Court of Justice of the European Union
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Press and Information

Judgment in Case C-307/18
Generics (UK) and Others

The Court of Justice clarifies the criteria governing whether a settlement agreement with respect to a dispute between the holder of a pharmaceutical patent and a manufacturer of generic medicines is contrary to EU competition law

In the judgment Generics (UK) and Others (C-307/18), delivered on 30 January 2020, **the Court has clarified the criteria applicable to the characterisation of settlement agreements with respect to disputes between the holder of pharmaceutical patents and manufacturers of generic medicines having regard to the prohibition on practices or agreements that have as their object or effect the restriction of competition** (Article 101 TFEU) **and the prohibition on abuse of a dominant position** (Article 102 TFEU).

The Competition Appeal Tribunal (UK) sent to the Court a request for a preliminary ruling for the purposes of its examination of the lawfulness of a decision imposed by the Competition and Markets Authority (UK) on various manufacturers of generic medicines and the pharmaceutical group GlaxoSmithKline ('GSK') concerning settlement agreements with respect to patent disputes ('the contested decision'). GSK was the holder of a patent for the active pharmaceutical ingredient of the anti-depressant medicine paroxetine and of secondary patents protecting some processes for the manufacture of that ingredient. When GSK's principal patent expired in 1999, a number of manufacturers of generic medicines contemplated introducing generic paroxetine on the UK market. Against that background, GSK brought infringement proceedings against those manufacturers of generic medicines, and the latter challenged the validity of one of GSK's secondary patents. GSK and the manufacturers of generic medicines thereafter concluded settlement agreements with respect to those disputes, whereby the latter chose to refrain, for an agreed period, from entering the market with their own generic medicines, in return for payments made by GSK ('the agreements at issue'). By the contested decision, the Competition and Markets Authority held that the agreements at issue infringed the prohibition on concluding agreements that restrict competition and constituted, on the part of GSK, an abuse of its dominant position in the relevant market. Consequently, the CMA imposed financial penalties on the parties to those agreements.

The Court stated, first, that an agreement between undertakings is subject to the prohibition laid down by Article 101(1) TFEU only if it has a negative and appreciable effect on competition within the internal market, which presupposes that those undertakings are at least in a relationship of potential competition. With respect to manufacturers of generic medicines who had not yet entered the market at the time when such agreements were concluded, the Court stated that **the required relationship of potential competition presupposes that it is demonstrated that there are real and concrete possibilities of access to the market**. To that end, the Court held that it is necessary to assess, for each manufacturer of generic medicines concerned, whether the manufacturer of generic medicines concerned has a firm intention and an inherent ability to enter the market, having regard to the preparatory steps it has taken, and that there are no insurmountable barriers to entry. **Any patent rights do not constitute, in themselves**, such **barriers**, according to the Court, **since their validity can be contested**.

As regards the concept of a **'restriction of competition by object'**, the Court recalled that if the agreements at issue are to be so characterised, that presupposes a finding that those agreements

reveal a sufficient degree of harm to competition, having regard to the content of their provisions, their objectives, and their economic and legal context. According to the Court, taking into consideration the appreciable fall in the sale price of the medicines concerned following the market entry of their generic version, that degree of harm may be identified where the transfers of value provided for by an agreement such agreements at issue cannot, because of their scale, have any explanation other than the commercial interest of the parties to the agreement not to engage in competition on the merits and, accordingly, act as an incentive to the manufacturers of generic medicines to refrain from entering the market concerned. For the purposes of characterisation as a 'restriction of competition by object', the Court also required that any pro-competitive effects arising from agreements at issue be taken into consideration, provided that those effects are demonstrated. The Court made clear however that taking into consideration such effects is merely a part of the analysis of whether the agreement under examination causes a sufficient degree of harm. The Court concluded that it is for the national court to assess, with respect to each agreement under examination, whether the demonstrated pro-competitive effects are sufficient to permit a reasonable doubt as to whether it causes a sufficient degree of harm to competition.

As regards whether a settlement agreement such as those at issue may be characterised as a **'restriction of competition by effect'**, the Court states that, in order to assess the existence of potential or real effects of such an agreement on competition, it is necessary to determine how the market will probably operate and be structured in the absence of the concerted practice, but it is not necessary to establish the probability of the manufacturer of generic medicines concerned being successful in the patent proceedings or of a settlement agreement being concluded that is less restrictive of competition.

In response to the questions in relation to the concept of an **'abuse of a dominant position'**, the Court held, first, that the product market must be determined taking into account also the generic versions of the medicine whose manufacturing process remains protected by a patent, provided that it can be established that their manufacturers are in a position to enter the market with sufficient strength to constitute a serious counterbalance to the manufacturer of originator medicines already on that market. Second, the Court stated that the finding of an abuse of a dominant position presupposes an adverse effect on the competitive structure of the market that exceeds the specific effects of each of the agreements concerned with respect to which penalties were imposed under Article 101 TFEU. More particularly, the Court observes that, taking into consideration the possible cumulative effects that are restrictive of competition of the various agreements, the conclusion of those agreements, in so far as it is part of an overall contract-oriented strategy, has a significant foreclosure effect on the market, depriving the consumer of the benefits of entry into that market of potential competitors manufacturing their own medicine and, therefore, reserving that market directly or indirectly to the manufacturer of the originator medicine concerned. The Court recalled, last, that such conduct can be justified if the party engaged in it proves that its anti-competitive effects may be counterbalanced, or outweighed, by advantages in terms of efficiency that also benefit consumers. For the purposes of that weighing of effects, the Court states that the favourable effects on competition of the conduct concerned must be taken into consideration regardless of the objectives pursued by the party engaged in that conduct.

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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