agreements infringed the prohibition on anti-competitive agreements and constituted an abuse by GSK of its dominant position on the relevant market. That authority therefore imposed fines on the parties to those agreements. Those parties challenged the Competition and Markets Authority's decision before the Competition Appeal Tribunal (UK) which is currently seeking guidance, by a request for a preliminary ruling addressed to the Court of Justice, on whether an agreement in settlement of a patent dispute in the pharmaceutical sector may constitute a restriction of competition by object or effect[2] and whether entering into such an agreement, possibly in combination with entering into other agreements, may constitute an abuse of a dominant position[3]

In today's opinion, Advocate General Juliane Kokott proposes that the Court should reply to the Competition Appeal Tribunal that, subject to certain matters to be determined by that tribunal, an agreement in settlement of a patent dispute may constitute a restriction of competition by object or by effect and that entering into such an agreement may be an abuse of a dominant position.

In support of her proposal, the Advocate General observes first of all that uncertainty regarding the validity of the patents at issue and whether the generic products infringe them, where it is not known whether these generic products have been manufactured in accordance with the processes protected by those patents, does not preclude a relationship of potential competition existing between the patent holder and the manufacturers of the generic products. According to the Advocate General, the disputes giving rise to entering into the agreements at issue are, as preparations for the market entry of the generics, themselves capable of demonstrating that potential competition exists between the parties to those agreements.

[1] IVAX Pharmaceuticals UK, Generics (UK) Ltd and Alpharma, LLC.
[2] Prohibited by Article 101 TFEU.
[3] Prohibited by Article 102 TFEU.

The assessment of whether potential competition exists between those parties is therefore subject not to an evaluation of the strength of the contested patents or the likelihood of the parties being successful in the litigation between them, but rather to whether there are, for the generic manufacturers concerned, real concrete possibilities to enter the market despite the existence of the patents at issue. In assessing those possibilities, a competition authority must take account of all relevant contextual factors, such as how far advanced the generic manufacturers are in preparing to enter the market.

So far as concerns the concept of **restriction of competition by object**, the Advocate General points out that the modalities of exercising the exclusive rights granted by a patent can be caught by the prohibition on restrictions of competition. Thus, such rights are not intended to afford protection against actions challenging the validity of the patent from which they are derived, those actions forming part of normal competition in the pharmaceutical sector. It follows, according to the Advocate General, that an agreement between the holder of a pharmaceutical patent and a generic manufacturer under which the generic manufacturer undertakes, in exchange for payment by the patent holder, not to enter the market and not to challenge the patent, eliminates normal competition and constitutes a restriction of competition by object if the sole consideration for the payment at issue is that undertaking. The Advocate General states, however, that the assessment of whether there is a restriction of competition by object must include, where appropriate, an assessment of the benefits to consumers afforded by the agreements at issue since, depending on their nature and their significance, such benefits may cast doubt on the anti-competitive object of those agreements. However, subject to matters to be determined by the Competition Appeal Tribunal, that does not appear to be so in the present case.

So far as concerns the concept of **restriction of competition by effect**, the Advocate General states, as a preliminary point, that it is necessary to assess the effects of an agreement only where such an agreement does not constitute a restriction of competition by object. In any event, in the case of an agreement in settlement of a dispute between the holder of a pharmaceutical patent and a generic manufacturer, such assessment must not focus on the likelihood of the patent being found to be invalid, but must rather seek to determine whether the agreement has had the effect of eliminating competition between the operators concerned and whether that effect is appreciable based on the context of the agreement.

As regards the **definition of the market** for the purposes of finding whether there has been a possible abuse of a dominant position, the Advocate General states that account must be taken of the generic versions of the pharmaceutical product protected by the patents at issue for the purposes of that market definition, where it is determined that their manufacturers were in a position to enter the market with sufficient speed and strength at the time when the agreements at issue were entered into to be able to exert a significant competitive constraint on the patent holder, irrespective of the uncertainty surrounding the patents' validity and whether the generic products infringed those patents.

Next, the Advocate General examines the conditions that must be met if an **abuse of a dominant position** is to be established. She observes, in that respect, that entering into an agreement that is subject to the prohibition on restrictions of competition by an undertaking in a dominant position is capable, additionally, of constituting a prohibited abuse of a dominant position if such an agreement - by itself or in conjunction with other agreements of the same type – is capable of influencing the structure of competition on the relevant market so as to hinder or eliminate competition on that market. Possible benefits afforded to consumers by the agreements concerned must, also in that context, be taken into account. The Advocate General points out, however, that conduct capable of constituting an abuse of a dominant position can only be justified by such benefits when it can be shown that those benefits offset the agreement's adverse effects on competition on the relevant market. That would not be the case, in her view, if the agreements at issue afforded consumers only limited benefits while otherwise eliminating effective competition by removing all or most existing sources of potential competition.

NOTE: The Advocate General's Opinion is not binding on the Court of Justice. It is the role of the Advocates General to propose to the Court, in complete independence, a legal solution to the cases for which they are responsible. The Judges of the Court are now beginning their deliberations in this case. Judgment will be given at a later date.

NOTE: A reference for a preliminary ruling allows the courts and tribunals of the Member States, in disputes which have been brought before them, to refer questions to the Court of Justice about the interpretation of European Union law or the validity of a European Union act. The Court of Justice does not decide the dispute itself. It is for the national court or tribunal to dispose of the case in accordance with the Court's decision, which is similarly binding on other national courts or tribunals before which a similar issue is raised.

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